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OVERVIEW AND ORGANIZATION

This document summarizes and responds to public comments submitted to the Department of Toxic Substances Control (DTSC) on the proposed rulemaking titled *Safer Consumer Products,* which was released to the public on July 27, 2012.

- The proposal was available for comment for 45 days, with the public comment period closing on September 11, 2012. DTSC then extended the public comment period for an additional 30 days. Thus, the public comment period for the July 27, 2012 version of the regulations ended on October 11, 2012.
- A public hearing was held on September 10, 2012.
- A revised proposal was released to the public on January 29, 2013 for a 30-day public comment period. That public comment period ended on February 28, 2013.
- DTSC then released another version of the proposed regulations for a 15-day public comment period that ran from April 10 to April 25, 2013.

This Response to Comment (RTC) document addresses the comments received during the public comment period that ended on October 11, 2012. For a list of commenters and response to comments received on the proposed regulations dated January and April 2013, please refer to the January and April 2013 Response to Comments documents, respectively.

In this document, where a response references a provision of the regulations that was revised in January 2013, and then remained unchanged in April 2013, a parenthetical will indicate this change as “(January 2013).” Where the provision changed in both January and April 2013, the parenthetical will indicate this change as “(January and April 2013).” Finally, if the provision changed only in April 2013, the parenthetical will indicate this change as “(April 2013).”

Although the proposed regulations are process regulations and do not establish a regulatory threshold for protection of public health and/or the environment, DTSC submitted the proposed regulations for review by an External Scientific Peer Review, in accordance with Health and Safety Code section 57004(a)(2). DTSC submitted the proposed regulations and requested scientific input on the "scientific basis" and/or "scientific portions" of the proposed rule for review by the ESPR entities on the two following occasions:

- On July 18, 2012, DTSC requested the ESPR entities to begin their reviews and to submit their reviews by August 30, 2012 on the July 2012 version of the proposed regulations, with an extension granted until October 11, 2012;

- On January 30, 2013, DTSC requested the ESPR entities to begin their reviews and submit their reviews by March 4, 2013 on the January 30, 2013 version of the proposed regulations.

While the input received by the EPSR entities was reviewed and taken into account where appropriate at each of the iterations; for simplicity and added clarity DTSC has summarized the ESPR's input under a separate standalone document. For a list of the ESPR entities, their findings, the public comments on their findings, and DTSC responses, please refer to the July 2012 and January 2013 External Scientific Peer Review Findings.

In excess of 800 letters commenting on the initial version of the proposed regulations were received. Comments from the public hearing on the proposed standard were recorded, and a transcript of the hearing was placed in the project docket. The docket number for this project is R-2011-02. DTSC received in excess of 800 letters commenting on the initial version of the proposed regulations. Comments made during the public hearing on the proposed regulations were recorded, and a transcript of the hearing was placed in the project docket. Responses to the public hearing comments are included in this Response to Comments document and are listed as comment number 108 under Table 1. In addition to, 174 unique comment letters, listed in Table 1, DTSC received three sets of form letters on different topics. One set of letters requested a 60-day extension for this initial public comment period. DTSC has included in Table 2 a list of those who submitted letters requesting a 60-day extension. A second set of letters requested that DTSC postpone the implementation of the regulations. DTSC has included Table 3 of the names of those who submitted these letters. Finally, the third set of letters expressed support for the Chemicals of Concern list. DTSC included Table 4 of the names of commenters who submitted this letter. Copies of all of the letters have been included in the final rulemaking file, and they have been responded to in this document.

An alphabetical list of the unique commenters, their affiliations, and the number assigned to their correspondence are all included in Table 1. Each comment letter was issued a number. DTSC subsequently numbered each of the comments contained in the letter and collated similar comments together. The designation "1-1" means comment letter number 1, comment number 1 and so forth. For the purpose of orderly presentation, the comments have been categorized by the article in the regulation that they address. The comments that are general in nature or have overarching applicability have been addressed under the most applicable subject area under General Comments. For all other comments related to a specific article or section,

please refer to the respective article or section. An index has been provided at the end of the document for quick reference to the page number(s) on which responses to the comments appear.

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#	Name of Entity	Number of Comments
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4	Airlines for America and Boeing	18
5	Alliance of Automobile Manufacturers	186
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7	American Apparel & Footwear Association	28
8	American Cancer Society Cancer Action Network	2
9	American Chemistry Council	117
10	American Chemistry Council (2nd)	10
11	American Cleaning Institute	73
12	American Coatings Association	22
13	American Forest & Paper Association	17
14	American Wood Council	8
15	Amway	7
16	Applegate, John	*
17	Art & Creative Materials Institute	10
18	Ashford, Nicolas	*
19	Association of Global Automakers	52
20	Association of Home Appliance Manufacturers	7
21	AT & T	6
22	Auto Aftermarket Industry Association	11
23	Auto Manufacturers (Alliance of Auto Manufacturers & Global Automakers)	8
24	BASF Corporation	5
25	Battery Council International	13
26	Bay Area Clean Water Agency	11
27	BEHR	4
28	Bennet, Deborah	*
29	BizNGO	23
30	BlueGreen Alliance	5
31	Blyth	6
32	Breast Cancer Action	1
33	CA Attractions & Parks Association	5

Table 2. List of Commenters		
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35	CA Department of Public Health	2
36	CA for a Healthy Green Economy (CHANGE)	121
37	CA Grocers Association	35
38	CA Healthcare Institute	11
39	CA Healthy Nail Salon Collaborative	31
40	CA Industrial Hygiene Council	16
41	CA Manufacturers & Technology Association	85
42	CA New Car Dealers Association	32
43	CA Product Stewardship Council	2
44	CA Retailers Association	22
45	CA Stormwater Quality Association	4
46	CA Travel Association	4
47	CalChamber	34
48	CalRecycle	5
49	Chemical Industry Council of California	18
50	Christensen, Norm	*
51	Chula Vista Public Works Department	2
52	City of Torrance	2
53	Clean Water Action	5
54	Clorox Company	12
55	Complex Durable Goods Coalition	28
56	Consumer Healthcare Products Association	6
57	Consumer Specialty Products Association	99[1]
58	Cradle to Cradle Products Institute	2
59	Creative Nail Design	16
60	Daimler Trucks North America	7
61	Defoamer Industry Trade Association	9
62	Delta Diablo Sanitation District	2
63	Direct Selling Association	1
64	Dow Chemical Company	15
65	Ecolab	6
66	Electronics Industry: ITIC TechAmerica, CEA, SIC	85

[1] Comment 57-6: Due to an inadvertent numbering error comment letter 57 does not include a comment number 6. The numbering for that letter jumps from 57-5 to 57-7.

Table 3. List of Commenters		
#	Name of Entity	Number of Comments
67	European Semiconductor Industry Association	1
68	European Union	47
69	Food Packaging Coalition	31
70	Gradient	10
71	Gray, George	*
72	Green Chemistry AA Coalition	27
73	Green Chemistry Alliance	41
74	Grocery Manufacturers Association	97
75	Hattis, Dale	*
76	Hewlett Packard	75
77	Imperial Valley Resource Management Agency	2
78	Independent Cosmetic Manufacturers Distribution Association	7
79	Indie Beauty Network	1
80	Intel	15
81	Intelligent Global Pooling Systems Company	7
82	International Fragrance Association	8
83	IPC	5
84	Japan Chemical Industry Association	5
85	Japanese Government	2
86	Japanese Industries: JEITA, CIAJ, JBMIA, JEMA	29
87	Koch Industries	12
88	Locke, Paul	*
89	Marin County Hazardous & Solid Waste Management	3
90	Marin Sanitary Service	2
91	Martz Emerson, Marjorie	16
92	Metal Finishing Association	7
93	MWS Wire Industries	3
94	National Association of Chemical Distributors	7
95	National Electrical Manufacturers Association	10
96	National Shooting Sports Foundation	7
97	Natural Products Association	5
98	North American Insulation Manufacturers Association	3
99	North American Metals Council	3
100	Ortwin, Renn	*
101	Personal Care Products Council	40
102	Pharmavite	2
103	Plastic Pipe & Fittings Association	5
104	Plastics Industry Trade Association	5

Table 4. List of Commenters		
#	Name of Entity	Number of Comments
105	Plumbing Manufacturers International	10
106	PLZ Aeroscience	4
107	Procter & Gamble	95
108	Public Hearing	186
109	Rubber Manufacturers Association	23
110	San Benito County Integrated Waste Management Department	2
111	Santa Barbara County Public Works Department	2
112	Sass, Jennifer	*
113	Semiconductor Industry Association of Korea	1
114	Sierra Club	20
115	SNR Denton	7
116	Sonoma County Water Agency	2
117	Specialty Equipment Market Association	2
118	State Water Resources Control Board	14
119	Stoner Incorporated	5
120	Taiwan Semiconductor Industry Association	1
121	TDC Environmental	7
122	Test & Measurement Coalition	9
123	Torrance City (Please see # 52)	--
124	Toy Industry Association	36
125	Tri-Iso	10
126	Tri-TAC	7
127	Truck Engine Manufacturers Association	13
128	UC Berkeley Labor Occupational Health Program	5
129	UCLA Sustainable Technology & Policy Program	24
130	Unifrax	8
131	Unilever	10
132	Valero	8
133	Vinyl Institute	2
134	Warner Babcock Institute	7[2]
135	Water Quality Association	3
136	Western States Petroleum Association	12

[2] Comment 134-2: Due to an inadvertent numbering error comment letter 134 does not include a comment number 2. The numbering for that letter jumps from 134-1 to 134-3.

137	WF Taylor Co., Inc.	2

Table 5. List of Commenters

#	Name of Entity	Number of Comments
138	Worksafe	24
139	Writing Instrument Manufacturers Association	10
140	Attaguile, Faith	1
141	Betancourt Jr. Robert	1
142	Dull, Julie	1
143	Everall, Patricia	1
144	France, Susan	1
145	Garner, Dylan	1
146	Ingalls, Diane	1
147	Klawans, Becky	1
148	Lemons, Sheila	1
149	Levy, Robert	1
150	Littlejohn, Toni	1
151	Lorenzen, Nan	1
152	Mahboubian, Maggie	4
153	McKinley, Cameron	1
154	McMullin, Robyn	1
155	Mendelson, Roger	1
156	Meyer, Amy	1
157	Mezzavilla, Richard	1
158	Mikaily, Adit	1
159	Moran, Marcella	1
160	Newman, Jane	1
161	Newman, Peter	1
162	O'Brien, Kevin	1
163	Palmer, Donald	3
164	Pierce, Yvonne	1
165	Prutzman, Annie	1
166	Reynolds, Allan	1
167	Rivera, Alana	1
168	Rowley, Carol	1
169	Sjostrand, Margaret	1
170	Snow, Andrea	1
171	Tapley, Dennis	1
172	Townsley, Rory	1
173	Vernier, Mary	1
174	Wick, Kristen	1

*External Scientific Peer Review Entity; please refer to July 2012 External Science Peer Review Findings document

FORM LETTERS

Extension Requests

The 77 letters listed below in Table 2 requested a 60-day extension of the public comment period, citing the close proximity of the public hearing on September 10, 2012 and the public comment period closing on September 11, 2012. These letters also mentioned the length of the ISOR and the proposed regulations as reasons why the public comment period should be longer than 45 days. DTSC provided a 30-day extension to the public comment period in response to the numerous requests received for such an extension. DTSC chose not to provide a 60-day extension, as many commenters requested. This was due to the large number of documents associated with this rulemaking package that DTSC had to draft, revise and release for additional public comments and responses to those comments. DTSC believes that the public comment period of July 27, 2012 through October 11, 2012 was sufficient time to allow for public comments.

Table 2. List of Entities Requesting Extension of Public Comment Period

#	Name of Entity
1	A.G. Layne, Inc.
2	Alabaster, Pam
3	American Chemistry Council
4	American Cleaning Institute
5	American Forest & Paper Association
6	Bansal, Mayank
7	BASF Corporation
8	Black, Vivian
9	Blyth Inc.
10	Bryson, Paul
11	California Chamber of Commerce - Coleman
12	California Grocers Association
13	California Healthcare Institute
14	California New Car Dealers Association
15	California Retailers Association
16	Callaway Golf Company
17	Chase Products Co
18	Chemical Industry Council of CA
19	Clement Pappas Co

Table 2. List of Entities Requesting Extension of Public Comment Period	
#	Name of Entity
20	CND
21	Colomer Beauty Brands
22	Colomer Group
23	Copelin, Cheryl
24	Consumer Specialty Products Association
25	Defoamer Industry Trade Association
26	DOW
27	Eubanks, Mitch
28	Fantetti, Elizabeth
29	Food Packaging Coalition
30	Global Automakers
31	Graham Packaging
32	Grayson, Robbi
33	Grocery Manufacturers Association
34	Guiding Faith Cafe
35	Hensley, Bobbie
36	Hickey, Beth
37	Hickey, Emmett
38	IFRA North America
39	Independent Lubricant Manufacturers Association
40	Industrial Environmental Association
41	IPC
42	Irizarry, Myra
43	Keare, Eleanor
44	Kirschner, Harland
45	Lees, Mark
46	Linard, Jack
47	Lopez, Belinda
48	Masterson, Brad
49	National Aerosol Association
50	National Candle Association
51	New, Pam
52	Owen, Patricia
53	Pachova, Valentina
54	Personal Care Products Council
55	Plumbing Manufacturers International
56	Porcaro, Marissa
57	Raasch,Karen

Table 2. List of Entities Requesting Extension of Public Comment Period	
#	Name of Entity
58	Ranney, Brandon
59	Renegade Candles
60	Rubber Manufacturers Association
61	Searles Valley Minerals
62	Seybold, Lawrence
63	Shakour, Renee
64	Sharpe, Bridget
65	Silicon Valley Leadership Group
66	Smith, Vincent
67	SNR Denton US LLP
68	Stefan/George Associates
69	Stewart, Kenneth
70	Toy Industry Association
71	Traylor, Paul
72	Tri-Iso, Inc.
73	Van Steelandt, Cindy
74	Vinyl Institute
75	Walck, Christopher
76	Walker, Susan
77	Wright, Patricia

Postpone

The 96 letters listed below in Table 3 requested that DTSC postpone the initiative—these regulations—until the economic impacts of the regulations, and other issues of concern could be addressed, and any potential changes could be discussed at a future public hearing. DTSC was directed to adopt these regulations no later than December 31, 2010, and therefore could not postpone the adoption of these regulations any further. DTSC has revised the proposed regulations twice since the July 2012 version, and submitted the revised versions for public comment. This has allowed the public multiple opportunities to voice issues of concern, and for DTSC to consider and address those concerns when DTSC agreed with the suggestions and recommendations made by the commenters.

Table 3. List of Entities Requesting Postponement of Implementation	
#	Name of Entity
1	Bade, David
2	Bansal, Mayank
3	Barbalunga, Jonalee

4	Barnaby, Brenda
5	Beaumont, Kaye
6	Bissell, Jacquelyn
Table 3. List of Entities Requesting Postponement of Implementation	
#	**Name of Entity**
7	Bowen, Amber
8	Bracco, Janine
9	Brown, Wes
10	Brunner, Thomas
11	Bufis, Mary
12	Burke, Dan
13	Case, Cindy
14	Chayes, Angelica
15	Cho, Jessica
16	Clark, Scot
17	Corkill, Katherine
18	Crawford, Timothy
19	Csiszar, Steven
20	Dandurand, Curran
21	Delaney, Thelma
22	Dietrich-Ganz, Candy
23	Elgueta, Elias
24	Ferrall, Gina
25	Flacks, Martin
26	Forno, Patrico
27	Fricano, Polly
28	Golin, Julie
29	Gupta, Mukat
30	Guyer, Denis
31	Hamad, Fayez
32	Harand, Harand
33	Hatch, Courtney
34	Heldenfels, Shelley
35	Hellman, Matthew
36	Henrietta, James
37	Hersey, Richard
38	Hill, Beverly
39	Irizarry, Myra
40	Irving, Alexander
41	Johnson, Jared
42	Jones, Cindy
43	Kadosh, Orit
44	Kaegi, Miles
45	Katz, Stanley
46	Kemp, Jamie
47	Lamanno, Margherita
48	Lavinio, Marie

49	LeBeau, Denise
50	Lee, Christine
51	Lee, Grace
Table 3. List of Entities Requesting Postponement of Implementation	
#	**Name of Entity**
52	Libby, Susan
53	Lippmann, Mark
54	Locatell, Pamela
55	Maly, John
56	McCluskey, Vincent
57	Mendelson, Kevin
58	Miles, Anna
59	Mount, Linda
60	Murad, Jeff
61	New, Pam
62	O'Connor, Mary
63	Ornstein, Steve
64	Owen, Patricia
65	Patterson, Tony
66	Peck, April
67	Persons, Richard
68	Pinto, Juan
69	Pruett, Claire
70	Pum, Gregory
71	Rauchwerger, Jerry
72	Reyzis, Irene
73	Rhoades, Dean
74	Rivera, Lois
75	Robbins, Patricia
76	Ross, William
77	Salzano, Marinella
78	Schmucker, Patty
79	Serruys, Kari
80	Shah, Devyani
81	Shargani, Alan
82	Sharpe, Bridget
83	Sheman, Linda
84	Sill, Garth
85	Smith, Connie
86	Smith, Jill Ann
87	Swan, Jennifer
88	Tran, Ann
89	Tran, Maily
90	Veljkovic, Ivana
91	Villalobos, Sally
92	Waite, Debbie
93	Werner, Dan

94	Winters, Carri
95	Wiseth, Wendy
96	Witwit, Ali

Support for COC list

Although 1,120 letters expressing support where submitted, only 552 letters listed below in Table 4, were timely submitted. The letters expressed support for the regulations and specifically the Chemicals of Concern list. The letters also expressed the opinion that the regulations represent an opportunity for promoting innovation and economic growth. DTSC appreciates the support and sentiments expressed in this letter.

Table 4. List of Entities Supporting COC List

#	Name of Entity
1	Abbott, Joanna
2	Abraham, Gabe
3	Acosta, Alberto
4	Acwich, Yael
5	Adams, David
6	Adams, Michael
7	Agostini, Luisa
8	Aikawa, Mark
9	Alexander, Beverley
10	Alvarado, Frank
11	Ambra, Leia
12	Anderson, Audrey
13	Anderson, Clifford
14	Anderson, Talaya
15	Andrews, Matt
16	Anson, Robert
17	Apple, Joy
18	Attrache, Ghaleb
19	Aubrey, Frances
20	Ayala, Gloria
21	Backer, Hans
22	Bailey, John
23	Baker, Beth
24	Balestreri, Barbara
25	Ballard, Nicholas
26	Bambery, Richard
27	Barry, Dwight
28	Barton-Paine, Dianne
29	Bass, Jennifer
30	Batallar, Abril
31	Battaglia, Rosemarry
32	Bautista, Ernesto
33	Beal, Jon

34	Bebb, Matthew
35	Becker, Chris
36	Bellak, Nina
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
37	Beltran, Cathy
38	Benjamin, Elaine
39	Benoit, Diane
40	Beres, Donna
41	Berkers, Jeff
42	Berry, Thomas
43	Bettendof, Lisa
44	Bhalla, Richa
45	Bill, Eileen
46	Billson, Christian
47	Birdsong, Kathy
48	Bithell, Marianne
49	Blakely, Dave
50	Bloom, Brendan
51	Bloomquist, Linda
52	Blossom, Deborah
53	Blunt, Gerry
54	Bob, Michelle
55	Bogin, Ronald
56	Bonfield, Timothy
57	Bonnet, Guillaume
58	Borska, Erika
59	Boskin, Gertrude
60	Boudart, Jan
61	Bower, Rendall
62	Boyd, Ernest
63	Bozzuto, Joe
64	Bradshaw, Catherine
65	Brannan, Diane
66	Brazier, Helene
67	Broderick, Barbara
68	Brown, Deena
69	Brown, Elliott
70	Bruce, Linda
71	Bruce, Melissa
72	Brunner, Alison
73	Buckingham, Kim
74	Buskirk, Van
75	Caidoy, Krystal
76	Calado, Liesl
77	Calbreath, David
78	Cape, Rown

79	Caputo, Nicole
80	Carlisle, Lindsay
81	Carney, Thom
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
82	Cattarin. John
83	Cavanaugh, Clay
84	Cavelli, Eva
85	Centurion, Bobboe
86	Chacon, Carol
87	Chambers, Lisa
88	Chandrasekaran, Vidya
89	Chavez, Nola
90	Chen, Jeffrey
91	Chen, Tracey
92	Chin, Yvonne
93	Ciarra, Marcella
94	Clark, Jeff
95	Clark, Julie
96	Clark, Thomas
97	Cockle, Justine
98	Cohen, Eleanor
99	Cohen, Howard
100	Connelly, Kristin
101	Conteras, Alma
102	Cook, Craig
103	Corrigan, Sean
104	Costello, James
105	Couch, Charles
106	Courtney, Courtney
107	Cowing, Deborah
108	Cox, Molly
109	Craven, Will
110	Cripe, Teri
111	Cross, Pauline
112	Crow, Steve
113	Dagilis, Danielle
114	Dahl, Pamela
115	Daly, Robert
116	DamHorst, Kris
117	Danis, Susan
118	Dau, Lynn
119	Davila, Lea
120	Davis, Rebecca
121	Decker, Karen
122	Declercq, Tamara
123	Delrahim, Sandra

124	Denton, Deborah
125	Dev, Gita
126	Diaz, Mario
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
127	Dow, Linda
128	Dreyfus, Stuart
129	Edwards, Allan
130	Ehrke, Erik
131	Eklund, Steve
132	Emanuel, Myra
133	Engels, Thomas
134	Entenman, Richard
135	Ewald, William
136	Farnes, Randy
137	Feldman, M
138	Feldman, Ruth
139	Ferguson, Ezekiel
140	Finney, Barbara
141	Firshein, David
142	Fisher, Evelyn
143	Fleeman, Jeff
144	Flores, Josephine
145	Foss, Chris
146	Foss, Janice
147	Fox, Louis
148	Francis, Lena
149	Frank, Linda
150	Fraser, Alex
151	Friedland-Brown, Karen
152	Fruchey, Kate
153	Fuezy, Jon
154	Gab, Margie
155	Gaitanis, Constantine
156	Gallagher, Kathrun
157	Gallegos, Mark
158	Garcia, Felipe
159	Garcia, Mark
160	Garneau, Paul
161	Garvey, Henry
162	Gatheral, Tracey
163	Gebbie, Peter
164	Gembka, Lori
165	Georgia, Romola
166	Getter, Camile
167	Ghini, Elle
168	Gibb, Wayne

169	Gibbs, Nancy
170	Giddings, Linda
171	Giddings, Ron
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
172	Gilchrist, Tom
173	Gill, Katherine
174	Gillespie, Rhiannon
175	Gilliam, Jeffrey
176	Gilson, Miriam
177	Goff, Fred
178	Golden, Charlie
179	Golias, Theresa
180	Gonzalez, Katie
181	Gonzalez, Nydia
182	Goodwin, Truss
183	Gorham, Linda
184	Gosman, Amy
185	Gottfried, David
186	Graham-Ramos, Briana
187	Grande, Shari
188	Grave, Philip
189	Graves, Carolyn
190	Graves, Caryn
191	Gray, Ralph
192	Green, Don
193	Green, Tracy
194	Green, Will
195	Grosso, Anthony
196	Gueriera, Daniel
197	Guida, William
198	Guitierrz, Richard
199	Gulassa, Harriet
200	Hadley, Douglas
201	Haenk-Clark, Pam
202	Hagiu, Ioana
203	Hagstrom, Earl
204	Halizak, Kimberly
205	Hall, Anthony
206	Hammett, Cindy
207	Hammond, Sue
208	Hanna, Helen
209	Hardbarger, Michel
210	Harmon, Lucille
211	Harper, Darby
212	Hartman, Nancy
213	Hauf, John

214	Hedger, Deb
215	Hedley, Janet
216	Heinze, Aliyah
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
217	Hendershott, Kurt
218	High, Nicole
219	Hilyer, Lisa
220	Ho, Marjorie
221	Hodder, Mary
222	Hohle, Maggie
223	Holmes, Joseph
224	Holn, Harvey
225	Hong, Dary
226	Hope, John
227	Horsfall, Nathan
228	Houston, Ellie
229	Huang, Hongbin
230	Huang, Janey
231	Hughes, Eric
232	Hunt, Karen
233	Hyde, Karen
234	Ingra, G. Mason
235	Ino, Tiffany
236	Irvin, Katja
237	Jacobson, Rachel
238	Jenkins, Dan
239	Jerome, Jane
240	Johnsen, Brent
241	Johnson, Brandie
242	Johnston, Christina
243	Jones, J. Ray
244	Jones, Janet
245	Jordan, Christian
246	Joseph, Kazimieras
247	K, Patrick
248	Kaluza, Natasha
249	Katell, Katell
250	Kaufmann, Suzanna
251	Kaylor, Steve
252	Kelly, Charlotte
253	Kelly, Nancy
254	Khan, Seema
255	Khouri, Julianne
256	Kidambi, Madhava
257	Kiesling, Nancy
258	Kim, John

259	Kim, Meena
260	Kirby, Kathryn
261	Kirk, John
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
262	Kosanovic, Bruce
263	Koss, James
264	Kroemer, Harry
265	Kubota, Charleen
266	Kuczynski, Kathleen
267	La Puma, Karen
268	LaBrecque, Charyl
269	Lampman, Joscelyn
270	Landau, Jean-Claude
271	LaNew, Maryann
272	Lavensaler, Kurt
273	LeCount, David
274	Lee, Kathy
275	Lemons, Sheila
276	Leung, Lily
277	Lewis, Patrick
278	Liang, Ming
279	Linderman, Eileen
280	Lish, Christopher
281	Little, Ryan
282	Littlejohn, Will
283	Lockhart, Rebecca
284	Lockwood, Margo
285	Lombard, Ruth
286	Longland, Martiza
287	Lopez, Jimmy
288	Louie, Jo
289	Loustalot, Colin
290	Lucas, Steve
291	Luenow, Brian
292	Luikart, Heather
293	Lum, William
294	Lund, John
295	Lyman, Robert
296	M, Shunay
297	Maas, John
298	Macis, Michelle
299	Mack, Tina
300	Maddox, Terry
301	Mahoney, Dawn
302	Malik, Chinta
303	Mariposa, Virginia

304	Martin, Dalton
305	Martins, Sarah
306	Matson, Melissa
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
307	McAlister, Christopher
308	McCaig, David
309	McCallister, Gloria
310	McCaughey, John
311	McCool, Mike
312	McCullough, Denali
313	McDaniel, Shannon
314	McDonald, Kristen
315	McGraw, Stepheny
316	McNeely, Rhiannon Gillespie
317	McQuiston, Elizabeth
318	Meldon, Carolyn
319	Melvin, Joseph
320	Messer, Mark
321	Mewhinney, Bruce
322	Mezey, Jennifer
323	Michaels, Dana
324	Mihalovics, Dariko
325	Miller, Abigail
326	Miller, John
327	Miller, Lisa
328	Minault, Kent
329	Mintz, Kevin
330	Miracle, Cindy
331	Misuraca, Melinda
332	Moats, Jasmine
333	Montalvo, Chris
334	Moore, Gailen
335	Morales, Paul
336	Moreau, Jenny
337	Morelli, Randall
338	Moss, Elizabeth
339	Mueller, Barry
340	Murnane, John
341	Murphy, Joanie
342	Murphy, Katie
343	Murphy, Lisa
344	Nattenberg, Edward
345	Nelson, Ted
346	Nice, Robert
347	Nichols, Crystal
348	Nitzan, Ben

349	Nixon, Amy Jane
350	Noe, Lynn
351	Noonan, Robert
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
352	Norris, Jon
353	O'Connor, Meave
354	Odezynskyj, Maria
355	Oliver, Nancy
356	Olson, Dean
357	Omander, Susanne
358	Oporto, Christopher
359	Ornelas, Karen
360	Ory, Rhona
361	Ostrom, Gavin
362	Padgett, Susan
363	Page, Sydne
364	Paone, Anne
365	Pardini, Jenny
366	Parikhn, Mandar
367	Parker, Daniell
368	Parrish, Joan
369	Parrish, Kristoffer
370	Patti, Vincent
371	Peate, R.
372	Pena, Gustavo
373	Perlscy, Alex
374	Petrinovich, L.
375	Phillips, Marilyn
376	Phipps, Connie
377	Pichumani, Ramani
378	Pippen, Karma
379	Pletschet, Fran
380	Porter, Ted
381	Posch, Michael
382	Pounds, James
383	Prado, Rene
384	Pratt, Joe
385	Price, Charlotte
386	Prieto, Maria
387	Rabinowitz, Noel
388	Ramaswamy, Jagaw
389	Ramos, Cynthia
390	Rearden, Chance
391	Reed, Robert
392	Reiff, Shauna
393	Respecke, David

394	Rhodes, Lori
395	Richard, Anne Marie
396	Richard, Cheryl
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
397	Richter, Steve
398	Rickman, Roz
399	Roachford, Tom
400	Roberts, Les
401	Roberts, Leslie
402	Robie, Lisa
403	Rodocker, Mary
404	Rogers, Mike
405	Rohwedder, Shawn
406	Ross, Zack
407	Round, Lorraine
408	Rowe, Susan
409	Rudinow, Mattie
410	Russell, Teresa
411	Ruth, Carol
412	Rutland-Brown, Wesley
413	Ryan, Irmi
414	Rye, Cameron
415	S, Jeff
416	S, Robert
417	Salamander, Gilad
418	Sanchez, Henry
419	Sanders, Jason
420	Sandoval, Dore
421	Sapkin, Joshua
422	Sarkany, Jen
423	Sato, Nancy
424	Sato, Susan
425	Sawyer, Marvin
426	Saxon, Rolf
427	Scharich, Jeannette
428	Schmidt, Sunshine
429	Schmit, Joe
430	Schroder, Tim
431	Schwalbenberg, Peter
432	Scopazzi, Jennifer
433	Seifert, David
434	Seltzer, Jody
435	Semereaux, Melody
436	Seto, Jeneele
437	Shearer, Julie
438	Sheppard, Patrick

439	Sheridan, Lydia
440	Shiplacoff, David
441	Simms, Ellen
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
442	Sinclair, Ron
443	Singh, Madhulika
444	Singh, Rayeena
445	Sipan, Carol
446	Sjostrand, Margaret
447	Smelker, James
448	Smith, Glenn
449	Smith, Greg
450	Smith, Isabelle
451	Smith, Lawrence
452	Smith, Nicki
453	Sohn, Jennifer
454	Solari, Noreen
455	Solin, Donna
456	Songster, Jeff
457	Sox-Harris, Lara
458	Spencer, John
459	Spickler, Julie
460	Sprague, Belle
461	Standish, Jennifer
462	Stark, Marilyn
463	Starkweather, CK
464	Stellanova, Tammy
465	Stevens, Eric
466	Strugnell, Ann Christine
467	Suen, Aimee
468	Sultan, Yaldah
469	Sutherland, Megan
470	Sutton, Ellyn
471	Sweek, Tyler
472	Szmcak, Mark
473	Talbot, Michael
474	Tang, Carol
475	Tarlow, Carol
476	Tatman, Robin
477	Taylor, Leon P.
478	Taylor, Mary
479	Theil, Niki
480	Thompson, Catherine
481	Thurman, Anna
482	Tichman, Nadya
483	Timms, Dana

484	Tokay, Hale
485	Tomaselli, Richard
486	Tompt, Jay
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
487	Torres, Alicia
488	Tracy, Glen
489	Trahan, Judy
490	Ulam, Jim
491	Ungar, Ruth
492	Up, Fed Coles
493	Usman, Susan
494	Usmani, Ozair
495	Van Kol, Elise
496	Van Sidcu, Michelle
497	Vanapalli, Kishore
498	Vancor, Lisa
499	Vaningen, Chris
500	Vargas, Yessenia
501	Velez, Erin Alden
502	Velicescu, Adrian
503	Venekatram, Saras
504	Vezian, Marc
505	Vidales, Angel
506	Vierra, Steve
507	Vinay, Sharon
508	Vizir, Vitali
509	Von Dehn, Verena
510	Vukic, Vesnar
511	Wahdan, Jo
512	Walker, Aurea
513	Wallin, William
514	Walsh, Dana
515	Warila, Jennifer
516	Warren, Patricia
517	Warrilow, Joanne
518	Watson, Donna
519	Watson, Fran
520	Watson, Mary Lou
521	Wattenberg, Jane
522	Watts, Nancy
523	Weissbuck, Brian
524	Weiss-Lampert, Laura
525	Welch, Heidi
526	Whitman, Jill
527	Whittle, Jeffrey
528	Wiebe, Tobey

529	Williams, Albert
530	Williams, Linda
531	Willis, Kimberly
Table 4. List of Entities Supporting COC List	
#	**Name of Entity**
532	Wilson, Barbara
533	Wilson, David
534	Wilson, Gary
535	Wilson, Jennifer
536	Wimsatt, Casey
537	Wolfs, Saul
538	Woodruff, Toni
539	Woods, Peter
540	Wright, Natalie
541	Wrucke, Robert
542	Wu, Chen
543	Wyckoff, Julia
544	Wyss, Marianne
545	Yamat, Yasmin
546	Yau, Dennis
547	Yoshida, Irene
548	Youabian, Anita
549	Yuen, Genevieve
550	Zerzan, Paula
551	Zhu, Meng
552	Zimmerman, Marjorie

ACRONYMS

AA	Alternatives Analysis
APA	Administrative Procedure Act
Cal/OSHA	California Occupational Safety and Health Administration now known as Department of Industrial Relations (DIR)
CEPA	Canadian Environmental Protection Act
COC	Chemical of Concern
DTSC	Department of Toxic Substances Control
EC	European Commission
EPA	Environmental Protection Agency (U.S.)
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FPLA	Fair Packaging and Labeling Act
FSOR	Final Statement of Reasons
GHS	Globally Harmonized System
GRSP	Green Ribbon Science Panel
IARC	International Agency for Research on Cancer
ISOR	Initial Statement of Reasons
OEHHA	Office of Environmental Health Hazard Assessment
OSPAR	Oslo/Paris Convention for the Protection of the Marine Environment for the Northeast Atlantic
PBT	Persistent, Bio-accumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation (EC) No. 1907/2006 of the European Parliament and the Council
TSCA	Toxic Substances Control Act
U.S.	United States

ARTICLE 1. GENERAL

The applicability of these regulations is to all consumer products placed into the stream of commerce in California. It is necessary to take into account current and anticipated methods of selling or offering for sale consumer products containing a Chemical of Concern, through mail order catalogs and internet sales as well as traditional brick and mortar entities. Some interested parties have expressed concern over the vastness and scope of the regulations and have urged DTSC to narrow the scope to make the universe of products subject to these regulations smaller. However, DTSC has determined that consistency with existing statutory reach, both as to what is included and excluded, is necessary and that exempting any other consumer products would not be in line with the intent and purpose of the authorizing legislation, and would impermissibly shrink the scope of consumer products set out in statute that are subject to the regulations.

§ 69501 Purpose and Applicability

§ 69501(a) Purpose

Comment: 5-134

Comment Summary:

The comment suggests revising the term “product” to “Priority Product” in the first sentence to describe the goal of these regulations.

Response**:**

DTSC has revised the language as suggested by the comment to clarify the goal and applicability of the regulations. The first sentence is now, “This chapter specifies the process for identifying and prioritizing *Priority Products* and their Chemicals of Concern, and identifying and analyzing alternatives to determine how best to eliminate or reduce potential exposures to, or the level of potential adverse impacts posed by, the Chemical(s) of Concern in *Priority Products*” (emphasis added).

Comments: 36-62, 39-8

Comments Summary:

The comment suggests changing the language to describe the goal of these regulations by replacing the phrase “to limit exposures to” with “reduce the use of toxic chemicals.”

Response**:**

DTSC understands the desire to reduce the use of toxic chemicals but feels that this is addressed by the goal of reducing the level of adverse impacts posed by the Chemical of Concern. This, in turn, reflects the statutory language in Health and Safety Code 25253(a), which requires DTSC "to determine how best to limit exposure or to reduce the level of hazard posed by a Chemical of Concern." Reducing the level of adverse impacts covers reducing or eliminating adverse public health impacts, and/or environmental impacts. "Adverse public health impacts" and "adverse environmental impacts" are both defined in the regulations. Therefore, the regulations adhere to the statutory language but get at the concern raised by the commenter. DTSC is not making any changes to the regulations in response to these comments.

§ 69501(b) Applicability and Non-Duplication

§ 69501(b)(1) Applicability

Comments: 21-1, 21-2

Comments Summary:

The above comments are critical of the purportedly unprecedented scope and applicability of the proposed regulations.

Response:

The comment expressed concern over the vastness and scope of the regulations. However, DTSC has determined that the regulations are consistent with existing statutory reach and it is in line with the intent and purpose of the authorizing legislation. Further, no suggestions or proposed revisions are included within this comment; no additional detailed response is possible. However, in the Procedural, Legal, and Overarching Issues portion of this Response to Comments document there is extensive discussion of the scope of these regulations, as well as their consistency with the authorizing legislation. See that discussion for additional information on this topic. DTSC is not making any changes to the regulations in response to these comments.

Comment: 44-3

Comment Summary:

The commenter seeks confirmation that businesses would not have responsibilities for chemical products used internally within a company in conducting its business, when

those products are not themselves made available to the public. The comment contends that these “products” are not placed into the stream of commerce in California.

Response:

Health and Safety Code section 25251 defines “consumer products” to mean a product or part of the product that is used, bought, or leased for use by a person for any purpose. The definition of consumer product does not include prescription drugs and medical devices, dental restorative materials, diagnostic or treatment instruments, packaging (for prescription drugs and devices, dental restorative materials, and medical instruments), food, and pesticides products. “Person” in Health and Safety Code section 25118 is defined to mean more than just an individual; “person” can also mean a company or governmental agency. Therefore, this statutory definition of “consumer product,” which has been incorporated into the regulations, provides the possibility for the regulations to apply to products purchased by a commercial user/consumer.

The regulations only apply to products “placed into in the stream of commerce” in California, which takes into account current and anticipated methods of selling or offering for sale consumer products containing a Chemical of Concern. Applying the regulations to products placed into the stream of commerce in California maintains a level playing field between products manufactured in California and those manufactured outside of California regardless of their point of origin. Thus, businesses would not be subject to the substantive requirements of the regulations if the consumer products were used internally within a company conducting its business, if those products are not themselves made available to the public.

DTSC is not making any changes to the regulations in response to this comment.

Comment: 36-109

Comment Summary:

DTSC should specify that being placed “in the stream of commerce in California” includes internet/online purchases.

Response:

DTSC declines to explicitly specify internet/online purchases under section 69501(b) because the definition of “placed into the stream of commerce” under section 69501.1(a)(50) [previously numbered 69501.1(a)(47)] already includes transactions conducted through the Internet or other similar electronic means (January 2013).

§ 69501(b)(2) Criteria for Exemptions

Comment: 36-41

Comment Summary:

The commenter strongly objects to this section and recommends that it be deleted because there is no reason a product used to make an exempted product should itself be exempt from the regulations. The statute excludes certain products but not all chemicals used in their manufacture.

Response:

In response to this comment, DTSC has removed this provision from section 69501(b)(2) as an exemption. This provision has been moved to section 69503.3(b)(4)(C) in the proposed regulations (January 2013) and is no longer an upfront exclusion. Instead, this criterion of a product being used in the manufacturing of an exempt product is now included as a prioritization factor in the evaluation of products.

§ 69501(b)(3) Products for Use Outside of California

Comments: 30-5, 36-42, 39-12, 138-9, 138-10, 138-11, PH17-4, PH32-8

Comments Summary:

The comments object to this section in the regulations that excludes from this program products made in California but not sold in the State. The concern is that this will expose workers who make the products and communities through which the products are transported to hazards that the regulations are meant to prevent. Workers who use the products are typically exposed to larger quantities, on a daily basis, for years.

The comments contend that the provision also seems to subvert the statute's goal of incorporating life cycle thinking, which is defined in the regulations to include manufacture, transportation, and distribution. The regulations include the “manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices” as one of the product prioritization factors (section 69503.2(a)(1)(B)4.a.).

Response:

In response to these comments, DTSC has removed this provision from section

69501(b)(3) as an exemption. The provision has been moved to section 69503.3(b)(4)(B) of the proposed regulations (January 2013), where it serves as a prioritization factor in the evaluation of products.

§ 69501(b)(new) Add New Subsection for Exemptions

Comments: 5-124, 5-135, 25-2, 55-25, 57-11, 130-1, 130-8

Comments Summary:

The above comments provide various versions of suggested language to reinstate the prior exemption that was included in a previous October 2011 informal version of the regulations. The new provision would explicitly exempt products already regulated by the State and federal laws and prevent regulatory duplication.

Response:

DTSC has revised the regulations to include a new provision exempting from these regulations any regulated by another State of California or federal regulatory agency if the specified criteria for the exemption are met. The commenters should note that pursuant to Health and Safety Code section 25257.1 and the new proposed section 69501(b)(3) of the proposed regulations (January 2013), DTSC does not intend to implement the regulations in a manner that duplicates or conflicts with existing State of California and/or federal regulations. The new provision implements and makes clear the prohibition in Health and Safety Code section 25257.1 without DTSC exceeding its authority by the adoption of exemptions beyond those set out in the authorizing legislation. As DTSC implements the proposed regulations, it will consider information and justification that any person provides to DTSC that is relevant to a determination that a particular chemical or product qualifies for the exclusion in section 69501(b)(3) of the proposed regulations (January 2013). Such determinations will also be posted on DTSC's website. See the Legal, Procedural and Overarching Issues portion of this Response to Comments document for a detailed discussion on section 69501(b)(3).

Comments: 130-1, 130-3, 130-8

Comments Summary:

The comments urge DTSC to restore the prior exemption for bulk chemical products found in a previous draft (October 2011, section 69505.1(b)(2)). The comments go on to say that this provision should allow for the exemption at an earlier stage in the process where warranted. Bulk products present no potential for consumer exposures, provided applicable workplace regulations are satisfied.

Response:

DTSC does not agree that this exclusion should be reintroduced and did not restore this exemption. DTSC recognizes that occupational hazards may lead to greater exposures than those encountered under normal consumer use scenarios. The regulations have been revised to include various factors to account for workers and worker exposures in the product-chemical prioritization process. (See discussion of Article 3, Process for Identifying and Prioritizing Product-Chemical Combinations in the January 2013 version for a detailed discussion of the prioritization factors.) Further, the definition of "sensitive subpopulations" has also been revised to address workers with greater exposures to chemicals due to the nature of their occupations. It would be inconsistent with that definition and the concepts embedded in it to then exempt bulk chemicals. Accordingly, DTSC will not be making changes to exempt bulk chemical products.

Comments: 102-1, 102-2

Comments Summary:

The commenter seeks to revise section 69501(b) to state explicitly that food, as well as its ingredients, is not a consumer product for purposes of these regulations and to clarify that under California law, as well as federal law, food ingredients (including dietary supplement ingredients) are defined as food.

Response:

DTSC has provided an exemption in these regulations for food. That exemption is in section 69501(b)(2). That provision reads: "This chapter does not apply to any product that is exempted from the definition of 'consumer product' specified in Health and Safety Code section 25251." In turn, "food," as defined, is exempted from the definition of "consumer product" and thus these regulations at section 25251(e)(4). Accordingly, it is not necessary to restate the exemption provided in Health and Safety Code section 25251 for food, which is further defined in subdivision (a) of section 109935 of the Health and Safety Code. DTSC will explain in the Final Statement of Reasons that the exclusion for food applies to food as a finished product and to food ingredients used or intended for use as a component of food as specified in the Health and Safety Code. Although the federal definitions in law and in regulations are slightly different than the California definition of food, all are similar for purposes of implementation. For example, finished dietary supplement products and dietary ingredients are excluded as food in these regulations.

§ 69501(b)(new) Add new Section for Specific Exemption Requests

Comments: 4-7, 13-9, 13-11, 19-42, 20-7, 23-1, 25-1, 25-6, 25-10, 25-11, 25-12, 25-13, 56-1, 56-4, 69-1, 69-2, 69-20, 69-21, 69-22, 81-3, 101-1, 101-10, 101-14, 107-10, 109-2, 109-3, 115-3, 117-1, 122-2, 122-8, 130-1, 130-3, 132-1, 132-4, 132-5, PH14-2

Comments Summary:

The above comments request that specific exclusions or exemptions be included in the regulatory language and provide justifications why these requests should be granted. The commenters explain various arguments as to why the exclusions should be granted and state the following reasons:

- The information gaps identified in The Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation report do not apply;
- Without the exemption, safe products will be withdrawn from the California market;
- DTSC is not equipped with financial support or personnel, to administer the responsibilities of the regulations;
- Regulations may force the use of products less proven to be effective;
- The recycling rate is very high in the U.S.;
- There are no viable substitutes;
- New designs have made the products safer in many applications;
- Product is the most affordable option in the marketplace;
- Product is a naturally occurring substance that presents unique problems when reformulating;
- If the regulation is applied to fuels, the impacts would extend beyond modifications to the refining process and include the supply chain;
- Manufacturers will reformulate or drop the Chemicals of Concern; and
- Resource will be diverted to California compliance activities rather than research and development of new, safer products.

These exclusions requests include:

- Any consumer product that is required to be certified or approved by the Federal Aviation Administration or the Department of Defense;
- Home appliances;
- Light-duty vehicles in the proposed program;
- Lead-acid batteries from the requirements of the SCP regulations;
- Recycled materials contaminated with Chemicals of Concern;

- Tires, if an alternative conflicts with, or prevents meeting motor vehicle safety standards;
- Test and measurement products subject to the Consumer Product Safety Commission;
- Bulk chemical products not sold directly to retail consumers;
- Transportation fuels;
- Over-the-counter drugs regulated by FDA;
- Food contact materials;
- Food packaging;
- historic products; and
- Chemicals that have no exposure pathway.

Response:

The authorizing statute at Health and Safety Code section 25251 defines the universe of "consumer products" that will be subject to the regulations adopted by DTSC pursuant to Health and Safety Code sections 25252 and 25253, among other key provisions of the authorizing statute. The Legislature crafted an exhaustive list of products that were rendered exempt from the regulations authorized and mandated by these statutes. This was done by virtue of the content of Health and Safety Code section 25251's exclusions from the definition of "consumer product" and thus, from the reach of these regulations.

Under well-established principles of the proper exercise of rulemaking authority granted to administrative agencies, the implementing regulations may neither expand nor shrink the scope of the authority conferred by the authorizing statute. Here, DTSC is being urged to shrink the scope of the statute by adopting exemptions that were not set out in the authorizing statute. DTSC has no authority to limit the reach of the statute by drafting such exemptions when the Legislature did not confer such authority.

Therefore, DTSC declines to adopt any of the partial or complete exemptions urged by the above comments. See Procedural, Legal, and Overarching Issues portion of this Response to Comments document for a detailed discussion of the issue of Regulatory Duplication and Conflict. That discussion is applicable in response to these comments as well.

§ 69501(b)(new) Add New Section for Duplicative or Conflicting Regulations

Comments: 5-50, 5-51, 5-52, 9-108, 13-10, 13-12, 13-13, 13-14, 23-5, 25-3, 25-4, 25-5, 25-7, 25-8, 25-9, 46-3, 56-2, 57-11, 59-3, 60-2, 69-3, 69-4, 69-5, 69-6, 69-7, 69-8, 69-

9, 69-10, 69-11, 69-12, 69-13, 69-14, 69-15, 69-16, 69-17, 69-18, 69-19, 69-23, 69-24, 69-25, 101-12, 101-13, 109-4, 124-7, 130-4, 132-2

Comments Summary:

A prior version of these regulations allowed for a product to be exempted from the listing as a Priority Product and subsequent regulatory processes if DTSC determined that existing regulation was adequate throughout the life cycle of the product and there are no significant gaps in regulatory coverage. This exemption is not in the current proposal and has been replaced with a provision that makes existing regulation only one of many considerations in the prioritization process. The prior exemption should be reinstated in the final rule.

All of the above comments claim that DTSC created too narrow an exclusion for products already adequately regulated and/or assert that a particular product is, or should be, outside of the reach of the proposed regulations because the regulation of the enumerated products by these regulations would violate the provision in Health and Safety Code section 25257.1. These other regulatory schemes either obviate the need for governance under these regulations or supersede these regulations due to nationally mandated safety requirements, say the commenters.

The comments provided details on a variety of federal or state programs or requirements that the commenters contend provide a high level of regulation for specific product categories. Most of these comments submitted explained how these other regulatory requirements address specific potential adverse impacts that could be the basis for the product being listed as a Priority Product. These other regulatory considerations include the following:

- Occupational Safety and Health Administration (OSHA) regulations for bulk chemicals;
- Division of Occupational Safety and Health (Cal/OSHA) regulations for control of worker exposures to lead;
- Federal Food, Drug and Cosmetic Act (FDCA), the Food and Drug Administration (FDA), and Generally Regarded as Safe and Effective for the safety of over the counter drugs;
- Food, Drug, and Cosmetic Act (FDCA) and Food and Drug Administration (FDA) for food contact material;
- National Environmental Policy Act for assessment of environmental impacts for the use and disposal of a new food contact materials;
- California's Proposition 65 (Prop 65) for labeling;

- Consumer Products Safety Commission requirements for labeling lead-acid batteries for consumer use;
- CalRecycle's program for end-of-life management of lead-acid batteries;
- National Emissions Standards for Hazardous Air Pollutants and the National Ambient Air Quality Standard requirements for lead;
- California's hazardous waste laws and the Clean Water Act for the manufacturing and recycling of lead-acid batteries;
- California Air Resources Board regulations for motor vehicle emissions;
- Clean Air Act for emissions of lead and diesel engines;
- National Highway Traffic Safety Administration for safety-related automotive systems;
- California Diesel Fuel Program, the California Vehicle Code, and the federal Clean Air Act for diesel exhaust and greenhouse gas emissions;
- Corporate Average Fuel Economy (CAFE) for vehicle fuel economy standards;
- Mobile Source Air Toxics Rule, Reformulated Gasoline, Reid Vapor Pressure, Renewable Fuel Standard, Toxic Substances Control Act (TSCA), Department of Transportation regulations, Pipeline and Hazardous Materials Safety Administration, and OSHA for transportation fuels; and
- Department of Transportation and Department of Homeland Security for the movement and transport of chemical goods.

Response:

The language in the prior version of these regulations has been reinstated under section 69501(b)(3) (January 2013).

As DTSC implements the program, DTSC will review any regulations that are applicable to a specific product that is being considered or proposed as a Priority Product. It will be more effective to review these other regulatory considerations once a product has been identified as a potential Priority Product or when product categories have been listed in the Priority Product Work Plan.

Further, in addition to making exemption determinations on products based on the criteria in in the new section 69501(b)(3)(A) of the proposed regulations (January 2013), the regulations require formal rulemaking with opportunities for public review and comment prior to finalizing the list of Priority Products. This should provide ample opportunity for interested parties to provide evidence to DTSC that one or more products proposed for the Priority Products lists should not be included on those lists.

Finally, DTSC notes that it has provided additional detailed responses to these and related comments in the Procedural, Legal and Overarching Issues discussion of this Response to Comments document. Those responses are relevant here as well. See, in particular, discussions regarding: Preemption, Requests for Exemption, and Regulatory Duplication/Conflict.

§ 69501.1 Definitions

§ 69501.1 Harmonization

Comments: 57-12, 59-4

Comments Summary:

Comments suggest that the definitions be harmonized with existing international and national definitions used in other chemical and product regulations (*e.g.*, EPA, Globally Harmonized System (GHS), TSCA, Organization of Economic Cooperation and Development to promote clarity. The use of a non-harmonized definition leads to great uncertainty and to infinite variations and impracticality. For example, Health and Safety Code section 69501.1(a)(18) (January 2013) defines “bioaccumulation” to be broader than the definition found in section 69405.2. Section 69501.1(a)(3) (January 2013) defines “adverse ecological impacts” and refers to Article 4 which is entitled ”Adverse Environmental Impacts” of Chapter 54 of Title 22 of the California Code of Regulations, OEHHA’s Green Chemistry Hazard Traits for California’s Toxics Information Clearinghouse regulations (Chapter 54). DTSC should coordinate with the Office of Environmental Health Hazard Assessment (OEHHA) on these issues to ensure that definitions and standards are consistent and work in concert with the statute’s prioritization mandate.

Response:

DTSC carefully considered existing definitions for other chemical regulatory schemes and has modified the definitions to provide greater clarity for the various requirements when applying these terms to consumer products. The terminology selected by DTSC to capture the activities undertaken under these regulations does not restrict DTSC’s ability to gather, review, and use information gathered from other sources. Very few scientific organizations adopt and employ identical language to carry out their missions. DTSC is not hamstrung in adopting language tailored specifically to this program.

DTSC has revised the definition of “bioaccumulation” to match OEHHA’s definition specified in section 69405.2 of Chapter 54 in the amended text. However, the definition of “adverse ecological impacts” will remain unchanged and continue to refer to Article 4

of chapter 54 along with criteria for animals, plants, ecosystems, and contamination of soils.

The proposed definition also makes use of, and is consistent with, the related OEHHA regulations in Chapter 54. This, in turn, allows for ease of use and a common understanding of terms used. This is also necessary to harmonize these regulations with the development of the Toxics Information Clearinghouse, which will be a web-based system for the collection, maintenance and distribution of hazard traits and environmental and toxicological endpoints data. DTSC is mandated to create the clearinghouse and OEHHA is mandated to specify the relevant environmental and toxicological data to be included. DTSC and OEHHA have coordinated on these issues to ensure that definitions and standards are consistent and work in concert with the statute's mandate.

DTSC does note, however, that numerous changes were made to the definitions in Article 1 of these regulations. Each of these changes is discussed in the portion of this document pertaining to Article 1. In addition, there is further discussion of the concept of harmonization of these regulations with other state and federal regulatory schemes in the portion of this document addressing Procedural, Legal, and Overarching Issues. The reader is directed there as well in further response to these comments.

§ 69501.1 Thresholds for Definitions

Comments: 57-14, 74-24, 107-13, 107-26

Comments Summary:

Concern with the various definitions of adverse impacts, chemical properties, "reliable information," and "reliable information demonstrating the occurrence of exposures" is that there are no threshold levels to provide a context for what is of concern. The definitions focus on the existence of a hazard or exposure only. The definitions should include threshold levels and should clearly convey the potential for adverse impacts in the context of thresholds.

Response:

DTSC respectfully disagrees, in part, with this comment. First, these definitions expressly reference other regulatory requirements that may contain thresholds. Second, the regulations take a narrative approach that prompts the evaluation of chemicals in products for a wide spectrum of potential public health and environmental impacts.

The definition of “adverse impacts” includes both public health adverse impacts and environmental adverse impacts. These two terms are also defined. DTSC has adopted the hazard traits and environmental and toxicological endpoints specified in OEHHA’s regulations, which are required by Health and Safety Code section 25256.1. The link between the two sets of regulations is required by Health and Safety Code section 25252(b)(1). For example, OEHHA’s regulations include the following, “Evidence for environmental persistence includes … half-lives in marine, fresh or estuary water of greater than 40 to 60 days, in sediment of greater than 2 months, in ambient air of greater than 2 days, or in soil of greater than 2 months.” OEHHA also provides, within this evidence, narrative descriptions of what else is acceptable.

Other state and federal requirements for air, water, ecology, soil, and waste relating to the protection of the environment have also been included in the various definitions. In the definitions of both “adverse public health” and “adverse environmental impacts,” DTSC has a provision that an adverse impact has occurred when a chemical exceeds an enforceable standard associated with the protection of public health or the environment. The inclusion of this this provision ensures that specific impacts, which are sufficiently important as to be regulated under local, state, or federal environmental laws and regulation, are considered. Further, the statutory language directs DTSC to reference and use the work of other regulatory agencies and authoritative bodies.

While there is some value in greater certainty and predictability with a prescriptive process with defined threshold levels, than with a narrative approach, there may also be some negative consequences as well. A prescriptive process would only reflect decisions based on current science and understanding and creates the possibility that the current process in place ignores new science and understanding for future decisions. There is valid concern that under a prescriptive approach, DTSC will constantly be behind new science and understanding, will constantly be amending regulations, and will be strapped into making regulatory decisions knowing that the regulatory process will not allow consideration of new scientific understanding of chemicals and products.

DTSC will not be revising the regulations in response to these comments. DTSC prefers to maintain a narrative approach rather than strictly a prescriptive process; as such, there will not be quantitative thresholds for the above definitions. Also see sections 69501.1(a)(3) through (10), (52), and (53) of this document for additional discussion regarding these definitions.

§ 69501.1(a) Requests for New Definitions

§ 69501.1(a) Requests for "Authoritative Bodies"

Comment: 82-2

Comment Summary:

The comment requests DTSC to define the term "authoritative bodies." Since this term relates to the selection of chemicals on the Chemicals of Concern list, it is extremely important that there be a clear definition of what constitutes an authoritative body.

Response:

The term "authoritative bodies" is not used in Article 2 of the regulations in describing the sources of the various lists of Candidate Chemicals. However, "authoritative organization" was used once in section 69505.4(b)(4)(B) (July 2012) qualified by the phrase, "as defined in section 69401.2(b)" of chapter 54.

The proposed regulations (January 2013) have been amended, but neither the term "authoritative bodies" nor "authoritative organizations" is used. DTSC does not feel "authoritative bodies" needs to be defined to clarify the language of these regulations since the term is not used in the regulations. DTSC will not be making any changes to the regulations.

§ 69501.1(a) Request for "Assembled Product"

Comment: 76-40

Comment Summary:

The comment suggests deleting the definition for "highly durable products" in section 69503.4(a)(2)(B)3. and reinstating the now-deleted definition for "assembled product" in the definitions section 69501.1(a). The definition for highly durable products does not distinguish between Priority Products types. Further, the requirement that entities demonstrate that the product is intended to have a useful life of five or more years may exclude many complex products because the type of information required (*i.e.*, warranty statements) will not indicate five or more years.

Response:

In the proposed regulations (January 2013), the term assembled products is used throughout to denote products that are assembled. Although, the October 2011

informal draft did include a definition for “assembled products,” the purpose of this prior definition was included to distinguish between formulated and assembled products.

DTSC will not return to using the definition of “assembled product” to make clear what a “highly durable product” is for three reasons. First, the term “assembled product” is used throughout the text to refer to products that are articles, which is a much broader scope than highly durable products. Second, two new terms, “assemble” and “assembler” have been added to the revised text to distinguish a “manufacturer” and an “assembler.” It may be confusing to add “assembled product” that represents a highly durable product, not just an assembled product. Finally, DTSC has revised the term “highly durable products” to “complex durable products.” Section 69503.5(d) limits how many components of a complex durable product can be listed as a Priority Product in a three-year period (January and April 2013). The definition was not moved to the definitions section because it is germane to the requirements listing Priority Products.

Documentation to indicate that the product’s useful life is five years or more is required to establish the criteria for complex durable products. The commenter correctly points out that the most common way to communicate useful life to consumers may be the warranty statements. However, DTSC is not limiting the type of information provided to the consumers to a warranty only. Warranty periods are more of a relative measurement (conservative estimate) as opposed to an absolute reference as to how long the product should last. The useful life of five or more years is appropriate for this requirement.

There will be no changes in response to this comment.

§ 69501.1(a)(new) Add “Contaminant”

Comments: 11-2, 11-3, 11-4, 81-5, 124-9, 124-16

Comments Summary:

The comments request a definition for “contaminant” be added to the regulations, which differentiates between contaminants and intentionally added ingredients. This term is a recurring concept in the Initial Statement of Reasons (ISOR) and is critical to the workability of the regulations. Chemicals that are contaminants serve no useful function in a product. However, the comments concede that DTSC may need manufacturers to address and reduce contaminants in products; however, they question the meaningfulness of an Alternatives Analysis (AA) for a contaminant in a product.

Comments recommend use of Washington State’s WAC 173-334-040 definition:

> "'Contaminant' means trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products."

Response:

DTSC has added a definition for "contaminant" in the proposed regulations (January 2013) in response to public comments regarding drafting and implementation concerns. This definition is not the same as Washington State's definition but is similar in scope.

DTSC respectfully disagrees that requiring an AA for a contaminant in a Priority Product is meaningless. Preparing an AA will require manufacturers to evaluate their feedstock and possible alternatives. There are known examples of contaminants found in feedstock that can be potential sources of a Chemical of Concern, such as perchlorate in Chilean sodium nitrate fertilizer and heavy metals in ores. Finding alternative sources or refining the feedstock are just two alternatives that may be considered.

§ 69501.1(a)(new) Add "Economic impacts"

Comment: 36-105

Comment Summary:

The comment recommends restoring a definition of "economic impacts" to include internalized and externalized costs. The term "economic impacts" should capture all appropriate costs, including to public health, occupational health, and the environment. The regulations should use consistent language about economic impacts throughout the document.

Response:

DTSC has revised the language and added a new term for "economically feasible," which defines when an alternative product or a replacement chemical can be considered viable. There are various places in the regulations that require an economic evaluation. First, economic feasibility is a factor to determine if there are safer alternatives as a product prioritization factor. An economic evaluation of external costs is required in the Final AA Report, and if a manufacturer retains the Priority Product, an evaluation of internal costs is also required. Economic feasibility is also a consideration for regulatory responses. Because the purposes of all of these evaluations differ, the economic impact cannot be treated consistently throughout the regulations. In light of

the above reasons and the addition of a definition for the term “economically feasible,” DTSC is not changing the regulations to restore the definition of “economic impacts.”

§ 69501.1(a)(new) Add “Exposure pathway”

Comment: 129-2

Comment Summary:

A definition of “exposure pathway” needs to be developed since it is a significant concept for both - prioritization of Priority Products and in the AA. Section 69503.2(a)(1)(B) can be used as a basis for developing the definition.

Response:

“Exposure pathway” is a term of art in environmental science. “Exposure pathway” is typically used to mean the manner by which human populations—and/or aquatic, avian, or terrestrial animal or plant organisms—may be exposed to a Chemical of Concern or contaminant. A complete exposure pathway consists of a source, a release from a source, a migration and transport mechanism, an exposure medium (*e.g.*, air) or media (in cases of intermediate transfer), an exposure point, and an exposure route. Since DTSC is not deviating from the typical usage and meaning of this well-understood term, no further definition is needed in the regulations. DTSC is not making any changes to the regulations in response to this comment.

§ 69501.1(a)(new) Add “Federally Certified Product”

Comment: 4-12

Comment Summary:

DTSC must require consideration of the preemptive effect of federal law in the determination of Priority Products. The comment provides suggested language for the definition of “Federally Certified Product.”

Response:

The suggested language provided is intended to address an exemption request for products that are certified by the Federal Aviation Administration or the Department of Defense in order to avoid preemption under federal law. DTSC does not intend to implement these regulations in a manner that will invoke a federal preemption. Health and Safety Code section 25257.1 prohibits DTSC from adopting regulations that duplicate or conflict with existing government regulations. See Procedural, Legal, and

Overarching Issues discussion for a detailed discussion of the Regulatory Duplication/Conflict issue. Those responses are applicable here as well.

DTSC will not be including this proposed new definition and exemption in the regulations, and this conforming language will not be included in the regulations.

§ 69501.1(a)(new) Add "Historic product"

Comments: 5-141, 117-2

Comments Summary:

Add a new definition, "'Historic product' means a product manufactured prior to the effective date of the regulatory response selected by DTSC for the Priority Product, including all service, repair and replacement parts associated with the historic product even if manufactured after a regulatory response."

Response:

DTSC has reviewed this and other various comments that are relevant to the term "historic product," such as "consumer product," "manufacturer," "interim part," and "replacement part." In order to eliminate any further confusion on this issue, DTSC has removed altogether any mention of the term "historic product." Deleting the term obviates a new definition for historic product.

The original intent of this provision was to set the date of applicability for consumer products subject to AA, not to provide an exclusion. Products that ceased to be manufactured prior to the date the product is listed as a Priority Product would not be subject to substantive requirements of the regulations. As currently written, if a service, repair, or replacement part is listed as a Priority Product, any existing inventories of parts made before the Priority Product listing will not be subject to the regulations. Priority Products, produced after the date of the listing, will be subject to the AA and any subsequent regulatory response.

The suggested language in the comments to "include all service, repair and replacement parts associated with the historic product even if manufactured after a regulatory response" is a request to exclude replacement parts produced after the regulatory response date. DTSC has reviewed the European End-of-Life Vehicle Directive and finds that the principle "repaired as produced," applicable for these vehicles and their spare parts without any time limitation, is not appropriate to be applied to all consumer products subject to these regulations. Therefore, DTSC will not

revise the regulations to include this exclusion for all products. DTSC may, however, address this issue when a regulatory response is proposed for a specific Priority Product with an extended useful life.

See also section 69501.1(a)(22) "consumer product," and 69501.1(a)(40) "manufacture" of this document.

§ 69501.1(a)(new) Add "Inaccessible," "Inaccessible component" or "Accessible component"

Comments: 17-6, 33-3, 57-20, 74-44, 124-1, 124-14, 124-18

Comments Summary:

The comments suggest adding definitions for "inaccessible," "inaccessible components," or "accessible components" for assembled products. Health and Safety Code section 25252(a) directs DTSC to consider potential exposure, which supports the exclusion of inaccessible components from coverage by the regulations. The regulations should define these terms and reference them in several key places where there is no reasonable likelihood of exposure and DTSC should focus on accessible components. The regulations should exclude inaccessible components from prioritization.

DTSC has established the "highly durable product" category that is treated differently under the regulations because of inaccessibility or lack of exposure to a priority chemical. This category is similar to the "inaccessible components" concept. In both cases, there is an assumption that exposure will be low during the useful life of the product.

If a definition of "inaccessible" is needed, the current standard in use by the U.S. Consumer Product Safety Commission, found at Title 16, Code of Federal Regulations, parts 1500.48 and 1500.49 should be adopted.

Response:

First, DTSC points out that the regulations do not use the terms "inaccessible" nor "accessible." Therefore, adding a definition for either term would be necessary only if DTSC became convinced that it should introduce this term into the regulations for the reasons offered by the comments. However, DTSC respectfully disagrees that inaccessible components should be excluded from these regulations due solely to inaccessibility. There may be exposure pathways (*e.g.*, inhalation) that may need to be assessed that are unaffected by a component simply because it is out of reach. There

may also be potential human or environmental exposure or consequences during other phases of the product's life cycle other than use (*e.g.*, manufacturing, transportation, waste, and end-of-life.). However, DTSC notes that the frequency, extent, level, and duration of exposure to the Chemical of Concern across all phases of the life cycle of the product will remain a prioritization factor.

There is an erroneous assumption that DTSC established the "highly durable products" concept and related definition because of inaccessibility or lack of exposure to a Chemical of Concern. The term "highly durable product" was necessary to limit how many components could be listed as a Priority Products subject to an AA during any three year period. It was done then solely on the basis of limiting potential burdens on certain industry sectors, and had nothing to do with accessibility or inaccessibility of parts.

Finally, the definitions found in Title 16, Code of Federal Regulations, parts 1500.48 and 1500.49 are Consumer Product Safety Commission standards for exposure to sharp edges in toys that may present a potential risk of injury. Again, these regulations need to address exposure to chemicals. Therefore, the use of this definition of "inaccessible," which was intended for purposes of preventing physical harm is not appropriate or sufficient to assess potential adverse impacts.

DTSC will not be revising the regulations in response to these comments.

§ 69501.1(a)(new) Add "Intentionally added chemical"

Comments: 11-2, 124-9, 124-19

Comments Summary:

There is a need to define "intentionally-added chemicals" to distinguish between ingredients and potential contaminants. The proposed regulations do make such a distinction with respect to components of assembled consumer products defining them as "required to complete or finish an item," "performs a distinctive and necessary function in the operation of a system," or "is intended to be included as a part of a finished item. The same concepts should be extended to ingredients used in a formulated consumer product. One comment recommends the use of Washington State's regulation (WAC 173-334-040).

Response:

DTSC has revised the regulations to include a definition of "intentionally added ingredient" in response to these comments and to distinguish this term from the term "contaminant." The definition in the proposed regulations (January 2013) is similar but not identical to Washington State's definition.

See also section 69501.1(a)(new) Add Contaminant of this document for additional discussion related to these comments.

§ 69501.1(a)(new) Add "Interim Part"

Comment: 19-11

Comment Summary:

"Interim Product" is a consumer product manufactured between the time it was identified in a proposed or final Priority Products list and the effective date for any related regulatory response, and includes spare parts or components used for repair or maintenance of such a consumer product. No regulatory response should be imposed on any interim products.

Response:

DTSC did not revise the regulations to add this definition or modify when the exemption provided in the definition of "consumer products" applies. DTSC understands that the regulated industry must continue to conduct business, but this issue is more appropriately addressed at the time the regulatory response is imposed. Extending the exemption to the effective date of the regulatory response may not be adequate to address additional time necessary for reformulation, or a redesign of the Priority Product in some cases, and could encourage delay with making product changes in others. Regulatory responses may be different for products that are in production but have not yet made it market versus products that are manufactured after the effective date of the regulatory response. See discussion of Regulatory Responses under Article 6 for further discussion of this issue.

No changes were made in response to this comment.

§ 69501.1(a)(new) Add "Mode of Action"

Comment: 76-35

Comment Summary:

Mode of action is an important concept in risk evaluation and cumulative risk. This definition should be restored and it should be used as part of a defined risk evaluation process for determining any AA Threshold level.

Response:

The mode of action refers to the mechanism by which a chemical produces an effect on a living organism or in an environmental compartment. The mode of action for various hazard traits of many of the chemicals is not known, so the identification of the molecular targets of a chemical (mode of action) would have hampered DTSC's implementation efforts. This term is no longer used in these regulations; therefore, there is no need to define mode of action.

AA Thresholds, set at the practical quantitation limit (PQL) of the Chemical of Concern, are now applicable for Chemicals of Concern that are contaminants in a Priority Product in the proposed regulations (January 2013). A risk evaluation is no longer a provision for determining the AA Threshold in these regulations.

However, when the Priority Products are established through rulemaking, DTSC may consider proposing AA Thresholds for intentionally added ingredients or for contaminants above the PQL. If the modes of action for Chemicals of Concern are known, this criterion may be evaluated at the time of the rulemaking. No changes were made in response to this comment.

§ 69501.1(a)(new) Add "Practical Quantitation Limit"

Comments: 5-77, 5-112, 5-143

Comments Summary:

The comments provide suggested language for the definition of the "Practical Quantitation Limit (PQL)" to mean the minimum concentration of a chemical that can be precisely quantified (percent relative standard deviation within +/- 10%) with an acceptable bias (percent recovery within 90-110%). An analytical result below the PQL obtained from an accepted analytical test method for the Chemicals of Concern in the listed Priority Product would result in an exemption for that product from the AA process.

Response:

DTSC appreciates the suggestion and in response to comments, has added a definition of PQL to the proposed regulations (January 2013). Instead of using the suggested

language, however, DTSC has inserted U.S. EPA's definition of "PQL." The PQL means the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.

§ 69501.1(a)(new) Add "Replacement parts"

Comments: 19-10

Comment Summary:

The cleanest way to exempt replacement parts is to include a new definition for "replacement parts" that includes the language "repair as produced," as used in the European End of Life Vehicle Directive.

If DTSC does not want to add a new definition for "replacement parts," then to ensure the clear exemption for replacement parts that is needed, additions to the current "Historic Product" definition and a new definition for "Interim Parts" should be included in the regulations.

Response:

The definition of the verb "manufacture" exempts the installation of replacement parts but not the replacement parts themselves. There is no exemption for replacement parts anywhere in the regulations. It is not DTSC's intent to exempt replacement parts. The ISOR has been revised to correct this mistaken impression on the part of some stakeholders (See December 2012 Revised ISOR). Further, DTSC deleted the examples in the revised ISOR to eliminate any additional clarity issues.

If a service, repair, or replacement part is named as a Priority Product, any existing inventories of parts made before the Priority Product listing will not be subject to these regulations. However, parts produced after that date will not be treated the same under these regulations as parts produced before the Priority Product listing date. That is, if they meet the specifications of the identified Priority Product, they will be subject to an AA.

If a listed Priority Product includes parts that require service, repair, or replacement, then all of its parts will be subject to the AA and any subsequent regulatory response that is imposed. The regulatory response may address the product as a whole or it may allow for parts to be addressed differently depending on the presence of Chemicals of Concern.

For example, if the Priority Product is a baby bottle containing a specific phthalate, the baby bottle may include the bottle itself, the ring, the nipple, a liner, and/or a cap/cover. If all the parts of the baby bottle contain the Chemical of Concern, then DTSC could name the entire assembled product as a Priority Product. Each part of the baby bottle that contains the Chemical of Concern would be subject to the AA and regulatory responses. However, if only two of the parts contain the Chemical of Concern, then DTSC could only list the two parts containing the Chemical of Concern as Priority Products subject to the AA.

This would affect replacement parts in the following manner. If the entire baby bottle is named a Priority Product, any replacement part for the baby bottle (bottle, ring, nipple, liner, or cap) that contains the Chemical of Concern would also be subject to the substantive requirements of these regulations. Any replacement parts that do not contain the specific phthalate (the Chemical of Concern that is the basis for the listing) are not subject to these regulations. If only one of the parts (a replacement part) is listed as the Priority Product, then the replacement part is subject to the AA and any regulatory responses.

DTSC is not revising the text in response to this comment.

§ 69501.1(a)(2) "Accreditation body"

Comment: 76-25

Comment Summary:

Commenter strongly urges DTSC to delete the accreditation bodies' procedures in Article 8 and this related definition.

Response:

In response to public comments, DTSC has eliminated the accreditation bodies and certified assessors program from these regulations. The provisions of Article 8 of the July 2012 version have been deleted in their entirety in the January 2013 version of the regulations. Accordingly, DTSC has also deleted this corresponding definition.

§ 69501.1(a)(3) "Adverse air quality impacts"

Comments: 36-40, 138-7

Comments Summary:

Comments suggest that the language explicitly include “indoor and outdoor” air emissions.

Response:

DTSC has revised the January 2013 version of this definition in response to these comments. The term “indoor and outdoor” has been added to make it clear that air emissions of both are included under these regulations.

Other changes were made to the text to be clearer and consistent with the other parts of this article. The term quality was added to modify soil and water impacts, and the term ability was changed to potential.

Comment: 3-9

Comment Summary:

The proposed regulations define greenhouse gases like hydrofluorocarbons (HFCs), nitrogen oxides and nitrous oxides as air contaminants that have adverse impacts on air quality, but it is not clear what the basis for this classification is. DTSC has not accounted for the existing federal and state regulations on greenhouse gases. HFCs are currently regulated by U.S. EPA and have never been classified by U.S. EPA as air pollutants.

Response:

Greenhouse gases fit within the definition of "air contaminant" under California law (Health and Safety Code section 39013). The definition of “adverse air quality impacts” in these regulations lists the seven greenhouse gases, including HFCs, that are included in California law as constituting greenhouse gases (Health and Safety Code section 38505(g)(1)-(7)). Therefore, DTSC has accounted for existing state law and regulatory status of HFCs. This greenhouse gas definition was adopted as part of the California Global Warming Solutions Act of 2006 (Ch. 488, Stats. 2006, “AB 32”). The California Legislature included the following finding as part of AB 32: “The potential adverse impacts of global warming include the exacerbation of air quality problems, a reduction in the quality and supply of water to the state from the Sierra snowpack, a rise in sea levels resulting in the displacement of thousands of coastal businesses and residences, damage to marine ecosystems and the natural environment, and an increase in the incidences of infectious diseases, asthma, and other human health-related problems.”

Under federal law, states are allowed to adopt more expansive approaches to the regulation of air pollutants. However, the U.S. EPA has just recently begun regulating greenhouse gases under the Clean Air Act (Clean Air Act section 302(g), Clean Air Act section 202, part C of Title 1 of the Clean Air Act) after a 2012 court case (*Coalition for Responsible Regulation v. U.S. Environmental Protection Agency, No. 09-1322 (D.C. Cir. June 26, 2012)*).

[NOTE: The ability to limit greenhouse gas emissions already exists under various Clean Air Act authorities that Congress has enacted. DTSC understands there may be additional pending legislation that might affect this approach.]

Although the federal determination of greenhouse gases as air pollutants may still be controversial, in California, greenhouse gases meet the definition of air pollutants (Health and Safety Code section 39013). The California law is the basis for classifying greenhouse gases as air contaminants for purposes of these regulations. DTSC cannot remove all references to HFCs because there is no basis for removing them. HFCs are defined as greenhouse gases, and the enabling statue requires the AA process developed by these regulations to include consideration of greenhouse gas emissions. (Health and Safety Code section 25253(a)(2)(I)).

DTSC is not making any changes to the regulations in response to this comment.

Comments: 5-54, 5-55, 5-56, 5-57, 11-14, 57-13

Comments Summary:

These comments are concerned that the current definition of “adverse air quality impacts” is so broad that it exceeds the scope of DTSC's authority under the authorizing legislation. The existence of transparent, quantifiable thresholds gives responsible entities a clear understanding of what constitutes an adverse impact. The comments recommend that this definition be revised to include quantitative thresholds to ensure that the process for selecting Priority Products is appropriately transparent. A review of thresholds applicable in California Environmental Quality Act (CEQA) context, Public Resources Code section 21151.4(a) is suggested.

Response:

The regulations, under section 69501.1(a)(4), already provide for manufacturers to consider air quality standards or any projected air quality violations for determining if there are adverse environmental impacts (January 2013). Any exceedance of air quality thresholds is defined as an adverse impact in the regulations just as the

exceedance of the reporting quantities in Public Resources Code section 21151.4(a) disallows the certification of an environmental impact report. In both of these provisions, an exceedance of an established regulatory requirement is deemed detrimental.

For example, a manufacturer preparing an AA is required to consider any levels set by the South Coast Air Quality Management District for greenhouse gas emissions or any levels set by California's Air Resources Board if the manufacturer is located within these jurisdictions. Thus, the regulations use a blend of narrative and objective standards for this impact. DTSC believes this is the best approach to capturing the impacts that are the subject of these regulations. DTSC is not making any changes to the regulations in response to these comments.

Comment: 9-101

Comment Summary:

This comment suggests refinements in the language to add clarity. The commenter requests clarification as to what is meant by the ability of air contaminants to result in adverse impacts.

Response:

Air contaminants can result in both public health and environmental impacts. Air quality adverse impacts on public health have been well documented and may include:

- Increased mortality;
- Incidence of cancer;
- Frequency of symptomatic asthmatic attacks;
- Incidence of lower respiratory tract infections;
- Exacerbations of disease in persons with chronic cardiopulmonary problems;
- Rates of decline in pulmonary function;
- Prevalence of wheezing, or incidence of chest tightness;
- Incidence of acute upper respiratory infections; and
- Eye, nose, and throat irritation.

Global warming poses a serious threat to the quality and supply of water, and damage to marine ecosystems and the natural environment.

The effects are too numerous to enumerate in regulations. The comment did not provide any suggestions as to how to clarify the language to further explain the ability of air quality to cause adverse impacts.

DTSC has revised this definition and other text in the regulations in response to similar comments. Throughout the regulations, the term "ability" has been revised to "potential," which has now been defined in the regulations to mean that a "phenomenon described is reasonably foreseeable based on reliable information." (See discussion of section 69501.1(a)(51)(A) in the Response to Comments document for the January 2013 version of the regulations.) These revisions eliminating the use of "ability to cause" with "potential" and providing a definition of "potential" provides greater clarity to these regulations.

§ 69501.1(a)(4) "Adverse ecological impacts"

Comments: 5-58, 11-15, 124-15

Comments Summary:

The comments contend that this definition lacks clarity in two ways. First, the language contains several subjective terms that lack standards and clear definition for determining an actual adverse impact. Specifically, "deterioration or loss of environmentally sensitive habitats" and "changes in ecological communities" are terms that lack clear definition and exposition regarding how the DTSC will evaluate these impacts. Second, the definition lacks clarity regarding the threshold at which the stated adverse impacts occur. The definition should be revised so that those thresholds are clearly identified.

Response:

This definition of "adverse ecological impacts" lists the ecological resources that need to be assessed. The assessment should relate to relevant environmental statutory mandates but can also be a qualitative narrative that addresses relevant available information. The terms used in this definition are a combination of definitions established under California and federal law (endangered and threatened species, impaired water bodies, sensitive habitats, etc.) and terms used in ecological science (population size, biodiversity, ecological communities, etc.).

The protection of sensitive habitats is part of an ecological assessment. There are various California regulations and federal regulations and/or guidance documents that specifically protect sensitive habitats. The agencies that implement these resource regulations provide information for the conservation of sensitive habitats that can be used in making findings of adverse ecological impacts. For example, sensitive habitats are identified as follows:

- Environmentally sensitive habitat areas as defined by the Coastal Act (Public Resources Code, section 30107.5);
- Those marine areas designated by the California State Water Resources Control Board as areas of Special Biological Significance (Resolution No. 74-28);
- Areas which provide habitat for species of special concern as listed by the California Department of Fish and Game (renamed California Department of Fish and Wildlife) in the special animals list, natural diversity database;
- Areas which provide habitat for rare or endangered species which meet the definition of section 15380 of the California Environmental Quality Act guidelines; and
- Areas which provide habitat for rare, endangered or threatened species as designated by the California Fish and Game Commission or U.S. Fish and Wildlife Service.

"Ecological community" means a set of interacting populations (a group of organisms) that inhabit a certain geographical area. The most common effect of human activity on communities is an overall reduction of species diversity, but DTSC has also included changes in population size, and other changes. Communities are subject to threats of pollution (*e.g.*, acid deposition, stratospheric ozone depletion, air pollution, the greenhouse effect) and human activities (*e.g.*, soil erosion, deforestation) that can lead to the deterioration or loss of environmentally sensitive habitats, and consequently impact the characteristics of communities.

DTSC will not be establishing thresholds for any of these ecological impacts. This definition is not intended to be prescriptive and dictate the scale, complexity, or protocols for this assessment. There are various existing regulatory provisions that have designated various ecological resources (*e.g.*, habitat, fisheries) as impaired, or have established criteria for ecotoxicity, or endangered species.

The term "adverse impacts" is defined in the regulations under section 69501.1(a)(5) to mean adverse public health and/or environmental impacts (January 2013). These two terms are further defined under sections 69501.1(a)(4) and (6). DTSC did revise the definition of "adverse ecological impacts" in section 69501.1(a)(3) by changing the defined term "adverse impact," to "adverse effect" (January 2013). The term adverse effect should provide greater clarity because it does not introduce the broader scope of adverse impact.

Also see section 69501.1 Thresholds for Definitions of this document for additional discussion.

Comment: 57-15

Comment Summary:

There is a lack of clarity with the term “indirect,” what it encompasses, and how one measures this. That same definition further identifies “changes in population size” as a relevant endpoint. The definitions must be revised to include quantitative thresholds that can be easily understood and referenced during the research and development and AA process, and so that the process for selecting Priority Products is appropriately transparent. It is not clear how the baseline is determined to ascertain whether there has been an increase or decrease, the metric to use, or whether the metric or baseline has been shared with and agreed upon by stakeholders and regulators.

Response:

DTSC will assume this comment is referring to the use of the term “indirect” in the definition of “adverse ecological impacts” which contains the terms “indirect” and “changes in population size.”

Ecological communities are shaped by both direct and indirect interactions. Indirect effects consist of a sequence of at least two direct effect steps. The ISOR had examples of direct and indirect effects. The first was that biological organisms may also be contaminated with a chemical through chemical absorption or uptake of the chemical into plants or animals—with or without direct consequences of the biological organism’s survival (direct). Absorption without direct consequences may result in bioaccumulation in the plant or animal and eventually adversely affect higher organisms, which results in the loss of biodiversity (indirect).

A second example in the ISOR was that chemical contamination may cause direct vegetation contamination or damage (direct) and may also lead to the loss of biodiversity through acute toxicity of organisms in the soil (indirect). This may result in the loss of organic matter and other physical changes in the environment, such as erosion, soil compaction or other soil structural changes (indirect), which impact vegetation survival and negatively affect environmentally sensitive habitats, especially in environments already designated as impaired (indirect).

Indirect effects may be harder to determine than direct effects and there may be data gaps for the effects of exposure to every chemical. However, when there are well documented studies for direct and indirect exposure to chemicals having adverse effects on ecological receptors, this information should be used in the AA.

The above comment also implies that adverse impacts must be quantified with metrics that are then compared to specific thresholds or predetermined baselines for all the criteria listed under each of the definitions. This is simply not the case. Adverse impacts may be determined either with quantitative or qualitative assessments, which is another reason these regulations do not include thresholds.

No changes were made to the regulations in response to this comment.

Also see section 69501.1(a) Thresholds for Definitions of this for additional discussion on this comment.

§ 69501.1(a)(4) and (6) Reference to OEHHA Hazard Traits

Comments: 5-58, 11-16, 74-23

Comments Summary:

The OEHHA regulations referenced in these definitions are too broad. In addition to the due process concerns raised by references to definitions from another potential rulemaking, the definitions lack a scientific basis, and exceed the grant of authority provided by the authorizing legislation. DTSC is urged to coordinate with OEHHA and to provide an opportunity for the public to comment on both sets of proposed regulations in the same rulemaking process.
The OEHHA Green Chemistry Hazard Traits regulations (Chapter 54), as proposed, include many elements that are not authorized by the statute, unnecessary to effectuate the purpose of the statute, inconsistent and duplicative of other California statutes, and do not comport with current scientific consensus. The regulations should not reference OEHHA's Chapter 54 regulations.

Response:

The OEHHA regulations became effective on January 19, 2012, so there are no due process issues raised by the references to definitions from another *potential* rulemaking. Moreover, the fact that OEHHA and DTSC pursued separate rulemakings in coordination with each other is not a violation of due process; it was required by the authorizing legislation. Pursuant to Health and Safety Code 25256.1, OEHHA has consulted with DTSC in developing the hazard traits regulations. As further required by Health and Safety Code section 25252(b)(1), DTSC included the OEHHA criteria among the entirety of criteria it included for identifying and prioritizing Chemicals of Concern under these regulations. In addition, this approach gave stakeholders additional

opportunities for public comment, not fewer. Thus, the commenters got "due process plus" in this regard. DTSC also notes that it reviewed the OEHHA regulations and concurs with the format and content of those regulations. DTSC has continued to coordinate with OEHHA, to ensure that OEHHA regulations and these regulations complement each other. For additional discussion of the interaction of these regulations and the OEHHA regulations, see Procedural, Legal, and Overarching Issues discussion of due process issues. DTSC is not making any changes to the regulations in response to this comment.

§ 69501.1(a)(5) "Adverse environmental impacts" (ISOR Clarification)

Comment: 57-100

Comment Summary:

In the ISOR, section 69501.1(a)(5) defines "adverse environmental impacts" and refers one to "subsection (E)" for clarification of when a chemical exceeds an enforceable standard and the occurrence of an adverse impact. Subsection (E) does not exist in the regulation. The comment recommends that DTSC revise the text accordingly to address the lack of clarity.

Response:

In the ISOR, DTSC used "subsection (E)" to refer to "subparagraph (E)" in section 69501.1(a)(5)(E) of the regulations (July 2012). The FSOR will correct this reference to make this clearer. However, DTSC need not, and is not, revising the regulations text in response to this comment.

§ 69501.1(a)(6) "Adverse public health impacts"

Comments: 30-1, 36-43, 39-1, 39-2, 39-13, 86-10, 138-6

Comments Summary:

The comments support the consideration of occupational health as fully integrated into the regulations due to workers experiencing chemical exposures that are generally of higher levels and/or longer duration than experienced by the general public. The comments support the regulation's inclusion of "occupational health" as part of the definition of "public health."

Conversely, an opposing comment suggests deleting "occupational health" from the definition of "adverse public health impacts" so that the regulations can focus on consumer products.

Response:

Workers may be found at virtually every stage of a consumer product's life cycle. Workers extract ingredients for these products, make the products, recycle them, and dispose of them. Workers who may be exposed to numerous chemicals daily are sometimes the first group to manifest the effects of high exposure to industrial chemicals. Many environmental health hazards that have later been found to affect the health of the general population were first detected in the work environment and/or in the working populations. Thus, the occupational environment provides an early warning system for certain environmental health hazards[3]. Occupational health is included in this definition to address the workplace exposures that may be considered the cause of illness and disease. In addition, the inclusion of "occupational health" within the term "public health," is in keeping with general usage of these terms in the public health community.

DTSC appreciates this support. No changes were made in response to these comments.

Comment: 129-3

Comment Summary:

Adverse public health impacts should also include public health-related "exposure potential hazard traits" identified in OEHHA's regulations; namely, lactational or transplacental transfer, particle size, fiber dimension, and physical chemical hazards. Since the term almost exclusively refers to hazard traits as listed in Chapter 54, the name should be changed to "Public Health Hazards."

Response:

In the regulations, lactational or transplacental transfer is included in the definition of "reliable information demonstrating the occurrence, or potential occurrence of exposure" to a chemical. Further, if a chemical is identified by the federal Centers for Disease

[3] Global strategy on occupational health for all: The way to health at work, Recommendation of the second meeting of the WHO Collaborating Centres in Occupational Health, 11-14 October 1994, Beijing, China; www.who.int/occupational_health/globstrategy/en/index3.html

Control's biomonitoring program, or as a priority chemical under California's biomonitoring program, then it is identified as a Candidate Chemical under these regulations. This is due to the inclusion of these two biomonitoring lists as part of the Candidate Chemicals list in Article 2. Biomonitoring is also used as an exposure factor for the prioritization of products.

Particle size or fiber dimension is included in the definition of "adverse air quality impacts" which is then by reference also deemed to be an "adverse environmental impact." Under OEHHA's regulations, particle size is listed under exposure potential hazard traits.

Physical hazards are evaluated in the AA under these regulations. DTSC has determined that this is the most appropriate use of these hazard traits.

DTSC has determined how to best use the OEHHA's hazard traits that were developed for inclusion in the Toxics Information Clearinghouse under Health and Safety Code section 25256. DTSC has determined that not all of OEHHA's identified hazard traits and the scientific information, Articles 4 through 7 of Chapter 54 of Title 22 of the California Code of Regulations, fit under the definition of "adverse impacts" in these regulations. DTSC will not be revising these regulations in response to these comments.

Comment: 138-21

Comment Summary:

This section talks about "exceedance of an enforceable … standard relating to the protection of public health." When applying this definition, DTSC should not include the standards known as occupational exposure limits (permissible exposure limits in the U.S.). They are out-of-date in terms of current toxicological information. The comments recommend that in guidance materials describing "adverse public health effects," DTSC make it clear that occupational exposure limits, and U.S. permissible exposure limits in particular, are not enforceable standards that protect public health. Therefore, DTSC should expressly exclude permissible exposure limits and other occupational exposure limits from the standards that are related to public health.

Response:

DTSC respectfully declines the suggestion to revise this provision. DTSC does not agree that the occupational exposure limits named are out-of-date. In addition, even if these levels were somehow determined to be less than a reflection of the current state

of science, they remain enforceable regulatory limits. As such, they merit being reflected in these regulations. DTSC will not be revising the language to exclude occupational exposure limits or permissible exposure limits.

§ 69501.1(a)(7) "Adverse public health and/or environmental impacts"

Comments: 74-22, 107-24

Comments Summary:

Adverse impacts and chemical properties are defined for air quality, ecological, public health, soil quality, water quality, and waste/end-of-life related to hazard traits. Many traits are traditional endpoints addressed in state, federal, and international chemical programs.

Response:

The comment makes no recommendation for revisions or modification of this language. It is merely observational. DTSC is not making any changes to the regulations in response to these comments.

§ 69501.1(a)(8) "Adverse soil quality impacts"

Comments: 11-17, 68-12

Comments Summary:

DTSC should revise this definition to read, "means emissions to soil of contaminants in quantities that present an unacceptable public health or environmental risk." It seems highly unlikely that a chemical substance could have the adverse impacts mentioned.

Response:

The comment suggests that chemical substances do not affect soil function or properties, so the definition should be revised to address soil contaminants that may cause adverse public health or environmental impacts.

The definition of "adverse public health impacts" implicitly includes any exposure pathway that may affect public health including exposures to contaminated soils. In addition, DTSC explicitly included biological or chemical contamination of soils under the definition of "adverse ecological impacts." Both of these definitions address unacceptable public health or environmental risk due to contaminated soil.

DTSC has added a definition for “adverse soil quality impacts” to address the effects on soil function or properties caused by a Chemical of Concern, a Priority Product, or a potential alternative during any of the life cycle phases in the AA. As stated in the ISOR, if a Chemical of Concern, a Priority Product, or a chemical substitute for a Priority Product degrades biological activity, this degradation may result in the loss of biodiversity and organic matter. This, in turn, may lead to soil compaction or other soil structural changes, erosion, and soil sealing. Therefore, there is no need to change this definition to address the adverse public health or environmental impacts of a chemical substance.

§ 69501.1(a)(9) “Adverse waste and end-of-life impacts”

Comments: 5-59, 11-17

Comments Summary:

The comment contends that the definition is unclear. No adverse impacts are identified, so the definition should be revised to indicate what adverse waste and end-of-life impacts are covered by the definition.

Further, this definition requires that end-of-life impacts address not only the Chemicals of Concern but also other chemicals contained in the alternatives that differ from the chemicals contained in the Priority Product. Manufacturers of Priority Products may ultimately be subject to end-of-life management requirements that have no rational connection to the chemicals or components that are the subject of this regulatory process.

Response:

Many products sold have hazardous constituents that require special handling in order to reduce contamination to storm water, sewer systems, wastewater treatment plants, landfills, and the natural environment and that are very expensive to properly manage or remediate.

This definition does not address adverse public health and environmental impacts but instead addresses the effects that a Chemicals of Concern, a Priority Product, or a chemical substitute may have on the storage, treatment and disposal of solid waste, wastewater, or storm water discharges. This definition has been revised in the regulations (January 2013) in response to these comments. First, the term “adverse impact” has been removed from this definition. Second, the name of this term “adverse waste and end-of-life impacts” has been changed to “adverse waste and end-of-life

effects" to distinguish it from the other "adverse impacts" definitions. Finally, the definition has been revised to also include wastewater and recycled materials.

The definition does specify the types of effects that need to be assessed for waste materials and byproducts during the life cycle of a product in an AA. The assessment should relate to:

- Volume or mass;
- Special handling requirements;
- Effects on solid waste and wastewater treatment and disposal;
- The ability to use recycled materials;
- Discharges, or disposal to storm drains and sewers; and
- Releases into the environment as a result of any of these activities.

This assessment can also be quantitative or a qualitative narrative that addresses relevant available information.

DTSC has revised these regulations (January 2013) in response to comments to limit the focus or scope of the AA only on the Chemical(s) of Concerns in a Priority Product that led to its listing as a Priority Product or an alternative chemical selected chosen after the AA. This is true for regulatory responses dealing with end-of-life effects as well. DTSC agrees that the narrowing of this definition for purposes of regulatory response is appropriate and has made this conforming change.

§ 69501.1(a)(10) "Adverse water quality impacts"

Comment: 11-18

Comment Summary:

It should be clear that any of the "increases" cited in the definition should be of a magnitude that results in an unacceptably high increase in risk to public health or the environment. With respect to subsections (A) Increase in biological oxygen demand and (B) "Increase in chemical oxygen demand" they are effectively measures of biodegradability and the oxidizeable content of a chemical; these are generally not characterized as adverse impacts. Likewise, in subsection (D), "total dissolved solids" is simply a description of physical state of a material within water. These three subsections should be eliminated or a threshold at which the increase is adverse should be defined.

Response:

This definition lists factors that should be considered when evaluating adverse water quality impacts. These factors include water pollutants and indicators of water pollution listed under water quality laws and regulations. The requirement is to evaluate all existing available water quality-related data and other information on the factors listed in this definition.

Biological oxygen demand chemical oxygen demand or total dissolved solids are included as criteria because these three are all regulated under the Clean Water Act, which sets federal and state regulatory standards. Biological oxygen demand is listed as a conventional pollutant in the U.S. Clean Water Act and biological oxygen demand values above normal may indicate pollution by industrial, domestic, or agricultural sources and may cause low dissolved oxygen conditions within a water body. Chemical oxygen demand is regulated under the National Pollutant Discharge Elimination System (NPDES) in accordance with the Clean Water Act and the discharge limits are specific to a category of industrial users. Total dissolved solids are regulated under state and federal drinking water standards have designated secondary maximum contaminant levels.

DTSC will not revise this definition to remove these three criteria nor to include thresholds for any of these three factors into the text. Biological oxygen demand and chemical oxygen demand are listed by specific categories of industrial users and have different values, while maximum contaminant levels for total dissolved solids are provided in a range. Thus, it would be inappropriate for DTSC to establish generic numeric values for these three criteria.

§ 69501.1(a)(10)(E)2 Section 303(d) of the Clean Water Act

Comment: 26-2

Comment Summary:

The comment supports the fact that the proposed regulations define “adverse water quality impacts” to include introduction or increases in pollutants that impair water bodies listed under section 303(d) of the federal Clean Water Act.

Response:

DTSC appreciates the support for this definition. DTSC is not making any changes to the regulations.

§ 69501.1(a)(11) "Alternative"

Comments: 29-7, 76-26

Comments Summary:

The comments support this definition and the change proposed by DTSC that expands the definition of "Alternative" to include alternatives resulting from the removal of a substance and adjusting the ratio of remaining chemicals.

Response:

DTSC appreciates the support for this definition. DTSC is not making any changes to the regulations.

Comments: 5-60, 5-136, 9-101, 36-63, 39-9

Comments Summary:

The following comments all suggest revisions to this definition:

- Subparagraph (A) should be removed from this definition;
- Subparagraph (D) should be amended and use this alternative as a secondary option only if removal, reformulation, or redesign is not feasible;
- DTSC should add a new subparagraph to expand the definition of an "alternative" to include a technology substitution that would make the product type being considered unnecessary; and
- Subparagraph (C) should be amended to eliminate the phrase "using different materials."

Response:

The first suggestion to remove subparagraph (A) is unnecessary, because if a responsible entity can remove the Chemical of Concern in the Priority Product without making any other changes, it will not be subject to a regulatory response. In those circumstances, a Chemical Removal Notification (January 2013) may be submitted in lieu of either the Preliminary AA Report or a Final AA Report. This excuses the responsible entity from the regulatory response provisions as well, since a regulatory response may be imposed only after completion of an AA.

The suggestion for subparagraph (D) infers that removal, reformulation, or redesign is more favorable than any other possible "alternative." The comment did not explain why it is necessary to restrict "alternatives" under subparagraph (D). DTSC disagrees that

the “alternatives” should be restricted or tiered. When a responsible entity is identifying possible “alternatives” for the AA, there should not be any restriction to what is being considered. Stakeholders will have the opportunity to weigh in with preferred “alternatives” during the public notice for the regulatory response. DTSC will not amend the language to include this revision.

The suggestion for a new subparagraph to address the concern about substitute technologies is not necessary because subparagraph (D) covers any other changes, such as new technologies.

DTSC will not revise the definition in response to the first three comments. These suggestions are either not necessary or do not add additional clarity.

DTSC has revised this provision to address the suggestion to remove the phrase, “using different materials,” in subparagraph (C). Subparagraph (D) was also revised to clarify that an “alternative” is allowed that will reduce “adverse waste and end-of-life effects.”

§ 69501.1(a)(12) “Alternatives Analysis” or “AA”

Comments: 5-137, 76-27

Comments Summary:

These comments provide suggested language to narrow the scope of the definition, which are paraphrased as follows:

- “Alternatives Analysis” or “AA” means an evaluation and comparison of <u>the Chemical(s) of Concern within</u> a Priority Product and one or more alternatives to the <u>Chemical(s) of Concern</u>. (In order to align with the statutory language, an AA should be defined as an evaluation of a Chemical of Concern and its functionally equivalent alternatives in a consumer product.); and
- “Alternatives Analysis” or “AA” means an evaluation and comparison of a Priority Product and one or more alternatives to the <u>Priority</u> Product.

Response:

The language in the definition states an “‘Alternatives Analysis’ means an evaluation and comparison of a *Priority Product* and one or more *alternatives* to the product.” The term “Priority Product” is a specific product-chemical combination. Under subsection 69503.5(b)(2)(B) of the January 2013 version of the regulations, when a product-chemical combination is listed as Priority Product, the Candidate Chemical is designated as a Chemical of Concern. The term “alternative” is also defined.

The first comment suggests that adding the phrase, “the Chemicals of Concern within” the Priority Product will align the definition of “Alternatives Analysis” with the statutory goal to evaluate a Chemical of Concern in a consumer product and their potential alternatives (Health and Safety Code section 25253(a)). A Priority Product in the regulations is a “Chemical of Concern” in a “consumer product,” so adding the phrase “Chemical of Concern within” a Priority Product is redundant. DTSC respectfully disagrees that the current definition of the “Alternatives Analysis” needs to be revised to add “Chemical of Concern.”

The second comment suggests that the term product in this definition be replaced with “Priority Product.” This is unnecessary because the term “alternative” in this definition includes by reference “Priority Product.” DTSC will not be revising the language in the regulations in response to these comments.

§ 69501.1(a)(13) “Alternatives Analysis Threshold” or “AA Threshold”

Comment: 29-7

Comment Summary:

The comment supports the definition.

Response:

DTSC appreciates the support and is making no changes to the regulations in response to this comment.

Comment: 76-28

Comment Summary:

The development of each AA Threshold will be resource-intensive. Having a default threshold for triggering an AA, which can be modified as necessary, may:

- Make the process for setting AA Thresholds less challenging;
- Provide guidance to industry; and
- Facilitate a reasoned discussion about the Chemical(s) of Concern instead of the detection limit.

The comment supports a default AA threshold of 0.01% or 100 parts per million (ppm) that could be adjusted based on reliable information. The suggested language provided

includes an AA Threshold to be 100 ppm that can be adjusted higher or lower based on reliable information.

Response:

In response to comments, DTSC has revised this section. The AA Threshold is now defined as "(A) the Practical Quantitation Limit (PQL) for a Chemical of Concern that is solely present as a contaminant; or (B) The applicable concentration, if any, specified by the Department under section 69503.5(c)." (January and April 2013) Chemicals of Concern that are intentionally added to a consumer product do not qualify for this exemption from the AA.

However, when the Priority Products are established through rulemaking, DTSC may consider proposing AA Thresholds for intentionally added ingredients or for contaminants above the PQL if reliable information is available to substantiate modifying the default values in the regulations. The public review and comment period for each proposed Priority Product listing will give interested parties the opportunity to present information to DTSC to support: (i) an AA Threshold proposed by DTSC in the proposed Priority Product listing; (ii) a request that DTSC revise or eliminate the AA Threshold proposed by DTSC; or (iii) a request that DTSC specify an AA Threshold in the Priority Product listing in the event that DTSC has not proposed an AA Threshold.

This approach also addresses the concern regarding DTSC resources needed to set an AA Threshold. If DTSC does not have resources, then the default values are not revised. The defaults will provide greater certainty for industry. Also see section 69503.5(c) Alternatives Analysis Threshold in the Response to Comments document for the April 2013 version of the regulations for additional discussion on this comment.

§ 69501.1(a)(14) "Alternatives Analysis Threshold Exemption Notification"

Comments: 5-138, 76-29

Comments Summary:

The comments urge DTSC to delete the AA Threshold Exemption Notifications and thus, this definition as well. The comments urge DTSC to delete section 69501.1(a)(14) in its entirety.

Response:

DTSC will not revise the language as urged in this comment. This provision is necessary so that DTSC, other responsible entities for the Priority Product, and

interested parties are made aware that the Priority Product qualifies for an AA Threshold exemption, and thus know not to expect an AA Report for the Priority Product. It is also necessary for DTSC to plan its work and maximize its limited resources in reviewing AA Reports. Each of the particular content pieces is necessary in order for the responsible entity to be confident in its determination, DTSC to have an ability to monitor and follow up on claims of exemption from the AA requirement, and to engender confidence in this largely self-implementing piece of the program. Also see section 69503.6 Alternatives Analysis Threshold Exemption Notification of this document for additional discussion on this comment.

§ 69501.1(a)(17) "Bioaccumulation"

Comments: 11-19, 74-25, 107-27

Comments Summary:

The definition of "bioaccumulation" includes the previous DTSC definition and a reference to OEHHA's hazard traits. It is not clear why such an important chemical property should be defined uniquely in California. This will slow the program's progress as DTSC attempts to translate all of the extensive information, learning and actions from global programs into a California-unique approach.

There are two recommendations to fix this concern:

- The definition should be revised to adopt thresholds consistent with the scientific consensus of the Society of Environmental Toxicology and Chemistry's Pellston Workshop; and
- The "bioaccumulation" definition should be changed to be consistent with the U.S. EPA policy statement entitled 'Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances' (64 Federal Register 60194; Nov. 4, 1999).

Response:

DTSC has revised language in this definition to reference only OEHHA's definition of "bioaccumulation" for increased clarity. However, DTSC disagrees that this definition or the previous definition is inconsistent with nationally and internationally accepted definitions, which include thresholds. The referenced OEHHA definition lists various criteria and corresponding thresholds that may be considered as evidence of bioaccumulation. Except for the bioaccumulation factor the OEHHA thresholds are the same as the Society of Environmental Toxicology and Chemistry Workgroup's recommendations. The OEHHA evidence threshold for bioaccumulation factor or

bioconcentration factor is 1,000, which is in line with U.S. EPA's policy statement which limits the bioconcentration factor to 1,000 (64 Federal Register. 60194; Nov. 4, 1999). Please note that both the Society of Environmental Toxicology and Chemistry and the EPA policy on bioaccumulation are only guidance and are not regulatory standards, while OEHHA's thresholds are in regulations in Chapter 54.

§ 69501.1(a)(18) "Certified assessor"

Comments: 76-30, 86-11

Comments Summary:

The comment strongly urges DTSC to delete the certified assessor procedures and thus, this corresponding definition. The comment urges DTSC to delete section 69501.1(a)(18) in its entirety.

Response:

DTSC has eliminated the entirety of the Accreditation Bodies and Certified Assessors program previously set out in Article 8. This change occurred with the January 2013 version of the regulations. Thus, the definition was also removed from the text in the January 2013 version.

§ 69501.1(a)(19) "Chemical" and "Molecular Identity"

Comments: 11-20, 36-37, 36-68, 68-14, 74-13, 101-15, 107-14, PH24-2

Comments Summary:

The definition of "chemical" needs to be revised to the following issues:

- "Chemical ingredient" should be revised to include intentionally added chemicals;
- Subparagraphs (A)(1) and (A)(2) need to be more closely connected;
- The term "molecular identity" needs clarification; and
- The indirect references to precursors and traces need to be removed.

This definition should be consistent with other regulations whereby ingredients are recognized as functional components of a product intentionally added to impart a function. Contaminants could be considered as a "chemical ingredient," under this definition. Suggested language is provided.

Second, in the definition of "chemical ingredient," the qualifiers are disconnected from the qualifiers that exist in the previous subparagraph. Suggested language is provided.

Third, the definition for the term "molecular identity" is somewhat confusing. It might be better to use the term, “substance identity.” Conversely, a second comment supports this definition of “molecular identity,” which is used as a descriptor for “chemical.”

Fourth, the definition of “chemical” contains an indirect reference to traces and precursors, which appears to be an attempt to sweep within the ambit of the regulations everything that conceivably might be of interest rather than focusing attention on the subset of chemicals of interest. However, two commenters disagree and support the addition of “degradates, metabolites, and reaction products” in the definition of a “chemical,” and consideration of a Chemical of Concern’s ability to degrade, form reaction products, or metabolize into another Chemical of Concern.

Response:

The definition of “chemical” has been revised to address two of these concerns. DTSC has simplified the definition of “chemical ingredient” to mean a substance comprised of one or more substances. This revision removes the issue of disconnected qualifiers. In response to these comments, “Molecular identity” has been further defined and a list of the substance’s properties has been added.

DTSC did not revise the definition of “chemical ingredient” as suggested to specify that “chemical ingredient” means only intentionally added chemicals that impart or serve a function in the consumer product. That was not DTSC’s intention in using this term and crafting its definition. The intent of the term “ingredient” is to address compositions or complex combination of different molecules. DTSC respectfully disagrees that including a substance, element, ion, uncombined radical, degradate, metabolite, or reaction product of a substance gives DTSC unlimited authority. As stated in the ISOR, this definition merely captures the different forms a chemical may take. DTSC appreciates the support for this definition expressed by some of the commenters. Again, DTSC made the two revisions noted above, and declines to make changes in response to the other two suggestions.

Comment: 14-6

Comment Summary:

DTSC defines “chemical” as an “organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or part, as a result of a chemical reaction or occurring in nature, and any element or

uncombined radical." The definition of "chemical" should exclude natural products that are not chemically altered, such as wood in lumber products.

Response:

Natural products that are not chemically altered meet the current definition of a chemical in the regulations. Further, there are naturally occurring chemicals that are identified as Candidate Chemicals under section 69502.2 of the regulations. It would be inappropriate to exclude natural products that exhibit hazard traits from the regulations if they are used in a consumer product. This is because the risk of harm to the public health and/or the environment would be the same whether the chemical occurs naturally or as a result of human activity(ies). No changes will be made to this provision in response to this comment.

Comments: 68-13, 101-16

Comment Summary:

The definition of "chemical" is rather specific and not in line with international standards such as "substance" and "mixture" defined in the United Nation's GHS. This can lead to confusion, and clarity could be increased by specifying that a "chemical" is either a substance or a mixture and then using the GHS definitions for these two terms.

Response:

The GHS is designed as a set of guidelines for ensuring the safe production, transport, handling, use, and disposal of hazardous materials, including bulk. GHS's framework involves classifying chemicals according to their hazards, and communicating hazard information through standardized label elements and safety data sheets. The GHS definition of "substance" is:

> *"Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition…"*

These regulations need to address Chemicals of Concern in Priority Products, so the GHS definition of substances that allows for additives and impurities is not appropriate for these regulations. First, a Chemical on Concern in these regulations can be a contaminant or an intentionally added ingredient. The GHS definition allows impurities and additives to be grouped together with the substance and does not distinguish between the two. For example, GHS provides chemical mixtures to be generally

classified based on the hazards of the ingredients that are present in the mixture above specified generic thresholds. These threshold values can range between 0.1% and 10%, depending on the specific hazard, and would, therefore, not be listed on the Safety Data Sheet or label. While this definition of substance may be appropriate for handling of bulk substances, the goals of the regulations and the GHS are different enough to require a different definition for “chemical.” Second, “chemical” in these regulations can include ions, uncombined radicals, degradates, and metabolites, while in the GHS definition, they are not identified separately. “Molecular identity” is included in the definition of “chemical” to be able to specify nanomaterial, if needed. The GHS does not address this issue.

The suggestion to redefine “chemical” as either a substance or a mixture, and then use the GHS definitions for these two terms, again does not address the issues of additives, impurities, inconsistent thresholds, lack of additional specificity to address molecular identity, ions, radicals, degradates, or metabolites.

The language in Health and Safety Code 25251 et seq. (AB 1879, the authorizing legislations) discusses only chemicals in products, and not substances or mixtures. By defining the term “chemical,” the regulations makes specific what is meant by its use in the statutory language. DTSC will be identifying Candidate Chemicals and Priority Products, including the Chemical(s) of Concern that is/are the basis for the listing. Therefore, there should be no confusion as to what is a “chemical.” Further, the AA does not narrow the alternatives to be considered to chemicals only.

The definition has been amended in the proposed regulations (January 2013) to expand the term molecular identity, but no additional changes were made in response to these comments.

§ 69501.1(a)(20) “Chemical of Concern”

Comments: 5-139, 11-21

Comment Summary:

The comments suggest revisions to this definition. The definition should be based on DTSC’s listing, not on lists developed by authoritative bodies. Chemicals of Concern should be limited to ingredients intentionally added to a consumer product. The following suggestions were received:

- Revise the definition to read "means an ingredient not chemical listed by the Department under section 69502.3(b).”; and

- A second comment requested that the language should be revised to include, "or identified as a Chemical of Concern by the European Commission under the REACH initiative."

Response:

The previous list of Chemicals of Concern is now called the Candidate Chemicals list. The regulations define Candidate Chemical as a chemical that is a candidate for designation as a Chemical of Concern. A Candidate Chemical that is the basis for a product-chemical combination being listed as a Priority Product is designated as a Chemical of Concern with respect to that product. These comments pertain to the newly defined Candidate Chemicals that were previously called Chemicals of Concern.

The language will not be revised to limit chemicals on this list to chemicals intentionally added to products. These regulations cover both intentionally and unintentionally added chemical ingredients. This is consistent with the purposes of the authorizing legislation and these regulations to accelerate the quest for safer consumer products. There is no good scientific or policy reason for DTSC to refrain from protecting public health and the environment from unintentionally added ingredients as well as intentionally added ingredients.

The Candidate Chemicals list will continue to be based on the work already done by authoritative bodies. Building on their work will allow DTSC to speed up the implementation of these regulations. It is also consistent with the statutory directive to leverage the work of other "nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy." (Health and Safety Code section 25252(b)(2))

REACH considers substances to be of very high concern if they are carcinogenic, mutagenic or toxic for reproduction, persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, and endocrine disruptors. The Candidate Chemicals list includes various regulatory lists adopted by the European Union, which include all of the above traits. The regulations have been revised to now include respiratory sensitizers. It is not clear if there is a specific list that the commenter is requesting to be included. For a detailed discussion of each of the 23 lists that comprise the Candidate Chemicals list, see discussions of Article 2 in this Response to Comments document and in the ISOR.

§ 69501.1(a)(21) "Component"

Comments: 5-12, 5-61, 5-153, 9-103, 19-19, 19-20, 19-24, 22-9, 22-10, 66-10, 80-5, PH2-4, PH9-3

Comments Summary:

The definition of "component" remains vague, allowing for complex assemblies or multi-components systems to be the subject of an AA. By adopting a more focused definition, the AA process becomes more workable, because the target product is better defined. The definition of “component” should satisfy all needs for the focus of an AA. “Component” is preferable to “homogenous material” because analytical testing is easier, and the information collected in supply chains is at the component level.

Some of the comments recommend focusing on materials within a uniquely identifiable part or piece and delete the phrase “assembly or subassembly, system or subsystem.” There was additional suggested language in many comments to redefine the term “component,” narrow the scope of the definition of component to address complex durable goods, or to include this definition within section 69503.4(a)(2)(B)4.

Response:

As stated in the ISOR, the concept of “component” is used as a way to target materials within a product that are cause for concern, and as such, must undergo an AA. In this manner, a Priority Product may be identified by DTSC as specifically as necessary to determine public health and/or environmental impacts.

Contrary to the comments, the intent of this term is to have the flexibility so as to not have to name an entire consumer product as the focus of an AA. Again, as an example, let us assume that the Priority Product is a baby bottle containing Bisphenol A (BPA). The Priority Product (baby bottle) may include four parts, the bottle itself, the ring, the nipple, and a cap/cover. As the regulations are written, DTSC could name all of the parts or a single part that contain the Chemical of Concern. Therefore, the Priority Product could be the entire baby bottle (the bottle itself, the ring, the nipple, and a cap/cover) containing Bisphenol A, or the Priority Product could be listed as the nipple containing Bisphenol A. Depending on the complexity of the product, the definition will allow DTSC to name a part, a piece, an assembly, or a subassembly.

DTSC has amended the regulations to delete references to “system or subsystem” in order to narrow the scope of the AA, as appropriate. The terms assembly or subassembly were not removed because it may be necessary to include these terms to narrow the description of the Priority Product.

The term “homogenous material” has been defined within the definition of “component” to simplify the language. The revised definition of “component” now satisfies all needs for the focus of an AA. DTSC may pick either when identifying a Priority Product, which is subject to the Administrative Procedure Act (APA). As such, during the rulemaking there will be public notice of the proposal and opportunity for comments on any issues that may affect implementation, such as analytical testing, or supply chain communication.

DTSC is not revising the regulatory language to limit the definition of “component” to apply only to “highly durable products” (now renamed “complex durable products”). The term “component” is necessary in the regulations to apply to all products whether they are assembled, or packaged. DTSC also did not incorporate any of the suggested language provided because DTSC’s revised language addresses the issue of “a material within a part, piece, assembly, or subassembly.”
Comments: 5-139, 46-1, 57-17, 57-20, 74-16

Comment Summary:

The above comments suggest a revision or provide language to exempt inaccessible components from the definition of “component” or to delete this definition altogether. The term component is unnecessary if the definition of “consumer product” is revised to include components.

Response:

DTSC has modified the definitions of “component,” “homogenous material,” and “consumer products” in response to some of these concerns. Instead of adopting any of the suggested language, however, DTSC has incorporated the term “homogenous material” to better define “component.” The concept of “component” is critical to these regulations because it allows DTSC to name a Priority Product to be an entire product or more likely, some unique part of a product. By defining “component,” DTSC can narrow the scope of an AA as appropriate. Deleting this term does not address the concern about the broad scope of these regulations.

DTSC did not include a new subparagraph to exclude inaccessible components. The proposed Priority Products will go through a formal APA process before being adopted in regulations. As such, public comment periods will provide an opportunity for any stakeholder to present data that shows that an inaccessible component should not be listed and subject to an AA. In addition, see the earlier discussion in this document on

why it is appropriate for the reach of these regulations to extend to inaccessible components.

ISOR Comment – "Component"

Comments: 5-50, 5-52, 5-53

Comments Summary:

The ISOR posits an example of how the regulations may be used to impose new requirements on components. The example given was catalytic converters. Tailpipe emissions from catalytic converters may overlap and potentially interfere with the regulatory authority of another agency. Priority Products should be selected based on the Chemicals of Concern in the product, which is the intent of the enabling statute.

Response:

The example cited in this comment has been removed from the ISOR to eliminate any confusion. A Priority Product subject to these regulations is the combination of a consumer product and a Chemical of Concern, which is in line with the statutory intent of the enabling legislation. DTSC will not be implementing these regulations in a manner that will interfere or duplicate existing regulations. See responses to comments regarding the Revised ISOR for further discussion of the elimination of catalytic converters from the initial ISOR.

§ 69501.1(a)(22) "Consumer product" or "Product"

Comments: 1-1, 1-2, 5-140, 9-103, 19-36, 65-1, 132-3

Comments Summary:

The following comments are suggestions to revise the definition of "consumer product." Concerns regarding this term included:

- The definition is overly broad and will allow few exceptions;
- The regulations should be clearly geared towards those "consumer products" for which more frequent and/or intimate contact is common, thus increasing any risk of potential exposure to align with the goals of the statue;
- There should be good definition of "products" upfront in the document; and
- As DTSC and California Air Resources Board are within the Cal/EPA, multiple definitions of "consumer product" within an Agency will create ambiguity and unnecessarily complicate business planning.

Suggestions to revise the language fell into two categories. One set of comments provided general requests for revisions and the second set provided specific edits to the definition. The general suggestion was that this definition should omit substances that are already heavily regulated and are outside of retail transactions. Specific revisions provided included various versions of the following:

- Harmonize the definition with California Air Resources Board's "consumer product" definition, which provides a manageable scope of that regulation;
- Combine the terms "product" and "component";
- Clarify that "component" may also include a uniquely identifiable material within a component instead of using the term "homogenous material";
- Delete the term "historic product" from the definition of "consumer product" and create a standalone definition for "historic product";
- Add a new subparagraph that exempts a product that is regulated or pending regulation by another federal or state entity, with respect to one or more adverse impacts or exposure pathways, for the same or essentially equivalent health or environmental concerns for the listed Chemical of Concern; and
- Use the ISOR description of product categories (section 69503.3(f)) and/or use the global product classification standards, as the definition of consumer products.

Response:

DTSC respectfully disagrees that the definition of "consumer products" should be harmonized with California Air Resources Board's consumer products regulations. The definition under the California Air Resources Board's regulations (Title 17, California Code of Regulation, section 94508) applies only to chemically formulated products. This California Air Resources Board regulation specifically addresses volatile organic compound emissions from consumer products. The authorizing legislation for these regulations (Health and Safety Code section 25252(a)(2)) requires the regulations to address exposures to chemicals, which is much broader than just releases of volatile organic compounds to the air. Accordingly, given this wide divergence in scope of the two programs, this definition will not be revised in response to these comments.

As for the specific suggestions for revising the language, DTSC did not incorporate the definition of "component" into the definition of "consumer product." "Consumer product" is defined in the authorizing legislation (Health and Safety Code section 25251). DTSC felt that the concept of "component" needed a separate definition for clarity and that combining it within the definition is more confusing.

The suggestion that “component” should include a uniquely identifiable material within a component instead of using the term “homogenous material” was made as part of the suggestion to merge the definition of component into the definition of “consumer product.” The definition of component has been revised and the term “homogenous material” has been defined within the definition of “component.” DTSC did not revise the regulations to delete the term “homogenous materials” because this term may be extremely useful for purposes of determining the AA Thresholds. See section 69501.1(a)(21) of this document for further discussion on this issue.

The original intent of section 69501.1(a)(24)(B) was to set the date of applicability for consumer products subject to AA. Use of the term “historic product” was to make clear that a product manufactured before being listed as a Priority Product would be referred to as a “historic product” and not subject to an AA. The same product would be referred to as a “Priority Product” after being listed as a “Priority Product” and subject to the substantive requirements of the regulations. This terminology created confusion for some stakeholders, because it seemed to create an exclusion from the regulations. DTSC has revised the definition and has removed the term “historic product” from this definition and the concept of when a Priority Product is subject to the substantive requirement of the regulations still remains in the definition of “consumer product.” The term “historic product” no longer is used in the January 2013 version of the proposed regulations; thus, DTSC will not be revising the regulations to add a definition for historical products. See also section 69501.1(a)(new) Add “Historic Product” of this document for further discussion on this issue.

The language regarding duplicative regulatory considerations was not added to this definition, but DTSC did provide similar language in section 69501(b)(3)(A) of the January 2013 version of the proposed regulations. See Legal, Procedural, and Overarching Issues portion of this Response to Comments document for a detailed discussion of the Regulatory Duplication/Conflict issue.

DTSC will not redefine consumer product as a product category because these are two different concepts in the regulations. DTSC may use the global product classification standards to describe product categories that will be listed on the Priority Product Work Plan. This work plan is intended to provide interested parties some certainty as to what type of products will be under consideration for the next three-year period. Consumer products listed as Priority Products will be much more specific than a general product category. For example, a product category may be as broad as cleaning products, but a Priority Product will be defined as a product-chemical combination, such as manual dish washing soap (consumer product) with a specific surfactant (Chemical of Concern).

Accordingly, DTSC is not making changes to the regulations in response to these comments.

"Consumer product" – Exemption Requests

Comments: 4-6, 4-10, 19-36, 107-15, 122-1, 122-9, 132-3, 132-7, 132-8, PH2-1, PH14-3, PH34-3, PH34-4

Comment Summary:

The above comments request that a specific exemption be incorporated into the definition of "consumer products" to exempt products with which they are affiliated and some provided specific language.

Response:

Under well-established principles of the proper exercise of rulemaking authority granted to administrative agencies, the implementing regulations may neither expand nor shrink the scope of the authority conferred by the authorizing statute. Here, DTSC is being urged to shrink the scope of the statute by adopting exemptions that were not set out in the authorizing statute. DTSC has no authority to limit the reach of the statute by drafting such exemptions when the Legislature did not confer such authority. See the discussion in the Procedural, Legal, and Overarching Issues portion of this Response to Comments document for a detailed discussion of exemption requests.

Therefore, DTSC declines to adopt any of the partial or complete exemptions urged by the above comments.

§ 69501.1(a)(22)(B)1 and 2 Historic Product and Replacement Parts

Comments: 5-62, 5-110, 19-4, 19-5, 19-6, 19-7, 19-8, 19-9, 19-11, 21-3, 23-1, 22-8, 42-6, 42-13, 42-14, 42-15, 42-16, 42-17, 44-4, 44-5, 55-16, 55-17, 65-1, 66-9, 66-11, PH1-1, PH2-5, PH9-4, PH34-4

Comments Summary:
There are concerns that the exemption for historic products is too narrow and does not exempt products necessary to service, maintain, or repair existing products. Comments state the following:

- The difficulty to reengineer service parts that perform as well as the original parts in the product;

- Definition of “historic product” is not consistent with the definition of “manufacture” which exempts repair or refurbishment from the definition of manufacture;
- There is a potential inconsistency with California’s Song-Beverly Consumer Warranty Act; and
- Expanding this definition would make it wholly consistent with the “Repair as Produced” approach adopted by the European Commission (EC) for the End of Life Vehicle Directive.

Further, the authorizing legislation (Health and Safety Code section 25253(b)) makes it clear that the Legislature did not intend to regulate certain products that were manufactured prior to development of a Priority Products list.

The recommendations for amending the definition for "historic product" are to revise the definition as follows:

- Exempt replacement parts that are manufactured or produced prior to the date the component(s) are listed as a Priority Product or regardless of when it was manufactured;
- Exempt replacement parts that are manufactured before the regulatory response is imposed;
- Exempt replacement parts that are ordered prior to being listed as Priority Products; or
- Exempt from regulatory response requirements interim products manufactured after the Priority Product Listing but before the regulatory response is determined and add a definition for “interim products.”

Response:
The term “historic product” was introduced to clarify that any product that ceased to be produced before the Priority Product listing of that product is outside the scope of these regulations. Instead, this term seems to have created confusion and concerns. DTSC has revised these regulations in response to these comments and has eliminated this term; but has not eliminated the concept, which is still needed to specify when the regulations apply.

DTSC did not include service, replacement, repair, or spare parts in the definition of “consumer products” because it was never DTSC’s intent to exempt replacement parts. Replacement parts listed a as a Priority Product would be not be subject to the substantive requirements of these regulations, if the manufacturing of replacement parts ceases prior to the replacement part being listed as a Priority Product. Including an explicit exemption in the regulations for any repair or maintenance part, regardless of

when the component is manufactured, would basically exempt all replacement parts or components of a product from these regulations.

Further, DTSC respectfully disagrees that the regulations should be revised to be consistent with the European Directive for end-of-life vehicles, which exempts replacement parts regardless of when the part is manufactured. These regulations will have to apply to a much wider category of products than just automobiles. Regulatory responses will be subject to a public comment period. If an automotive component is the subject to a regulatory response, DTSC may consider adjusting the implementation of the regulatory response depending on which regulatory response is being considered. Most regulatory responses would not be applied retroactively, except for end-of-life management requirements.

Exempting replacement parts before the regulatory response would also exempt replacement parts from the AA, which is not the intent of these regulations. Without a completed AA, a regulatory response determination cannot be made.

Exempting replacement parts that are ordered prior to being listed as a Priority Product is already included in the regulations. Retailers and assemblers have at least 90 days after DTSC has notified them that the manufacturer or the importer has not complied. The 90 days does not start when the Priority Product is listed but starts when the manufacturer or the importer has failed to meet the 60-day deadline for submitting a notification to DTSC. This provision was renumbered in the proposed regulations as section 69501.2(b)(1) (January 2013). Accordingly, the regulations do not need to be revised to add a provision that already exists in the regulations.

Exempting replacement parts from regulatory response before the regulatory response, but after the Priority Product listing, may not be necessary. DTSC understands that the regulated industry must continue to conduct business, but this issue is more appropriately addressed at the time the regulatory response is imposed. Again, extending the exemption to the effective date of the regulatory response may not be adequate to address additional time necessary for reformulation or a redesign of the Priority Product. This should be addressed at the time the regulatory response is being proposed.

The definition of “manufacture” exempts repair or refurbishment as activities that are not considered manufacturing for purposes of these regulations. DTSC respectfully disagrees that the definition of “historic products” needs to exempt replacement parts in order to be consistent with the definition of “manufacture.” The regulations have been

revised to eliminate the term “historic product.” The provision in the definition of “consumer product” that originally included the term “historic product” was intended to establish the date for applicability of these regulations. The provision in the definition “manufacture” was to exclude from the substantive requirements any person that repaired a Priority Product. This same exclusion was not meant to be extended to the manufacturer of the Priority Product.

The Song-Beverly Consumer Warranty Act (Civil Code section 1790 et seq.), which is also known as the Lemon Law, provides protection for consumers who lease or buy new motor vehicles. The law requires that if a new vehicle cannot be serviced or repaired to meet the terms of a warranty, the manufacturer be required promptly to replace the vehicle or return the purchase price to the lessee or buyer. It is DTSC’s understanding that when a new vehicle is produced that many of the service parts are also manufactured to maintain a multi-year inventory of original equipment parts. If DTSC were to propose a Priority Product that is critical to the repair of a new motor vehicle, there would be ample opportunity to address this concern during the rulemaking process, which is now included in the revised text, for the issuance of the Priority Products list. DTSC believes this is a more appropriate approach than just exempting all repair and replacement parts for all products regardless of when they are manufactured. This would also be true if a specific part created a re-engineering dilemma. DTSC will not revise the language in response to these comments.

DTSC finds that there is no support for the statement that the statutory language disallows the regulation of certain products that were manufactured prior to development of a Priority Products list. The term Priority Product only exists in the proposed regulations; therefore, it is not clear to DTSC how the statutes may be interpreted as excluding products prior to the development of a Priority Products list. The only statutory exemptions to these regulations are found in Health and Safety Code section 25251; Priority Products is not one of them.

Comment: 114-18

Comment Summary:

DTSC should remove the exemption for “historic products.” This blanket exemption should not be made without further evaluation of public and environmental health threats from the product. DTSC should strike this definition out of the regulation and make these considerations when developing product-specific regulatory responses, using the established principles.

Response:

DTSC respectfully disagrees with this comment and finds that it is necessary to exempt products that are manufactured prior to the date the Priority Product is listed. Listing a Priority Product that is no longer being manufactured would be inconsistent with the statutory intent to evaluate the potential for alternatives for consumer products. DTSC sees limited or no purpose to evaluate alternatives for products that have already been manufactured. For example, floor tiles with asbestos are no longer being made but still exist in some homes. If DTSC named floor tiles with asbestos as a Priority Product and required the AA to be completed by the manufacturer, assuming the manufacturer still exists, what would be an appropriate regulatory response for this product that would limit exposure or reduce the level of hazard? The regulatory response(s) would be severely limited because the product is no longer manufactured.

A different scenario that could occur is that DTSC could name a Priority Product that some manufacturers have stopped producing, while others continue to make. The manufacturers that continue to make the Priority Product would be subject to the regulations. Manufacturers that remove the Priority Product from the stream of commerce in California can submit a Priority Product Removal Notification in lieu of an AA and be exempt from regulatory response requirements. Providing an exemption for products that ceased to be manufactured before the Priority Product is listed is in line with this notification option. The statute did not empower DTSC to order the embargo, recall of, or confiscation of any products offered for sale that do not meet the requirements of these regulations. However, the regulations allow retailers or assemblers to continue to sell or use any remaining inventories as long as they do not order any additional product while exhausting their inventory. DTSC will not be revising the regulations is response to this comment.

§ 69501.1(a)(22)(C) "Consumer product" or "Product" Previously Owned

Comment: 42-12

Comment Summary:

The proposed definition does not carve out products that have been purchased for resale prior to being named a Priority Product. Retailers who purchase products for resale that have not been declared Priority Products expect that the products will be perfectly suitable for sale. A better approach would be to ensure that consumers and retailers who purchased products prior to being listed as Priority Products should not face negative consequences for their choices.

Response:

This comment reflects a misunderstanding of the proposed definition. Subparagraph (C) provides an exemption for products previously owned or leased by someone other than the manufacturer, importer, distributor or retailer. For example, if the products being offered for resale were previously owned by a private individual, then this exemption applies and there is no requirement to complete an AA.
Retailers are allowed to sell any inventory they own at the time of a Priority Product listing. If neither the manufacturer nor the importer conducts an AA and the retailer has chosen not to proceed with an AA, then the retailer is required to cease ordering any more of the product. Depletion of existing inventories and any inventory ordered prior to the Priority Product listing is allowed. No changes were made to this definition in response to this comment.

Recycling of Consumer Products

Comments: PH23-2, PH23-3

Comments Summary:

It is not clear if the definition attempts to address the issue of recycling being regulated because “consumer product” does not include previously owned products. If a product has been transferred to a consumer and that consumer is recycling the material, the transferred material would no longer be a “consumer product” subject to these regulations. However, if a manufacturer or retailer recycles this same material and then sells the product, the responsible entities are required to comply with the regulations. Additional clarification is needed.

Response:

This provision states that a previously owned product is not a “consumer product” for purposes of these regulations. This provision does not provide an exemption for recycled materials. To clarify the first scenario, the recycled material ceases to be considered a “consumer product” for purposes of these regulations because the previous owner was not a responsible entity. A customer would not be a responsible entity required to comply with the requirements of the regulations.

In the second scenario, it is not clear if the recycled material is the product or if the recycled material is used to make a product. For purposes of this response, DTSC will assume that the product is the recycled material. Therefore, if a responsible entity recycles the material and then sells this product, it would be subject to these regulations

if the recycled material was listed as a Priority Product at the time of the material was produced. The regulations do not need to be revised in response to this comment.

Bulk Consumer Product

Comments: 36-44, 39-14, 65-1, 138-7

Comments Summary:

DTSC should provide clear administrative guidance and regulatory clarification of how the regulations apply to industrial product uses, not within the common sense understanding of "consumer product." The definition of “consumer product” should make clear that chemicals and products used in the workplace, including bulk purchases, are included. The definition of "consumer product" in the Health and Safety Code indicates that industrial products in the California marketplace may be designated as Priority Products.

The definition of “consumer product” should make clear that chemicals and products used in the workplace, including bulk purchases, are included in this program in order to address occupational health. The comment suggests the following language be added under a new section 69501.1(a)(22)(A)4, “Chemicals and products used in the workplace, including bulk purchases.”

Response:

The proposed definition of “consumer product” captures industrial products, which could be listed as a “Priority Product” if the product-chemical combination meets the criteria for prioritization. It would be too cumbersome in regulations to list all the types of products that could be included. DTSC prefers to incorporate the definition of “consumer product” from the one found in the authorizing legislation with minimal edits. DTSC will not revise the regulations in response to the comment, since such a revision is unnecessary.

Occupational health issues and other issues related to sensitive subpopulations are best addressed as exposure prioritization factors in Article 3 of these regulations. Inserting this subparagraph into this definition would give occupational health greater importance than all other exposure factors. DTSC is not revising this definition in response to these comments.

ISOR – “Consumer product” Replacement Parts

Comments: 19-5, 19-6, 19-9, 42-13, 42-15, 44-5, 66-9

Comments Summary:

The comments assert that DTSC's failure to exempt replacement parts for historic products conflicts with the ISOR. The ISOR discussion of proposed section 69501.1(a)(40) (defining "manufacture") states that "existing products, especially durable goods, may need to have replacement parts available for service, repair, and maintenance." Despite the ISOR's statements recognizing the need for reliable replacement parts, DTSC's failure to exempt replacement parts for historic products would subject such parts to the regulations and jeopardize the useful life of historic products themselves. The ISOR continues with examples that clearly highlight that all replacement parts regardless of when they are manufactured should be excluded. The ISOR's explanation and description of the definition of historic product states, "[t]his regulation is forward looking and its goal is to accelerate the quest for safer consumer products."

Including a clear and comprehensive exemption for replacement parts in the regulatory text is critical to establishing that replacement parts are not subject to these regulations since the regulations, not the ISOR are the basis for compliance. The comments recommend that the definition of "historic product" be restored to the May 2012 unofficial version.

Response:

DTSC appreciates all the recommendations provided. In response to these comments regarding the explanation of necessity in the ISOR of the July 27, 2012 definition of "manufacture," DTSC has revised the ISOR to make clear that the definition of manufacture does not exempt replacement parts but the "installation of replacement parts." This amended language was included the Revised ISOR that DTSC released for public comment from December 21, 2012 through January 22, 2013. DTSC issued a Revised ISOR to provide further explanatory information about the regulations despite the fact that DTSC's first ISOR fully complied with the APA. DTSC's actions allowed stakeholders another opportunity to submit additional comments before the release of the proposed regulations on January 29, 2013.

The regulatory language for the definition of "consumer product" under section 69501.1(a)(22)(B) has also been revised and has eliminated the term "historic product," but essentially, this provision remains the same in its effect. This change was made to prevent further confusion for the definition of "consumer product" now renumbered as section 69501.1(a)(24)(B) of the proposed regulations (January 2013).

The examples in the ISOR have also been removed from the Revised ISOR to further reduce the apparent conflict with the regulatory language and to clarify that the definition of “manufacture” and “manufacturer” are necessary in order to establish a proper scope of responsible entities subject to/not subject to these regulations.

DTSC never intended to exempt replacement parts, so the regulations will not be revised to exempt replacement parts used to perform these exempted activities. Instead, manufacturers may avail themselves of the provision in the definition of “consumer products” which sets the date of applicability for consumer products subject to the substantive requirements of the regulations. As stated in the ISOR this provision for consumer products will avoid unnecessary compliance obligations for products that have already been manufactured and introduced into the California marketplace.

§ 69501.1(a)(26) “End-of-life”

Comments: 66-13

Comments Summary:

This definition as drafted would encompass stages of a product life cycle when products may be reused or refurbished and are not considered to be at their “end-of-life.” This is an important distinction for electronic products. The comments suggest tying the end-of-life definition to when a product enters the waste stream and no longer has useful life. DTSC could address this concern by changing the definition to read: “‘End-of-life’ means the point when the product is at the end of its useful life, and is discarded for recycling or disposal by the consumer.”

Response:

DTSC understands this concern, but the regulations are written in a manner that will address a wide variety of products. The AA is very flexible as to how a responsible entity establishes the scope of various life cycle phases. For products that have no other foreseeable use, it would be appropriate to include reuse or resale during the “use phase” of the product’s life cycle. For example, the continued use of an electronic product for the same purpose, changing ownership could still be considered the consumer use phase. However, as drafted, the definition also allows for an evaluation of activities that may differ from the original use in a manner that is foreseeable but inconsistent with the original use. DTSC will not revise the language to disallow a different use scenario as an activity during end-of-life.

§ 69501.1(a)(29) "Environmental or toxicological endpoints"

Comment: 11-22

Comment Summary:

The comment urges DTSC to reject this definition and the entire OEHHA regulations, and to develop scientifically sound definitions of "environmental and toxicological endpoints." The comment claims that there are serious flaws in the process used by OEHHA to develop the OEHHA Green Chemistry Hazard Traits regulations (Chapter 54).

Response:

DTSC respectfully disagrees with this comment. OEHHA's regulations, adopted in January 2012, identify the types of information (hazard traits, toxicological and environmental endpoints, and other relevant data) to be included in the Toxics Information Clearinghouse that the authorizing legislation requires DTSC to establish. DTSC has included OEHHA's information on hazard traits into the regulations. This, too, is required by the authorizing legislation. (See discussion of OEHHA regulations in the discussion of Procedural, Legal, and Overarching Issues portion of this Response to Comments document.) Not only will this information be critical during the implementation of the regulations, this information is intended to be available in the Toxics Information Clearinghouse for all to use. No changes were made in the regulations in response to this comment.

§ 69501.1(a)(31) "Functionally acceptable"

Comments: 4-15, 36-67, 39-27, 39-28, 41-7, 55-26, 74-14, 76-31, 107-16, 107-61

Comments Summary:

The definition of "functionally acceptable" is inadequate. The term "functionally acceptable" is critical in the prioritization of products, in evaluating alternatives and in the imposition of product sales prohibitions. There are various concerns regarding this definition in the July 2012 proposed regulations including:

- There is some confusion between the terms "functionally acceptable" and "technically feasible";
- The regulations should account for all the characteristics that companies must consider when formulating or designing a product, such as durability, safety, performance consistent with product brand functional performance based on designated use, and aesthetics;

- Allowing for sufficient consumer testing will add many months to the AA time line;
- The previous definition for “functionally acceptable” is preferred because it is more directly and quickly measurable;
- “Performs …sufficiently well” is not an acceptable criterion because it lowers the performance requirement of alternatives product; and
- Using acceptability as a factor in determining feasibility and functionality is an undeterminable indicator that would be essentially impossible to define and measure. Clarify who will judge this criterion.

The comments suggest that the definition should codify additional criteria for "functionally acceptable," such as:

- Applicable regulatory safety standards, regulatory approval or certification requirements, and any internal safety standards;
- Product criteria applicable to the specific nature of the product including durability, and functional performance;
- Performance and functionality requirements of the Priority Product;
- Product performs the functions of the original product sufficiently well;
- Consumer acceptability, legal compliance, and a finished product that meets or exceeds performance of the original Priority Product; or
- Avoidance of significant administrative or other burdens.

Response:

In response to the concerns raised regarding use of the terms “functionally acceptable” and “technically and economically feasible,” DTSC has revised the second term. The previous term “technically and economically feasible” has been redefined using two distinct terms—“technically feasible” and “economically feasible”—so that these two terms are used accurately and consistently throughout the regulations both for prioritization process under Article 3 and for the AA in Article 5.

As for the comment that the language should account for all the characteristics that responsible entities must consider with respect to the product, DTSC has written the current definition in the July 2012 version to have enough flexibility to allow a responsible entity to make product specific determinations for relevant characteristics. These regulations incorporate the minimum requirements for compliance. If a responsible entity wishes to evaluate additional criteria, this may be done but needs to be documented in the AA Reports.

DTSC will not reintroduce a previous version of this definition, which specified that the alternative "substantially equals or exceeds the performance and functionality of the original product." While this previous version may have been more directly and quickly measurable, DTSC felt that it unduly limited the range of potential alternatives that may be considered under these regulations. In response to the comment that the definition as currently drafted may result in additional time being necessary to establish whether there is consumer acceptance, DTSC points out that the regulations include sufficient flexibility in the process to allow for additional time if a responsible entity wishes to complete consumer testing to assure consumer acceptance during the AA.

In response to objections that "performs …sufficiently well" is not an acceptable criterion because it lowers the performance requirement of an alternative product, DTSC notes that market economics will de-select a lower level of product performance due to unwillingness to accept trade-offs in performance or price by consumers. This will happen by the invisible hand of the market, which will determine which alternatives perform "sufficiently well." This standard may not be one that is frequently articulated as a regulatory standard, but it is a standard at work in the market on a continuous and widespread basis. DTSC will not revise this definition. DTSC notes that a responsible entity is not required to set a lower criterion for performance, but "sufficiently…well" does not preclude setting a standard equal to what is acceptable performance for the existing product.

As for the suggested language provided in the comments, DTSC has reviewed these comments and has determined that the current definition already addresses these concerns. Functional performance, safety standards to meet regulatory requirements, certification standards, and product acceptability are all included in this definition as written. Internal safety standards, durability and other product characteristics that are applicable to the specific nature of the product may be determined by the responsible entity when conducting an AA. When DTSC applies this term during prioritization, all the specific product criteria relevant to the product may or may not be known to DTSC. DTSC may consider the fact that there is a product that exists in the market that is marketed to perform that same function of a Priority Product as part of the evaluation of whether an alternative is functionally acceptable.

The definition does not set the standard, as the finished product meets or exceeds the performance of the original Priority Product. That standard would conflict with the product prioritization process in Article 3 and would unduly limit the alternatives considered in the AA conducted under Article 5. The concern expressed regarding cost avoidance is not an appropriate criterion for functionality. This criterion is better suited

for evaluating economic feasibility. DTSC has created a new definition for "economic feasibility" in the January 2013 revised proposed regulations to address this issue. DTSC will not be revising this language in response to these comments.

As to who will judge what is acceptable, this is one of many factors that need to be considered to evaluate alternatives. During product-chemical prioritization, it will be DTSC that judges what consumers can be reasonably anticipated to accept, what is functionally acceptable, and what is a safer alternative. This happens as part of many factors considered by DTSC during product prioritization. During the AA, it will be the responsible entity that determines what is functionally acceptable. While it is true that it may be difficult to define and measure the acceptance of an alternative for the Priority Product, this determination may also be done qualitatively. DTSC will also be evaluating this criterion during the regulatory response determinations that it makes under Article 6.

The public will also be given an opportunity to review DTSC's rationale and supporting documents for proposed Priority Products and the contents of the AA Reports. DTSC has revised the AA process to include a public comment period for the Final AA Reports and the Abridged AA Reports submitted to DTSC, to provide the public an opportunity to comment on the reports. DTSC will then review the public comments and prepare a list of issues that the responsible entity must address in an AA Report Addendum, if any. Thus, if a responsible entity has disregarded an alternative because the responsible entity concluded it was not functionally acceptable, the public will be able to submit comments regarding that conclusion. There will also be public notice and opportunity for public comment before DTSC imposes regulatory response(s) under Article 6. DTSC is not making any further changes to the regulations in response to these comments.

§ 69501.1(a)(32) "Hazard trait"

Comments: 11-23, 29-7

Comments Summary:

While one comment supported this definition, another took an opposing opinion on the definition of "hazard trait." Hazards are, in the context of chemicals, inherent properties that have the potential to lead to adverse effects in humans or wildlife under particular conditions and levels of exposure. In the context of the present regulations, they are toxicities. The definition should be amended accordingly and references to Chapter 54 eliminated.

Response:

As stated in OEHHA's FSOR dated January 2012, for the adoption of OEHHA's regulations at Title 22,California Code of Regulations, Division 4.5, Chapter 54, *"The term hazard trait is used in the statutory language SB 509 requires OEHHA to develop a product that is unique. The term 'hazard trait' is not used in any classification system or database in the world, to OEHHA's knowledge. No systems exist that define hazard traits, per se, or that cover the full spectrum of hazards and endpoints that are important considerations for the DTSC consumer-products regulatory program. There are no other frameworks available that lay out, in a structured way, hazard traits, toxicological and environmental endpoints and other relevant data that would meet the needs of DTSC's program. OEHHA considered various textbooks, chemical test data entry templates, hazard classification systems, guidelines, and other products while developing the regulation."*

DTSC is building on the work done by OEHHA and other authoritative bodies mandated by the authorizing statue. DTSC's definition of "hazard trait" references any of the hazard traits specified or defined in Chapter 54. (See Procedural, Legal and Overarching Issues section of this Response to Comments document for additional discussion of OEHHA's regulations as they influence these regulations.)

DTSC concurs with OEHHA's regulations and is not making any changes to this definition in response to these comments.

§ 69501.1(a)(33) "Hazard trait submission"

Comments: 9-101, 36-72

Comments Summary:

The provision states that "[W]hen any study or datum indicates that a chemical manifests any hazard trait, chemical identity is part of any hazard trait submission." It does not apply if a study indicates that a chemical does NOT manifest a hazard trait. The comments suggested the following language: "When any study or datum provides information relating to whether a chemical manifests any hazard trait, chemical identity is part of any hazard trait submission."

Conversely, a second comment was critical of this provision, contending that given the breadth of OEHHA's Green Chemistry Hazard Trait Characteristics, every chemical will manifest some hazard trait—making this provision meaningless.

Response:

This term is defined to implement and make more specific Health and Safety Code section 25257(f), which precludes hazard[ous] trait submissions for chemicals, including chemical ingredients, from being protected as trade secret. This provision does not affect the type of information that may be submitted in an AA Report but makes explicit what can be claimed as trade secret under trade secret protection provisions of the regulations. (See detailed discussion of Trade Secret Protection in Article 9 of the January 2013 and April 2013 versions of the regulations, and Article 10 of this Response to Comments document. DTSC specifically explains its authority and decision-making regarding the drafting of trade secret provisions relating to chemical identity and related issues. Those responses to comments are applicable here, too. No changes to the regulations were made in response to these comments.

§ 69501.1(a)(34) "Homogenous material"

Comments: 5-142, 9-102, 29-7, 57-16, 66-4, 66-8, 74-15, 74-16, 76-32, 80-2, 80-3, 80-4, 80-5, 107-17, 124-14, 124-17

Comments Summary:

There were two comments that supported this definition as an option for defining the AA Thresholds for substances in assembled products because it allows Chemicals of Concern to be narrowly targeted to the materials of interest without setting inappropriately low AA Thresholds. It also allows industries, such as the electronics industry, to use compliance data and analytical test results from existing frameworks that reference homogenous materials, such as European Union Restriction of Hazardous Substances (RoHS).

There were many more comments that identified issues with the term "homogenous material" and urged DTSC to remove it. Some comments claimed that the "homogenous material" definition is based on the RoHS Directive and is not readily scalable to the intent or to the scope of these regulations. There have been issues with many different interpretations of the RoHS definition of "homogenous" that has made it difficult to fully demonstrate compliance and to enforce. Further, DTSC already uses the term "homogenous material" in title 22, California Code of Regulations, section 66260.202, (sometimes referred to as "CA RoHS"). Having the same definitions in for both DTSC regulations is necessary because they refer to the same concept.

There was additional support for the ability to regulate specific uses of a material in certain clearly defined cases and the ability to set threshold levels at the material level,

rather than the part or component level. The general agreement is to use the term component to satisfy all the needs for the focus of an AA. By modifying the definitions of “component” to include a reference to a uniquely identifiable material and removing the term homogenous from the definition of “consumer product,” DTSC will have the ability to target Chemicals of Concern in specific materials but will not propagate a still problematic definition contained in another regulatory program.

Response:

In response to these comments and related comments and concerns, the term “homogenous material” is now defined as a subset of the definition of “component”; and corresponding sections of the regulations have been modified to clarify the pertinent requirements. (January 2013)

§ 69501.1(a)(35) “Import”

Comments: 4-10, 4-11, 42-4, 42-5, 68-15

Comments Summary:

The proposed regulation defines “Import” as “to bring, or arrange to bring, a consumer product into the United States for purposes of placing the product into the stream of commerce.” This definition directly ties into the definition of “importer” pursuant to proposed section 69501.1(a)(36), and effectively allocates the secondary burden of compliance on any person who performs an activity covered under the definition of “import.” The proposed definition encompasses a wide range of activities, not normally considered importation, and would subject many unintended parties to the regulations. Suggested language provided for the definition of “import” that would exempt aircraft, vessels, and vehicles, if they cross borders for the purpose of import” that would exempt aircraft, vessels, and vehicles, if they cross borders for the purpose of providing transportation.

Suggested language includes: “‘Import’ does not include ordering a product either manufactured outside of the United States, or containing components manufactured outside of the United States, if the order is placed with a person or company located within the United States.” It is unclear why the term "import" also includes imports into the rest of the U.S.

Response:

This definition of “import” only addresses whether the product has been imported but does not address whether the product would be subject to the regulations. It would not

be appropriate to include an exemption for a product within the definition of "import." The concern stated is that the act of providing transportation services is interpreted to be the act of "import" which may or may not be the case depending on specific circumstances.

The definition of "import" includes the phrase, "for the purposes of 'placing the product into the stream of commerce.'" The definition for "place into the stream of commerce" means to sell, offer for sale, distribute, supply, or manufacture a consumer product. Bringing an aircraft or vessels into California for use in the state would meet the definition of import. If the aircraft or vessel resides outside of California and is brought into the state only to provide transportation, this would not meet the definition of import. The distinction is that in the first scenario, the product has been brought into the state and sold, versus the second scenario where the product arrives drops off passengers and leaves without aircraft or vessel being sold, offered for sale, distributed, supplied, or manufactured. The regulations will not be revised to include an exemption for aircraft, vessels or vehicles that only provide transportation services from abroad. Further, the regulations do not need to be revised to address this concern.

DTSC agrees that "responsible entities" that order products through companies within the U.S. should not be required to comply with the substantive provisions of the regulations. The definition of "import" has been amended in the January 2013 version of the regulations to exempt ordering products by persons located within the U.S. This should narrow the responsibility for importing a product to the party who arranges with a foreign manufacturer to bring the product into the U.S.

Products can arrive via any port of entry in the country and later be placed into the stream of commerce in California. DTSC is revising the definition to make clear that these regulations only apply at the point a product is placed into the stream of commerce in California.

§ 69501.1(a)(36) "Importer"

Comments: 4-10, 4-11, 42-4

Comments Summary:

This definition of "import" directly ties into the definition of "importer" pursuant to proposed section 69501.1(a)(36), and effectively allocates the secondary burden of compliance on any person who performs an activity covered under the definition of "import." The concern is that the proposed definition encompasses a wide range of

activities not normally considered importation, and would subject many unintended parties to the regulations. Comments provide the following suggested language, to amend the definition of "importer," to "A person does not become an importer for purposes of these regulations, by importing products only for use in its own workplaces, and not to sell or distribute to consumers."

Response:

In response to these comments, the definition has been amended (January 2013) to exempt from the definition of "importer" a person that imports a product solely for use in that person's workplace if that product is not sold or distributed by that person to others.

ISOR – "Importer"

Comments: 4-10, 42-4, 42-5

Comments Summary:

The ISOR describing "importer" appears to take the opposite approach to common sense and states that "importer' does not include the distributor that purchases products from the manufacturer and resells them to retailers or to customers." No guidance is provided as to the extent that a person must be involved in arranging for a product to be brought into the U.S. before he/she is considered by DTSC to be conducting "import" activities. The ISOR's statement that distributors are not considered importers directly conflicts with the regulatory language itself.

The regulatory record fails to include substantial evidence demonstrating that retailers and consumers, who order products through companies within the U.S., should be required to comply with the substantive provisions of the Green Chemistry Program. Such evidence does not exist, since only one party should bear the responsibility for importing a product—the party who arranges with a foreign manufacturer to bring the product into the U.S.

DTSC should at least explain in the FSOR that the operation of aircraft into or out of the U.S. would not constitute the "import" of such aircraft, nor would it constitute "import" of any part or component thereof.

Response:

The ISOR explained the use of the term "import" is to keep with common and ordinary usage. For purposes of these regulations, the importer is the responsible entity to

ensure compliance with regulations that apply to the products that are imported but only if the manufacturer fails/declines to do so.

The comment erroneously assumes that consumers and retailers will have to comply with the requirement to perform an AA under these regulations. This is not the case; consumers do not have any duty to comply with the regulations. Retailers who order products through companies within the U.S. have an option in lieu of complying with the duty to perform an AA under the regulations. A retailer has up to five months from the time a Priority Product is listed to cease ordering a product to avoid any additional requirements. There is no need for substantial evidence demonstrating the necessity for consumers and retailers to comply with the regulations. This is because in the first case there is absolutely no requirement to comply (consumers) or there is a simple and very inexpensive means of opting out of the requirement to perform an AA (retailers).

DTSC intends to provide further explanation in the FSOR on the provision that have been amended such as the provision to exclude persons that import products solely for use in that person's workplace. However, DTSC will not be providing any additional discussions or explanation in the FSOR regarding the operations of aircraft into or out of the U.S.

Comment: 36-110

Comment Summary:

Add the words "or entity" to the definition of "importer" so it reads: "Importer means a person or entity who imports a consumer product into the United States." The commenter is not convinced that regulation automatically leads to negative impacts on a responsible entity's balance sheet.

Response:

The term "person" as used in the regulations means "an individual, trust, firm, joint-stock company, business concern, partnership, limited liability company, association, and corporation, including, but not limited to, a government corporation. "Person" also includes any city, county, district, commission, the State or any department, agency, or political subdivision thereof, any interstate body, and the federal government or any department or agency thereof to the extent permitted by law." It is not necessary to include "entity" to clarify that a person is not just an individual for purposes of the regulations. No changes to the regulatory language will be made in response to this comment.

§ 69501.1(a)(38) "Legal requirements"

Comments: 74-17, 101-17, 107-18, PH2-6

Comment Summary:

The regulations fail to account for labeling, and existing requirements to obtain other government certifications or approvals prior to making changes to a product or its components. They also fail to take into account intangible characteristics, such as aesthetics. The following language was suggested: "'Legal requirements' means specifications and/or performance standards that a chemical, or a product, or product packaging or labeling is required to meet by federal, California or other state or international law."

Response:

DTSC has revised this definition (January 2013) to include labeling but is not adding language to acknowledge other state or international law to apply to consumer products that are placed into the stream of commerce in California. Further, DTSC is not aware of any intangible characteristics that would be a legal requirement, but if they exist in state or federal law, then this definition will cover these characteristics as legal requirements.

§ 69501.1(a)(40) "Manufacture"

Comments: 4-13, 19-7, 22-5, 22-6, 22-7, 42-6, 42-7, 55-22, 55-23, 66-12, PH2-3, PH9-2

Comment Summary:

Some of the comments support the provisions found in subparagraphs (A), (B), and (C), which exempt certain activities from the term "manufacture." For example, the majority of automotive aftermarket entities involved in the business of repairing vehicles or returning them to working order do not possess the capabilities to "manufacture" consumer products in the generally understood sense of the term.

The remaining comments address the concern that these exemptions do not go far enough to make the regulations workable. The definition disallows the exemption if any of these activities result in the addition of or the increase in the concentration of a Chemical of Concern. Recommendations include removing the restrictive language, "unless the action results in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product." Given the very large

list of Chemicals of Concern, this condition effectively nullifies the exceptions for replacement parts that contain Chemicals of Concern.

Replacement parts are needed to support the repair and refurbishment of automobiles and should be exempt from these regulations. The definition of “manufacture” should be revised to include an exemption for the manufacture of repair or replacement parts.”

As noted in the ISOR, the definition of “manufacture” is intended to exclude “replacement parts” that may be required to repair or refurbish an existing consumer product, although the actual proposed definition fails to reference “replacement parts.”

Response:

DTSC has significantly revised this term in response to comments submitted regarding assembled products. The new definition, in the proposed regulations (January 2013), has eliminated subparagraphs (A) through (C) that included the exemptions for repair, refurbishment, installation of replacement parts, and making alterations. Instead, the amended language for “manufacture” no longer includes assembly activities. New terms “assemble” and “assembler” have been added to the proposed regulations (January 2013), and later the term “assemble” was revised. (April 2013) The net effect of these changes is that the regulatory obligations for assemblers have been greatly reduced compared to those of a manufacturer.

Replacement parts for either repair or maintenance have not been added to the definition of “manufacture.” DTSC never intended to exclude or exempt replacement parts categorically from these regulations. The only regulatory relief for replacement parts maybe found in the provision that Priority Products that ceased being manufactured prior to the date of the Priority Product listing are not subject to the substantive requirements of the regulation.

ISOR – “Manufacture”

Comment: 66-12

Comment Summary:

As noted in the ISOR, the definition of “manufacture” is intended to exclude “replacement parts” that may be required to repair or refurbish an existing consumer product, although the actual proposed definition fails to reference replacement parts.

Response:

The ISOR has been revised. DTSC posted the amended language and provided a second public notice period for the Revised ISOR. The Revised ISOR included new text to clarify that the activity excluded from the regulations was the act of installing replacement parts, and not the replacement parts themselves. DTSC appreciates the comments that brought this to our attention. See the Revised ISOR (December 2012) and Response to Comments document regarding the Revised ISOR for a more detailed discussion of this issue. DTSC is not making any further changes to the ISOR or the regulations text in response to this comment.

§ 69501.1(a)(41) "Manufacturer"

Comments: 19-23, 37-1, 37-2, 42-8, 44-1, 44-2, 55-22, 117-2, PH33-8

Comment Summary:

The comments urge DTSC to make it clear whether it is DTSC's intent that product assemblers, such as the automotive manufacturers, would or would not have a duty to comply as a "manufacturer." DTSC should clearly provide a definition that expressly exempts assemblers and remove "assemble" from the definition of manufacturer. Based on the existing definition, there is no distinction between producer, manufacturer, or assembler.

The rest of the comments request that the definition be revised so that modifying or altering a product does not render a person a manufacturer. Further, the phrases "controls the specifications" and controls the "design of or use of materials in a products" are sufficiently unclear as to be able to determine precisely which entities will be deemed manufacturers. DTSC must establish a clear line of demarcation to clarify when an activity crosses the line from merely causing a product to be manufactured, as opposed to manufacturing activity itself. DTSC should provide language in the definition to clarity what is expressly excluded from the definition of "manufacturer."

The comments also provided suggested language that serves to ensure that those with actual knowledge of and control over specific formulations and chemical usage are assigned an appropriate level of responsibility. A second suggestion was to return to the previous definition, "'Manufacturer' means any person who manufactures a product," so that the definition no longer creates conflicts with the responsibilities of manufacturers and retailers in the Duty to Comply section (section 69501.2(a)).

Response:

The definition of “manufacturer” has been revised in response to these comments (January 2013). The phrase “any person that controls the specifications and design of, or use of materials in such a product,” has been removed and replaced with “any person that controls the manufacturing process for or has the capacity to specify the use of chemicals in such a product.” This provision was further revised to amend the phrase “has the capacity to specify the use of chemicals” to “specifies the use of chemicals.” This revision clarifies that a person must specify the use of chemicals to be a manufacturer. (April 2013) Note that specifying what chemicals NOT to use in the manufacture of a product does not make a retailer a "manufacturer".

DTSC also modified the definition of “manufacture” such that it no longer includes the term “assemble.” This essentially eliminates an assembler as a manufacturer. The term assembler has been added to the term “responsible entity” and is now subject to requirements and options similar to those of a retailer. These changes are intended to clarify and confirm that product assemblers do not have a duty to comply with these regulations as a “manufacturer.”

Comment: 19-22

Comment Summary:

The comment seeks clarification on the term “manufacturer,” in light of the definition of “component.” If a unique component of an assembled product is named as the Priority Product, it is not clear if the manufacturer of the unique component or the manufacturer of the assembled product has the duty to comply with these regulations.

Response:

DTSC has redefined the term “manufacture” and has eliminated the word “assemble” in this definition in response to public comments expressing implementation concerns regarding the definition of “manufacture.” (January 2013) Further, in section 69501.1(a), definition of “responsible entity,” the term “assembler” has been added. Under section 69501.2(b), the duty to comply for an assembler as a responsible entity has been added. An assembler’s duties and options are now equivalent to that of a retailer.

The following scenario explains by way of example how these changes have impacted the duty to comply. An automobile component is selected as an example because this comment came from the automobile industry. Assume hypothetically that DTSC lists as a Priority Product a component of an automobile—such as vehicle car seat with a

specific brominated flame retardant. If the automobile company makes or produces the actual seat listed as the Priority Product, then the automobile company is the manufacturer and is responsible for complying with the requirements of these regulations. If the automobile company buys this car seat and only assembles this seat into the vehicle, then the manufacturer of the car seat itself is the responsible entity for this Priority Product and who must comply with the regulations—not the automobile company that assembled the seat into an automobile.

Hypothetically, the component could be made even more narrow and specific. For example, DTSC could in theory list as a Priority Product the foam portion of a vehicle car seat that contains a specific brominated flame retardant. Again, the manufacturer that made or produced the foam would be the primary responsible entity to comply with these regulations as the manufacturer of the Priority Product. (These duties include, but are not limited to, notifications, AA Reports, and compliance with any regulatory responses imposed by DTSC.) The assemblers of car seats (the supplier of the car seats or the automobile manufacturer) using this Priority Product would have same requirements under these regulations unless the assembler chooses instead to submit a Product Cease Ordering Notifications in lieu of these requirements.

See also sections 69501.1(a)(21) and 69501.1(a)(40) of this document for additional discussion of the definitions and uses of the terms “component” and “manufacture.”

§ 69501.1(a)(43) “Persistence”

Comment: 11-24

Comment Summary:

The reference to section 69405.3 should be eliminated. The commenter and provided suggested language which would limit the definition to organic chemical substances.

Response:

DTSC is not revising the language that references the term “environmental persistence” as specified in section 69405.3 of OEHHA’s companion regulations. DTSC prefers OEHHA’s criteria for persistence so as to ensure consistency between the two agencies and their related programs. Further, OEHHA’s term does not restrict chemicals to organic chemical substances and the benchmarks used for half-lives are shorter.

§ 69501.1(a)(44) “Person”

Comment: 115-2

Comment Summary:

There are at least three reasons why the definition of "person" should be revised in these regulations to reflect an individual rather than the vastly broader definition presently offered. First, the word "person" should be the user of a "consumer product." Second, the current definition defines anything as a “consumer product,” including industrial products. Third, this definition expands "consumer product" to mean any product and thus, renders the word "consumer" in the statute meaningless.

Each word in a statute should be given meaning and the ISOR fails to explain how DTSC has given meaning to the word "consumer" in this statute. The ISOR explains DTSC's choice of the definition of "person" as follows: "This definition is consistent with other uses in programs administered by DTSC.” The definition of person that DTSC proposes to incorporate is from the California Hazardous Waste Control Law, which is a different context from how to define the reach of a "consumer product" law.

Response:

DTSC respectfully disagrees with this comment. The regulations state that a "consumer product" has the same meaning set out in Health and Safety Code section 25251(e). This statutory definition of “consumer product” resides within Chapter 6.5 of Division 20 of the Health and Safety Code. This same portion of the Health and Safety Code (Chapter 6.5) has an existing definition for the term “person” (Health and Safety Code section 25118). If the Legislature had intended that there be a different definition of “person” for this program, then the Legislature could have provided one. The Legislature could also have specified a more narrow definition of “consumer product” than the one it crafted for this program. Taken together, the two terms “consumer product” and “person” evidence the Legislature’s intent to have a comprehensive program adopted and implemented by DTSC.

The language in the ISOR mentioned above is in regards to the definition of “‘person’ which has the same meaning as Health and Safety Code section 25118.” In these regulations, the term “person” is not used to define “consumer products,” but is used in the definitions of “importer,” “manufacturer,” “retailer,” and “assembler” in the proposed regulations text. The term “person” is used throughout the regulations to identify the entity that has submitted any of the various notifications. DTSC is not making any changes to the regulations in response to this comment.

§ 69501.1(a)(46) “Physicochemical properties”

Comment: 5-58

Comment Summary:

The commenter is concerned that the OEHHA regulations that are referenced in these definitions are too broad. In addition to the due process concerns raised by references to definitions from another potential rulemaking, the definitions lack a scientific basis, and exceed the grant of authority provided by the authorizing legislation. DTSC should coordinate with OEHHA, and provide an opportunity for the public to comment on both sets of proposed regulations in the same rulemaking process.

Response:

OEHHA's regulations that were undergoing the APA process have now been adopted into Title 22, Division 4.5, Chapter 54; therefore, there is no due process concerns raised by references to definitions from another *potential* rulemaking. In effect, the interested parties were given two separate opportunities to comment on the OEEHA definitions and other provisions in their regulations—once at the time OEHHA's regulations underwent the APA process and a second time in conjunction with these regulations. In addition, the authorizing legislation for both the OEHHA and DTSC regulations requires that the two agencies coordinate their efforts on these related sets of regulations, and the agencies have done so. (See the Due Process discussion within the Procedural, Legal, and Overarching Issues portion of this Response to Comments document for more information about the interrelationship between the OEHHA regulations at Chapter 54 and these regulations being proposed by DTSC.)

§ 69501.1(a)(48) "Priority Product"

Comment: 80-14

Comment Summary:

DTSC should clarify that a Priority Product must contain a Chemical of Concern. The ISOR is clear that products that do not contain a Chemical of Concern are not subject to the requirements of this chapter. However, the regulations are not clear on this key point. DTSC should modify the definition of "Priority Product" to mean "a product containing one or more Chemicals of Concern as identified and listed as a Priority Product by Department under section 69503.4."

Response:

DTSC has revised the regulations text in response to this and other comments to help clarify this issue. First, the Chemicals of Concern list (approximately 1,200) has been

renamed as the Candidate Chemicals list. This was done to distinguish between the total universe of chemicals that are identified as Candidate Chemicals and those chemicals that have been identified and prioritized within a Priority Product (Chemicals of Concern). In the proposed regulations, a Candidate Chemical that is the basis for a product-chemical combination being listed as a Priority Product is designated as a Chemical of Concern for that product (section 69503.5(b)(2)(B) (January 2013)). DTSC is of the opinion this change achieves the clarification sought by the comment.

§ 69501.1(a)(52) "Reliable information"

Comments: 5-63, 5-64, 5-65, 9-32, 9-104, 11-25, 47-22, 57-18, 66-14, 70-1, 74-4, 74-18, 74-19, 74-20, 86-12, 101-18, 107-11, 107-19, 107-20

Comments Summary:

The definition of "reliable information" deems information to be "reliable" because it has been published in peer reviewed journals or by state regulators. Defining "reliable" information from sources not widely recognized in the scientific community as "authoritative bodies" unnecessarily introduces questions into a program that is intended to be science-based. The regulations do not require a means to assess the quality of information and the proposed definition lacks any description or characteristics of what constitutes reliable information or studies.

Suggested amendments include:

- Adding a weight of evidence approach or analysis;
- Providing an outline of how a weight of evidence approach will be followed throughout the regulations;
- Adding a statement listing the factors that DTSC will consider when determining whether information is reliable;
- Adding the Organization for Economic Cooperation and Development (OECD) procedure to judge studies for relevance and reliability, suggested language provided;
- Adding the list of internationally-accepted guidelines, practices and protocols in the regulation that are detailed in the ISOR;
- Adding into the regulations a public process for disputing the reliability of information, suggested language provided;
- Issuing stakeholders' consultation or encouraging stakeholders to establish a forum, like the EU's Substance Information Exchange Forum to assist in the determination of chemical hazards; and

- Adding the Organization for Economic Cooperation and Development, and its member countries to the definition of "authoritative organization."

Response:

The term “reliable information” is used throughout the regulations to qualify the data sources that will be acceptable to inform various parts of the prioritization and AA processes. Reliable information is data, studies, and information that is widely accepted by the scientific community that are acceptable to be used by DTSC to evaluate chemicals and products, by responsible entities in conducting AA, and finally by DTSC, in determining which regulatory response(s), if any, to impose.

DTSC agrees with the reviewers’ comments that evaluating information about the strength of evidence for chemicals will be the right approach to pursue with stakeholders during implementation. DTSC will rely heavily upon the examples identified in the ISOR for reliable information. The process must remain flexible due to the diversity of the potential product universe and variance in known associated information.

Organization for Economic Cooperation and Development’s guidelines for testing, good laboratory practices, and the manual for investigating high production volume chemicals are among the list of internationally accepted guidelines, practices, and protocols that are listed in the ISOR as examples of documents that would meet the definition of “reliable information.” These documents are all guidelines and manuals that are not regulatory requirements. The regulations will not be revised to add the weight of evidence approach, the precise methodology and factors for the assessing available data, or to include the Organization for Economic Cooperation and Development’s guidelines.

There will be various opportunities to comment on the quality, relevance, and reliability of the information used to implement throughout the chemical and product prioritization processes, as well as through evaluation of the AAs, and ultimately in determining the regulatory response(s), if any. The APA process will be required to list a Priority Product. Therefore, there is ample opportunity for notice and comment regarding the proposed regulations. DTSC will be convening the Green Ribbon Science Panel (GSRP) during the implementation of the regulations to potentially assist on such matters as hazard evaluations. The regulations will not be revised in response to these comments. DTSC did amend the definition of “reliable information” in the proposed regulations (January and April 2013) to provide appropriate criteria for assessing the quality and reliability of non-scientific data. DTSC does not intend to make any changes

to the regulations in response to the last suggestion. The definition of "authoritative organization" is unnecessary in the regulations because this term is not used at all in the regulatory text. Nor is the concept of an "authoritative organization" helpful or necessary to be included in the regulations.

Comment: 138-14

Comment Summary:

Single studies or case reports can point to the early warning signs or clues of possible hazards, and help researchers, practitioners, and worker representatives make sense of their personal experiences, leading to further investigations. Recommendation: consult with the University of California San Francisco researchers about how their findings in the study[4] can provide a better definition of reliable information, one that accounts for industry bias and considers when a single study should be used.

Response:

The process to assess reliable information must remain flexible due to the diversity of the potential Priority Products universe and the associated information. During implementation, there will be various opportunities to comment on the quality, relevance and reliability of the information and the GSRP will be available to assist on such matters. And, as mentioned elsewhere, many of the decisions made by DTSC and the responsible entities are subject to public comment. This will undoubtedly lead to the submission of comments related to the quality of the information relied on to make a decision. The comment did not suggest any revisions to the regulations; therefore, no changes were made in response to this comment.

§ 69501.1(a)(52) and (53) "Reliable information" and "Reliable information demonstrating the occurrence of exposures"

Comments: 5-63, 5-64, 74-12, 74-20

Comments Summary:

The definitions of both "reliable information" and "reliable information demonstrating the occurrence of exposures" although modified, are overly broad and not based on solid scientific principles. There is no clear indication about why studies "conducted,

[4] Lundh A, Sismondo S, Lexchin J, Busuioc OA, Bero L. Industry sponsorship and research outcome. Cochrane Database Syst Rev. 2012; 12:MR000033.

developed, submitted, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes" would constitute "reliable information."

Both definitions focus on the existence of a hazard or exposure only. No thresholds are included to account for potency and likelihood of harm in making decisions and implementing the regulations. It is not clear why two separate definitions are required here.

Suggestions include the following: 1) both definitions should be consolidated with a single definition for "scientifically reliable information"; and 2) DTSC should provide separate definitions for "information sources" to include the diverse sources listed in paragraphs (52) and (53) and then determine reliability by subjecting those studies to new and separate definition of "reliable information" based on the OECD Manual.

Response:

DTSC explains in the ISOR that these terms will ensure that DTSC uses information that is reliable. Sources of scientific studies and information must meet one or more of the criteria described in section 69501.1(a)(57) to qualify as "reliable information" and may include mechanistic data, environmental monitoring data, and animal or human scientific studies (January and April 2013). The definition of "reliable information demonstrating the occurrence of exposures to a chemical" (section 69501.1(a)(58) (January and April 2013)) clarifies the type of information that qualifies as evidence of an occurrence of exposure and will ensure conformance to existing general scientific approaches and concepts.

DTSC will not be revising the text in response to these comments. DTSC respectfully disagrees that these suggestions will address the concerns stated in the comments. The second suggestion create two definitions with acceptable "information sources" for hazard traits and for exposure information and then create a third new definition for assessing the "information sources" and does not work within the existing structure or the processes detailed in the regulations. First, DTSC needs flexibility to address not only the information that is currently available but also the data gaps. Second, in the proposed regulations, the term "reliable information" is used to define the term "potential" (January 2013). This new defined term "potential" is used as a qualifier to modify "adverse impacts." The two terms are used throughout the regulations and redefining them would affect the multiple provisions. DTSC will not be revising these two definitions to address these comments.

§ 69501.1(a)(53) "Reliable information demonstrating the occurrence of exposure"

Comments: 5-64, 11-26, 74-20, 36-45, 39-15, 76-36

Comment Summary:

The following comments address a specific subparagraph or a combination of three or more subparagraphs denoted as (A), (B), (C), (D), or (E) within this definition. For ease of reference, the use of subparagraphs (A), (B), (C), (D), or (E) is also used below.

(A) Comment supports the use of the monitoring data that shows the chemical to be present in the home or places employment.

(B) The use of biomonitoring data to demonstrate exposure is problematic because there will be sources of exposure that have nothing to do with consumer products.

(B) The comment recommends the use of biomonitoring data from other states and Europe that meets the test of reliable information. Biomonitoring data are too scarce to rely solely on data from California.

(C) Chemical properties do not inform whether exposure has occurred and should be eliminated.

(D) Eliminate this provision. Modeling results for exposure assessments should be confirmed with collected monitoring data.

(D) A point concentration at a single location is not necessarily "associated with adverse public health or environmental impacts." Reference doses and other risk values are based on average daily intake over time.

(D) This subparagraph describes exposure or modeled point concentrations associated with adverse public health impacts. This comparison makes great scientific sense. Similar language should be added to (A), (B), and (C) in this definition.

(A)-(D) This subparagraph should include or reference quantifiable standards for determining whether an occurrence, potential occurrence, or exposure to a chemical can be demonstrated.

Response:

DTSC made a few editorial changes to the language, but none of the revisions address the concerns stated or the recommendation made. DTSC appreciate the support expressed in the comments.

DTSC will not revise the subparagraphs for the following reasons:

(B) DTSC's primary focus is to assess exposure in California, so using data from other states and Europe may not reflect exposure in California;
(C) The chemical properties listed rely on information that is predictive of exposure based on calculations that are described in Article 5 of Chapter 54 regulations; and
(D) Properties listed are based on exposure modeling that may be used to determine exposure to a chemical of interest.

DTSC disagrees that subparagraphs (A)-(D) need to have quantifiable standards explicitly included in the regulatory text. DTSC is aware that there are many data gaps in this type of information and may develop guidance to provide additional clarity.

§ 69501.1(a)(54) "Responsible entity"

Comments: 5-67, 9-105, 11-27, 42-9, 44-6, 107-21

Comments Summary:

For clarity and consistency with other existing regulations (California Air Resources Board and Consumer Product Safety Commission), DTSC should adopt a definition of "manufacturer" that is consistent with the Fair Packaging and Labeling Act (FPLA; Title 15, U.S. Code, sections 1451-1461). For products manufactured in a foreign country and imported into the U.S., FPLA requires compliant labeling that identifies the entity for which the product is "manufactured for" or "distributed by." It is practical to start with the entity identified on the product label pursuant to FPLA requirements as an initial point of contact for imported products rather than assign the duty to comply with a foreign manufacturer or retailer. As such, paragraphs (B) and (C) should be eliminated.

Contextual language should be added to this definition for consistency with section 69501.2. DTSC should include language that describes the limited circumstances under which a retailer may be considered a responsible entity, in a manner consistent with the "Duty to Comply" provisions of section 69501.2. The definition of "responsible entity" should be limited to manufacturers, importers, and retailers of "Priority Products," rather than manufacturers, importers and retailers of any "consumer product."

Response:

While it may be practical use an FPLA label to help identify the manufacturer, using the label to assign responsibility for compliance with the regulations is not appropriate. The definition of "responsible entity" in these regulations has to meet the objective of having someone assess the Chemical of Concern in consumer products. The label required by FPLA allows the manufacturer, packer, or distributor to be named; this is not consistent with the entities identified in these regulations. DTSC has determined that it is not appropriate or feasible to have a distributor be deemed a responsible entity. The definition will not be revised.

DTSC respectfully disagrees that additional verbiage is needed to reiterate the requirements that are already specified in section 69501.2. The suggested language will not be added to this definition, and DTSC will not revise the definition to limit it to the manufacturers, importers, and retailers of Priority Products. A regulatory response may be imposed on an alternative chosen that contains any Candidate Chemicals—not just to Priority Products that are retained by the responsible entity. Amending this definition would prevent DTSC from imposing a regulatory response on the manufacturers as a responsible entity if the alternative selected is no longer the original Priority Product.

§ 69501.1(a)(55) "Retailer"

Comments: 4-14, 68-16

Comments Summary:

DTSC should revise this definition to clarify that "retailer" does not include a person who purchases products (*e.g.*, replacement parts or maintenance supplies) for use in its own workplaces and who does not sell or distribute these products to "consumers."

In the Health and Safety Code section 25251, the term "consumer product" also includes products sold to professional users. Therefore, a retailer selling such a product to professionals would also be covered by the rules of the regulation. The definition seems to conflict with the law.

Response:

A retailer is the person to whom the product is delivered or sold for the purpose of sale or distribution. In the example given in this comment, the person buying the product is not then selling or distributing the product; thus, this person is not a retailer.

The second comment reflects an erroneous understanding of how the law and the regulations work together. Health and Safety Code section 25251 does not use the term "professional." Rather, there is a cross reference to the California Business and Professions Code as a simple means of incorporating that Code's definitions of a "dangerous drug or dangerous device," "dental restorative materials," and "device." (*See* Health and Safety Code section 25251(e)(1)-(3).) These are products that the Legislature excluded from the definition of "consumer products," and, thus, from these regulations. A retailer selling one of these excluded products is not subject to the regulations. The definition of "retailer" applies only to products are not statutorily excluded. DTSC will not be revising the language in response to these comments.

§ 69501.1(a)(56) "Safer alternative"

Comments: 11-28, 74-21, 76-32, 76-33, 107-22, 131-3, 131-4

Comment Summary:

The comments suggest revisions to the definition of "safer alternative" to more accurately state what should be considered an alternative that is "safer" than a Chemical of Concern. The definition may not result in a "safer formulation."

The following are recommendations to insert phrases needed to clarify the term:

- "Means a functionally acceptable alternative that,...";
- "Is technically feasible";
- "So as is determined by the Alternatives Analysis" to reduce adverse public health and environmental impacts;
- "In comparison to the Chemical of Concern with the existing Priority Product," not just the Priority Product; and
- "Has no unacceptable level of burden shifting."

Response:

This definition was changed in response to the comments suggesting modifying the considerations for what constitutes a "safer alternative." However, DTSC did not modify the language to include the term "functionally acceptable" nor "technically feasible." "Functionally acceptable" and "technically and economically feasible" are used throughout the regulations to qualify both "alternatives" and "safer alternatives."
In the January 2013 version of the regulations, the term "technically and economically feasible" was redefined as two terms "technically feasible" and "economically feasible," and all three terms are used to modify "alternative" and "safer alternative " more selectively throughout the regulations. DTSC prefers to leave this definition of safer

alternative as it reads in the January 2013 version and still be able to use the terms "functionally acceptable," "technically feasible," and "economically feasible" when needed. See also section 69501.1(a)(35) "Functionally acceptable" in the Response to Comments document for the January 2013 version of the regulations for additional discussion on this issue.

Further, "safer alternative" will not be revised to limit the determination of a safer alternative solely to an AA. Although the AA is used by the manufacturer to make a product specific determination for safer alternatives, DTSC also has the ability to assess safer alternatives at its discretion when an AA is available that does not meet the requirements of the AA pursuant to the regulations.

Comments: PH4-1, PH4-2

Comments Summary:

The following are concerns regarding the term "safer alternative," but did not include specific suggestions on how to address their concerns in this definition. These comments state issues regarding the process for assessing a "safer alternative":

- It is not clear how the AA will be put on a common scale for comparison of "safer alternatives";
- Safer Alternatives may have regrettable substitutes; and
- Safety assessments of products, which include human health, environmental safety, occupational safety, microbiological safety, and physical safety in the risk assessments, are more protective than individual ingredients assessments.

Response:

DTSC will not be developing a scale for the comparison of safer alternatives; this would be infeasible and inappropriate, given that each responsible entity is responsible only for its own Priority Product and AA. The whole purpose of the AA is to ensure that in the quest for safer alternatives, regrettable substitutes are avoided. This program is aimed at reducing risk of harm from chemical or chemical ingredients in consumer products. The authorizing legislation is limited to that type of risk of harm—as opposed to physical safety and the like. DTSC is not making any changes to the definition of "safer alternative" in response to these comments.

See also Article 5 Alternatives Analysis in this Response to Comments document for additional discussion of this issue.

Comment: 29-7

Comment Summary:

The comment supports the definition.

Response:

DTSC appreciates the support.

§ 69501.1(a)(58) "Sensitive subpopulations"

Comments: 30-1, 30-5, 36-50, 36-51, 36-52, 39-3, 39-4, 138-7, 138-8

Comments Summary:

While workers are appropriately included in the definition of "sensitive subpopulations," due to the nature of their occupations that can result in longer and more frequent exposure to chemicals, there are recommendations for revising the language.

Suggested language to expand this definition included:

- Add the phrase, "or workers with greater exposures than the general population, due to the nature of their occupation and specific duties";
- Replace the term "pregnant women" with "women of childbearing age" as a healthy pregnancy is largely dependent on the health of women before conception; and
- Incorporate environmental justice communities that have different susceptibility or are more likely to be exposed because they are bigger users of certain Priority Products.

Response:

According to the World Health Organization, the period of development in the womb is critical for the health of the child, both at birth and long afterwards. Maternal exposures to environmental hazards during pregnancy can thus have a major impact on children's health. Further, the World Health Organization considers women between the ages of 15 to 49 to be of childbearing age. In light of the huge segment of the population that would be captured by this very expansive definition, DTSC respectfully disagrees that women of childbearing age should be a sensitive population for purposes of these regulations. The difficulty of adding women of childbearing age is that at both the low and high end of the range of the child bearing age, the range comes close to or potentially overlaps with the age range of children and the age range of the elderly. This in essence would capture almost all women. The inclusion of the term "pregnant

women" in the regulations addresses maternal exposures to chemicals during pregnancy without diluting the term "sensitive subpopulations."

There is no universally accepted definition of the term "sensitive subpopulation," but the term "environmental justice communities" is currently outside the scientific mainstream as a subset of the term "sensitive subpopulations." Environmental justice is commonly considered for local land use decisions and for siting hazardous waste facilities but not for evaluating differential susceptibility to harm from exposure to chemicals.

Factors such as socioeconomic status have mostly indirect effects, thus, making it very difficult to address during prioritization. To date, regulatory agencies have addressed this issue through policy and guidance. DTSC will not be adding environmental justice communities to this definition in the regulations for all these reasons.

DTSC has reviewed the comments and will not be revising the language to address these issues. DTSC considers tasks or activities within an occupation to be within the nature of their occupation; therefore, no revision is necessary. DTSC respectfully disagrees that women of child bearing age should be a sensitive population in these regulations. The inclusion of the term "pregnant women" in this definition addresses maternal exposures to chemicals during pregnancy can thus have a major impact on children's health. DTSC feels that it would be difficult to include environmental justice communities in regulations. To date, regulatory agencies have addressed this issue through policy and guidance. Again, no revisions will be made in response to these comments.

Comment: 9-106

Comment Summary:

The definition of "sensitive subpopulations" is too broad and may present significant issues of compliance for responsible entities depending on how this term is interpreted. The use of the phrase "including, but not limited to…" inappropriately confers upon DTSC unlimited and arbitrary discretion to define the universe of "sensitive subpopulations" in ways that the regulated community cannot anticipate. It is not clear what DTSC means by sensitive subpopulations representing "a meaningful portion of the general population." It is similarly not clear why the proposed regulation include workers and their occupational exposures as a "sensitive subpopulation."

Response:

When the term "sensitive subpopulations" is used in these regulations, it applies to

DTSC's evaluation in order to: add a new Candidate Chemical (formerly Chemicals of Concern); to list Priority Products; to set a specific AA Threshold for a Priority Product; or to determine a regulatory response. In each of these cases, DTSC will have to document and make public its analysis of whether a sensitive subpopulation was considered for each of these determinations. Therefore, if a sensitive subpopulation has been identified during any of these processes, the public will get to comment on the specific chemical and any subgroups that may be identified as being at greater risk of harm from exposure to these chemicals. DTSC will not be revising this definition in response to this comment.

As to the addition of workers, when workers experience greater chemical exposures due to the nature of their occupation, they are individuals who would be at a greater risk of adverse health effects in comparison to the general population. Inclusion of workers in this term recognizes that occupational hazards often lead to greater and longer exposures than those encountered in other settings. The exposures may be both of a higher concentration, for a greater length of time, and more frequent, making the hazard significant.

Comments: 41-72, 93-2, 101-18, 107-23

Comments Summary:

The scope of the definition has been expanded inappropriately to encompass workplace exposures. Occupational health and safety regulations that offer worker protection already exist. As such, this inclusion of workplace exposures in the proposed regulations is redundant and duplicative with existing obligations to prevent workplace exposures to hazardous chemicals and to warn workers of the hazards of the products they encounter in the workplace.

It is unclear what "greater exposure" means. A worker, who has been given information, training, protective equipment and a properly engineered work environment, has reduced exposure. DTSC should delete all references to workers (whose health is regulated by Cal/OSHA), before finalizing the regulation.

The phrase "individuals with a history of illness," is exceedingly broad and essentially makes the term so expansive as to be moot. The recommendation is to delete this reference to individuals with a history of illness (or modifying the term to conform to DTSC's intent to cover only those with "serious" or "chronic" illness affecting a meaningful portion of the population).

Response:

The fact that there exists some overlapping protection of workers by Cal/OSHA does not mean that DTSC is precluded for taking into account differential risk of harm from chemical exposure experienced by workers. The Cal/OSHA regulatory regime has little in common with these regulations. That program certainly does not regulate risk of harm from chemical exposure equivalent to or more extensive with these regulations.

The phrase "greater exposure" is essentially self-explanatory. That is, it refers to the fact that exposures to chemicals by workers in the workplace may be of greater concentration, duration, and frequency than exposures to the same chemical experienced by the general population. The phrase "with a history of illness" is also straightforward. It describes those at greater risk of harm from chemical exposure in comparison to the general population due to their underlying medical condition. As there is no universally accepted definition of the term "sensitive subpopulation," the definition of sensitive subpopulations is intended for the purposes of this regulation and furthers the purposes of the authorizing statute to protect "sensitive subpopulations." DTSC's definition of this term is well within the scientific mainstream. DTSC will not be making any changes in response to this comment.

Comments: 39-1, 39-2

Comments Summary:

The comments support the consideration of occupational health is fully integrated into the regulations.

Response:

DTSC appreciates the support for these regulations.

§ 69501.1(a)(59) "Technically and economically feasible"

Comments: 76-34, 129-4

Comments Summary:

The statute lists "technically" and "economically feasible" alternatives as separate criteria. They are fundamentally different, and they should be evaluated separately. The definition of "technical feasibility" in the proposed regulation relates to the possibility of manufacturing the alternative and conforms to standard business definition of the term. The definition of "economic feasibility" is not related to the possibility of manufacturing the product and does not conform to the basic business definition of the

term, such as the Cambridge Business English Dictionary and the definition developed by the European Chemicals Agency in their guidance.

The commenter is concerned that the definition of "technically and economically feasible alternative" is too subjective and provides no sound criteria for making this determination. The regulations already include a separate analysis of "economic impacts," in section 69505.4(a)(2)(C).

The comment recommends the following:

- Separate the definitions for "technically feasible" and "economically feasible" and provide more objective criteria for what is economically feasible;
- Seek information on "economically feasible" alternatives only as part of the "Economics Impacts" of section 69505.4(a)(2)(C); and
- Require an "economic impacts"/"economically feasible" assessment only for AA when cost is used as a criterion for continuing use of a Chemical of Concern.

Response:

DTSC has revised the definition of "technically and economically feasible" into two separate definitions, "technically feasible" and "economically feasible," in the proposed regulations (January 2013), as the commenter recommended. The text has been further modified in response to these comments. A new provision requires the responsible entity to explain in the Final AA Report the reasoning for the entity's alternative selection decision if it is to retain the Priority Product based in whole or in part on internal cost impacts (section 69505.6(a)(3)(B) (January 2013)).

§ 69501.1(a)(59)(A) Technically feasible

Comments: 9-107, 29-8, 36-65, 36-66, 39-29, 130-1, 130-6, 130-7

Comments Summary:

One comment supported the incorporation of consumer acceptance as part of the overall feasibility of a potential alternative; another comment strongly objected to the phrase, "meet consumer demand" in this definition. A commenter urges the language in section 69501.1(a)(59)(A) be amended by deleting "and to meet consumer demand after an appropriate phase-in period."

It is not clear what the phrase, "are expected to be sufficient" means when used in this provision, "[t]he technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the

alternative, and to meet consumer demand after an appropriate phase-in period." A better articulation would be that the information "is sufficient."

Feasibility determinations should be based on acceptable alternatives that are currently available and the affordability of any such alternatives. It should not be based on speculation as to products that are "expected to be sufficient." A comment urges DTSC to adopt final regulations that include the prior definition of "feasibility" and state clearly that all of the factors specified in the statute for evaluation of alternatives, such as:

- Product function or performance;
- Materials and resource consumption;
- Air emissions;
- Production, in-use, and transportation energy inputs;
- Energy efficiency; and
- Greenhouse gas emissions.

Response:

The proposed regulations have been modified in response to the objection to the phrase "meet consumer demand" (January 2013). This phrase has been removed in the new definition for "technically feasible." DTSC made this change to narrow the focus on the knowledge, equipment, materials, and other resources that are expected to be sufficient to develop and implement the alternative. The phrase "expected to be sufficient" is still in the language to allow for the evaluation of near term foreseeable conditions that may not currently exist for the manufacturer. For example, the responsible entity may not currently have equipment or the materials to produce an alternative, but the equipment and materials may be commercially available. The manufacturer can expect that it will be sufficient to implement an alternative, but the manufacturer may not know if it is sufficient until more detailed plans are developed and approved.

DTSC will not be reintroducing the prior definition of a "technologically and economically feasible alternative" because it was meant to be specific to the preparation of an AA. The new revised definitions for "technically feasible" and "economically feasible" are used throughout the proposed regulations (January 2013) in a consistent manner.

§ 69501.1(a)(59)(B) Economically feasible

Comments: 4-16, 29-8, 36-65, 36-66, 74-59

Comments Summary:

A manufacturer's operating margin is not a good choice as a criterion for this definition. This economic feasibility should be focused on the impact of the alternative on the cost

to produce a product. The proposed regulations should additionally allow the responsible entity to also consider the availability of the "functionally acceptable" alternative, affordability, and the cost to produce the product.

Various recommendations for revising the language were provided to modify this provision. They are as follows:

- Add new language reading "There is not an associated material increase in consumer or business costs";
- Replace all of (B) with the following language, (B) "That is commercially available on the market for similar applications";
- Amend as follows, (B) "The manufacturer's operating margin is not significantly reduced based on the following:
    - The extent to which a functionally acceptable alternative is currently available in the marketplace;
    - The affordability of any currently available functionally acceptable alternative; and
    - The cost differential to produce a product, including not only the actual material cost difference but also any difference in the processing/manufacturing conditions, between the Priority Product and the alternative."; and
- Strike out (B) entirely.

Response:

Although the previous definition of "technically and economically feasible" has been deleted, the new definition for economically feasible does not include any of the suggested language above. There was no consensus on whether it needed improving and how to improve it. One commenter pointed out that economic feasibility cannot be verified in a public and transparent manner; it can only be known by the manufacturer because the operating margin will never be released publicly. This statement is only partially true. Under the regulations, a manufacturer must still submit required information to DTSC even if it is claimed to be subject to trade secret protection. Therefore, DTSC will have access to this information even if the general public does not. Accordingly, DTSC may serve as a check on overly broad claims of economic infeasibility.

§ 69501.1(a)(60) "Trade secret"

Comments: 36-75, 86-13

Comments Summary:

The definition of “trade secret” should provide that trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient” as specified in 69510(f).

This definition should also include language like “‘trade secret’ may also include the information which can be obtained through the daily course of business, such as, but not limited to, the name of the players in the supply chain or the information obtained through their activities in the supply chain, or the information which the responsible entity cannot obtain through the daily course of business.”

Response:

The exclusion from trade secret protection for chemical identity and related hazard trait information is already clarified in section 69510(f) and does not need to be duplicated in the definition. No revisions were made in response to this comment.

Finally, there is no obvious legal authority offered for the proposition that information not claimed as a trade secret should nonetheless be withheld. The statute is clear on this point: Health and Safety Code section 25257(c) states that “[i]nformation not identified as a trade secret pursuant to subdivision (a) shall be available to the public unless exempted from disclosure unless exempted from disclosure by other provisions of law.” The inclusion or exclusion of contextual information related to, but not part of, a trade secret claim may be handled under existing law by way of the “reasonably segregable” clause in the Public Records Act (see Government Code 6253(a)). DTSC does not have the authority to further restrict this process. For a detailed discussion of section 69510(f), renumbered as section 69509(f), see the discussion of Article 10 Trade Secret Protection in this Response to Comments document. Those responses are applicable here as well.

§ 69501.2 Duty to Comply and Consequences of Non-Compliance

§ 69501.2 General

Comment: 86-14

Comment Summary:

The total lead time through supply chain to produce a consumer product may be quite long, and each portion of the supply chain is always keeping some amount of inventory at each stage. The restriction of a Priority Product should consider sufficient time to allow the elimination of inventory in a reasonable manner and time frame in order to

avoid unnecessary disposal of materials, including those in the supply chain, which may cause another kind of environmental impact.

Response:

In the regulations, under Duty to Comply, the manufacturer or the importer may submit a Priority Product Removal Notification within sixty (60) days in lieu of compliance with the substantive requirements of the regulations. The concern stated is having sufficient time to allow for depletion of inventory. First, the regulations do not include an inventory recall provision and do allow for a sell-through of existing inventory. Second, a clarification, this specific requirement does not prohibit the sale of existing inventories of Priority Products but instead prohibits the placing of additional Priority Products into the stream of commerce in California sixty (60) days from the date the Priority Product is listed. Any Priority Products existing in inventory in California are not required to be disposed. Third, DTSC has revised the regulations to allow for additional time to comply with this provision. In addition to the option of submitting Priority Product Removal Notification within sixty (60) days, this notification can be submitted later at the time the Preliminary AA Report (within about six [6] months) is due if a manufacturer or importer have submitted a Priority Product Notification within the sixty 60 days.

DTSC is confident that manufacturers and importers will have sufficient time to manage their inventories because the Priority Products will be adopted through rulemaking with various opportunities for public stakeholder involvement. By the time a Priority Product has been listed, manufacturers and importers should have had enough time to manage their inventories.

The provision to adopt a final Priority Products listing requires APA rulemaking, which can take up to one year to complete. Thus, there will be adequate lead-time for responsible entities to determine how to comply with the requirements of the regulations. Responsible entities do not have to wait for the finalization of the Priority Products list to begin addressing their inventory management issues.

Inventories may need to be managed if there is a regulatory response that may impose a product sales prohibition after the completion of an AA. The issue of inventory depletions can be addressed when determining any regulatory response. Again, the regulations do allow a sell-through of existing inventory even for products subject to a product sales prohibition. See the discussion of the Article 6, Regulatory Responses discussion in this Response to Comments document for further detailed discussion.

§ 69501.2(a) Duty to Comply

Comments: 11-29 , 42-11, 107-28

Comments Summary:

The manufacturer has the knowledge of the formulary science that produced the Priority Product and is the most knowledgeable entity in the supply chain to manage the AA requirements, including the potential selection of a functionally acceptable alternative that is compatible with the product formulation.

The requirements for compliance should be limited to the manufacturer of the product or responsible entity as identified on the product label, per the requirements of the Fair Packaging and Labeling Act and references to the importer or retailer should be eliminated.

The regulations should provide for importer notice of duty to comply. Subsection (a) of proposed section 69501.2 appropriately specifies that product manufacturers have the primary obligation to comply with substantive regulatory requirements, followed by the importer. While the regulation provides for a mechanism to notify retailers of their duty to comply with a mandate, the regulation provides no mechanism for notice to the Priority Product's importer. Suggested fix – add a provision to proposed section 69501.2 to notify importers of their duty to comply with a regulatory requirement if the manufacturer fails to do so.

Response:

As stated in the ISOR, a vast number of consumer products are placed into the stream of commerce in California by someone other than the actual manufacturer of the product. Given these circumstances, DTSC determined that the option of placing the duty to comply with these regulations solely on the product's manufacturer was neither viable nor desirable for two reasons:

First, when the product manufacturers that have no presence in California, DTSC has no practical, and in most cases no legal, ability to compel such manufacturers to comply with these requirements. DTSC's ability to implement the directives of Health and Safety Code sections 25252 and 25253 requires that DTSC be able enforce compliance with the requirements of these regulations in California. As such, the proposed regulations are similar to the duty to comply approach embodied in other California statutes and regulations that impose requirements on products that are sold in California, but manufactured both in-state and out-of-state (*e.g.*, California's Toxics in

Packaging Prevention Act, Article 10.4 of Chapter 6.5 of Division 20 of the Health and Safety Code). Second, placing the duty to comply solely on product manufacturers would create a significantly uneven playing field for California product manufacturers.

No changes were made in the language to restrict the responsible entity to solely the manufacturers.

With regard to using the Fair Packaging and Labeling Act, the label may help identify the manufacturer, but using the label to assign responsibility for compliance with the regulations is not appropriate. The definition of "responsible entity" in these regulations has to meet the objective of having someone assess the Chemical of Concern in consumer products. The label required by the Fair Packaging and Labeling Act allows the manufacturer, packer, or distributor to be named; this is not consistent with the entities identified in these regulations. DTSC has determined that it is not appropriate to use the Fair Packaging and Labeling Act to designate the entities and assign duty to comply responsibilities.

In response to the comments suggesting a notice to importers, DTSC has revised section 69501(a) to add a provision that DTSC will notify importers of their duty to comply with a regulatory requirement if the manufacturer fails to do so.

§ 69501.2(a)(2) Consortia and Trade Associations

Comments: 12-1, 57-22, 66-15, 84-5, 97-4

Comments Summary:

This collective approach is likely to be unworkable for a variety of reasons:

- First, competitors all have intellectual property and other confidential information that they will either not share or will be reluctant to share and there may be potential antitrust concerns;
- Potential "free rider" problems will arise when only some parties will fund an AA, but many more can rely on the results;
- The process of forming a consortium is time-consuming and must address a variety of issues including antitrust, trade secret, data sharing, cost sharing, and intellectual property;
- Most products, even though similar, will not have uniform properties, and making collective assessments is prone to inaccuracies, as they relate to any one product, or impossible to complete; and

- This approach could result in selecting a single source replacement for an entire industry. This might compel activities that violate antitrust laws, lead to commoditization of goods, and stifle innovation results in competitive markets.

DTSC should explore how it might revise the proposal to address these concerns and potential conflicts that may arise. Comment suggests adding antitrust language to undertake a collective AA.

A comment fully supports this option to allow a consortium, trade association, or other entity acting on behalf of the responsible entity, as it will provide the most effective manner for its members to engage in the regulatory process. DTSC needs to provide more information on conditions and operation procedures for consortia formation, as they are not described in the proposed regulations.

Response:

The comments have enumerated a variety of anticipated difficulties for a collective approach to complete an AA. A group of manufacturers, whether large, medium, or small, may work together to offset the costs of performing an AA on their own and achieve a common goal, but this is not required under the proposed regulations. Further, the provisions in the proposed regulations do not require a responsible entity to enter into a contractual agreement with a contractor to perform the AA. A responsible entity may perform parts of the AA or the entire AA in-house. The provision to allow consortia, trade associations, public-private partnerships, or other entities to fulfill the AA is not a requirement but an option that industry requested to be able to leverage their resources.

Contractual business arrangements between the responsible entities, and any contractors, a collaborative, and/or consortium, may well need to address issues regarding release of intellectual property confidential business information. The regulations do not change this sort of arrangement. Consultants frequently work for multiple clients and are privy to confidential business information. This concern must be addressed by nondisclosure agreements between the responsible entity, their consultants and/or their clients or between members of the consortium.

Responsible entities making same Priority Products would be subject to the AA at essentially the same time, which should limit those entities relying on the work funded by other competitors. Trade secret protections and nondisclosure agreements will further prevent this from happening.

Given that DTSC will make public the Priority Products under evaluation for review and comment prior to finalizing the Priority Products lists, responsible entities will have one to two years, in some instances longer, to be informed of the chemicals and the products that are being considered for prioritization. Responsible entities can choose to begin forming a consortium, collaborative and/or similar partnerships to address similar concerns in the event that their product-chemical combination is ultimately listed.

DTSC recognizes that AAs undertaken by a consortia, collaborative, trade association and/or similar partnerships representing an industry segment or an entire industry may have limited utility for all parties involved. As indicated earlier in the other approaches considered, a collaborative or trade association-created AA will, in many respects, be similar to a state sponsored AA, where the AA is conducted in a generic sense and would not address any product-specific or use-specific impacts. The results from a collaborative or trade association AA may not adequately address the appropriate regulatory responses and would require that each responsible entity conduct their own to address the product specific impacts.

As stated, a collaboratively undertaken AA will be generic, may not address any product-specific nor use-specific impacts, and may focus on filling the data gaps of common interest. Responsible entities will have to independently evaluate those parts of the AA that are product-specific. Although it is possible that regulatory responses may be similar, it is unlikely that every manufacturer will be given the same regulatory response to replace the Chemical of Concern with a single replacement chemical if the AA addresses product specific life cycle impacts.

There may be issues that need to be addressed when implementing this option to use consortia for the preparation of the AA. DTSC believes that these business arrangements are best negotiated by the affected responsible entities that wish to use this option and that the conditions and operation procedures for consortia formation must be agreed to by the parties involved. DTSC will not be amending the regulations in response to these comments.

DTSC appreciates the support for this concept. Additional information may be provided on the conditions and operational procedures of these groups, at a later date.

Comments: 66-15, 76-37

Comment Summary:

The comment suggests that DTSC explicitly clarify which notices must be filed directly

by responsible entities and which can be filed on their behalf (by a consortium, trade associations, etc.). The provision under section 69501.2(a)(2) cites only the Priority Product Notification and the AA Threshold Exemption Notification that are required to be submitted specifically by the responsible entity. Section 69501.3(c) and the corresponding discussion in the ISOR seems to indicate that a responsible entity would need to make a certification for more notifications than specified in section 69501.2(a)(2).

Other comments suggest that DTSC should allow a consortium, trade association, public-private partnership, or other entity to submit the Priority Product Notifications or the AA Threshold Exemption Notification (sections 69503.6 and 69503.7), rather than each company being required to do so independently as required in section 69501.2(a)(2).

Response:

The text has been revised to in response to the first comment. DTSC reviewed all the required notifications in light of the requirement to certify submittals to DTSC. In the proposed regulations (January 2013), DTSC has expanded the list of notifications that can be submitted only by a responsible entity. These changes were made because DTSC believes that given the content of the notifications and their significance, only the responsible entity is in a position to submit them. Further, allowing for these documents to be submitted by consortia is counter to the requirement for certification for submittals of documents. Section 69501.3(c) requires a certification signed by both the owner or an officer of the entity, and the individual in charge of preparing the document when submitting notifications and all other documents.

Section 69501.2(a) has been revised to disallow consortia to submit any of the following notifications:

- Priority Product Notification;
- Chemical Removal Intent Notification and Chemical Removal Confirmation Notification;
- Product Removal Intent Notification and Product Removal Confirmation Notification;
- Product-Chemical Replacement Intent Notification and Product-Chemical Replacement Confirmation Notification; and
- AA Threshold Notification (previously named AA Threshold Exemption Notification).

§ 69501.2(b) Manufacturer and Importer Options

§ 69501.2(b)(1)&(2) Removal Notifications and Replacement Notifications

Comments: 12-1, 5-144, 17-1, 42-3, 66-16, 76-38, 76-39, 86-15, 131-10, PH10-8

Comments Summary:

Eliminating the Priority Product Replacement Notification is a simple means to reduce DTSC's regulatory burden without compromising the integrity of the program. These advantages outweigh any perceived benefit for DTSC to obtain information regarding Priority Products that are no longer in commercial distribution in California.

The notification requirements are impractical, since manufacturers sell products to many retailers and distributors located outside California, who in turn bring products into the state:

- A manufacturer may not know contact information for all such persons in the State of California because the products are not sold directly to them;
- It is hard to understand why such information is required. There is no rationale to limit the time scale to the prior twelve months; and
- The information requested includes trade secrets; therefore, they have to be granted as "trade secrets" protection. Due to this, any player further down the supply chain than the direct customer is unknown to the player.

The replacement notification seems unnecessary because any new product containing a Chemical of Concern that is the same as or similar to a Priority Product would be considered a Priority Product, such that a responsible entity would need to submit a notification when that new Priority Product is introduced and would be responsible for conducting an AA, or if a regulatory response has already been imposed, be subject to that response.

Suggest the following changes:

- Recommend changing subparts (b)(1) and (2) to be self-implementing by eliminating the notification requirement and only requiring the manufacturers to demonstrate compliance upon request. Delete section 69501.2(b)(1) and (2) in their entirety; and
- Under section 69501.2(b)(1) change "product" to "Priority Product" for clarity.

Response:

DTSC has not revised the requirement in response to the first two recommendations, which are both variations of eliminating this requirement. The Priority Product Removal

Notification and the Priority Product Replacement Notification provide DTSC with information regarding Priority Products that are no longer in commercial distribution in California and that information will be posted on the DTSC website. The disclosure in the notification of the identity of the responsible entities and retail sales outlets is necessary to provide DTSC information regarding the locations where the Priority Products or their alternatives are destined to be distributed in California. A manufacturer should know contact information for all persons to whom the manufacturer has directly sold the product within twelve (12) months. The time scale is short enough so that record keeping should be within a normal one-year business cycle. If a responsible entity believes that the information requested is trade secret, the law and Article 9 (January 2013) of the regulations affords protection of this information.

The term "product" has been changed to "Priority Product" as suggested. In addition, DTSC has significantly revised the language for these two notifications to better organize them within the text and provide additional uniformity among all notifications required under these regulations. The Priority Product Removal Notification and the Priority Product Replacement Notification are declarations to DTSC that a responsible entity that has a Priority Product will be removing or replacing the Priority Product in lieu of complying with the substantive requirements of the Safer Consumer Products Regulations—*i.e.*, conducting an AA. The notifications have been renamed and are each now comprised of two documents. The intent notification is submitted first followed by the confirmation notification within ninety (90) days. These notification requirements for all these documents are now located in Article 5 in section 69505.2(a)(1)(A) in the January 2013 version of the regulations.

§ 69501.2(c) Retailer Option

§ 69501.2(c)(2) Priority Product Cease Ordering Notification

Comments: 21-4, 33-1, 37-3, 37-4, 42-10, 44-7, 66-16, 97-3, PH7-1, PH13-2, PH13-5, PH26-1, PH26-2

Comments Summary:

These notification requirements will only serve to burden manufacturers with no discernible benefit to the environment. The concerns regarding retailers as responsible entities are as follows:

- While there is a tiered approach to compliance duties, retailers could be required to undertake significant duties even though they lack the knowledge to complete an AA;

- Compliance would be difficult, especially for small retailers;
- Many retailers will be unable to provide information regarding all entities other than final purchaser/lessee;
- Retailers may be forced to begin tracking the intended use of Priority Products to ensure compliance;
- All retailers cannot continuously monitor websites for Priority Products and other proceedings;
- Retailers may choose to stop selling a Priority Product if they have to identify themselves as sellers of Priority Products;
- The regulations penalize retailers and consumers from the benefits of being able to offer and utilize lawfully produced products; and
- The 60-day manufacturer/importer deadline and the 90-day retailer deadline to submit a Product Cease Ordering Notification need to be aligned

DTSC should limit the compliance obligations to the actual manufacturers who control the materials and limit any obligations on the part of retailers. Retailers should not be included in the group of "responsible parties." DTSC should either eliminate the notification or require the retailer to demonstrate compliance upon request only or suspend retailer duties of any sort until the AA process is complete.

If this provision remains, the comment suggests amending the regulations to unify the deadlines for compliance exemption at ninety (90) days—by changing the sixty (60) days allowed in (c)(1) to ninety (90) days after DTSC issues the notice.

Response:

The approach in the proposed regulations is similar to the duty to comply approach embodied in other California statutes and regulations that impose requirements on products that are sold in California. The primary responsibility to comply with the substantive requirement of the regulations falls on the manufacturer of a Priority Product; however, if a manufacturer fails to comply, the responsibility falls on the importer or retailer of the consumer product. Although a retailer may elect to prepare AA, the majority of retailers will simply cease ordering a Priority Product making the performance of an AA strictly optional.

DTSC acknowledges that retailers will face some challenges complying with new regulations. However, DTSC has determined that these provisions are necessary to implement the regulations, and the duties imposed may be satisfied by retailers. DTSC disagrees that requiring retailers to cease ordering Priority Products goes far beyond the intent of the enabling legislation and effectively penalizes retailers and consumers

from the benefits of being able to offer and utilize lawfully produced products in California. Without enforcement at point of sale, DTSC cannot compel manufacturers located out of state to comply. DTSC is not revising the language to eliminate the notifications, or removing retailers from the list of responsible entities, which are both critical for implementation.

As explained in the ISOR, the information required to be submitted in the Priority Product Cease Ordering Notification will establish the identity of the retailer(s), manufacturer and importer, their contact persons, the sales outlets for the Priority Product, the name of the person immediately upstream from the retailer, product description and brand names. A statement is also required from the retailer to certify that the retailer will not re-initiate the ordering of the Priority Products until information is posted on DTSC's website that the manufacturer or importer has remedied the non-compliance. All of this is aimed at tracking and ensuring compliance with the requirements of these regulations.

It is not necessary to revise the language to suspend retailer duties until the AA is complete. If the manufacturer or the importer submits a Priority Product Notification, a Preliminary AA Report, and a Final AA Report in a timely manner, retailers are allowed to continue to sell Priority Products during this entire process. It is only when a responsible entity fails to comply with a requirement that a retailer needs to cease ordering the Priority Product. There is no need to suspend the retailer duties. Retailers will not be charged with having to conduct an AA, because retailers may instead choose to cease ordering a Priority Product.

In response to the comment regarding aligning deadlines for manufacturers, importers and retailers, DTSC has revised section 69501.2(c) to allow retailers ninety (90) days, instead of sixty (60) days, after DTSC issues the notice that the manufacturer and importer have failed to comply with their obligations under the regulations.

§ 69501.2(d) Failure to Comply List

Comment: 36-114

Comment Summary:

"Failure to comply" and "failure to respond" should trigger more meaningful penalties, including significant fines. If the most stringent or only punitive measure to address "failure to comply" is a DTSC website listing, this is inadequate to compel compliance by responsible entities. The comment suggests that it is up to those parties to comply with

the regulations and that not doing so should result in listing without warning, until they rectify the situation.

Response:

It is usual and customary for DTSC to assist regulated entities with compliance, and it is not uncommon to issue warnings before imposing severe consequences. This is under the general heading of "good government." Due to a lack of resources, it will be difficult to do outreach and educate business entities about the regulations. Providing a warning before posting a failure to comply is fair to these businesses.

However, being placed on the Failure to Comply List is not the only consequence for non-compliance. If the responsible entity does not comply with Priority Product Notifications, AA, or regulatory responses, retailers are compelled to cease ordering the Priority Product which is, in essence, a de facto ban on the product. Chapter 6.5 of the California Health and Safety Codes gives DTSC the authority to impose penalties if needed, so it is unnecessary to revise the regulations to explicitly state that there will be penalties.

Comment: 5-144

Comment Summary:

The comments provide suggested language to amend section 69501.2(d) which is the "failure to comply" provision:

- 69501.2(d)(1)(B) add the phrase, "describing the steps necessary to achieve compliance";
- 69501.2(d)(2) delete the phrase, "to the satisfaction of the Department";
- 69501.2(d)(2) add the phrase, "as specified in the notice of non-compliance or a rationale justifying its infeasibility is not provided"; and
- 69501.2(d)(6) revise to require the removal of the information within five (5) days of the notice.

Response:

Under section 69501.2(d), If DTSC has determined a requirement has not been complied with and then DTSC issues a notice of non-compliance to the manufacturer to the manufacturer and the importer, the manufacturer and the importer have forty-five (45) days to remedy the non-compliance. If the non-compliance has not been remedied, then DTSC posts the information regarding the determination of non-compliance on the "Failure to Comply List."

DTSC agrees with the first suggestion that the phrase, “the steps necessary for compliance,” should be added to this provision and has revised the language in section 69501.2(d)(1)(B) accordingly.

It is unclear why the second suggestion is to remove the phrase, “to the satisfaction of the Department” for determining if the non-compliance has been remedied. DTSC reserves the right to determine whether the non-compliance has occurred or whether the non-compliance has been remedied. The language in 69501.2(d)(2) is similar to the language in sections 69501.2(d)(1)(A) and 69501.2(d)(5). The language has not been revised in response to this comment.

The third suggestion to allow for a justification of infeasibility of compliance would seem to encourage manufacturers or importers to avail themselves of this defense with no criteria for determining if the infeasibility is defensible. Additionally, allowing for a justification of infeasibility at this stage will greatly delay communicating this critical issue to DTSC. The delays include the time allowed for the requirement that has not been complied with, time need to send and receive the notice to the manufacturer or importer of the non-compliance, and the time provided to remedy the non-compliance. It would be more appropriate to submit this type of justification before the deadline of the requirement. DTSC prefers to not revise the regulations to permit this justification under the failure to comply process.

DTSC also disagrees with the recommendation to remove the information regarding retailers from the Failure to Comply List automatically within a five-day time limit without concurrence from DTSC. DTSC will strive to keep the Failure to Comply Lists as accurate as possible, but due to lack of resources, DTSC does not feel it can commit to the five-day time limit in the regulations and be able to determine if all the steps needed to achieve compliance have been met. The five-day limit may also require that the website postings be done on a continuous basis instead of updating these posting in batches. Further, weekends and holidays may make meeting the five-days more difficult for DTSC. This provision (renumbered section 69501.2(c)(6) in the April 2013 version of the regulations) has been revised to apply to retailers and assemblers.

§ 69501.3 Information Submission and Retention Requirements

§ 69501.3(a) Required Signatures

Comments: 5-66, 9-37, 57-23

Comment Summary:

Only the responsible individual in charge preparing the relevant document should need to verify the accuracy of the document that they prepared. The requirement for two sets of signatures is over-reaching and impractical and will not further the accuracy of the documents, since the person with most knowledge is already required to sign. Further, the additional certification requirement is unnecessary in the situation where an AA is conducted by a certified assessor.

Response:

DTSC is not making any changes to the regulations regarding the requirement that there be two signatures on specified documents. The signature requirements specified in this section will require action at an executive level, and the person with lead responsibility for preparation of the document who will be accountable for providing the most complete and accurate information for submittals to DTSC. Upper management should be aware of efforts to comply with the regulations. Also, the requirement for certified assessors has been eliminated in the proposed regulations (January 2013); therefore, the signature of an assessor no longer supports the comment that suggests only one signature is necessary.

Comment: 12-2

Comment Summary:

This suggested antitrust language may need to be inserted into a brand new section. DTSC counsel should examine the language for form and sufficiency.

Response:

DTSC will not be revising the regulations in response to this comment. Explicitly inserting antitrust language into the regulations will not protect responsible entities from antitrust liability if this language is in conflict with any of the provisions of the laws specified. This regulation cannot supersede the law or the regulatory authority of any other agency; this includes the applicability of antitrust law. For a detailed discussion of antitrust issues related to these regulations, see the Antitrust discussion in the Procedural, Legal, and Overarching Issues portion of this Response to Comments document.

§ 69501.3(b) Format

Comments: 57-23, 68-17

Comments Summary:

The comment agrees with benefits of the usage of an electronic format, but it is also critical that the specifics of the required submission format be provided as soon as possible. It is unclear what will be the "manner and electronic format" for data submission. The comments recommend that DTSC consider using internationally recognized formats such as the International Uniform Chemical Information Database.

Response:

DTSC will not revise the regulations in response to these comments. Implementing these regulations will require extensive coordination between all entities involved and a uniform protocol for collecting, tracking, and posting the required information. These details have not been fully resolved; therefore, it is premature to specify the data protocol in these regulations. It is too early to tell what the time line will be for specifying the required format for submittals. And there is no reason to conclude it will be identical for all required submittals.

[Note: Reporting data under REACH following submission and acceptance by the European Chemicals Agency (ECHA) is captured in the International Uniform Chemical Information Database (IUCLID).]

§ 69501.3(c) Certification Statement

Comments: 5-145, 11-30, 12-2, 36-113, 57-23, 109-22, 109-23, 129-5

Comments Summary:

This provision significantly enhances the integrity of the program by ensuring that persons in positions of authority at the responsible entity engage in a meaningful way in the process. The comments support the use of the phrase, “under the penalty of perjury” in the certification and that signatures are required for the person who prepared the information and the owner of the company or an official or authorized representative. In addition, the comments recommend that responsible entities be required to post a bond or otherwise provide proof of insurance regarding the information they submit to DTSC.

Conversely, another commenter believes that responsible entities should not face penalty of perjury for errors made on information submitted. Nothing in the statute confers authority on DTSC to require that an owner or an officer of a company must certify under penalty of perjury that the substantiating information is correct. This requirement results in the potential imposition of a criminal penalty if a question is raised about the accuracy of the information. DTSC lacks the authority to create

circumstances that give rise to a criminal penalty; only the California Legislature has this authority.

A comment recommends revising the certification language to parallel what the U.S. EPA requires for the TSCA Inventory Update Reporting Modifications. The new language would certify that the submitted information has been "completed in compliance with the requirements of this rule and that confidentiality claims are true and correct."

Delete the AA Threshold Exemption Notifications and the Chemical of Concern Removal Notification from the list of documents that need to be certified.

Response:

DTSC appreciates the support for this certification language and the requirement for two signatures. However, DTSC will not be revising the language to add the requirement to post a bond or otherwise provide proof of insurance. DTSC does not have the authority to require financial assurance on the accuracy of the submittals nor does DTSC believe this to be an appropriate or necessary requirement.

In response to comments regarding the phrase, "under penalty of perjury," DTSC has revised the certification language and has deleted this phrase, thereby eliminating the question of whether the deleted language would create a new crime.

The certification language applies to all documents submitted to DTSC—which may include notifications, AA Reports, and submissions of information claimed to constitute trade secret. The suggestions to revise the language to include, the following phrase - "completed in compliance with the requirements of this rule and that confidentiality claims are true and correct" may not be pertinent or necessary for these documents. For example, submittals of notifications would not need this language because the request for trade secret needs to be submitted separately. DTSC will not revise the certification document in response to this comment.

The language for the certification was revised and simplified by deleting the list of specific documents that require a certification and replacing the entire list with the word "documents." The result of this amendment now requires that all documents submitted must now include the certification statement. No further changes were made in response to the request to eliminate the AA Threshold Exemption Notifications and the Chemical of Concern Removal Notification from the list.

§ 69501.3(d) Document Retention

Comment: 9-109

Comment Summary:

The purpose of section 69501.3(d) is unclear, and DTSC should clarify its intention. The provision requires that information prepared but not submitted to DTSC, be retained for a period of three years. A literal reading of the provision would require persons not subject to the regulation (those not required to submit information) to retain information.

Response:

This provision does not apply to persons not subject to these regulations. There is information that is required to be obtained or prepared when complying with the regulations but may not be required to be submitted to DTSC. This documentation must be retained for a minimum of three years in case DTSC requests this additional information be submitted to support any determination or conclusion in an AA Report, a regulatory response determination, a revised report in response to a notice of deficiency or an audit.

This provision sets the retention period at three years for information obtained or prepared but not submitted. Conversely, there is no required retention period for any information that is submitted to DTSC. This provision is necessary to ensure DTSC has continued access for a reasonable period of time to information that may be needed to support fulfillment of DTSC's responsibilities under these regulations, while acknowledging that not every piece of information must initially be submitted to DTSC.

§ 69501.4 Chemical and Product Information

Background:

In these regulations, there are two mechanisms that DTSC may use to acquire information. First, DTSC has laid out four approaches for the collection of data in section 69501.4(a)(1) through (4) of the proposed regulations. Information will be collected from the public domain that is readily available at no charge, and by subscription. DTSC may also request existing data from "responsible entities" or chemical manufacturers or importers; and may request the generation of new data necessary to implement these regulations. Second, as a regulatory response, DTSC may require additional information needed to assess a Chemical of Concern and its potential alternatives. Note that this provision was revised in the January 2013 and the April 2013 versions of the regulations. For purposes of this section, this provision now

includes the manufacturer, importer, assembler, and retailer of any product or chemical, not just Priority Products or Candidate Chemicals, except for those products exempted from the definition of "consumer product" specified in Health and Safety Code section 25251.

The data gaps will be challenging but will not make prioritization impossible. The prioritization approach is not a systematic way to assess all data on all chemicals, but rather a comprehensive process by which DTSC will prioritize Chemicals of Concern in consumer products. The regulations need to allow consideration of available reliable information for both Chemicals of Concern and consumer products.

The authorizing legislation did not specifically give DTSC authority for data call-ins prior to the completion of an AA. However, existing authority for DTSC to request data is found in Health and Safety Code sections 57018 through 57020 (also known as AB 289). Under this law, DTSC may request information regarding analytical test methods, fate and transport in the environment, and other relevant information about specified chemicals. The law applies to individuals and companies who produce a chemical in California and to those who import a chemical into California for sale.

§ 69501.4(a) Information Gathering

Comments: 9-45**,** 9-46, 9-47, 9-48, 9-49, 9-50, 9-51, 9-52, 47-16

Comments Summary:

The legislative authority cited for this provision does not grant DTSC the authority to compel a responsible entity or a chemical manufacturer to generate new information. Health and Safety Code section 25252 is silent on this issue and Health and Safety Code section 25253 merely authorizes regulations that require "additional information." The statutory language further limits this information to "additional information needed to assess a Chemical of Concern and its potential alternatives." (Health and Safety Code section 25253(b)(2)) The logical reading of the word "additional" in this context is that it means existing information not otherwise available from other nations, governments and authoritative bodies. The legislative analysis of the final version of AB 1879 stated that the statute does not actually give DTSC a grant of authority to impose the range of regulatory responses on the affected community. There is nothing to suggest a grant of authority to require the generation of new testing data or analyses.

Response:

Section 69501.4 merely authorizes DTSC to request information. There is no regulatory requirement for a responsible entity or other person to submit any information to DTSC before one's product is identified as a Priority Product. And, at that stage, there are still no data generation requirements, only self-identification as a responsible entity for a Priority Product. The status of parties' responses to information requests will be posted on the Response Status Lists, but there are no true compliance requirements.

Draft regulatory provisions that were not expressly authorized by the authorizing legislation are based on DTSC's determination that such provisions are implicitly authorized as necessary to have an effective regulatory program. DTSC drafted the proposed regulations to be fully compliant with the APA, including the authority cited. Thus, DTSC struck a balance between the lack of express authority to require data generation prior to an AA, with the desire to have robust information on which to make chemical and product prioritization decisions. Accordingly, DTSC declines to make any changes to the proposed regulations in response to these comments.

§ 69501.4(a)(3)&(4) Request for Chemical and Product Information

Comments: 5-67, 5-146, 5-147, 7-1, 9-51, 9-52, 9-110, 11-31, 37-5, 37-6, 47-13, 47-14, 47-16, 57-24, 66-17, 86-16, 87-5, 87-6, 87-7, 107-29

Comment Summary:

As currently drafted, subsection (a) is much broader than the stated intent for this provision as described in the ISOR—which is to support and inform the chemical and product prioritization processes. The APA demands of all administrative agencies that they give specificity and clarity to their regulations. The concerns include:

- No description of the type or amount of new information that may be requested;
- No limits specified in the regulation as to the scope and breadth of new information that may be requested;
- No time frames provided for how often "new information" might be requested;
- Not clear who may be responsible for information submissions in the future;
- No criteria or standard that must be met when submitting information;
- No due process for those to whom DTSC is making the request;
- Unclear how confidential business information and trade secret information will be protected;
- Potential antitrust issues;
- Responsible entities may not have the information being requested; and
- Conflicting information between different sources of information.

This presents an undue burden upon companies to generate information without any requirement for DTSC to justify the benefit of the information. Businesses cannot adequately provide comments in this rulemaking on the reasonableness of potential future data requests.

Recommendations to address some of these issues include revising the language to:

- Specify that the requested information shall be limited to only the review and that DTSC should expressively give a basis for why the information is requested and for which area of review such information is used;
- Limit the requests for information related to Priority Products or product categories on a Priority Product Work Plan during the three year time frame of the Priority Work Plan;
- Limit the requests for information to that information essential to evaluating and communicating potential adverse public health and environmental impacts of the Chemicals of Concern and Priority Products;
- Include time frames for responses to these information requests that are reasonable and/or achievable. This is especially problematic given most data calls/information requests are contemplated via posting on a web site and/or through an electronic mailing list(s). At a minimum, a reasonableness standard should apply to all time lines and ideally time lines would include the qualifier of "not less than 30 business days"; and
- Specify that the approaches outlined are in order of preference, so that information requests from responsible parties are not made unless publicly available sources of information have been exhausted.

Response:

Section 69501.4 merely authorizes DTSC to request information. There is no regulatory requirement for a responsible entity or other person to submit any information to DTSC before one's product is identified as a Priority Product. Businesses receiving a request from DTSC for information are not required by the regulations to provide the information. California does not have legal authority to require the submittal of information unless, the entities are located in California or if the Priority Product is placed into the stream of commerce in California and is subject to a regulatory response. However, DTSC will be making these requests and is required to maintain and post on its website a Response Status List that will identify the status of responses to the request (such as, information was provided, information not provided, or business was unable to provide information) and which businesses were subject to the request.

DTSC drafted the proposed regulations to be fully compliant with the APA and the authorizing legislation. DTSC disagrees with the comments that the regulations do not comply with the requirements of the APA.

The first three suggestions are very similar in that they are all recommendations to limit the scope of information requests. The suggestions have some merit but limit DTSC's ability to successfully implement the regulations in ways not contemplated by the commenters. DTSC will not limit the scope of the information requests to information about Priority Products because once the Priority Product is listed there is little need to gather additional information for the prioritizing products. Although DTSC may want additional information on the product categories listed in a Priority Product Work Plan, there may be a need to include information on chemicals that would be considered outside this limit. Limiting the information requests to information essential to evaluating and communicating potential adverse public health and environmental impacts of the Chemicals of Concern and Priority Products would not allow DTSC to request existing information on possible ingredient content or volume of a chemical in commerce. Thus, the suggested language change would unduly restrict DTSC's information gathering efforts, and interfere with DTSC's ability to implement an effective regulatory program. DTSC did not revise the language to make more specific the scope and breadth of the information request provisions in previously numbered sections 69501.4(a)(3) and (4). These sections are now renumbered 69501.4(a)(1)(C) and (D), (January 2013) and these provisions only authorize DTSC to request the information.

The suggestion that the regulations specify universal time frames for replying is problematic because requesting existing information will need a shorter time frame for response than generating new information.

DTSC had in previous versions of the draft regulation language explicitly stated the order of preference for gathering information. DTSC has determined that dictating an order or preference may impede implementation. It would disallow taking advantage of more than one approach to acquire information. It is as stated, DTSC's intent to follow an approach where the least burdensome means of seeking information is used first, followed by the next in a hierarchical order, but DTSC needs to reserve the right to go out of order or to use more than one approach if necessary to efficiently and effectively implement these regulations. DTSC will not make changes in response to this comment.

Comments: 68-1, 68-18, 86-16

Comments Summary:

The provisions lead to potential discriminatory treatment between responsible entities solely due to whether they are known to DTSC and receive requests for input or not. Failure to comply with information requests results in the responsible entity being on the Response Status List. An arbitrary selection of economic operators for soliciting information would create obligations for some but not for others. Hence, solely being known or not known to DTSC will potentially lead to discriminatory consequences for responsible entities. The commenter seeks clarification on whether this provision includes manufacturers in other countries and how DTSC will ensure that other countries will be treated the same as manufacturers in the U.S. The concern is that they might not be aware of the obligations under the regulations and correspondence or communication may be more difficult.

Response:

Businesses receiving a request from DTSC for information are not required by the regulations to provide the information. However, DTSC is required to maintain and post on its website a Response Status List that will identify the responses (information provided, information not provided, or business was unable to provide information) to the request and which businesses were subject to the request. DTSC may request the information from businesses in California and outside of California including businesses located out of the country. Therefore, there is no discriminatory intent or effect. While it is true that foreign entities may not be quite as easy to identify for purposes of information requests as are California or other U.S. firms, DTSC intends to keep a level playing field by conducting necessary research and outreach so that its information requests are fair and even-handed.

These regulations allow DTSC to request one or more chemical or product manufacturers, importers, assemblers, and/or retailers to provide existing information or to generate new information based on a schedule developed by DTSC. The information requested may be any information about any chemical or product, not just those products that are covered more specifically by the regulations, that DTSC determines is necessary to implement the regulations. DTSC is may also request chemical and product information that is already available in the public domain.

DTSC is cognizant of the need to provide clear, well-articulated requests for data that provide the detailed descriptions of what is being requested. DTSC is confident that it will be able to implement this provision of the regulations effectively.

Comments: 36-55, 39-22

Comments Summary:

DTSC should exert its call-in authority under AB 1879 and require, not just request, the generation of new health and environmental impact data and the development of new safer alternative chemicals and products. DTSC should exercise this authority as early as possible in the program's implementation. DTSC should replace the word "request" with "require."

Response:

DTSC will not revise the language in 69501.4(a) to require the generation of data. The authorizing legislation confers authority on DTSC to require authority only upon the completion of an AA. (See Health and Safety Code section 25253(b)(3))

Comment: 63-1

Comment Summary:

The proposed regulations cover over 1,200 chemicals with the potential to trigger a duty to disclose. The individual distributor or retailer has no control over the chemical composition of the products he/she sells. Nor does the retailer exercise any control as to how products are labeled by a manufacturer. Requiring an individual distributor to be responsible for notifying or disclosing chemical contents to his/her customers is an unreasonable expectation.

Response:

This is an erroneous understanding of the regulations. As written, there is no duty to disclose the chemical composition of products or if products contain any of the Candidate Chemicals (named Chemicals of Concern in the July 2012 version). If there was a Priority Product named that the distributor sold, the distributor could cease ordering the Priority Product in lieu of being subjected to the substantive requirements of the regulations and continue to sell any remaining inventory of their product. DTSC will not be making any changes to the regulations in response to this comment.

§ 69501.4(b) Information Requests

§ 69501.4(b)(2) Effectiveness of Communication Method

Comments: 37-5, 47-15, 68-18

Comments Summary:

An entity may not even be aware that this information is being requested of them since the proposed regulations do not require notice to affected entities. "The Department may request that information be made available by mail, by listserv or by merely posting it on their website." Even though an entity may not receive actual notice of the request, the entity risks being placed on DTSC's Response Status List as non-compliant unless it has "demonstrated to the Department's satisfaction that it does not have and is unable to produce the requested information" (section 69501.4(c)(1)(C)).

Response:

DTSC may utilize two methods to communicate information requests. Under section 69501.4(b)(1), DTSC may request the information from individual responsible entity, chemical manufacturer, or importer, by correspondence that will be sent either electronically or by U.S. mail. If, however, DTSC chooses to do a data call-in that applies to all manufacturers, importers, assemblers, or retailers of a specific chemical, group of chemicals or products (January 2013), then DTSC will post the call-in on its website and provide notice to individuals on the electronic mailing list established by the DTSC.

There are various steps that DTSC can take to ensure that all entities have the same opportunities and will be treated fairly under this provision. First, is ensuring that the appropriate manner of communicating the request is used. DTSC may be able to identify to the extent possible all the entities that would be the subject of a request, before making such a request for information to ensure greater success. DTSC may instead, choose to use a hybrid approach. In all cases, DTSC may be limited due to resources or time considerations. It is due to the lack of funding that DTSC cannot commit in the regulations to any one method of communicating these information requests, so the language will not be revised in response to this comment.

The provision in section 69501.4(c)(1) allows for DTSC, once the request is made, to make a determination if the information: 1) was provided; 2) was not provided; or 3) was unavailable. It would be extremely unlikely to identify an entity that did not comply if DTSC is not aware of its presence in the marketplace. If, however, this entity is known to DTSC and there is some assurance that the entity has received notice of the request but does not provide the information requested, the status on the Response Status List would indicate that the entity had failed to respond.

§ 69501.4(c) Response Status List

Comments: 68-1, 87-8

Comments Summary:

The public listing of companies for having failed to respond to requests from DTSC for information even before a decision has been taken on whether or not a product and/or Chemical of Concern will be selected for prioritization is not justified. Rather than contacting individual companies with information requests and denouncing companies for not having submitted information at this stage of the process, DTSC might wish to limit the information requests to general calls for information as specified in subsection (b)(2) and then publish the names of those companies that have co-operated and responded. This would then be a reward and incentive for companies to participate in line with what is already foreseen in subsection (d). The collection and dissemination of this information in a public forum will stifle innovation and remove the incentives for pursuing new products and markets.

Response:

Section 69501.4 merely authorizes DTSC to request information. There is no regulatory requirement for a responsible entity or other person to submit any information to DTSC before one's product is identified as a Priority Product. Although the status of parties' responses to information requests will be posted on the Response Status Lists, there are no true compliance requirements.

DTSC will not be revising this language in response to these comments because the provision already allows for this incentive. DTSC believes that it can utilize the Safer Consumer Products Partner Recognition List (section 69501.4(d)) to acknowledge entities that have voluntarily provided information that advances the quest for Safer Consumer Products or the Response Status List (section 69501.4(c)) to publish the names of companies that have co-operated with a call-in request.

DTSC disagrees that the collection of information will stifle innovation. The transparency of this chemical and product information process will:

- Provide DTSC critical information that is not publically available;
- Allow sharing of information, except for trade secrets;
- Allow entities to observe the type of information being requested and associated time lines;
- Provide stakeholders useful information regarding the participation of various entities; and
- Accelerate the quest for safer products.

DTSC is not revising the language in response to this comment.

§ 69501.4(c)(1)(C) DTSC Concurrence

Comments: 5-148, 9-111, 37-7

Comments Summary:

DTSC should revise section 69501.4(c)(1)(C) by deleting the phrase, "to the Department's satisfaction" when demonstrated that an entity does not have and is unable to produce the requested information.

It is unclear how a responsible entity, chemical manufacturer, or importer may demonstrate to DTSC's satisfaction that it is not able to produce the requested information. This provision is highly subjective and provides no indication of what actions would be necessary to comply. At a minimum, DTSC should outline the steps required to meet the standard established under this section to better articulate the objective standard of proof for such demonstrations.

Response:

DTSC cannot predict every possible type of information and provide the objective standard of proof for each possible request in regulations. It is more appropriate and feasible to clearly communicate the details regarding:

- The nature of the request;
- The scope and objectives of each of these requests;
- due dates;
- Time frames;
- The entity that is being asked to provide the information; and
- Other details which should resolve most of these issues during the implementation of the regulations, as opposed to in regulations text.

These details may be included when the requests for information is issued.

No changes were made to the language in response to these comments. The phrase "to the Department's satisfaction" will not be removed because it is the only criteria for whether a person has demonstrated that it does not have or is unable to produce the requested information. DTSC reserves the right to make this determination. Absence of any standard for what is responsive information would allow parties to ignore or partially comply with DTSC's requests with absolutely no incentive or consequence. Again, DTSC needs the flexibility in these regulations identify the appropriate scope and breadth of each of these requests.

§ 69501.4(c)(3) Response Status List Updates

Comment: 5-148

Comment Summary:

The comment recommends modifying the language in section 69501.4(c)(3) as follows:

> *"The Department shall update the ~~information on its website upon~~ ~~determining that the responsible entity or the chemical manufacturer or importer, or another person, has taken action to change its status under paragraph (1)~~ Response Status List within five (5) days of receiving the requested information or a demonstration that the responsible entity or the chemical manufacturer or importer, or another person does not have and is unable to produce the requested information."*

Response:

DTSC disagrees with this recommendation to revise the regulations to require that the updates to the Response Status List occur within five (5) days. DTSC will strive to keep the Response Status List as accurate as possible, but due to lack of resources, DTSC does not feel it can commit to the five-day time limit in the regulations and be able to determine if the response status has changed. The five-day limit may also require that the website postings be done on a continuous basis instead of updating these posting in batches. In addition, weekends and holidays may make meeting the five days more difficult for DTSC. Accordingly, DTSC is not making that requested change.

The second part of the recommendation does change the effect of the regulations but is another way of stating the same outcome. The phrase, "receiving the requested information" simply restates paragraph (c)(1)(A) and the phrase, "demonstrating that the person does not have and is unable to produce the requested information" restates paragraph (c)(1)(C). Because this suggested language does not change the provision, DTSC will not make the revision to the language in response to this comment.

§ 69501.4(d) Safer Consumer Products Partner Recognition List

Comments: 9-110, 12-3, 29-9, 57-25, 109-21, 129-6

Comments Summary:

These comments generally support the Safer Consumer Products Partner Recognition List (Recognition List) as a means for creating support of the program. There are various suggestion and cautions regarding this provision as follows:

- Posting an AA of a product that is not a Priority Product would imply that an AA or reformulation by others should be completed;
- Voluntary AAs should undergo public comment and/or peer review to the same level of rigor as mandated AAs;
- Do not exclude from the Safer Consumer Products Partner Recognition List any AA Reports that demonstrate that no economically or technically feasible alternative exists;
- Voluntary AAs completed by third-party certified assessors should be required to be considered "safer alternatives" when DTSC prioritizes products under section 69503.3(d);
- DTSC should acknowledge manufacturers who reformulate their products in advance of being required to do so by DTSC;
- Identify the specific information that would be most helpful to DTSC in advancing the "quest for safer consumer products"; and
- The Recognition List should allow an entity to post their information onto DTSC's website without any reporting nor DTSC's involvement or control to reduce the work for the agency.

Response:

DTSC has considered all these comments and will not be making any changes to the proposed regulations in response to these comments. DTSC created this provision both to acknowledge contributions to this program and create an incentive to others. It is highly likely that innovative companies seeking added visibility will conduct AAs voluntarily to gain visibility and market shares.

DTSC respectfully disagrees with the argument that a voluntary AA on products that have not been listed as a Priority Products may stigmatize these products. If a person has conducted an AA similar to what is required in the regulations, the benefits would far outweigh any perceived stigma. A person who has completed an AA would have added insights on the product; could reformulate a product before ever being listed; and form profitable partnerships with other entities. These AAs would show how to prepare and evaluate the criteria for adverse impacts and identify any alternatives that should be considered and/or avoided.

DTSC disagrees that a voluntary AA should be subject to the same level of review and rigor of the formal process described in this regulation, including public comments and peer-review. If the regulations require an AA, review and public input is part of the process, as well as being subject to regulatory responses. A voluntary AA and a required AA are not treated the same under the regulations and do not have to be.

While DTSC understands the desire to have assurance of a certain level of quality, the voluntary AA are there as an example and possible a learning tool. DTSC will not revise the regulations to require peer-review of a voluntary AA.

A voluntary AA will not be excluded if it demonstrates that no economically or technically feasible alternative exists. This AA conclusion, by itself, does not make the AA deficient. Conversely, DTSC would exclude any AA that is not sufficiently equivalent to what is required. The point of the posting voluntary AAs is to provide examples that others can learn from or follow. If a voluntary AA submitted does not meet these criteria, it would serve DTSC's purpose to acknowledge it under the Safer Consumer Products Partner Recognition List.

DTSC has removed the requirement for certified assessors from the regulations, thus, considering a voluntary AAs completed by third-party certified assessors to be a "safer alternatives" is a moot point. No changes to this provision were made in response to this comment.

Acknowledging manufacturers that reformulate their products in advance of being required is not appropriate for the Recognition List, unless there is an AA to support the reformulation or there is a robust evaluation regarding the reformulation. Although DTSC would encourage reformulating products to eliminate Candidate Chemicals, this is not the best use of the Recognition List. DTSC will not be making any changes in response to this comment.

Except for the AA, until DTSC begins implementation, it will be difficult revise this provision to specify in advance what specifically is helpful to support the program. In general, what would be considered helpful is anything that advances the development of AA, any tools that would facilitate the comparison of hazard traits, or new methods of evaluating exposure pathways, the development of new life cycle assessment tools, etc. DTSC feels that all these are captured in the provision; the language is "information that is helpful to the Department in implementing this chapter." DTSC will not be making any additional changes in response to this comment.

DTSC is unwilling to allow any entity to post their information on DTSC's website without DTSC's concurrence that the content should be acknowledged on the Recognition List and is appropriate for posting on a state government webpage. DTSC appreciates the desire to reduce DTSC's workload but feels this is unworkable.

§ 69501.5 Availability of Information on DTSC's Website

Background:

Section 69501.5 specifies a list of documents that DTSC will post on its website, in order to implement these regulations and make information available to the public, consumers, responsible entities and other persons in the supply chain, is critical. The benefit is transparency for this process. This section clearly specifies the information that DTSC will post to assist responsible entities in complying with these regulations. This information will also assist the public and consumers to make informed choices regarding consumer products.

§ 69501.5 General

Comment: 36-46

Comment Summary:

The comment supports this section that will make information available on DTSC's website, which will enhance workers' right to know about the hazards of products they use, and the Injury and Illness Prevention Programs their employers must prepare.

Response:

DTSC appreciates this support.

Comments: 11-32, 107-30

Comments Summary:

DTSC should use official state regulatory dissemination methods (*e.g.*, California Regulatory Notice Register) as the primary means of communicating its policies and decisions regarding the regulations.

Response:

DTSC will not be revising the language in response to this comment. The information will be posted on DTSC's website and emails will alert individuals regarding availability of these documents and any updates. These two means are aimed at making pertinent information known on both a general level and specific level at the same time. The California Regulatory Notice Register was considered in a previous version, but DTSC concluded that was a less convenient and effective means of communicating with responsible entities and other interested parties as part of implementation of these regulations.

Comments: 36-47, 39-11, 138-24

Comments Summary:

Any information provided, either as hard copy written materials or on the website, should be translated. The lists of Chemicals of Concern and Priority Products should be available in Spanish and other relevant languages. This also will assist retailers and other users. Other state government agencies already do this (*e.g.*, Cal/OSHA, Division of Labor Standards Enforcement).

Recommendation: Post information in Spanish when possible, and definitely when it is available in that language.

Response:

It will not be at all feasible for DTSC to translate every document it receives into Spanish and/or any other language. DTSC anticipates receiving and posting dozens and dozens of technical, scientific and regulatory documents on a rolling basis. It simply does not have the resources to translate each of these documents into Spanish or any other language. The regulations will not be changed in response to these comments.

Comments: 9-35, 9-36, 57-26, 76-1

Comments Summary:

There is a concern with the lack of clarity and benefit of this activity, while the costs associated with maintaining and updating information are undefined and potentially burdensome to the agency or misleading to the public and/or stakeholders if not readily maintained. Extensive resources may be diverted from implementation of the regulations. The comments recommend that DTSC clarify these issues and ensure that this activity is warranted.

DTSC is proposing an unprecedented level of information about products. There is concern that DTSC will not have the resources to properly manage the volume of information. DTSC should confer with Washington State and Maine regarding the data collection challenges faced during implementation of the Children's Safe Product Reporting Rule, and the Regulation of Chemical Use in Children's Products, respectively. What will be clear is that to maximize the efficiency and utility of data and its collection, the regulatory need for specific data should be the driver for regulatory requirement for submission, not perceived gaps in the data DTSC possesses.

In order to implement these regulations, making information available to the public, consumers, responsible entities and other persons in the supply chain is critical. This information will assist responsible entities in complying with the requirements and assist the public and consumers in making informed choices regarding consumer products. Each of the required postings is necessary to provide accurate, current, and important information regarding the operation of these regulations and necessary to motivate compliance, engender confidence in the program and reward early and voluntary action.

Response:

The recommendation that DTSC may want to remove from the listing less critical information and then optionally post them is not desirable. DTSC wants to make sure all pertinent documents are tracked and can be accessed. Each of the documents is either required or specified in the regulations. DTSC appreciates the concern regarding the utilization of DTSC resources to maintain all this information on the website, but DTSC is confident that it has the expertise and resources to administer the proposed regulations in an effective manner. DTSC has crafted the proposed regulations in a manner that maximizes the use of existing information. DTSC is not making any changes to the language in response to this comment.

DTSC has crafted the proposed regulations in a manner that maximizes the use of existing information. DTSC is not making any changes to the language in response to these comments.

Comment: 41-46

Comment Summary:

DTSC assumes that responsible entities will be required to provide the sensitive information and unless the company can meet certain requirements, that information will be made available to the public on easily accessible websites. Such information includes market information, decision-making, supply chain information, targeted customer base, and chemical formulations and ingredients can then be used by competitors to copy the work that has been done, reverse engineer the solutions identifies, and in the case of market information be used in an anti-competitive manner.

Response:

The comment concern is for the protection of sensitive business information but does not provide a specific remedy for this issue. DTSC is confident that it will be able to implement these regulations in a manner that will successfully provide trade secret

protections. In fact, DTSC has an entire article in the regulations devoted to the submittal of claimed trade secret information and the review of these claims for trade secret status. These provisions work to address the concerns raised in this comment. See the Trade Secret Protection discussion at Article 10 of this Response to Comments document for a detailed discussion of how trade secrets are protected under these regulations. No changes were made in response to this comment.

§ 69501.5(a) Website Postings with Electronic Mailing Notices

§ 69501.5(a)(8) Regulatory Response Exemption Requests and Notifications

Comment: 5-149

Comment Summary:

Delete subsection 69501.5(a)(8) "A list of regulatory response exemption requests submitted to the Department under section 69506.11, and copies of all notifications issued by the Department granting, denying, or rescinding a regulatory response exemption."

Response:

The commenter recommended that the provision for "regulatory response exemption" under section 69506.11 in the July 2012 version be deleted and be made self-implementing; thus, making section 69501.5(a)(8) unnecessary because there would be no regulatory response exemption provision. However, DTSC did not delete the provision for the regulatory response exemption in the proposed regulations (January 2013) to make it self-implementing, so no conforming changes are needed in section 69501.5(a)(8).

§ 69501.5(b) Website Postings without Electronic Mailing Notices

Comments: 26-7, 114-8, 118-9, 118-10

Comments Summary:

The implementation process should be transparent, and offer more information and opportunities for the public to provide comments before key decisions are made. Below are some specific suggestions to add to the list of documents that DTSC will make post on the DTSC website:

- Add a posting for the public comments that are referred to in section 69505.1(h);
- Add a posting to for all notices, public comments, and correspondence with stakeholders to be published;

- Add a posting for a conceptual model if a simple conceptual model is added under section 69505.3;
- Add a posting for public comments on Alternate Process AA Work Plans if a requirement for public comments on Alternate Process AA Work Plans is added under section 69505.3;
- Add a posting for any input from state and local government agencies and the public prior to approving stewardship plans if a requirement for this provision is added under section 69506.8(a)(2)(A); and
- Add a posting for proposed stewardship plans prepared under section 69506.8(a)(2)(A), and the proposed end-of-life management requirements, in addition to the final stewardship plans and the final end-of-life management requirements.

Response:

The commenters erroneously interpret section 69505.1(h) which states, "A responsible entity conducting an AA under this article shall consider all relevant information made available on the Department's website, including any relevant public comments, and any additional information or technical assistance the Department may provide regarding AA. The responsible entity shall summarize these efforts in the Alternatives Analysis Report." This provision in Article 5 simply instructs the preparer of an AA to go to DTSC's website and use the publicly available information that is posted. Accordingly, DTSC will not be revising the language to add the public comments that are referred to in section 69505.1(h) (now 69505.1(d) (January 2013)) which are already listed to be posted.

The second recommendation to add a posting for all notices, public comments, and correspondence with stakeholders is already included in this provision. Section 69501.5 currently requires posting all written comments for modifications to the Candidate Chemicals list (formerly named the Chemicals of Concern list), proposed Priority Products lists, and regulatory responses. DTSC has revised the regulations and has added a public comment period for the Final AA Report and the Abridged AA Report; so, DTSC has revised the language in section 69501.5(b) to require DTSC to post any comments received under this new provision. DTSC did not revise the regulations to include "correspondence" because most of the important communications between DTSC and responsible entities are already included in section 69501.5. The notices that DTSC sends to responsible entities, the determinations of completion, determinations of deficiency, determinations of disapproval, the requests for information, copies of disputes, etc. are all correspondence in this sense. DTSC did not make any additional changes in response to these comments.

Article 5 has not been revised to include a conceptual model in section 69505.3, public comments period for the Alternate Process AA Work Plan, nor any public input prior to approving the plans for the product stewardship plans or for the end-of-life management information. There is no draft Alternate Process AA Work Plan, draft product stewardship plan, or draft end-of-life management to post for public input. Revisions have not been made to Article 5 in response to these recommendations; therefore, no revisions are needed in Article 1 to make conforming changes. DTSC has not made any revisions in response to these recommendations.

[NOTE: DTSC has revised the language in the proposed regulations (April 2013) to require a public comment period for the Final AA Report and the Abridged AA Report. The regulatory language has been revised to include the public comments.]

§ 69501.5(b)(3) Website Postings: Priority Product Information

Comment: 5-150

Comment Summary:

Section 69501.5(b)(3) states, "As the following information becomes available, the Department shall add it to the Priority Products list for each product that is a Priority Product, and maintain and update this information for as long as the Priority Product continues to be placed into the stream of commerce in California."

The recommendation is to replace the term "product" with "Priority Product."

Response:

The recommendation to change product does not specify which of the five uses of the term "product" in section 69501.5(b)(3) needs to be amended. DTSC believes that the introduction to this section makes it very clear that this provision applies to only to Priority Products and that this change to subsection 69501.5(b)(3) is unnecessary. Changing product to "Priority Product" does not provide additional clarity. No changes were made in response to this comment.

§ 69501.5(b)(3)(D) Website Postings: Person Identified to Fulfill AA Requirements

Comments: 57-27, 68-20

Comments Summary:

Section 69501.5(b)(3) sets out a long list of information to be made available on DTSC's website, much of which will require almost constant updating. As this will be very resource-intensive, and bears a high risk of displaying inaccurate information, DTSC might wish to consider prioritization of a more selected list of information for publication. How will DTSC ensure that the publication of the names of individual persons is compatible with rules on the protection of personal data? The commenter urges DTSC to remove this provision.

Response:

These comments erroneously interpret the term “person” to mean an individual. “Person” is defined in these regulations as having the same meaning as Health and Safety Code section 25118. In that statute, a “person” is defined as “an individual, trust, firm, joint stock company, business concern, partnership, limited liability company, association, and corporation, including, but not limited to, a government corporation. ‘Person’ also includes any city, county, district, commission, the state or any department, agency, or political subdivision thereof, any interstate body, and the federal government or any department or agency thereof to the extent permitted by law.” The provision is requiring the name of the entity that will be preparing the AA.

DTSC appreciates the concern regarding the utilization of DTSC resource to maintain all this information on the website but is confident that it has the expertise and resources to administer the proposed regulations in an effective manner. DTSC has crafted the proposed regulations in a manner that maximizes the use of existing information. DTSC is not making any changes to the language in response to this comment.

§ 69501.5(b)(3)(F)2.Website Postings: Notifications, Reports and Other Documents Submitted to DTSC

Comments: 5-151, 124-20

Comments Summary:

Delete the AA Threshold Exemption Notification—Notification of the fact that a company has provided a threshold exemption would require disclosure of potentially confidential information, with no public benefit.

Response:

DTSC respectfully disagrees with this comment. There is no reason to believe that the trade secret protections elsewhere in the regulations would fail to protect any trade

secret information submitted as part of an AA Threshold Notification. DTSC and the public need to have access to information on all Priority Products and information on any Priority Product that is conditionally exempt under the AA Threshold provision. Otherwise, DTSC has no means of auditing to ensure compliance with the regulations.

[Note: the AA Threshold provision has been significantly revised. The AA Threshold is defined as the Practical Quantitation Limit for a Chemical of Concern that is present in a Priority Product solely as a contaminant. DTSC may specify in the proposed or final Priority Products list an AA Threshold concentration for any Chemical of Concern that is an intentionally added ingredient or may specify an AA Threshold concentration greater than the applicable PQL for any Chemical of Concern that is a contaminant. DTSC is making no change in response to these comments.]

§ 69501.5(b)(3)(F)4.Website Postings: Chemical of Concern Removal Notifications

Comment: 5-151

Comment Summary:

Delete the Chemical of Concern Removal Notification requirement.

Response:

This comment was submitted to suggest conforming changes to text if recommendations were accepted to delete related provisions. All these notifications are still included in the proposed regulations, so there is no need to delete these documents from the list that will be posted on DTSC's website. No changes we made in response to this comment.

§ 69501.5(b)(4) through (6), and (8) Website Postings: Various Documents

Comments: 11-33

Comment Summary:

DTSC proposes to require itself to post non-critical information on its websites. These provisions should be eliminated from the regulations as requirements, but DTSC might optionally post them electronically as resources are available for such lower priority tasks. The following paragraphs under section 69501.5(b) should be eliminated: (4), (5), (6), and (8).

Response:

DTSC respectfully disagrees that the AA guidance documents, the sample AAs, all the AA Reports, and the product stewardship plans are non-critical information. DTSC also notes that if it chose to post each of these items on a routine basis without having specified in regulation that it would do it would be open to an accusation that it was engaging in an "underground regulation." DTSC did not revise the regulations in response to these comments.

§ 69501.5(b)(6) Website Postings: AA Reports and Alternative Process Work Plans

Comments: 3-6, 29-10

Comments Summary:

One comment strongly supports the public availability of all Preliminary and Final AA Reports and Abridged AA Reports. Transparency will be critical to the success of the program. Providing AA Reports to the public will enhance the quality of AA submissions and further the development and dissemination of safer alternatives. DTSC should provide incentives for releasing AA with few to no redactions.

Conversely, another comment is concerned about the fact that all Preliminary AA Reports and Final AA Reports that will be posted on DTSC's website. Such language has the potential of publicizing a manufacturer's future production plans, thereby impeding innovation and competition, and could expose industry participants to liability under applicable federal antitrust laws. The proposed regulations should be amended to clarify that any information designated by a manufacturer to be a trade secret shall not be included on DTSC's website.

Response:

DTSC greatly appreciates the support for this provision.

DTSC will not be revising the language in section 69501.5(b)(6). Section 69501.5 is only meant to be a listing of all the documents that will be made available on DTSC's website. It does not undermine the protection for trade secret information set out in Article 10 of the July 2012 version of the regulations (Article 9 in the January 2013 and April 2013 versions). The implementation of this provision is still subject to the trade secret provisions elsewhere in the regulations. Therefore, there is no need to repeat those protections in this section. DTSC is not making any changes to the regulations in response to these comments.

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ARTICLE 2. PROCESS FOR IDENTIFYING CANDIDATE CHEMICALS

Support

Comments: 11-34, 11-35, 27-1, 29-11, 30-2, 36-3, 36-6, 36-7, 36-11, 36-14, 39-21, 57-30, 68-21, 76-41, 91-1, 106-1, 107-36, 107-39, 128-2, PH6-1, PH6-2, PH17-1, PH32-1

Comments Summary:

The above commenters expressed support for the provisions contained in Article 2. The provisions in Article 2 clarify the directives in Health and Safety Code sections 25252 and 25253 and the overarching legislative intent of the "Green Chemistry" statutes embodied in Health and Safety Code section 25255(a). Article 2 specifies the process to identify chemicals as Candidate Chemicals (previously known as Chemicals of Concern (COCs)). The process described in section 69502.2(a) of the proposed regulations for identifying chemicals, establishes a robust initial list of Candidate Chemicals compiled from chemicals listed on the authoritative organizations' lists identified in section 69502.2(a). Section 69502.2(b) specifies the process for additions to the list of Candidate Chemicals and section 69502.3 specifies the process for listing Candidate Chemicals.

The initial list of Candidate Chemicals (previously known as COCs), established pursuant to section 69502.2(a), will serve as a market signal for consumers to be aware of what chemicals are in the consumer products they purchase and to manufacturers to take voluntary actions before they are compelled by the regulations. Regulatory requirements are initiated only when a product-chemical combination containing a Candidate Chemical is prioritized and listed as a Priority Product. Once a Priority Product is listed, a Candidate Chemical is designated as a Chemical of Concern for that product. Priority Product listing requires rulemaking pursuant to the Administrative Procedure Act (APA) commencing with Government Code section 11340, as specified in Article 3 of these regulations.

Following is a summary of the provisions that were the subject of the commenters' remarks in expressing support for inclusion of specific provisions in Article 2:

1. Section 69502.2(a) Initial list of Candidate Chemicals:
    - Support identification of hazard traits and use of chemical lists by authoritative organizations to rapidly identify the scope of chemicals under the proposed regulations;
    - Occupational exposures, sensitive populations, neurotoxicity, endocrine disruption, and developmental effects are reflected in the regulations;

- Lists from authoritative organizations that use deliberative scientific processes with opportunity for stakeholder input; to identify initial list of Candidate Chemicals is appropriate and useful as a starting point;
- The compilation of the chemicals listed on the authoritative organizations' lists identified in section 69502.2(a); represents a comprehensive list of all the important lists of known hazard traits from authoritative organizations and all of the chemicals listed are known to be potentially harmful;
- Large list sends a reasonable signal to the market that some chemicals can and should be recognized as toxic and should be avoided wherever possible;
- Commenter supports the wisdom of starting with a manageable number of chemicals which DTSC will identify based on chemical hazard information together with indicators of exposure; and
- Ranking chemicals would be a misguided effort to identify and prioritize “worst” chemicals and is inherently impossible because of pervasive data gaps and difficult judgments that would be required to compare and rank different kinds of harm.

2. Section 69502.2(a)(1)(C) Category 1 Endocrine Disruptors - support the initial list, including the Category 1 endocrine disruptors list and also provided the correct reference for section 69502.2(a)(1)(C).
3. Section 69502.2(a)(2)(F) Priority Chemicals List of the California Environmental Contaminant Biomonitoring Program—commenter supports the addition of California Biomonitoring Program to the initial list.
4. Section 69502.2(b) Additions to the Candidate Chemicals list:
   - Factors listed for adding chemicals to the list of Candidate Chemicals based on reliable information are good; and
   - It is important to provide a mechanism for additions to the list of Candidate Chemicals (previously known as COCs) for chemicals that do not appear on existing authoritative body lists.
5. Section 69502.2(b)(1) Adverse impacts – the commenter appreciates inclusion of data indicating presence in the indoor environment as a factor in determining Adverse air quality impacts in identification of Candidate Chemical.
6. Section 69502.3 Informational List – commenters support compilation of a robust list of chemicals within 30 days of the effective date of these regulations that relies on the work of authoritative bodies.
7. Section 69502.3(c) Public Notice of Proposed List Revisions:
   - Support was expressed for the opportunity for formal public input on proposed revisions to the list of Candidate Chemicals (previously known as COCs)

Response:

DTSC acknowledges the support offered by these commenters. Please note that the term “Chemical of Concern” has been redefined and the old definition of Chemical of Concern applies to a new term “Candidate Chemicals.” The revised proposed regulations (January 2013 and April 2013) have defined the “Candidate Chemicals” and “Chemical of Concern” as follows:

“Chemical of Concern” (new definition as of January 2013) is defined in section 69501.1(a)(21) as: “a Candidate Chemical that has been designated as a Chemical of Concern under section 69503.5(b)(2)(B).”

“Candidate Chemical” (previously known as COC) is defined in amended section 69501.1(a)(19) as: “a chemical that is a candidate for designation as a Chemical of Concern, and that is identified in section 69502.2.”

DTSC sought to identify chemicals with hazard traits that may yield partnerships with other California, state and national chemical programs to leverage resources and achieve results benefiting common goals–preventing exposures to harmful chemicals in consumer products. Starting with a manageable number of chemicals identified as Candidate Chemicals (previously known as COCs), with hazard traits and indicators of exposure based on deliberative work conducted by authoritative organizations; and compiled from lists of chemicals listed on one of the authoritative organizations' lists identified in section 69502.2(a), will allow DTSC to learn while making progress in the initial years of the program, and concurrently send an important signal to the marketplace.

The Category 1 list of chemicals identified as endocrine disruptors, in section 69502.2(a)(1)(C), are the highest priority within the prioritization scheme chosen by the European Commission (EC) and where there is clear evidence for endocrine disrupting effects in an intact organism.

Priority Chemicals that are identified under the California Environmental Contaminant Biomonitoring Program in section 69502.2(a)(2)(F) have been identified as Candidate Chemicals because there is a concern that humans are being exposed to harmful chemicals and have the potential of causing a health risk or toxicological endpoint.

It is important to include indoor air as a factor, as adverse air quality impacts resulting from indoor air emissions affect the air quality of homes, offices, transport vehicles, and public buildings. Therefore, DTSC agrees with the commenter that provisions for adding chemicals to the list of Candidate Chemicals (previously known as COCs) is an

important avenue for new chemicals to be identified as soon as possible, and it distinguishes the Safer Consumer Products program as forward-looking program.

DTSC will post an informational list of Candidate Chemicals on its website pursuant to section 69502.3 of the proposed regulations within thirty (30) days from the effective date of these regulations. The proposed regulations incorporated extensive public input in the regulatory process for transparency, and DTSC will continue to work with stakeholders and interested parties during the implementation of these regulations. DTSC is not making any changes to the regulations in response to these comments.

Oppose

Comment: 101-21

Comment Summary:

One commenter expressed concern with section 69502.2(a), urging DTSC to eliminate the compilation of chemicals listed on the authoritative organizations' lists identified in section 69502.2(a) for a more scientifically valid and defensible approach to chemical identification.

Response:

As mentioned above, starting with a manageable number of chemicals identified as Candidate Chemicals (previously known as COCs), with hazard traits and indicators of exposure based on deliberative work done by authoritative organizations; and compiled from lists of chemicals listed on one of the authoritative organizations' lists identified in section 69502.2(a), will allow DTSC to learn while making progress in the initial years of the program, and concurrently send an important signal to the marketplace. Having this initial list of Candidate chemicals (previously known as COCs) within 30 days of the effective date of these regulations allows DTSC to hit the ground running with this program and conserve scarce resources as it begins implementation of this program. Another advantage of this approach is that compilation of the chemicals listed on authoritative organizations' lists identified in section 69502.2(a), allows DTSC to leverage the work of other authoritative organizations, as was mandated in the authorizing legislation. (See Health and Safety Code section 25252(b)(2).)
Please see Response to Comment 101-21 under Chemical Prioritization, Hazard Traits, Weight of Evidence, and Risk Assessment. DTSC is not making any changes to the regulations in response to this comment.

Section Specific Comments

§ 69502 Data Call-In Authority

Comments: 36-53, 36-54, 36-56, 36-59, 39-23

Comments Summary:

These commenters recommend that DTSC should use the authority to request further information so that chemicals for which there is little or no toxicity information can be assessed for consideration as Candidate Chemicals (previously known as COCs) under AB 1879. Commenters' remarks include:

- DTSC should use its call-in authority under AB 1879 to require the generation of new health and environmental data in order to accurately identify Candidate Chemicals (previously known as COCs), safer alternatives, and to impose regulatory responses;
- DTSC should exercise DTSC's broad call-in authority to request new information instead of relying on the "the availability of reliable information to substantiate the potential adverse impacts and exposures" as early as possible in the program's implementation; and
- This will ensure that the burden of proof to demonstrate a chemical's hazards is on the companies making the chemical or product containing the chemical to demonstrate it will not cause harm.

Response:

DTSC respectfully declines to make any changes to the proposed regulations in response to these comments.

DTSC itself does not have the necessary information or personnel resources to administer this program without gathering information from various sources. Therefore, DTSC will need to engage in information gathering activities to support and inform the product-chemical prioritization processes, as explained in the Initial Statement of Reasons (ISOR).

There are provisions in the proposed regulations for DTSC to gather information as is suggested in these comments. These regulations include specific and broadly framed information gathering tools that allow DTSC to request information prior to and in support of the prioritization process of product-chemical combinations in Article 3. While DTSC lacks the authority to compel the generation or submittal of data at that stage of regulations implementation, it has created a process for requesting information

and posting information on its website about which parties provided information or not. (See detailed discussion under section 69501.3 Information Submission and Retention Requirements in Article 1 of this Response to Comments document.) At later stages of implementation, DTSC may require gathering of existing data and even the generation of new data by businesses subject to these regulations (see Articles 5 and 6).

The proposed regulations set out a sequential information gathering process that uses existing information, including databases for chemicals, to gather information on a chemical such as environmental fate of a chemical or use of a chemical, in evaluating a product-chemical combination for listing as Priority Product. If additional information is needed and public sources of information do not provide the data/information required, DTSC may conduct a data/information call-in on responsible entities. These information gathering provisions are also applicable in the early stages of implementation—even before a chemical has been identified as a Candidate Chemical (previously known as COC). The groundbreaking nature of these public health and environmental protection regulations will require a flexible and adaptive process for prioritizing diverse patterns of product-chemical combinations.

Although responsible entities are not required to fill data gaps up-front as part of the prioritization of chemicals and products under Article 3, additional scientific or technical work may be productive and could be a part of regulatory responses (section 69506.9), in advancing green chemistry requirements, among other situations where additional information may be required.

§ 69502.1 Applicability

Hazard Traits

Comments: 1-4, 3-3, 9-71, 9-74, 11-35, 11-36, 24-1, 38-7, 41-5, 49-2, 59-11, 61-7, 65-2, 73-3, 92-6, 94-6, 101-21, 105-7, 125-7, PH18-1

Comments Summary:

These commenters claim difficulty in tracking the expansive list of chemicals and request clarity on the list selection and chemical characterization criteria. Other commenters express concern that the list of hazard traits identified by OEHHA (Chapter 54) is extensive and some of the lists are not good indicators of hazard. A few commenters support the process but recommend additional screening criteria to make the process more credible and transparent. Another recommendation is to focus only on greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMRs) and substances known to be persistent, bioaccumulative

and toxic (PBTs) in the environment, as designated by United States Environmental Protection Agency (US EPA) and others.

Response:

DTSC does not totally understand the comment that "some of the lists are not good indicators of hazard" but will attempt to respond to the comment to the extent that it is able to do so.

DTSC has identified the hazard traits for each of the lists from authoritative organizations that are specified in section 69502.2(a). These lists are from authoritative organizations charged with protecting public health and the environment and have identified chemicals with regulatory or risk management consequences. DTSC sought to use the evaluative work already done by these authoritative organizations in identifying chemicals with hazard traits for these regulations rather "reinventing the wheel."

As explained in the ISOR, a type of chemical "prioritization" occurred in identifying the hazard traits for the initial list of Candidate Chemicals (previously known as COCs list). Chapter 54 identifies many hazard traits, but only a subset were identified for this list of Candidate Chemicals established in the regulations. The criteria DTSC considered to identify the sources of chemicals with hazard traits are based on stakeholder input, and a reasonable and practical approach to identify chemical lists. These criteria are listed below (in no particular order):

- Chemical list was supported, sponsored, and/or developed by an authoritative organization, such as, a state, federal, or international agency, to protect public health or the environment;
- Chemical list was developed to prevent or limit exposures and/or adverse impacts to public health and the environment, *i.e.*, same purpose as these regulations;
- Chemicals on the list meet "strong evidence" criteria for toxicological hazard traits or the "evidence" criteria for the exposure potential hazard traits, as specified in Chapter 54 to ensure that each chemical exhibits the highest level of evidence for its hazard trait;
- Chemical list is reviewed and updated periodically to ensure that the chemical list not a one-time effort or static; and
- Chemical list is consistent with chemical lists and hazard traits identified by the States of Washington, Maine, and Minnesota with similar chemical programs for harmonization.

Other factors influencing the identification of chemical hazard traits or chemical lists necessary for effective and meaningful program implementation by DTSC are as follows:

- DTSC desired a "manageable" number of Candidate Chemicals (previously known as COCs) on the initial list that would provide a robust list of chemicals without having to add chemicals in the early implementation years;
- Availability of state resources to implement the Safer Consumer Products program was considered in determining a "manageable" number of chemicals;
- Chemical list adds value to the initial Candidate Chemicals (previously known as COCs List); that is, the given chemical list does not excessively duplicate chemicals that are already named by other chemical lists; and
- Identify chemical hazard traits that may yield partnerships with other California, state and national chemical programs to leverage resources and achieve results benefiting common goals—preventing exposures to harmful chemicals in consumer products.

Using all of these criteria for identification of chemical lists and chemical hazard traits, DTSC essentially identified and "prioritized" the following chemical hazard traits for the initial list of Candidate Chemicals (previously known COCs):

- Carcinogenicity
- Developmental toxicity
- Reproductive toxicity
- Genotoxicity (mutagenicity)
- Endocrine toxicity
- Neurotoxicity
- Respiratory toxicity
- Bioaccumulation
- Environmental persistence

For all of the reasons stated above, DTSC is making no changes to the regulations in response to these comments.

Comments: 36-7, 39-20

These commenters suggest that the proposed COCs list should ensure that all hazard traits identified by OEHHA are captured, including neurodevelopmental hazard traits.

Response:

DTSC acknowledges the suggestion but respectfully declines to make any changes to

the proposed regulations.

Neurodevelopmental toxicants are included when identified by the authoritative organization(s) on the lists specified in section 69502.2(a). DTSC has endeavored to start this program with hazard traits, chemicals, and chemical lists that were generally in agreement with the recommendations of the Green Ribbon Science Panel (GRSP) and stakeholders to allow all parties to learn, gain experience, build a knowledge base, and make informed decisions before full scale implementation of these regulations.

Furthermore, DTSC sought to have a "manageable" number of chemicals, taking into consideration whether the chemical list adds value to the initial list of Candidate Chemicals (previously known as COCs). DTSC considered whether or not each given chemicals list excessively duplicates chemicals that are already named by other chemical lists. DTSC also considered the availability of state resources to implement the Safer Consumer Products program in harmonization with other state programs.

The Candidate Chemicals list (previously known as the COCs list) in the proposed regulations has been essentially prioritized and captures nine (9) of the hazard traits identified by OEHHA in its regulations (Chapter 54). DTSC may, in the out years of implementation, add additional chemicals lists to the list of Candidate Chemicals set out in section 69502.2. DTSC also notes that stakeholders may petition DTSC to add any other chemical or chemicals lists to the regulations pursuant to Article 4 of the proposed regulations. (See Article 4 of this Response to Comments documents for a detailed discussion of the petition process.) For all of these reasons, DTSC declines to make any changes to the proposed regulations.

Comment: 49-12

Comment Summary:

This commenter recommends that DTSC include as chemicals on the list of Candidate Chemicals (previously known as COCs) only those chemicals that have a documented link to a hazard trait on the basis of "strong evidence," in accordance with the OEHHA criteria. One suggestion was to classify the reasons for chemicals being on the Candidate Chemicals list (previously known as COCs).

Response:

The proposed regulations identify the initial list of Candidate Chemicals (previously known as COCs) to include chemicals that exhibit a hazard trait or an environmental or toxicological endpoint and if the chemicals are listed on one or more of the enumerated

authoritative organizations' lists in section 69502.2(a). The lists enumerated in section 69502.2(a) were selected based on the criteria that all of the lists are not only developed by authoritative organizations, but they all also meet the "strong evidence" criteria for toxicological hazard traits or the "evidence" criteria for the exposure potential hazard traits, as specified in Chapter 54 for the hazard traits. In other words, the chemical exhibits the highest level of evidence for the hazard trait for which it is listed on a particular list.

The informational list of Candidate Chemicals to be published by DTSC within thirty (30) days from the effective date of these regulations will indicate the hazard traits for each chemical, as identified by the authoritative organization in developing the source list.

No changes to the proposed regulations are necessary in response to this comment.

Comment: 99-1

Comment Summary:

Certain environmental endpoints used to screen, assess, or prioritize organic compounds, particularly bioaccumulation and persistence—are not appropriate for assessing the hazard of metals. The comment suggested that DTSC highlight specifically in the final regulations the fact that metal substances will require specialized review and reference the US EPA's Framework for Metals Risk Assessment as the guideline that DTSC will use in its evaluation of such substances.

Response:

Comment noted as to the portion of the comment pointing out that assessing the hazard of metals may require a different approach from assessing the hazard of other chemicals. DTSC encourages this commenter to provide this type of specific input with details during the listing process for adding chemicals to the Candidate Chemicals list and for listing of Priority Products. DTSC is not making any changes to the regulations in response to these comments because DTSC does not need to change the regulations text to get at the concern mentioned. Rather, DTSC may address this as an implementation issue. Please also refer to the Response to Comment 99-1 under Risk Assessment and Chemical Prioritization.

Chemicals of Concern

Comments: 1-3, 1-4, 3-1, 3-3, 5-18, 5-68, 5-106, 7-2, 7-5, 9-5, 11-36, 11-38, 12-4, 17-9, 21-5, 24-1, 30-2, 34-11, 36-4, 36-30, 38-6, 38-7, 39-18, 41-5, 41-6, 49-1, 49-2, 49-3,

49-5, 49-6, 49-11, 49-15, 49-16, 64-2, 64-3, 66-18, 66-19, 69-21, 74-27, 82-4, 84-1, 86-17, 101-2, 101-20, 101-21, 103-4, 107-34, 107-35, 119-2, 120-1, 132-6, 133-2, 139-6, 139-7, PH12-9, PH17-2

Comments Summary:

These commenters refer to the term "Chemicals of Concern" used in the proposed regulations for chemicals subject to the Safer Consumer Products program. The views expressed range from retaining the term, to using the term for a discrete subset of chemicals after further prioritization. The specific comments include the following:

- The language in AB 1879 explicitly requires in Health and Safety Code section 25252(a) states that DTSC identify Chemicals of Concern. The statute does not mention a category called "chemicals under consideration" and, therefore, the comment suggests that retaining the term "Chemicals of Concern" in the proposed regulations is not appropriate;
- There may be a large number of chemicals that will not come under consideration by the DTSC process for a number of years; yet, in the interim, formulated products containing those chemicals may be implicated as hazardous to consumers simply because of a poorly chosen list title;
- DTSC should utilize a subsequent prioritization to identify a discrete subset of the highest priority chemicals in that group of 1,200 plus chemicals, which should rightly be identified as "Chemicals of Concern"; and
- DTSC should identify 1,200 chemicals as "Chemicals of Interest," then prioritize first to COCs and then further prioritize a COC in a product as a "Priority Chemical."

Response:

DTSC agrees with the statement that the language in AB 1879 explicitly requires DTSC to identify Chemicals of Concern. Health and Safety Code section 25252(a) states that DTSC is to adopt regulations "to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a Chemical of Concern…"

DTSC has met the intent of the underlying statute in the proposed regulations (July 2012), "to identify Chemicals of Concern." The regulatory requirements are initiated only when a COC (new definition as of the January 2013 version) is paired with a product for prioritization and is listed as a Priority Product. Thus, DTSC has amended the regulations to clearly effectuate the legislative directive in the authorizing legislation to develop a process that identifies and prioritizes Chemicals of Concern. Under the amended version of the proposed regulations (January 2013 and April 2013 versions),

first chemicals are identified as Candidate Chemicals. Then, subsets of these chemicals are further prioritized by evaluating product-chemical combinations and thus prioritized chemicals are identified as Chemicals of Concern. This is clearly consistent with the directives in Health and Safety Code section 25252(a), discussed above.

In response to these comments, the proposed regulations retain the term "Chemicals of Concern," but the definition has been revised and the new definitions are as follows:

i) Candidate Chemical (previously known as COC) means "a chemical that is a candidate for designation as a Chemical of Concern, and that is identified as a Candidate Chemical under section 69502.2."
ii) Chemical of Concern (new definition) means a Candidate Chemical that that has been designated as a Chemical of Concern under section 69503.5(b)(2)(B)."

Sections 69501.1(a)(19) and sections 69501.1(a)(21) of the proposed regulations have been revised to include the definitions discussed above.

Authoritative Organizations

Comments: 9-71, 9-72, 82-2

Comments Summary:

These comments refer to the compilation of the chemicals listed on the authoritative organizations' lists identified in section 69502.2(a) and state that these lists should be developed by authoritative bodies and suggest inclusion of a definition for "authoritative bodies" as follows:
"Authoritative bodies" include government agencies and formal scientific organizations, that:

- "Authoritative bodies" include government agencies and formal scientific organizations, that:
    - Characterize chemicals in an open, deliberative, and transparent scientific process;
    - Are widely perceived to be objective, scientifically based, and do not engage in advocacy;
    - Conduct chemical characterizations based on a weight-of-the-evidence approach; and
    - Publish their characterizations of chemicals through governmental regulations, periodic reports, monographs, or similar publications.

Response:

DTSC agrees with the commenters that the lists in section 69502.2(a) should be developed by authoritative organizations, and points that the aforementioned lists have been developed by "authoritative organizations," as defined in Chapter 54.

Section 69502.2(a) of the proposed regulations, specifies the criteria for the initial list of Candidate Chemicals (previously known as COCs). A chemical is a Candidate Chemical if it exhibits a hazard trait or an environmental or toxicological endpoint and is listed on one or more of the enumerated authoritative organization's lists in sections 69502.2(a)(1) or 69502.2(a)(2). Thus, section 69502.2(a) establishes a robust list of chemicals based on work already conducted by authoritative organizations.

Essentially, the definition of "authoritative organizations" in Chapter 54, meets the criteria desired by the commenters as "authoritative bodies." The term "authoritative organizations" as defined in Chapter 54 (section 69401.2(b)) includes a non-exhaustive list of governmental and non-governmental institutions and California agencies that provide the scientific basis for formal public health protections by government entities. The legal and administrative processes applied by these agencies help ensure the validity of scientific documents supporting California public health and environmental regulations and guidance.

DTSC notes that no specific reasons were given in the comments for the objection to the current definition of "authoritative organization." Based on the above analysis of the term "authoritative organization" in the companion regulations that has been used by DTSC in shaping the Candidate Chemicals list, DTSC does not see the need to use the term "authoritative body" in these regulations. Therefore, DTSC is maintaining its current definition of "authoritative organization." Please also refer to the Response to Comment 9-71 under Hazard Traits above.

Chemical Prioritization

Comments: 1-3, 1-4, 3-1, 3-3, 5-10, 5-68, 5-71, 5-106, 7-2, 7-3, 9-5, 11-37, 12-4, 15-2, 15-3, 21-5, 24-1, 34-11, 38-5, 38-6, 38-8, 41-4, 41-6, 47-10, 47-11, 47-12, 49-1, 49-2, 49-3, 49-4, 49-5, 49-11, 49-15, 49-16, 57-28, 57-29, 59-9, 59-10, 59-11, 59-13, 61-5, 61-6, 64-1, 64-2, 64-3, 64-4, 64-5, 65-2, 66-18, 66-19, 69-21, 73-1, 73-2, 73-4 73-5, 74-26, 74-27, 74-28, 74-29, 74-30, 82-1, 82-4, 84-1, 86-17, 92-5, 94-5, 99-1, 101-2, 101-19, 101-20, 101-21, 103-1, 103-2, 103-3, 103-4, 105-6, 107-6, 107-32, 119-2, 120-1, 124-21, 125-6, 129-8, 139-6, PH12-9, PH18-1, PH34-7, PH36-1

Comments Summary:

These comments are in reference to the compilation of the chemicals listed on the authoritative organizations' lists identified in section 69502.2(a)for the initial list of chemicals and state that the list of approximately 1,200 COCs is large and should be further refined if the regulations are to maintain consistency with the statute. The commenters expressed concerns regarding the following:

- This expansive list of chemicals titled “Chemicals of Concern” will implicate products containing those chemicals as hazardous to consumers and will cause undue alarm;
- The prioritization approach is seriously flawed and lacks scientific prioritization principles and process for prioritizing chemicals;
- This approach creates an unpredictable framework and will increase uncertainty for businesses;
- Prioritization should be based on real exposure and hazard; deficiencies include conditions of use of a chemical and level of “reasonable and foreseeable exposures” justifying prioritization; and
- Some of these commenters suggest a subsequent prioritization as follows:
    - List of 300 or less chemicals prioritized on science-based prioritization scheme;
    - Identify a discrete subset of highest priority chemicals identified as Chemicals of Concern; and
    - Document specific rationale and types of uses, and greatest concern.

Response:

The proposed regulations have been revised in response to the comments about the large list of chemicals identified as “Chemicals of Concern” and implicating products containing chemicals on the list. The proposed regulations have redefined “COC” and the old definition of “COC” now applies to the new term “Candidate Chemicals.” Please refer to the Response to Comment 1-3 above under Specific Comments for a detailed discussion of the meaning and use of these terms.

DTSC respectfully disagrees with the comment that the proposed regulations lack scientific prioritization principles and provisions. The commenters did not provide specific suggestions on scientific prioritization. Without specifics, DTSC can only respond in general terms. DTSC has met the intent of the underlying statute in the proposed regulations (July 2012), to identify Chemicals of Concern, and regulatory requirements are initiated only when the COC is paired with a product for prioritization and listed as a Priority Product. The structure of the regulations ensures that chemicals are first identified, and to a limited extent, prioritized by being named as Candidate

Chemicals. These Candidate Chemicals are then further prioritized as product-chemical combinations are listed as Priority Products, and the Candidate Chemicals are then designated as Chemicals of Concern.

DTSC has drafted the regulations to take into account the statutory mandates and limitations by using narrative criteria that incorporates the newest and sound scientific principles, with checks and balance processes for transparency, as well as the amount and type of resources available. The proposed regulations are comprehensive and lay out an appropriate framework for the Safer Consumer Products program in California.

The proposed regulations employ flexible, narrative, and objective standards. In fulfilling requirements and responsibilities under these regulations, DTSC, manufacturers, other responsible entities, and those acting on their behalf will, in essence, conduct analyses and make decisions and determinations based on the best scientific principles and practices. Specific integration of the prioritization factors into a generic static prioritization system for all chemicals (*and products*) in the marketplace would only reflect decisions based on current science and understanding. This would create the possibility of the process remaining ignorant to new science and understanding for future decisions.

The process depicted in section 69502.2(a) of the proposed regulations for identifying chemicals, includes chemicals that exhibit hazard trait(s) or an environmental or toxicological endpoint(s) and that are listed on one or more of the enumerated authoritative organizations' lists in section 69502.2(a). Thus, chemicals with hazard traits and/or environmental or toxicological endpoints have been identified and essentially prioritized by listing the chemicals list(s) in sections 69502.2(a)(1) and (2). This process establishes a robust list of approximately 1,200 chemicals based on work already conducted by authoritative organizations and identifies the initial list of Candidate Chemicals that are subject to the later implementation stages of the Safer Consumer Products program.

The ranking methodology desired by the commenter is not conducive to jumpstarting the program. Having a robust list of Candidate Chemicals (previously known as COCs), as of the effective date of these regulations is necessary to enable DTSC to immediately focus on the identification and prioritization of product-chemical combinations for listing as Priority Products for which responsible entities will be required to perform Alternatives Analyses and search for safer products. This robust list will also enable consumers to be more informed about the Candidate Chemicals that may be present in the products they purchase; and manufacturers, importers, assemblers, and retailers (also referred to as responsible entities) to take early

voluntary actions regarding the Candidate Chemicals in their quest for safer consumer products. The approach suggested by the commenter would unnecessarily bog DTSC down, requiring the expenditure of precious staff resources and time to conduct a ranking. This is a potential tremendous time sink that would lead to no better scientific approaches or results with regard to this program.

In response to the comment about prioritizing for the "highest priority concern," DTSC notes that the Candidate Chemicals list (previously known as COCs List) in the proposed regulations has been essentially prioritized and captures nine (9) of the hazard traits that meet the strong evidence criteria for toxicological hazard traits, as specified in Chapter 54. DTSC is of the opinion that any further ranking or ordering of chemicals will result in a tremendous expenditure of staff resources and take a great deal of time for no real pay-off. DTSC could be dragged into extended arguments about the relative harm of two chemicals to no useful end. Instead, the approach DTSC is taking frees it from such counterproductive arguments. Instead, DTSC has the ability to regulate chemicals based on the information available in an effective and efficient fashion.

Additionally, the proposed regulations provide a number of opportunities for the regulated community and other stakeholders to provide information on chemicals and products to DTSC throughout implementation of the regulations. There is the opportunity to petition DTSC to remove a chemical or product from being considered for listing as a Priority Product altogether, among other public comment opportunities. Thus, in implementing the proposed regulations, DTSC and interested parties will, in a sense, together determine the priority of the chemicals to be addressed, based on reliable information for the factors to be considered by DTSC.

Proposed section 69503.3 requires DTSC to issue a Priority Product Work Plan and, prior to January 1, 2016, DTSC may select only those chemicals that meet both of the following criteria as the basis for a product being identified as a Priority Product:

i) Chemical has a hazard trait or toxicological or environmental endpoint listed on one or more of the authoritative organization's chemical lists in section 69502.2(a)(1); and
ii) Chemical appears on an exposure or monitoring-related chemical list specified in section 69502.2(a)(2).

This shortened list of a discrete set of chemicals meets the demands for certainty during early stages of implementation and sends better signals to the marketplace as to which chemicals may be identified as COCs (new definition as of January 2013 draft).

Consumers will be more informed about the COCs (new definition as of January 2013 draft) that may be present in the products they purchase, which is key to creating the market for safer alternatives, and is not intended to alarm consumers. In addition, this limiting of the chemicals that may serve as the basis for the listing of a Priority Product in the initial stages of implementation is a further priority setting mechanism by DTSC, consistent with the Legislative directive to have a prioritization process in the regulations for identifying Chemicals of Concern.

Therefore, the first Priority Products list may include no more than five (5) Priority Products, as specified in proposed section 69503.6 (January 2013). The proposed regulations require DTSC to establish the Priority Products list through rulemaking pursuant to the Administrative Procedure Act (commencing with Government Code section 11340). This is consistent with the underlying statute and also provides additional certainty to the stakeholders, as well as ample opportunities for public notice and comment regarding the adoption of the Priority Products list. Once more, it is another regulatory provision that ensures that the regulations establish an identification and prioritization process for Chemicals of Concern in consumer products.

Please also see the Response to Comment 5-68 under Chemicals of Concern above and the Response to Comment 21-5 under section 69502.2(b)(2). Please also refer to the discussion on prioritization in sections 69503.2 and 69503.3 for Article 3 in this Response to Comments document for prioritization based on exposure and hazard criteria. The proposed regulations do not preclude the use of conditions of use of a chemical and level of “reasonable and foreseeable exposures” in justifying prioritization when evaluating the product-chemical combinations for listing as a Priority Product.

DTSC is not making any changes to the regulations in response to these comments.

Comments: 11-37, 49-16, 74-29, 74-30

These commenters suggest additional screening criteria for identification of Candidate Chemicals (previously known as COCs) to include:

- Chemicals permitted in commerce in the US;
- Large volume in commerce; and
- Chemicals known to be used in consumer products

Response:

DTSC has reviewed the suggestions and has determined that the regulations do not require revisions to use the criteria recommended in the comments.

While these specific criteria are not expressly named in the proposed regulations, the process by which DTSC considers screening criteria in Article 3 implicitly includes the suggested criteria. DTSC will consider these criteria when product-chemical combinations are evaluated to identify proposed Priority Products and when it prioritizes products for the Priority Product work plan, to the extent these criteria are already embedded in the regulations at Article 3.

The ISOR, in section 69502.2(a), explains that the initial list of Candidate Chemicals (previously known as COCs) is based on lists from authoritative organizations, which is consistent with the authorizing legislation at Health and Safety Code section 25252(b)(2). That provision requires DTSC to use "to the maximum extent feasible, available information from other authoritative bodies (*i.e.*, "organizations") that have undertaken similar chemical prioritization processes."

Prioritization, as specified in Article 3, begins with evaluation of product-chemical combinations to determine the associated potential adverse impacts and potential exposures. Chemicals in consumer products will be prioritized by considering factors described in section 69503.2 and 60503.3, which address human health and ecological impacts. These include:

- Adverse impacts posed by COCs (new definition) in consumer products due to exposures during the life cycle of the product; and
- Exposures to the COCs (new definition) in consumer product(s) based on several factors, which include market presence information for the product based on the following:
    - Sales volume;
    - Intended product use; and
    - Exposures during manufacturing, use, storage, transportation, waste, and end-of-life management practices and location of these practices.

The universe of chemicals is not static; it is dynamic and, with the globalization of commerce, there is a rapidly increasing flow of products from international markets. Additionally, the proposed regulations require DTSC to consider exposures from chemicals in products during waste and end-of-life management practices, when the product is discarded. In order to ensure a level playing field for all responsible entities that have a market presence in California, limiting the scope of the proposed regulations solely to chemicals used in the US would not be a meaningful addition to the criteria.

Please also refer to discussion on prioritization in sections 69503.2 and 69503.3 of Article 3 in this Response to Comments document. DTSC is making no changes to the regulations in response to these comments.

Comment: 5-69

Comment Summary:

This comment suggests that only a carefully and thoughtfully developed and prioritized Chemicals of Concern list will send signals to the marketplace and stimulate cooperation of the industry to find safer substitutes.

Response:

DTSC agrees and firmly believes that these regulations have been thoughtfully developed, and the list of Candidate Chemicals (previously known as COCs) for these regulations will send immediate signals to the marketplace about chemicals subject to this program. The list of Candidate Chemicals (previously known as COCs) is the product of tremendous amount of research, advice from expert consultants, GRSP, and input received during numerous informal and formal public comment periods, considered by DTSC scientists and other staff, as well as learning from other chemicals management regulatory programs, etc.

In the absence of more specific information, DTSC presumes that this commenter is objecting to the number of chemicals on the initial list of Candidate Chemicals (previously known as COCs), and the method of arriving at this list of Candidate Chemicals.

As explained in the ISOR, DTSC had various scientific and policy criteria in mind when it selected the chemical lists that it selected to comprise the universe of Candidate Chemicals (previously known as COCs). These lists all are credible; the product of rigorous scientific processes and criteria and within the scientific mainstream. See the ISOR for a detailed discussion of the criteria that these lists exhibit that make them appropriate for inclusion in this program. The size of the Candidate Chemicals list (previously known as COCs) is not inconsistent with the size of similar chemicals pools used in other regulatory schemes. DTSC also notes that many companies are already using chemical lists for disclosure purposes or to restrict products containing certain chemicals for purchase for use in their products, while others use chemical lists to implement their quest for safer consumer products. For example, some companies, such as Wal-Mart and Staples, are using chemical lists for disclosure purposes or to restrict products containing certain chemicals for purchase at their retail stores. Others,

such as the automotive industry, through their use of the Global Automotive Declarable Substance List (GADSL), use chemical lists to implement their quest for safer consumer products. Manufacturers who wish to begin proactive efforts and voluntarily redesign their products may use this initial list of Candidate Chemicals (previously known as COCs) as part of their process to make decisions regarding potential chemical alternatives or substitutions to consider.

The provisions in Article 2 are consistent with the overarching legislative intent, and reflect DTSC's consideration of the GRSP and stakeholder input, in meeting the authorizing statute requirement to establish the identification and prioritization processes. Further, there are many opportunities for regulated entities to submit information and data (sections 69501.4, 69502.2, and 69503.3) to inform DTSC why chemicals and products should not be on the finalized lists of Candidate Chemicals and/or Priority Products. No changes have been made to the proposed regulations in response to this comment.

Comment: 5-106

Comment Summary:

The comment states that the ISOR (see ISOR at pp. 56-57) does not include the rationale for DTSC's determination that a regulatory scheme that does not better "prioritize" is necessary to carry out the purpose and address the problem for which it is proposed. Therefore, one can assume that there is a means to better prioritize COCs and develop a more manageable initial list of COCs. Further, the ISOR does not explain why each of the included lists is necessary to fulfill the statutory mandates.

Response:

DTSC respectfully disagrees. First, DTSC notes that the ISOR at pages 55 through 57 provides background information on the identification and prioritization processes for both chemicals and products. The ISOR illustrates that the provisions in Articles 2 and 3 meet the statutory directives in Health and Safety Code sections 25252 and 25253, and the overarching legislative intent of the "Green Chemistry" statutes which is discussed in Health and Safety Code section 25255(a). In addition, the ISOR gives a detailed discussion of the workings of each of the authoritative organizations whose lists are included in these regulations to make up the Candidate Chemicals list (previously known as COCs). Further, the ISOR gives a narrative description of the procedural and scientific criteria that these organizations and their lists meet.

The ISOR also provides the rationale for the selected prioritization process in these regulations. DTSC consulted with the GRSP, and also reviewed stakeholder comments in response to an informal draft of the regulations (December 2011). The proposed regulations (July 2012, January 2013 and April 2013) in Articles 2 and 3 reflect DTSC's consideration of the GRSP's and other stakeholder comments in meeting the authorizing legislation's requirement to establish an identification and prioritization process for chemicals and products.

As explained in the ISOR, DTSC endeavored to start program implementation with hazard traits, chemicals and chemical lists that were generally in agreement with the recommendations of the GRSP and other stakeholders to allow all parties to learn, gain experience, build a knowledge base, and make informed decisions before full-scale implementation of these regulations. The criteria specified were based on stakeholder input and not only ensure transparency, but also reasonable criteria and a sound approach to identifying chemical lists.

The list selection criteria considered by DTSC for selecting the lists from authoritative organizations as sources of Candidate Chemicals (previously known as COCs) with hazard traits for the initial list, as explained in section 69502.2(a) of the ISOR (starting at page 60) are summarized below:

- Chemical lists supported, sponsored and/or developed by an authoritative organizations to protect public health or the environment; based on determination that the chemical exhibits a hazard trait. The list is for:
    - Adoption as part of a regulatory scheme with an enforcement component; or
    - Used to support or make policy or risk management decisions to protect public health and the environment.
- The chemical list was developed to prevent or limit exposures and/or adverse impacts to public health and the environment, *i.e.*, same purpose as these regulations.

Another factor influencing the identification of chemical hazard traits and/or chemical lists, in section 69502.2(a) of the proposed regulations, was harmonizing chemicals lists with other similar programs. DTSC sought to identify chemical hazard traits that may yield partnerships with other California, state and national chemicals programs to leverage resources and achieve results benefiting common goals of preventing exposures to harmful chemicals in consumer products.

Lists enumerated in section 69502.2(a) were selected based on these criteria and all of the lists are not only developed by authoritative organizations but also meet the “strong evidence” criteria for toxicological hazard traits, or “evidence” criteria for exposure potential hazard traits, as specified in Chapter 54, for the hazard traits specified. In other words, the chemical exhibits the highest level of evidence for its hazard trait for which it is listed on a particular list.

Finally, DTSC notes that the identification and prioritization scheme has been changed since the version of the regulations that is the subject of this comment (July 2012). More specifically, the proposed regulations were amended in January 2013 to change the name and function of the Chemicals of Concern list in section 69502.2. The Chemicals of Concern list is now called the Candidate Chemicals list in the proposed regulations (January 2013). But, much more importantly, DTSC must engage in additional identification and prioritization of chemicals from the Candidate Chemicals list before any chemical on the list is subject to the requirement to perform an Alternatives Analysis (AA). DTSC must further identify and prioritize product-chemical combinations by designating Candidate Chemicals as Chemicals of Concern upon listing of a Priority Product containing a Candidate Chemical. This one development alone renders virtually all of this comment as moot. The proposed regulations do have a more involved and step-wise identification and prioritization process for chemicals as was urged by the commenter. As demonstrated above, the basis for the selection of each of these Candidate Chemicals lists (previously known as COCs lists) was explained in great detail in the ISOR.

Please also see the Response to Comment 5-106 above and also under Chemicals of Concern and Chemical Prioritization. DTSC is not proposing any additional changes to the proposed regulations in response to this comment.

Comments: 73-2, 74-27, 107-33

Comments Summary:

These comments state that listing 4,000 or 1,200 chemicals is meaningless, as nearly 50% of the 4,000 substances are not in the Toxic Substances Control Act (TSCA) inventory and more than 80% are not reported as manufactured or imported in US EPA’s most recent Chemical Data Reporting update and 90% are not in consumer products.

Response:

DTSC is uncertain about which 4,000 or 1,200 chemicals are being referred to with the

statistics provided. For purposes of this response, DTSC will assume that the reference to the approximately 1,200 chemicals refers to the Candidate Chemicals list. With this interpretation in mind, DTSC respectfully disagrees that the inclusion of this number of Candidate Chemicals is meaningless. DTSC is firmly believes that this number of Candidate Chemicals puts responsible entities on notice that one of their chemicals could become identified as a Chemical of Concern in combination with a product, resulting in it being a Priority Product. This number of Candidate Chemicals is not so large as to make an expectation of voluntary reformulation an unreasonable assumption. The size of the list of Candidate Chemicals is not too dissimilar with the broad pool of chemicals for later consideration in other chemicals regulatory schemes. No changes to the proposed regulations are necessary to accommodate this comment.

Two-Step Prioritization

Comments: 1-4, 38-7, 41-5, 49-1, 49-5, 49-6, 49-16, 59-11, 61-7, 64-5, 73-3, 73-5, 74-27, 74-29, 74-30, 82-4, 84-1, 84-2, 92-6, 94-6, 105-7, 125-7

Comments Summary:

These comments request that DTSC include a two-step approach that would prioritize the chemicals first as “Chemicals under Consideration” and then as Chemicals of Concern. A few comments suggest that the prioritization process refer to “Chemicals of Interest” and then Chemicals of Concern. There was one suggestion for a three-step approach—first a list of “Chemicals of Interest” then a pared-down “Chemicals of Concern” list and finally a “Priority Chemical” identification that is paired with a Priority Product that is the focus of any regulatory responses that stem from the AA.

Response:

In response to similar comments, DTSC revised the proposed regulations (January 2013) to include a two-step prioritization process for chemicals. The first step is the immediate identification of approximately 1,200 Candidate Chemicals (previously known as COCs) compiled from lists by authoritative organizations, as enumerated in the proposed regulations. The second step is further prioritization of Candidate Chemicals (previously known as COCs) in consumer products to identify and prioritize product-chemical combinations. As specified in Article 3 of the revised proposed regulations, DTSC will evaluate product-chemical combinations for proposed listing as Priority Products. A Candidate Chemical that is the basis for a product-chemical combination being listed as a Priority Product is designated as a Chemical of Concern for that product.

The identification and prioritization process specified in Article 3 to evaluate product-chemical combinations is more efficient than a discrete two-step process for identification of chemicals alone. Efficiencies will be gained with DTSC's proposed approach, since the information needed to identify and prioritize products containing COCs (new definition) would most likely be from the same information source, *i.e.*, the manufacturer of the product or in the public domain. The GRSP and other stakeholders frequently pointed out that the prioritization of chemicals and products does not happen in a vacuum independent of each other. Rather, they urged DTSC to conduct prioritization of chemicals and products in tandem. That is, they thought the prioritization of one informed the relative prioritization of the other and should take place in a concerted manner.

As explained in the ISOR, prioritizing chemicals is very much dependent on information about both chemicals and products. Consider the factors in the authorizing legislation that DTSC must take into account "to establish a process to identify and prioritize" COCs (new definition) in consumer products:

- Volume of the chemical in commerce in California;
- The potential for exposure to the chemical in the consumer product; and
- Potential effects on sensitive subpopulations, including infants and children.

Chemical information and data is needed to inform the factors regarding volume and potential effects on sensitive subpopulations. However, *consumer products information* is needed to evaluate the potential for exposure to the chemical in the consumer product. Consumer product use, physical form, and the chemical concentration and function in the consumer product all influence the potential for exposure to the chemical in the consumer product, as well as the potential effects on sensitive subpopulations.

Conversely, chemical prioritization cannot be done practically without at least some consumer product information. It is apparent that evaluating COCs (new definition) in consumer products to determine how best to limit exposures and/or adverse impacts pursuant to Health and Safety Code section 25253 cannot be done without identifying the consumer products. In order to meet the authorizing legislation's intent and mandate, information regarding consumer products need to be considered with chemical information gathered during identification of COCs (new definition) for the prioritization process in the regulations.

Identifying and establishing a list of Candidate Chemicals (previously known as COCs) lays out the scope of chemicals under the proposed regulations that may ultimately be further prioritized as COCs under the new terminology. Next, DTSC will begin

evaluating and prioritizing product-chemical combinations for listing on the proposed Priority Products list. This, in essence, provides a "list" of newly defined COCs. Thus, DTSC and interested party resources can be more efficiently utilized by focusing on a single list of chemicals that is paired with products to identify those Priority Products subject to the requirement to perform an AA or alternate means of compliance.

Articles 2 and 3 are consistent with the authorizing statutory requirements, taking into consideration stakeholders' input, and by making policy decisions that incorporate science, practicality, efficiency and transparency. Please also refer to the Response to Comment 1-3 under Chemical Prioritization above. For the above stated reasons, DTSC is making no changes to the proposed regulations in response to these comments.

Comment: 101-21

Comment Summary:

This comment states that the regulations should be amended to have DTSC working on only one chemical at a time. Alternatively, DTSC should start with an initial list of chemicals with well-established hazards (*e.g.*, CMRs) then gradually add to it rather than trying to list everything at once. The comment also suggests that the program be as rigorous as the Proposition 65 listing process.

Response:

DTSC respectfully disagrees with the suggestion to work on only one chemical at a time. This suggestion is short- sighted and does not take into account that the proposed regulations will establish a regulatory program for the long-term. Hence, the regulations include process language that reflect the long-term function of the regulations rather than a "start off slow and then build" approach.

Nonetheless, DTSC has incorporated into the regulations some provisions that accommodate these competing tensions. For example, some provisions reflect an approach that "starts off slow" to accommodate industry concerns of regulating everything at once. For example, in proposed section 69503.6(a), scope of Candidate Chemicals (previously known as COCs) to be considered has been narrowed for the Priority Products list adopted prior to January 1, 2016. Further, section 69503.6(b) limits the initial final list of Priority Products to no more than five (5) Priority Products. DTSC has indicated that it will work on a number of chemicals and products "as resources permit." Much will depend on the depth and breadth of information known about the chemical.

In response to comments suggesting that DTSC start with well-established hazard traits, that is exactly what DTSC has done in the proposed regulations. The proposed initial list of Candidate Chemicals (previously known as COCs), which is a compilation of the chemicals listed on the authoritative organizations' lists identified in section 69502.2(a), has only nine (9) hazard traits out of over 40 different hazard traits identified in Chapter 54.

As expressed in the comment, OEHHA uses the "authoritative bodies" mechanism under Proposition 65. OEHHA notices chemicals under the Proposition 65 program and accepts public comment before the final listing of chemicals on the Proposition 65 list. In a similar vein, additions to the list of Candidate Chemicals (previously known as COCs) will be accompanied by a statement of basis, including DTSC's rationale for an addition of the Candidate Chemicals list. Any revisions to the list are to be finalized after considering public comment and stakeholder input. The process is specified in of the proposed regulations and also explained in the ISOR.

In addition, there are many other opportunities for regulated entities to submit information and data (*e.g.*, proposed sections 69501.4, 69502.2, and 69503.3) to inform DTSC why chemicals should or should not be on the finalized list of Candidate Chemicals and/or the Priority Products list.

The initial list of Candidate Chemicals (previously known as COCs) which is a compilation of the chemicals listed on the authoritative organizations' lists identified in section 69502.2(a), is intended to set out a scope of chemicals and "jumpstart" the Safer Consumer Products program. The lists are from authoritative organizations charged with protecting public health and the environment and have identified chemicals with regulatory or risk management consequences. These chemicals have in turn been identified in section 69502.2(a) of the proposed regulations. DTSC sought to use the evaluative work these authoritative organizations have done. These authoritative organizations use deliberative scientific processes with opportunity for stakeholder input and comment. By relying on other authoritative organizations' work, including their recommendations and regulations that support protecting human health or the environment to identify the initial list of Candidate Chemicals, DTSC is able to maximize resources, while minimizing DTSC staff time and costs to California in establish an initial list of chemicals subject to further requirements under the proposed regulations.

It is important to note that all of the chemicals on the lists in regulations meet criteria as "strong evidence" for toxicological <u>hazard traits</u> or as "evidence" for the <u>exposure</u> potential hazard trait in Chapter 54.

Further, this list of lists approach in identifying chemicals with hazard traits for these regulations, is consistent with the underlying statute Health and Safety Code section 25252(b)(2), “In adopting these regulations, the Department shall reference and use, to the maximum extent feasible, available information from other nations, governments and other authoritative bodies that have undertaken similar chemical prioritizations processes….”

Please refer to the Response to Comment 101-21 in Article 5 for discussion on the AA provisions of the regulations. DTSC is not making any changes to the proposed regulations in response to this comment.

Narrative Standard

Comments: 5-68, 5-71, 9-10, 9-15, 11-5, 11-38, 49-3, 49-5, 49-6, 49-13, 64-2, 64-3, 65-2, 73-2, 73-4, 73-5, 74-30, 84-2, 107-6, 107-34, 107-46, 124-2, PH18-1

Comments Summary:

These commenters state that the process of identifying Candidate Chemicals (previously known as COCs) is too loose and overbroad. The narrative standard for identifying and adding chemicals to the list of Candidate Chemicals (previously known as COCs) is not sufficiently transparent and does not indicate the thresholds for the factors to be used. Following are the specific remarks and suggestions relevant here:

- The comments suggest a stepwise approach to identify Chemicals of Concern in a fair and transparent process, without increasing the regulated community’s burden. (Note: other portions of the comments addressing the size of the Candidate Chemicals list have been responded to elsewhere in this Response to Comments document and are not repeated here);
- DTSC's approach ignores the statutory mandate to identify and prioritize COCs. While it may be appropriate to use the various lists to identify Candidate Chemicals, there should be clear criteria and en established process for screening which chemicals are ultimately deemed a COC;
- The process is not sufficiently transparent; DTSC needs to provide additional clarity to this process so that it is objective and repeatable if conducted by different sources; and
- Citizens may not be able to interpret that a thousand of the most commercially important substances that are designated as subjects of the State’s “concern,” based only on a loose assessment of hazard characteristics gleaned from lists compiled by non-state entities.

Response:

DTSC respectfully disagrees that just because the identification and prioritization process identifies many chemicals within its scope, it is inappropriate. The initial Candidate Chemicals list (previously known as COCs list) of approximately 1,200 chemicals is comparable to other chemicals lists from other jurisdictions.

DTSC acknowledges that some manufacturers may wish to take proactive steps to evaluate and possibly remove Candidate Chemicals from their products, even though they are under no obligation to do so. A prescriptive process for identifying and prioritizing chemicals and products, with rigid criteria for DTSC to evaluate and make decisions, may provide a greater level of predictability and certainty to manufacturers for chemicals and products not yet listed as Chemicals of Concern or Priority Products. However, there may also be some negative consequences to that approach as well. More specifically, by definition, a prescriptive process for decision-making entails a fairly rigid adherence to a set of steps and/or specific weighting of various factors or criteria. This, in turn, can be challenging to DTSC, especially since it greatly restricts DTSC from bringing its particular expertise and judgment to bear on a decision.

In addition, a prescriptive process would only reflect decisions based on current science and understanding and creates the possibility that a prescriptive process could ignore new science and understanding for future decisions. While regulations could be amended to reflect new science, by the time the regulations are amended, the regulations may need further amendment because the science has progressed again. There is a valid concern that under a prescriptive approach, DTSC will constantly be behind new science and understanding, will constantly be amending regulations, and will be trapped into making regulatory decisions knowing that the regulatory process will not allow consideration of new scientific understanding of chemicals and products.

In addition, there is a lack of knowledge and experience with a regulatory program of this scope and breadth since this regulatory program is the first of its kind in the world. DTSC consulted with the GRSP, and it was recognized that the processes in regulations need a measure of predictability and certainty. However, the regulations also need to remain relevant and appropriate as the Safer Consumer Products program grows and matures with the need to incorporate advances in science, knowledge, and experience. After considering extensive GRSP and stakeholder input on this issue, DTSC determined that any such benefits would be outweighed by the negative consequences.

For all these reasons, DTSC is not specifying a prescriptive process with a numerical

weighting or ranking system for chemicals and products but is instead using a narrative approach that allows DTSC to use best available scientific information and practices to identify COCs (Article 2) and prioritize product-chemical combinations (Article 3). It is necessary for the DTSC to employ a narrative approach to decision-making to effectuate the statutory provisions in a timely and meaningful way, and DTSC takes its responsibility very seriously.

With regards to the commenters' views that the process should be objective, repeatable and transparent, the initial list is a compilation of the chemicals listed on authoritative organizations' lists identified in section 69502.2(a), of the proposed regulations. DTSC sought to use the evaluative work done by the authoritative organizations using deliberative scientific processes with opportunity for stakeholder input and comment. It is important to note that all of the chemicals on the lists in regulations meet criteria as "strong evidence" for toxicological hazard traits or the "evidence" criteria for the exposure potential hazard traits, as specified in Chapter 54. In addition, the rationale for inclusion of each of these lists was set out in detail in the ISOR. The process for including these existing chemical lists into these regulations is also transparent and repeatable. That is, the lists are all subject to public notice and comment as a component of the rulemaking package. As such, DTSC has given extensive explanation regarding why each of the lists was included and describing how each of the authoritative organizations conducts its work and makes scientific judgments. Of course, this process of explanation and inclusion could be repeated any number of times. DTSC does not know what is meant by the process being "objective." The work of the underlying authoritative organizations is conducted without there being a pre-selected desire or outcome. There is no purely objective means of evaluating chemicals that is universally agreed on or whose results are universally accepted.

For any revisions to the initial list of Candidate Chemicals (previously known as COCs), proposed regulations require DTSC to public notice proposed additions to the list with a statement of basis and DTSC's rationale. DTSC will finalize the list only after reviewing all of the public comment(s) and stakeholders' input. As mentioned before, there are other opportunities also for the regulated entities to submit information and data (sections 69501.4, 69502.2, and 69503.3) to inform DTSC why chemicals and products should not be in the finalized lists.

A robust list of Candidate Chemicals (previously known as COCs) serves as a market signal for consumers to be aware of what chemicals are in the consumer products they purchase and for manufacturers to take voluntary actions before thy are compelled by the regulations, if they so choose. The compliance requirements are only applicable to

the COCs (new definition) present in Priority Products and the Priority Product listing requires rulemaking pursuant to the APA (commencing with Government Code section 11340). Therefore, there are ample and redundant protections to provide opportunities for public notice and comment before any chemicals and products are subject to regulatory action as Priority Products.

The revisions to both Articles 2 and 3 embody the goals and intent of the authorizing legislation and have clarified the prioritization process to provide regulated entities a more defined prioritization process for screening potential product-chemical combinations and opportunities to review product-chemical combinations proposed by DTSC which are subject to public comment. Accordingly, DTSC is making no changes to the regulations in response to these comments. Please also see the Response to Comment 1-3 under Chemical Prioritization.

Weight of Evidence

Comments: 5-68, 9-15, 9-16, 9-34, 11-38, 12-4, 24-2, 40-5, 49-16, 101-21, 107-46, PH34-7

Comments Summary:

These comments refer to the definition of “reliable information” as the basis for listing a chemical as Candidate Chemical (previously known as COC) and suggest that the only valid scientific approach is to consider the weight-of-evidence as part of the standard protocol. Concerns expressed by the commenters were as follows:

- Without a weight-of-evidence approach, a single study, regardless of its quality, could be used, specifically in prioritizing Chemicals of Concern and products;
- The lack of thresholds for the factors to be considered in selecting additional COCs makes the process unrepeatable if conducted by different sources;
- The process of adding COCs should be clarified by incorporating a specific and scientific weight-of-the-evidence assessment; and
- The process of relative (quantitative) weighting of both the COCs and the products associated with them, such that the focus in the end will be on those posing the greatest threat is clearly a quantitative judgment that will have to be defended in court.

Response:

DTSC respectfully disagrees with the commenters that the only valid scientific approach for the identification and prioritization of chemicals and products is to consider the weight-of-evidence as part of the standard protocol. DTSC believes that this type of

rigid prioritization approach (*i.e.*, using a strict weighting and ranking system to list chemicals and products) would ultimately lead to prioritization decisions that could *not* be fully scientifically supported for the following reasons:

1. Regulatory inflexibility:

   The immediate and specific integration of the prioritization factors into a generic static prioritization system for all chemicals and products in the marketplace would only reflect decisions based on current science and understanding. This would create the possibility of the process remaining ignorant to new science and understanding for future decisions and therefore being inflexible if adopted into regulations. Historic attempts to modernize and update chemical regulatory schemes have met resistance (*e.g.*, federal TSCA and California's Hazardous Waste Classification system), and remain largely unchanged since inception.

2. Science-based decisions are not "pure" science:

   The clear goal is to identify Candidate Chemicals (previously known as COCs) on the basis of actual and/or potential for harm to public health and the environment using the prioritization factors listed in revised sections 69502.2(a) and (b) of the proposed regulations (January 2013).

A call for a generic methodology to establish rank order from highest to the lowest order of concern for chemicals and products seems to assume that this can be easily achieved through the development of a fully scientific process. The underlying assumption is that such a process can be designed that will be devoid of bias and provide "pure" scientific results to the decision maker. While many inputs into such a prioritization system are scientific in origin, the development of this type of prioritization scheme does not reflect science alone. A mathematical algorithm that generates a rank order or relative priority among chemicals and products would have its scientific origins, but the ultimate nature of its construction would reflect many subjective decisions in at least three major ways:

(1) Prioritization Factors - Identifying and determining a basis for scoring and weighting of the key prioritization factors to consider, while based upon scientific information, should also be based upon current regulatory goals.
(2) Accommodating Uncertainty - Scientific data sets will be incomplete, dissimilar, and unlikely equal. Accommodating such "uncertainty" in the diversity of information will be based on decisions not wholly based on science, but perhaps based on acceptable uses in the scientific community that involves scientific expertise and not just "pure" science.

(3) Coping with Dissimilar Hazards - Chemical hazards may be dissimilar, and products will have different patterns of exposure. The potential of causing chemical burns to all in the population versus the potential to cause birth defects in a developing fetus associated with any product and its chemical content will require careful consideration. Science-based and risk management decision-making may be difficult in this instance.

Regulatory decisions need to be informed by the best scientific information available, not stifled by waiting for "perfect" data and information, and not misled by a lack of information of chemical behavior in a product's design and life cycle and related exposures to the chemical(s) in the product that could lead to misinformed policy tradeoffs. A balance needs to be reached between the science available and the regulatory decisions that are made.

It is widely recognized that the information on the nature of chemicals' presence in a product, product concentrations, toxicity, exposure, fate and transport, and observed human morbidity and/or mortality available in the open literature, to the government, or in private holding on chemicals that end up in consumer products and thereafter, ranges from nothing to very substantial.

In anticipation of the variability of available information, on chemicals and products, DTSC's regulations do not define a formulaic process or describe a rigid and explicit process that demands the absolute existence and consideration of quantitative criteria to explicitly prioritize chemicals or to make regulatory decisions on chemicals in consumer products. Since a full complement of toxicity and exposure information has rarely followed the placement of every chemical or product in the marketplace by manufacturers, such an approach would be impractical to implement.

While DTSC shares a preference for such information with the commenters, DTSC cannot be constrained in making public health protection and environmental protection decisions because of the lack of precise quantitative exposure information. The groundbreaking nature of these public health and environmental protection regulations will require a flexible and adaptive process for prioritizing diverse patterns of product-chemical combinations.

In fact, pursuant to Health and Safety Code section 25252, the prioritization process used by DTSC must include, but not be limited to, considerations of the volume of the chemical in commerce in the state and the potential for exposure in consumer products.

DTSC is responsible for implementing an approach that it will use in assigning hazard traits to chemicals, identifying and prioritizing Chemicals of Concern, and making regulatory decisions on chemicals in consumer products. Such an approach will include, but is not limited to, the evaluation of the quality/validity of the assays, reliability of the results, nature of the effects observed, consistency and interrelationship among endpoints reported in an individual assay, and relevance, specificity, and sensitivity of the endpoints measured within and across all assays.

This approach will be embedded in a rulemaking process that will be public and transparent. All decisions about hazards by DTSC will be based upon information available to DTSC and its thinking made visible through the rulemaking process that DTSC will be required to follow in the adoption of the Priority Products list. All stakeholders will be welcome to provide scientific data to broaden and inform (rebut, clarify or support) DTSC's approach and decisions.

In considering this universe of chemicals, US EPA intends to build a prioritization scheme based on broader general concepts as articulated in National Academy of Sciences *Toxicity Testing in the Twenty-first Century: A Vision and a Strategy*. Prioritization tools include the consideration of physicochemical properties, structure activity relationships, and high through-put computational methods to integrate all existing knowledge and multiple tools to generate a more practical, scientifically based prioritized list of chemicals. This is in line with the proposed regulations. DTSC has its own expert scientists and toxicologists on staff and is confident that it has the resources available to evaluate scientific studies and information, and make informed decisions by balancing science and regulatory goals.

The criteria for determining the reliability of non-scientific information has been added to the revised section 69503.3(b)(1)(C) of the regulations (April 2013). It is important to note that the criteria specified for DTSC to consider for various sources of information in the revised section 69503.3(b)(1)(C) of the regulations (April 2013) are consistent with common practices of the scientific community in supporting sound science-based decisions.

For all of these reasons, DTSC is not specifying a weighting or ranking system for chemicals and products but is proposing to use the best available scientific information and practices, with public comment and stakeholder input to identify and prioritize chemicals and ultimately products.

DTSC encourages these commenters to provide specific input as it applies to the

Chemicals of Concern and products being evaluated for possible listing during the listing process for adding chemicals to the Candidate Chemicals list and for listing of Priority Products. Please refer to the Response to Comment 5-68 on Reliable information and also refer to the discussion on weight of evidence in Article 1. DTSC is not making any changes to the regulations in response to these comments.

Risk Assessment

Comments: 5-68, 12-4, 21-5, 38-6, 47-11, 57-35, 59-9, 59-13, 61-5, 64-1, 64-2, 64-4, 64-5, 66-18, 69-21, 73-1, 82-1, 86-17, 92-5, 94-5, 99-1, 101-19, 101-21, 103-2, 103-3, 103-4, 105-6, 124-21, 139-6, PH18-1, PH34-7

Comments Summary:

These commenters state that DTSC should develop a risk-based chemicals management system that screens chemicals to develop a narrower, focused list of Candidate Chemicals (previously known as COCs) that actually represent the greatest potential risk. This will allow DTSC to conduct a step-wise, methodical evaluation of chemicals in consumer products. The commenters' specific remarks include the following:

- DTSC should allocate each of these chemicals into a risk characterization scheme (such as seriousness and probability of harm, exposure, and characterization of vulnerable endpoints);
- There must be a clear safety-based approach to prioritizing Chemicals of Concern within these regulations;
- DTSC is encouraged to utilize use information in conjunction with exposure information to aid in risk-based determinations of potential adverse impacts;
- DTSC should focus on chemicals used in consumer products that meet specific hazard criteria and have exposure and use patterns that may pose risks;
- DTSC should truly focus on limiting exposure to and adverse impacts posed by Priority Products that contain Chemicals of Concern in consumer products. This targeted approach encourages the evaluation of chemicals and products of concern where there is a reasonable or foreseeable pathway for exposure;
- While it is true that all the chemicals on these lists were reported to have demonstrated some hazard trait in some test that landed them on a particular list for some specified purpose, it does not follow that they all pose a risk of harm if used in a consumer product; and
- The lists are not relevant to the levels of chemical exposure in consumer products, and the prioritization and evaluation process must be based on exposure as well as hazard.

Response:

Please note that “Chemical of Concern” has been redefined. The term “Chemical of Concern” has been redefined in response to similar comments. Please refer to the response to comment under Chemicals of Concern in section 69502.1 of this document.

DTSC disagrees with the comments and notes that the proposed regulations are based on scientific principles, though the use of risk assessment in proposed regulations is not favored, for the reasons stated below.

Citing the "Science and Judgment in Risk Assessment," National Academy of Science (NAS) Committee on Risk Assessment of Hazardous Air Pollutants, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, National Academy Press, Washington, D.C., 1994. As described in the NAS Committee report:

- “Human-health risk assessment entails the evaluation of scientific information on hazardous properties of environmental agents and on the extent of human exposure to those agents. The product of the evaluation is a statement regarding the probability that populations so exposed will be harmed, and to what degree. The probability may be expressed quantitatively or in relatively qualitative terms.”
- *“Risk Management* is the term used to describe the process by which risk-assessment results are integrated with other information to make decisions about the need for method of, and extent of risk reduction.”

Chemical hazards come in many forms. Risk assessment can be carried out for any form of chemical toxicity and could be used to prioritize chemicals. However, risk assessment sometimes consists only of a hazard assessment designed to evaluate the potential of a substance to cause human health effects. Regulators sometimes take the additional step of ranking the potency of a number of chemicals—which is known as hazard ranking. Sometimes potency information is combined with exposure data to produce a “risk ranking." It should be noted that (1) the efficacy and robustness of such a process will always be dependent, in part, upon the quality and quantity of the available scientific data, and (2) in practice the use of the term “risk” is commonly associated with carcinogens and not non-carcinogens.

Prioritization is a risk management decision and is not viewed as simply a “risk ranking.” It is a decision that can be informed by risk assessment approaches, but also reflects other potential policy influences and administration priorities. Specific policy targets could move from removal of carcinogens to the removal of teratogens and then on to

the removal of neurotoxins depending on the magnitude of the issues within a specific decision or policy time frame. Prioritization is informed by science, but it is not solely a scientific decision.

Developing a single list with strict ordinal ranking would be irrational since there is no accepted valuation system that allows for the strict scientific ranking of adverse outcomes that are due to different pathological mechanisms or affect different biological systems or different biological species.

DTSC has intentionally avoided relying upon terminology such as "risk" to avoid the misconception that chemicals with unlike hazard traits can be simply compared based upon a single common “risk” metric. For example, carcinogens whose adverse human health impacts are often expressed using “risk” metrics (where a common agent is presumed to operate by a mechanism that has no toxicity threshold) cannot be easily compared with toxic agents that exhibit dissimilar hazard traits, such as developmental toxicity, into a single list and strictly ranked. These regulations are applicable to hazard traits that include both *carcinogenic* and *non-carcinogenic* endpoints *in both human and non-human species*.

DTSC reserves the option to take preventative regulatory action based upon newer toxicity information that is not being developed in traditional animal bioassays. Such information may not be easily integrated into the traditional paradigm of risk assessment if the expected outcome is a “risk” metric.

Therefore, absolute adoption of a quantitative risk assessment process including full uncertainty analysis as the sole approach to prioritization is neither practical nor reasonable due to obvious gaps in scientific data. Exposure information may not be directly available within reasonable time frames to allow for preventative regulatory action. Complete information on hazard and the lack of precise information on hazard within the strict boundary of a risk assessment requirement could stifle timely responses. DTSC reserves the option to use information about the magnitude of the presence in the marketplace as a surrogate for exposure data to be available.

The proposed regulations are consistent with the intent of the underlying statute and have been clarified and streamlined to represent the essential steps to implement AB 1879. DTSC is confident the regulations will be workable and effective.

Article 3 of the proposed regulations requires DTSC to consider use information in conjunction with the exposure information, in determining potential adverse impacts from chemicals in consumer products. As expressed by the commenter, all of the

chemicals on the initial list of Candidate Chemicals are known to have a hazard trait and are listed on a particular list for a specified purpose. However, the lists are not relevant to the levels of chemical exposure in consumer products. In evaluating product-chemical combinations, one of the many criteria that DTSC needs to consider includes evaluating if the Candidate Chemical poses a risk of exposure and the product use patterns that may pose risks when that Candidate Chemical is used in a consumer product. This must occur before proposing the product-chemical combination for listing as a Priority Product, which will follow the rulemaking process pursuant to the APA. Thus, together with the stakeholders, DTSC will prioritize the evaluation of product-chemical combinations where there is a reasonable or foreseeable pathway for exposure.

Article 2 provisions specify the process for identifying and listing Candidate Chemicals (previously known as COCs). Please refer to Article 3 for prioritization based on exposure to, and adverse impacts posed by, Priority Products that contain Chemicals of Concern in consumer products. DTSC is not making any changes to the proposed regulations in response to these comments.

§ 69502.2 Chemicals of Concern Identification

§ 69502.2(a) Initial Chemicals of Concern List

Comments: 1-3, 1-4, 3-3, 5-10, 5-69, 5-71, 5-106, 11-5, 12-4, 15-1, 21-5, 24-1, 36-5, 36-30, 38-6, 39-17, 41-4, 41-14, 49-2, 49-3, 49-5, 49-6, 49-11, 49-16, 57-29, 57-34, 59-6, 61-6, 64-2, 64-5, 66-18, 73-1, 73-2, 73-4, 73-5, 74-26, 74-27, 74-28, 74-29, 74-30, 84-1, 92-5, 94-5, 103-1, 107-6, 107-31, 107-34, 107-37, 107-38, 114-2, 119-2, 124-21, 139-6, PH12-9, PH18-1, PH36-1

Comments Summary:

These comments refer to the initial List of COCs based on the list of chemicals from various states, U.S., and international government bodies and state that their count of chemicals yields over 4,000 chemicals not 1,200 chemicals. These commenters would like DTSC to explain the difference as well as the criteria and process for screening from over 4,000 (or ≈3,000) chemicals to 1,200 chemicals, which are then further filtered to ≈185 chemicals in the work plan.

Response:

DTSC will attempt to further clarity the process of compiling list of Candidate Chemicals (previously known as COCs) from the lists enumerated in section 69502.2(a).

The initial list of Candidate Chemicals (previously known as COCs) is a compilation of the chemicals listed on authoritative organizations' lists identified in section 69502.2(a), of the proposed regulations. All of the lists are from authoritative organizations, and all of the chemicals on these lists meet the criteria for “strong evidence” for toxicological hazard traits or the “evidence” criteria for the exposure potential hazard traits, as specified in Chapter 54 regulations.

As explained in the ISOR, the informational list of Candidate Chemicals (previously known as COCs) is a list of approximately 1,200 chemicals. This represents a compilation of the chemicals listed on authoritative organizations' lists identified in section 69502.2(a) of the proposed regulations with the exception of: (1) chemicals exempted under Health and Safety Code section 25251 (e.g. pesticides and prescription drugs); (2) non-chemicals (e.g., nutrients); (3) duplicate chemicals that appear on more than one list; and (4) chemicals that are known not to exhibit a Chapter 54 hazard trait or environmental or toxicological endpoint. Chemicals known to fall into one of these four (4) categories will not be included in the informational list of Candidate Chemicals (previously known as COCs) posted on DTSC’s website under section 69502.3(a).

The initial informational list will be published within 30 days of the effective date of these regulations, as specified in section 69502.3 when the lists enumerated in the proposed regulations have been finalized. The initial informational list of Candidate Chemicals (previously known as COCs) compiled from chemicals listed on authoritative organizations' lists identified in section 69502.2(a) will be a clean list of Candidate Chemicals, and the final Priority Products list (established through rulemaking) will specify the Chemicals of Concern (new definition). In other words, the final Priority Products list will identify Candidate Chemicals, designated as Chemicals of Concern, used in consumer products. Both of these lists will be published on DTSC’s website.

Article 3 specifies a consistent set of factors for DTSC to consider in its evaluations and gives responsible entities, the public, and other interested parties a better understanding of the prioritization factors that are considered in identifying and prioritizing consumer products containing a Chemical of Concern (new definition) as Priority Products.

Section 69503.3(f) requires DTSC to issue a Priority Product Work Plan and, no later than January 1, 2016, DTSC may select only those chemicals that meet both of the following criteria as the basis for a product being identified as a Priority Product:

i) Have a hazard trait or toxicological or environmental endpoint listed on one or more of the authoritative organization’s chemical lists in 69502.2(a)(1); and

ii) Appear on an exposure or monitoring related chemical list in 69502.2(a)(2).

This winnowed down list is approximately 230 Candidate Chemicals (previously known as COCs) that meet the demands for certainty during early stages of implementation and sends better signals to the marketplace as to which chemicals may be identified as Chemicals of Concern during the early days of implementation.

Please also see Response to Comment 49-16 on Chemical Prioritization and the Two-Step Prioritization. DTSC is not making any changes to the regulations in response to these comments.

Chemicals Identified by European Commission

Comment: 68-21

Comment Summary:

This commenter suggested additional language for reference in sections 69502.2(a)(1)(B), (C) and (G) as follows:

- Add "or identified as a Chemical of Concern by the European Commission under the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) initiative" after the reference number in 69502.2(a)(1)(C); or
- Add "or identified as a Chemical of Concern by the European Commission under the REACH initiative" after the reference number in 69502.2(a)(1)(C).

Response:

DTSC has reviewed the suggested revisions provided. After careful consideration, DTSC revised the proposed regulations (April 2013) as follows:

- Revised section 69502.2(a)(1)(B) -

  "Chemicals classified by the European Commission as carcinogens, mutagens and/or reproductive toxicants Categories 1A or 1B in Annex VI to Regulation (EC) 1272/2008";

- Revised section 69502.2(a)(1)(C) -

  "Chemicals included as Category 1 endocrine disruptors by the European Commission in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006"; and

- Revised section 69502.2(a)(1)(G) -

"Chemicals included as persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative by the European Commission in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006."

List: Other Programs

Comments: 9-36, 36-9, 138-12

Comments Summary:

These commenters recommend that all of the following lists should be included in the proposed regulations:

- Washington State Department of Ecology *Reporting Lists of Chemicals of High Concern to Children;*
- Minnesota's list of 1,700 chemicals of high concern in 2010 under *Minnesota Toxic Free Kids Act;*
- Maine's list of 1,700 chemicals of high concern in 2009 under *Maine Toxic Chemicals in Children's Products Law;*
- The Skin Disease portion of Haz-Map database from US National Library of Medicine;
- The Green Chemistry and Commerce Council's *An analysis* of corporate *restricted substance list (RSL) and their implications for green chemistry and design for environment, November 2008* (Chemicals in Appendix 1);
- European Union Dangerous Substances Directive (67/548/EEC), being replaced June 1, 2015 by GHS-related Regulation (EC) No 1272/2008;
- European Chemicals Agency Candidate List of Substances of Very High Concern;
- US EPA TSCA Section 8(e) Existing Chemical Substance Significant New Use Regulation;
- US EPA Existing Chemicals Action Plans; and
- US EPA TSCA Section 8(e) submissions.

Response:

DTSC has reviewed the commenters' suggestions and has determined that no regulatory changes are necessary.

DTSC sought to have a "manageable" number of chemicals, taking into consideration: whether the chemicals list is from an authoritative organization, adds value to the initial

COCs List (now known as Candidate Chemicals list)—the given chemical list does not excessively duplicate chemicals that are already named by other chemical lists—and availability of state resources to implement the Safer Consumer Products program in harmonization with other state programs.

As explained in the ISOR, harmonization and consistency with chemicals lists and hazard traits identified by the states of Washington, Maine, and Minnesota with similar chemical programs is one of the list selection criteria in the proposed regulations. Thus, Washington State's *Lists of Chemicals of High Concern to Children,* Minnesota's list of 1,700 Chemicals of High Concern, and Maine's list of 1,700 Chemicals of High Concern would be redundant. Similarly, there is much overlap between the European Chemicals Agency Candidate List of Substances of Very High Concern, US EPA TSCA Section 8(e), Existing Chemical Substance Significant New Use Regulations, US EPA Existing Chemicals Action Plans, and the lists set out in section 69502.2(a) of the proposed regulations. Thus, adding any of these lists would not meet DTSC's criterion of extensive non-duplication between lists.

All of the other suggested lists have been reviewed by DTSC and found to be not suitable for inclusion in the initial list of Candidate Chemicals (previously known as COCs) at this time, as discussed below:

- Section 8(e) of the federal TSCA requires US chemical manufacturers, importers, processors, and distributors to notify US EPA immediately after obtaining information on any of their chemical substances or mixtures that reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment. Most of the submissions claim confidentiality for the chemical name and related chemical information. Accordingly, there would be little, if any, useful information for DTSC coming from adding this list.

  The Skin Disease portion of Haz-Map database from the US National Library of Medicine is an occupational health database designed for health and safety professionals and for consumers seeking information about the adverse effects of workplace exposures to chemical and biological agents. The information in Haz-Map comes from textbooks, journal articles, the *Documentation of the Threshold Limit Values* (published by American Conference of Governmental Industrial Hygienists), and electronic databases such as Hazardous Substances Data Bank. The purpose of Haz-Map is "decision support" that is meant to assist the expert by providing easy access to key information. This Haz-Map database

would not be appropriate for inclusion in this program as it does not meet the list selection criteria for the proposed regulations.

- The Green Chemistry and Commerce Council is a business-to-business forum that advances the application of green chemistry and design for environment across supply chains. It provides an open forum for cross-sector collaboration to share information and experiences about the challenges to and opportunities for safer chemicals and products. This list would be inappropriate for inclusion here because the list is compiled from shared information based on business to business collaborations. This does not meet the definition of an authoritative organization as defined in Chapter 54.
- The Restricted Substances Lists (RSL) is a list compiled by the Green Chemistry and Commerce Council from restricted substances lists of member companies, to analyze key differences, trends, and the importance of RSLs within various industrial sectors. The report—*An analysis* of corporate *restricted substance list (RSL) and their implications for green chemistry and design for environment, November 2008* (Chemicals in Appendix 1)—concluded that it is difficult to know how restricted chemicals are used in particular sectors or the rationale for particular restriction. This list would be inappropriate to include here because the list is compiled from restricted substances lists of member companies and it is not a list from an authoritative organization.

Section 69502.2(b) specifies the process to identify new Candidate Chemicals (previously known as COCs) based on their hazard traits or environmental or toxicological endpoints. This is an important avenue for new chemicals to be identified, as explained in the ISOR.

DTSC encourages commenters to petition DTSC with specific details, pursuant to Article 4 of the proposed regulations, to evaluate a chemical or a consumer product or list of chemicals using the chemical identification or product prioritization processes specified in Articles 2 and/or 3 for adding chemicals and/or chemical lists during implementation.

This is an important avenue for DTSC to make an informed decision regarding the chemicals that may not be on any list but are responsible for environmental endpoints. For all of the reasons stated above, DTSC is making no changes to the regulations in response to these comments.

List: Environmental Contaminants

Comments: 53-3, 53-4, 114-3, 118-2, 118-4, 121-2, PH24-3, PH24-4

Comments Summary:

These comments state that there are no ecotoxicity lists for water and other environmental chemical contaminants. The specific concern is that chemicals that may not comply with sections 69502.2(a)(1) or (2) also contaminate water or other environmental strata and many of these will not be eligible initially for action under these regulations. The commenters expect that at least one of the first combinations selected by DTSC will respond to an environmental endpoint. The commenters suggest adding the following water quality lists:

- Chemicals of Emerging Concern List generated by a scientific panel in accordance with the State Water Board's Recycled Water Policy; and
- The European Union's list of Priority Substances under the Water Framework Directive in Annex II of the Directive on Environmental Quality Standards (Directive 2008/105/EC).

Response:

DTSC agrees with the commenter that there are no ecotoxicity lists for water and other environmental strata.

DTSC's research on the suggested lists revealed that the Chemicals of Emerging Concern list is a proposed list in a staff report that has not yet been finalized as of January 2013. Therefore, the majority of chemicals on the Chemicals of Emerging Concern list are pesticides, pharmaceuticals, and a natural hormone—all of these are statutorily excluded from the definition of "consumer product," and a few chemicals anticipated to be from consumer products are redundant.

The list developed by the Water Boards, under section 303(d) of the Clean Water Act, identifies the state's priority water pollution problems by listing chemicals that pose the greatest threats to water quality in California. The inclusion of the 303(d) list will support the State and local regulatory agencies in their efforts to comply with the federal Clean Water Act and the State Water Code by controlling problem chemicals at the original source—in consumer products. Consequently, state and local agencies will not be forced to install, maintain, and operate expensive treatment facilities in order to prevent the water pollutants from threatening aquatic life and human health. DTSC's pursuit to have a "manageable" number of chemicals combined with the reasons stated above and resulted in selection of the list developed by the Water Boards under section 303(d)

of the Clean Water Act over the European Union's list of Priority Substances under the Water Framework Directive.

There are other opportunities for stakeholders and the regulated entities to submit information and data (sections 69501.4, 69502.2, and 69503.3) to inform DTSC why chemicals and products should or should not be in the finalized lists, as specified in the ISOR. Therefore, please refer to the Response to Comment 36-9 for additional information regarding the petition process in the proposed regulations.

Although DTSC has limited resources and may be constrained by the availability of information, DTSC has not limited itself in the regulations to working on particular product-chemical combinations. DTSC cannot at this time estimate with any precision how many or which product-chemical combinations it will be able to address. Much will depend on the depth and breadth of information known about the chemical or product. DTSC is not making any changes to the regulations in response to these comments.

Initial List of Candidate Chemicals

Comments: 49-7, 49-8, 49-9, 49-10, 57-31, 57-33, 69-27, 73-2, 74-27, 82-3, 95-3, 101-20, 103-2

Comments Summary:

These comments refer to DTSC's approach of compiling the chemicals listed on authoritative organizations' lists identified in section 69502.2(a) for the initial list of Candidate Chemicals (previously known as COCs), and state that there is neither consistency nor continuity among the source lists and sometimes within them. These lists have been developed for purposes far removed from consumer product regulation—specifically, the Proposition 65 list, Oslo and Paris Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) list and Washington State list, Integrated Risk Information System (IRIS) and International Agency for Research on Cancer (IARC) carcinogens lists. The comments are concerned that there has been subordination of California regulations to scientific standards that may not be as rigorous as those that would be imposed within the state, in selecting its initial list of Candidate Chemicals.

Response:

DTSC respectfully disagrees. DTSC remains motivated and committed to use the best available scientific information. DTSC's leveraging of some of the existing work by other credible scientific organizations is not a form of subordination. DTSC was very

discriminating in which authoritative organizations' lists were included in these regulations to ensure that California's regulations are of appropriate scientific rigor.

Health and Safety Code section 25252(b)(2) requires DTSC to use, to the maximum extent feasible, available information from other authoritative bodies (*i.e.*, "organizations") that have undertaken similar chemical prioritization processes. It is important to note that DTSC relies on this foundational requirement to support the first step in the prioritization process, that is, the identification of Candidate Chemicals (previously known as COCs).

Section 69502.2(a) of the proposed regulations specifies that a chemical that exhibits a hazard trait or an environmental or toxicological endpoint, and that is listed on one or more of the identified chemical lists, is known as a Candidate Chemical (previously known as COC). The lists are from "authoritative organizations," as defined in Chapter 54.

By relying on other authoritative organizations' work, recommendations, and regulations that support protecting human health or the environment to identify the initial list of Candidate Chemicals (previously known as COCs), DTSC is able to maximize resources and minimize time and costs to California. The Safer Consumer Products programs is "jumpstarted" by starting with a robust initial list of Candidate Chemicals (previously known as COCs) and this approach allows DTSC to immediately begin evaluating consumer products containing COCs (new definition) to create the first Priority Products list.

These lists may have been developed by different organizations and for different purposes, but the deliberative work conducted by these organizations in developing these lists, evaluating the chemicals, and identifying their hazard traits based on a high level of evidence, as well as the ultimate goal—protection of human health and the environment—remains the same as that of the proposed regulations.

The principal criterion that placed these chemical lists together in section 69502.2(a) is that DTSC is accepting the chemical's hazard trait identification by each authoritative organization that is responsible for the chemicals list. The chemicals on these chemicals lists exhibit "strong evidence" criteria for toxicological hazard traits or "evidence" criteria for the exposure potential hazard traits, as specified in Chapter 54. Again, each of these chemicals lists was evaluated and analyzed for conformance with the important scientific and policy principles, and each of them is included as necessary

to effectuate the statutory mandate to advance the search for safer chemicals in consumer products.

DTSC notes that the variations between the various lists could be attributable to a variety of reasons. The authoritative organizations act independently of each other for the most part but have studied many of the same agents. For example, many known or suspected carcinogens appear on IRIS and IARC carcinogens lists. But because an agent appears on one and not on the other does not necessarily mean there is a controversy, as one agency may not have evaluated it as yet. Therefore, many of the substances and exposures on the lists often go by different names, and they may not always use the most common term. This can make it challenging to find a particular substance on one or more lists. DTSC is making no changes to the regulations in response to these comments. Please also see the comments below and the accompanying responses for each of the lists that were the subject of comment.

Comments: 9-75, 9-76, 9-77, 9-78, 9-79, 9-80, 11-37, 49-8, 49-9, 49-10, 57-31 69-27, 69-28, 69-29, 69-30, 74-31, 78-3, 82-3

Comments Summary:

These comments refer to the initial list of chemicals compiled from chemicals listed authoritative organizations' lists identified in section 69502.2(a) and suggest deleting specific lists from the lists in section 69502.2(a), with some comments criticizing certain authoritative organizations. Following are the lists criticized for inclusion and/or suggested for removal:

- Delete Category 1 Endocrine Disruptors list;
- Category 1 Endocrine Disruptors list has been disavowed by European Union;
- Delete IARC Group 2B carcinogens;
- Delete National Toxicology Program (NTP), Office of Health Assessment and Translations (OHAT) Reproductive or Development Toxicants;
- Only include NTP and OHAT monographs indicating high level of evidence;
- Delete Washington State Persistent, Bioaccumulative and Toxic Chemicals (PBTs) list (1)(N);
- Delete OSPAR List;
- Delete Canada’s PBTs list;
- Include Canada’s Chemical of Interest and Chemical Of Concern lists;
- California Environmental Contaminant Biomonitoring Program (CECBP)—only include those chemicals that have been tested by the Centers for Disease Control and Prevention (CDC);

- Add Clean Water Act section 303(d) list; and
- Add Asthmagens and other sensitizers list.

Response:

Please see specific comments below for each of the lists and the accompanying responses.

§ 69502.2(a)(1)(A) Proposition 65

Comments: 49-7, 57-33

Comments Summary:

These comments refer to DTSC's approach of compiling the chemicals listed on authoritative organizations' lists identified in section 69502.2(a) for the initial list of Candidate Chemicals (previously known as COCs), and state that there is neither consistency nor continuity among the source lists and sometimes within them. Specifically, Proposition 65 listing methods and underlying scientific rigor vary greatly. The comments recommend that DTSC limit listing to chemicals that undergo a scientifically defensible determination under Proposition 65.

Response:

The California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) was enacted as a California ballot initiative in November 1986 and was intended by its authors to protect California citizens and the state's drinking water sources from chemicals known to cause cancer, birth defects, or other reproductive harm, and to inform citizens about exposures to such chemicals.

OEHHA is a constituent entity within the California Environmental Protection Agency (Cal/EPA) with responsibility for evaluating public health and environmental risks from chemicals. Proposition 65 is an enforceable, regulatory program implemented by OEHHA as the lead agency appointed by the Governor.

Proposition 65 protects the public from carcinogens and reproductive toxins by requiring businesses to warn Californians about significant amounts of chemicals in the products they purchase, in their homes or workplaces, or that are released into the environment. By providing this information, Proposition 65 enables Californians to make informed decisions about protecting themselves from exposure to these chemicals. Proposition 65 also prohibits California businesses from knowingly discharging significant amounts of listed chemicals into sources of drinking water.

OEHHA administers the Proposition 65 program and each year publishes an updated list of chemicals that are “Proposition 65 chemicals.” As explained in detail in the ISOR, there are four principal mechanisms by which chemicals that exhibit carcinogenic, developmental and/or reproductive toxicity are added to the Proposition 65 list:

1. State’s qualified experts committees decide that a chemical has been clearly shown to cause cancer or reproductive toxicity;
2. Chemical has been formally identified as a carcinogen or reproductive toxicant by a body considered authoritative under Proposition 65;
3. State or federal agency formally requires a chemical to be identified or labeled as a carcinogen or reproductive toxicant ; and
4. Listed if it is identified by reference in Labor Code section 6382(b)(1) or (d).

These listing and delisting processes are excluded from the requirements of the APA by Health and Safety Code section 25249.8(e). However, it is important to note that each listing procedure involves, at a minimum, public notice that chemicals are under consideration, solicitation of comments, deliberation on comments received, and notice of the final decision. More importantly, each of the listing mechanisms is grounded in scientific rigor and each of the Proposition 65 listing mechanisms is of equal dignity as the others. That is, regardless of the mechanism used to place a chemical on the Proposition 65 list, once it is on the list all of the legal obligations related to a chemical are the same. Proposition 65 makes no distinction between listing mechanisms in terms of consequences, nor should DTSC. DTSC is making no changes to the proposed regulations in response to these comments. Please also refer to responses below for other lists.

§ 69502.2(a)(1)(C) Category 1 Endocrine Disruptors

Comments: 9-75, 9-76, 49-10, 57-31, 65-2, 69-27, 69-29, 74-31, 95-3, 101-22, 101-23, 107-39

Comments Summary:

These commenters refer to the European Commission’s Category 1 endocrine disruptors list (section 69502.2(a) (1)(C), and the central theme of these comments is that the report cited in the proposed regulations was intended as a screening exercise and therefore it should not be included. Specific remarks and suggestions by these commenters were:

- This report was prepared by a consultant for the European Commission and explicitly states that the report was intended as "a first step towards the

establishment, by the Commission, of a priority list of substances for further evaluation of their role in endocrine disruption;

- The list was disavowed by the European Union and should be deleted, as endocrine-mediated effects have already been captured by other lists selected by DTSC;
- The list does not meet the "endocrine disruptors" definition of the World Health Organization (WHO);
- Endocrine disruption is nascent science, and most importantly, the potential to interact with the endocrine system does not necessarily constitute a health risk;
- The list does not meet the authoritative body criteria of being a deliberative scientific process with stakeholder input; and
- Limiting the listing of some of the possible endocrine disrupting chemicals to those produced in amount exceeding 1,000 tons per year is unnecessarily permissive. Very low concentrations of endocrine-impacting chemicals also pose serious risks, so this large volume trigger in the classification is unjustified on public health grounds.

Response:

DTSC agrees with the comment that the reference listed in section 69502.2(a)(1)(C) of the proposed regulations refers to the very first report by BKH Consulting Engineers (Delft, the Netherlands) dated November 2000.

BKH Consulting Engineers was commissioned by European Commission Directorate General of Environment (DG ENV) to conduct a study on endocrine disruption. This was the first step towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption by the European Commission.

This first report has been superseded by subsequent chemical evaluations and reports. In direct contradiction with the comment referring to European Union's rejection of the endocrine disruptors list, several studies have been conducted since the first screening. A total of 428 (out of 588) candidate chemical substances with endocrine disruptor effects have been evaluated. 158 substances were not evaluated because they were mixtures, duplicates, or there was no data. The chemicals evaluated have been categorized as follows:

Category 1:
194 substances categorized as Category 1 endocrine disruptors with at least one *in vivo* study providing clear evidence for endocrine disruption in an intact organism.

Category 2:
125 substances categorized as Category 2 endocrine disruptors with potential for endocrine disruption based on:

- *In vitro* data indicating potential for endocrine disruption in intact organisms; and
- Effects *in vivo* that may, or may not, be endocrine disruption-mediated

Category 3a:
No scientific basis for inclusion on list because although there are endocrine disruption studies available, there is no indication of endocrine disruption effects.

Category 3b:
109 substances with insufficient data or no data at all

Further, Article 59 of European Commission's regulation, (EC) 1907/2006, states that by June 1, 2013, the commission shall carry out a review, taking into account latest scientific knowledge, and assess whether or not to subject substances identified as endocrine disruptors to Authorizations, the next step for Candidate Chemicals in the European Union's REACH Program.

In response to comments from the European Union and to rectify the inadvertent omission of "Category 1" from the reference for the list of endocrine disruptors, section 69502.2(a)(1)(C) of the proposed regulations has been revised as follows: "*Chemicals included as Category 1 endocrine disruptors by the European Commission in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006."*

The European Commission defines endocrine disruptor as follows: "Endocrine disruptor is an exogenous substance that causes adverse health effects in an intact organism, or its progeny, secondary to changes in endocrine function"; and a potential endocrine disruptor is defined as follows: "A potential endocrine disruptor is a substance that possesses properties that might be expected to lead to endocrine disruption in an intact organism."

This is comparable to the WHO's definition: "'Endocrine disruptor' is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations."

The endocrine system is important for the control and regulation of all the major functions and processes of the body. A similar endocrine system to that of humans is found in nearly all vertebrates including other mammals, fish, amphibians, reptiles, and birds, although the precise structures and roles of the various organs and hormones differ between different groups. Invertebrates such as mollusks, crustaceans, and insects also have endocrine systems that control a similar range of body functions, although markedly different from those of vertebrates. Endocrine disruption activity acts as evidence of a hazard trait.

The main focus has been on disruption to those hormones that play a major role in the control of reproduction and development due to a series of observations in both humans and wildlife. However, endocrine disruptors also influence the immune system and general metabolism as well as affecting reproduction and sexual behavior, fetal differentiation and development, and maturation.

Research into endocrine disrupting effects from chemicals is rapidly evolving and shows that endocrine disruptors may pose the greatest risk during prenatal and early postnatal development when organ and neural systems are forming. Recently, research has indicated that some chemicals may disrupt thyroid function, with concerns focusing particularly on the role of the thyroid in the developmental process and there is some evidence that known endocrine disruptors may cause neurotoxicity.

DTSC disagrees with the comment that endocrine disruption is a nascent science; in fact, this is far from true. Although endocrine disruption has been disputed, research on the topic continues to evolve. Work sessions from 1992 to 1999 have generated consensus statements from scientists regarding the hazard from endocrine disruptors, particularly in wildlife and also in humans. Even the ancients were familiar with the actions of various herbal preparations to modulate what we *now* know to be hormonally regulated processes. For centuries, farmers have observed reproductive problems in female sheep and cows grazing on pastures rich in certain clover species, which later were found to contain estrogenic compounds such as coumestrol.

For the reasons stated above, DTSC declines to remove the endocrine disruptors list from the proposed regulations.

§ 69502.2(a)(1)(E) IRIS Carcinogens

Comments: 57-32, 57-33

Comments Summary:

These comments state that IRIS and IARC define carcinogenicity differently, especially with respect to their treatment of evidence of carcinogenicity in animals, and it is unclear which list would be given precedence and why.

Response:

DTSC notes that US EPA's IRIS and IARC carcinogens are included in the initial list of Candidate Chemicals (previously known as COCs). The purpose and procedures of each authoritative organization may be different, but the goal remains the same—to protect human health and the environment.

Government and private entities use IRIS, combined with specific exposure information, to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains data on over 540 chemical substances, approximately 90 of these are carcinogens characterized as follows:

A = Human carcinogen;
B1 = Probable human carcinogen (limited evidence in humans);
B2 = Probable human carcinogen (sufficient evidence in animals);
C = Possible human carcinogen;
D = Not classifiable as carcinogenic to humans (inadequate information); and
E = Evidence of non-carcinogenicity for humans.

As expressed in the comment, IRIS has further subdivided the group of "probable carcinogens" in two subcategories based on data in animals:

- B1(Probable human carcinogen) based on limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in animals; and
- B2 (Probable human carcinogen) based on sufficient evidence of carcinogenicity in animals.

DTSC will not give precedence to any one list over another. More often than not, chemicals listed as IARC Group 2A (probably carcinogenic to humans) are also identified as IRIS B1 or B2 carcinogens. However, there are few chemicals that are unique to each list. The variations between these two lists could be attributable to a variety of reasons. The authoritative organizations act independently of each other, for the most part, and the focus of study and evaluation may be different.

For example: Aniline with CAS RN 62-53-3 is listed by IRIS as Group B2 (Probable human carcinogen) and IARC identifies Aniline as a Group 3 carcinogen. In this

instance, IRIS identifies it as a probable human carcinogen based on sufficient evidence of carcinogenicity in animals; whereas, IARC identifies the same chemical as Group 3 *(not classifiable as to its carcinogenicity to humans)* carcinogen. Group 3 is not a determination of non-carcinogenicity or overall safety; it often means that further research is needed, especially when exposures are widespread or the cancer data are consistent with differing interpretations. Exceptionally, agents for which the evidence of carcinogenicity is *inadequate* in humans but *sufficient* in experimental animals may be placed in this category, and also agents that do not fall into any other group are also placed in this category.

Thus, IRIS classifications are very comparable to IARC classifications of carcinogens considering that two different organizations evaluated the chemical. Aniline will be included in the list of Candidate Chemicals (previously known as COCs) as an IRIS, Group B2 (probable human carcinogen).

The proposed regulations only include chemicals that meet the "strong evidence" criteria for toxicological hazard traits or "evidence" criteria for the exposure potential hazard traits, as specified in Chapter 54. Thus, only IRIS Group A, Group B1, and Group B2 carcinogens are included in section 69502.2(a)(1)(E). From IARC, only Group 1, Group 2A, and Group 2B carcinogens are included in section 69502.2(a)(1)(I).

Please also see the Response to Comment 57-32 under Initial Candidate Chemicals List. DTSC is making no changes to the proposed regulations in response to these comments.

§ 69502.2(a)(1)(H) Canada's List of PBiT Chemicals

Comments: 49-9, 49-10, 57-31, 74-31, 76-41, 107-40

Comments Summary:

These comments express concern that Canada's prioritization list of potential PBiT compounds is mostly based on modeling and completed in 2007, and suggest Canada's Chemical of Interest and Chemicals of Concern list should be adopted instead. Another suggestion is to include Schedule 1 list as it includes both existing and new substances used in commerce.

Response:

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) required that all 23,000

of the Domestic Substances List be sorted or "categorized" to determine which need further attention. Using information from Canadian industry, academic research and other countries, scientists with the Canadian government worked with partners in applying a set of rigorous tools to the 23,000 chemical substances on the Domestic Substances List. In September 2006, Canada completed this scientific evaluation and the information is being used to focus on those chemical substances of highest priority.

The results of categorization indicated that 397 substances on the Domestic Substances List are persistent, bioaccumulative and inherently toxic (PBiT) to non-human organisms, according to the categorization criteria.

The proposed conclusion of the draft screening assessment was that the 148 PBiT substances are currently not entering, or likely to enter, the environment as a result of commercial activity *in Canada*. However, given the hazardous PBiT properties of these substances, there is concern that new activities for the above 148 substances which have not been identified or assessed under Canadian Environment Protection Act (CEPA) 1999 could lead to the substances meeting the criteria set out in section 64 of the CEPA for toxicity. Therefore, it was recommended that the 148 substances be subject to the Significant New Activity provisions specified under subsection 81(3) of the Act to ensure that any new manufacture, import, or use of any of these substances in quantities greater than 100 kg/year is notified and will undergo ecological and human health risk assessments, prior to the substance being introduced into Canada.

It is important to note that although some of the chemicals were of no interest to industry in Canada, Environment Canada suggested the Significant New Activity provisions, given the hazardous PBiT properties of these substances. For all these reasons, the substances listed as PBiTs by Environment Canada have been included in the initial list of Candidate Chemicals (previously known as COCs), in section 69502.2(a) of the proposed regulations.

Schedule 1 is one of the regulations under CEPA 1999 that allows the Government of Canada to protect the environment and human health and establishes strict time lines for managing substances found toxic under the Act. The Schedule 1 list only includes substances that are determined to be "toxic" under CEPA 1999. Preventive or control actions such as regulations, guidelines, or codes of practice are then considered for any aspect of the substance's life cycle from the research and development stage through manufacture, use, storage, transport, and ultimate disposal or recycling.

Section 69502.2(a)(H) lists chemicals identified as persistent, bioaccumulative and

inherently toxic (PBiT) to the environment by CEPA Environmental Registry. Many of the persistence and bioaccumulation calculations are estimated because of uncertainty of calculations and recognition that chemicals can biomagnify to a considerable extent if released in substantial amounts over an extended period of time even with modest bioconcentration factors.

Therefore, DTSC respectfully declines to include the suggested list in the proposed regulations. Commenters may petition DTSC to add the list pursuant to Article 4 during implementation of the proposed regulations. DTSC is making no changes to the regulations in response to these comments.

§ 69502.2(a)(1)(I) List of Respiratory Sensitizers

Comments: 30-3, 36-8, 36-9, 39-21, 91-1, 138-12

Comments Summary:

These comments refer to the initial list of Candidate Chemicals (previously known as COCs) compiled from chemicals listed on authoritative organizations' lists identified in section 69502.2(a) and suggest that DTSC should augment the list with substances of particular relevance to workers and consumers. Specific remarks and concerns expressed by these commenters include all of the following:

- Chemicals that cause sensitization should be part of the list;
- Add one or more of the authoritative list of asthmagens to the foundational documents for the Chemicals of Concern;
- Current Chemical of Concern list is a good start, but it needs to be expanded to be as protective as possible for nail salon and other workers and consumers; and
- Augment the list with substances of particular relevance to workers and consumers—asthmagens, respiratory sensitizers, and skin irritants/sensitizers.

The above commenters refer to OEHHA's list of hazard traits (Chapter 54) and US Hazard Communication Standard for respiratory toxicity to support the suggestion to add one or more of the following lists of asthmagens, respiratory sensitizers, and skin irritants/sensitizers to section 69502.2(a) of the proposed regulations for initial list of Candidate Chemicals (previously known as COCs):

- National Institute for Occupational Safety and Health (NIOSH) information about skin irritants and sensitizers;
- Association of Occupational and Environmental Clinics (AOEC);

- European Chemical Substance Information System, Table 3.1, search for H317 Skin sensitizer Cat 1 and H34 Respiratory sensitizer Cat 1; and
- Green Screen Supporting Lists.

Response:

In response to these comments, proposed regulations section 69502.2(a)(1)(I) (January 2013) includes the list of chemicals identified as Respiratory sensitizers Category 1 in Annex VI to Regulation (EC) No 1272/2008).

DTSC reviewed all of the other suggested lists and our findings are summarized as follows:

- NIOSH does not include a list of skin sensitizers or irritants. It has all the information on skin sensitizers and their effects. This will serve as an excellent resource during implementation;
- The AOEC lists a total of 433 asthmagens and respiratory sensitizers. However, the AOEC is a non-profit organization that encourages open access to the information and resources it has developed. The AOEC Exposure Code List includes a wide range of exposures including not only chemicals but exposures to metals, dusts, plants, animals, etc., as well as physical hazards (*e.g.*, falls, lifting, repetitive strains, etc.). Neither the AOEC exposure code list nor the asthmagens designations are considered an official document of any governmental agency; and
- Clean Production's Green Screen v1.2 Supporting Lists is actually a list of chemicals for different hazard traits, categorized as screening lists or authoritative lists.

Proposed regulations are protective of workers—specifically, section 69501.1(a)(6) "adverse public health impacts" definition includes *occupational health* to address the workplace exposures that may be considered the cause of illness and disease. Therefore, section 69501.1(a)(58) defines "sensitive subpopulations" to identify subgroups that are at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait or toxicological endpoint. This definition also includes those individuals who have a greater risk of adverse health effects because of a serious illness <u>or due to the nature of their occupation</u> (emphasis added).

The proposed regulations include the list of chemicals identified by the European Union as Category 1 respiratory sensitizers in section 69502.2(a)(I) (January 2013).

§ 69502.2(a)(1)(J) IARC Group 2B Carcinogens

Comments: 9-77, 9-78, 49-10, 57-31, 57-32, 57-33, 69-27, 69-28, 74-31, 107-41

Comments Summary:

These comments state that the IARC Group 2B carcinogens is a list of substances with limited human evidence and insufficient animal evidence of carcinogenicity. Also, concern was expressed that there are number of issues when evaluating chemicals with limited evidence of carcinogenicity, and it was suggest that IARC Group 2B classification should be removed.

Response:

DTSC acknowledges these comments but respectfully declines to make any changes to the proposed regulations.

IARC is part of the World Health Organization. IARC's mission is to coordinate and conduct research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer prevention and control. Public health agencies use this information as scientific support for their actions to prevent exposure to carcinogens and agents that may be carcinogens. The objective of the program is to prepare, with the help of international Working Groups of experts, and to publish in the form of *Monographs*, critical reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures.

Interdisciplinary working groups of expert scientists review the published studies and evaluate the weight of the evidence that an agent can increase the risk of cancer. The principles, procedures, and scientific criteria that guide the evaluations are described in the Preamble to the *IARC Monographs.*

Since 1971, IARC has evaluated more than 900 agents and characterized as:

Group 1 = carcinogenic to humans;
Group 2A = probably carcinogenic to humans;
Group 2B = possibly carcinogenic to humans;
Group 3 = not classifiable as carcinogenic to humans (inadequate information); and
Group 4 = probably not carcinogenic to humans.

As explained in the ISOR, Group 2 category includes agents for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost sufficient, as well as those for which, at the other extreme, there is no human data but for which there is

evidence of carcinogenicity in experimental animals. Agents are assigned to either Group 2A (probably carcinogenic to humans) or Group 2B (possibly carcinogenic to humans) on the basis of epidemiological and experimental evidence of carcinogenicity and mechanistic and other relevant data. The terms "probably carcinogenic" and "possibly carcinogenic" have no quantitative significance and are used simply as descriptors of different levels of evidence of human carcinogenicity, with "probably carcinogenic" signifying a higher level of evidence than "possibly carcinogenic."

IARC also classifies "evidence" into four categories:

i) *Sufficient evidence of carcinogenicity;*
ii) *Limited evidence of carcinogenicity;*
iii) *Inadequate evidence of carcinogenicity; and*
iv) *Evidence showing lack of carcinogenicity* .

Group 2B category is used for chemicals when:

- There is *limited evidence* of carcinogenicity in humans and *less than sufficient evidence* of carcinogenicity in experimental animals; or
- There is *Inadequate evidence* of carcinogenicity in humans but *sufficient evidence* of carcinogenicity in experimental animals; or
- There is *Inadequate evidence* of carcinogenicity in humans and *less than sufficient evidence* of carcinogenicity in experimental animals; together with supporting evidence from mechanistic data and other relevant data; or
- Strong evidence from mechanistic data and other relevant data.

IARC is continually evaluating chemicals for carcinogenicity and reflecting updated evaluations through the monographs that are made available. It is important to note that as new information or studies become available, the conclusion regarding a chemical's characterization (grouping) may change.

As specified in Chapter 54, meeting IARC criteria for Group 1, 2A, and 2B classification constitutes strong evidence of carcinogenicity for a given chemical substance. For reasons stated above, DTSC is making no changes to the regulations in response to these comments.

§ 69502.2(a)(1)(L) NTP Reproductive or Development Toxicants

Comments: 9-79, 9-80, 49-10, 57-31, 69-27, 69-30, 74-31, 107-42

Comments Summary:

These commenters state that the NTP, OHAT reproductive or development toxicants lists are inappropriate for the purposes of qualifying COCs. Specifically, OHAT monographs classify chemicals based on the weight of evidence on adverse effects expressed on a seven-part scale, and the agency's concern that a chemical is associated with various effects expressed on a five-part scale.

These commenters recommend that the list of reproductive or development toxicants from OHAT be removed from the list of list. Alternatively, these commenters suggest that only NTP monographs indicating high level of evidence and concern be considered for adding to the COCs list.

Response:

DTSC acknowledges these comments but respectfully declines to make any changes to the proposed regulations.

Section 69502.2(a)(1)(L) specifies that reproductive or developmental toxicants identified in Monographs on the Potential Human Reproductive and Developmental Effects (2003 - 2008), NTP, Office of Health Assessment and Translation (formerly the Center for the Evaluation of Risks to Human Reproduction) are Candidate Chemicals (previously known as COCs).

The NTP is an interagency program managed by the US Department of Health and Human Services (DHHS) whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The NTP and the National Institute of Environmental Health Sciences established the NTP Office of Health Assessment and Translation (OHAT) to serve as an environmental health resource to the public and to regulatory and health agencies for policy and risk management decisions.

The NTP provides toxicological evaluation on substances of public health concern to provide a scientifically-based, uniform assessment of the evidence for reproductive and developmental toxicity of man-made or naturally occurring chemicals or chemical mixtures. Nominations of chemicals to be evaluated come through solicitations from the public and scientific communities, including industry, federal, state, and local governments, academia, environmental groups, citizens, and workers.

OHAT conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. The OHAT

assessments are published as NTP monographs. OHAT considers the weight of evidence from human and experimental animal data separately and uses the following levels of evidence criteria for individual study (which is different from the seven-part scale for hazard identification that was used by CERHR):

- Clear evidence of toxicity;
- Some evidence of toxicity;
- Equivocal evidence of toxicity;
- No evidence of toxicity; and
- Inadequate study.

And, as expressed by the comment, a five category scale for levels of conclusions as shown below:

- Serious concern for adverse effect;
- Concern for adverse effect;
- Some concern for adverse effect;
- Minimal concern for adverse effect; and
- Negligible concern for adverse effect.

All OHAT evaluations follow a similar process with opportunities for external scientific review, public review, and interagency input. Draft monographs are released for public comment and peer reviewed either by a peer review panel (federally chartered advisory group) or by ad-hoc reviewers. Peer review information is then presented to NTP Board of Counselors before final monographs are published.

As specified in Chapter 54, meeting NTP criteria as having clear or sufficient evidence of adverse effects for reproductive and for developmental toxicity constitutes strong evidence of carcinogenicity for a given chemical substance. For the reasons stated above, DTSC is making no changes to the regulations in response to these comments.

§ 69502.2(a)(1)(N) Washington State PBT List

Comments: 11-37, 49-8, 49-9, 65-2, 107-43

Comments Summary:

These commenters state that Washington State's PBT list does not use criteria consistent with the US EPA PBT list (section 69502.2(a)(1)(K)). Further, the provisions for management of the Washington State's list are not clear.

Response:

DTSC disagrees. Washington State Department of Ecology (Ecology) meets the foundational definition of "authoritative bodies" in Health and Safety Code section 25252(b), as well as the definition of "authoritative organizations" in Chapter 54.

Ecology published "Strategy to Reduce PBTs" in December 2000 and worked with an advisory committee to publish the "PBT Rule" with input from the public in January 2006. Ecology's PBT rule includes the PBT criteria and a list of PBTs that meet these criteria, as well as procedures to periodically update the list. The Washington PBT list contains 17 chemicals, eight (8) chemical groups, and two (2) metals that were identified using the categorization criteria, as explained in the ISOR and described below:

Persistence: Half-life of the chemical in water, soil and sediments is = or > 60 days

Bioaccumulation: The bioconcentration factor (BCF) in aquatic species for the chemical is > 1,000 or log-octanol water partition coefficient (log Kow) is > 5;

Toxicity: The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on:

- The chemical (or chemical group) is carcinogen, a developmental or reproductive toxicant or a neurotoxicant;
- Reference dose or equivalent toxicity measure is < 0.003 mg/kg/day;
- Chronic No Observed Effect Concentration (NOEC) or equivalent toxicity measure is < 0.1 mg/L;
- Acute NOEC or equivalent toxicity measure that is < 1.0 mg/L; or
- Metal that it is likely to be present in forms that are bioavailable.

Section 69502.2(a)(1)(K) specifies the PBT Chemicals identified by the US EPA National Waste Minimization Program.

US EPA established the National Waste Minimization Program (NWM), which supports efforts to promote a more sustainable society, reduce the amount of waste generated, and lower the toxicity and persistence of wastes that are generated. The NWM established a list of Priority Chemicals (PCs), which consists of 28 organic chemicals and chemical compounds and three (3) metals and metal compounds. Based on its review, EPA concluded that the chemicals are persistent, bioaccumulative, and toxic (PBTs).

The NWM Program is voluntary in nature and US EPA is focusing its waste minimization efforts on the 31 PCs identified here. In addition, US EPA remains receptive to any waste minimization efforts, including efforts to address chemicals other than, or in addition to, these PCs. US EPA will rely on close cooperation with its regulatory partners to carry out these shared priorities and will need their input to ensure that local and regional PBT problems are adequately addressed.

The comparison of Washington State's criteria for persistence and bioaccumulation to those used by US EPA is as shown below:

Table 2-1. Comparison of Washington State and US EPA PBT Criteria

PBT Criteria	Washington State	US EPA NWM
Persistent: Half-life in water, soil, and sediment	Half-life >= 2 months (>= 60 days)	Half-life >= 2 months (>= 60 days)
Very Persistent: Half-life in water, soil, and sediment	--	Half-life > 6 months (> 180 days)
Bioaccumulative: Bioconcentration factor (BCF) Log-octanol water partition coefficient (log Kow)	BCF = 1,000 or (log Kow) = > 5	BCF = 1,000 and < 5,000

US EPA also includes criteria for very persistent chemicals and toxicity is identified based on a chemicals chronic toxicity to fish using criteria developed in US EPA's New Chemical Program as follows:

Table 2-2. US EPA's Criteria for Very Persistent Chemicals

Toxicity	Low Concern	Moderate Concern	High Concern
Fish ChV (mg/L)	> 10 mg/L	0.1 mg/L - 10 mg/L	< 0.1 mg/L

Ecology's PBT initiative focuses on one toxic substance at a time to prepare and implement Chemical Action Plans. The Chemical Action Plan is developed in collaboration with other agencies and experts representing various business, agricultural, and advocacy sectors. The Chemical Action Plan is not legislation or a rule but a comprehensive plan to protect human health and the environment that identifies, characterizes, and evaluates all uses and releases of a specific PBT, a group of PBTs, or metals of concern. The Chemical Action Plan recommends actions to reduce and/or phase out PBTs, conduct ambient monitoring or biomonitoring to inform decision-making, and encourage voluntary measures to reduce and/or phase out PBT uses.

Some of the Chemical Action Plan recommendations may lead to new legislation or rules and those would go through the normal legislative or rulemaking process. DTSC is making no changes to the regulations in response to these comments.

§ 69502.2(a)(2)(D) Priority Toxic Pollutants in Water Quality Control Plans

Comments: 26-2, 26-3, 36-9, 36-10, 36-38, 45-2, 53-1, 114-9, 118-1, 118-4, 121-1, 126-2, PH19-1, PH21-1, PH24-4, PH32-2, PH32-4

Comments Summary:

These commenters state that the initial list of COCs (now known as Candidate Chemicals list) does not include the list of impaired waterways from priority pollutants developed by Water Boards under section 303(d) of the Clean Water Act, which lays out the state's priority water pollution problems. The concerns expressed include a central theme—"include both 303(c) pollutants and 303(d) pollutants in the list of Candidate Chemicals (previously known as COCs).

Response:

In response to these comments, DTSC has revised the proposed regulations to include the pollutants listed under section 303(d) of the Clean Water Act in section 69502.2(a)(2)(D).

Federal Clean Water Act section 303(d) requires that the Water Boards assess water quality data for California's waters every two years to determine if they contain pollutants in excess of water quality standards. The resulting list is based on actual water quality data and sets forth California's highest water quality priorities.

The list is consistent with the chemical list criteria.as explained in ISOR. As specified in section 69502.3(a), DTSC will periodically update the COCs list (now known as Candidate Chemicals list), as the source lists are updated, using the procedures specified in subsections (c) and (d) and in compliance with the APA to the extent applicable.

§ 69502.2(a)(2)(F) California Biomonitoring Program

Comments: 49-10, 57-31, 74-31, 107-44

Comments Summary:

These commenters refer to the Priority Chemicals List of the CECBP and state that this program is in early stages with little completed testing. It is suggested that DTSC should not consider listed chemicals in this program that are beyond the scope of the US Centers for Disease Control and Prevention (CDC) Biomonitoring program, as they have yet to be studied as those having "exposure information."

Response:

DTSC respectfully disagrees. The purpose of the CECBP is to:

- Determine levels of environmental chemicals in a representative sample of Californians;
- Establish trends in the levels of these chemicals over time; and
- Help assess the effectiveness of public health efforts and regulatory programs to decrease exposures to specific chemicals.

The selection of priority chemicals is a two-step process. The first step is to identify "designated chemicals"—those chemicals that should be considered for biomonitoring. The enabling legislation (Senate Bill 1379, Perata, Chapter 599, Stats. 2006) identified as the initial set of designated chemicals roughly 300 chemicals currently biomonitored by the CDC. Additional designated chemicals were recommended by the Scientific Guidance Panel for inclusion in the program as designated chemicals.

The Priority Chemicals selected for the CECBP include those designated chemicals for which there is a concern that humans are being exposed to harmful chemicals and causing a health risk or toxicological endpoint.

As explained in the ISOR, one of the factors considered by DTSC in selecting a list is whether the chemical list adds value to the initial COCs List (now known as Candidate Chemicals list); that is, the given chemical list does not excessively duplicate chemicals that are already named by other chemical lists. If DTSC were to include only those chemicals tested under CDC program, then the CECBP list would be a redundant list.

CECBP adds significant value to the national biomonitoring efforts by providing information on chemicals of particular concern in California and by studying diverse populations in the state. The program has continued to make great progress, and it has developed laboratory capacity and infrastructure to analyze more than 100 different chemicals, and has tested over 700 samples of California residents. Therefore, it is important to retain this list of Priority Chemicals from CECBP in the proposed regulations for California's Safer Consumer Product Program. DTSC is making no changes to the regulations in response to these comments.

§ 69502.2(a)(2)(H) OSPAR List

Comments: 11-37, 49-7, 49-8, 49-9, 49-10, 57-31, 65-2, 74-31, 107-45

Comments Summary:

These comments refer to the Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) List of Chemicals for Priority Action and recommend that this list should be dropped from the proposed regulations, expressing concerns as follows:

- Not an authoritative list;
- Does not meet the authoritative body criteria of being a deliberative scientific process with stakeholder input;
- OSPAR is no longer maintaining that list, and it did not meet reasonable criteria as an expert organization in the first place;
- Provisions for its management are not clear, and this raises a concern regarding the subordination of California regulation to scientific standards that may not be as rigorous as those that would be imposed within the state;
- Lists considered initially should be restricted to those which are clearly established forums of national and international renown, recognized as centers of scientific expertise in their respective areas—OSPAR nor the Washington State lists would seem to fit; and
- Initial compilation of OSPAR list did not include a deliberative scientific process or opportunity for stakeholder input.

Response:

Section 69502.2(a)(2)(H) species the Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) List of Chemicals for Priority Action.

OSPAR is the mechanism by which fifteen governments of the western coasts and catchments of Europe, together with the European Commission, cooperate to protect the marine environment of the North-East Atlantic. It started in 1972 with the Oslo Convention against dumping. It was broadened to cover land-based sources and the offshore industry by the Paris Convention of 1974. These two conventions were unified, up-dated, and extended by the 1992 OSPAR Convention. The new annex on biodiversity and ecosystems was adopted in 1998 to cover non-polluting human activities that can adversely affect the sea. The fifteen governments referred to as “Contracting Parties” include Belgium, Denmark, Finland France, Germany, Iceland

Ireland Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and United Kingdom.

Work to implement the OSPAR Commission and its strategies is undertaken through the adoption of decisions, which are legally binding on the Contracting Parties, recommendations, and other agreements. Decisions and recommendations set out actions to be taken by the Contracting Parties. The OSPAR Commission also issues publications comprising background documents and data reports on the issues covered by each strategy, and the results of evaluations and assessments of data are reported to OSPAR by the Contracting Parties. OSPAR works primarily through the resources of the Contracting Parties, to examine the background to new issues, to develop proposals for the actions and measures to be taken by OSPAR, and to prepare assessments on the effectiveness of its work.

Health and Safety Code section 25252(b)(2) requires DTSC to use "to the maximum extent feasible, available information from other authoritative bodies, *i.e.*, 'organizations,' that have undertaken similar chemical prioritization processes." As explained in the ISOR, DTSC relies on this foundational requirement and on other authoritative organizations' scientific work, recommendations, and regulations that support protecting human health or the environment to identify the initial list of Candidate Chemicals (previously known COCs). It is important to note that all of the chemicals on the lists meet "strong evidence" criteria for toxicological hazard traits or "evidence" criteria for the exposure potential hazard traits, as specified in Chapter 54 and the chemical lists are reviewed and updated periodically.

The OSPAR Commission meets the definition of "authoritative organization" and the OSPAR List of Chemicals for Priority Action was revised in 2011 (reference number 2004-12). There are currently 42 substances or groups of substances on the List of Chemicals for Priority Action, and OSPAR action is focused on the substances on Part A of the list. For each of these substances or groups of substances, a background document has been prepared which describes the information to be collected in order to monitor progress towards the cessation target. OSPAR has adopted monitoring strategies for the hazardous substances for which background documents have been prepared.

Chemicals are included on the lists because there is evidence, as scientifically evaluated and vetted by authoritative bodies, that they exhibit a hazard trait. By relying on other authoritative organizations' work, recommendations, and regulations that support protecting human health or the environment to identify the initial list of COCs

(now known as Candidate Chemicals list), DTSC is able to maximize resources, while minimizing time and costs to California.

The list of Candidate Chemicals (previously known as COCs) is not an “un-appealable” list—please see discussion under section 69502.2(b) Additions to the Candidate Chemicals. DTSC is intently focused on our mission to protect California's people and environment and is highly motivated and committed to make the regulations work efficiently and effectively. There will be no changes to the regulations in response to these comments.

§ 69502.2(b) Additions to the Chemicals of Concern List

Comments: 138-19, 138-20

Comment Summary:

These comments state that it is appropriate for DTSC to have the responsibility to identify other substances that should be on the Chemicals of Concern list. The commenter also expresses a concern regarding unavailability of information on sales, use, and monitoring data. Widespread adverse impacts may be difficult to determine, and the commenter provides sources of information that could be used during implementation, and suggests working with California Division of Occupational Safety and Health (Cal/OSHA).

Response:

DTSC acknowledges the support and welcomes the opportunity to work with California Division of Occupational Safety and Health. Lack of accurate information would be a problem; however, the proposed regulations has information gathering provisions (section 69501.4) related to the technical and scientific criteria set out in the authorizing statute that DTSC is required to consider in identifying and prioritizing Candidate Chemicals (previously known as COCs) and Priority Products. DTSC has the ability to fill data gaps regarding chemical use, safety, and environmental impacts. Accordingly, DTSC is not making any changes to the proposed regulations in response to this comment.

Comments: 5-68, 7-3, 11-38, 24-2, 41-13, 47-11, 57-38, 59-12 73-2, 86-18, 86-19 107-37, 107-46

Comment Summary:

These commenters state that there should be more refined and specific requirements

for adding chemicals. Other concerns and suggestions were as follows:

- Provide additional clarity to this process so that it is objective and repeatable if conducted by different sources;
- Clarify whether COCs can be added or deleted based upon comments from stakeholders;
- DTSC needs to specify the types of information or comments that would lead to a removal or addition of a COC;
- The process of using "reliable information" to assess whether a chemical should be added to the "Chemicals of Concern" list should be clarified by incorporating a specific and scientific weight-of-evidence assessment; and
- Moving beyond the commencement of the program, there should be a periodic (and transparent) process by which DTSC identifies a narrowed list of chemicals on the basis of hazard and indicators of exposure.

Response:

DTSC will further clarify the process for adding chemicals to the Chemicals of Concern list.

In order for a chemical to be identified as a Candidate Chemical (previously known as COC), the chemical must exhibit a hazard trait and/or environmental or toxicological endpoints by considering reliable information on the factors specified in section 69502.2(b).

As explained in the ISOR, section 69502.2(b) specifies the process for adding chemicals to the Candidate Chemicals list (previously known as COCs list) to ensure that the list is updated and relevant. It is important to note that DTSC is not required to consider *all* the factors listed in this section, in *every instance,* for a chemical to be identified as a Candidate Chemical (previously known as COC), but DTSC is required to consider at least one factor for which reliable information is available and to consider potential exposures based on reliable information.

"Reliable information" as defined, includes studies, information, or reports conducted by or submitted to a local, state, national, or international government agency. The methods and analyses must be scientifically valid and conducted according to generally accepted principles. This would include monitoring data submitted to or conducted by local, state, or international government agencies that would indicate widespread impacts (January 2013). Section 60503.2(b)(1)(C) has been revised to specify the criteria for determining reliability of the non-scientific information in the proposed regulations (April 2013).

It is Important to note that the sources of information specified in the definition of reliable information (section 69501.1(a)(57) in the January 2013 version of the regulations) are viewed by the scientific community as reliable sources for supporting sound, science-based decisions. DTSC has its own expert scientists and toxicologists on staff and is confident that it has the resources that can evaluate scientific studies, whether a single study or multiple studies, to determine the quality of the study and data and make decisions by balancing science and regulatory goals. Further, any revisions will be made with public comment and stakeholder input, thus providing stakeholders the opportunity to review the proposed changes, for quality, reliability, and reproducibility.

Article 4 specifies the petition process for the addition to or removal of chemicals and products from the Candidate Chemical list and the Priority Products list. Article 4 specifies the type of information necessary to be provided to DTSC, such as information that demonstrates a chemical or product poses a threat and should be evaluated for its potential listing as a Candidate Chemical (previously known as COC) or Priority Product, as well as to remove a chemical. Such information may reflect increased knowledge about or a change in market circumstances with respect to a chemical or product that was original added to either the Candidate Chemical list or the Priority Product list.

DTSC will post an informational list of chemicals identified as Candidate Chemicals (previously known as COCs), under section 69502.2(a), on its website within 30 days of the effective date of these regulations. As specified in section 60502.3(a), DTSC will periodically update this list to reflect changes to the underlying lists and sources from which it is drawn. Proposed revisions will be available for public review and comment along with supporting documentation, including DTSC's rationale for the proposed Candidate Chemicals (previously known as COC). All comments will be considered before the list is finalized and posted on DTSC's website. For these reasons, DTSC is making no changes to the proposed regulations in response to these comments.

Reliable information

Comment: 40-5

Comment Summary:

This comment is related to data quality and states that it is not clear how DTSC will consider the potential variability in data sources. Further, the comment points out that reliability and reproducibility are potentially significant and impacts final assessment

determinations. The suggestion is to consider use Klimisch Score and be consistent with other agencies, including the European Chemicals Agency.

Response:

DTSC notes that the proposed regulations are process regulations. DTSC encourages this type of input, information, and evaluation tools be brought up during the listing process, as it applies to the rationale used in the proposed listing of Candidate Chemicals, Chemical of Concerns, or Priority Products in accordance to the processes in these regulations.

DTSC has clarified the definition of reliable information that includes the comments and suggestions in revised section 69501.1(a)(57) (April 2013 version).

Section 69501.1(a)(57) (April 2013 version) defines “reliable information” to mean a scientific study or other scientific information that meets both of the following criteria:

(A) The study or other scientific information was:

1. Published in a scientifically peer reviewed report or other literature;
2. Published in a report of the United States National Academies;
3. Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or
4. Conducted, developed, submitted, prepared for or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes.

(B) With respect to a scientific study, the study design was appropriate to the hypothesis being tested, and sufficient to support the proposition(s) for which the study is presented to DTSC.

While the definition of “reliable information” does not explicitly contain the comments’ suggested terms, they are included under the umbrella of the references cited. DTSC is making no other changes to the proposed regulations in response to this comment.

Comments: 5-68, 9-15, 24-2, 36-53, 36-54, 36-56, 36-59, 39-23, 39-26, 40-5, 57-36, 72-14, 91-5, 129-7, 138-20

Comments Summary:

These comments are regarding the term “reliable information” in the provisions for adding chemicals to the Candidate Chemicals list (previously known as COCs List)

substantiating the potential exposure or adverse impacts to be considered in section 69502.2(b). The concerns expressed are as follows:

- Current definition of “reliable information” raises concerns, as DTSC is allowed to add to the COC List at any time based on “reliable information”;
- The broad scope and complexity of the regulation is exacerbated by an approach that relies on loosely defined “reliable information” as the basis for listing a Chemical of Concern;
- DTSC should clarify the process of using “reliable information” to assess whether a chemical should be added to the “Chemicals of Concern” list;
- It is not clear how DTSC will consider exposures to chemicals, considering reliable information regarding exposures to the chemical and reliable info demonstrating occurrence of exposures to the chemical;
- The provision works as long as the definition of “reliable information” is clarified, and the use of “cause” instead of “potential” is dealt with; and
- Journal papers by academic researchers should be considered reliable, as academic researchers are often at the forefront of identifying new Chemicals of Concern.

Response:

The definition of “reliable information” has been revised (April 2013). Journal papers published in a scientifically peer reviewed report or other literature are exactly the type of information that DTSC considers reliable. Please refer to the response to comments on the definition of “reliable information” in Article 1. Furthermore, Section 60503.2(b)(1)(C) has been revised to specify the criteria for determining reliability of the non-scientific information in the proposed regulations (April 2013).

The revised proposed regulations (April 2013) section 69502.2(b) requires DTSC to consider “reliable information” for:

- Evaluating the potential for the chemical to contribute to or cause adverse impacts;
- Potential exposures to the chemical; and
- Demonstrating the occurrence or potential occurrence of exposures to the chemical

As explained in the ISOR, any of the scientific studies and other information considered by DTSC must meet one or more of the criteria specified in section 69501.1(a)(57) (April 2013 version) of the proposed regulations to ensure that it is viewed by the scientific community as reliable sources for supporting sound science-based decisions.

DTSC will use reliable sources for scientific studies and information and will evaluate all the "reliable information" obtained from these sources for suitable use in meeting the purpose~~s~~ of these regulations. Reliable information may include, but is not limited to, mechanistic data, environmental monitoring data, and animal or human scientific studies, etc.

It is important to clarify that a responsible entity may have valid scientific studies or other information on animals, humans, or mechanistic data relevant to a chemical that would be important to consider for these regulations but that does not meet the reliable information definition. However, by responding to information requests under section 69501.4, the responsible entity may submit the aforementioned information to DTSC. In so doing, the scientific study or information will meet the first condition for rendering it reliable information—it is "conducted, developed, or submitted" to DTSC. The second condition for rendering such information submitted by responsible parties to be reliable information is dependent on DTSC's acceptance of the scientific studies or information as valid. Thus, responsible entities have the capability of submitting information to DTSC under these regulations and have it regarded as "reliable information" that DTSC may make use of.

"Reliable information demonstrating the occurrence of exposures to a chemical" is a subset of "reliable information" and is necessary to expressly define the types of reliable information that could demonstrate the occurrence of exposures. This definition provides DTSC and responsible entities methods to assess exposures to the chemical of interest. It is important to note that these methods demonstrating exposure must satisfy the definition of "reliable information."

While the mere presence of a chemical in an organism or environmental medium cannot be directly linked to a chemical in a product, the presence of this chemical is indicative of releases from a source. Exposure demonstrated through various monitoring programs, such as chemical presence in an indoor setting may be considered reliable information showing exposure. Other methods include: biomonitoring information, information that is predictive of exposure based on calculations that are described in Article 5 of Chapter 54, or exposure modeling that may be used to determine exposure to a chemical of interest shows that exposure is occurring. Therefore, monitoring data related to wastewater or storm water collection and treatment systems presents evidence of exposure to the public and/or the environment.

Upon acceptance of the scientific study or information, DTSC will evaluate all the reliable information gathered or received to determine the appropriate course of action

to implement these regulations, *i.e.*, whether or not to add a chemical to the list of Candidate Chemicals, (previously known as COCs List). Please also see discussion on Exposures under Article 3 of this document. DTSC is making no changes to the proposed regulations in response to these comments.

Ability vs. Potential

Comment: 41-13

Comment Summary:

This commenter is referring to the use of the word “ability” in place of “potential” compared to an earlier version of the proposed regulations and expresses concern that it is not clear if this is intended to direct DTSC to look at the physiochemical properties of a chemical to make the determination of hazard rather than simply grouping chemicals into categories that might be acceptable.

Response:

DTSC will clarify the use of the term “potential” instead of “ability” in the revised proposed regulations.

In section 69501.1(a)(51) of the proposed regulations (January 2013) “potential” is defined as follows: “‘the phenomenon described is reasonably foreseeable based on reliable information.” As expressed by the commenter, it is intended to direct DTSC to look at the inherent properties of a chemical to make the determination of the chemicals’ potential to contribute to or cause adverse impacts.

The difference between ability and potential is that ability refers to being capable of performing a function and, as the word describes, it is present here and now. Potential, on the other hand, is to become capable of performing a function that has not been tapped into just yet. In the context of the proposed regulations, the ability of a chemical to cause an adverse impact refers to an inherent property of a chemical that is capable of causing an adverse impact. The potential of a chemical to cause an adverse impact refers to the probability that an adverse effect will occur with specific exposure conditions. Thus, a chemical will present the same hazard in all situations due to its innate chemical or physical properties. However, considerable differences may exist in the adverse impacts from a chemical, depending on how the chemical is contained or handled and other conditions that result in or limit exposures and/or adverse impacts. Therefore, the term “potential” has been used instead of “ability” in the revised proposed regulations.

As described in detail in section 69502.2(b) of the ISOR, the proposed regulations require DTSC to consider one or more of the following factors in order to evaluate the potential of any chemical to contribute to or cause adverse public health and/or environmental impacts using reliable information:

1. Chemical's hazard trait(s) and/or environmental or toxicological endpoint(s);
2. Chemical's aggregate effects;
3. Chemical's cumulative effects with other chemicals with similar hazard traits and/or environmental or toxicological endpoints;
4. Chemical's physicochemical properties;
5. Chemical's environmental fate;
6. Chemical's potential to affect human populations and/or aquatic, avian, or terrestrial animal or plant organisms; and
7. Chemical's potential to degrade, form reaction products, or metabolize into another chemical that exhibits one or more hazard trait and/or toxicological endpoint.

One of the very basic factors in determining whether or not a chemical should be a Candidate Chemical to consider in evaluating adverse impacts is the chemical's hazard trait(s) and/or environmental or toxicological endpoint(s).

Aggregate effects are the chemical's effects resulting from exposure to the same chemical from multiple sources. Whereas, the chemical's cumulative effects, refers to chemical's effects resulting from exposure to other chemicals with similar hazard traits and/or environmental or toxicological endpoints. Both chemical's aggregate effects and cumulative effects are factors to consider in evaluating adverse impacts. Some chemicals may not cause a toxic effect through exposure by itself but combined with other chemical exposures will cause a toxic effect.

Reliable information that relates to the chemical's toxicity profile, physical properties, and its mobility in the environment may be used to evaluate a chemical and its adverse public health and environmental impacts. A chemical's physicochemical properties provide basic information on a chemical and its behavior in manufacture and uses. Therefore, physicochemical properties may be used to some extent as predictive indicators of behavior in humans, wildlife, ecosystem, and the environment. The chemical's environmental fate identifies a chemical's behavior and its exposure potential hazard trait, as defined in Chapter 54. The chemical's potential to affect human populations and/or aquatic, avian, or terrestrial animal or plant organisms is also a consideration in the evaluation of adverse impacts.

The chemical's potential to degrade, form reaction products, or metabolize into another Chemical of Concern or a chemical that exhibits one or more hazard trait and/or toxicological endpoint is a consideration in the evaluation of adverse impacts. This factor is important since not only may chemicals themselves be harmful, but their metabolites, degradation, and reaction products may be as well.

Please also refer to the Response to Comment 41-13 in Article 3 of this Response to Comments document. DTSC is making no change to the proposed regulations in response to this comment.

Delist Chemicals

Comments: 9-54, 101-20

Comments Summary:

These comments pertain to the petition process (Article 4) and ability to delist a chemical from the list of Candidate Chemicals (previously known as COCs). The commenters express concern that delisting is likely to be impossible with the provision limiting petitions to delist any chemical identified by DTSC in these regulations. These commenters suggest that DTSC establish a California list-specific process for delisting chemicals.

Response:

In response to similar comments, DTSC has revised the proposed regulations to provide greater clarity. The revised language in section 69504(b) (January 2013) institutes a more streamlined approach to delist any chemical and/or chemical lists as follows:

- The previous version specified:
  "*A person may not petition the Department to delist any chemical identified as a Chemical of Concern under section 69502.2(a), unless that chemical is no longer listed on any of the lists identified in section 69502.2(a).*"
- Revised section 69504 includes the following criteria for limitations on petitions:
  "1) A person may not petition the Department to delist any chemical identified as a Candidate Chemical under section 69502.2(a), unless that chemical is no longer on any of the lists specified in section 69202.2(a); and
  2) A person may not petition the Department to remove an entire chemicals list from the lists specified in section 69502.2(a) until three (3) years after the effective date of these regulations."

This provision is necessary to preclude a wasteful expenditure of scarce DTSC resources on petitions for removal of chemicals that have been well-established as possessing one or more hazard traits and that are appropriately captured as Candidate Chemicals.

DTSC respectfully declines the suggestion to have a California list-specific process in the regulations for delisting chemicals for the reason stated above. DTSC is making no further changes to the regulations in response to these comments. Please also see Response to Comment 9-54 under Article 4.

§ 69502.2(b)(1) Adverse Impacts

Comment: 138-7

Comment Summary:

This commenter would like DTSC to emphasize the inclusion of occupational health and workplaces and provides specific suggested language to be included in the proposed regulations.

Response:

The language provided for the process of identifying Candidate Chemicals (previously known as COCs) in Article 2 has been incorporated in the following definitions in Article 1 of the January 2013 version of the regulations, as these concepts are also applicable in other sections of the proposed regulations:

- Section 69501.1(a)(2) “adverse air quality impacts” – “‘adverse air quality impacts’ means indoor or outdoor air emissions of any of the air contaminants”;
- Section 69501.1(a)(6) “adverse public health impacts” – “‘Public health’ includes occupational health”;
- Section 69501.1(a)(64) “sensitive subpopulations” – “Sensitive subpopulations” also include persons at greater risk of adverse health effects when exposed to chemicals because they are either individuals with a history of serious illness or greater exposures to chemicals, or workers with greater exposures to chemicals due to the nature of their occupation.

DTSC is not making any changes to the regulations in response to this comment. Please also refer to the Response to Comment 138-7 in Article 1.

Comment: 54-4

Comment Summary:

This commenter would like DTSC to emphasize the inclusion of occupational health and workplaces and provides specific suggested language to be included in the proposed regulations.

Response:

The language provided for the process of identifying Candidate Chemicals (previously known as COCs) in Article 2 has been incorporated in the following definitions in Article 1 of the January 2013 version of the regulations, as these concepts are also applicable in other sections of the proposed regulations:

- Section 69501.1(a)(2) "adverse air quality impacts" – "'adverse air quality impacts' means indoor or outdoor air emissions of any of the air contaminants";
- Section 69501.1(a)(6) "adverse public health impacts" – "'Public health' includes occupational health";
- Section 69501.1(a)(64) "sensitive subpopulations" – "Sensitive subpopulations" also include persons at greater risk of adverse health effects when exposed to chemicals because they are either individuals with a history of serious illness or greater exposures to chemicals, or workers with greater exposures to chemicals due to the nature of their occupation.

DTSC is not making any changes to the regulations in response to this comment. Please also refer to the Response to Comment 138-7 in Article 1.

Comment: 54-4

Comment Summary:

This comment refers to consideration of degradates and metabolites in evaluating the potential of a chemical to contribute to or cause adverse impacts and states that degradates capture a suite of antimicrobial products and there is difficulty with degradation kinetics.

Response:

As explained in the ISOR, section 69502.2(b) specifies the process for adding chemicals to the COCs (now known as Candidate Chemicals) list. For a chemical to be identified as a COC (now known as Candidate Chemical), the chemical must exhibit a hazard trait or environmental or toxicological endpoints based on reliable information for the factors in this section.

Adverse Impacts is one the factors that DTSC may consider in deciding whether to add a chemical to the COCs List (now known as Candidate Chemicals list). This is one of

the most important bases for scrutinizing chemicals used in consumer products.

DTSC is to consider the potential of a chemical to contribute to or cause adverse public health and/or environmental impacts using reliable information relevant to the factors specified in section 69502.2(b)(1). These factors relate to the chemical's toxicity profile, physical properties, and its mobility in the environment, as well as the chemical's potential to degrade, form reaction products, or metabolize into another Candidate Chemical (previously known as COC) or a chemical that exhibits one or more hazard traits and/or toxicological endpoints is a consideration in the evaluation of adverse impacts.

This inclusion of degradates and metabolites is important since not only chemicals themselves may be harmful, but their metabolites, degradates, and reaction products may also be as well. For example, as expressed by the commenter, sodium hypochlorite, which is the active ingredient in antimicrobial products, forms chloroform and chlorines that impact water quality.

In some instances, the original Candidate Chemical (previously known as COC) may not be detected any longer, but the adverse impact continues due to the chemical's potential to degrade, form reaction products, or metabolize into another chemical that exhibits one or more hazard trait and/or toxicological endpoints. The type of data or information that may be considered and that may be used to account for degradation includes use of:

- Computational modeling for structural activity relations to predict chemical behavior;
- Short term in-vitro bioassays to predict chemical behavior; and
- Information or data from public health and environmental agencies pertaining to a chemical's potential to degrade, metabolize, form reaction products, or transform into chemicals that are affecting public health and the environment.

It is important to note that DTSC is not required to consider all the factors listed in this section in every instance for a chemical to be identified as a COC (now known as Candidate Chemical), but DTSC is required to consider at least one factor for which reliable information is available and to consider potential exposures based on reliable information.

Additionally, in accordance with section 69502.3, DTSC will provide a Statement of Basis when the proposed Candidate Chemicals list is made available to the public that includes DTSC's rationale and supporting information for proposed Candidate

Chemicals (previously known as COCs) available for public comment and stakeholder input prior to revising the list. DTSC is not making any changes to the regulations in response to this comment.

§ 69502.2(b)(1)(A) Cumulative Effects

Comment: 9-20

Comment Summary:

Commenter states that assessment of cumulative effects with other chemicals is not practical for the vast majority of chemical substances, mixtures and uses. Commenter expressed concern that the level of knowledge required to conduct an assessment of cumulative effects with other chemicals is orders of magnitude over and above that required to conduct an assessment of aggregate effect.

Response:

DTSC has revised the regulations (January 2013) such that DTSC will evaluate the potential for the chemical to contribute to or cause adverse impacts based on aggregate or cumulative effects based on the availability of reliable information. If reliable information is not available, DTSC has the prerogative to propose and list a Candidate Chemical based on other adverse impacts or exposures.

DTSC has drafted the regulations taking into account all of the statutory mandates and limitations, sound science and scientific policy, and the amount and type of resources available to DTSC and the regulated entities to implement these regulations

To overcome the challenge to incorporate aggregate and/or cumulative effects in the chemicals listing process, DTSC has incorporated a number of regulatory pathways, such as voluntary data call-ins and stakeholder workshops in the proposed regulations. Therefore, the regulatory process includes stakeholder comments on the proposed Candidate Chemicals with the accompanying statement of reasons to explain the rationale for listing the chemical, review of stakeholder public comments, and solicit external scientific peer reviews for the scientific portions that serve as a foundational basis for listing. These pathways provide stakeholders opportunities to engage in the aggregate and/or cumulative effects discussion so that DTSC may be able to adopt additional Candidate Chemicals using a foundation of sound science.

Further, DTSC is responsible for implementing an approach that it will use in assigning hazard traits to chemicals, identifying and prioritizing Chemicals of Concern, and

making regulatory decisions on chemicals in consumer products. This approach will be embedded in a rulemaking process that will be public and transparent. This approach will not only include traditional toxicity and exposure information as described by the commenter (where available) but must also be capable of considering and incorporating newer scientific methodologies and data (when available). All decisions about hazards by DTSC will be based upon information available to DTSC and its thinking made visible through the rulemaking process that will be used to list Priority Products. All stakeholders are welcome to provide reliable scientific data to broaden and inform (rebut, clarify or support) DTSC's approach and decisions.

DTSC has its own expert scientists and toxicologists on staff and is confident that it has the resources to administer the proposed regulations in an effective manner. DTSC is making no changes to the proposed regulations in response to this comment.

§ 69502.2(b)(1)(B) Sensitive Subpopulations

Comments: 36-33, 36-34

Comments Summary:

This commenter suggests language for adding other environmental factors—such as nutrition, built environment, and socioeconomic status in considering cumulative effects of chemicals in section 69502.2(b)(1)(A)3.

Response:

DTSC respectfully declines to place the suggested in the proposed regulations. The suggested environmental factors have already been addressed in the proposed regulations. More specifically, section 69502.2(b)(1)(B) allows DTSC to give special consideration to the potential listing of a chemical as a Candidate Chemical if it contributes or causes adverse impacts to sensitive subpopulations.

In section 69501.1(a)(58), the proposed regulations define the term "sensitive populations" more specifically than the statutory language. As explained in the ISOR, "sensitive subpopulations" can be thought of as groups of individuals who respond biologically at lower levels of exposure to a contaminant or who have more serious health consequences than the general population.

The definition of "sensitive subpopulations" is drafted to identify subgroups that are at greater risk of adverse health effects when exposed to one or more chemicals, and this includes infants, children, pregnant women, and elderly individuals. This definition also

includes those individuals who have a greater risk of adverse health effects because of a serious illness or due to the nature of their occupation. Exposures to Candidate Chemicals may exacerbate existing serious or chronic illness or disease thereby increasing an individual's susceptibility to adverse health impacts. Workers may experience chemical exposures at higher levels and/or longer duration than the general public, and individuals living next to manufacturing sites can be exposed to chemicals as products are manufactured, stored, or transported through their communities. Thus, the definition that DTSC has crafted addresses important factors to be considered including life stages, gender, genetic traits, health status, and exposure. Thus, it is also consistent with a broad, health-protective approach to protect the most vulnerable members of society as DTSC adopts and implements these regulations.

DTSC will also consider potential exposures to a chemical based on reliable information demonstrating the occurrence, or potential occurrence, of exposures to the chemical and any chemical presence in an indoor setting such as household dust, indoor air, drinking water, and monitoring data may be considered reliable information showing exposure.

Section 69501.1(a)(53) defines "Reliable information demonstrating the occurrence of exposures to a chemical" as the types of reliable information that could demonstrate the occurrence of exposures and provides DTSC and responsible entities methods to assess exposures to the chemical of interest. This definition includes:

- Paragraph (A) describes exposure demonstrated through various monitoring information;
- Paragraph (B) identifies sources of biomonitoring information in humans;
- Paragraph (C) relies on information that is predictive of exposure based on calculations that are described in Chapter 54 as evidence for the hazard traits;
- Paragraph (D) identifies exposure modeling that may be used to determine exposure to a chemical of interest; and
- Paragraph (E) is specific to monitoring data related to wastewater or storm water collection and treatment systems.

In addition, indoor air emissions of any air contaminants that have the potential to result in adverse public health and/or ecological impacts are also included with the outdoor air emissions in the proposed regulations to be evaluated in determining adverse air impacts.

As explained in the ISOR, section 69502.2(b)(1)(A)3 lists the chemical's cumulative effects with other chemicals with similar hazard traits and/or environmental or

toxicological endpoints as one of the factors to consider in evaluating adverse impacts. “Cumulative effect” refers to a chemical causing the same effects in the organism from multiple chemicals. This factor is appropriate to consider, as some chemicals may not cause a toxic effect through exposure by itself, but combined with other chemical exposures will cause a toxic effect.

The groundbreaking nature of these public health and environmental protection regulations will require a flexible and adaptive process. In implementing these regulations, DTSC will give full consideration to all available and reliable evidence of actual exposure in the prioritization process. Unfortunately, complete information about chemicals that end up in consumer products and thereafter, ranging from product concentrations, toxicity, exposure, and fate and transport that is available in the open literature, to the government, or in private holding, ranges from nothing to very substantial. Finding data on geographic distribution of products containing Candidate Chemicals (previously known as COCs) and consumer habits will also be challenging; although, over time this type of information will be generated to fill the knowledge gaps.

Thus, DTSC is not accepting the proposed substitute language or making any changes to the regulations in response to these comments.

§ 69502.2(b)(2) Exposures

Comments: 21-5, 39-5, 47-11, 57-35, 59-9, 59-13, 61-5, 64-1, 64-2, 64-4, 66-18, 66-19, 69-21, 69-27, 73-1, 74-27, 82-1, 86-17, 92-5, 94-5, 101-19, 101-21, 103-2, 103-3, 103-4, 105-6, 120-1, 124-21, 125-6, PH18-1, PH36-1

Comments Summary:

These comments state that the prioritization and evaluation processes must be based on exposure and hazard, avoiding duplication and conflicting regulatory requirements. One of the commenters is concerned with the strong focus on specific hazard traits in identifying COCs and suggests potency and level of exposure is a more focused approach. A few others suggest limiting the term “Chemical of Concern” to those chemicals determined to present a serious risk of harm and exposure to consumers, with the rest of the chemicals identified as “chemicals of interest.”

Response:

DTSC will attempt to further clarify and explain section 69502.2.

Health and Safety Code section 25252(b)(1) states, “the department shall develop criteria by which chemicals and their alternatives may be evaluated. These criteria shall include, but not be limited to, the traits, characteristics, and endpoints…”

The evaluation of chemicals for subsequent identification and listing as Candidate Chemicals (previously known as COC) is based on the chemicals’ hazard traits and exposure potential. Article 2 of the proposed regulations identifies the initial list of Candidate Chemicals (previously known as COCs) compiled from chemicals listed on authoritative organizations' lists identified in section 69502.2(a) of the proposed regulations. Section 69502.2(b)(1) of the proposed regulations specifies the hazard traits and section 69502.2(b)(2) specifies exposure potential of the listed chemicals.

Many authoritative organizations are charged with protecting public health and the environment and have identified chemicals with regulatory or risk management consequences. DTSC sought to use the evaluative work these authoritative organizations that use deliberative scientific processes with opportunity for stakeholder input and comment. It is important to note that all of the chemicals on the lists in regulations meet criteria as “strong evidence” for toxicological hazard traits or “evidence” criteria for the exposure potential hazard traits, as specified in Chapter 54.

This approach of identifying chemicals with hazard traits listed on authoritative organizations' lists identified in section 69502.2(a) of the proposed regulations is consistent with Health and Safety Code section 25252(b)(2). That provision states that “In adopting these regulations, the Department [DTSC} shall reference and use, to the maximum extent feasible, available information from other nations, governments and other authoritative bodies that have undertaken similar chemical prioritizations processes …”

DTSC relies on this foundational requirement in the identification process of Candidate Chemicals (previously known as COCs). By utilizing other authoritative organizations’ scientific work, recommendations, and regulations that support protecting human health or the environment to identify the initial list of COCs (now known as Candidate Chemicals list), DTSC is able to maximize resources, while minimizing time and costs to California.

Therefore, when adding additional chemicals to the list of Candidate Chemicals (previously known as COCs), DTSC is to consider reliable information regarding public or environmental exposures to the chemical and reliable information demonstrating the occurrence of exposures to the chemical. As explained in the ISOR, discussion of

section 69502.2(b), hazard trait and exposure are necessary to identify a chemical as a Candidate Chemical (previously known as COC); without exposure, adverse impacts would not occur.

DTSC notes there is a detailed discussion in the Procedural, Legal and Overarching Issues discussion elsewhere in this Response to Comments document. This discussion applies here as well. In addition, the duplication concern has been addressed by the revisions to the prioritization process for product-chemical combinations in Article 3 of the January 2013 version of the proposed regulations. The revised proposed regulations have been streamlined so as to conserve and focus resources on evaluating the COCs (new definition).

The non-duplication provision in statute has been further clarified and made more specific regarding federal and State of California regulatory programs that may apply to consumer products. The overall non-duplication of regulatory programs provision is in section 69501(b). In addition, there is consideration of other regulatory agencies' impacts in the prioritization process for product-chemical combinations in section 69503.2(a)(3) of the proposed regulations. The reader is directed to Article 3 of this Response to Comments document for a more detailed discussion of that non-duplication provision.

As expressed by the commenter, chemicals can have various hazard traits that can occur at different doses or may be found in different test species. DTSC may identify a chemical with more than one hazard trait where applicable based on reliable information. Evaluation of product-chemical combinations considers frequency, extent, level and duration of potential exposures to the Candidate Chemical(s) (previously known as COCs) in the product during the products lifecycle and end-of-life effects as specified in Article 3.

The provisions in Articles 2 and 3 are consistent with the authorizing statutory requirements, by taking into consideration stakeholders' input and by making policy decisions that incorporate science, practicality, efficiency, and transparency. DTSC is making no changes to the proposed regulations in response to these comments.

Comment: 57-35

Comment Summary:

This comment expresses concern that the proxies for exposure only consider potential presence and do not take into account of risk-based determinations or potential for

adverse impacts or harm.

Response:

While risk-based determinations are not expressly written in the proposed regulations, they are being considered in adding chemicals to the list of Candidate Chemicals as well as in evaluating exposures from product-chemical combinations.

As written, section 69502.2(b)(2) and section 69302.3(b) refer simply to potential exposure or potential occurrence. Risk-based determinations or potential for adverse impacts or harm are in essence covered in sections 69502.2(a) [Candidate Chemicals identification], 69502.2(b)(1) [adverse impacts], and 69503.3(a) [adverse impacts]. Further, when a product-chemical combination is listed as a Priority Product, the manufacturer will have the burden when conducting an AA, to make a "risk-based" determination if exposure to their Priority Product has the potential for adverse impacts/harm or if there is a "safer" alternative product-chemical combination that is feasible.

DTSC is making no changes to the proposed regulations in response to these comments.

§ 69502.2(b)(3) Availability of Information

Comments: 36-53, 36-54, 36-56, 36-59, 39-23, 39-26, 57-36, 129-7

Comments Summary:

These commenters refer to section 69502.2(b)(3) of the proposed regulations that allows DTSC to consider availability of reliable information to substantiate adverse impacts and exposures in identifying a COC (now known as Candidate Chemical) and expressed the following concerns:

- Greater amount of reliable information should improve the robustness of decision-making, but reliable information substantiating the lack of potential exposure or adverse impacts should also be considered;
- Giving preference to a chemical that has more data regarding adverse impacts is an absolute presumption and this could codify the view that absence of data is evidence of (relative) safety;
- When there is reason to believe that a chemical may exhibit a hazard trait, DTSC should have discretion to view the absence of data as favoring identification;
- Instead of merely considering “the availability of reliable information to substantiate the potential adverse impacts and exposures,” DTSC should require

responsible entities to provide or produce the needed data for additions to the COCs list;

- By giving preference to, and relying on, the current availability of chemical data, DTSC will find itself perpetuating the data gap that continues to limit innovation or the development of green chemistry based alternatives;
- This sends a wrong signal to the marketplace and deters innovation and the development of new alternatives;
- This could be interpreted to mean that no information implies a COC is "safe";
- DTSC should not unnecessarily limit its decisions based on the availability of a safer alternative;
- The language “all other factors being equal” does not sufficiently address the situation when there is reason to believe that a chemical may exhibit a hazard trait and makes the absence of data a “tie-breaker” in favor of exclusion as a COC;
- The Safer Consumer Products program should formally identify chemicals with little or no toxicity information; and
- At a minimum, regulations should at least create a mechanism to identify these chemicals—a “yellow flag” that sends a message to the market and the public that they are under study and not necessarily “safe.”

Response:

In response to these comments and other similar comments, “availability of information” was dropped from the revised section 69502.2(b) of the proposed regulations (January 2013). However, “availability of information” has been reinstated in the revised proposed regulations (April 2013) in section 69502.2(b)(3) for the following reasons -

- Chemical potency data are available for some chemicals, although not for a great many chemicals. Unfortunately, information about chemicals that end up in consumer products and thereafter, ranging from product concentrations, toxicity, exposure, and fate and transport, that is available in the open market or in literature ranges from nothing to very substantial. A full complement of quantitative exposure information has rarely accompanied any chemical or product into the marketplace;
- Health and Safety Code sections 25251-25257 do not provide DTSC with authority to require responsible entities to submit information regarding Candidate Chemicals prior to completion of the Alternatives Analysis;
- Although DTSC has included provisions that allow DTSC to request information relevant to chemical and product identification and prioritization, responsible entities are not compelled to provide DTSC with the requested information;

The statute mandates DTSC to minimize costs and maximize efficiencies. Clearly, it is more cost-efficient to work with existing data than to have to order, wait for, and create costs for the generation of new data. As expressed in the above comments, robust data would assist in making informed and appropriate prioritization decisions including reliable information substantiating the lack of potential exposure or adverse impacts. However, lack of information or availability of information does not mean that a chemical is safe. DTSC will give full consideration to any available and reliable quantitative evidence of actual exposure or lack of exposure in the prioritization process. Please see discussion on Product Prioritization in Article 3 of this document.

With regard to the suggestion of providing a "yellow flag," it is DTSC's conviction that the list of Candidate Chemicals (previously known as COCs) will act as a cautionary signal or "yellow flag." That is, DTSC is of the opinion that inclusion of a chemical on the Candidate Chemicals list will send a message to the market and the public that these chemicals are under study, having already been identified as posing a concern by other authoritative organizations and not necessarily "safe." After all, the term "**Candidate** Chemical" refers to the fact that these chemicals are candidates for further evaluation and possible listing as Chemicals of Concern. DTSC is making no further changes to the proposed regulations in response to these comments.

Comment: 9-34

Comment Summary:

This comment states that it is not clear in how or whether a weight-of-evidence assessment will be applied in evaluating chemicals or products.

Response:

In response to similar comments, DTSC has revised the proposed regulations to provide greater clarity.

Section 69502.2(b) has been revised to require DTSC to consider reliable information to substantiate adverse impacts and exposures when evaluating chemicals to add to the Candidate Chemicals list (previously known as COCs). The extent of reliable information that is available to substantiate adverse impacts and exposures has been deleted in section 60502.2(b)(3) from the proposed regulations (January 2013). Please refer to the Response to Comment 9-34 for discussion on Weight of Evidence in section 69502.1 above. Also please refer to the discussion on product prioritization in Article 3.

§ 69502.2(b)(4) Safer Alternatives

Comments: 36-53, 36-60, 39-23, 57-37, 70-2, 76-42, 91-1, 124-22, 128-5, 129-8

Comments Summary:

These commenters refer to the availability of safer alternatives as a factor to be considered in adding chemicals to the Candidate Chemicals list and state the following:

- It is not reasonable to suggest that any chemical that has a “safer alternative” should be considered a COC. Any chemical that is added to a COCs list must demonstrate a realistic potential for exposure and adverse impacts to human health or the environment;
- DTSC should not consider the availability of a safer alternative in determining whether to list a chemical as a COC;
- Identification of a safer alternative in another product without going through a detailed analysis of the functions and requirements of a chemical in the product is not advisable and is pathway fraught with regrettable substitutions;
- New chemicals, and existing chemicals that have not been sufficiently studied, frequently lack the data sets that the definition of "safer alternative" could be interpreted to require;
- Being able to classify a chemical as a COC on the basis of the availability of a safer substitute is extremely important as it ties together risk assessment and alternatives assessment and should be retained:
    - Availability of a safer alternative should be used as a factor to evaluate if it weighs in favor of or against identification of a COC.
    - Exposure under real-world conditions of use must be considered if a chemical can potentially be replaced with another exhibiting lower hazard, but such substitution (due to reduced performance or other factors) results in a greater exposure, this may not be the desired outcome; and
- This provision is overly restrictive to allow only for safer chemical alternatives. Recommend that the regulations include “safer engineering and administrative approaches that produce a similar, safer function.”

While a few commenters recommend expanding the “safer alternative” beyond the chemical alternative by including “safer technological or administrative approach that delivers comparable, but safer functional purpose,” other commenters urge DTSC to delete section 69502.2(b)(4) from the proposed regulations.

Response:

DTSC acknowledges these comments, and section 69502.2(b)(4) has been deleted

from the revised proposed regulations (April 2013).

The existence of a "safer alternative" makes sense in the context that work has been done and information is available for responsible entities to evaluate to determine if the identified alternative works for their product design and formulations. However, in the context of adding chemicals to the Candidate Chemicals list (previously known as COCs list); it makes perfect sense to focus on the chemical's potential for exposure and adverse impacts to human health or the environment; and availability of reliable information. Additionally, if DTSC determines that a chemical does not exhibit a hazard trait and/or environmental or toxicological endpoint that satisfy the listing criteria, then the chemical should not be listed. Therefore, availability of a safer alternative section 69502.2(b)(4) has been deleted from revised proposed regulations (January 2013).

With regard to the suggestion for adding "safer technological or administrative approach that delivers comparable, but safer functional purpose," please refer to the definitions for "alternative" and "safer alternatives" in Article 1 and discussion on AA in Article 5. No further changes to the regulations are being made in response to these comments.

§ 69502.3 Chemicals of Concern List

§ 69502.3(a) Informational List

Comments: 3-1, 5-18, 7-4, 7-5, 9-53, 17-9, 47-10, 47-11, 47-12, 57-28, 57-38, 64-3, 86-17, 152-4, PH36-1

Comments Summary:

These comments refer to the initial informational list of Candidate Chemicals (previously known as COCs list). Some of these comments are based on the understanding that the initial list has been already finalized and commenters expressed the following concerns:

- DTSC refers to the initial list of Candidate Chemicals (previously known as COCs) as its "flexible palette," giving DTSC unlimited selection discretion, yet not affording the public the benefit of DTSC's compliance with the APA so that informed input can be provided on those selections;
- DTSC has not performed the duties required by the statute and has not assembled the names of the chemicals on a list where a company could ascertain if it is affected by this proposal;
- It is incomprehensible why DTSC cannot provide the list of chemicals it intends to regulate since DTSC has stated in public forums that such a list presently exists;

- Initial list of COCs will be adopted upon the finalization of the regulations and does not allow for a dedicated public comment period;
- With no dedicated public comment period for this initial list, the net effect is that over 1,200 chemicals will be on the COCs list without a proper chance for the public to comment on them;
- We need to comment both on the criteria used for narrowing down the chemicals from several thousand to 1,200 and also the application of those criteria;
- Add initial list of COCs immediately upon finalization of the current regulations, as a single appendix, and the list should cross reference various other chemical management regulations to help them see the overlaps and redundancies;
- The process of listing COCs is particularly troubling since DTSC and the GRSP expended significant resources attempting to address stakeholder concerns and to maintain transparency in the process;
- Without receiving all of the stakeholder opinions and holding discussions among them, the determination may not be considered fair;
- Failure to publish the chemical list of 1,200 COCs is a total failure of transparency;
- Regulations create an uncertain regulatory environment since the COC List and Priority Product List will not be published until after the effective date of these regulations;
- Not clear when information on many of the key milestones—first COCs list, proposed Priority Products list, and AA Guidance—will be released to the public and how this information will inform the various processes;
- DTSC does not have the authority to establish a final list of COCs without public review and comment; and
- There was a request for DTSC to follow the requirements of Health and Safety Code and the APA in identification and prioritization of chemicals and name the chemicals on the list of Chemicals of Concern.

Response:

These comments are based on a mistaken premise. That premise is that the initial list of Candidate Chemicals (previously known as COCs) has already been finalized. As explained in the ISOR, the initial list of Candidate Chemicals (previously known as COCs) is a compilation of chemicals listed on the authoritative organizations' lists identified in section 69202.2(a) of the proposed regulations. All of the source lists are from authoritative organizations and all of the chemicals on these lists meet the criteria “strong evidence” for toxicological hazard traits or “evidence” criteria for the exposure potential hazard traits, as specified in Chapter 54. Section 69502.3(a) specifies that

DTSC shall post an informational list of Candidate Chemicals (previously known as COCs) on its website within 30 days from the effective date of these regulations, and DTSC will comply with this requirement.

DTSC has identified the chemicals listed on authoritative organizations' lists enumerated in section 69502.2(a) of the proposed regulations for the initial list of Candidate Chemicals (previously known as COCs). These source lists identified in the proposed regulations have been subject to public review and stakeholder comments. Prior to that, DTSC consulted with the GRSP and also reviewed stakeholder comments in response to an informal draft of the proposed regulations (October 2012). The proposed regulations public noticed in July 2012, January 2013 and April 2013; reflect DTSC's consideration of the GRSP and stakeholder comments and meet the authorizing statute requirement to establish the identification and prioritization process.

As expressed in the above comments, the initial informational list of Candidate Chemicals (previously known as COCs) is approximately 1,200 chemicals when compiled from the list of chemicals listed on the authoritative organizations' lists identified in section 69502.2(a) of the proposed regulations. This represents a compilation of the chemicals listed on authoritative organizations' lists identified in section 69502.2(a) of the proposed regulations with the exception of: (1) chemicals exempted under Health and Safety Code section 25251 (e.g. pesticides and prescription drugs); (2) non-chemicals (e.g., nutrients); (3) duplicate chemicals that appear on more than one list; and (4) chemicals that are known not to exhibit a Chapter 54 hazard trait or environmental or toxicological endpoint. Chemicals known to fall into one of these four (4) categories will not be included in the informational list of Candidate Chemicals (previously known as COCs) posted on DTSC's website under section 69502.3(a).

DTSC's ongoing development of the informational list includes combining groups and fractions of chemicals, for example, all PCBs are listed as one group and all dioxins are listed as one group. Similarly, all of the petroleum fractions, all petroleum naphtha fractions are combined and listed as one group. This too is part of the ongoing development of the initial informational list, which clearly cannot be finalized until after the proposed regulations are finalized.

Once again, the informational list of Candidate Chemicals (previously known as COCs) will be published after the proposed regulations are final, within 30 days of the effective date of these regulations as specified in section 69502.3(a). The provisions in Article 2 are consistent with the overarching legislative intent and were developed in consultation

with the GRSP, established pursuant to Health and Safety Code section 25254, and extensive stakeholder participation and public comments.

In addition, there are many opportunities for regulated entities to submit information and data (sections 69501.4, 69502.2, and 69503.3); as well as petition (Article 4) DTSC to add or remove chemicals and products to/from the finalized lists.

The initial proposed Priority Products list will be available for public review and comment within 180 days after the effective date of these regulations. The proposed regulations require DTSC to identify and prioritize consumer products containing COCs (new definition) and to establish the Priority Product list through rulemaking pursuant to the APA (commencing with Government Code section 11340).

Finally, section 69505 states that before finalizing the initial list of proposed Priority Products, DTSC shall prepare and make available guidance materials to assist persons in performing AAs. Efforts are under way to make guidance materials available and will potentially be online before finalization of the initial Priority Products list. DTSC is making no changes to the regulations in response to these comments.

Comments: 9-73, 57-34, 65-2, 74-26

Comments Summary:

These comments refer to the informational list of Candidate Chemicals (previously known as COCs) and suggest that DTSC list chemicals by their individual Chemical Abstract Services Registration Number (CAS RN).

Response:

DTSC notes that no changes to the proposed regulations are necessary in response to these comments.

Chemical Abstract Services Registry Numbers (CAS RN) are assigned by Chemical Abstract Services, a division of the American Chemical Society, to every chemical that has been described in literature. The registry maintained by CAS is an authoritative collection of disclosed chemical substance information.

CAS RN is the most commonly known and widely accepted form of chemical identification. However, it is not free of controversy. Therefore, some of the source lists identified in section 69502.2(a) of the proposed regulations do not list chemicals by their

CAS RNs. Therefore, it is important to note that there are some outliers in the CAS registry database. Such as:

- Occasionally whole classes of molecules receive a single CAS number. For example: the group of enzymes known as alcohol dehydrogenases (CAS RN 9031-72-5); and
- A standard mixture of otherwise identified compounds may receive a corporate CAS number. For example: mustard oil (CAS RN 8007-40-7).

DTSC will list chemicals on the informational list of Candidate Chemicals (previously known as COCs) pursuant to section 69502.3 of the proposed regulations, by the chemicals CAS RN *to the extent possible*.

Update the List

Comments: 29-12, 36-7, 36-13, 39-19, 138-3

Comments Summary:

These comments refer to section 69502.3(a). Commenters suggest that DTSC update the list every 2 years (24 months), to reflect the changes to the underlying lists. Especially since the authoritative organizations that generate the lists referred to in section 69502.2(a) regularly update their lists, DTSC needs to develop a process for keeping the list up-to-date. Another suggestion, DTSC should specify that when any lists it relies on are updated, the updated list becomes the version that DTSC uses in its own list.

Response:

DTSC has considered the recommendations for updating the list of Candidate Chemicals (previously known as COCs). As explained in the ISOR, the initial informational list of Candidate Chemicals is intended to be revised to reflect updates in the science that forms the basis for the source lists.

While DTSC shares a preference with the commenter for a specific schedule for updating the list of Candidate Chemicals (previously known as COCs), DTSC has limited resources to implement the proposed regulations. Therefore, specifying in the proposed regulations that when any of the source lists are updated, the updated list becomes the version that DTSC uses in its own list will be counter-productive.

The proposed regulations confer a great deal of flexibility on DTSC regarding the scope and number of tasks that it takes on at key points of the regulations' implementation.

Thus, DTSC may shape its workload on major tasks "as resources allow," to ensure that DTSC maximizes the effective use of its resources in implementing the regulations effectively. In addition, the commenters' suggestion is problematic under the APA. Therefore, DTSC will not make any changes to the proposed regulations in response to these comments.

§ 69502.3(c) Public Notice of Proposed List Revisions

Comments: 27-1, 36-14, 106-1

Comments Summary:

These commenters support the opportunity for formal public input on proposed revisions to the COC List and note that the process used by DTSC allows for extensive input from all stakeholders.

Response:

DTSC acknowledges the support. The proposed regulations incorporated extensive input in the process for transparency and information gathering. DTSC will continue to work with stakeholders and interested parties during the implementation of these regulations (section 69503.2(c) of April 2013 version of the regulations). Again, no change to the regulations was urged, or is being made in response to these comments.

Comments: 86-17, 86-19

Comments Summary:

The above comments state that some of the chemicals are not explicitly hazardous and others do not have enough information. Therefore, the process of COC identification is quite dependent on DTSC's study and decision, and these determinations may not be fair without considering public opinions and holding stakeholder discussions.

Response:

DTSC respectfully declines to make any changes to the proposed regulations in response to these comments. The proposed regulations have been crafted in a manner that maximizes the use of existing information. They also include provisions for DTSC to gather information and confer a great deal of flexibility, and include time lines that are reasonable.

In response to the chemical identification process, DTSC respectfully disagrees with the commenter. While these regulations require DTSC to identify the Candidate Chemicals

(previously known as COCs), the process involves public comment and stakeholder input. The initial list of Candidate Chemicals (previously known as COCs List) is a compilations of chemicals listed on the authoritative organizations' lists identified in section 69502.2(a) of the proposed regulations. All of the source lists are from authoritative organizations that have been charged with protecting public health and the environment and have identified chemicals with regulatory or risk management consequences. DTSC sought to use the evaluative work of these authoritative organizations that use deliberative scientific processes with opportunity for stakeholder input and comment. As part of these regulations, all of these lists have been subject to extensive public comment opportunities, both during the informal, non-APA public comment periods and under public comment periods in July 2012, January 2013 and April 2013; held under the APA.

For any revisions to the initial list of Candidate Chemicals (previously known as COCs), factors listed in sections 69502.2(b) will be considered to the extent relevant reliable information is available. The choice of chemicals to be identified and placed on the list will be based on the decision-making factors specified in revised, renumbered sections 69502.2(b) and the process specified in section 69502.3. DTSC will consider the factors specified in these sections to sequentially evaluate the chemicals and propose them for listing as Candidate Chemicals (previously known as COCs).

As explained in the ISOR, DTSC will make the proposed revisions to the Candidate Chemicals list (previously known as COCs list) available on its website, along with supporting documents and a bibliography of the information sources. The supporting documents include DTSC's rationale, data, and information, as well as the sources of information, to provide the public an understanding of the bases for the proposed listing decisions so that all parties can submit comments taking into consideration these bases.

Stakeholders have other opportunities to submit information and data (*e.g.*, *s*ections 69501.4 and 69503.3) to inform DTSC why chemicals and products should or should not be in the finalized lists, as specified in the ISOR. Further, stakeholders may also petition DTSC (Article 4), use the dispute resolution processes (Article 7) or Government Code section 11340.6 to interact with DTSC regarding potential additions to the Candidate Chemicals list. Note, the commenter may also petition DTSC to remove chemicals from the list of Candidate Chemicals (previously known as COCs). Please also refer to Response to Comment 86-17 under section 69502.2(b)(2).

Comments: 57-29, 57-38, 86-19

Comments Summary:

These commenters state that 45 days public notice is insufficient time to adequately review the chemicals list and request clarification on the what actions will follow a comment period. The commenters suggest that DTSC:

- Consider similar time frames to European Union REACH regulations;
- Define actions that can or will be taken upon completion of the comment period; and
- Publish the initial, and any proposed revisions to, the COCs List on DTSC's website for public review and comment.

Response:

DTSC respectfully declines to make any changes to the proposed regulations in response to these comments for the reasons set forth below.

Although the two programs, California's Safer Consumer Products program and the European Union's REACH program sound similar, the similarity really ends at the goal—"to improve the protection of human health and the environment" and intent of the two programs - " to enhance innovation and competitiveness of the industry." The proposed regulations are focused on the quest for safer consumer products in California, while the aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances.

REACH places the burden on chemical companies to provide information on how the chemicals they make affect human health and the environment. REACH has two parts: the collection and sharing of data throughout supply chains, and the authorization of chemicals of higher concern to human and environmental health. REACH time frames are staggered based on volume of chemicals that must be registered for a subsequent risk analysis, which is very different from the Alternative Analysis required in these proposed regulations for the Safer Consumer Products program. Longer time frames in REACH are necessary, as it tries to fill the data gaps to ensure that industry is able to assess hazards and risks of the substances and to identify and implement the risk management measures to protect humans and the environment.

The proposed regulations focus on all available reliable information to evaluate and identify adverse impacts, as well as substantiating the lack of potential exposure or adverse impacts, including identification of lack of reliable information. The statute mandates DTSC to minimize costs and maximize efficiencies. Clearly, it is more cost-

efficient to work with existing data than to have to order, wait for, and create costs for the generation of new data.

The 45-day public notice and comment period is the minimum comment period, and DTSC has the ability to provide a longer comment period if needed. The proposed regulations require DTSC to issue a public notice for any proposed additions or revisions to the Candidate Chemicals list (previously known as COCs list) along with a supporting document and DTSC's rationale. Therefore, during the public comment period of forty-five (45) days at a minimum, DTSC may host one or more public workshop(s).

DTSC will consider all of the public comments and may respond to some or all of the public comments received before finalizing the proposed revisions to the Candidate Chemicals list (previously known as COCs list).

As specified in the proposed regulations at section 69502.3(a), DTSC will post an informational list of Candidate Chemicals (previously known as COCs) on DTSCs website within 30 days of the effective date of these regulations. Therefore, the final revisions to the Candidate Chemicals list will be posted on DTSCs website, as specified in section 69502.3(d).

§ 69502.3(d) Website Posting of Final List Revisions

Comments: 9-112, 24-3

Comments Summary:

These comments state that DTSC should respond to comments received during the public comment period in the COCs listing process and that there is a lack of due process. The regulated entities and the public need to understand the basis for DTSC's reasoning in accepting or rejecting particular recommendations, data, or information.

Response:

These commenters seem to object to the provision in section 69502.3(d) that allows DTSC to respond to some, but not necessarily all, of the comments received during the public comment period for proposed list revisions.

DTSC will make the proposed revisions to the Candidate Chemicals list (previously known as COCs list) available on its website for public review and comment, along with supporting documentation, including DTSC's rationale and a bibliography of the supporting information and information sources. The public comment period will be at

least 45 days, and DTSC will hold one or more public workshop(s) during that time to engage all stakeholders.

DTSC will consider *all* of the public comments received on proposed revisions to the list before finalizing the Candidate Chemicals list (previously known as COCs list). DTSC may respond to only some of the public comments received, because some of the comments received may not be relevant to the decision to list a chemical. Additionally, any comments received that affect the rationale for listing the chemical will be noted or the rationale itself may be updated prior to finalizing the list. Thus, reserving the option to respond to some, but not necessarily all, of the comments will streamline the listing process. For the reasons stated above, DTSC is not making any changes to the proposed regulations in response to these comments.

Miscellaneous Comments

Statute Compliance

Comments: 5-68**,** 5-106, 38-5, 38-8, 47-10, 49-1, 73-2, 74-26, 74-27, 105-6, 107-32, 139-6

Comments Summary:

These commenters are concerned that the COC identification process does not comply with the plain language of Health and Safety Code section 25252. There are slight variations, but the central theme of these comments is that the proposed regulations do not prioritize chemicals that are found in consumer products as the Legislature intended when it adopted the authorizing legislation.

Response:

DTSC respectfully disagrees with the commenters that the proposed regulations do not comply with the authorizing legislation.

Health and Safety Code section 25252(a) requires DTSC to “establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a Chemical of Concern “

Articles 2 and 3 of the proposed regulations lay out the processes and criteria that DTSC will follow in identifying and prioritizing Candidate Chemicals (previously known as COCs), COCs (new definition), and Priority Products. It is particularly noteworthy, that Article 2 is now a more explicit and step-wise identification and prioritization process. First, there is a fairly broad universe of Candidate Chemicals that have, in

effect, been identified and prioritized among all the tens of thousands of chemicals used in commerce. In addition, there is then a further identification and prioritization from among these Candidate Chemicals to arrive at Chemicals of Concern (newer usage as of January 2013). In particular, Article 3 of the proposed regulations specifies the process and factors DTSC is required to consider in evaluating product-chemical combinations (January 2013) for possible identification and prioritization as Priority Products which contain Chemicals of Concern (January 2013).

The entirety of both Articles 2 and 3 establishes the processes for accomplishing these key statutory and regulatory tasks. All of the regulatory language is couched as establishing the processes and describing how the processes will be carried out. Please also refer to the responses to comments on Chemical Prioritization in this document for additional explanation. DTSC is not proposing any changes to the regulations in response to these comments.

Regrettable Substitutions

Comments: 36-30, 36-31

Comments Summary:

These commenters express concern that companies may switch out of COCs before their product is designated as a Priority Product, leading to regrettable substitutions. Therefore, the proposed regulations do not include:

1) No data, no market requirement for all or most of the chemicals in commerce; or
2) Detailed reporting requirements anytime a COC is altered in any product.

One of the commenters suggests prioritizing classes or groups of chemicals or products, rather than taking them up individually or relying on an authoritative organization listings to minimize regrettable substitutions. Another commenter suggests regulatory provisions to help accumulate information as to whether and how often companies may switch out of COCs prior to entering the formal AA process, while one commenter is not clear how consumers will be informed about these chemicals.

Response:

DTSC notes that a robust list of Candidate Chemicals (previously known as COCs) in the regulations is anticipated to help avoid regrettable substitutions by sending immediate signals to the marketplace about chemicals indirectly subject to this program and that may later become directly subject to the regulations. That is, responsible entities are on notice that Candidate Chemicals may ultimately be designated as COCs

within a consumer product that is listed as a Priority Product subject to the AA requirement.

Manufacturers, importers, and retailers (also referred to as responsible entities), who wish to begin proactive efforts and voluntarily redesign their products, may use this initial list of Candidate Chemicals (previously known COCs) as part of their process to make informed decisions regarding potential chemical alternatives or substitutions to consider.

As explained in the ISOR, section 69505.1(g) of the proposed regulations allow a responsible entity to reformulate and remove the COCs (new definition), after the Priority Product has been listed by DTSC, as long as the reformulated product does not contain any Candidate Chemicals (previously known as COCs) or a substitute chemical. A responsible entity that elects to reformulate or redesign or replace the Priority Product in lieu of conducting an AA must submit all or any one of the following notifications as applicable after their product is listed by DTSC as Priority Product:

- Chemical Removal Intent and Confirmation Notification;
- Product Removal Intent and Confirmation Notification; and/or
- Product-Chemical Replacement Intent and Confirmation Notification.

This provides responsible entities an incentive to elect to remove COCs (new definition) that are not necessary for the product performance or function, or when a readily available safer alternative exists, without being required to undergo the process of conducting an AA. The incentive of limited DTSC oversight is necessary to allow reformulations, redesigns, or replacements when the revised product poses little to no risk of a “regrettable substitute,” as well as to expedite the push towards safer consumer products. Again, establishing a robust list of Candidate Chemicals (previously known as COCs) will act not only as a market signal but also a deterrent for regrettable substitutions.

These notifications will help DTSC accumulate information on whether and how often companies switch out of COCs prior to entering the formal AA process. All responsible entities may not voluntarily disclose information about the chemicals in their products. However, there are provisions in the proposed regulations for DTSC to gather information (section 60501.4) even prior to listing a Priority Product, which will follow the rulemaking process pursuant to the APA. All information on this subject submitted to DTSC will be posted on DTSC’s website for public review and comment.

With regard to the suggestion of prioritizing classes or groups of chemicals or products, DTSC has indicated that it will work on a number of chemicals and products "as resources permit." The prioritization will proceed along the scientific criteria specified in Article 3. DTSC will not make any changes to the proposed regulations in response to these comments.

Workability

Comments: 5-10, 5-71, 49-5, 49-11, 49-15, 73-2, 74-26, 74-27, 107-6

Comments Summary:

The above comments express concern with respect to workability of the proposed regulations, specifically:

- An expansive initial list of Chemicals of Concern is not achievable, as there is no prioritization of chemicals required by the statute, and DTSC contemplates addressing trace amounts of chemicals;
- This is absolutely not consistent with the aim of the enabling statute to allow the COCs listings to drive widespread, indiscriminate pressure against use of these listed chemicals, regardless of the application or its threat; and
- Scope of chemicals to be regulated is not practical, meaningful, or legally defensible.

Response:

DTSC respectfully disagrees with these comments. DTSC has worked diligently with stakeholders—the public, industry, non-governmental organizations, local, state and federal government agencies, and in consultation with the GRSP established pursuant to Health and Safety Code section 25254—in drafting the proposed regulations to ensure that they carry out the purpose and goals of the authorizing legislation to the greatest extent possible.

In response to the concern that the large list of chemicals will cause widespread, indiscriminate pressure against use of these listed chemicals, regardless of the application or its threat, the list of chemicals has been renamed as the Candidate Chemicals list and the COC definition has been redefined. Both are defined in the proposed regulations (January 2013) as:

i) Candidate Chemical (previously known as COC) - "a chemical is a Candidate Chemical if it exhibits a hazard trait or an environmental or toxicological endpoint

and is listed on one or more of the enumerated authoritative organizations' lists in section 69502.2(a)."

ii) Chemical of Concern (new definition) - " a Candidate Chemical that is the basis for a product-chemical combination being listed as a Priority Product is designated as a Chemical of Concern with respect to that product."

The initial list of Candidate Chemicals (previously known as COCs) is a compilation of chemicals listed on the authoritative organizations' lists set out in section 69502.2(a). This list of chemicals compiled from the source lists, establishes a robust list of approximately 1,200 chemicals based on work already conducted by authoritative organizations and identifies the initial list of chemicals that are subject to this program. Having a robust Candidate Chemicals list as of the effective date of these regulations is necessary to enable DTSC to immediately focus on the identification and prioritization of product-chemical combinations for listing as Priority Products for which responsible entities will be required to perform alternatives analyses to identify safer products. This robust Candidate Chemicals list will also enable: (1) consumers to be more informed about the Candidate Chemicals that may be present in the products they purchase; and (2) manufacturers to take early voluntary actions regarding the Candidate Chemicals (previously known as COCs) as part of their process to make informed decisions regarding potential chemical alternatives or substitutions to consider in their quest for safer consumer products.

DTSC has no interest in adopting regulations that do not meet the goals of the statute and is confident the regulations will accomplish the purpose of the statute. DTSC is not proposing any other changes to the regulations in response to these comments. Please also refer to the Response to Comment 5-10 under Chemical Prioritization in section 69502.1 above for discussion of trace chemicals.

Comments: 5-10, PH34-7

Comments Summary:

It is essential to have a program that is achievable in terms of scope for prioritization of products, for identification and prioritization of chemicals, for AA, and for reporting.

Response:

DTSC respectfully disagrees that the regulations are of an unachievable scope. These comments are based on a mistaken premise. While there may be more than 1,200 chemicals that meet the definition of a "Candidate Chemical" (previously known as COC) in the regulations, this certainly does not mean there will be more than 1,200

chemicals later identified and prioritized as COCs (new definition) in Priority Products that require further regulatory action.

The proposed regulations are achievable and have been drafted in consultation with the GRSP and taking into consideration stakeholder comments—which includes the public, industry, non-governmental organizations, as well as several local, state and federal governments. The first Priority Products list will consist of no more than five (5) Priority Products, as is required by section 69503.6 (January 2013 version). Accordingly, an AA and reporting requirements will apply to no more than five (5) product-chemical combinations. DTSC has revised the proposed regulations in response to stakeholder comments to make them more streamlined and flexible. DTSC is confident the regulations are workable and effective. Please also see the responses to comment PH34-7 above under Chemical Prioritization.

Comment: 23-4

Comment Summary:

This comment states that automakers and suppliers worldwide use a collaborative database that provides in-depth reviews of over 2,500 substances used in automotive components. Adding a separate list from DTSC would require them to create additional processes to check viability of safer ingredients from another list.

Response:

DTSC itself does not have access to the database that automakers and their supply chain use. Whereas, the initial list of Candidate Chemicals (previously known as COCs) is a compilation of chemicals listed on the authoritative organizations' lists as listed in section 69502.2(a) of the proposed regulations, and there will likely be overlaps between the current list of over 2,500 substances tracked for automotive components and the list from the proposed regulations. DTSC's list of Candidate Chemicals (previously known as COCs) is intended to inform consumers about the chemicals that may be present in the products they purchase. It also enables manufacturers, importers, and retailers (also referred to as responsible entities) to take voluntary actions on chemicals in products in their quest for safer consumer products. There is virtually no way that DTSC could have come up with a Candidate Chemicals list that applies to all consumer products that has no overlap with large industry sectors, such as the automobile industry. DTSC is making no changes to the proposed regulations in response to this comment.

Implementation Cost

Comments: 9-5, 15-3, 49-1

Comments Summary:

These commenters express concern that the complexity, scope, and burden of the proposed regulations will undermine the statutory objectives. Specifically, the expansive initial list of chemicals will result in significant implementation costs and produce a marginal improvement in human health and environment safety. Another concern is with the large number of COCs—more than DTSC has capacity to evaluate in depth in the context of the enabling statute.

Therefore, there is no assurance that resources are being directed toward highest priority items and the uncertainty facing the regulated community. The sheer workload awaiting DTSC staff when the regulatory submissions begin and the expected economic impacts that will reverberate throughout industry, as a result of compliance activities and loss of trade secret information collectively, screams that this proposed regulation is far from practical.

Response:

The regulatory text is entirely consistent with the statutory provisions, is well within DTSC's authority, and does nothing to impermissibly contract or expand the scope of activities described in the authorizing statute that are subject to these regulations.

Without specific facts that support the allegation, DTSC cannot, in any detail, refute the statements regarding significant costs resulting in marginal improvements in human health and environmental safety or that compliance and trade secret concerns make the proposed regulation far from practical.

DTSC acknowledges that there will be some costs imposed on some businesses as a result of the implementation of the regulations. DTSC has greatly streamlined the regulatory processes and, thus, reduced the related costs on businesses that would be incurred during such steps. Tremendous flexibility has been built into the regulations to accommodate businesses' concerns about the burdens the regulations impose. Information gathering requirements, among many others, have been revised to limit costs incurred, while still providing DTSC with the information it needs to make the regulations work. DTSC believes that the regulations, when implemented, will deliver demonstrable public health and environmental protection to the people of California, as the Legislature envisioned in passing the authorizing legislation.

With regard to implementation of the regulations, DTSC is confident that it has the expertise and resources to administer the proposed regulations in an effective manner. The proposed regulations have been crafted in a manner that maximizes the use of existing information. Many provisions are self-implementing and several provisions in the regulations specifically allow DTSC to limit the reach of its activities "as resources permit." All of this leads DTSC to believe that the proposed regulations are consistent with the goals and purpose of the authorizing legislation and that DTSC can effectively and efficiently implement the regulations. Accordingly, DTSC is not making any changes to the proposed regulations in response to this comment. Please also see responses to comments under Chemical Prioritization and Marginal Health Gains elsewhere in this Response to Comments document.

Potential Costs to Local Governments

Comment: 45-4

Comment Summary:

This commenter suggests modifications to sections 69502.2(b) and 69503.2 to include the potential costs to local governments, as a major factor in determining which chemicals to list as Chemicals of Concern and which products to prioritize.

Response:

DTSC notes that Article 2 specifies the scope of chemicals that could be considered in the identification process for listing as Candidate Chemicals (previously known as COCs) and evaluation of product-chemical combinations for listing as Priority Product. The factors in Article 2 relate to adverse impacts and exposures. While potential costs to local governments are important, it is not a factor for identification of Candidate Chemicals (previously known as COCs).

DTSC reckons the cost to local government is a more appropriate factor when prioritizing product-chemical combinations. As explained in the ISOR, regarding Article 3, cost may be used as an indirect method to measure or quantify exposure when evaluating product-chemical combinations for prioritization as Priority Products. For example, the cost of the publicly owned treatment works to treat or remove the COC (new definition) or its metabolites before the treated water is discharged into California waters may be considered. This is because if the treatment or removal is not conducted, the consequence is an increase in the likelihood of exposure to the public and the environment to the COC (new definition).

Revised section 69503.2(b)(1)(B) of the January 2013 version of the proposed regulations allows DTSC to consider adverse waste and end-of-life effects associated with the Candidate Chemical(s) in the product(s). DTSC may propose listing a product-chemical combination as a Priority Product if it determines that listing would meaningfully enhance protection of public health and/or the environment with respect to potential adverse waste and end-of-life effects. DTSC is making no changes to the proposed regulations in response to this comment.

Timeline

Comment: 7-3

Comment Summary:

This comment refers to the initial list of COCs and states that the time line for implementation of the proposed regulations has been shortened.

Response:

DTSC notes that although the commenter's point is not completely clear, DTSC will attempt to clarify the process regarding identifying and prioritizing chemicals.

Article 2 describes the process to identify chemicals as Candidate Chemicals (previously known as COCs). This process as laid out in section 69502.2(a) of the proposed regulations for identifying chemicals, establishes a robust initial list of Candidate Chemicals (previously known as COCs) compiled from lists by authoritative organizations.

As explained in the ISOR, DTSC is relying on other authoritative organizations' work, recommendations, and regulations that support protecting human health and the environment to identify the initial list of Candidate Chemicals (previously known as COCs). This will allow DTSC to focus its limited resources in evaluating product-chemical combinations for listing as Priority Products which contain COCs (new definition).

Implementation of the Safer Consumer Products Regulations will be initiated by publishing an informational list of Candidate Chemicals (previously known as COCs list) within 30 days of the effective date of these regulations. This list will be periodically updated with public comment and stakeholder input.

The manufacturers who wish to begin proactive efforts and voluntarily redesign their products may use this initial informational list of Candidate Chemicals (previously known as COCs) as part of their process to make informed decisions regarding potential

chemical alternatives or substitutions, before the regulations compel them to do so. (Note: it is not a given that a product containing a Candidate Chemical will inevitably be identified as a Priority Product.)

Next, DTSC will make the initial proposed Priority Products list available for public review and comment within 180 days after the effective date of these regulations. The proposed regulations require DTSC to establish the Priority Products list through rulemaking pursuant to the APA.

There are many other opportunities for regulated entities to submit information and data (sections 69501.4, 69502.2, and 69503.3) to inform DTSC why chemicals and products should or should not be in the finalized lists. The proposed regulations have been crafted in a manner that maximizes the use of existing information, confers a great deal of flexibility, and time lines are reasonable, with allowance for petitions and extension requests. DTSC is making no changes to the regulations in response to this comment. Please also see Response to Comment 7-3 under Chemical Prioritization and section 69502.2(b).

Harmonize

Comments: 86-18, 86-19

Comments Summary:

The above comments assert that European Union REACH concepts and information generated under it should be taken into account in these regulations to harmonize the approach.

Response:

DTSC notes that revising the regulations is not needed to use information generated by any domestic and foreign entities that have information or other resources that they are willing to make available to DTSC.

With regard to European Union's REACH, the proposed regulations expressly mention data submitted under the REACH program as one of the types of existing data that may be submitted to DTSC to fulfill requirements under these proposed regulations. This was done to allow parties that had already submitted data under REACH to rely on this data, to the extent it met DTSC's requirements, without having to incur the time and expense necessary to generate new data. DTSC will continue to be open to working with other regulatory regimes to minimize costs and maximize efficiencies.

This also allows companies to minimize costs and maximize efficiencies when complying with these regulations. DTSC understands that there may be some difficulty, for a variety of reasons, that makes it difficult for some parties to submit requested information. DTSC anticipates the difficulties will be very case-specific. If and when such difficulties arise, DTSC will work with the affected parties on a case-by-case basis to try to resolve the difficulty and find an alternate source or means of acquiring the desired information.

Comments: 1-3, 41-4, 59-10, 73-1, 73-4, 74-27, 84-1, 92-5, 94-5, 105-6, 125-6

Comments Summary:

These commenters state that no other state, federal or international jurisdiction apart from these regulations in California, has sought to begin with 1,200+ actionable chemicals.

Response:

Based on DTSC's research and review of chemical lists from different jurisdictions, DTSC respectfully disagrees with the comment that no other jurisdiction has sought to begin with a large list of chemicals similar in size to California's list.

Table 6. Chemical List Comparison

Jurisdiction	Broad List	Focused List
Washington	High Priority Chemicals (~2,000)	Chemicals of High Concern for Children (~66)
Maine	Chemicals of Concern (~1,400)	Chemicals of High Concern (~70)
Minnesota	Chemicals of High Concern (~1,700)	Priority Chemicals (~9)
Canada	Priority Chemicals (~4,300)	Highest Priority Chemicals (~200)
Australia	Priority Existing Chemicals for Assessment (~3,000)	Priority Chemicals (~800)
Europe	Restricted Substances List (~1,000)	Substances of Very High Concern (~84)[1]
Japan	Monitored Chemicals (~1,550)	Priority Chemicals (~88) reporting
U.S.EPA	Candidate List (~345)	TSCA Work Plan Chemicals (~83)
California	Candidate Chemicals (~1,200)[2]	Chemicals of Concern Work Plan** (~250)[3]

[1] not a subset of the Restricted Substances List
[2] estimated number of Candidate Chemicals (previously known as COCs) excluding pesticides and drugs.

[3] estimated number of Chemicals of Concern (new definition) that may be a basis for products on the initial Priority Products list.

Table 5 shows chemical lists from different jurisdictions that are conceptually similar to the initial list of Candidate Chemicals (previously known as COCs) in the proposed regulations but are used for a variety of purposes, such as chemical data reporting or data gathering. The lists from Washington, Maine, and Minnesota are most similar in their intent or purpose to the initial list of Candidate Chemicals (previously known as COCs), and the broad list of chemicals from most of the different jurisdictions are quite similar in size to California's proposed list of chemicals.

DTSC is making no changes to the regulations in response to this comment.

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ARTICLE 3. CHEMICALS OF CONCERN AND CONSUMER PRODUCT PRIORITIZATION PROCESS

Support Article 3

Comments: 5-72, 5-77, 7-8, 7-10, 7-11, 12-5, 13-4, 13-6, 14-3, 29-13, 30-2, 36-15, 36-16, 36-17, 36-18, 64-7, 66-21, 70-3, 70-7, 73-6, 74-40, 78-4, 78-6, 80-9, 81-6, 70-3, 70-5, 74-34, 91-2, 91-4, 91-5, 107-47, 118-3, PH6-3, PH17-5, PH22-1, PH32-5

Comments Summary:

The above comments expressed support for specific provisions in Article 3. The provisions in Article 3 clarify, interpret and make specific the provisions of Health and Safety Code section 25253(a) (1). More specifically, the article establishes the process for evaluating Chemical(s) of Concern in consumer products. Consumer products listed as Priority Products containing Chemical(s) of Concern will be subject to the requirement to conduct a comprehensive Alternatives Analysis (AA) under Article 5. There are exceptions to this requirement also specified in Article 5 that are described in detail in the Response to Comments document for the January 2013 version of the regulations.

The comments expressed support for the following provisions:

- Section 69503.2(a), which specifies the product prioritization factors the Department of Toxic Substances Control (DTSC) will take into account in prioritizing consumer products;
- Section 69503.2(a)(1)(B)4.c., which takes into account the intended uses, frequency and duration of a consumer product containing a Chemical(s) of Concern to establish the likelihood of exposure;
- Section 69503.2(a)(1)(B)4.d., which takes into account how well a Chemical(s) of Concern is contained within a product as a practical way to assess exposure;
- Section 69503.2(a)(1)(B)4.f., supports DTSC's decision to not include shared mode of action as a basis for considering adverse impacts, as was included in previous versions of this regulation. Assessing mode of action is complex, not fully elucidated, and would add unnecessary uncertainty and controversy to Chemical(s) of Concern analysis;
- Section 69503.2(a)(2), which specifies DTSC will give greater priority (all other factors being equal) to products where there are more data to substantiate adverse impacts and exposures;

- Section 69503.3(f), which specifies that DTSC will develop a Priority Product Work Plan that identifies and describes product categories that DTSC will evaluate to identify products for the Priority Products list;
- Section 69503.4(b), which specifies that DTSC shall hold one or more public workshops to provide opportunity for input on the proposed Priority Product list;
- Section 69503.4(e), which specifies that the first Priority Products list will be limited to no more than five Priority Products;
- Section 69503.5, which specifies the AA Threshold Exemption is a product-specific concentration for Priority Products;
- Section 69503.5(a), which specifies that the AA Threshold Exemption is provided by filing an AA Exemption Notification;
- Section 69503.5(c), which allows the AA Threshold to be adjusted based on sound science and reliable information;
- Section 69503.5(c)(1)(C), which specifies that the AA Threshold may be adjusted for recycled feedstock;
- Section 69503.5(d), which limits the AA Threshold for multiple Chemical(s) of Concern with the same hazard trait; and
- Section 69503.6, which specifies the notification requirements for an AA Threshold Exemption.

Response

DTSC is not making any changes to the regulations in response to the above comments, unless otherwise amended in response to more specific comments which are set forth in the subsequent sections.

In response to comments related to the potential size of the chemicals list, consideration of existing resources, and to provide the appropriate and necessary market signals for the chemicals being prioritized and the products that contain them, DTSC renamed the Chemical(s) of Concern to Candidate Chemical(s) in the revised proposed regulations dated January 2013. This renaming convention more appropriately sends the market signals that those chemicals and/or chemical ingredients appearing on authoritative lists could be further evaluated and subsequently prioritized as a Chemical of Concern in a Priority Product. Further, this renaming convention remains consistent with Health and Safety Code section 25252(a), which mandates that the DTSC “adopt regulations to *establish a process* to identify and prioritize those chemicals and chemical ingredients in consumer products that may be considered as being a Chemical of Concern….” (emphasis added).

The renaming convention continues to allow DTSC to "reference and use, to the maximum extent feasible, available information from other nations, governments and authoritative bodies that have undertaken similar chemical prioritization processes. The proposed regulations leverage the work and costs already incurred by those entities and minimize costs and maximize benefits for the state's economy" (Health and Safety Codes section 25252(b)(2)).

In response to the above overarching change, Article 3 in the proposed regulations dated July 2012, was also renamed to *Process for Identifying and Prioritizing Chemical Combinations.* In addition, to streamline and remove duplicative provisions, DTSC combined provisions where appropriate and re-arranged some provisions to present the requirements more sequentially.

§ 69503 General

Comment: 9-36, 10-5, 104-2, 107-11

Comment Summary:

The above comment expressed concerns with the provisions in Article 3, which clarify, interpret and make more specific the provisions of Health and Safety Code section 25253(a)(1). More specifically, the article establishes the process for evaluating Chemical(s) of Concern in consumer products. Consumer products listed as Priority Products containing Chemical(s) of Concern will be subject to the requirement to conduct a comprehensive AA under Article 5, subject to specified exceptions in Article 5. In summary the following concern was expressed:

- The proposed regulations raise significant concerns that DTSC does not intend to consistently apply an objective, science-based process, but instead structure and administer a program that responds to the latest sensationalist media story or activist agenda. The concerns start with the use of the narrative standard, which is ultimately subjective and facilitates a political, not scientific, basis for prioritization.
- The proposed regulations seem to include all commercially available products and packaging and not simply everyday consumer products. Full implementation of the rule as proposed will be costly and require substantial government resources and the sustainability of this program remains questionable.
- DTSC should consider a step-wise, methodical evaluation of chemicals of concern in priority consumer products, provide appropriate notice and information to the public, enhance health and environmental protection, minimize the potential burden to both the State and the regulated community, leverage the

considerable work already done by other governments (which is required by statute), and avoid unwarranted negative impacts on the market.

Response:

The use of narrative standards offers significant advantages over other approaches because they establish the standards or goals and objectives that must be achieved and allow for varying methods and/or criteria that can be used to demonstrate whether the goals and objectives have been met. In contrast, a prescriptive standard would prescribe concentrations, methods of detection, intended uses of the products, etc., without stating goals and objectives and would limit the options the regulated entities and DTSC would have at their disposal. Given the breadth and scope of the proposed regulations, it would be simply unthinkable that DTSC would know the all the varying types and pieces of information to make the regulations prescriptive and protective at the same time, as intended by AB 1879. Narrative standards allow DTSC to focus on the characteristics of the final product and the adverse impacts it has on human health and the environment. In addition, narrative standards allow DTSC to take advantage of new technologies, innovation, public input, and create efficiencies while ensuring human health and the environment are being protected.

As stated in the Initial Statement of Reasons (ISOR), by definition, a prescriptive process for decision-making entails a fairly rigid adherence to a set of steps and/or specific weighting of various factors or criteria. This, in turn, creates a tension between the prescriptive requirements and advances in technology to allow for good decision-making, not only for DTSC but for the regulated community as well. A prescriptive process would only reflect decisions based on current science and understanding, thus creating the possibility that the current process in place ignores new science and understanding for future decisions. While regulations may be amended to reflect new science, by the time the regulations are amended, the regulations may need further amendment because the science has progressed again. Predictably, the regulations would always be out of step with advances in technology if a more rigid, static prescriptive approach were adopted.

DTSC is mindful that the processes in regulations need a measure of predictability and certainty, while remaining relevant and appropriate as the program grows and matures. There will be a continuing need to incorporate advances in science, knowledge, and experience. Regulatory decisions need to be informed by the best scientific information and approaches available. For all these reasons, DTSC is not specifying a prescriptive process with numerical weighting or ranking system for chemicals and products. Instead, DTSC is using narrative standards that allow DTSC to use the best available

scientific information and practices to identify and prioritize chemicals and products. It is necessary that DTSC employ a narrative approach to decision-making to effectuate the statutory provisions in a timely and meaningful way.

DTSC recognizes that before decisions are made *final*, stakeholders need to examine the rationale, data, and information sources that led DTSC to the decisions it made. Transparency and stakeholder input (public comment periods and public workshops) are built into Articles 2 and 3 by requiring DTSC to provide its rationale for proposing to remove or add additional Candidate Chemicals and Priority Products with Chemical(s) of Concern and by allowing ample opportunity for public comment on those decisions and the reasons for them.

DTSC has designed the proposed regulations to be pertinent, transparent and flexible: 1) to accommodate the availability and type of chemical and product information being considered and evaluated; and 2) to stand the test of time by allowing DTSC to consider chemical information based on advances in science and technology. Flexibility and ease of implementation are important values that may be undermined by application of by rigid, formulaic, numerical approaches. Thus, DTSC adopted a more scientifically appropriate and flexible approach that outlines factors and criteria that DTSC will consider, but without putting a rank order on the importance of these considerations or criteria. Accordingly, DTSC is not making any changes in response to the above comment.

§ 69503.1 Applicability

Comments: 66-20

Comments Summary:

The above comments expressed the view that while the ISOR is clear, the proposed regulations do not clearly state that products that do not contain a Chemical of Concern are outside the scope of these regulations. The comments recommend making this clarification in section 69503.1 or in the definition of Priority Product.

Response:

DTSC respectfully disagrees. Section 69503.1 already provides: “Except as provided in section 69501(b), this article applies to all products *that contain one or more Candidate Chemicals* [previously Chemicals of Concern] and that are placed into the stream of commerce in California” (emphasis added) (January 2013). Conversely, if a product

does not contain a Candidate Chemical, it is not subject to Article 3 or subsequent articles.

As described in Article 2, the authorizing legislation requires DTSC to identify and prioritize chemicals or chemical ingredients in consumer products. The prioritization process in Article 2 identifies chemicals or chemical ingredients that have adverse health and/or environmental endpoints. While earlier versions of the proposed regulations have referred to the initial chemicals list as Chemical(s) of Concern, for simplicity and to explicitly create a multiple stage chemical identification and prioritization process, these chemicals are now called Candidate Chemicals. It is only after a Candidate Chemical has been identified in a consumer product and paired with a product that these two are then referred to as Chemical(s) of Concern/Priority Product. Amendments to this provision or the definition of "Priority Product" are not necessary.

In response to overarching comments related to the size and scope of the initial chemicals list being proposed, DTSC adopted a two tiered approach to: 1) provide the necessary signals to industry; and 2) allow for a narrower list of chemicals to be evaluated without unnecessarily creating confusion. While the comments are summarized in relation to Chemical(s) of Concern, the responses will refer to the Candidate Chemical(s) and Chemical(s) of Concern as appropriate to reflect changes made in the January 2013 version of the proposed regulations.

§ 69503.2 Priority Products Prioritization Factors

§ 69503.2(a) Product Prioritization Factors

Comments: 3-4, 5-73, 7-6, 9-81, 9-83, 11-6, 11-39, 24-4, 47-17, 49-13, 54-2, 64-7, 64-8, 66-26, 74-33, 83-3, 107-11, 136-4, 15-4, PH12-8, PH16-1, PH16-2, PH16-4, PH36-2

Comments Summary:

The above comments expressed concern with section 69503.2(a), which specifies that DTSC may evaluate products to determine the adverse impacts and exposures associated with the product by considering the factors in sections 69503.2(a)(1) through (a)(3). In summary, the following concerns were expressed:

- The proposed regulations do not provide necessary predictability, lacks transparency, and is seriously flawed;
- The highest priority chemicals such as carcinogens, developmental or reproductive toxins, and persistent and bio-accumulative toxins, or the most

serious chemicals that contribute most to the adverse impacts should be prioritized;

- The lack of clarity will discourage investments in green chemistry research;
- DTSC has too much discretion in its decision-making, allowing arbitrary decisions, which is not acceptable from a scientific or public policy standpoint, is ripe for legal challenge, will result in misallocation of resources, and future administrations may take different approaches than the current administration;
- It is not possible for different people conducting this process to generate the same result;
- The proposed regulations should provide an objective, step-by-step process that clearly outlines how DTSC will identify Priority Products and make a decision;
- The proposed regulations should incorporate/utilize a quantitative process and/or rank or weigh the severity of the adverse impacts;
- DTSC should design a process that engages in triage and prioritization based on sound scientific principles, using robust peer and public review; and
- The proposed regulations should provide an indication to stakeholders of what products are not likely to be identified as Priority Products; and
- The prioritization process is wide open and anything can occur, even if it is not cost effective or efficient. The categories of Priority Products need to be carefully defined and very narrowly focused.

Response:

As stated in the ISOR, the proposed regulations are consistent with Health and Safety Code section 25252 of the authorizing legislation, which mandates that DTSC adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being of concern. The prioritization processes in Articles 2 and 3 implement that mandate. While Article 2 focuses on identifying the chemicals that may be of concern, Article 3 focuses on identifying the criteria and process by which those chemicals will be evaluated by DTSC to determine if the consumer products that contain them should be prioritized for further evaluation by the responsible entity under an AA, as specified in Article 5.

The prioritization process in Article 2 identifies chemicals that have been listed on authoritative lists as having adverse impacts on human health and/or the environment. Those chemicals are designated as Candidate Chemicals. When a consumer product contains a Candidate Chemical, those products may be evaluated and prioritized using the factors specified in sections 69503.2 and 69503.3 (January 2013). Collectively,

these provisions carry out the legislative mandate to establish an identification and prioritization process that includes, but is not limited to:

1) The volume of a chemical in commerce in California;
2) The potential for exposure to a chemical in a consumer product; and
3) Potential effects on sensitive subpopulations, including infants and children.

Consumer products will be listed as Priority Products taking into account these criteria as well as the other criteria set out in Article 3.

The provisions specify that DTSC may evaluate products to determine their adverse impacts and associated exposures by considering the factors listed in section 69503.3 for which information is reasonably available (January 2013). Based on the evaluation, DTSC will determine which products should be proposed and listed as Priority Products, in accordance with the process laid out in subsequent sections.

As stated in the ISOR the regulations need to remain relevant and appropriate as the Safer Consumer Products program grows and matures, hence the narrative criteria. As advances in science, knowledge, and experience evolve, implementation of the proposed regulations must be adaptable to those advances. Regulatory decisions need to be informed by the best scientific information and approaches available. For these reasons, DTSC is not specifying a prescriptive process with numerical weighting or ranking system for chemicals and products but is instead using a narrative approach that allows DTSC to use best available scientific information and practices to identify and prioritize chemicals and products. It is necessary that DTSC employ a narrative approach to decision-making to effectuate the statutory provisions in a timely and meaningful way.

As stated in the ISOR, while a prescriptive process for identifying and prioritizing chemicals and products, with rigid criteria for DTSC to evaluate and make decisions, may provide a greater level of predictability and certainty to manufacturers who wish to evaluate their chemicals and consumer products—especially for chemicals and products not yet listed as Chemical(s) of Concern or Priority Products—it also greatly restricts what DTSC and the regulated community may take into account in the out years.

DTSC is mindful that some manufacturers may wish to take proactive steps to examine alternatives to one or more chemicals in a consumer product that the manufacturers make even before the consumer product is subject to these regulations. DTSC, therefore, recognizes the value these regulations may serve as a market driver for

manufacturers to voluntarily step up and develop safer consumer products, use safer alternative chemicals, or redesign the manufacturing processes of consumer products.

While there is some value in greater certainty and predictability with a prescriptive process than with a narrative approach, there may also be some negative consequences. More specifically, by definition, a prescriptive process for decision-making entails a fairly rigid adherence to a set of steps and/or specific weighting of various factors or criteria. A prescriptive regulatory process can only reflect current science and creates the likelihood that the process adopted in the proposed regulations would ignore advances in science. While regulations may be amended to reflect advances in science, by the time the regulations are amended, the regulations may become quickly outdated and need further amendment. Under a prescriptive approach, DTSC may constantly be behind advances in science and may constantly be amending the proposed regulations. Not only would this constitute a poor use of limited state resources, it would also limit the regulated community from making positive changes in the chemicals and products that are manufactured.

DTSC agrees that the proposed regulations need a measure of predictability and certainty. However, the regulations also need to remain relevant and appropriate as the Safer Consumer Products program grows and matures. The Green Ribbon Science Panel (GRSP), while not a consensus-forming body, overwhelmingly supported DTSC not specifying a prescriptive process with numerical weighting or ranking system for chemicals and products. Instead, the GRSP and DTSC both supported the use of a narrative approach that allows DTSC to use best available scientific information and practices to identify and prioritize chemicals and products. It is necessary that DTSC employ a narrative approach to decision-making to effectuate the statutory provisions in a timely and meaningful way.

DTSC recognizes that before decisions are made final, stakeholders need to examine the rationale, data, and information sources that led DTSC to the decisions made. Thus, transparency and stakeholder input (public comment periods and workshops) are built into Articles 2 and 3. DTSC is required to provide its rationale for proposing to remove or add additional Chemical(s) of Concern and Priority Products, and the public is allowed to comment on the proposed decisions and the reasons offered for those decisions.

Section 69503.2 and 69503.3 specifies the factors DTSC will consider and process by which DTSC will evaluate product-chemical combinations (January 2013). While the regulations do provide narrative standards, there is some predictability and certainty offered by those standards. DTSC does not have unfettered discretion in how to

evaluate or select products as Priority Products. In addition, predictability and certainty are also ensured by the scope of the regulations. In other words, standards, factors, and/or criteria not detailed in the proposed regulations cannot be later considered, thus affording the regulated community the predictability they seek. Future administrations are locked into the provisions of the proposed rule unless and until the regulations are amended under the Administrative Procedure Act (APA).

Additional predictability is afforded through the list of Candidate Chemicals established in Article 2. Manufacturers using Candidate Chemicals in their products may begin to consider alternatives to those Candidate Chemicals even though they are not required to do so. In addition, the Priority Product Work Plan, issued periodically that is required under the proposed regulations (beginning one year after the effective date of these regulations), will provide predictability because it identifies product categories that will be subject to evaluation by DTSC for possible listing as Priority Products.

DTSC is not making any changes to the regulations in response to these comments.

§ 69503.2(a)(1)(A) Adverse Impacts Associated with Chemical(s) of Concern

Comments: 9-33, 9-85, 9-86, 9-90, 41-13, 74-5, 101-25, 107-12

Comments Summary:

The above comments expressed concern with section 69503.2(a)(1)(A), which is the first of two overarching criteria used in evaluating consumer products and prioritizing them for adverse impacts and exposures that are associated with the Chemical(s) of Concern. In summary, the following concerns where expressed:

- The type of information DTSC will use while considering potential adverse public health and environmental impacts is too ambiguous, extremely diffuse, difficult to reliably obtain, or may be claimed as confidential information;
- The decision-making process should be consistent, objective, transparent, and rely on accurate scientific information;
- The regulations should establish a framework to integrate information from all relevant studies, giving the greatest weight to those of most relevance and highest quality; and
- The regulations should present detailed and objective hazard and risk information, along with assumptions and full disclosure of key information in a manner understandable to stakeholders and risk managers.
- It is not clear with the use of the word “ability” in place of “potential” if this is intended to direct DTSC to look at the physiochemical properties of a chemical to

make the determination of hazard rather than simply grouping chemicals into categories that might be acceptable.

Response:

The proposed regulations specify that when considering the potential of a Chemical of Concern in a product to contribute to or cause adverse public health and/or environmental impacts, DTSC must consider reliable information relevant to the specified factors. This provision coupled with section 69501.1(a)(57) of the January 2013 version of the regulations, which defines the term “reliable information,” ensures that the information DTSC takes into account is of the appropriate rigor and reliability. Reliable information may include peer reviews by other qualified disinterested parties. The proposed regulations require that reliable information be used, and it will be taken into account if the reliable information demonstrates a lack of adverse impacts or exposures.

DTSC recognizes that while some of the information related to the factors and/or criteria that will be evaluated is currently available, some is not. However, the proposed regulations will undoubtedly create demand for that information. The information, while slow to be obtained at the onset, will become more and more available in the later years. As stated earlier in response to comments on section 69503.2(a) “Product Prioritization Factors”, the proposed regulations cannot include prescriptive criteria and/or processes with numerical weighting or ranking systems for chemicals and products if the regulations are expected to evolve and address consumer product impacts in the coming years. The proposed regulations do, however, establish a consistent objective framework to integrate information from all relevant studies and on a case-by-case basis, and attribute the most relevance to the studies of highest quality.

In addition, the public review of and comment on the proposed Priority Products List, provided under section 69503.5 of the January 2013 version of the regulations, will provide additional objectivity, transparency, and scientific accuracy.

In response to the above comments, other comments, and as part of DTSC’s streamlining efforts, the provisions formerly in 69503.2(a)(1)(A) are now in section 69503.3(a)(1).

DTSC is not making any other changes to the regulations in response to these comments.

§ 69503.2(a)(1)(A)1a Hazard traits and/or Environmental and Toxicological Endpoints

Comment: 124-2

Comment Summary:

The above comment expressed concern with section 69503.2(a)(1)(A)1.a., which specifies that in evaluating consumer products and prioritizing them for adverse impacts and exposures that are associated with the Chemical(s) of Concern, DTSC must take into account the Chemical(s) of Concern's hazard traits and/or environmental and toxicological endpoints. In summary, the following concerns where expressed:

- How will it be determined that a specific product is a significant contributor to exposure as various products contains those Chemical(s) of Concern;
- It is unclear how eliminating the Chemical(s) of Concern from a product will affect the overall exposure to such chemicals;
- Is there anything that would encourage manufacturers to consider this chemical in other consumer products; and
- The burden of proof is placed on the regulated community.

Response:

Health and Safety Code section 25252 specifies that in establishing an identification and prioritization process for chemicals, chemical ingredients, and consumer products, DTSC must include the following:

1) The volume of the chemical in commerce in California;
2) The potential for exposure to the chemical in a consumer product; and
3) Potential effects on sensitive subpopulations, including infants and children.

As stated in the ISOR, these provisions establish the process to evaluate the adverse impacts of a Candidate Chemical and its presence in a product as a consideration for listing the product as a Priority Product. The relevant information that is obtained on the Candidate Chemical is further evaluated for its physical traits and toxicity profile that may have an impact when it is in a consumer product. Additionally, when there are a number of products being evaluated at the same time that contain the same Candidate Chemical, this information may serve to tip the scales to list one particular product containing a Candidate Chemical as a Priority Product over another. This is necessary to further evaluate the public health and environmental significance of the Candidate Chemical in a given consumer product, as opposed to the chemical in the abstract. For instance, because different products that have the same function and contain the same

Candidate Chemical may be manufactured differently and have different physical forms (*e.g.*, liquid or solid), the products may behave, react, and cause public health, ecological and environmental harm differently. DTSC will use this information to assess the exposure to the Candidate Chemical in these products and their ability to contribute to or cause adverse impacts as a basis for determining which products to list as Priority Products. For example, the Candidate Chemical's impact to terrestrial animal or plant organisms may be greater for a Priority Product in powder form due to its ability to disperse with the wind and contaminate a larger area of the environment than the same or similar Priority Product in larger solid form.

Prioritizing a Chemical of Concern in certain products will likely be those with the highest propensity to cause or contribute to an exposure. Exposure to Chemical(s) of Concern will diminish as the products with the highest potential to cause an exposure or release are prioritized and addressed. In addition, the responsible entities wanting to stay out of regulatory oversight will naturally select safer alternatives to Chemical(s) of Concern. The burden of proof in not placed on the regulated community until the product is prioritized. DTSC is responsible for prioritizing the products that contain Chemicals of Concern.

DTSC is not making any changes to the regulations in response to these comments.

§ 69503.2(a)(1)(A)1.b. & c. Aggregate and Cumulative Effects

Comments: 9-17, 9-18, 9-19, 9-20, 9-21, 9-22, 9-91, 9-92, 9-93, 9-94, 36-34, 36-64, 64-9, 91-2, 107-50, PH6-5

Comments Summary:

The above comments expressed concern with section 69503.2(a)(1)(A)1.b. and c., which specify that in prioritizing products for adverse impacts and exposures, DTSC will take into account the Chemical(s) of Concern's aggregate effects and cumulative effects with other chemicals with the same or similar hazard trait(s) and/or environmental or toxicological endpoint(s). In summary, the following concerns were expressed:

- Assessing aggregate effects and risks requires considerable data and information that manufacturers of individual products typically do not have and may be difficult to readily obtain;
- It is unclear when, how often, and through what process DTSC will determine when evaluating aggregate and cumulative effects is necessary;

- Aggregate assessments should only be performed on a case-by-case basis for chemicals that meet specific criteria, such as cases that have very narrow margin of exposure;
- Include environmental factors;
- Evaluating these effects requires considerable data, is onerous, will divert resources, may not be available, may not be predictable, and may present implementation challenges;
- Assessing cumulative effects requires orders of magnitude more data than that for aggregate effects and is not practical;
- Clarification is needed regarding whether aggregate effects and cumulative effects refers to an assessment of human health and/or environmental risks, noting in particular that typically the term “risk” rather than “effect” is used;
- The approaches to evaluating aggregate and cumulative exposure are “complex” and “far from settled science,” which “currently lacks the guidance of available and validated scientific methodologies”;
- Adding exposure to the evaluation would result in a virtually infinite analysis loop; and
- The regulations should adopt the best available framework and/or conform to state of science, developed and endorsed by the World Health Organization/International Program on Chemical Safety and U.S. EPA.

Response:

Article 3 in its entirety addressed the process by which DTSC will prioritize chemicals and the products that contain them. The burden of prioritizing products is not placed on the responsible entities. DTSC is responsible for prioritizing the Candidate Chemical(s) and identifying the products that they are contained in. The products that contain those chemicals are then the Priority Products that contain the Chemical(s) of Concern. DTSC will follow the process contained in Article 3 every time that it considers prioritizing a product.

Taking into account the adverse impacts being observed, DTSC will determine if evaluating aggregate and/or cumulative effects is necessary and appropriate for the consumer products under evaluation and will evaluate these effects for which data are reasonably available. DTSC acknowledges that in some cases the information may be difficult to obtain. However, identifying the aggregate hazard traits associated from single chemicals arising from multiple sources and the cumulative hazard traits arising when two or more chemicals share a common mechanism of toxicity must be addressed to meet the intent and goals of AB1879 which mandates that DTSC prioritize

those chemicals that may be of concern by taking into account, including but is not limited to, the traits, characteristics, and endpoints of those chemicals.

The proposed regulations provide the necessary latitude that allows DTSC to consider all factors, to the extent the information is available. This flexibility prevents a "paralysis by analysis" effect and allows DTSC to prioritize products for which sufficient and reliable information demonstrates adverse impacts and exposures.

As stated earlier, the proposed regulations establish a consistent objective framework to integrate information from all relevant studies and on a case-by-case basis, attributing the most relevance to the studies of highest quality. In identifying the adverse impacts associated with the Chemical(s) of Concern, DTSC will take into account all of the factors enumerated in section 69503.3(a)(1)(A) through (G) (January 2013) and make a case-by-case determination on relevance of those factors. The information will be sought by searching the public domain and requesting manufacturers to provide this information voluntarily through data call-ins conducted under section 69501.4. DTSC may also consider using survey techniques to obtain this information. It is not necessary to specify in regulation other existing statutory or regulatory information gathering authorities available to DTSC. During implementation of the regulations, DTSC will use existing and available authorities to gather data as necessary.

The narrative standards of the proposed regulations allow DTSC to use the methods of U.S. EPA or the World Health Organization/International Program on Chemical Safety or other methods to evaluate chemicals without the need to include these methods in the regulations. The narrative standards allow DTSC to use the most appropriate method.

Hazard traits and environmental or toxicological endpoints are both defined in section 69501.1(a). These defined terms are consistent with the terms adopted by the Office of Environmental Health Hazard Assessment (OEHHA) in the Chapter 54 companion regulations to these proposed regulations. The terms, as defined and summarized below, do not require amendments to include environmental factors; they are already included through:

- A "Hazard trait" as defined means properties of chemicals that fall into broad categories of toxicological, environmental, exposure potential and physical hazards that may contribute to adverse effects in exposed humans, domesticated animals, wildlife, or in ecological communities, populations or ecosystems;
- An "environmental endpoint" for a specific hazard trait is a measured or otherwise observed adverse environmental effect in ecological systems, or in

components of ecological systems, or in non-human organisms within ecological systems that indicates the presence of the hazard trait; and/or

- A "toxicological endpoint" for a specific hazard trait is a measured or otherwise observed adverse effect in a biological system that indicates the presence of the hazard trait.

The proposed regulations use the terms "impacts" and "effects" to remain consistent with Health and Safety Code sections 25251-25257.1. In evaluating the aggregate and cumulative effects, DTSC does not intend to quantify the human health and/or environmental risks. The goals of the proposed regulations are to identify and prioritize those chemicals that may be of concern (*i.e.*, pose a hazard) by taking into account the intrinsic traits of the chemical, the characteristics and the endpoints of the chemical, and to identify how to best limit or reduce the hazard (*i.e.*, risk) that is posed. The proposed regulations do not contemplate a full risk assessment which quantifies risks.

The public review of and comment on the proposed Priority Products list, provided under section 69503.5, provides transparency and opportunity for the public to comment on the approach and evaluation of the products listed as Priority Products.

As part of DTSC's streamlining efforts, the provisions formerly in section 69503.2(a)(1)(A) are now in section 69503.3(a)(1), the provisions formerly in section 69503.2(a)(1)(A)1.b. are now in section 69503.3(a)(1)(B), and the provisions formerly in section 69503.2(a)(1)(A)1.c. are now in section 69503.3(a)(1)(C). DTSC is not making any further changes to the regulations in response to these comments.

§ 69503.2(a)(1)(A)1.d. Physical Chemical Hazards

Comment: 70-4, 41-3

Comment Summary:

The above comment expressed concern with section 69505.3(a)(1)(A)1.d. In summary, the following concerns were expressed:

- Physical chemical hazards are specifically included in section 69503.2(a)(1)(A)1.d. when hazard traits (which include physical hazards) are already included under section 69503.2(a)(1)(A)a.

Response:

In response to the above comment, the duplicative reference has been deleted. In response to streamlining efforts, the provisions formerly in section 69503.2(a)(1)(A) are

now in section 69503.3(a)(1). DTSC is not making any further changes to the regulations in response to the above comment.

§ 69503.2(a)(1)(A)2.a. Adverse Impacts: Sensitive Subpopulations

Comment: 9-87, 41-3

Comment Summary:

The above comment expressed concern with section 69503.2(a)(1)(A)2.a., which specifies that DTSC shall give special consideration to the ability of the Chemical(s) of Concern in the product to contribute to or cause adverse impacts to sensitive subpopulations. In summary the following concern was expressed:

- The term "sensitive subpopulation," as defined in Article 1, is vague and highly subjective. The term may include different demographics or conditions depending on the context, and is not just limited to children and pregnant women.

Response:

Health and Safety Code section 25252 specifies that in establishing an identification and prioritization process for chemicals, chemical ingredients, and consumer products, DTSC must include the following:

1) The volume of the chemical in commerce in California;
2) The potential for exposure to the chemical in a consumer product; and
3) Potential effects on sensitive subpopulations, including infants and children.

The proposed regulation appropriately defines the term "sensitive subpopulation" to include more than just infants, children, and pregnant women.

While infants, children and pregnant women may be sensitive subpopulations, they are not the only sensitive subpopulations. Section 69501.1(a)(64) of the proposed regulations defines "sensitive subpopulations" to mean "subgroups that comprise a meaningful portion of the general population that are identifiable as being at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait and/or toxicological endpoint, including, but not limited to, infants, children, pregnant women, and elderly individuals. 'Sensitive subpopulations' also include persons at greater risk of adverse health effects when exposed to chemicals because they are either individuals with a history of serious illness or greater exposures to chemicals, or workers with greater exposures to chemicals due to the nature of their occupation." (January and April 2013)

DTSC respectfully disagrees that the term “sensitive subpopulation” is vague and highly subjective. It is consistent with common usage in the relevant scientific community, and is appropriate for use in these regulations. While it employs a narrative, rather than prescriptive standard, this is also appropriate for the reasons set out earlier in this Response to Comments document for Article 3.

As part of DTSC’s streamlining efforts, the provisions formerly in section 69503.2(a)(1)(A) are now in section 69503.3(a)(1). DTSC is not making any further changes to the regulations in response to the above comment.

§ 69503.2(a)(1)(B)1. Exposures: Market Presence

Comments: 13-4, 14-3, 37-8, 37-9, 49-13, 55-27, 55-28, 73-7, 74-35, 80-6, 91-2, PH2-7

Comments Summary:

The above comments expressed concern with section 69503.2(a)(1)(B)1., which specifies that in prioritizing products for exposure to the Chemical(s) of Concern, DTSC will take into account the market presence of the product. This includes considering the following for the product: the statewide sales by volume, sales by units, and or the intended uses, targeted customer base(s) types and age groups. In summary, the following concerns were expressed:

- Market place presence of products, and market volume are inadequate surrogates for exposure, compromising science-based decisions and should deleted from the regulation;
- Prioritization must be based on quantitative considerations that can be readily understood and defended;
- The authority in section 69501.4(a) may be used to require retailers to submit information to DTSC that would otherwise be proprietary;
- It is unclear what kind of information could be considered trade secret; and
- This information could provide competitors with information they otherwise would not have available to them.

Response:

As stated in the ISOR, this section appropriately identifies criteria that are relevant to science-based evaluations of exposure. Some examples include the frequency, extent, level, and duration of potential exposure, and containment of the Candidate Chemical(s) within the product. It is necessary to include factors such as market presence, as it is a valuable substitute, *i.e.* surrogate, to extrapolate or measure predicted potential

exposure, for which there is little data. These criteria are necessary to effectuate the statutory mandate in Health and Safety Code section 25252(a)(1) that the regulations specifically include criteria related to volume of sales in California. Naturally, if a chemical is not in commerce or present in products one could extrapolate that exposure to the chemical is unlikely. It is not necessary to quantify a risk to lower or minimize the hazard posed by a chemical.

As stated earlier, DTSC may rely on information about products obtained from a responsible entity under section 69501.4, but is not limited to using only that information in performing its duties under Article 3. The proposed regulations provide DTSC sufficient latitude and flexibility to seek out and utilize a broad range of scientific data and other information it determines is necessary to ensure that this process and the resulting Priority Products list is based on sound science and reliable information.

The regulations reflect the authorizing legislation, which specifies the type of information that can be claimed as trade secret—or more precisely—the kind of information that may not be claimed as trade secret. While the proposed regulations do not require that all critical business decisions be released to external entities, they do require that information related to hazard traits for chemicals be made public. Information submitted to DTSC with valid trade secret claims will not be made publicly available. For a more detailed discussion on trade secret provisions, please refer to the discussion under Article 10 of this Response to Comments document.

In response to the above comment, no changes were deemed necessary. As part of DTSC's streamlining efforts, the provisions formerly in section 69503.2(a)(1)(A) are now in section 69503.3(a)(1).

§ 69503.2(a)(1)(B)4. Exposures: Public and/or Environmental

Comments: 26-4, 36-36, 36-39, 53-2, 53-5, 66-22, 66-21, 66-24, 101-26, 118-4, 121-3, 126-3, PH32-3

Comments Summary:

The above comments expressed concern with section 69503.2(a)(1)(B)4., which specifies that in prioritizing products for exposure to the Chemical(s) of Concern, DTSC will take into account the public and/or aquatic, terrestrial animal or plant organism exposures to the Chemical(s) of Concern in the product during the product's life cycle. In summary, the following concerns were expressed:

- Amend the regulations to better address non-human environmental pollution, including serious water quality concerns;
- Postponing consideration of some of the highest priority water quality problems in the state (*e.g.*, copper, nickel, phosphates, nitrates, selenium, boron) is not acceptable;
- Chemicals selected as initial priorities must meet both human health and environmental criteria;
- Many serious water pollutants may pose significant water quality threats, while often posing few human health risks;
- Provide assurances to environmental justice communities and local agencies;
- Exposures during manufacturing processes are already covered under existing authority by OSHA and should not be included here; and
- DTSC should include the chemicals listed under sections 303(c) and 303(d) of the federal Clean Water Act, and select one of the initial Priority Products to address a purely water quality threat; this would better illustrate the applicability and benefits of these regulations.

Response:

As described in Article 2, the chemical prioritization process identifies chemicals or chemical ingredients that have adverse health and/or environmental endpoints. Section 69502.2 specifies that any chemical that exhibits a hazard trait and/or environmental or toxicological endpoint and is listed on one or more of the lists set out in section 69502.2(a)(1) and/or (2) is on the initial list of Candidate Chemicals. Consistent with Health and Safety Code section 25252(b)(1) of the authorizing legislation, the proposed regulations reference and make use, to the maximum extension feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes. The initial Candidate Chemicals list is comprised of chemicals that have been determined to be of concern by one or more of the numerous authoritative organizations whose work is reflected in the Candidate Chemicals list. As such, chemicals listed on the lists developed under section 303(c) and/or 303(d) of the federal Clean Water Act are already included. It is important to note, however, that a chemical on one of these lists does not automatically trigger all consumer products containing those chemicals as a proposed Priority Product.

It is only after the Candidate Chemical(s) have been identified in consumer products and subjected to the product prioritization process that product-chemical combinations are then referred to as Chemical(s) of Concern and Priority Products, discussed in

section 69503.5 (January 2013). Persons wishing to petition DTSC to add a Candidate Chemical to the list may submit a petition in accordance with the requirements of Article 4.

As stated earlier in the response to comments on § 69503.2(a)(1)(A)1.b. & c. *Aggregate and Cumulative Effects*, hazard traits and/or environmental or toxicological endpoints have been defined in Article 1 to be consistent with the terms adopted by OEHHA, in its companion regulations at Chapter 54, to ensure that all endpoints are adequately evaluated not only for the potential to cause adverse impacts but also for the potential for exposure. While the provisions in section 69503.3(a) focus on the propensity for adverse impacts associated with the Candidate Chemicals, the provisions in section 69503.3(b) focus on the propensity for exposure to the Candidate Chemicals (January 2013). The two provisions ensure that the goals and intent of AB 1879 is met.

The provisions do not require that a Candidate Chemical pose an adverse health impact and environmental impact in order for it to be evaluated. Instead, the provisions allow for consideration of an adverse human health impact, an environmental impact, or both. Those Candidate Chemicals in consumer products that exhibit a higher volume in commerce, a significant propensity for exposure, and propensity for exposure to a sensitive subpopulation will have all of those factors taken into consideration by DTSC as part of its prioritization process.

The proposed regulations address the adverse health and environmental impacts and the propensity for exposure associated with the Candidate Chemicals during the life cycle of the product. To the extent that existing regulatory and/or statutory programs adequately regulate any potential adverse health and environmental impacts or the propensity for exposure to the Candidate Chemicals, the proposed regulations will take that into account and not duplicate those efforts. However, an evaluation of those existing regulatory or statutory programs is necessary to determine if the impacts are adequately being addressed. The provisions related to impacts during manufacturing are, therefore, necessary. For a more detailed discussion on non-duplication please refer to the discussion on Other Regulatory Programs in sections 69503.2(a)(3) and 69503.3(b) of this document.

In response to the above concerns and other related comments, Article 3 has been rearranged to remove repetitive provisions. The amended provisions in section 69503.2(a) contain the *Key Prioritization Principles*, which specify that any product-chemical combination identified and listed as a Priority Product must meet *both* of the following 1) potential exposure to public and/or aquatic, avian, terrestrial animal or plant organism; and 2) potential to cause significant or widespread adverse impacts. As part

of DTSC's streamlining efforts, the provisions formerly in section 69503.2(a)(1)(A) are now in section 69503.3(a)(1).

§ 69503.2(a)(1)(B)4.a. Life cycle Impacts of Manufacturing, Use and End-of-Life

Comment: 36-107

Comment Summary:

The above comment expressed concern with section 69503.2(a)(1)(B)4.a., which specifies that in prioritizing products for exposure to the Chemical(s) of Concern (now called Candidate Chemicals), DTSC will take into account the life cycle impacts considering manufacturing, use, storage, transportation, waste, and end-of-life management practices to limit exposure to a Chemical(s) of Concern. In summary, the concern expressed: that the extraction of raw materials should be added to section 69503.2(a)(1)(B)4.a.

Response:

This revision is not necessary because the proposed regulations state that exposure includes the entire life cycle of the product. The definition of "life cycle," in turn, includes the extraction of raw materials. Thus, consideration of the extraction of raw materials is already included, even if the phrase is not expressly repeated in this provision.
As part of DTSC's streamlining efforts, the provisions formerly in section 69503.2(a)(1)(A) are now in section 69503.3(a)(1).

§ 69503.2(a)(1)(B)4.d. Containment of Chemical of Concern

Comments: 36-59, 66-21, 66-22, 66-23, 80-7, 80-8, PH28-3

Comments Summary:

The above comments expressed concern with section 69503.2(a)(1)(B)4.d., which specifies that in prioritizing products for exposure to the Chemical(s) of Concern, DTSC will take into account how well a Chemical(s) of Concern is contained within the consumer product. In summary, the following concerns were expressed:

- Clarify that containment means that it is in an inaccessible component within a product;
- Inaccessible components are not an exposure concern, as stated in the ISOR, and should be removed from prioritization. Inclusion of them is inconsistent with the authorizing statute, Washington's children's product laws, the Federal

Hazardous Substance Act, and the Consumer Product Safety Improvement Act; and

- Restricting exposure by confining a chemical within a product may be an improvement, but it fails to meet the innovative intent of AB 1879.

Response:

As stated in the ISOR, how the Chemical of Concern is contained or bound during the use of the product determines, in part, the extent of exposure that may occur. For instance, the Chemical of Concern may be a component inside a product and may not be accessible to the user; in which case, there is little to no exposure as a result of use of the product. The ISOR does *not* state that this scenario would not constitute an exposure concern. Further, "containment" is not synonymous with "inaccessible components." The provisions are consistent with the goals and intent of AB 1879, and it is not necessary to modify California regulations to be consistent with Washington's children's product laws, the Federal Hazardous Substance Act, and the Consumer Product Safety Improvement Act. California's Safer Consumer Products Regulations are far more comprehensive than those other regulatory programs, and the proposed regulations are consistent with Health and Safety Code sections 25251 through 25257.1—the authorizing legislation. One of the goals of the authorizing legislation is to limit or reduce exposure to chemicals in products. (See Health and Safety Code section 25253(a).) This provision is consistent with that goal.

In response to the above comments, clarifying language was added to this provision. The revised language specifies "the potential accessibility to the Candidate Chemical(s) during the useful life or the product and the potential for releases of the Candidate Chemical during the useful life and at the end-of-life" will be taken into account in establishing the potential for exposure. The revised provisions can be found in section 69503.3(b)(4)(F).

§ 69503.2(a)(1)(B)4.e. Engineering and Administrative Controls

Comments: 36-60, 36-61, 39-5

Comments Summary:

The above comments expressed concern with section 69503.2(a)(1)(B)4.e., which specifies that in prioritizing products for exposure to the Chemical(s) of Concern, DTSC will take into account engineering and administrative controls in place to limit exposure to a Chemical(s) of Concern. In summary, the following concerns were expressed:

- Consider engineering safety measures or administrative controls as “interim actions”; and
- Modify the ISOR for section 69503.2(a)(1)(B)4. to specify that these controls are taken into consideration when assessing exposure but should also recognize that the use of these controls in actual practice may be low.

Response:

Consistent with the intent and goals of AB 1879, section 69503.3 specifies that DTSC will consider the adverse impacts associated with the Candidate Chemical(s) in the product and the likelihood of exposure to the Candidate Chemical(s) to evaluate any adverse impacts or exposures to the Candidate Chemical(s) in consumer products during the product’s life cycle (January 2013). Health and Safety Code section 25253(a) states that one of the purposes of the regulations is to “determine how best to limit exposure to or the level of hazard posed by a Chemical of Concern.” One way to limit exposure is to remove the chemical or reduce its concentration, and another is to use engineered safety measures or administrative controls in order to limit and/or reduce exposure.

In evaluating engineering or administrative controls during the product prioritization process in Article 3, DTSC will take into account the efficacy and frequency of these engineered or administrative controls to ensure that the Candidate Chemical(s) is/are not released into the environment throughout the life cycle of the product. If engineering or administrative controls are in place, but these alone do not prevent a release, DTSC may consider this factor as well. For example, there could be emerging contaminants in water bodies or demonstrated to be present in human tissue with associated with adverse impacts. The exposures could result, at least in part, from a given product—despite engineering and/or administrative controls in place. Such a product could be listed as a Priority Product.

After a Priority Product has undergone an AA in accordance with Article 5, regulatory responses under Article 6, may be required. Priority Products that did not have engineering and/or administrative control may be required to have these as part of the regulatory response. However, if a product already had these in place and adverse impacts were still being observed, other regulatory responses could be imposed.

Please refer to Article 6 for a more detailed description of the various regulatory Responses that may be required. As part of DTSC’s streamlining efforts, the provisions formerly in 69503.2(a)(1)(A) are now in section 69503.3(a)(1). No further changes to the regulations are being made in response to these comments.

§ 69503.2(a)(2) Availability of Information

Comments: 36-57, 64-10, 70-5, 107-48, PH16-3

Comments Summary:

The above comments express concern with section 69503.2(a)(2), which specifies that DTSC may consider the extent of information that is available to substantiate adverse impacts and exposures. In summary, the following concerns were expressed:

- Amend the provisions to require responsible entities to provide or produce information needed to make an informed decision;
- This provision undercuts the focus on "reliable information" in the prior sections;
- All available data, the totality of relevant and reliable information, and weight of evidence should be considered to arrive at a scientifically defensible decision; and
- Higher priority should be given to products that have a quantitative evidence of actual exposure and a greater degree of reliable high quality information.

Response:

Health and Safety Code sections 25251-25257 do not provide DTSC with authority to require responsible entities to submit information regarding Candidate Chemicals. Thus, DTSC has included provisions that allow DTSC to request information relevant to chemical and product identification and prioritization, but responsible entities are not compelled to provide DTSC with the requested information. After products are included on the Priority Products list, however, responsible entities for Priority Products will be subject to the requirement to conduct a comprehensive AA under Article 5 unless an alternate means of compliance is chosen. (*See* sections 69505.2 and 69505.3 (January and April 2013).)

DTSC will give full consideration to any available and reliable quantitative evidence of actual exposure in the prioritization process. Unfortunately, information about chemicals that end up in consumer products and thereafter, ranging from product concentrations, toxicity, exposure, and fate and transport, that is available in the open market or in literature ranges from nothing to very substantial. A full complement of quantitative exposure information has rarely accompanied any chemical or product into the marketplace.

In anticipation of the variability of available information, such as exposure data, on chemicals and products, these regulations do not specify a rigid and explicit process that demands the absolute existence and consideration of quantitative exposure information prior to DTSC making a regulatory decision. In fact, pursuant to Health and Safety Code section 25252, the prioritization process established by DTSC must include, but not be limited to, considerations of the volume of the chemical in commerce in the state and the potential for exposure in consumer products. While DTSC shares a preference for direct evidence of exposure, DTSC cannot be constrained in making public health and environmental protection decisions because of the lack of precise quantitative exposure information. DTSC will give full consideration to any available and reliable scientific evidence of potential harm, actual harm, potential exposure and actual exposure in the prioritization process.

DTSC recognizes that the available scientific information has to be viewed in the overall context of the available information on a specific chemical in deciding whether or not a chemical has a hazard trait or whether a product-chemical combination should be listed as a Priority Product. In addition, DTSC recognizes that the available information regarding market presence, product type and concentration, toxicity, exposure, and fate and transport may become available from various sources such as scientific peer reviewed literature, other governments or authoritative sources, and from private research holdings, which can range from non-existent to very substantial.

The groundbreaking nature of these public health and environmental protection regulations require a flexible and adaptive process for prioritizing diverse patterns of product-chemical combinations. DTSC is responsible for implementing an approach that it will identify and prioritize Chemical(s) of Concern, and making regulatory decisions on chemicals in consumer products. DTSC's approach will include, but is not be limited to, the evaluation of the quality/validity of the assays, reliability of the results, nature of the effects observed, consistency and interrelationship among endpoints reported in an individual assay, and relevance, specificity, and sensitivity of the endpoints measured within and across all assays.

The intent of the proposed regulations is one of "prevention of harm" and NOT "recovery from harm." A rigid process like that described by the comments "quantitative evidence of exposure" would limit regulatory action by DTSC until all suggested information areas are filled. This would imply that human suffering as measured by morbidity and/or mortality or environmental damage, such as loss in biodiversity, must be first observed before DTSC can act. This is inconsistent with the regulations' intent of "prevention of harm."

If DTSC were to adopt such an approach, actions under the regulations would be delayed as manufacturers engaged in comprehensive campaigns to generate such information about their chemicals and products under DTSC demand. Information needed would not be limited to the filling of all data gaps concerning hazards for all chemicals currently of interest to DTSC, if not more, but would also logically require manufacturers to develop equally comprehensive data packages to support a complete safety case for all new chemicals, products or alternatives subject to the regulations following the same rubric. Again, across the universe of chemicals and products in the marketplace, those responsible for their presence in the marketplace have not equally filled the marketplace with similar safety information.

The proposed regulations require a rulemaking process at the time DTSC lists Priority Products. Further, all decisions will be based upon information available to DTSC and all stakeholders will be welcome to provide scientific data to broaden and inform (rebut, clarify, or support) DTSC's approach and decisions.

As part of DTSC's streamlining efforts, and in response to related comments on Key Prioritization Factors, these provisions have been modified and are now found in section 69503.2(b)(1)(C). No other changes to the regulations are being made in response to these comments.

§ 69503.2(a)(3) Other Regulatory Programs

Comments: 43-2, 45-3, 45-4, 51-2, 52-2, 54-5, 62-2, 77-2, 86-20, 89-2, 90-2, 110-2, 111-2, 116-2, 118-13, 130-2, 130-5, PH1-2, PH10-4

Comments Summary:

The above comments expressed concern with section 69503.2(a)(3), which specifies that DTSC will consider the scope of other State of California and federal laws and applicable treaties or international agreements with the force of domestic law under which the product or the Candidate Chemical(s) in the product is/are regulated and the extent to which these other regulatory requirements address, and provide adequate protections with respect to the same potential adverse impacts and potential exposure pathways, and adverse waste and end-of-life effects, that are under consideration as a basis for the product-chemical combination being listed as a Priority Product. In summary, the following concerns were expressed:

- European Union regulations must also be considered;

- Although pesticide products appear to be exempt by the statute, this section gives the appearance of piercing that exemption along with the protection it provides against multiple regulatory reviews of chemicals/products, notably without reference to further rulemaking;
- The regulation should eliminate duplicative regulation by following the statute and ensuring that products regulated by another federal or state program are not subject to these regulations;
- To meet both the spirit and the letter of the statute, DTSC should exempt chemical and product categories that are already regulated or pending regulation in the U.S.;
- The costs incurred as a result of removing chemicals should be included; and
- Include the costs to government agencies, municipalities, publicly owned treatment works and non-profit organizations and private business as a consideration as it would lead to Household Hazardous Waste programs managing fewer products, or sanitation systems not needing to remove as many contaminants, thus lowering the financial burden on taxpayers and ratepayers.

Response:

DTSC believes it is not necessary or wise to include or cite other regulations such as the European Union regulations in the proposed regulations. Further, it is not necessary to repeat exemptions granted in statute or other sections of the proposed regulations in this article. As such, there was no need to repeat any of the statutory or regulatory exemptions set out in Article 1 again in Article 3. Nothing in Article 3 is intended to diminish or limit the scope of the exemption for pesticides specified in the authorizing legislation and in Article 1 of the regulations.

In response to the above comments and other overarching comments related to costs to government agencies and municipalities, the proposed regulations have been modified to include and consider the scope of other State of California and federal laws under which the product or the Candidate Chemical(s) in the product is/are regulated and the extent to which these other regulatory requirements address, and provide adequate protections with respect to the same potential adverse impacts and potential exposure pathways, and adverse waste and end-of-life effects, that are under consideration as a basis for the product-chemical combination being listed as a Priority Product (January 2013). If a product is regulated by another entity with respect to the same potential adverse impacts, potential exposure pathways, and/or potential adverse waste and end-of-life effects, DTSC may list such a product-chemical combination as a Priority Product only if it determines that the listing would meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts, potential

exposure pathways, and/or potential adverse waste and end-of-life effects that are the basis for the listing.

For a more detailed discussion on how the proposed regulations may regulate products that are already regulated without running afoul of Health and Safety Code section 25257.1, and a discussion of preemption issues, please refer to the discussion of Duplication and Conflicts under the Procedural, Legal, and Overarching Issues of this Response to Comments document.

The proposed regulations, dated July 2012, in sections 69503.2(a)(3) and 69503.3(b) stated that DTSC shall consider the scope of other laws and agreements under which the product is regulation and the extent to which these other regulatory requirements address and provide adequate protections with respect to the same adverse public health and environmental impacts and exposure pathways. In an effort to streamline the provisions the sections have been combined under section 69503.2(b)(2) of the proposed regulations dated January 2013.

§ 69503.2(b) Key Prioritization Factors

Comments: 3-4, 7-7, 9-38, 9-81, 9-82, 9-84, 9-85, 11-7, 41-16, 49-13, 49-14, 57-41, 64-7, 66-25, 73-8, 73-6, 74-34, 74-36, 76-43, 80-6, 80-8, 92-4, 107-5, 107-47, 107-50, 124-2, 124-3, 124-23, 124-24, 133-2, PH28-1, PH28-4

Comments Summary:

The above comments expressed concern with section 69503.2(b), which specifies two key prioritization principles that DTSC will employ in prioritizing products that contain Chemical(s) of Concern. The Chemical(s) of Concern ability to contribute to or cause adverse public health and environmental impacts and there is a significant ability for the public and/or aquatic avian, or terrestrial animal or plant organism to be exposure to the Chemical(s) of Concern. In summary, the following concerns were expressed:

- The three statutory criteria in Health and Safety Code section 25252(a) are not addressed;
- Products that contain Chemical(s) of Concern that: 1) have a significant potential to cause adverse impacts; 2) are widely distributed and used by consumers; 3) have significant potential for exposure to the Chemical(s) of Concern; *and* 4) contain more than one Chemical(s) of Concern if the product is an assembled product should be given the highest priority;
- Need for clarity on how these factors will be used in relation to the other factors/criteria that are used, as supporting evidence is necessary;

- Amend proposed regulatory text to assess exposure potential to the chemical and not the product;
- Utilize quantitative information to evaluate Chemical(s) of Concerns that "contribute to" adverse impacts;
- Incorporate reasonable and foreseeable processing, use, misuse, and end-of-life management into the exposure criterion;
- Incorporate potential inhalation of or dermal contact with the Chemical(s) of Concern in the product into the exposure criterion;
- Amend "contribute to" or "cause" to "potential" to cause;
- How will "significant ability" be determined by including a threshold or creating a process; and
- Support not using the term "potential," as had been found in previous versions, and support for the intended use of the product.

Response:

In response to the above comments and concerns expressed with the provisions of section 69503.3(e) of the proposed regulations dated July 2012, this section has been modified to clarify and centralize the prioritization principles under section 69503.2(a) in the January 2013 version. Section 69503.2 has been modified to set out the overarching *Product-Chemical Identification and Prioritization Factors*. This section includes the Key Prioritization Principles and the sequencing of the considerations of the factors under evaluation that will be applied in subsequent sections.

The criteria mandated by Health and Safety Code section 25253, of establishing an identification and prioritization process that includes, but is not limited to:

1) The volume of a chemical in commerce in California;
2) The potential for exposure to a chemical in a consumer product; and
3) Potential effects on sensitive subpopulations, including infants and children (in section 69503.2 of the proposed regulations dated July 2012, and are now contained in section 69503.3).

DTSC believes it is in the best interest of Californians to retain the flexibility granted in statute and thus not limit itself to ensure that all three of the above mentioned criteria must be met, as is suggested, before prioritizing a product.

As formerly stated in sections 69503.2(b) and 69503.3(a) through (e) of the proposed regulations dated July 2012 and now in section 69503.2(b) of the proposed regulations dated January 2013, DTSC's decision to identify and list a product-chemical

combination as a Priority Product will be based on an evaluation of the product-chemical combination to determine its associated potential adverse impacts and potential exposures, the extent to which other regulatory programs address them, and the existence of safer alternatives.

The proposed regulations dated July 2012 contained language that DTSC would assess exposure potential to the chemical and does not need to amend the requirements. Further, as state earlier, DTSC cannot logically restrict itself to *only* use quantitative information to evaluate Chemical(s) of Concern that "contribute to" adverse impacts as much of that information is not routinely developed by the manufacturers who produce the products.

Section 69503.2(a)(1)(B) of the proposed regulations dated July 2012 contains the provisions which do take into account use, misuse, potential inhalation of or dermal contact, end-of-life management and other factors not requested in the above comments. Those provisions have been moved and are now in section 69503.3(b) of the proposed regulations dated January 2013.

Although there was some support for the change from "potential" to the term "ability to cause," DTSC has determined it created more confusion than clarity or specificity. The term "potential," previously in earlier versions of the proposed regulations, has been reinstated. It is consistent with Health and Safety Code sections 25253(a)(2) and (3) which mandate that in establishing an identification and prioritization process, at a minimum, the "potential" for exposure to a chemical in a consumer product and "potential" effects on sensitive subpopulations be included. For a more detailed discussion on the appropriateness of the use of the term "potential" please refer to the discussion of Causation at the end of this document.

As part of DTSC's streamlining efforts, and in response to related comments on Key Prioritization Factors, these provisions have been modified and are now found in section 69503.2(a) and that subsection has been renamed to Key Prioritization Principles.

§ 69503.3 Process to Evaluate Products Using Prioritization Factors

§ 69503.3(a) Adverse Impacts and Exposures and Availability of Information

Comment: 101-24

Comment Summary:

The above comment expressed concern with section 69503.3(a), which sets out the sequencing of the steps for product evaluation and identification. In summary, the following was expressed:

- DTSC should allow the use of opinions from recognized cosmetic authoritative bodies (*e.g.*, the Cosmetic Ingredient Review (CIR) and Scientific Committee on Consumer Safety) when identifying Chemical(s) of Concerns in Priority Products;
- If a human health and safety concern is the motivation for identifying a Chemical(s) of Concern in a cosmetic product, then conclusions from CIR and SCCS should necessarily be considered and possibly used to justify their inclusion or removal; and
- If CIR makes a conclusion about an ingredient as to human safety, then that information should be viewed as authoritative and conclusive in the prioritization phase of the process.

Response:

The proposed regulations require DTSC to use "reliable information," as defined. If the kind of information described in the comment is submitted to DTSC in response to a proposed Priority Products listing, or as part of a petition for indentification and prioritization of Chemicals and Products under Article 4, meets the requirments of "reliable information, then that information may be used by DTSC as part of its decision-making process. The opinion alone of a person submitting a petition, will not be sufficient to demonstrate "reliable information" for the process laid out under the proposed regulations.

As part of DTSC's streamlining efforts, and in response to related comments on Key Prioritization Factors, these provisions have been modified and are now found in section 69503.2(b)(1)(C).

§ 69503.3(b) Other Regulatory Programs

Comments: 4-12, 9-55, 12-5, 19-32, 19-33, 19-35, 47-17, 54-8, 57-40, 66-22, 81-6, 92-4, 93-1, 107-49, PH2-2, PH6-4, PH14-4, PH22-2, PH34-1

Comments summary:

The above comments expressed concern with section 69503.3(b), which requires that DTSC, in evaluating the adverse impacts and the exposure pathways associated with the product and the Chemical(s) of Concern (now Candidate Chemical(s)), consider whether any of these adverse impacts and/or exposures pathways are adequately addressed by other State of California and federal laws, and international agreements

with the force of domestic law. If a product is regulated or is subject to pending regulation by another entity, with respect to one or more adverse impacts or exposure pathways, DTSC is required to adjust the prioritization of the product based on whether listing the product as a Priority Product would meaningfully enhance protection of public health and/or the environment with respect to the adverse impacts and/or exposure pathways associated with the product. In summary, the following concerns were expressed:

- The prioritization factors invade the regulatory jurisdiction of other agencies and conflict with well-established regulatory programs;
- DTSC should reconsider its broad inclusion of workers and worker exposure as part of the product prioritization process;
- While it is appropriate to consider worker exposure in a retail setting, or perhaps worker exposure to products used in schools or hospitals or other institutional settings, we question whether DTSC has the authority to request information about workers in California or outside the state;
- Further regulation of food packaging would be duplicative and in conflict with current federal regulatory scheme;
- The commenter disapproves of industry suggestions to exempt any product regulated by another agency;
- The regulations should incorporate by reference existing statutory authority in the California Water Code because this regulation captures cleaning products with a waste stream that terminates in a sewer environment, which overlaps with State Water Resource Control Board and its regional boards, and poses a double jeopardy situation; and
- The regulations should consider the extent to which other regulatory programs preempt the regulation of the product.

Response:

Health and Safety Code section 25251(e) defines “consumer products” as that term pertains to the proposed regulations. DTSC is not allowed to provide exemptions beyond what is authorized in statute. Any product not specifically exempted in statute that is listed as a Priority Product because it contains a Candidate Chemical—thus rendering the chemical a Chemical of Concern—is subject to the requirements of the proposed regulations. Therefore, DTSC cannot create a new exemption in regulations for food packaging materials. (*See* the Requests for Exemption section in the Procedural, Legal and Overarching Issues portion of this Response to Comments document for a detailed discussion of DTSC’s inability to add to the exhaustive list of exemptions set out by the Legislature in the authorizing legislation.)

Health and Safety Code sections 25251(e) and 25257.1 collectively require that DTSC take into account the degree to which consumer products are adequately regulated to address the potential adverse impacts and potential exposure pathways and adverse life cycle impacts that are under consideration as a basis for the product-chemical combination being considered for listing as a Priority Product. That mandate is implemented in Article 1, which establishes the basis for a complete exemption from the regulations consistent with section 25257.1, and again here in Article 3. In Article 3, DTSC considers the extent of regulation by one or more other regulatory programs not as an all-or-nothing evaluation of whether the product is exempt. Rather, DTSC considers the extent of existing regulation along a continuum as part of the prioritization process. Again, a product that is only regulated during a portion of its life cycle, or only as to a given aspect of use, etc. may still be ineligible for listing as a Priority Product. This is due to the provision that allows DTSC to list a product that is regulated by another entity with respect to the same concerns as these regulations as a Priority Product only if DTSC "determines that the listing would meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts and/or exposure pathways that are the basis for the listing."

The proposed regulations specify the factors that DTSC will take into account, if the information is reasonably available, in prioritizing a product and do not specify that DTSC will be "requesting" information about workers in California or outside the state.

For a more detailed discussion on how the proposed regulations may regulate products that are already regulated without running afoul of Health and Safety Code section 25257.1, and a discussion of Preemption Issues, please refer to the discussion of Duplication and Conflicts under the Procedural, Legal and Overarching Issues of this Response to Comments document.

As part of DTSC's streamlining efforts, and in response to related comments on Key Prioritization Factors, these provisions have been streamlined and are now found in section 69503.2(b)(2) of the proposed regulations dated January 2013.

§ 69503.3(d) Safer Alternatives

Comments: 76-44, 37-10, 42-18, 44-8, 70-2, 129-9

Comments Summary:

The above comments expressed concerns with section 69503.3(d), which specifies that DTSC may, at its discretion, consider whether there is a readily available safer

alternative, that is functionally acceptable and technically and economically feasible, to further adjust the prioritization prior to listing a product as a Priority Product. In summary, the following concerns were expressed:

- Remove the consideration of this discretionary factor unless DTSC will also take into consideration legal issues and economic and functionally feasibility;
- Using this factor may lead to mandating alternatives;
- Require consideration of the availability of reasonable alternatives products when determining whether to list a product as a Priority Product;
- While the regulations intend to improve public safety, they should not remove a necessary type of product from the market when no other alternative exists; and
- The process of conducting an AA (which follows as a result of the listing) will indicate whether an alternative exists. Would DTSC's determination be based on an Alternatives Analysis that has previously been submitted for similar products?

Response:

As stated in the ISOR, this section provides DTSC the necessary discretion to consider whether there is a readily available safer alternative that is functionally acceptable and technically and economically viable, in order to adjust the prioritization prior to listing a product as a Priority Product.

This provision allows DTSC to list a product that contains a Candidate Chemical that is not necessary for the performance and function of the product and for which a known alternative exists but which some responsible entities have chosen not to remove. The existence of a safer alternative is not a necessary requirement for listing a consumer product as a Priority Product; DTSC may list a consumer product as a Priority Product despite the absence of a known safer alternative. While it is not the goal of the proposed regulations to remove a "necessary" product from the market—meaning a product with social utility when no other alternative exists—if the concerns posed by the Candidate Chemical are significant, those products may be prioritized. In addition, if DTSC knows of an existing alternative to the Candidate Chemical even before an AA is conducted that product may be listed.

The initially proposed and revised proposed regulations require the responsible entity, and in this instance DTSC, to consider whether the safer alternative is readily available, functionally acceptable, which includes legal concerns, and economic feasibility. Therefore, no changes were needed to address these concerns. The concern regarding the use of this factor to mandate the use of alternative is unfounded, as this would be beyond the scope of DTSC's authority. Responsible entities are required to perform an AA and select an alternative or choose to retain the Priority Product. The

responsible entities may be subject to regulatory responses, but these do not include a DTSC-mandated alternative.

As part of DTSC's streamlining efforts, and in response to related comments on Key Prioritization Factors, the Safer Alternatives provisions have been streamlined and are now found in section 69503.2(b)(3).

§ 69503.3(f) Priority Product Work Plan

Comments: 27-2, 36-121, 73-6, 101-27, 107-47, 129-10, 76-45

Comments Summary:

The above comments expressed concern with section 69503.3(f), which specifies that by January 1, 2014 DTSC will issue a Priority Product Work Plan that identifies and describes the product categories that DTSC will evaluate to identify products to be considered for the Priority Products list during the next three (3) years. The work plan must include a general explanation of the decision to select the identified product categories for evaluation during the life of the work plan. In summary, the following concerns were expressed:

- DTSC must specify a finite number of chemical/product combinations that will be chosen each year;
- DTSC should consider relying on this list for at least seven years;
- The work plan should specify the number of products that will be identified in the subsequent round of proposed Priority Products, either as a minimum or maximum;
- The work plan should specify that only a handful of products will be selected; and
- DTSC should not limit itself to a small number of products or be prevented from responding to new science about Chemical(s) of Concern and products.

Response:

The proposed regulations appropriately do not limit the number of Priority Product and/or Chemical(s) of Concern at this stage. These provisions are intended to provide signals to the marketplace regarding the scope of product *categories* that will be under evaluation over the next three years. Thus, DTSC believes that the three-year cycle is more helpful and appropriate than the seven-year suggested cycle. The work plan will not specifically identify the Priority Products or Chemical(s) of Concern, or the list of products that DTSC will be evaluating. Thus, it would be extremely inappropriate to establish a minimum or maximum number of products that will be evaluated. That information is provided in the Priority Products listing process, which comes later after a

public workshop(s) and opportunity for public comment. DTSC is not limiting itself in these regulations to only working on a fixed small number of products in later stages of implementation. Please refer to the discussion under Priority Products List of this Response to Comments document for a better understanding of how these companion provisions work together.

In response to the above comments, streamlining efforts, and responses to related comments on the Priority Products list, these provisions related to the Priority Product Work Plan are now contained in section 69503.4. In addition, the Priority Product Work Plan is no longer due on January 1, 2014. Instead, it is due within one year of the effective date of these regulations.

§ 69503.3(f)(1)(B) Priority Product Work Plan: Executive Order

Comments: 54-6, 57-42, 66-27

Comments Summary:

The above comments expressed concern with section 69503.3(f)(1)(B), which specifies that DTSC may revise the Priority Product Work Plan subsequent to being issued, to include an additional product category to the work plan. The work plan may be revised if required by a Governor's Executive Order to take action on a particular chemical or product, or both, prior to the expiration of the work plan. In summary, the following concern was expressed:

- This factor is not transparent and removes the opportunity for public comment, and introduces a political element into what was envisioned to be a science-based approach.

Response:

The circumstances that constitute a basis for DTSC to revise an adopted work plan, found in section 69503.4(c) (January 2013) are either of the following:

(1) DTSC is legally required to take action on a particular chemical or product, or both, prior to the expiration of the work plan; and/or
(2) DTSC grants a petition under section 69504.1 to add or remove a product from the Priority Products list.

Therefore, in the first instance, providing public comment would be moot. If DTSC is legally compelled to take action, no amount of public comment can change that. In the second instance, the petition process requires that DTSC "grant or deny a petition in

accordance with the criteria and processes specified in Article 2 and/or Article 3, as applicable….” (section 69504.1(a)). As a result, the public comment processes set out in sections 69503.5 and 69503.6 (January 2013) will apply in those instances. Therefore, it would be redundant here to have another public comment period.

As part of DTSC’s streamlining efforts, and in response to related comments on the work plan, the provisions related to the work plan are now in section 69503.4. The provisions related to these comments are now found in section 69503.4(c)(1). In the interest of not creating unnecessary alarm, the provision has been modified to include “the department is legally required to take action on a particular chemical or product, or both, prior to the expiration of the Work Plan.” In addition, section 69503.4(e) of the proposed regulations dated January 2013 specify that DTSC will provide public notice when these changes occur.

§ 69503.3(f)(4) Priority Product Work Plan: Notice

Comment: 47-18

Comment Summary:

The above comment expressed concern with section 69503.3(f)(4), which specifies that DTSC will send to individuals on the electronic mailing list that DTSC establishes related to these regulations and post on its website a notice of the availability of each work plan. In summary, the following concern was expressed:

- DTSC will consider the prioritization factors in the absence of objective criteria and will post a draft work plan of Priority Products, and businesses will have 60 days to determine whether its products contain the Chemical(s) of Concern in amounts that would trigger further regulatory review.

Response:

The commenter appears to have misunderstood when the responsible entity is required to evaluate their products for a Chemical(s) of Concern. The work plan discussed in these provisions identifies and describes the product categories DTSC will be evaluating over the following three years. There are no requirements imposed on responsible entities at this point for anyone—including responsible entities that make a product that is within one of the product categories that will be evaluated. The work plan merely provides the necessary signals and predictability that the regulated community desires regarding possible future regulatory actions by DTSC.

There are no requirements for responsible entities to identify Chemical(s) of Concern in products as a result of the work plan. In fact, section 69503.4(a) states that the work plan describes the product categories that DTSC will evaluate to identify product-chemical combinations to be added to the Priority Products list.

There are ample measures for transparency included in the proposed regulations, including a public workshop prior to releasing the work plan, and prior to proposing the Priority Products list. Further, DTSC must follow APA procedures in adopting the Priority Products list. This ensures ample notice and comment opportunities. As a result of these efforts, there will be widespread communication regarding the product categories and products prior to finalizing the regulations that list Priority Products. DTSC routinely reaches out to stakeholders and potentially impacted parties in ways that are not prescribed in regulation.

No changes in response to the above comment were made. As part of DTSC's streamlining efforts, and in response to related comments on the Priority Product Work Plan, all the provisions related to the Priority Product Work Plan, formerly in section 69503.3(f) and (g), have been combined with the provisions in section 69503.4(b) through (g) and are contained in section 69503.4 of the proposed regulations (January 2013). The provisions related to these comments are now found in section 69503.4(e) (January 2013).

§ 69503.3(g) Initial Priority Products list

Comments: 41-3, 41-17, 57-43

Comments Summary:

The above comments expressed concern with section 69503.3(g), which specifies that in the Initial Priority Products list(s), issued prior to January 1, 2016, DTSC may list a product as a Priority Product only if the product is being listed on the basis of one or more Chemical(s) of Concern (now Candidate Chemicals) in the product that meet both of the following criteria:

(1) The chemical meets one or more of the criteria specified in subsection (a)(1) of section 69502.2; and
(2) The chemical meets one or more of the criteria specified in subsection (a)(2) of section 69502.2.

In summary, the following concerns were expressed:

- The Initial Priority Product list focused on chemicals meeting adverse impacts/exposures and available information prior to January 1, 2016 is unclear;
- This section is unclear and appears to contradict the "Changes" document issued by DTSC, which describes the initial list as limited to chemical selection from seven hazard traits and from the chemicals listed on one of 22 lists; and
- The process being used to narrow the list of chemicals is unclear.

Response:

The initial list of proposed Priority Products will contain Candidate Chemical(s) that is/are listed on at least one of the lists in section 69502.2(a)(1) *and* (a)(2). The lists identified in section 69502.2(a)(1) include seven hazard traits (*i.e.*, bioaccumulation carcinogenicity, developmental toxicity, endocrine disruption, environmental persistence, genotoxicity (mutagenicity), neurotoxicity, reproductive and Developmental toxicity, respiratory toxicity), and the lists identified in section 69502.2(a)(2) which include chemicals with exposure concerns as evidenced through biomonitoring, water quality and/or air quality lists. In short, the initial list of Priority Products will include those product-chemical combinations that are on both of the lists cited above. Candidate Chemicals meeting the criteria will be identified in products containing those chemicals. The process provides certainty to the general public and the regulated community about which chemicals may lead to identification of a product as a Priority Product on the initial Priority Products list.

DTSC respectfully disagrees with the comment that the process used to create the initial Priority Products list is unclear. It is as simple as the process described in the previous paragraph. DTSC also does not see any conflict between the process set out in regulations, described here, or in the "Changes" document DTSC issued as a courtesy to interested parties.

As part of DTSC's streamlining efforts, and in response to related comments on the Priority Product Work Plan, the provisions related to the Priority Product Work Plan, formerly in section 69503.3(f) and (g), have been combined, as appropriate, with the provisions in formerly in section 69503.4(b) through (g) and are contained in section 69503.4 of the proposed regulations (January 2013). All provisions regarding the Priority Work Plan, whether initial or subsequent, have been included in this section. DTSC is not making any further changes to the regulations in response to the above comments.

§ 69503.4 Priority Products List

§ 69503.4(a)(1) Priority Products List: Factors and Process

Comments: 5-73, 12-6, 68-24, 92-4, 101-27, 137-1, 137-2, PH22-3

Comments Summary:

The above comments expressed concern with section 69503.4(a)(1), which specifies the procedures and factors DTSC will use to identify and list Priority Products. In summary, the following concerns were expressed:

- Regardless of the size or complexity of a consumer product, DTSC rightfully should retain the ability to list it or its components as a Priority Product;
- Listing use of isocyanate containing urethane adhesive in installation of hardwood flooring products as a Priority Product is “unacceptable”;
- the number of Chemical(s) of Concerns in the initial list of proposed Priority Products is not prescribed;
- One listing of a Chemical(s) of Concern in a Priority Product could impact thousands of formulations; and
- In order to implement a workable, science-based program, a comprehensive solution must be found, rather than simply addressing one or two industry concerns at the expense of the others.

Response:

The goals and intent of AB 1879 are to find alternatives to Chemical(s) of Concern to reduce adverse public health and environmental impacts, regardless of whether alternatives have been identified or not. The statute does not limit DTSC in the number of Chemical(s) of Concern that may be regulated. Nor does DTSC believe it is appropriate or necessary to limit the number of chemicals that will be the basis for identifying products as Priority Products. DTSC needs the flexibility to make a sound science-based decision when evaluating product-chemical combinations to list Priority Products. DTSC would be tying its hands unnecessarily if it were to impose an arbitrary limit on the number of chemicals that may serve as the basis for listing a Priority Product.

The identification and prioritization process in Article 2 focuses on identification of the Candidate Chemicals that have been listed on authoritative lists as having adverse impacts on human health and the environment. When consumer products are identified as a source of the Candidate Chemicals, those products may be listed as Priority Products. As of the January 2013 version of the proposed regulations, a Priority

Product is a consumer product containing a Candidate Chemical that is prioritized and is, thus, a Chemical of Concern in that product.

The initial Candidate Chemicals list is comprised of chemicals that are of identified as posing concern by numerous authoritative governments and organizations. The proposed regulations establish an initial list of approximately 1,200 Candidate Chemicals that are based on work already done by other authoritative organizations. As stated in the proposed regulations, an informational list identifying all Candidate Chemicals will be made available within 30 days of the effective date of the regulations. Chemicals on these lists are already under scrutiny; however, they may not all be subject to regulatory regimes. It is important to note, however, that identification as a Candidate Chemical does not equate to any or all consumer products containing those chemicals as Priority Products.

It is only after Candidate Chemicals have been identified in consumer products and subjected to the product prioritization process that the pairing of these two are then referred to as Chemical(s) of Concern/Priority Product, discussed in section 69503.5 of the January 2013 version of the regulations. The number of responsible entities impacted will be commensurate with the number of Priority Product/Chemical(s) of Concern listed. Given that DTSC is limiting the initial list of Priority Products to no more than five (5), it is unlikely that thousands of formulations, as suggested in the comments, will be impacted.

As detailed in the ISOR and in responses to comments related to Article 3, a Priority Product that is listed could be the entire product or components of a larger product. The final list made available pursuant to section 69503.5, after public review and input, will provide the level of detail necessary to inform manufacturers which products or components are being listed as Priority Products and subject to the AA Requirements (January 2013).

DTSC recognizes that some existing consumer products may have safer alternatives available, but some manufacturers may choose to continue using their existing product formulation over one using the safer alternative. The proposed regulations address these instances by taking into account the existence of safer alternatives as one of the criteria/factors that DTSC will use in determining the priority for possibly listing a product as a Priority Product.

As part of DTSC's streamlining efforts, and in response to related comments to the Initial Priority Products list, the provisions relating to these comments are now contained

in section 69503.5(a)(1). DTSC is not making any further changes to the regulations in response to the above comments.

§ 69503.4(a)(2) Priority Products List: Contents

Comments: 11-8, 57-39, 68-24, 74-38, 76-46, 107-51

Comments Summary:

The above comments expressed concern with section 69503.4(a)(2), which specifies that the proposed and final Priority Products list must include the following:

(A) The Chemical of Concern and the hazard traits that is/are the basis for the product being listed; and
(B) If applicable, the component to which the AA or AA Threshold Exemption applies.

In summary, the following concerns were expressed:

- If the Priority Products are identified in a manner that is too broad, the AA would be extremely difficult, excessively complex or meaningless, and will likely encompass an unmanageable number of responsible entities;
- Priority Product categories should be described at the class level for the purposes of the work plan but not for the Priority Product List;
- The list should use a standardized product nomenclature system; and
- The GS1 Global Product Classification is an appropriate source for describing products and that Priority Products.
- DTSC should include a level of product specificity for each listed product, as required for notifications, *i.e.*, general application type, representative product, products by model, product SKU.

Response:

The proposed regulations clearly state that the proposed and final Priority Products list will identify the Chemical(s) of Concern and the hazard traits that is/are the basis for the product being listed, and if applicable, the component to which the AA or AA Threshold Exemption applies. While the work plan will identify categories of products DTSC will work on in the next three years, the Priority Products list will identify one or more consumer products. That is, the listed item on the proposed and final Priority Products list will be more specific than the product categories in the work plan. DTSC will make every attempt to identify products by commonly understood terms used in industry, but it will not restrict itself in regulation by identifying one classification method over another, such as the Global Product Classification system. In addition, due to the wide variety of

products that may be identified as Priority Products, DTSC does not believe that one classification system will work for all products. Stakeholders may provide input during the public comment period on the naming convention of proposed Priority Products and if appropriate, DTSC will make the corresponding changes.

As part of DTSC's streamlining efforts, and in response to related comments to the Initial Priority Product list, the provisions have been streamlined and moved to section 69503.5(b). DTSC is not making any further changes to the regulations in response to the above comment.

§ 69503.4(a)(2)(B)1 Priority Products List: Components

Comments: 4-12, 5-108, 5-109, 5-152, 5-153, 5-157, 29-13, 55-18, 55-19, 66-30, 74-34, 127-6, 127-7, 127-8

Comments Summary:

The above comments expressed concern with section 69503.4(a)(2)(B)1, which specifies that, if applicable, the list will include the components and/or homogenous material(s) within a component which is the subject of the AA or AA Threshold Exemption. In summary, the following concerns were expressed:

- Amend regulatory text to redefine the terms "homogeneous and "component";
- Component manufacturers should be responsible for conducting the AA or submitting the AA Threshold exemption;
- Early versions of the proposed regulations distinguished between assembled and formulated products. The comment supports the proposed regulations, which do not have such unnecessary distinction; and
- The term "component" needs to be more clearly defined.

Response:

In response to the above concerns, the proposed regulations were amended in companion provisions of the proposed regulations. The definition of "manufacture" in section 69501.1(a)(43) has been revised to explicitly state that "manufacture does not include acts that meet the definition of "assemble." (January 2013) "Assemble" is defined to mean to "fit, join, put, or otherwise bring together components to create, repair, refurbish, maintain, or make non-material alterations to a consumer product." (January and April 2013) "Assembler" is defined as someone who "assembles a product containing a component that is a product subject to the requirements" of the regulations (*i.e.*, a component that is listed as a Priority Product) (January 2013). In the event that the manufacturer and/or importer of a Priority Product that is a component

does not comply with applicable requirements, assemblers who use that component have the same option as do retailers—they can comply with the requirements themselves, or cease ordering the Priority Product component.

In addition, reference to the term 'homogenous' has been deleted from the regulations as it is unnecessary. DTSC has the flexibility to refer to a subset of an entire product at the time it lists a Priority Product. Inclusion of the term created more confusion than clarity. As such, it is also not necessary to define component.

As part of DTSC's streamlining efforts, the above referenced provisions are now found in section 69503.5(b) (January 2013).

§ 69503.4(a)(2)(B)2 & 3 Priority Products List: Highly Durable Products

Comments: 5-7, 5-75, 5-108, 5-109, 5-152, 17-7, 19-21, 29-14, 55-18, 55-19, 66-28, 66-30, 68-22, 76-47, 109-12, 109-13, 109-14, 114-12, 124-4, 124-26, 127-9, 127-11, 127-12, PH10-6, PH21-2, PH21-3

Comments Summary:

The above comments expressed concern with sections 69503.4(a)(2)(B)2and 69503.4(a)(2)(B)3, which establishes a definition for "highly durable products" and places a ten (10) component limit for a three year period for a highly durable product that may be listed as a Priority Product. The provisions define a "highly durable product" as one that is assembled from 100 or more components, the products has a useful life of greater than five (5) years, and it typically not consumed, used or destroyed after a single use. In summary, the following concerns were expressed:

- Why does "highly durable products" have to meet the criterion of having more than 100 manufactured components, noting there are many highly durable goods with fewer components (furniture, mattresses, and carpet);
- Art materials may be considered highly durable products, as they may last for centuries;
- "Highly" should be changed to "complex";
- Delete these sections as they are confusing and not practical, and all products should be held to the same requirements;
- Revise to list no more than five components in four years, as the proposed ten components in three years is unreasonable and will disrupt a delicate balance in the complex global logistics;
- Revise to list no more than three components in three years;
- Revise to increase the number of components that may be listed;

- Revise to 50, not 100, or more manufactured components;
- Delete section 69503.4(a)(2)(B)3.b as manufacturers do not generally "routinely prepare" information on anticipated useful life;
- Add an exemption for spare parts to existing products;
- The definition of “highly durable products” should be revised to allow tires to be included, as they have long testing times before the product can be placed on the market; and
- The regulations should limit the number of components in a complex durable product by the percentage of the components in the product, rather than as a discrete number; and
- The proposed regulatory steps and structure do not accommodate the unique considerations of automobiles and their parts.

Response:

There appears to be confusion on what the provisions allow or require. A product composed of 100 or more components may theoretically be required to address 10 components over a three-year period, meaning ten percent (10%) of the product’s components could be required to undergo an AA over a three-year period. Lowering the number from 100 to 50 and simultaneously lowering the number of components to five achieves the same result—10%. There is no benefit in this. Lowering the number of components that could get listed on the Priority Products list lowers the percentage of products addressed over a three-year period; it does not create any advantage over what is already in the proposed regulations. Similarly, lowering the number of components and simultaneously increasing the span to every four years lowers the number of components that may be evaluated to less than 10% in three years. DTSC believes that having the ability to require a responsible entity to address approximately 10% of components in complex durable goods is a fair starting point, and as the program matures regulatory amendments will be made accordingly.

The provisions are not exemptions to the requirements; they provide a limit on the number of AAs, under Article 5, that any responsible entity for a complex product may be subject to over the course of a three-year period. As such, exemptions for spare parts or tires are not appropriate. For a more detailed discussed on the authority to exempt consumer products, please refer to the discussion under Request for Exemptions in the Procedural, Legal and Overarching Issues portion of this Response to Comments document.

The provisions create a practical framework for products that are made up of numerous components so that these products are not disproportionately regulated. While it is true

that furniture, mattresses, carpets and some art materials could be viewed as highly durable because they last longer than five (5) years they are not made up of 100 or more components. As such, and to provide greater clarity, the use of the term “highly” has been replaced with the term “complex” to more accurately reflect the makeup of the product and not primarily the life span of the product.

As part of DTSC’s streamlining efforts, the above provisions are now found in section 69503.5(c).

§ 69503.4(a)(2)(B)4.a Priority Products List: Products Intended for Children

Comment: 57-44

Comment Summary:

The above comment expressed concern with section 69503.4(a)(2)(B)4.a, which specifies that the ten (10) component limit on a highly durable goods is not applicable to products intended for children twelve (12) years of age or younger. In summary, the following concern was expressed:

- The definition for products designed or intended for children is overly broad and unique and the commenter recommends that the definition be harmonized with the Consumer Product Safety Improvement Act (CPSIA).

Response:

DTSC respectfully disagrees. It is not necessary in these regulations to call out “apparel, shoes, personal care products, accessories and jewelry, home furnishings, bedding, toys, electronics and video games, books, school supplies, educational materials and science kits,” etc., in the proposed regulations to accurately specify “products” designed for or intended primarily for children twelve (12) years of age or younger. DTSC has chosen a more flexible approach in defining a product intended primarily for children twelve years of age or younger. DTSC believes this flexible definition is more appropriate for this regulatory program.

It is not necessary to incorporate the Consumer Product Safety Commission’s definition to effectuate the goals of California’s Safer Consumer Products Regulations.

As part of DTSC’s streamlining efforts the above provisions are now found in section 69503.5(d)(3)(A) (January 2013). No other changes to the regulations were made in response to this comment.

§ 69503.4(a)(2)(B)4.b Priority Products List: Body Contact or Aerosols

Comments: 57-45, 68-23, 70-6, 124-26

Comments Summary:

The above comments expressed concerns with section 69503.4(a)(2)(B)4.b, which specifies that the ten (10) component limit on a highly durable goods is not applicable to products intended to be worn or placed on the human body, dispersed as an aerosol or vapor or applied on a hard surface with the likelihood of runoff or volatilization. In summary, the following concerns were expressed:

- Remove the exemption for these product categories or revise the regulations to address the clarity issue; and
- Another comment states that products dispersed as an aerosol or vapor or applied to hard surfaces seems misplaced, as by their nature, they cannot be highly durable.

Response:

As stated in this document under section 69503.4(a)(2)(B)2 & 3, Priority Products List: Highly Durable Products, these provisions are not exemptions. Rather, they create a workable solution to complex consumer products made up of numerous components. The provisions in section 69503.4(a)(2)(B)4. specified that regardless of the number of components in a consumer product, if the product is intended for children 12 years of age or younger and/or the products that will be worn or placed on the human body, dispersed as an aerosol or vapor or applied on a hard surface with the likelihood of runoff or volatilization that the limit does not apply.

DTSC agrees that products dispersed as an aerosol or vapor or applied to hard surfaces with the likelihood of runoff or volatilization, may represent an extremely small portion of complex durable goods, and is not necessary in this section. As such, the proposed regulations have been modified and reference to “dispersed as an aerosol or vapor or applied on a hard surface with the likelihood of runoff or volatilization” has been deleted. The proposed regulations do not limit the number of components that may be prioritized in a complex durable good if the consumer products are intended for children 12 years of age or younger or the products will be worn or placed on the human body.

As part of DTSC’s streamlining efforts, the above provisions are now found in section 69503.5(d)(3) (January 2013).

§ 69503.4(a)(2)(C) Priority Products List: Preliminary Report Submission

Comments: 68-2, 76-48, 114-13

Comments Summary:

The above comments expressed concern with section 69503.4(a)(2)(C), which specifies that the due date for submission of the Preliminary AA Report required under Article 5 is 180 days after the date the product is listed on the Final Priority Products list, unless DTSC specifies a shorter or longer period of time. In summary, the following concerns were expressed:

- Preliminary AA Reports should not be submitted more than 180 days after a product is listed as a Priority Product;
- The deadline for the Preliminary AA Reports may not be the same for all responsible entities; and
- To ensure a level playing field, DTSC should clearly state that the deadline will be the same for the responsible entities and that any extension granted for one responsible entities will apply to all responsible entities for a given Priority Product.

Response:

Section 69503.4 allows DTSC to take public and stakeholder input in establishing the due date for the Preliminary AA Report. The complexity of products will be taken into account when determining a practical time frame for submittal of the Preliminary AA Report. DTSC expects to receive stakeholder input when the Priority Products list is published, allowing DTSC to set appropriate due dates tailored to the complexity of the products.

As stated in the ISOR the provisions give DTSC latitude to provide a due date based on the complexity of the Priority Product being listed. It is not one-size fits all. It is essential that DTSC maintain this latitude because the regulations are intended to address a broad range of products, each with unique circumstances that are impossible to be fully taken into account in a one size fits all approach in regulation. This flexibility in the proposed regulation may provide manufacturers with the opportunity to work with their supply chain and develop meaningful AAs.

As further detailed under Article 5, the goals and intent of stage 1, and the subsequent Preliminary AA, is to establish the goals and scope of the AA. Information to prepare the Preliminary AA Report can be collected from any reliable source and does not require specific testing or analysis. However, some responsible entities may elect to

undertake a more comprehensive first stage and collect data or evaluate additional alternatives in the corresponding Preliminary AA Report. In those instances where the responsible entity needs more time to collect data they may request and extension to the 180-day deadline. It would be impractical to apply one deadline for all responsible entities who wish to conduct a more thorough Preliminary AA. As such, extensions granted to one entity may or may not be appropriate for another responsible entity. The scope of the AAs they undertake will determine this on a case-by-case basis. This ensures a level playing field without be overly punitive.

As part of DTSC's streamlining efforts the above provisions are now found in section 69503.5(b)(3) (January 2013). DTSC is not making any further changes to the regulations in response to the above comment.

§ 69503.4(b) Priority Products List: Workshop and Public Input

Comments: 7-8, 36-121, 114-8, 136-4

Comments Summary:

The above comments expressed concern with section 69503.4(b), which specifies that DTSC must hold one or more public workshops to provide opportunity for comment on the proposed Priority Products list. In summary, the following concerns were expressed:

- The public workshops should be hosted prior to proposing a list of Priority Products and prior to issuing the work plan;
- Public comment periods should have 45-day minimums and comments should be available online;
- It is important the Priority Product Work Plan have transparency and opportunity for public comment;
- Lack of criteria, standards, and methodology will result in misallocation of resources;
- Stakeholders would benefit from an indication of what products are not likely to be identified as Priority Products; and
- Lack of clarity will discourage investments in green chemistry research.

Response:

The proposed regulations specify that DTSC must hold one or more public workshop(s) to provide an opportunity for comment and input on the proposed Priority Products list. The provisions further specify that DTSC will make the proposed Priority Products list available on its website for public review and comment, along with DTSC's rationale.

The Priority Products list will be subject to the APA process and the work plan discussed in section 69503.4 is also subject to public comment. The work plan identifies the broad range of product categories that will be addressed in the next three years to provide industry the necessary signals regarding the product categories that will be addressed. The work plan will specify the product categories that will be evaluated for identifying product-chemical combinations. Any product category that is not included in an original or revised work plan cannot be identified as a Priority Product, unless it meets the exception criteria specified in section 69503.4(c) (January 2013). Given that the Priority Products list will be subject to the APA process, at least one 45-day comment period will be provided. More time can be afforded for public review and comment if determined to be necessary during implementation of these regulations. The public comment period will give interested stakeholders an indication of the types of products that may be prioritized.

It is unclear what criteria, standards, and/or methods are purportedly missing in the proposed regulations that would result in misallocation of resources. Section 69503.4(b) of the proposed regulations dated July 2012 specifies that DTSC will hold one or more workshops to provide the opportunity for comment on candidate products being considered for the proposed Priority Products list. The provisions subsequently provide that DTSC will post the draft Priority Products list on DTSC's website. Section 69503.4(c) of the proposed regulations dated July 2012 addressed specifies the types of comments and rationale that must be provided in response to the proposed Priority Product list. Section 69503.4(f) of the proposed regulations dated July 2012 specifies that DTSC will review and revise the Priority Products list at least once every three (3) years using the process in Article 3.

As part of DTSC's streamlining efforts, and in response to the above comments, the above provisions related to the initial work plan and subsequent work plans have been combined to the extent practical under section 69503.4 (January 2013). In addition, to add greater clarity regarding the sequencing of the work plan followed by the Priority Products list, two new sections have been created to place these provisions in the order of occurrence. Revised section 69503.4 contains the Priority Products Work Plan and revised section 69503.5 contains the Priority Products List (January 2013). In addition, section 69503.5 was amended to explicitly require that the Priority Products listing process comply with the APA process for rulemakings, and this is set out in section 69503.5(a)(2).

§ 69503.4(d) Final Priority Products List: Response to Public Comments

Comments: 66-29

Comments Summary:

The above comments express concern with section 69503.4(d), which specifies that DTSC will post the final Priority Products list on its website, and may respond to some or all public comment received on the Priority Products list. In summary, the comments express the view that DTSC should respond to all public comments that are received pursuant to section 69503.4(d)

Response:

In response to the above comments and other comments related to public input, provisions formerly in section 69503.4(d) have been amended and moved to section 69503.5 in the January 2013 version of the regulations, and now explicitly require that the listing process for Priority Products be undertaken as a rulemaking under the APA. As such, DTSC will be required to respond to all public comments regarding the listing process as part of its obligations under the APA. This requirement is now found in section 69503.5(a)(2) (January 2013).

§ 69503.4(e) Initial Priority Products List and Public Input

Comments: 7-9, 13-4, 14-3, 36-103, 57-39, 58-2, 59-1, 64-6, 83-4, 101-27, 106-2, 114-7, 119-1, 131-1, PH21-2

Comments Summary:

The above comments expressed concern with section 69503.4(e), which specifies that the *Initial*—meaning the first proposed Priority Products list—must be available within 180 days after the effective date of the regulations and that it must not include more than five (5) Priority Products. In summary, the following concerns were expressed:

- The initial list of proposed Priority Products should be released within ninety (90) days or twenty-four (24) months, as contained in earlier versions, after the regulations go into effect;
- Allowing adequate time for implementation of the regulations is essential to avoid rampant confusion within the industry;
- Limiting the first round to five products is not sufficient;
- The regulations need to “reward and incentivize voluntary behavior to move entire industries in the direction of safer materials,” and should include “Cradle to Cradle Certified” assessment;

- The scope of product categories will be very broad or multiple products with similar intended uses, similar targeted customer bases and function of the Chemical(s) of Concern in the Priority Product will be selected, potentially impacting thousands of products at one time; and
- The cost of Research and Development staff coupled with profit margins do not allow for an increase in the budget for increasing staff for the purposes of regulatory compliance, especially considering how broadly characterized the Priority Products may be.

Response:

As stated in the ISOR, DTSC will be taking action on a relatively small number of Priority Products in the initial list in order to gain experience and knowledge to refine implementation of these regulations. It is important to note that the initial number of Priority Products will be based on available resources to implement these regulations. Releasing the initial Priority Products list within 180 days after the regulations are adopted is necessary to implement the regulations in a timely manner, while also allowing DTSC adequate time to arrive at the first group of proposed Priority Products. It is conceivable that DTSC may be able to release the initial proposed Priority Products list sooner than180 days from the effective date of these regulations, and there is no prohibition against DTSC doing so.

Earlier versions of the proposed regulations never included a twenty-four (24) month period between the dates the proposed regulations went into effect until the date that the draft Priority Products list would be made public by DTSC. While DTSC is aware of the desire to expedite the process by compressing the deadline by when a draft Priority Product list is available for public review and comment, it is also aware of resource and logistical limitations. Compressing the deadline to ninety (90) days from when the proposed regulations are adopted is not sufficient for DTSC to address internal logistics. To the extent that a stated deliverable influences the impacts on industry (*i.e.*, confusion within industry, as cited by the comment), the proposed regulations allow for ample opportunity to become aware of the product types and ultimately the products that are being prioritized before industry is expected to submit a deliverable.

DTSC believes it is not in the best interest of this program to increase the number of products in the first round, as it may stall DTSC's ability to perform outreach and education, ensure compliance, and make adjustments in implementation as a result of lessons learned. The suggestion to include voluntary behavior to create safer materials, although desirable, is not appropriate for regulation. Regulations by their nature are minimum requirements/thresholds that must be met by the regulated entities.

Responsible entities are free to do as many voluntary activities as they choose. In addition, it is inappropriate to endorse specific companies such as Cradle to Cradle in regulation.

As part of DTSC's efforts to streamline the regulations and provide greater clarity, the above provisions are now found in section 69503.6, which pertains exclusively to the Initial Priority Products List (January 2013). No other changes were made to the regulations in response to these comments.

§ 69503.4(f) Priority Products list: Frequency

Comment: 5-76

Comment Summary:

The above comment expressed concern with section 69503.4(f), which specifies that DTSC must review and revise, as appropriate, the Priority Products list at least every three years. In summary, the comment expressed concern that DTSC may review and revise the Priority Products list more often than every three years, pursuant to section 69503.4(f), which would be too aggressive and should be revised accordingly.

Response:

DTSC has incorporated sufficient narrowing in the scope of the Initial Priority Products that could be listed, to allow for beta testing without unnecessarily delaying the process. As indicated in the ISOR and section 69503.6(b) of the January 2013 version of the proposed regulations, the initial list of Priority Products will include no more than five (5) Priority Products. The purpose of narrowing the number of Priority Products that may be required to undergo an AA in the first round is to help DTSC and responsible entities gain experience and address any flaws or issues with the requirements. During the initial three-year period, DTSC will determine what works well, and what could be improved upon and modify the regulations accordingly. An advantage to this approach is that consumer products that are currently of high concern can be quickly subjected to the requirements to expedite a move to safer alternatives, while simultaneously creating the framework for others to follow.

The knowledge and experienced gained from the Initial Priority Products will assist in understanding the resource requirements needed to implement these regulations. DTSC is also free, subject to the APA process, to amend these regulations if it is determined that changes are needed. In the meantime, the frequency of revising the Priority Products list will be influenced by the amount of available resources DTSC has

to implement the Safer Consumer Products program, and it is not necessary for DTSC to unduly limit itself to a less frequent cycle.

As part of DTSC's streamlining efforts and in an effort to provide greater clarity, the above provisions are now found in section 69503.5(e) (January and April 2013). No other changes to the regulations were made in response to these comments.

§ 69503.4(g)(2) Priority Products List: Notifications

Comments: 5-125, 5-154, 57-45, 57-53

Comments Summary:

The above comments expressed concern with section 69503.4(g), which specifies that each responsible entity for a Priority Product shall notify DTSC with one of the four notifications contained in section 69503.4(g)(1) though (4). In summary, the following concerns were expressed:

- An AA Threshold Notification and Chemical Removal Notification should not be required, and should be deleted;
- Allow responsible entities to provide reasonable evidence that their Priority Products do not contain the Chemical(s) of Concern above the AA Threshold;
- Allow responsible entities to provide reasonable evidence that the Priority Product does not result in exposure;
- Allow responsible entities to provide notice that the Priority Products will be withdrawn from the stream of commerce in California;
- There is a lack of clarity regarding when a responsible entity is required to submit an AA Threshold Exemption; and
- Allow responsible entities to provide notice that an AA will be performed.

Response:

DTSC respectfully disagrees with these comments. The Chemical of Concern Removal Notification is an important and necessary communication tool. It provides a means for responsible entities to demonstrate to DTSC that they are aware that their product is on the Priority Product list and specific compliance requirements are triggered. It provides DTSC, and by extension, the general public and interested parties, a means of monitoring the compliance actions of the responsible entities. Once a Priority Product is listed under Article 3, the responsible entity must comply with the requirements of Article 5.

In response to the above and other related comments, the proposed regulations dated July 2012, were amended to expand and clarify the instances under which an AA is not required for a Priority Product. A responsible entity is exempt from preparing an AA and submitting an AA Report if the manufacturer submits one of the following notifications by the due date for the Preliminary AA Report (or by the due date for the Final AA Report if a Preliminary AA Report has already been submitted):

- A Chemical Removal Intent and/or Confirmation Notification, certifying that the Chemical(s) of Concern will be or have been removed from the Priority Product without the use of any replacement chemical(s);
- A Product Removal Intent and/or Confirmation Notification, certifying that the manufacturer will or has ceased fulfilling orders for the product from persons selling or distributing the Priority Product in California; or
- A Product-Chemical Replacement Intent and/or Confirmation Notification, certifying that the Chemicals(s) of Concern will be or have been removed from the product and any replacement chemical meets one of the following criteria:
  - The replacement chemical is not on the list of Candidate Chemicals; or
  - The replacement chemical is a Candidate Chemical that is already in use, in lieu of the Chemical(s) of Concern, to manufacture the same product by the same or a different manufacturer.

All intent notifications must be followed by submission of a corresponding confirmation notification within ninety (90) days or by the due date for the Preliminary AA Report (or Final AA Report), whichever is later.

The amended provisions are intended to provide an incentive to responsible entities to elect to remove the Chemical(s) of Concern that are not necessary for the product performance or function, or when a readily available safer alternative exists, without being required to undergo the process of conducting an AA. In addition, the provisions provide a logical exemption to the requirement to conduct an AA if the Priority Product is no longer being manufactured with the Chemical of Concern which was the basis for its listing and/or the Priority Product is taken out of the California market.

The provision allows reformulations, redesigns, or replacements to occur without unnecessary DTSC oversight when the reformulated product does not contain any Chemical(s) of Concern or a substitute chemical and hence does not pose a risk of a “regrettable substitute.” As discussed in Article 5, a responsible entity may substitute Chemical(s) of Concern with a replacement chemical that is not on the Candidate

Chemicals list or a Candidate Chemical that is already in use, in lieu of the Chemical(s) of Concern, to manufacture the same product and not be required to conduct an AA.

The amended provisions have been moved to section 69503.7 and 69505.2 in the proposed regulations dated January and April 2013.

§ 69503.5 Alternatives Analysis Threshold Exemption Notifications

Alternatives Analysis Threshold Exemption Overview

A responsible entity is exempted from conducting an AA pursuant to Article 5 if a product that is listed as a Priority Product meets concentration level specified as the AA Threshold and the responsible entity of the Priority Product submits an AA Threshold Exemption Notification to DTSC. This AA Threshold Exemption is not self-implementing; rather, it requires a notification to be submitted to DTSC.

There have been various approaches to this exemption in earlier versions of the regulations. The following is a brief summary of the changes from the informal draft dated October 2011 to the April 2013 version of the formal proposed regulations.

In the informal draft dated October 2011, the term “de minimis level” was defined as 0.01% by weight for chemicals exhibiting nine specific hazard traits, such as carcinogenicity, developmental toxicity, endocrine toxicity, and reproductive toxicity. The “de minimis level” for all other hazard traits and environmental or toxicological endpoints was defined as 0.1%. The regulations had a provision that specified criteria to be used by DTSC when setting a de minimis level lower or higher than the default concentration levels of 0.01% or 0.1%.

In all of the formal versions (July 2012, January 2013, and April 2013) of the regulations, the term “de minimis level” has been replaced with the term “Alternatives Analysis Threshold” or AA Threshold. This was done to clarify DTSC’s rationale for including this concept. More specifically, the AA threshold denotes a concentration, thus threshold, where the requirements to conduct or not conduct an AA are triggered. An AA will be not be required for products that contain Chemical(s) of Concern below the AA Threshold; thus, an exemption from the duty to conduct an AA, and products containing Chemical(s) of Concern above the AA Threshold an AA will be required. Eliminating the use of the term “de minimis” is intended to minimize the possibility for confusion or misunderstanding that this threshold represents an insignificant or negligible risk—too small to be of concern.

In the formal draft dated July 2012, the AA Threshold was changed to a case-by-case determination for each Priority Product (product-chemical combination). Section 69503.5 of the July 2012 version of the regulations specified criteria to be used by DTSC when setting the AA Threshold for each Chemical(s) of Concern in a Priority Product. The criteria included:

(i) The ease or difficulty of removing the Chemical(s) of Concern from the product if the Chemical(s) of Concern is a contaminant rather than an ingredient;
(ii) The minimum detection limit for the Chemical(s) of Concern with available laboratory technology; and
(iii) Various public health and environmental protection considerations.

In no case, was the AA Threshold to be lower than the minimum detection limit for the Chemical(s) of Concern.

Revisions to the AA Threshold provisions have been made in the proposed regulations. The proposed regulations dated January 2013 no longer allow the exemption for both intentionally added ingredients and contaminants. The AA Threshold was amended and defined as the Practical Quantitation Limit (PQL) for Chemical(s) of Concern that is present solely as a contaminant. Additionally, the default AA Threshold for Chemical(s) of Concern that are intentionally added ingredients has been amended. However, in the April 2013 version of the regulations, an additional provision was added that explicitly states that DTSC may specify in the proposed or final Priority Products list an AA Threshold for intentionally added ingredients or an AA Threshold that is greater than the PQL for any Chemical of Concern that is a contaminant. The Priority Products lists will be established through rulemaking under the APA. The public comment process related to Priority Products listing will provide transparency to stakeholders, and will provide an opportunity for review and comment on setting the concentration for the AA Threshold exemption, among other issues. Stakeholders may provide evidence to address concerns about the uncertainty of a threshold for a given Priority Product or information on available analytical methods to document eligibility for the exemption.

§ 69503.5 AA Threshold Exemption - Replace Criteria with Default Values

Comments: 1-7, 1-8, 3-6, 7-11, 9-98, 9-99, 10-5, 11-9, 15-5, 17-5, 19-13, 19-14, 19-16, 19-17, 19-18, 41-3, 46-2, 49-16, 57-47, 61-8, 64-11, 65-3, 65-6, 73-9, 73-41, 74-39, 76-49, 80-15, 82-5, 91-7, 91-8, 91-9, 101-3, 101-29, 107-26, 107-54, 107-55, 109-15, 119-3, 124-10, 124-27, 128-3, PH1-3, PH12-2, PH12-3, PH16-6, PH34-2

Comments Summary:

These comments pertain to concerns regarding section 69503.5 of the July 2012 version of the regulations, which specifies the substantive criteria for the AA Threshold exemption and the criteria for modifying the AA Threshold. An AA Threshold exemption applies if the concentration of each Chemical(s) of Concern is less than or equal to the AA Threshold for the product, or component(s) identified as the basis for the Priority Product listing. This condition must be met as of the date DTSC lists a Priority Product or when a Priority Product is first placed into the stream of commerce in California, whichever is later. If a Priority Product is introduced into the stream of commerce on a date that occurs after the Priority Product is listed, then the exemption will apply on this later date. The July 2012 version of the regulations no longer specifies a default concentration. The comments express the need for reintroducing the default AA Threshold instead of the approach in the current provision, which sets a chemical-product-specific threshold rather than an "across the board" chemical threshold.

Concerns about the lack of a specific threshold concentration in the regulations include:

- The development of a case-by-case AA Threshold will be very challenging and will consume enormous, potentially unnecessary, DTSC resources. DTSC would have wide latitude in setting such levels thus resulting in further uncertainties for both large and small businesses alike. The case-by-case approach to determine the AA Threshold does not provide enough certainty because the language lacks a clear and predictable process for how AA Threshold levels will be determined, does not have standards to warrant a higher or lower AA Threshold level, leaves the AA Threshold concentration open-ended for different chemicals and different products, will add to the complexity for compliance, may require the need for responsible entities to hire experts and toxicologists to justify the thresholds, and may impede the success of this chemicals management regulations;
- A practical default AA Threshold will reduce any confusion for responsible entities to understand what constitutes a Chemical of Concern and avoid unnecessary assessments and reformulations based on the mere presence of trace amounts of a Chemical of Concern. Having a consistent list of declarable substances and consistent AA Thresholds is critical for ensuring timely and accurate part level chemical content data transfer throughout the supply chain;
- The AA Threshold should be harmonized with federal and international agencies. The established de minimis level of 0.1% has considerable precedent in the Globally Harmonized System for Classification and Labeling (GHS) and the European Union's REACH program. Other regulatory authorities from U.S. EPA to the European Union, to Canada, have established a de minimis concentration

level at 0.1%, unless there are specific scientific reasons that warrants a higher or lower level. DTSC's attempt to establish an AA Threshold that is inconsistent with other federal and international bodies will create an unnecessary level of confusion for implementation;
- The regulations do not address whether an unintentionally added ingredient or a trace contaminant impacts the AA Threshold;
- The process should be self-implementing and risk-based; and
- Commenter disagrees with the elimination of a default threshold replaced by a case-by-case threshold.

DTSC received a significant number of comments on the AA Threshold, and most requested a default level to provide responsible entities greater certainty instead of the current proposal in the July 2012 version of the regulations to have case-by-case determinations. The majority of the comments suggest a variation of setting a default AA Threshold. Most commenters suggest setting the AA Threshold to the concentration of 0.1% or 1,000 parts per million. Some commenters request a combination of 0.1% and 0.01% (100 parts per million), varied by hazard trait. Others commenters request the ability to adjust the default depending on whether the Chemical(s) of Concern is intentionally added or is present as a contaminant.

The commenters support or recommend that the AA Threshold be revised as follows:

- AA Threshold should be a default of 0.1%;
- The default AA Threshold could be 0.01% that can be adjusted higher or lower;
- The AA Threshold should be 0.1% and adjusted by factors related to public health and/or the environment rather than analytical method-based limits of detection;
- The AA Threshold should be at 0.01% or lower, rather than allowing for a level of 0.1%;
- The AA Threshold should be 0.1% only for any intentionally added chemicals which could be adjusted with input from stakeholders;
- The AA Threshold should be 0.01 % for chemicals with particular hazard traits (*e.g.*, carcinogens, neurotoxins, reproductive toxins, etc.) and 0.1 % for all other chemicals until DTSC can develop a credible risk-based approach. This process should be self-implementing;
- The default AA Threshold levels should be established for contaminants or trace amounts and included these in the definition of AA Threshold;
- The AA Threshold should be limited to intentionally added ingredients;

- The AA Threshold should be consistent with Washington and Maine—the regulations should set clear threshold levels and consider whether a chemical is intentionally added or is a contaminant in setting the AA Threshold level;
- The AA Threshold for an intentionally added chemical in an accessible component of a product should be the PQL;
- The AA Threshold should apply only to intentionally added ingredients that are in an accessible component;
- The AA Threshold should be 0.01% for a contaminant present in an accessible component;
- The AA Threshold exemption should apply at any concentration for chemicals in inaccessible in components that occur only as a contaminant, as long as the responsible entity has in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component; and
- Any adjustment by DTSC of a set default AA Threshold should be based on an assessment of available data on the potential risk to human health and environment.

Response:

The standards in the regulations for establishing the AA Threshold (section 69503.5) were narrative and thus, were not predictable or specific enough to assure the regulated community. DTSC understands that the latitude given to DTSC in setting such levels will increases the uncertainty for businesses and that developing specific AA Thresholds for Priority Products will be challenging and resource intensive.

In response to comments regarding the difficulty of setting a case-by-case AA Threshold and the appropriateness of the factors listed to establish a concentration level that will be protective of public health and the environment, DTSC has revised the regulations. DTSC has eliminated the provision to make a case-by case AA Threshold determination. In the January and April 2013 versions of the regulations, the AA Threshold is the PQL for any Chemical(s) of Concern that is/are present solely as contaminants in a Priority Product. If during the product prioritization process, DTSC determines that an AA Threshold is needed for a particular intentionally added chemical in a particular product this can be addressed in the rulemaking for that Priority Product listing. DTSC has reserved the right to establish specific AA Thresholds on a case-by-case basis for intentionally added chemicals or for setting the AA Threshold for contaminants greater than the PQL in a separate rulemaking.

The PQL, as the AA Threshold, will be practical. Because the Priority Product lists will be adopted through rulemaking, the PQL or the acceptable analytical methodologies will

be known when the Priority Products list is finalized. This will provide the certainty that the regulated community needs to ensure compliance and the success of these regulations. This default AA Threshold will not require responsible entities to hire toxicologists to justify product specific thresholds which are no longer part of determining the AA Threshold. Once the PQL is known for a product-chemical combination, this will allow for better communication throughout the supply chain.

These regulations do not establish a blanket requirement for all chemicals listed in the Candidate Chemicals list; the Candidate Chemicals list is not a list of declarable substances. There was some confusion regarding what requirements applied at what concentrations for chemicals listed on the previously named Chemical(s) of Concern list. DTSC has revised the regulations to rename the Chemical of Concern List to the Candidate Chemicals list, so it should be clearer that the Chemical(s) of Concern now only refers to the Chemical(s) of Concern that is/are the basis for the Priority Product listing. The regulations do not require AAs or reformulation based on the presence of a Candidate Chemical in concentrations greater than the AA Threshold level.

Regardless, if DTSC uses a case-by-case determination of a PQL for the AA Threshold, both of these approaches leaves the AA Threshold open-ended for different chemicals and different products. The PQL does not establish an AA Threshold for a single Chemical of Concern, but rather the PQL will establish an AA Threshold for product-chemical combination. A single Chemical of Concern could potentially have different AA Threshold values depending on the speciation of the Chemical(s) of Concern and the matrix of the Priority Product. Once the Priority Product is listed, there should not be uncertainty as to when an AA is required.

DTSC respectfully disagrees that the AA Threshold in these regulations should conform to or be harmonized with de minimis levels found in other state, federal, or international regulations. De minimis as is used in the European Union's Restriction of Hazardous Substances (RoHS) Directive, REACH and other programs is a reporting limit based on volume, not risk-based concentration. The overlapping and potentially conflicting uses of the term caused DTSC to reconsider the use of the term and instead create an independent term to minimize the unintentional assumption that the concentration equates an acceptable level of risk. DTSC has intentionally renamed this concentration level the AA Threshold because it has a specific effect in this regulation. It established the level at which a Priority Product can take an exemption provided the conditions of the AA Threshold Notification have been complied with and the Priority Products that are subject to the substantive requirements of the regulations.

The revised AA Threshold provision in the regulations (January and April 2013) does address both contaminants and intentionally added ingredients. DTSC has decided that the goals of the regulations can best be served by not allowing for a default threshold concentration for intentionally added ingredients. The AA Threshold is the PQL for Chemical(s) of Concerns that are contaminants and there is no AA Threshold for intentionally added Chemical(s) of Concerns. DTSC will not be making any additional changes in response to these comments.

The AA Threshold Exemption is not self-implementing because the exemption from the requirements of an AA is conditional, and based on the information submitted to DTSC. Once a Priority Product is listed, a responsible claiming an AA Threshold Exemption—exemption from conducting an AA under Article 5—must notify DTSC. The AA Threshold Exemption notification must contain the information specified in sections 69503.6(a) and (b).

The states of Maine and Washington have recently adopted laws and regulations for chemicals in children's products. These states have set the "de minimis" at the PQL for a chemical of high concern or priority chemical that is an intentionally added chemical and have set the concentration to 100 parts per million for a chemical that is a contaminant. DTSC has also addressed intentionally added ingredients and contaminants when setting the AA Threshold but has chosen to be more conservative for both.

DTSC has considered the issue of accessible and inaccessible and has found that it is not appropriate or prudent to treat components that are seemingly inaccessible differently from those that are more accessible. As discussed earlier in section 69503.2(a) Product Prioritization Factors, the potential exposures posed by the Candidate Chemical throughout the life cycle of the product will be assessed. The containment, hence accessibility and inaccessibility of the Candidate Chemical(s), will be taken into account during the prioritization process. Candidate Chemical(s) in a consumer product that is listed as a Priority Product, hence includes a Chemical(s) of Concern, will likely be those with the highest propensity to cause or contribute to an exposure. Given that the accessibility and inaccessibility is taken into account during the prioritization process, it is unnecessary and counterintuitive to create an exemption for Priority Products that have demonstrated a potential adverse human health and or environmental impact. The proposed regulations contain a more comprehensive manner to evaluate the potential risks of Candidate Chemicals in inaccessible components. DTSC will not be including a specific AA Threshold for inaccessible components in response to these comments. While DTSC believes that utilizing

manufacturing control practices and due diligence to minimize contaminants is good business practice, this alone is not sufficient to meet the goals and intent of AB 1879, that is, to find alternatives to Chemical(s) of Concern to reduce adverse public health and environmental impacts in California.

Although inaccessible is not synonymous with containment, there is a provision in section 69503.3(b)(4)(F) (January 2013) which considers potential exposures if the Candidate Chemical is contained within the product. How the chemical is contained or bound during the use of the product will determine, in part, the amount of exposure that may occur. This provision acknowledges those situations when a component inside a product that may not be accessible to the user has minimal or no exposure as a result of use of the product during product prioritization process.

Please see section 69501.1(a)(new) *Add "Inaccessible," "Inaccessible component," or "Accessible component"* of this Response to Comments document for additional discussion of accessible and inaccessible components.

DTSC did consider a default AA Threshold set at 0.1% and 0.01% with the ability to raise or lower it based on specified criteria. Commenters urged DTSC to abandon this approach because 0.1% is not protective enough of sensitive subpopulations which is required by the enabling statue and aligns with and is consistent with the goals and intent of AB 1879. Another major concern was that the various factors listed in section 69503.5 lacked standards and predictability. DTSC reconsidered both of these issues, and has revised the regulations to include a more conservative approach and to still allow for the possibility to adjust the AA Threshold if responsible entities can make compelling cases to change the AA Threshold during the rulemaking for any of the Priority Products proposed for adoption. DTSC will not revise the text to include a default of 0.1% or 0.01%. See discussion of related provisions for this article regarding the AA Threshold for further information about how this mechanism will work.

Comment: 12-7

Comment Summary:

The commenter would prefer that DTSC define this section as "de minimis," rather than "Alternatives Analysis Threshold." The term "de minimis" more clearly acknowledges that the risk is not actionable.

Response:

DTSC respectfully disagrees with the comment. De minimis limits are typically a policy

call made by regulatory agencies as an administrative convenience. There is no risk assessment associated with this type of administrative policy. They are most often default, universal values, not based on specific risk of harm. De minimis is also used by other regulatory programs to establish a variety of thresholds for labeling, notification, reporting, and chemical restrictions. The overlapping and potentially conflicting uses of the term caused DTSC to reconsider the use of the term and instead create an independent term to minimize the unintentional assumption that the concentration equates an acceptable level of risk. DTSC has chosen the term "Alternatives Analysis Threshold" as a more accurate way of describing the fact that the regulations provide a threshold to denote which Priority Products would be subject to the AA and which would not. DTSC believes that it is clearer to use the term AA Threshold in the regulations than to use the term de minimis. The term AA Threshold is used for the notification to assert exemption from the substantive requirements of this regulation.

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

Comments: 3-4, 19-40, 19-41, 34-10, 41-8, 49-7, 49-18, 64-11, 73-9, 74-37, 81-5, 82-5, 107-51, 124-10, 124-27, PH10-7, PH12-7, PH33-5

Comments Summary:

The proposal should differentiate between intentionally added materials and unintentionally added contaminants. The regulations should focus on intentionally added ingredients and exempt contaminants.

Response:

In response to these comments, there is no AA Threshold allowed for intentionally added ingredients in the proposed regulations (January 2013). The AA Threshold is now defined as the PQL, and the exemption applies only if the Priority Product contains the Chemical(s) of Concern solely as a contaminant chemical. However, the proposed regulations give DTSC the authority to set an AA Threshold for intentionally added ingredients on a case-by-case basis at the time it lists a Priority Product (April 2013).

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption

provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January 2013).

Comment: 69-26

Comment Summary:

Food and Drug Administration (FDA) has already established the appropriate threshold for safety for many products. Thus, DTSC should defer to the FDA and not be establishing threshold levels for products regulated under the FDA.

Response:
While changes in response to the above comment were not made in response to other related comments the AA Threshold provisions have been revised and moved to 69505.3 (January and April 2013).

§ 69503.5(a) Alternatives Analysis Threshold Exemption Notifications

Comments: 5-155, 11-40, 57-47, 65-4, 107-52, 124-5, PH12-4, PH12-5, PH12-7, PH28-5

Comments Summary:

The above comments expressed concern with section 69503.5(a), which requires a notification for an exemption from the requirement to conduct an AA for a Priority Product when specified criteria are met. The distinction between those Priority Products that are subject to the AA requirements in Article 5 and those that are exempt is based on the AA Threshold.

In summary, the following concerns were expressed:

- It is extremely resource-intensive to include analytical lab testing protocols and results and quality assurance/quality control information;
- Other jurisdictions establish a value below which there is typically no evidence of harm;
- Any Priority Product may have to be tested even if the Chemical(s) of Concern is/are not intentionally added or are not expected to be present;
- This is a significant distraction from the statutory purpose of the program;
- The process requires the release of proprietary data, which would be public when DTSC posts the AA Threshold exemptions on its website.

- DTSC should eliminate the AA Threshold Exemption Notification process in favor of a self-assessment process and strike the language in section 69503.5(a) to make conforming changes; and
- Another recommendation was to use OEHHA's self-assessment process under the Proposition 65 safe harbor provisions, which has been very successful and may be a model for the application of the de minimis provisions.

Response:

DTSC respectfully disagrees that the AA Threshold Exemption Notification should be deleted. Responsible entities should know what is in the products they make to ensure the quality of their products. In addition, DTSC, the general public, and interested parties may learn a great deal from the AA Threshold Exemption Notification. It provides an important check-and-balance to ensure responsible entities are complying with the regulations. This notification also provides an important source of information from which DTSC may conduct audits. It is also a source of technical information for those seeking to reduce the harmful chemical content of their products.

Similar comments were submitted for both sections 69503.5(a) and 69503.6. See section 69503.6 for additional discussion of this issue.

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January 2013).

§ 69503.5(b) AA Threshold Criteria

Comments: 5-155, 29-13

Comments Summary:

While the comments support this provision a recommendation to delete the phrase, "homogenous materials" in section 69503.5(b) in the first sentence was made.

Response:

In response to the above and other related comments the term "homogenous" is no longer a stand-alone definition. The term "homogeneous" is now included in the definition of the term "component" (January 2013).

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

§ 69503.5(c) AA Threshold Process and Criteria

Comments: 7-11, 7-12, 11-9, 19-15, 54-9, 76-46, 82-6, 91-8, 91-10, 95-6, 101-28, 129-11, 136-2, 136-3, PH28-6, PH34-2

Comments Summary:

The following comments are in regard to the general criteria, standards, methodology or process for determining the AA Threshold in section 69503.5(c):

- This section provides no clear criteria, standards, and methodology for deriving an AA Threshold value. Instead, an assortment of factors is identified that the DTSC may consider in deriving an AA Threshold value;
- A transparent and predictable regulations framework should be developed to establish an effective and workable program;
- The AA Threshold process is totally discretionary to the agency, limited only by available analytical methodology and the minimum detectable concentration for the Chemical of Concern(s) in a product;
- If the AA Threshold is not intended to make some distinction between chemicals present in concentrations that would cause concern and negligible concentrations that would not, then it is not clear what DTSC intended the proposed exemption to accomplish and what that threshold represents;
- There is too much focus on specific hazard traits in setting the AA Threshold. Chemicals can have various hazard traits that can occur at different doses or may be found in different test species. This would mislead the public because the data is too incomplete and concordance between test species and humans is not very good. Instead, potency and level of exposure is a more focused approach;
- There is an absence of a clear and articulated exit process for chemicals that fall under the AA Threshold. DTSC should establish a defined process applicable to cases in which the concentration of a Chemical of Concern falls outside of the minimum threshold set for a product;

- This section could offer more public health protection if the approach taken in classifying a chemical as a “Chemical of Concern” were also taken in determining whether a threshold exemption for a Priority Product ought to be available or allowed;
- Chemical-specific Priority Product risk evaluations should be conducted through an open, public process, with sufficient review times to provide opportunity for public input, review, comment, and debate before finalizing the threshold; and
- AA Threshold guidance should be prepared to inform responsible entities of how DTSC will implement this provision to reduce delays and compliance costs; and
- AA Thresholds should be set on a case-by-case basis, evaluated, and based on potential COC exposure for each product and sound science;
- DTSC should define the preferred test method(s) and practical quantitation limits when AA Thresholds are set.

Response:

This provision was written as a narrative standard, so there are no specific standards or methodology which would allow for the certainty that industry has requested. The use of narrative standards in the regulations offers significant advantages over other approaches because they establish the goals and objectives that must be achieved, and allow for varying methods and/or criteria that can be used to demonstrate whether the goals and objectives have been met. In contrast, a prescriptive standard would prescribe concentrations, analytical methods, hazard traits, chemical potencies, degree of severity, etc. for every possible chemical and for every possible exposure for every product. Without stating goals and objectives, a prescriptive process would limit the options the regulated entities and DTSC would have at their disposal. Given the breadth and scope of the proposed regulations, it would be simply unthinkable that DTSC would know all of the varying types and pieces of information to make the regulations prescriptive and protective at the same time, as intended by AB 1879. Narrative standards allow DTSC to focus on the characteristics of the final product and the adverse impacts it has on human health and the environment. In addition, narrative standards allow DTSC to take advantage of new technologies, innovation, public input, and create efficiencies while ensuring human health and the environment are being protected.

The intent of the AA Threshold in the July 2012 version of the regulations was to set a case-by-case concentration that would be protective of public health and the environment while considering the factors listed in subsections 69503.5(c), (d), and (e).

There were many hazard trait criteria but there were also exposure factors to be considered. The analytical detection limit was meant to be the lowest value that could potentially be set for the AA Threshold level, and in this manner it does limit how low an AA Threshold could be established.

This narrative provision for a case-by-case setting of the AA Threshold for all Priority Products has been eliminated. Instead, DTSC has revised the regulations to provide for an AA Threshold only for unintentionally added chemicals and has reserved the right to set an AA Threshold for intentionally added chemicals on a case-by-case basis at the time it lists Priority Products. The April 2013 proposed regulations make it clear that the default values for the AA Threshold can be changed during the APA process for the affected Priority Product. California's rulemaking process is an open public process with sufficient times for review and opportunities for public input. The rulemaking process will allow stakeholders to provide additional input on criteria, standards, and analytical methods, regarding other approaches that will inform responsible entities how DTSC will implement the AA Threshold for a specific Priority Product making a guidance document unnecessary.

In response to the above and related comments regarding exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

Comments: 5-155, 34-10, 124-27

Comments Summary:

The above comments recommend that real exposure and actual risk must be present to require a substitution. The comments further recommend that materials that are inaccessible to the product user should be exempt and that the entire subsection (c) should only apply to highly durable goods.

Response:

Inaccessible components will not be excluded from these regulations due solely to their inaccessibility. There may be exposure pathways (*e.g.*, inhalation) or end-of-life issues that may need to be assessed that are unaffected by a component simply because it is out of reach during the active use of the product. Potential exposure during the

product's life cycle (manufacturing, use, transportation, waste, and end-of-life) will remain a prioritization factor.

This provision has been eliminated. DTSC will not be making any changes in response to these comments. The reader is referred to the discussion of the definitions of "component" in Article 1, as well as the other relevant parts of Article 3 regarding the prioritization process for further information about how a component's inaccessibility is considered under these regulations.

§ 69503.5(c)(1) Ease of Removing Chemical of Concern

Comments: 9-97, 13-7, 15-5, 19-15, 33-4, 41-21, 57-47, 107-51, 107-52, PH33-5

Comments Summary:

Section 69503.5(c)(1) specifies a set of criteria for adjusting the AA Threshold level above the detection limit for the presence of contaminants. There are naturally-occurring contaminants and unintentionally added substances that fall under this regulation. Terms such as "contaminant," "unintentionally added," and "naturally occurring contaminant" are used interchangeably.

Concerns submitted regarding this provision were:

- DTSC should not list a Priority Products if the presence of the Chemical(s) of Concern is due to impurities in raw materials that are not a safety concern and are not economically feasible to remove;
- There may be some rare occasions of high hazard due to contaminants, but these instances have typically been managed by other programs of ingredient restriction;
- DTSC has not set a default AA Threshold and a Chemical(s) of Concern could be detected later as testing capabilities become ever more refined;
- The regulations do not include a supplier notification process—manufacturers have no way of knowing what impurities may be present in materials they further process or use. If a chemical is unintentionally present, it is likely that the manufacturer is unaware of its presence, it is likely present in very low concentrations and presents minimal exposure potential, and DTSC will not have any exposure data by which to prioritize the chemical/product category;
- Exempting unintentionally added chemicals from the regulations' requirements is consistent with other state, federal, and international chemical regulatory policies; and

- The provision for the consideration of the ease to remove contaminants provides no distinction between insignificant risk potential and potential risk and consequently provides no value in terms of priority setting.

The following are recommendations and suggestions to address the concerns stated above:

- The regulations need a definition for “contaminant” which should not be more restrictive than the definitions used by Washington and Maine. The term contaminant is referenced in the text but is not defined in the regulations;
- The regulations need a definition for “unintentionally” added chemicals;
- DTSC should consider only chemicals that are intentionally added above the AA Threshold level when making product prioritization decisions; and
- The regulations should phased-in unintentionally added chemicals by exempting contaminants for the first five years of the program.

Response:

This provision allows for the consideration of ease of removing contaminants as the source of the Chemical of Concern to establish an AA Threshold. In response to comments related to exemptions in this and other related sections, the AA Threshold provisions have been amended and moved to section 69505.3 of the proposed regulations (January 2013). Section 69503.5 has been amended and replaced with a default AA Threshold for Priority Products that contain a Chemical of Concern that is present solely as a contaminant (January 2013).

The new AA Threshold applies differently to contaminants and intentionally added ingredients. DTSC has added a definition for “contaminant” and for “intentionally added ingredient” under section 69501.1(a)(26) to the proposed regulations (January 2013). This should provide greater clarity to the regulatory language.

DTSC will not be including a phased-in approach for unintentionally added ingredients because the program will be starting with only a few Priority Products in the initial round of Priority Products. DTSC does not foresee a dramatic expansion of the number of Priority Products for the foreseeable future. The suggested five year time frame would cover the first cycle only of Priority Products. The language will not be revised in response to these comments.

Consumer products that contain low level impurities that are not safety concerns will still have to be evaluated if there is an adverse impact associated with the chemical and there is a potential for high exposures. Given that establishing the “safety” of a Priority

Product would entail the essential elements of conducting an AA— demonstrating a lack of adverse impacts on human health and/or the environment—DTSC does not understand how a product deemed safe by the manufacturer would be prioritized as a proposed Priority Product. Were the product in fact "safe," it would be hard to reconcile this fact with the prioritization factors for product-chemical combinations specified in Article 3. A Priority Product would contain a Chemical of Concern, it would have market presence in high enough volumes and there would have a propensity for exposure resulting from the product. Further, the Priority Product would have been subject to an open and public process before adoption through rulemaking with an opportunity to set a customized AA Threshold. If, after all that, the product-chemical combination were to be listed as a Priority Product, a responsible entity would be able to conduct the AA to demonstrate the "safety" of their particular Priority Product. The responsible entity could then elect to retain the Chemical of Concern in the Priority Product but would be subject to possible regulatory responses.

A commenter erroneously assumes that the AA Threshold applies to the all the chemicals listed on the previously named Chemical(s) of Concern list which is now named the Candidate Chemicals list. The AA Threshold only applies to the Chemical(s) of Concern in the Priority Product. The AA Threshold is not a universal default number that applies to the entire Candidate Chemicals list. The AA Threshold will only apply to the Chemicals of Concern in a listed Priority Product.

DTSC is not requiring a supplier notification process in the regulations for Priority Products because analytical data is required for the AA Threshold exemption. If the manufacturer wishes to submit an AA Threshold Notification in lieu of complying with the substantive requirements of the regulations, analytical testing will be required to qualify for this conditional exemption. Requiring certification of material content from suppliers is a business decision, but it does not meet the requirements for this exemption.

DTSC disagrees that the regulations should exempt unintentionally added chemicals consistent with other chemical regulatory policies. DTSC has tried to make allowances in the regulations for contaminants in products because there are issues that are distinct from intentionally added ingredients. This provision for example attempted to allow for the consideration of contaminants that cannot easily be removed. Commenters pointed out that the ability to remove contaminants provides no distinction between insignificant risk potential and potential risk and consequently provides no value in terms of priority setting. So this provision has been eliminated. In addition, DTSC does not feel that exempting contaminants is in line with the goals of the regulations.

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

§ 69503.5(c)(1)(A) Naturally Occurring Chemicals of Concern

Comments: 1-7, 3-6, 5-11, 5-78, 5-113, 5-155, 19-41

Comments Summary:

"Naturally occurring" contaminants should be exempt. The commenters' concern is that the regulations include naturally occurring contaminants. DTSC's interpretation, therefore, completely creates disincentives for automotive recycling (*e.g.*, steel) and further discourages the use of recycled metals and plastics out of concern for likely untraceable and inconsequential levels of naturally occurring and historic trace materials. Suggested language revision was to delete 69503.5(c)(1)(A).

Response:

The comments reflect an erroneous understanding of the language in former section 69503.5(c)(1)(A). This provision was a factor to be considered when setting a customized AA Threshold. If it were not technically feasible to remove contaminants in raw material, then special consideration of this factor would allow the AA Threshold to be adjusted to account for this situation.

The default AA Threshold for contaminants, including those that are naturally occurring, in products is set at the PQL. There will be an opportunity, during the rulemaking process to list Priority Products, to provide input regarding a specific product-chemical combination as a Priority Product, or setting a modified AA Threshold based on the chemical, the product, the contaminants, the analytical methods, etc. (January and April 2013).

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis,

and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

§ 69503.5(c)(1)(B) Air or Water Used During Manufacturing

Comment: 54-7

Comment Summary:

This provision addresses the indoor air quality concerns in both production and residential settings. As such, it is in conflict with air quality criteria under the purview of the California Air Resources Control Board. In addition, it captures “off-gassing” that may be related to functionality of a consumer product. Capturing this “source” as a driver in establishing the “Chemical(s) of Concern” list, as identified in Article 2, is duplicative and inappropriate.

Response:

The comment reflects an erroneous understanding of the language in section 69503.5(c)(1)(B). This provision is a factor to be considered when setting a customized AA Threshold.

This provision has been eliminated. No additional change has been made in response to this comment. See discussion of related provisions regarding the AA Threshold in this article for further details regarding how this exemption applies.

§ 69503.5(c)(1)(C) Chemicals of Concern in Recycled Materials

Comments: 5-11, 5-78, 5-113, 5-155, 11-13, 13-5, 13-6, 13-7, 19-41, 41-8, 81-1, 81-2, 81-5, 124-9, PH14-1, PH23-1

Comments Summary:
DTSC recognizes the importance of recycling and incorporates measures in this provision to promote it, when setting a threshold for a Chemical of Concern. Many of the commenters were concerned that by singling out "contaminants" in recycled materials when setting AA Thresholds, intentionally added chemicals were being treated more favorably. Many suggested that contaminants be exempt from the regulations. The concerns were as follows:

- The comments recommend that this section exempt recycled material contaminants from consideration;

- This provision will impose a disproportionate burden on those who use recycled feedstock, will create a disincentive to using recycled feedstock, will decrease demand for recycled feedstock and will ultimately be counterproductive to recycling programs;
- Recycled feed stocks should not be covered by these regulations. There are many challenges to recover the value of renewable products, and recycled materials and would likely contain Candidate Chemicals (formerly Chemical(s) of Concern);
- If consideration of Chemical(s) of Concern present in recycled materials is not completely exempted from the regulation, then DTSC should modify the proposed regulations to require consideration of all Chemical(s) of Concern present in recycled materials when setting AA Thresholds;
- Impacts of the AA Threshold provision of the regulations on recycled materials should be anticipated and analyzed. The AA Threshold will drive manufacturers to seek high purity source materials;
- As drafted, the proposal only requires DTSC to consider the existence of Chemical(s) of Concern present as "contaminants" in recycled materials when setting AA Thresholds. The threshold should apply to both intentionally and unintentionally added chemicals; and
- If DTSC does not provide a recycled materials exemption, it should eliminate the use of the term "contaminant" in section 69503.5(c)(1)(C) of the proposed regulations. As drafted, the proposal only requires DTSC to consider the existence of Chemical(s) of Concern present as "contaminants" in recycled materials when setting AA Thresholds. This appears inconsistent with DTSC's position in the Initial Statement of Reasons that the threshold will apply to both intentionally and unintentionally added chemicals.

Response:

Former section 69503.5(c)(1)(C), was not an applicability provision. Applicability requirements of these regulations are set out in section 69501. This provision sets out criteria for adjusting a threshold for a Chemical of Concern in a Priority Product for which an AA is required. Exempting the provision for recycled materials has the effect of not considering the difficulties in recovering valuable renewable materials.

DTSC has eliminated the approach to set a case-by-case AA Threshold for a Priority Product. The provision in section 69503.5(c)(1)(C) would have allowed the AA Threshold to be adjusted due to the difficulties of processing this material to remove residuals.

The regulations have been revised to include a new definition for “contaminant” which includes an embedded definition for “recycled material.” The regulations have also been revised to include a default for the AA Threshold to be the PQL for Chemical(s) of Concerns that is/are present solely as contaminants in a Priority Product in the proposed regulations (January 2013).

Section 69503.5(c) of the proposed regulations allows DTSC to consider modifying an AA Threshold during the rulemaking process. Stakeholders may provide input at that time regarding issues that impact recycled materials if these materials are being proposed as a Priority Product. Stakeholders can make the argument as to why these recycled materials should or should not be a Priority Product, or why the AA Threshold should be greater than the PQL. All the issues related to recycled materials being disfavored in favor of higher purity content, higher processing, and disincentives to recycling, can all be introduced during the public comment period (April 2013).

In response to the above and other related comments regarding exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis. (January and April 2013)

Comment: 91-10

Comment Summary:

The AA Threshold should be established to accomplish the purpose of this law—to protect public health and the environment. The AA Threshold should be set at a concentration below which there is no further need to consider limiting exposure throughout the product life cycle. This should be set regardless of whether the Chemical(s) of Concern is/are added as an intentional ingredient or present as a contaminant in the raw or recycled materials, processing agents, intermediates, air, or water used in the manufacturing process.

Response:

In response to the above and related comments the provisions regarding AA Threshold exemptions have been revised regulation (January and April 2013). For a more detailed discussion on the AA Threshold exemption please refer to other discussions under section 69503.5 of this Response to Comments document.

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

§ 69503.5(c)(1)(D) Chemicals of Concern as Processing Agents

Comment: 74-42

Comment Summary:

Zero is impractical as a threshold because it is a technically impossible regulatory standard to measure and comply with, and provides no additional benefit to public health and the environment. The comment included the suggestion that if DTSC continues with the proposed approach, they should add the terms, “reactant and by-product” in addition to the terms, “processing agent or intermediate” to this provision.

Response:

The proposed regulations do not recommend “zero” as a threshold. However, in response to the above comment and related comments, the provisions regarding AA Thresholds have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

Section 69503.5(c) of the proposed regulations allows DTSC to determine, if appropriate, product-chemical specific AA Thresholds s at the time the Priority Products are listed (April 2013). DTSC has reserved the right to establish specific AA Thresholds on a case-by-case basis for intentionally added chemicals in Priority Products and to raise the AA Threshold for contaminants from the PQL, if appropriate. If DTSC exercises this authority, it will do so at the time it lists Priority Products. Please refer to more detailed discussions regarding the AA Threshold exemption and the rationale for DTSC’s approach in the Article 3 of this Response to Comments document and section 69505.3 of the January 2013 Response to Comments .

§ 69503.5(c)(2) AA Threshold: Use of Minimum Detection Limit

Comments: 5-77, 5-155, 9-24, 9-39, 9-96, 9-97, 19-15, 34-9, 49-17, 54-9, 57-47, 64-12, 70-7, PH10-7, PH33-4

Comments Summary:

The above comments expressed concern with section 69503.5(c)(2)(A) and (B), which specify that DTSC must consider the minimum concentration of the Chemical of Concern that can be detected with available laboratory methodology when setting the AA Threshold. Further, the AA Threshold cannot be set lower than the minimum detection level. In summary, the following concerns and recommendations were expressed:

- A minimum laboratory detection limit concentration cannot function as an exemption threshold. Defining a threshold according to "available laboratory analytic methodology" renders it more uncertain from the perspective of companies. Present day laboratory detection limits are far below any regulatory standard for health or environmental protection;
- There are possible interferences of matrices on the ability to detect chemicals in different types of materials and DTSC is urged to work closely with product manufacturers and/or their suppliers to establish thresholds that can be reliably and economically tested;
- There can be considerable variability in analytical detection limits from one laboratory to another and DTSC may want to account for this factor;
- The detection limit is only a binary (present/not present) outcome, rather than a quantitative amount. It is unclear how a responsible entity would use a minimum detectable concentration to be able to demonstrably reduce the level of a Chemical(s) of Concern in the Priority Product below the limit of detection;
- Establishing the limit of detection as a regulatory threshold effectively sets a moving target. The degree to which businesses would have access to and resources to put toward this level of analytical chemistry is impractical;
- DTSC should adopt the PQL as the AA Threshold for intentionally added ingredients. The comments recommend revising the language in 69503.5(c)(2) to remove the terms "minimum concentration" and "minimum detectable concentration," and replace both with the PQL. AA thresholds should then be set at or above the PQL;
- A de minimis level should be set well above the laboratory detection limit. Any criteria or process to determine this threshold must be technically feasible, cost-effective, workable, and based upon risk considerations;
- DTSC should make a clear statement of the value derived from this requirement to use an analytical method for establishment of an AA Threshold and should clarify if the limit of detection will be the preferred AA Threshold; and
- The reliance on the limit of detection, in conjunction with precautionary language, is establishing a framework focused on chemical elimination rather than safe use.

Response:

DTSC has revised the approach for the AA Threshold, which is now defined in section 69501.1(a)(12) as the PQL for a Chemical of Concern that is present in the Priority Products solely as a contaminant; or the applicable concentration, if any, specified by DTSC under section 69505.3(c) (April 2013). See section 69501.1(a)(12) and the discussion of related changes to the AA Threshold for further details regarding the practical basis of the PQL. In response to the above comments references to the minimum detection limit have been removed.

Comments: 9-23, 9-95

Comments Summary:

Language in the ISOR suggests that the default AA Threshold will be the minimum detectable concentration for intentionally added chemicals:

Response:

The ISOR has been revised (December 2012) to clarify that the minimum concentration is one of the criteria that will be considered when setting the AA Threshold. It is not the default, but the lowest possible concentration that can be set for the threshold concentration. For practical reasons, DTSC could never set the AA Threshold below the level of detection.

Further, the proposed regulations were revised to address these concerns, and this provision has been eliminated (January 2013). The AA Threshold is now defined as the PQL for Chemical(s) of Concern that is/are present solely as contaminants. There is no longer an exemption from the AA for intentionally added ingredients. But DTSC reserves the right to establish an AA Threshold for an intentionally added ingredient on a case-by-case basis (April 2013). There should not be any laboratory analysis required if a manufacturer adds a chemical as an ingredient. That is, since the manufacturer knows it added the chemical into its product, no testing is required to determine whether or not the chemical is present. And since there is no default AA Threshold for intentionally added ingredients, a manufacturer need not test its products to determine at what level an intentionally added ingredient is present.

§ 69503.5(c)(3) AA Threshold based on Reliable Information

Comment: 70-8

Comment Summary:

Subsection (c)(3) appears to state that the DTSC can set a threshold below the analytical detection limit based on considerations such as inherent toxicological potency, bioaccumulative potential or detection in biological tissues (*i.e.*, problematic language is at "notwithstanding paragraph 2A," which specifies the detection limit as the minimum value for the threshold). How can a threshold below the achievable detection limit serve as a screening criterion for conducting Alternatives Analysis in any practical way?

Response:

The comment is based on an erroneous understanding of the regulatory text. The full content and operation of the provision prohibited the AA Threshold from being set lower than the minimum detection limit. Thus, the AA Threshold could not be set below a detection limit, based on the criteria specified in paragraph (c)(3). This provision has since been eliminated (January 2013). Therefore, no additional response to this comment is necessary. However, this comment and response are related to the other discussion in this article regarding the AA Threshold, so the reader is referred to the related sections in this article for a fuller understanding of the AA Threshold.

Comments: 129-11, 136-2

Comments Summary:

An exclusion from the AA should be based primarily on health and environmental factors, *i.e.*, a showing based upon reliable information that the potential for adverse impacts is extremely low—well below what would normally be set as an acceptable exposure level under conventional standard setting methods. Paragraph (3) is insufficient to accomplish this goal because it would allow the agency to set a threshold at conventionally derived acceptable exposure limits. Failure to address the risk-based factors in section 69503.5(c)(3) will likely lead to stakeholder objections in the product prioritization process under Article 3 and petitions under Article 4 seeking development of product-specific AA Threshold values.

Response:

DTSC has eliminated this provision in response to these and other comments. Please see discussion of the related sections of Article 3 in this Response to Comments document for a fuller understanding of the new AA Threshold provisions that DTSC drafted in the January and April 2013 versions of the proposed regulations.

§ 69503.5(c)(3)(F)&(G) AA Threshold for Aggregate and Cumulative Exposures

Comment: 49-18

Comment Summary:

The issue of "aggregate exposures" raises serious questions of process and scientific underpinnings. It implies consideration of a simple "additive" notion of effects of such exposure, but this is not sorted out in contemporary toxicology. The same questions apply to the handling of "cumulative exposure" to other Chemical(s) of Concern in the product. Does this exist independent of any consideration of the potential mechanism of such cumulative impacts? Does it exist independent of potential routes of exposure?

Response:

This provision has been eliminated in response to this comment. Therefore, no further response to this comment is necessary. Please refer to the discussion of related comments regarding the AA Threshold in this Response to Comments document for a fuller understanding of the revised approach to the AA Threshold.

§ 69503.5(d) AA Threshold for Multiple Chemicals of Concern

Comments: 36-35, 57-50, 66-31, 74-41, 80-9, 80-10, PH16-5

Comments Summary:

This provision of the regulations allows the AA Threshold to apply to multiple Chemical(s) of Concern and allows DTSC to set a single threshold that applies to the total concentration for multiple Chemical(s) of Concern.

The following comments expressed support for this provision:

- The comments support the fact that DTSC will specify a single AA Threshold, which may refer to a group of substances with the same hazard trait. The comments recommend that the cumulative chemical concept be removed from the AA Threshold determination; and
- The comments strongly support this section, which provides that if multiple Chemical(s) of Concern exhibit the same hazard trait and/or environmental or toxicological endpoint(s) that have been identified as the basis for the products being listed as a Priority Product, DTSC may specify a single AA Threshold that applies to the total concentration in the Priority Product of all such Chemical(s) of Concerns.

The following comments expressed concern on how this provision would be applied:

- It is not clear how an AA Threshold would be set if there were multiple Chemical(s) of Concern identified in the Priority Product;
- The commenter does not support the concept that the threshold should be based on adding the concentrations of multiple Chemical(s) of Concern with similar hazard traits. No other threshold system in the world employs this approach;
- It is not clear if DTSC's intent is to regulate within a single chemical family (*e.g.*, phthalates) or across multiple chemical families (*e.g.*, inorganic and organic chemicals). The cumulative threshold concept is only practical if it is focused on a single chemical family, where it is difficult to differentiate between substances using known analytical methods. If the cumulative chemical concept is kept in the regulation, it should be clarified that the cumulative threshold will only apply to chemicals within the same chemical family that exhibit the same hazard trait;
- The electronics industry acknowledges the importance of considering cumulative chemical effects; however, we believe this should be considered during the product prioritization phase and can be addressed through regulatory responses, but it is not appropriate for a threshold determination; and
- Multiple Chemical(s) of Concern will further complicate the ability to analytically quantify all chemicals in a consumer product, especially for assembled products which may have matrix interferences, or some inorganic compounds with only analytical methods for the elements but not the full chemical compound.

Response:

This provision has been eliminated. No further response to this comment is necessary. Please refer to the discussion of related comments regarding the AA Threshold for a fuller understanding of the revised approach to the AA Threshold.

§ 69503.5(e) Amending AA Threshold Established by DTSC

Comments: 7-12, 49-17, 70-9

Comments Summary:

Section 69503.5(e) allows DTSC to lower or raise a previously established AA Threshold based on new, or newly considered, information. The first concern was that there is no indication of what kind of new information would constitute a basis for a change in threshold levels. This leaves open the possibility that every laboratory advanced in “ability to detect” could end up rendering some products out of compliance. The second concern was that the language should include the term “reliable” as used elsewhere in the regulations (*i.e.*, “…based on new, or newly considered reliable information”).

Response:

This provision has been eliminated from the regulations. No further change to the language is necessary. Nor is any further response to the comments necessary. Please refer to the discussion of related comments regarding the AA Threshold for a fuller understanding of the revised approach to the AA Threshold.

§ 69503.6 Alternatives Analysis Threshold Exemption Notification

Alternatives Analysis (AA) Threshold Exemption Notification Overview

To be exempt from the requirement to conduct an AA, the regulations require that an AA Threshold Exemption Notification be submitted in lieu of the Priority Product Notification, as specified in section 69503.6. This exemption is not self-implementing. The regulations specify the information that must be included in an AA Threshold Exemption Notification, including the source of the contaminant Chemical(s) of Concern. The notification must identify the maximum concentration for the Chemical(s) of Concern and the methods used to determine this concentration. The manufacturer is required to notify DTSC if the information in the AA Threshold Exemption Notification significantly changes, or the product no longer meets the criteria for an AA Threshold exemption.

In response to the above and related comments provisions specifying the process for determining an AA Threshold have been amended. The new AA Threshold for contaminants is the PQL of the Chemical(s) of Concern present in a Priority Product.

As part of DTSC's streamlining efforts to provide greater clarity, these provisions are now found in section 69505.3 of the proposed regulations (April 2013). For a detailed discussion of the AA Threshold Exemption Notification, see the discussion below.

§ 69503.6 Alternatives Analysis Threshold Exemption: *Delete Provisions*

Comments: 5-79, 5-154, 5-156, 7-13, 33-2, 66-32, 74-43, 76-50, 80-11, 87-5, 107-53, 124-5, 124-20, 124-28, PH12-6

Comments Summary:

The following comments request that this provision be deleted to minimize administrative burdens for both reporting entities and DTSC. The concerns are that:

- The notification undermines the reason for having AA Threshold levels in the regulations;
- This is a burdensome requirement with no appreciable gain to consumer safety or chemical innovation;
- Companies not managing the chemicals in their products will simply not submit notifications, if they do not know the chemical content of their products;
- The exemption notification process will be redundant and unnecessary after DTSC establishes the AA Threshold; and
- The notification requires the release of proprietary data, which may become public, for products that are not a priority and pose no human health or environmental concerns.

Recommendations include deleting the requirement to submit an AA Threshold Exemption Notification and making the exemption self-implementing. Other options include replacing the notification with the following:

- A letter to DTSC that the responsible entity has a Priority Product that contains a Chemical of Concern below the AA Threshold level. DTSC could then request additional information if needed;
- A short form for exemption notifications and a certification that the Chemical of Concern is below the AA Threshold; and
- A compliance assurance process where DTSC may request information from the manufacturer.

DTSC respectfully disagrees that the AA Threshold Exemption Notification should be deleted or that the other approaches suggested are preferable to the approach taken by DTSC. As discussed above, DTSC believes that it needs to know about those responsible entities for Priority Products that will not be conducting an AA based on the AA Threshold Exemption. In addition, DTSC is of the mindset that the general public and interested parties should know who these responsible entities are as well. DTSC does not view this modest notification as burdensome or working to undermine the exemption itself. If companies do not submit the requisite notification to be eligible for the exemption, those companies would be out of compliance with the regulations and subject to audits and/or formal enforcement action by DTSC.

DTSC agrees with the comment, “The knowledge of materials and processes are only adequate as substantiation of the presence or absence and concentration of all Chemicals of Concern as long as the entire manufacturing process is under the direct control of the responsible entity. The more complicated the product and the more distant the suppliers and manufacturers of materials, ingredients, components, and final

assembly of manufactured and formulated products, the more analytical data that should be required to fully substantiate that the AA threshold exemption has been met." Responsible entities have working knowledge of and should know the chemicals that are in the products they manufacture and rightfully bear the burden to identify those chemicals or analyze for the chemicals to establish their presence or absence..

DTSC respectfully disagrees that proprietary data will be released. The public posting of the notifications is critical for the transparency of this program but is also subject to the trade secret protections afforded elsewhere in these regulations. (See Trade Secret Protection discussion at Article 10 of July 2012 version and Article 9 in the January and April 2013 versions of the regulations.)

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

§ 69503.6(a) Alternatives Analysis Threshold Exemption Notification Due Date

Comments: 7-14, 55-3, 74-43, 124-28

Comments Summary:

The capability to develop and validate test methods that will be reliable for a particular formulation, testing with lab quality assurance/quality control (QA/QC to produce data on all product variations, summarizing, signing, and submitting to DTSC would take much longer than the 60 days allotted.

Response:

The AA Threshold provision has been significantly revised. If a Chemical of Concern is added intentionally, an exemption is no longer allowed. An intentionally added chemical should not require any analytical procedure to verify that it has been added to a product. However, if a Chemical of Concern is present only because it is a contaminant in the material used to make a product, the AA Threshold is the PQL of the Chemical(s) of Concern in the Priority Product.

DTSC will be following the APA rulemaking process to finalize the Priority Products listed under these regulations. This effort will take much longer than 60 days due to the

APA process. This additional process should provide manufacturers adequate time to submit their AA Threshold Notifications. DTSC has also amended the regulations to allow for additional time to submit the AA Threshold Exemption Notification. Section 69505.3(a) allows the manufacturer to submit an AA Threshold Notification to DTSC concurrently with the Priority Product Notification, or by the due date for the Preliminary AA Report for the Priority Product which is sixty (60) or 180 days; respectively, from the effective date of the Priority Product listing (January 2013).

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

§ 69503.6(a)(3) Contact Information for all Known Responsible Entities for the Priority Product

Comment: 74-43

Comment Summary:

This section indicates that anyone submitting an AA Threshold Notification must report the name and contact information for all responsible entities for the product, which seems to indicate a manufacturer must report on every retail outlet where the product is sold. This is unnecessarily burdensome and goes beyond the authority provided in the statute.

Response:

This provision seeks the names for the other responsible entities to the extent known, and does not require the responsible entity to generate information that is not available. The AA Threshold Exemption Notification and the Priority Product Notification are due to DTSC at the same time. Together, the information submitted on these two notifications will provide a comprehensive listing of products that contain the Chemical(s) of Concern and their corresponding responsible entities. DTSC has determined that this information is reasonably necessary to effectuate the statute. Thus, it is within DTSC's authority to implement the statute. DTSC will not be revising the language in response to this comment.

In response to comments related to exemptions in other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

§ 69503.6(a)(5)-(7) Maximum Concentration and Analytical Testing

Comments: 57-48, 57-49, 57-51, 66-32, 74-43, 91-3, 91-4

Comments Summary:

Sections 59503.6(a)(5) through (7) requires that the AA Threshold Exemption Notifications include the maximum concentration at which the Chemical(s) of Concern is/are present in the product, the laboratory analytical testing protocols used to detect and measure the concentration, and a certification that the responsible entity does and will continue to meet the conditions of the exemption.

The comments express concerns about these reporting requirements. The issues raised were:

- It is also not clear what happens if the Priority Product contains other Chemical(s) of Concern exhibiting the same hazard trait as those included as the basis of listing the Priority Product but not included in the Priority Product listing;
- As proposed, the regulation does not distinguish between intentionally added constituents and contaminants, and every product might have a trace amount of a Chemical of Concern and would require analysis;
- The proposed regulation is not clear about what data are required to substantiate the presence or absence and the concentration of Chemical(s) of Concern; and
- Responsible entities cannot control the state or pace of analytical chemistry; therefore, this threshold effectively sets a moving target.

Recommendations were:

- Subsections 69503.6(a)(5) and (a)(6) should be revised to make it explicitly clear that this substantiation will not be limited to only analytical test data; and
- The EU's RoHS Guidance Notes allow for supplier declarations and/or testing for restricted substances. Testing "may be undertaken either to verify supplier declarations or to establish the presence or otherwise…" This twin approach of supplier assessment and material assessment, augmented where needed with

testing should be acceptable for California's Safer Consumer Products Regulations.

Response:

The regulations have been revised to change the name of the Chemical(s) of Concern list to the Candidate Chemicals list and section 69503.5(b)(2)(B) now states that for purposes of the regulations a Candidate Chemical that is the basis for a product-chemical combination being listed as a Priority Product is designated as a Chemical of Concern for that product. The proposed regulations (January 2013) now call the broad pool of chemicals established in Article 2, “Candidate Chemicals.” Collectively, these approximately 1,200 chemicals make up the Candidate Chemicals list. If a Candidate Chemical is later paired with a product to form a Priority Product, then from that point forward, the chemical is known as a Chemical of Concern. Again, a Candidate Chemical identified as part of a Priority Product will be known as a Chemical of Concern. This is a departure from the July 2012 version of the regulations that called the broad pool of approximately 1,200 chemicals “Chemical(s) of Concern.”

For the AA Threshold Notification submittal, analytical testing is required to be provided for the Chemical(s) of Concern that is/are the basis for the Priority Product listing. Testing of chemicals, including trace chemicals, on the Candidate Chemicals list (formerly named the Chemical(s) of Concern) is not a requirement. The commenter has erroneously assumed that the AA Threshold applies to all the chemicals listed on the Candidate Chemicals list that may be in the product. The AA Threshold will only apply to the Chemical(s) of Concern in a Priority Product; though, it is possible that more than one Chemical of Concern can be identified for the Priority Product.

At the time the Priority Products are adopted through regulations, it will be clear what Chemical(s) of Concern is/are the basis of the Priority Product listing, whether the Chemical(s) of Concern are an intentionally added ingredient or a contaminant, testing methodologies, and the AA Threshold level. This information will ensure uniform implementation across an industry sector.

The requirements to substantiate the presence of a Chemical of Concern below the AA Threshold are provided in subsection 69505.3 (January 2013). More specifically, responsible entities must submit in the notification, the identification of the PQL for each Chemical of Concern in the Priority Product, the information and method used to determine the PQL, the laboratory analytical testing methodology, associated quality control and assurance protocols used to measure each Chemical of Concern in the Priority Product, and identification of the testing laboratory.

DTSC disagrees that supplier declarations are adequate demonstrations for an AA Threshold. The knowledge of materials and processes are valid as long as the entire manufacturing process is under the direct control of the responsible entity. DTSC does not consider supplier declarations or other forms of documentation to be as reliable as analytical data and has determined that the burden of proof should be on the responsible entity.

All this information required for the submittal of an AA Exemption Notification will be specific to the Priority Product. The PQL is media and product specific and that it will ultimately require that manufacturers account for any concentration of intentionally added Chemical(s) of Concern in the products that they manufacture. Despite the potential variability in the concentrations detected, the proposed regulations are aligned with and consistent with the goals and intent of AB 1879 where continuous improvement is sought for safer alternatives in lieu of establishing safe harbors for chemicals that have been demonstrated to be of concern. As technological advances are made and the concentrations of chemicals are detected, assessments on whether they are of concern can be made. However, the AA Threshold established at the time the Priority Product is listed will stay fixed in time. Any advances will only make it easier to comply with this requirement. DTSC believes that this approach strikes the proper balance between innovation and safer consumer products.

Given that the AA Threshold for contaminants is set at the PQL, there is no practical way to confirm the presence or absence of an unintentionally added chemical without analytical testing. For intentionally added ingredients, DTSC is assuming that if a responsible entity adds an ingredient, no analytical testing will be required to confirm the presence or absence of this chemical in the product.

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January and April 2013).

§ 69503.6(c) Revised Alternatives Analysis Threshold Exemption Notifications

Comments: 5-79, 57-52

Comments Summary:

Section 69503.6(c) requires that an AA Exemption Notification continue to be revisited and refined over the life of any product. Again, self-policing under the threat of enforcement seems more practical, and would eliminate a significant administrative burden.

The comment is concerned about the phrase “significantly changed” in subsection (c) of section 69503.6. There is lack of clarity as to when a revised AA Threshold Exemption Notification would be required to be submitted. This provision must be revised to include quantitative thresholds that can be easily understood and referenced during the research and development and AA process, and so that the process for selecting Priority Products is appropriately transparent.

Response:

The comments reflect an erroneous understanding of this provision. This provision applies only to the information submitted as part of the AA Threshold Exemption Notification, such as the analytical data. Instead of requiring periodic submittals of the AA Threshold Exemption Notifications, DTSC is only requiring an updated notification, if any of the information submitted in the original submittal changes significantly. If nothing changes, a responsible entity will only be required to submit one notification. No changes were made in response to this comment.

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January 2013).

§ 69503.7 Priority Product Notifications

§ 69503.7(a) Priority Product Notifications: Deadline and Contents

Comments: 5-157, 12-8, 19-26, 37-11, 37-12, 55-3, 55-7, 57-46, 66-33

Comments Summary:

The above comments expressed concern with section 69503.7, which requires that a responsible entity for a Priority Product notify DTSC within sixty (60) days after the product is listed as a Priority Product or sixty (60) days after the product is first placed into the stream of commerce in California. The provisions further specify the contents of the notification which includes:

(1) The responsible entity's name and contact information, and a statement indicating whether the responsible entity is the product manufacturer, importer, or retailer;
(2) The type, brand name(s), and product name(s) of the Priority Product, and if applicable, information specifically identifying the component(s) and/or the homogeneous material(s) and its/their associated component(s) identified under section 69503.4(a)(2)(B); and
(3) If applicable, the name of and contact information for the person that will be complying with the requirements of Article 5 on behalf of or in lieu of the responsible entity.

In summary, the following concerns were expressed:

- In many cases, a grocery retailer will not have the required information, as they do not generally manufacture products. Therefore, retailers will not generally know what Priority Products they sell until information on the brand/product name(s) are publicly available;
- Increase the notification period from sixty (60) days to 180 days;
- The information necessary to determine if a Chemical of Concern is in the Priority Product above the AA Threshold may take several months of navigating through the supply chain, or the decision regarding the Priority Product removal or replacement within 60 days;
- 60 days is not adequate to determine whether a consortium will be formed and whether a company will join one;
- Include a provision for reasonable, justifiable extensions;
- This information will inundate DTSC; and
- It is not clear why DTSC needs all of the information in section 69503.7(a)(2).

Response:

As stated in the ISOR for section 69501.2, Duty to Comply and Consequences of Non-Compliance, the regulations place the primary responsibility to comply on the manufacturer of a Priority Product. However, if a manufacturer fails to comply, the responsibility falls on the importer, and then if still not met, the retailer of the consumer product. A "responsible entity" as defined, means any manufacturer, importer, assembler or retailer of the consumer product. For a more detailed discussion on the hierarchy of these responsibilities, refer to the ISOR for Article 1 and/or the Article 1 portion of this Response to Comments document and/or the Final Statement of Reasons (FSOR) for Article 1.

Given that a vast number of the consumer products placed into the stream of commerce in California are done so by someone other than the actual manufacturer of the product, the duty to comply in the proposed regulations is not entirely placed on the manufacturer. DTSC's ability to implement the directives of Health and Safety Code sections 25252 and 25253 requires that DTSC be able to compel and enforce compliance with the requirements of Chapter 55 in California. As such, the proposed regulations are similar to the duty to comply approach embodied in other State of California statutes and regulations that impose requirements on products that are sold in California but manufactured both in-state and out-of-state (for example, California's Toxics in Packaging Prevention Act, Article 10.4 of Chapter 6.5 of Division 20 of the Health and Safety Code).

Retailers of Priority Products that DTSC has listed may wait until the manufacturer and/or importer complies with the Priority Product Notification requirement or must cease ordering the Priority Product within ninety (90) days of DTSC's notice of non-compliance issued to the manufacture and importer and posted on DTSC' website. The retailer must submit a Priority Product Cease Ordering Notification.

Given that the Priority Product Notification is an acknowledgement by the responsible entity that the product it manufactures is subject to the requirements and testing is not specifically requested at this juncture, sixty (60) days is sufficient. A manufacturer can later elect to submit one of the notifications summarized in section 69503.5(f) (January and April 2013). Priority Product Notifications and other notifications specified in Article 5 are not eligible for extensions because it would create an unnecessary delay in complying with substantive requirements.

While the proposed regulations encourage the establishment of consortia, collaborative, or similar partnerships representing an industry segment or an entire industry, the Priority Product Notification requirements must be fulfilled by the manufacturer. The responsible entity may continue to pursue the development and/or participation in one of the above mentioned partnerships, as deemed appropriate, after having submitted the Priority Product Notification.

As stated earlier, notifications and information contained in them are important and necessary communication tools. These provide a means for responsible entities to demonstrate to DTSC that they are aware that their product is on the Priority Product list and specific compliance requirements are triggered. Despite the added workload it provides DTSC and by extension, the general public and interested parties, a means of monitoring the compliance actions of the responsible entities.

§ 69503.7(b) Priority Product Notifications: Compliance and Enforcement

Comment: 68-25

Comment Summary:

The above comment expressed concern with section 69503.7(b), which specifies that if DTSC determines that the notification requirements have not been complied with for a particular Priority Product DTSC shall post this information on the Failure to Comply List, as specified in Article 1. In summary, the comment expressed the following:

- How will DTSC ensure that all responsible entities will comply with their obligations pursuant to section 69503.7?

Response:

As state in the ISOR for section 69501.2, Duty to Comply and Consequences of Non-Compliance, the regulations place the primary responsibility to comply on the manufacturer of a Priority Product. However, if a manufacturer fails to comply, the responsibility falls next on the importer, and ultimately on the retailer of the consumer product. A “responsible entity” as defined, means any manufacturer, importer or retailer of the consumer product. For a more detailed discussion on the hierarchy of these responsibilities refer to the ISOR for Article 1 and/or the Article 1 portion of this Response to Comments document and/or the FSOR for Article 1.

If a responsible entity for a Priority Product fails to comply with the requirements of Articles 3 or Article 5, the Priority Product may not be offered for sale or distributed in California commerce. DTSC will work to ensure that responsible entities have complied with their obligations under these regulations by: conducting ongoing outreach and guidance efforts; using its audit authorities; and taking enforcement actions under its authority to do so under Chapter 6.5 of Division 20 of the Health and Safety Code. This includes, but is not limited to, taking enforcement action against retailers offering for sale products that have been placed on the Failure to Comply list.

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ARTICLE 4. PETITION PROCESS FOR IDENTIFICATION AND PRIORITIZATION OF CHEMICALS AND PRODUCTS

§ 69504 Applicability and Petition Contents

Comments: 5-81, 5-186

Comments Summary:

The above comments suggest that the regulations must include scientifically established thresholds and standards to indicate when a petition will be granted.

Response:

Article 4 provides that the petitions designated complete will be reviewed in accordance with the prioritization factors specified in section 69502.2 and/or 69503.2, whichever is applicable. These sections detail the scientifically established standards used to evaluate chemicals and product-chemical combinations for inclusion on either the Candidate Chemical or Priority Product lists. Thus, by referencing these two sections as the basis for how DTSC will review petitions, DTSC is making these same scientific standards applicable to the review of petitions. While these standards may be narrative in nature, they are, nonetheless, scientific standards. DTSC is not making any changes to the regulations in response to this comment.

Comment: 5-80

Comment Summary:

The above comment suggests that Article 4 must contain a requirement that DTSC include affected manufacturers and importers in the petition process and further claims that the absence of such a provision violates due process.

Response:

DTSC respectfully disagrees. The petition process will not directly affect manufacturers and importers. That is, even if DTSC were to grant a petition on the merits, that does not impose any obligations or duties upon manufacturers or importers of products. Upon review of the petition and supporting data, DTSC may include the chemical(s) or product-chemical combination, as applicable, in the chemical and/or product prioritization process. Manufacturers and importers are first potentially subject to any obligations or duties after the product prioritization process, as established by Article 3. More specifically, responsible entities, including manufacturers and importers, are subject to the requirement to conduct an Alternatives Analysis (AA) only if their products

are identified as Priority Products. There is ample opportunity for manufacturer and importer involvement in that process of identifying and prioritizing Priority Products. DTSC is not making any changes to the regulations in response to this comment.

Comment: 7-15

Comment Summary:

The above comment suggests that the petition process should be limited to citizens of California and organizations with a presence in California.

Response:

DTSC respectfully disagrees. First, the petition process has been designed to allow all interested parties to present DTSC with information reflecting whether a chemical or product poses a threat, and should be evaluated for its potential listing as a Candidate Chemical or Priority Product. Conversely, the petition process has been designed to allow all interested parties to present information to DTSC that a chemical and/or product should be removed from the prioritization process to reflect increased knowledge about, or a change in market circumstances with respect to, the chemical and/or product that was initially prioritized. DTSC recognizes that information about all of these factors is widely dispersed, and limiting the petition process to certain parties would unnecessarily limit the information provided to DTSC. This could result in less informed decision–making by DTSC regarding the identification and prioritization of chemicals and/or products. DTSC is not making a change to the regulations in response to this comment.

Comment: 109-1

Comment Summary:

The above comment suggests there should be an “early off ramp” in the petition process to delist chemicals or products that present no meaningful risk to consumers or the environment.

Response:

DTSC respectfully disagrees. The proposed regulations have been revised in response to comments about the large list of chemicals identified as “Chemicals of Concern” and negative implications about products containing chemicals on that list. The proposed regulations have redefined “Chemical of Concern” and the previous definition of Chemical of Concern applies to a new term “Candidate Chemicals.” A Candidate Chemical, as indicated by section 69502.2(a) of the January 2013 proposed regulations,

is one that exhibits a hazard trait and/or an environmental or toxicological endpoint and is listed on one or more of the enumerated authoritative organizations' lists in section 69502.2(a). "Chemicals of Concern" and "Priority Products" are listed as such only after DTSC determines that a product contains a Candidate Chemical and that there is the ability for that chemical to contribute to or cause adverse impacts due to exposure to the chemical in the Priority Product. Thus, by definition, a Priority Product containing a Chemical of Concern is a product-chemical combination that poses a threat to human health and/or the environment such that it has been prioritized as a Priority Product for the completion of an AA. DTSC is not making any changes to the regulations in response to this comment.

Comments: 109-1, PH5-3

Comments Summary:

The above comments suggest that the timing of determinations for petitions is too long, and responsible entities cannot wait until the next regular update of the Chemical of Concern or Priority Products list for a response to a petition. Manufacturers should be allowed to suspend their required AA until DTSC issues a notice to grant or deny a petition.

Response:

DTSC respectfully disagrees. The timing for petition determinations reflects the time DTSC needs to conduct a merits review and to set petition-review priorities, in light of resource constraints. Further, as outlined in section 69504(b)(3) in the January 2013 version of the proposed regulations, a person may not petition DTSC to remove a product–chemical combination from the Priority Products lists until three years after the date the product–chemical combination was placed on the Priority Products list. Section 69505.1(b) in the January 2013 version of the proposed regulations contains the time frames for compliance with the AA process. It provides that a Final AA Report is due no later than twelve months after the date DTSC issues a notice of compliance for the Preliminary AA Report, which is due no later than 180 days after the product is listed on the Priority Products list. Therefore, there will never be a situation in which a responsible entity subject to the requirement to conduct an AA could have been relieved of this obligation by virtue of a petition being granted. DTSC is making no changes to the regulations in response to these comments.

Comments: 29-15, 36-12, 101-31, 109-1, PH5-1, PH17-3

Comments Summary:

These comments express support for the petition process and specifically the ability to petition in order to add or remove entire lists of chemicals or individual Chemicals of Concern.

Response:

DTSC appreciates this support. No changes were made in response to these comments.

Comments: 66-34, 101-31

Comments Summary:

One comment suggests that DTSC needs to provide more criteria, beyond the appearance on a list, which will be considered when evaluating a petition to remove a Chemical of Concern from the list. The comments also suggest that the petition process should extend to chemicals on the initial Chemical of Concern list. Two comments suggest that it will take too long to get chemicals off the Chemical of Concern list if DTSC requires that a chemical be off all lists, as lists are updated on different cycles. When there is significant new information, petitioner should be allowed to show that delisting is appropriate by a “preponderance of the evidence” standard.

Response:

The proposed regulations have been revised in response to comments about the large list of chemicals identified as “Chemicals of Concern” and negative implications about products containing chemicals on that list. The proposed regulations have redefined “Chemical of Concern” and the previous definition of Chemical of Concern applies to a new term “Candidate Chemical,” defined in Section 69502.2(a) as a chemical that exhibits a hazard trait or an environmental or toxicological endpoint and is listed on one or more of the enumerated authoritative organizations’ lists in section 69502.2(a). Chemicals will now only be labeled as Chemicals of Concern once “a Candidate Chemical that is the basis for a product-chemical combination being listed as a Priority Product is designated as a Chemical of Concern with respect to that product.” With this new structure in mind, DTSC maintains that it is proper to grant petitions for removal of Candidate Chemicals only when they no longer appear on any of the lists enumerated in section 69502.2(a). The requirement that a chemical is no longer listed on any of the lists is necessary to preclude a wasteful expenditure of DTSC resources on petitions for removal of chemicals that have been well established as possessing one or more hazard traits and are appropriately captured as Candidate Chemicals. DTSC is making no changes to the regulations in response to these comments.

Comment: 74-32

Comment Summary:

The above comment suggests that Article 4 should not allow petitions to request the addition of entire lists of Chemicals of Concern; new Chemicals of Concern should be individually petitioned and considered on a case-by-case basis.

Response:

DTSC respectfully disagrees. The proposed regulations have been revised in response to comments about the large list of chemicals identified as “Chemicals of Concern” and negative implications about products containing chemicals on the list. The proposed regulations have redefined Chemical of Concern and the previous definition of “Chemical of Concern” applies to a new term “Candidate Chemical,” defined in section 69502.2(a) as a chemical that exhibits a hazard trait or an environmental or toxicological endpoint and is listed on one or more of the enumerated authoritative organizations’ lists in section 69502.2(a). Chemicals will now only be labeled as “Chemicals of Concern” once “a Candidate Chemical that is the basis for a product–chemical combination being listed as a Priority Product is designated as a Chemical of Concern with respect to that product.”

The list of Candidate Chemicals includes chemical lists that are supported, sponsored and/or developed by authoritative organizations, such as state, federal, or international agencies, to protect public health or the environment. Some lists were identified for inclusion in the proposed regulations based on a particular hazard trait that the list sought to address, such as the inclusion of the California Proposition 65 list to capture chemicals that are carcinogens or reproductive or developmental toxins. If a petition shows there is a list that addresses a hazard trait that DTSC has not yet included in the Candidate Chemical list, it will be appropriate to consider adding the entire list rather than individually assessing each chemical on such a list. Accordingly, DTSC is making no changes in response to this comment.

Comments: 97-1, PH13-4

Comments Summary:

The above comments suggest that the petition process allows for effective reopening of the rulemaking process since DTSC could be immediately flooded with hundreds of petitions for frivolous purposes such as attacking competition, creating an adverse public record, or sensationalism in the press.

Response:

DTSC respectfully disagrees. As stated in the Initial Statement of Reasons (ISOR), the information requested in sections 69504(a)(4) and (a)(5) is necessary to understand the petitioner's rationale and to deter frivolous petitions. Given that petitions must be submitted with the basis for the petition, it is unlikely that competitors or other organizations would launch frivolous efforts to burden their competitors. The burden would be on the petitioner to provide "reliable information" to DTSC. Additionally, as stated in the January 2013 revision of section 69504(b)(1), "a person may not petition the Department to delist any chemical identified as a Candidate Chemical under section 69502.2(a), unless that chemical is no longer listed on any of the lists specified in section 69502.2(a)."

Two additional limitations on petitions were added to the January 2013 revision of the proposed regulations regarding chemical lists and Priority Products. As outlined in section 69504(b)(2), a person may not petition DTSC to remove an entire chemicals list from the lists specified in section 69502.2(a) until three years after the effective date of the regulations. Similarly, section 69504(b)(3) now states that a person may not petition DTSC to remove a product-chemical combination from the Priority Products lists until three years after the date the product-chemical combination was placed on the Priority Products list. Because of these limitations set in the petition process, DTSC does not feel that the petition process will allow for effective reopening of the rulemaking process. Accordingly, DTSC is making no changes in response to these comments.

Comments: 97-2, 101-30, PH13-1, PH13-4

Comments Summary:

The above comments recommend suspending the petition process for several years to allow the program to unfold.

Response:

The proposed regulations have been revised to limit the petition process and the timing of petitions. As stated in the January 2013 revision of section 69504(b)(1), "a person may not petition the Department to delist any chemical identified as a Candidate Chemical under section 69502.2(a), unless that chemical is no longer listed on any of the lists specified in section 69502.2(a)." Two additional limitations on petitions were added to the January 2013 revision of the proposed regulations regarding chemical lists and Priority Products. As outlined in section 69504(b)(2), a person may not petition DTSC to remove an entire chemicals list from the lists specified in section 69502.2(a) until three years after the effective date of the regulations. Similarly, section

69504(b)(3) now states that a person may not petition DTSC to remove a product–chemical combination from the Priority Products lists until three years after the date the product-chemical combination was placed on the Priority Products list. DTSC believes these limitations will allow the program to unfold without undue delay. Thus, DTSC is making no changes in response to these comments.

Comments: 97-2, PH13-4

Comments Summary:

The above comments suggest that petitioners should be required to document the technical and scientific qualifications of the petitioner that pertain to the subject of the petition, and certify that petitioner has no financial stake in the outcome of petition process, thereby limiting the process to governments, trade associations, collective bargaining units, and established nonprofits.

Response:

DTSC respectfully disagrees. The information requested in sections 69504(a)(4) and (a)(5) is requested to understand the petitioner's rationale and to deter frivolous petitions. It is certainly possible that persons without specific advanced scientific education or training may have access to information that DTSC would find useful in reviewing a petition. DTSC would not want to deter such a person from coming forward with that information because he or she lacked specific training or credentials. The petition process has been designed to allow all interested parties to present DTSC with information that demonstrates a chemical or product poses a threat, and should be evaluated for its potential listing as a Candidate Chemical or Priority Product. Conversely, it was designed so that a chemical and/or product could be removed from the prioritization process to reflect increased knowledge about, or a change in market circumstances with respect to, the chemical and/or product that was initially prioritized. DTSC recognizes that information about all of these factors is widely dispersed, and limiting the petition process to certain parties would unnecessarily limit the information provided to DTSC. DTSC is making no changes to the regulations in response to these comments.

Comments: 101-31, 107-56

Comments Summary:

The above comments suggest that petitions to remove entire lists of chemicals should be allowed.

Response:

The proposed regulations have been revised, and Article 4 now provides a mechanism to petition to both add and/or remove entire lists of chemicals. See proposed section 69504(a) (January 2013). DTSC is making no changes to the regulations in response to these comments.

Comment: 107-56

Comment Summary:

The above comment suggests that all petitions that are complete and acceptable for merits review should require public notice and comment prior to decision to grant or deny petition.

Response:

DTSC respectfully disagrees. It would create undue delay and redundancy to allow for public notice and comment prior to issuing a merits decision on a petition. Upon review of the petition and supporting data, DTSC may include the chemical(s) or product–chemical combination, as applicable, in the chemical and/or product prioritization process. There is ample opportunity for public involvement in that process of identifying and prioritizing Priority Products. DTSC is making no changes to the regulations in response to this comment.

Comments: 5-80, 5-186, PH3-2

Comments Summary:

The above comments suggest that petitions must be based on sound scientific principles and the rigors of a science–based prioritization review subject to full due process rights of the Administrative Procedure Act (APA).

Response:

Article 4 provides that the petitions designated complete will be reviewed in accordance with the prioritization factors specified in section 69502.2 and/or 69503.2, whichever is applicable. These sections detail the scientifically established standards used to evaluate chemicals and product–chemical combinations for inclusion on either the Candidate Chemical or Priority Product lists. Thus, by referencing these two sections as the basis for how DTSC will review petitions, DTSC is making these same scientific standards applicable to the review of petitions. While these standards may be narrative in nature, they are, nonetheless, scientific standards.

The petition process will not directly affect responsible parties. That is, even if DTSC were to grant a petition on the merits, that does not impose any obligations or duties upon responsible parties. Upon review of the petition and supporting data, DTSC may include the chemical(s) or product-chemical combination, as applicable, in the chemical and/or product prioritization process. Responsible parties are first potentially subject to any obligations or duties after the product prioritization process, as established by Article 3. More specifically, a responsible entity is subject to the requirement to conduct an AA only if its products are identified as Priority Products. The prioritization process will comply with the APA. DTSC is making no changes to the regulations in response to these comments.

Comment: PH3-2

Comment Summary:

The above comment suggests that the petition process, including the adequacy of protection for trade secrets, must be further publicly vetted and assessed.

Response:

DTSC respectfully disagrees. These proposed regulations, and the included petition process, have undergone extensive public scrutiny in the form of both public workshops, a public hearing, and two formal notice and public comment periods. DTSC does not find that the petition process creates any risk to the protection of trade secrets. More specifically, DTSC will not be compelling the submission of any specific data from regulated entities. Rather, those persons submitting petitions will choose which information to submit to DTSC. Therefore, the only way in which trade secret information could come to DTSC's attention as part of the petition process is if someone submitting it were to waive the applicable privilege. DTSC also notes that these regulations reaffirm existing protections for trade secret information and establish protocols for protecting trade secret information that is submitted to DTSC. DTSC is not making any changes to the regulations in response to this comment.

Comments: 9-54, 101-20, 57-55

Comments Summary:

One comment suggests that the "list of lists" approach to establish the Chemicals of Concern list may be justified by resource constraints, but DTSC must take "ownership" of the resulting list. A California list of Chemicals of Concern developed by a California process must also have a California-based process to remove substances from the list. As proposed, the regulations permit petitions to delist a chemical from the Chemicals of

Concern list, and DTSC may do so, therefore, as long as that chemical is no longer listed on any of the underlying lists. This means delisting is likely to be impossible. Substances would likely remain on the Chemicals of Concern list indefinitely—even if they are used safely in consumer products or even if they are not used in consumer products at all. This comment urges DTSC to establish a California list-specific process for delisting chemicals.

Another comment similarly notes that the lists that create the Chemicals of Concern list were each compiled and reviewed for different purposes, and these chemicals were never evaluated for their presence in any category of product and any resulting human exposure. This approach makes it nearly impossible to create a list of true Chemicals of Concern that meet the criteria as established by California and distracts from a focus on reducing the chemicals that have true need for reduction.

One comment also noted that it would be particularly difficult to have a chemical removed from the Chemicals of Concern list when the chemical is included on a list that is derivative in nature. That is, some of the 23 authoritative lists that comprise the Chemicals of Concern list incorporate some or all of the other lists. For example, the Proposition 65 list of chemicals includes some of the International Agency for Research on Cancer (IARC) list of chemicals. This comment notes that all documents critical to implementation of the regulations should be subject to the APA process.

Response:

DTSC respectfully disagrees. The proposed regulations have been revised in response to comments about the large list of chemicals identified as “Chemicals of Concern” and negative implications about products containing chemicals on that list. The proposed regulations have redefined “Chemical of Concern” and the previous definition of Chemical of Concern applies to a new term “Candidate Chemical.” A Candidate Chemical is one that “exhibits a hazard trait or an environmental or toxicological endpoint and is listed on one or more of the enumerated authoritative organizations’ list in section 69502.2(a).” “Chemicals of Concern” and “Priority Products” are listed as such only after DTSC determines that a product contains a Candidate Chemical and that there is the ability for that chemical to contribute to or cause adverse impacts due to exposure to the chemical in the Priority Product. Thus, by definition, a Priority Product containing a Chemical of Concern is a product-chemical combination that poses a threat to human health and/or the environment such that it has been prioritized for the completion of an AA.

With this new structure in mind, DTSC maintains that it is proper to grant petitions for removal of Candidate Chemicals only when they no longer appear on any of the lists enumerated in section 69502.2(a). Further, DTSC does not find it necessary to "take ownership" of the Candidate Chemical list to allow for removal when chemicals still appear on an enumerated list. The requirement that a chemical is no longer listed on any of the lists is necessary to preclude a wasteful expenditure of DTSC resources on petitions for removal of chemicals that have been well established as possessing one or more hazard traits and are appropriately captured as Candidate Chemicals. Of course, DTSC will continue to comply with all requirements under the APA to the extent that they are applicable. DTSC is making no changes to the regulations in response to these comments.

Comments: 5-158, 5-159

Comments Summary:

The term "product" should be changed to "Priority Product" in section 69504(a)(2), (3), (4), and (6).

Response:

The proposed regulations have been revised. In the January 2013 version of the regulations, these subsections now use the term "product–chemical combination" in place of the term "product." DTSC is making no change to the January 2013 version of the regulations in response to this comment.

§ 69504.1 Merits Review of Petitions

Comments: 7-16, 57-54

Comments Summary:

One comment suggests that Stakeholders should be able to comment on and be notified of petition decisions. The comment also said that it is unclear whether accepted petitions will result in Chemicals of Concern or Priority Products being immediately added to the lists or put on proposed lists.

Another comment suggests that petition process should include opportunity for public comment and scientific review of the merits of the petition, similar to section 69502.3(c).

Response:

DTSC respectfully disagrees. The process created by the regulations includes ample

opportunity for public comment at various stages of implementation. Once a petition is granted, DTSC will include the chemical(s) or product-chemical combination, as applicable, in the chemical and/or product prioritization process. The prioritization process is subject to public input and any person may comment on the proposed inclusion of a chemical or product in the prioritization process. Granting a petition does not necessarily mean that a chemical or product-chemical combination will be included on any list; rather, it means that they will be included in the applicable prioritization process. DTSC is making no changes to the regulations in response to this comment.

Article 4 provides that the petitions designated complete will be reviewed in accordance with the prioritization factors specified in section 69502.2 and/or 69503.2, whichever is applicable. These sections detail the scientifically established standards used to evaluate chemicals and product-chemical combinations for inclusion on either the Candidate Chemical or Priority Product lists. Thus, by referencing these two sections as the basis for how DTSC will review petitions, DTSC is making these same scientific standards applicable to the review of petitions. While these standards may be narrative in nature, they are, nonetheless scientific standards. DTSC is making no changes to the regulations in response to this comment.

Comments: 66-35

Comments Summary:

The above comments suggest that the factors to be considered in a determination are only applicable to adding chemicals to the list; therefore, the comment suggests there is a need to add factors for removal of chemicals from the list.

Response:

The proposed regulations have been revised to reflect this concern. The provisions set forth in the January 2013 version of the proposed regulations of sections 69504.1(b)(4) and 69504.1(b)(5) address removal of a chemical or an entire list of chemicals, respectively, from the Candidate Chemicals list. Therefore, DTSC is not making any changes to the January 2013 version of the regulations in response to these comments.

Comments: 66-35

Comments Summary:

The above comments suggest that there need to be assurances that petition review will be based only on science and merits of petition.

Response:

Section 69504.1(b) provides that DTSC shall determine whether to grant or deny a petition based on the comprehensiveness and the quality of the information submitted in accordance with the prioritization factors specified in section 69502.3 and/or section 69503.3, whichever is applicable. These factors are all grounded in relevant scientific considerations. Therefore, DTSC is not making any changes to the regulations in response to these comments.

ARTICLE 5. ALTERNATIVES ANALYSIS

Support / Oppose Article 5

Comments: 7-23, 29-2, 29-17, 31-3, 36-76, 36-100, 36-101, 47-27, 74-47, 57-57, 73-11, 73-19, 74-47, 74-62, 76-55, 91-13, 107-60, 109-16, 118-5, PH21-4

Comments Summary:

The above comments expressed either support or general concern with the provisions contained in Article 5. The provisions in Article 5 clarify, implement, and make specific the provisions of Health and Safety Code section 25253. More specifically, the article specifies the requirements applicable to conducting a comprehensive Alternatives Analysis (AA) for consumer products that are listed as Priority Products under Article 3. As described in Article 3, consumer products that are listed as Priority Products are of concern due to the presence of one or more Chemicals of Concern in the consumer product.

Comments expressing support for the provisions expressed support for inclusion of the following provisions:

- Section 69505.1(c), which allows the use of a consortia, collaborative, or other similar partnership to complete all or parts of the AA;
- Section 69505.1(g), which allows a responsible entity to submit a Chemical of Concern Removal Notification if specified conditions are met;
- Section 69505.2(c), which allows a responsible entity to use an alternate AA process;
- Section 69505.2.(d)(1), which allows an entity to change the alternative selected after submission of a Final AA and conducting a Feasibility Analysis;
- Section 69505.3(b), which requires the first stage of the AA to identify the function, performance, and legal requirements associated with the Priority Products that must be met by the alternatives considered and determine, if the Chemical(s) of Concern or substitute chemical(s) is/are necessary to meet the Priority Product's requirements;
- Section 69505.3(b)(3), which allows a responsible entity to eliminate from further consideration alternatives that pose an equal or greater risk of adverse public health and/or environmental impact;
- Sections 69505.3 & 69505.4 which establishes a two stage process;
- Section 69505.3(b)(4), which allows the consideration of additional information not specifically called for in the first stage and elimination of alternatives for 'showstopper' reasons;

- Section 69505.4(a)(1)(A), which specifies that only relevant factors need to be considered further, while allowing the manufacturer to explain why other factors are not relevant to the analysis;
- Section 69505.4(b), which allows the use of qualitative as well as quantitative information to be provided for relevant factors;
- Section 69505.4(d)(4), which allows the consideration of additional information not specifically called for in the second stage and elimination of alternatives for 'showstopper' reasons;
- Section 69505.5(a)(6)(A), which requires that an AA containing claims of trade secret be provided in a redacted form for public review;
- Section 69505.5(d), which requires inclusion of supply chain information;
- Section 69505.5(h), which provides flexibility for the manufacturer to use most appropriate methodologies, models, tools, and decision-making process to assess the Chemical(s) of Concern/Priority Product;
- Section 69505.5(j), which allows a responsible entity to select the most appropriate alternative, based on supporting information, provided that information is made available to DTSC;
- Section 69505.5(k)(2)(A), which allows the opportunity within the implementation plan to identify any steps necessary to ensure compliance with existing law; and
- Section 69505.5(k)(2)(B), which requires that the implementation plan include identification of the regulatory responses that reduce the level of adverse public health.

The comments expressing general concern with the provisions in Article 5 stated that the regulations are extremely complex and will be exceptionally costly to both industry as well as taxpayers, and other appropriate methods to improve consumer product safety should be explored. The comments further indicated that "conducting an AA is expected to be an expensive endeavor," and further complicated by being required to hire a "certified assessor." Comments expressing the provisions were overly burdensome and/or costly, or were made in general to Article 5, and did not identify any specific provision(s).

Response:

Through the enactment of AB 1879 (2008), the Legislature directed the Department of Toxic Substances Control (DTSC) to develop a balanced, science-based approach to address the danger of hazardous chemicals contained in consumer products—citing that California consumers deserved a robust and thoughtful approach to addressing this issue. Health and Safety Code section 25253 mandates that DTSC adopt regulations that establish a process for evaluating Chemicals of Concern in consumer products, as

well as their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by these chemicals.

DTSC will retain the structure and provisions in Article 5 in general, unless otherwise amended in response to other (more specific) comments, which are set forth below. In addition, DTSC notes that the overall scope of the AA has been pared down from prior iterations. The requirement to have a certified assessor conduct the AA has been eliminated and the appropriate steps and scope for conducting the required analysis has been made more explicit (January 2013).

Alternative Process to Article 5

Comments: 9-14, 29-3, 29-5, 29-16, 31-3, 40-15, 55-5, 66-36**,** 68-9, 72-1, 76-2, 76-3, 76-4, 76-5, 76-6, 128-4, 133-2, 134-1, 134-2, 134-3, 134-4, 134-5, 134-6, 134-7, 134-8, PH10-9, PH13-8

Comments Summary:

The above comments suggested an alternative process to Article 5 of the proposed regulations dated July 2012 be explored for the following reasons:

- It will be exceptionally costly to both industry and taxpayers;
- It is too heavily focused on the demand side considerations and gives short shift to the supply side considerations, which are necessary to bring the promises of a future that is benign by design;
- It will require extensive DTSC resources that will divert resources from the core mission of gathering reliable data to make good decisions that protect human health and the environment;
- It is far more resource-intensive than it needs to be when an alternative exists. To simplify the structure of the program and increase the quality of the AAs developed, DTSC should create a small, central DTSC team capable of facilitating high quality, public AAs; and
- It will generate AAs that are not peer-reviewed, not transparent, and do not reflect the perspectives of other important stakeholders, including downstream users.

The comments expressed preferences for alternate methods which include variations of the following:

- *Process with open debate*: Establish a process where more open debate of the data and findings can take place so DTSC can benefit from the critical review of other stakeholders.

- *Process with State Sponsored AAs*: Establish a DTSC facilitated (or public) AA program to ensure that the best practices in AAs are being broadly applied and to ensure fairness by imposing a single regulatory response for each Chemical(s) of Concern/Priority Product combination, based on the aggregate finding of all AAs.
- *Establish Advisory Committee(s) to advise DTSC*:
  - *Option 1:* Establish a regulatory approach that addresses the need for an AA by establishing and convening an advisory committee and consulting with that committee regarding the potential alternative. This would consist of representatives from industry, regulators, and non-governmental organizations.
  - *Option 2:* Establish three subcommittees with the following elements:
    - Element one: Move from a list-based system to an assay-based system.
      - A committee of diverse stakeholders formed to create a set of tests and assays that quantify toxicity and environmental impact, called the Assay Committee.
      - A Compliance Committee that will describe how testing protocols and data management will be certified and documented.
      - An Approval Committee to determine how materials that perform unacceptably, in the assays should be handled.

These groups should meet on a regular basis to perform reviews and updates.

- Element two: Move from a molecule-based system to a product-based system.
- Element three: Identify and disclose hazardous materials.
- Element four: Focus on long-term solutions.
- Element five: Focus on jobs creation and workforce development that are fee-based.

Response:

As documented in the Economic and Fiscal Impact Statement 399 submitted with the proposed regulations and the Initial Statement of Reasons (ISOR) discussing the economic impact analysis, there will be an unquantifiable cost to industry, consumers, and taxpayers in implementing the regulations. It is also important to note that there is currently an unquantifiable cost that is passed on to Californians through added health care and/or added taxes from the production, use, and disposal of consumer products that contain harmful chemicals.

Over the span of the last four years, DTSC has considered, evaluated, and made the alternatives being considered available for public comment. This began with a straw proposal in 2009, followed by a proposed outline, and proposed regulatory text in 2010. In December 2010, DTSC issued a notice indicating that it was not going to proceed with the adoption of its proposed regulations. Therefore, in 2011, DTSC reconvened the Green Ribbon Science Panel (GRSP) to solicit input into key areas.

Three subcommittees were created to solicit input and refine recommendations as follows:

- Subcommittee #1: Chemical Identification and Prioritization met on April 4 and 13, 2011;
- Subcommittee #2: Tiered Alternatives Assessments met on June 2 and 14, 2011; and
- Subcommittee #3: De Minimis and Unintentionally-Added Chemicals, on April 6 and 18, 2011.

These subcommittee meetings were then followed by GRSP meetings on May 5 and 6 and July 14 and 15, 2011. The proposed regulations were then released for an informal comment period beginning on October 31, 2011 and ending on December 30, 2011. A GRSP meeting was held on November 14th and 15th, 2011 to discuss the proposed regulations.

The GRSP, while not a consensus-forming body, has overwhelmingly supported the following overarching principles:

- Avoid “paralysis by analysis”; it has diminishing returns;
- Establish a streamlined and tiered approach/process to invoke the life cycle thinking principles and expedite the process for “bad actors”;
- Reserve more in depth analysis for instances where warranted which are to be decided on a case-by-case basis;
- Create a process that fosters innovation;
- Resist the temptation to create a centralized command and control where industry would be crippled from moving because the State cannot keep up with the demand;
- Incremental improvement to design is good enough; do not let perfect be the enemy of the good;
- Do not mandate the outcomes; and
- Use market forces to drive change and innovation.

The proposed regulations are a culmination of the tireless efforts of external stakeholders and DTSC over the last six years, since the Green Chemistry Initiative was launched in 2007. While other alternatives to the proposed regulations were considered, they were eliminated at various stages in the deliberation process because they were either not practical, did not provide meaningful results, or were not legally defensible. A summary of the basis for dismissing some of the alternatives requested during this comment period is included below.

Establish Process with Open Debate or Peer Review

DTSC recognizes the benefits of open debate and input from stakeholders, which will not only improve the quality in the AA Reports submitted for DTSC review but also improve stakeholder confidence. In response to input received on Articles 5 and 8, DTSC has revised the proposed regulations to include public review and comment of Final AA Reports to make use of stakeholder input (January and April 2013).

As discussed in the ISOR (under Article 8), a peer review process was considered and dismissed as impractical. DTSC does not have any funding or staffing to oversee and implement a peer review program. In addition, this approach was rejected because of the additional conflicts it created surrounding trade secret information. A peer review process would require that upon completion of the AA, a responsible entity would submit the AA for review to one or more peer reviewers to ensure compliance with the requirements of Article 5. Given that some of the information in the AA may contain trade secret information, submitting the AA Reports to peer reviewers may be problematic. At a minimum, there would seem to be complexities related to confidentiality agreements. DTSC anticipates that responsible entities would want to submit their AAs to peer reviewers in redacted form. This, in turn, would make it difficult for the peer reviewer(s) to conduct their evaluations. While the proposed regulations do not require a responsible entity to seek peer review, the regulations do not prevent a responsible entity from soliciting peer reviews prior to the submittal of its AA Reports to DTSC.

Establish a State Sponsored AA or Open Source AA

A state sponsored AA or an open source AA functions similarly whether in lieu of or in combination with Article 5. While DTSC recognizes the utility of joint or collaborative efforts in addressing common issues, as with peer reviews, a state sponsored AA has limited utility and could potentially be costly to taxpayers for the State to administer. In addition, as discussed above, DTSC does not have the funding nor staffing to develop a state sponsored AA. Given that aspects of each type of consortium of companies—collaborative, public-private partnership, or a trade association—varies, and each has a

place in fostering and accelerating innovation, the proposed regulations contain provisions that allow responsible entities to collaborate in addressing some or all of the elements of an AA. However, collaboration amongst responsible entities is not required; mandating collaboration through regulations is impractical. Not all entities will "collaborate" equally, whether in technical knowledge or capital invested; therefore, requiring collaboration would place manufacturers who are eager to move toward safer alternatives at a disadvantage. The proposed regulations allow responsible entities to conduct an AA entirely on their own or form a collaborative.

Further, given the scope of the AA, a consortium of companies—collaborative, public-private partnership, or a trade association—may be limited in some circumstances regarding the amount of information participants are willing to share without compromising trade secret information.

As such, a state sponsored AA, in lieu of or in combination with the proposed regulations, would have limited utility. A state sponsored AA would only yield sufficient information to perform preliminary assessments, if that. State sponsored AAs would not address more in depth analyses to determine the hazards of a chemical that are product-type and use-specific or provide sufficient information for DTSC to impose the appropriate regulatory response. DTSC believes that the manufacturers of Priority Products are in the best position to determine the most appropriate alternative. Given that DTSC does not mandate an outcome of the AA, the manufacturer elects the alternative. The regulatory responses will be Priority Product-specific and alternative-specific; that is, the responsible entity may elect to continue using the Chemical of Concern while a broader range of regulatory responses are imposed.

DTSC evaluated the merits of conducting state sponsored AAs to create capacity and expedite the quest for safer alternatives; however, AB 1879 does not authorize DTSC to impose or assess fees for implementation of Health and Safety Code section 25253. Therefore, a state sponsored AA would be paid for by taxpayers not the responsible entities and/or consumers. Similarly, there is no funding allocated to DTSC for such an effort.

Establish an Advisory Committee(s)

While DTSC appreciates the merits of an advisory committee or committees, it remains concerned with this approach in that committees are typically comprised of knowledgeable and committed individuals who volunteer their own time. Many committee members are typically employed outside of the committees on which they serve. While DTSC may work toward providing ample recognition and rewards to

committee members, it is unlikely that DTSC could reward committee members enough to sustain long-term performance or mandate specified deliverables. The uncertainty in deliverables would significantly compromise and delay innovation, as well as the quest for safer alternatives. It is also important to note that while committee members volunteer their time, DTSC—and ultimately taxpayers—pay for their travel, lodging, and any logistics necessary. For the aforementioned reasons, advisory committees—which may be fostered outside of the proposed regulations—have not been included as part of the proposed regulations.

The proposed regulations allow for the recommendation in element two of *option 2*—that is, if a Priority Product is comprised of numerous components, the component exhibiting the hazard will be prioritized, if appropriate, or the entire product (whichever is applicable). A point of departure, however, is that the proposed alternative would then allow an entire product to be included in an assay to determine if the hazard is acceptable—meaning distributing the concentration of a Chemical of Concern in a component over the entire product that it is in. DTSC does not concur with this approach. The proposed regulations allow for DTSC to prioritize either the component or product, whichever DTSC determines is most appropriate. The proposed regulations require that upon completion of an AA, the hazard traits be identified and disclosed for Priority Products and their alternatives. Hence, this is consistent with the recommendation in element three of *option 2*.

In DTSC's proposed regulations, DTSC—in place of the "Approval Committee"—evaluates the information and determines the appropriate range of regulatory responses. These may include labeling and communication regarding the Chemical(s) of Concern. While the proposed regulations do not force a particular outcome or compel a responsible entity to select an alternative, DTSC retains the authority to restrict the use of Chemicals of Concern or, if necessary, prohibit their use altogether. Through DTSC's authority and stakeholder input, responsible entities will be held accountable to select safer alternatives as they become available. As such, element four of the proposed alternative to the regulations is addressed and included.

Finally, while DTSC considered the creation of a certified assessor program to stimulate the creation of a workforce skilled in conducting and preparing the required AAs, after much deliberation, DTSC has eliminated Article 8. DTSC will be focusing its efforts on developing AA guidance materials. And, if necessary, at a later date, DTSC may choose to adopt regulations that will create a more skilled workforce to conduct or support the conducting of AAs. Again, it is also important to note that AB 1879 did not authorize DTSC to create a fee based training program.

For the reasons cited above, revisions to the July 2012 proposed regulations have been made where appropriate. A more detailed description of each provision in the regulations and where it has changed in response to these comments is provided on a section-by-section discussion, which follows.

§ 69505 Guidance Materials

§ 69505(a) Guidance Materials on DTSC's Website

Comments: 5-160, 11-41 34-5, 34-6, 34-7, 34-8, 47-20, 68-27, 76-51, 101-39, 138-5, PH33-3

Comments Summary:

The above comments expressed concerns with the provisions in section 69505(a), which specifies timing by when the guidance materials for conducting an AA will be made available. The section specifies that before finalizing the initial list of Priority Products, DTSC must first make available on its website guidance materials to assist persons in performing the AAs, in accordance with Article 5. The comments expressed that the guidance materials developed by DTSC comport with the following:

- Be prepared and disseminated prior to Priority Products (subject to the AA process) being identified;
- Be developed in coordination with third world country authorities, trade associations, Cal/OSHA, the Department of Public Health's Occupational Health Branch, and other interested parties;
- Be included in these regulations and/or subject to the Administrative Procedure Act (APA);
- Be objective and use specific criteria to identify risks that are then evaluated with appropriate exposure models; and
- Be adequately reviewed and approved for use by others, so that a process that has less rigor than necessary is not promoted and accepted as guidance by DTSC and clarifies processes that are applicable to one type of product but is not used by others.

Response:

Consistent with Health and Safety Code section 25253(c), it is mandated that in developing the process and its regulations, DTSC ensures that the tools available are in a form that allows for ease of use and transparency of application. Section 69505(a) addresses this mandate and requires that prior to finalizing the initial list of Priority

Products, DTSC must prepare and make available guidance materials to assist persons in performing AAs. Efforts to make guidance materials available are under way; such materials will be available online before finalization of the initial Priority Products list.

DTSC contracted with the University of California, Santa Barbara (UCSB) to research background information on the current framework in chemical AA in order to provide a foundation for the development of AA guidelines. The findings are compiled in a report titled "Chemical Alternatives Analysis: Methods, Models and Tools," dated August 2010, and is available on DTSC's website.[5] The report evaluates existing tools, standards, methods, and models for assessing and comparing alternatives. More recently, DTSC has coordinated its efforts with numerous stakeholders in gathering information regarding assessment frameworks, methods, and tools. During implementation, DTSC will continue to coordinate with interested stakeholders to develop guidance materials but has intentionally not restricted itself in regulations to coordinate with other specific entities—whether foreign or domestic—to prevent any unintended delay in developing guidance materials, should the participation of other entities become limited. The proposed regulations appropriately place the responsibility on DTSC to develop and make available guidance materials. In developing its guidance materials, DTSC will ensure that adequate review has been conducted prior to posting on its website for use by others.

Consistent with Health and Safety Code section 25253(c), in developing the guidance materials, DTSC will make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, importers, and retailers can use to make safer consumer product decisions. Guidance materials may be developed to be product-specific if DTSC determines that is appropriate and useful. Thus, it is impractical to provide specificity in the regulations, as was requested by the comments. An approach that is applicable to one product type may not be appropriate for another. Hence, the guidance will not be a rule or standard of general application. The regulations provide the criteria with narrative standards that must be addressed to complete an AA. While the regulations contain the criteria and procedures, the guidance materials will guide preparers in performing the AAs (*i.e.*, sources of information, trends or emerging technologies, etc.). The guidance materials are non-binding materials that do not need

[5] http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/08-T3629-AA-Report-Final-Aug-24-2010.pdf

to be adopted under the APA. DTSC understands its obligations under the APA and proceeds to adopt regulations, when required—as demonstrated by its actions in adopting these regulations.

Changes in response to the above comments were not made.

§ 69505(b) Alternatives Analyses on DTSC's website

Comments: 34-5, 34-6, 34-8, 66-37, 76-51, 138-5, PH25-1, PH33-3

Comments Summary:

The above comments expressed concerns with section 69505(b), which specifies that various AA Reports will be made available on DTSC's website, and these reports are later required to be considered as part of section 69505.1(h). The companion provisions require the responsible entity to determine if the posted AAs contain relevant information that may be used to conduct their own AA. In summary, the following comments were expressed:

- Not all studies have been posted to DTSC's website, namely Cradle to Cradle Institute studies;
- "Not all methodologies to perform an assessment are of equal caliber";
- A less rigorous AA may be promoted and accepted as guidance by DTSC;
- Processes that are applicable to one type of product but not others may be used by assessors that do not understand the products, and how they are produced; and
- Stakeholder input should be sought for developing guidance materials posted on DTSC's website.

Response:

Although DTSC is currently engaging numerous stakeholders in scoping guidance development through various workshops, the AA workshop materials are not the final end products that will be made available to stakeholders for preparation of AAs. As such, documents prepared for the workshops may not be posted to DTSC's website as guidance materials. DTSC anticipates a separate site will be created to house guidance materials.

In response to the above comments, as well as comments related to public input in general, DTSC amended the July 2012 version of section 69505.1(h). The text previously found in Section 69505.1(h) is now found in section 69505.1(d) under Consideration of Information (January and April 2013). The responsible entity preparing

its AA must take into account "relevant" information and technical assistance provided by DTSC. DTSC will not promote the AAs that are submitted; however, DTSC will review and audit the AAs submitted for compliance with Article 5. Responsible entities should refer to the posted AAs to seek additional guidance on the level of detail necessary to arrive at desired outcomes. For example, an AA with little information on impacts may, in addition to filling data gaps as a regulatory response, result in additional regulatory responses being imposed than would an AA with very detailed findings.

The review and determination criteria for AA Reports were included in section 69505.6(a). In response to the above and related comments, more specific criteria for DTSC's review of AA Reports and work plans are now included in the proposed regulations in section 69505.9(a) (January and April 2013).

§ 69505.1 Alternatives Analysis: General Provisions

§ 69505.1(a)(1) & (2) Applicability

Comments: 5-81, 5-81, 5-82, 5-161 73-10, 73-13, 73-19, 86-2, 107-60, PH28-2

Comments Summary:

The above comments expressed concern with section 69505.1(a)(1) and (2), specifying the general applicability of the AA requirements. In summary, the following concerns were expressed:

- The term "Priority Product" may mean a listed product or the component(s) and/or homogeneous materials(s) within a component in the product that are the focus of the AA; however, this distinction is not made in the remainder of Article 5;
- The entirety of a "highly durable product" could ultimately become the focus of an AA, even though DTSC has repeatedly stated its position that this is not its intent; and
- Limit the scope of the AA to the single "Chemical(s) of Concern" that is/are the basis for the product being included on the Priority Products list.

Response:

The section used the term "Priority Product" as a naming convention for the product, component, or homogeneous material that was the basis for the product to be listed as a Priority Product and that is subject to the requirements of Article 5. In response to numerous comments related to the definition of the term "homogenous material(s)"—a companion definition to the term "Priority Product" used in this section—the previous

definition of “homogenous materials” is now defined as a subset of the definition of “component”; and corresponding sections of the regulations modified to clarify the pertinent requirements. As detailed in the ISOR and in responses to comments related to Article 3, the Priority Product that is listed under the criteria and procedures in Article 3 could be the entire product or components of a larger product. The final list of Priority Products made available pursuant to section 69503.5 (January 2013) will provide the level of detail necessary to inform manufacturers which product(s) or component(s) is/are being listed as Priority Products and must be subject to the AA requirements. In response to the above and other related comments, the provisions throughout the proposed regulations have been modified to make explicit that the AA requirements apply to the Chemical(s) of Concern that is/are the basis for listing the product and the alternatives.

As stated in the response to comments in section 69503.4(a)(2)(B)2. Priority Products list-Highly Durable Products, a responsible entity for a product composed of 100 or more components may be required to address up to 10 components over a three-year period. This means 10% of the components in a highly durable or complex product could be required to undergo an AA in three years. DTSC believes addressing approximately 10% of components in complex durable goods is a fair starting point, and as the program matures, regulatory amendments will be made accordingly—if DTSC deems them appropriate or necessary.

In addition, in response to comments related to exemptions from the requirement to conduct an AA under Article 5, all provisions related to exemptions have been moved to sections 69505.2 and 69505.3 (January 2013). These changes are explained in greater detail below as part of the response to comments regarding these sections.

§ 69505.1(b)(1) & (2) Exemptions to AA Requirements

Comments: 9-40, 9-41, 17-4, 68-8, 107-66

Comments Summary:

The above comments expressed concern with section 69505.1(b), which exempts responsible entities from the requirement to conduct an AA. Two conditions under which the requirements of Article 5 do not apply are specified in section 69505.1(b). The requirements of Article 5 do not apply if the Priority Product is no longer placed into the stream of commerce in California or the Priority Product contains a Chemical of Concern below the AA Threshold exemption criteria. The comments, however, requested that additional exemptions to the requirements of preparing an AA be included to address likely scenarios that the regulations have not addressed. The

additional scenarios, under which exemptions from the AA were requested, include the following:

- The responsible entity replaces the Chemical of Concern that is the basis for the Priority Product listing with a substitute chemical that is not on the Chemicals of Concern list and, thus, does not exhibit the toxicity trait(s) that caused the Chemical of Concern to be on the Chemicals of Concern list;
- The responsible entity determines that the Chemical of Concern is not necessary for the product to continue to meet function, performance, technical feasibility, and legal requirements. The entity must also certify within sixty (60) days of notifying DTSC of its determination its intent to stop using the Chemical of Concern in the Priority Product, and that they will not use a substitute chemical in place of the Chemical(s) of Concern that is the basis for the Priority Product designation. The entity must confirm that it has begun the process of removing the Chemical(s) of Concern that is the basis for the Priority Product determination, no later than 120 days after the date the entity notified DTSC of its intent; and
- There are no known substitutes for the Chemical of Concern.

Response:

In response to comments related to exemptions in this and other related sections (such as chemical removal notifications and AA Threshold notification), the exemption provisions have been amended. All provisions related to exemptions have been moved to sections 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis, and the corresponding previous sections have been shifted accordingly. Those new provisions are discussed in greater detail under section 69505.1(g) Chemical of Concern Removal Notification.

The comment requesting an exemption because an alternative to the Chemical of Concern does not exist cannot be reasonably accommodated because the proposed regulations are intended to stimulate the search for alternatives to chemicals that are of concern for which alternatives do not readily exist. Creating an exemption as requested would be counter to the intent and goals of AB 1879.

The provisions provide a necessary and logical exemption to the requirements of Article 5 if the responsible entity elects to no longer introduce the Priority Product into California commerce, or if the Chemical of Concern is at a concentration DTSC has determined is not of sufficient concern or priority.

Voluntary Alternatives Analysis

Comment: 68-19

Comment Summary:

The above comment expressed concern that while there are provisions to address a mandatory AA, there are no provisions to govern the quality and integrity of a voluntary AA.

Response:

Pursuant to section 69505.5(a)(1), once a Priority Product is listed under Article 3, the responsible entity must comply with the requirements of Article 5—that is, they must submit a Priority Product Notification, an AA Threshold Limit Notification or Chemical Removal Notification, or prepare and submit an AA under one of the four options reserved for an AAs (January 2013). A responsible entity may use the provisions in the proposed regulations to guide its internal AA to redesign or reformulate products prior to them being listed on the Priority Products list; however, once listed, the process is no longer voluntary. The purpose and scope of these regulations is to specify the criteria and procedures for conducting an AA required under this program. It does not extend to regulating voluntary conduct. Accordingly, no changes to the regulations are being made in response to this comment.

§ 69505.1(c)(1) Consortium and/or Collaborative

Comments: 7-17 7-19, 15-6, 57-57, 57-58, 68-7, 68-19, 68-26, 74-53, 74-62, 97-5 124-30, PH13-3, PH13-6, PH13-7, PH13-8

Comments Summary:

The above comments expressed concerns with section 69505.1(c)(1), which allows responsible entities to comply with the requirements of Article 5 entirely on their own, through a contract, consortium, collaborative, and/or similar partnerships. Responsible entities may conduct the analysis in-house or through contract with a consultant acting on behalf of the responsible entity, or the responsible entity may perform parts of the AA to comply with portions of the requirements while a person acting on its behalf complies with the other requirements of Article 5. The following concerns regarding flexibility, timing, and intellectual property of responsible entities were expressed:

- Administrative steps in the formation of a consortia, a collaborative, and/or a trade association require the issuance of a request for proposal —as well as a

selection of consultants that can take months to initiate and formalize—and require additional flexibility in timing for report submissions;

- Anti-trust requirements in the U.S. demand care in building such relationships, making them cumbersome since communication must involve a third-party for oversight and blinding of most communication. Thus, an additional provision should be included in which a consortium is permitted to form within one year of the Priority Product listing prior to having to conduct any AA;
- Intellectual property and other confidential information that entities are unwilling to share will prevent "group AAs" from being successful. Further, the same products will not have uniform properties, making assessments difficult and prone to inaccuracies as they relate to any one product;
- Due to the costs and complexity of AAs, "free rider" problems will arise when only some parties will fund an AA, but many more can rely on the results; and
- Intellectual property and other confidential information will prevent small parties from working together.

Response:

Responsible entities have 180 days after a product is listed as a Priority Product to submit a Preliminary AA Report. The provisions regarding the list of Chemicals of Concern and Priority Products have been streamlined and continue to allow for public input. Therefore, there is adequate lead time for responsible entities to begin forming, either through contract or other agreement, consortia, collaboratives, and/or similar partnerships. Quite simply, responsible entities do not have to wait for the finalization of the Priority Products list to begin forming collaboratives to work on AAs.

Given that DTSC m make public the chemicals and products under evaluation for review and comment prior to finalizing the Chemicals of Concern and Priority Products lists, responsible entities may have one to two years (in some instances longer) to be informed of the chemicals and products that are being considered for prioritization. Responsible entities can choose to begin forming a consortium, collaborative, and/or similar partnership to address similar concerns in the event that their chemical and/or product are ultimately listed.

A group of manufacturers, whether large, medium or small, may work together to offset the costs of performing an AA on their own and achieve a common goal, but this is not required under the proposed regulations. Further, the provisions in the proposed regulations do not require a responsible entity to enter into a contractual agreement with a contractor to perform the AA. A responsible entity may perform parts of the AA or the entire AA in-house.

The regulations intentionally do not carve out provisions for small to medium-sized manufacturers or manufacturers in third world countries; as such, they are subject to the same requirements as manufacturers located in the U.S. and California. Creating exemptions for small to medium-sized enterprises is not authorized under Health and Safety Code sections 25251 through 25257.1. Further, if exemptions were created for out-of-state manufacturers, it would create a disadvantage to California-based manufacturers. All manufacturers may contract with any parties to assist them in complying with the requirements specified in Article 5. They may choose to join or form a collaborative and /or consortium or independently comply with the requirements and must submit their work to DTSC within the time frames allocated.

Contractual business arrangements between the responsible entities and any contractor, a collaborative, and/or consortium may well need to address issues regarding release of confidential business information. The regulations do not change this sort of arrangement. Consultants frequently work for multiple clients and are privy to confidential business information. This concern may be addressed by nondisclosure agreements between the responsible entity, their consultants, and/or their clients.

Small companies without the technical capacity to develop an AA can join efforts to fill the data gaps of common interest and offset those costs, and then independently undertake those parts of the AA that are product-specific.

DTSC recognizes that AAs undertaken by consortia, collaboratives, trade associations, and/or similar partnerships representing an industry segment or an entire industry may have limited utility for all parties involved. As indicated earlier in the other approaches considered, a collaborative or trade association-created AA will, in many respects, be similar to a state sponsored AA where the AA is conducted in a generic sense and would not address any product-specific or use-specific impacts. The results from a collaborative or trade association AA may not adequately address the appropriate regulatory responses and would require that each responsible entity conduct their own to address the product-specific impacts.

In response to other related comments, the provisions have been modified and streamlined under AA requirements section 69505.1(b)(3) (January 2013).

§ 69505.1(c)(3) Alternatives Analysis Timelines

Comments: 3-5, 7-3,12-9, 19-25, 19-27, 19-28, 36-102, 40-10, 55-6, 55-9, 65-2, 66-37, 68-8, 74-48, 76-10, 76-52, 101-32, 109-5, PH3-3, PH5-5, PH17-7, PH20-3

Comments Summary:

The above comments expressed concern with section 69505.1(c)(3), which specifies the time frame by when the Preliminary and Final AA Reports must be submitted. The Preliminary AA Report must be submitted 180 days, unless otherwise specified, after the Priority Products list is finalized, and the Final AA Report must be submitted twelve (12) months after the Preliminary AA Report is determined complete, unless an extension of twenty-four (24) or thirty-six (36) months is requested and granted, pursuant to section 69505.5(k). While some comments expressed concern that time frames are adequate and overly generous in providing extensions, other comments expressed the following overall concerns:

- DTSC must facilitate or conduct the primary AA without requiring individual entities to submit notifications and conduct individual AAs (*i.e.*, state sponsored AA);
- The Priority Product notification period is too short, should be extended, made more flexible, or allow the regulated community to identify an appropriate time frame;
- Decouple the deadline for submitting the Preliminary AA Report, the Abridged AA Report, and the Chemical of Concern Removal Notification from the date the Priority Product list is published, and make the time frame more flexible or extend the periods;
- Industry faces uncertainty with respect to the Chemical(s) of Concern and Priority Product lists;
- Industry has to allocate a significant amount of time and resources to develop viable solutions that comply with the proposed regulations;
- Different deadlines should be tailored to address the wide range of complexity and differences between sectors;
- The deadline for submission of AA Reports should be the same for all responsible entities, and any extension granted for one responsible entity should apply for all responsible entities;
- The deadline for submitting the Preliminary AA Report, the Abridged AA Report, or the Chemical of Concern Removal Notification should be eighteen (18) months after the responsible entity submits the Priority Product Notification;
- The more specific the Priority Product/component that is identified, the more likely it is for the responsible party to complete the AA process, but even this detail will not correct for the necessary information exchanged between a multi-tiered, international supply chain, or the potential number of alternatives that will need to be assessed;

- The time frames detailed in the regulations do not provide the necessary flexibility for specialized applications. For example, the requirements in federal contracts cannot be easily or quickly modified.
- California manufacturers could be significantly disadvantaged or find themselves excluded from such contracts. Complex goods require years of design, supply chain complexity, research and development, testing, and validation. These regulations do not appear to take these actions into consideration;
- The time to complete an AA depends significantly on how many alternatives are being analyzed;
- The review periods for DTSC are too ambitious and short, potentially creating backlogs;
- There is too much time required to complete and report and achieve safer products, as well as too much flexibility to extend the process, creating a disincentive for responsible entities to complete the process sooner;
- The provisions only allow for one extension. Responsible entities may require more, and it should be allowed;
- Include a petition process with criteria that responsible entities can submit to receive additional time to complete AA Reports rather than the "one-size fits all" approach in the proposed regulations;
- The time frames to complete the Preliminary and Final AA Reports do not provide responsible entities adequate time to perform safety or performance testing and may take years;
- In our experience with the United States Environmental Protection Agency's (U.S. EPA) Design for the Environment Program, it can take as long as several years to identify, develop, and register a new product with a sustainable profile when involving an alternatives approach to reformulation. DTSC should propose a more realistic time frame that closely follows the U.S. EPA's experience; and
- The time frames and resources for conducting AAs reflect a naiveté and will be very challenging for manufacturers to meet.

Response:

As stated in the ISOR, the First and Second Stage AA, and the corresponding Preliminary and Final AA Reports, respectively, comprise the process for an evaluation of the availability of potential alternatives and address the impacts through a multimedia life cycle evaluation. During the first stage, the goal, scope, and range of alternatives being considered in the AA must be identified. In the subsequent second stage, the relevant factors are refined, compared, and assessed. Collectively, these processes, along with the accompanying reports, establish the basis for identifying the most

suitable alternative to the Priority Product, if any, and lay the foundation for imposition of the appropriate regulatory response(s) under Article 6.

The first and second stages of the AA each contain key steps that must be performed as part of the pertinent stage. The first stage and Preliminary AA Report are intended to identify and report existing or potential alternatives; whereas, the second stage and Final AA Report are intended to compare and report the selected alternative(s). The Preliminary AA Report must include an implementation schedule for the second stage AA, and the Final AA Report must include an implementation schedule for implementing the selected alternative and regulatory responses, if applicable.

Table 6. Alternatives Analysis

Two Stage AA		Abridged AA
First Stage	**Second Stage**	
Step 1: Identification of Product Requirements & Function of Chemicals of Concern.	**Step 1:** Identification of Factors Relevant for Comparison of Alternatives.	**Step 1:** Identification of Product Requirements and Function of Chemicals of Concern.
Step 2: Identification of Alternatives.	**Step 2:** Comparison of the Priority Product & Alternatives	**Step 2:** Identification of Alternatives.
Step 3: Identification of Factors Relevant for Comparison of Alternatives	**Step 3:** Consideration of Additional Information.	**Step 3:** Identification of Factors Relevant for Comparison of Alternatives
Step 4: Initial Evaluation an Screening of Alternative Replacement Chemicals.	**Step 4:** Alternative Selection Decision.	**Step 4:** Initial Evaluation and Screening of Alternative Replacement Chemicals.
Step 5: Consideration of Additional Information.	**Step 5:** Final AA Report Preparation	**Step 5:** Abridged Report Preparation *including but not limited to initiation of research and development pertinent to Priority Product.*
Step 6: Preliminary Report Preparation		

While former section 69505.1(c), now section 69505.1(b) specifies 180 days for submittal of the Preliminary AA Report, Article 3 allows DTSC to take into account public and stakeholder input in establishing the due date for the Preliminary AA Report. It is necessary to retain the interdependence of the deadline for submitting the Preliminary AA Report, the Abridged AA Report, and the Chemical of Concern Removal Notification from the date the Priority Product list is published to ensure the impacts posed by Priority Products are addressed in a timely fashion. The proposed regulations

provide sufficient flexibility to extend the periods. The complexity of products will be taken into account when determining a practical time frame. For complex products, DTSC expects to receive stakeholder input when the Priority Products list is published, allowing DTSC to set due dates for Preliminary AA Reports which could exceed 180 days from finalization of the Priority Products list. (January and April 2013)

As stated in the ISOR, the provisions give DTSC latitude to provide a due date based on the complexity of the planned AA and the scope of the alternatives to be considered; it is not "one size fits all" approach. As such, it is impractical to have the same deadline for all Preliminary AAs if the scope of each is vastly different. It is essential that DTSC maintain this latitude because the regulations are intended to address a broad range of products—each with unique circumstances that are impossible to be fully taken into account in a generally applicable regulations. This flexibility in the proposed regulations may provide manufacturers with the opportunity to work with their supply chain and develop meaningful AAs.

Further, specifying a due date for the Preliminary AA Report~~s~~ is necessary to ensure that:

- Responsible entities know how long they have to submit the Preliminary AA Report;
- The AA process proceeds on a timely basis; and
- To put all responsible entities on a level playing field.

Based on the activities conducted during the first stage, along with information required to be included in the Preliminary AA Report under former section 69505.5, now section 69505.7, 180 days will, in most cases, provide a sufficient amount of time for preparation of the Preliminary AA Report. An extension is provided in section 69505.1(c)(1) of the proposed regulations dated January and April 2013, to address those unusual situations for which 180 days is inadequate. Due to the anticipated scope of the Preliminary AA, only one ninety (90) day extension is provided.

It is anticipated that some alternatives may lend themselves to be quickly adopted and, as a result, will allow for concurrent development of the alternative, addressing other market requirements (such as consumer acceptance) and costs, and, unfortunately, other alternatives will not. The regulations do not require that the alternatives be ready for market distribution at the completion of the Final AA Report, but they require that the implementation plan include the anticipated period for making the alternative available in the marketplace—if an alternative is selected. As such, the concerns that the

proposed regulations fail to provide sufficient flexibility for federal contracts and/or place California manufacturers at a disadvantage are unfounded.

A crude comparison of this program to U.S. EPA's "Design for the Environment" may, at first blush, seem to demonstrate that the period for preparing the AA is not sufficient. However, it is important to note that "Design for the Environment" is a voluntary program comprised of partnerships between U.S. EPA, industry, environmental groups, and academia. The proposed regulations establish the framework, which may include (but does not require) coordination with other entities. A responsible entity may proceed with conducting the AA without coordinating its efforts with other entities. Further, the proposed regulations allow the responsible entity tremendous flexibility in establishing the scope of the AA; the scope will not be dictated by any other entity. Finally, the stepwise approach, specified in the proposed regulations, should lead to clear approaches and generate efficiencies. While voluntary programs have their place, mandatory programs (such as in the proposed regulations) create the necessary urgency to compel more accelerated results. A clear disadvantage with voluntary programs is that there are no deadlines or repercussions for failing to make progress.

AAs conducted by the State or "state sponsored AAs" have limited utility and are costly to taxpayers. Given the scope of the AA, a consortium of companies, collaborative, public-private partnership, or a trade association could be limited in the amount of information participants are willing to share without compromising trade secret information. A state sponsored AA would only yield sufficient information to perform the preliminary assessments, if that, and would not address more in-depth analyses to determine the hazards of a chemical that are product type and use-specific and provide sufficient information for DTSC to impose the appropriate regulatory response.

Manufacturers using Candidate Chemicals, as defined in Article 1 and as are specified in Article 2, in the products that they manufacture may commence in forming partnerships with other manufactures or chemical management programs to initiate the quest for safer alternatives prior to their product being named a Priority Product and perhaps avoid being listed in the long run. The chemicals lists specified in Article 2 provides some certainty for industry with respect to the Chemical(s) of Concern that are likely to be listed. Further, to offset costs, manufacturers may form partnerships to comply with the proposed regulations.

In addition to the market signals that will be provided, the proposed regulations provide multiple opportunities for responsible entities to request extensions, provided the responsible entity submits a request containing the specified information in section 69505.1(c).

In response to the above and other related comments, the provisions have been streamlined, and are now under section 69505.1(b)(2)(A) for AA requirements. AA extensions are now in section 69505.1(c) (January 2013).

§ 69505.1(c)(3)(A) Preliminary AA Report Timelines

Comments: 7-3**,** 19-27, 40-11, 54-10, 57-57, 84-3

Comments Summary:

The above comments expressed concern with the length of time a responsible entity has to prepare and submit a Preliminary AA Report. The comments predominantly stated that the time frame was too short and should be extended—by as little as an additional six (6) months, while others requested "several" years. The following is a summary of the concerns expressed:

- The Preliminary AA Report requires identification of functional requirements, alternatives, and an initial screen of the alternatives identified. Depending on the complexity of the chemical/product combination and the number of the alternatives to be considered, it could easily take much longer to complete a Preliminary AA Report that would meet DTSC's requirements and needs;
- In addition to the additional time needed for the notification process, there will be many circumstances where the Preliminary AA Report will take longer than ten months to prepare (12 months minus the 60 days for notification); and
- It is expected that a long period of time will be required for businesses to confirm the functions, quality, safety, etc. of products to which alternatives have been introduced.

Response:

Please refer to the above response on AA time lines for the timing, due dates, and extensions applicable to AA Reports. The first stage and corresponding Preliminary AA Report is in many aspects a work plan intended to allow responsible entities to gather as much available information to assess viable alternatives to be considered for further evaluation in the subsequent Final AA Report.

As discussed in the ISOR, the first and second stage AA and the corresponding Preliminary and Final AA Reports, respectively, comprise the process for an evaluation of the availability of potential alternatives and address the impacts through a multimedia life cycle evaluation.

During the first stage AA and corresponding Preliminary AA Report, the goal, scope, and range of potential alternatives being considered in the AA must be identified. The principal goal of the first stage AA and the Preliminary AA Report is to identify all potential alternatives to the Priority Product and eliminate those alternatives that pose greater aggregate or cumulative public health and environmental impacts than does the Priority Product-Chemical of Concern.

The first stage AA and Preliminary AA Report involve the gathering, organizing, and evaluating of the scientific and technical information necessary to decide whether a particular alternative is likely to be a potential alternative to the Chemical(s) of Concern in the Priority Product. The relevant information about an alternative is assembled for subsequent, thorough evaluation in the second stage and Final AA Report. Under section 69503.2, one of the key prioritization factors to list a Priority Product is based on the Chemical(s) of Concern's potential to cause adverse human health and environmental impacts. As such, alternatives to the Chemical(s) of Concern in Priority Products should be preferable to the Priority Product and be evaluated first for their potential adverse public health and environmental impacts. Other factors (such as consumer preference and economic impacts) are, therefore, not evaluated as part of the first stage analysis. Those factors are deferred until the second stage, when alternatives have been "short listed" for further consideration.

The Preliminary AA Report must include an implementation schedule for the second stage AA. Given the fact that responsible entities are not required to test or validate findings during the first stage but instead reserves that for second stage, DTSC believes that 180 days will, in most cases, provide a sufficient amount of time for preparation of the Preliminary AA Report. Again, if this is not the case, responsible entities may request a one-time extension of time from DTSC.

Substantive changes to provisions regarding submittal dates have not been made. In response to the above and related comments, as well as streamlining efforts, these provisions have been moved to section 69505.1(b)(1)(A) (January 2013).

§ 69505.1(c)(3)(B) Final AA Report Timelines

Comments: 7-3,19-29, 41-9, 55-4, 55-10, 57-56, 72-17, 74-45, 86-21, 86-22, 86-9

Comments Summary:

The above comments expressed concern with the length of time a responsible entity has to prepare and submit a Final AA Report. The comments predominantly state that

the time frame is too short and should be extended for a variety of reasons. In summary, the following concerns were expressed:

- Depending on the number of alternatives to be assessed during the second stage of the AA, twelve months may be insufficient to complete this process in any meaningful way and in such a manner that will be acceptable to DTSC;
- To be done well, these assessments will require extensive data collection, hazard and exposure assessment, functionality determinations, safety standard compliance determinations, economic impacts assessment, and in some cases consumer acceptance testing;
- The regulations must also build in time to obtain necessary regulatory approvals following the prototype building, testing, and validation process;
- The regulations allow all DTSC actions to be stayed during a dispute, until resolved. Allowing disputes at any stage can lead to frivolous delay tactics by those entities that are regulated;
- It is clear that DTSC will focus on chemical-product combinations that have enough evidence to suggest a high hazard to the public, and the public has a right to know which of these product combinations are of sufficient concern to warrant DTSC's request for an AA;
- If there are multiple AA submissions, DTSC must issue a single regulatory response for each Chemical(s) of Concern/Priority Product combination, based on the aggregate finding of all AAs. Therefore, if DTSC finds that a Chemical(s) of Concern in a Priority Product requires a regulatory response to protect human health and the environment, DTSC must act uniformly in requiring a regulatory response for all affected responsible entities. Likewise, any exemptions should be the same for all responsible entities;
- A validation process is necessary so that the manufacturer may lawfully produce the final alternative. And, as part of implementing this prototype process, the regulations must allow the Final AA Report to make a recommendation regarding what alternative(s) will go through the prototype build, test, and validation process, along with a recommendation regarding the time frame for such work—before any regulatory response is imposed;
- Additional special testing for specific claims or consumer tolerance in use may also extend the time frame needed. Not only is research and development necessary, but regulatory requirements must also be satisfied. It may be necessary to get a new chemical listed on the U.S. EPA Toxic Substances Control Act (TSCA) inventory—by submitting a Pre-Manufacturing Notification—in order for it to be manufactured in the U.S.;

- The activity related to AAs seems quite dependent on each company's product and activities; however, it is quite likely that each company doing its own research and development, evaluating the same Chemical(s) of Concern, may come up with the same chemical alternatives on their own; and
- To change to an alternative or to find an alternative chemical to fulfill the overall requirements could, in most cases, take a decade until they would become usable in the market.

Response:

During the second stage and corresponding Final AA Report, the relevant factors are refined, compared, and assessed. Collectively, the Preliminary and Final Reports establish the basis for identifying the most suitable alternative to the Priority Product, if any, and lay the foundation for imposition of the appropriate regulatory response(s) under Article 6.

The Final AA Report must include an implementation schedule for implementing the selected alternative and regulatory responses, if applicable. As such, any registrations, if not already done during the early stages of the Final AA, can be undertaken or accounted for at this point. In addition, market requirements (such as consumer acceptance and costs) can be further evaluated. As stated before and in the ISOR, the regulations do not require that the alternative be ready for market distribution at the completion of the AA Report, but they require that the implementation plan include the anticipated period for making the alternative available in the marketplace, if an alternative is selected. As such, the comments expressing concerns with the deadlines are largely unfounded.

A due date for the Final AA Report in the proposed regulations is necessary to ensure that the responsible entities know the time frame for submitting the Final AA Report, responsible entities are kept on a level playing field, and the AA process is completed on a timely basis. The proposed regulations, however, provide responsible entities opportunities to extend the due date for submitting the Final AA Report. While the provisions establish a set time frame for submitting the Final AA Report, they also provide flexibility for accommodating more complex Priority Products that require additional time in finalizing the Final AA Report. Because entities are not required to fill the data gaps associated with an alternative, twelve (12) months (or an extension up to twenty-four (24) or thirty-six (36) months) is ample time to compile existing information and summarize findings.

Section 69507(d), within the Dispute Resolution provisions, provides that any disputed requirement imposed by DTSC is stayed while the administrative dispute is pending, thus allowing the party disputing DTSC's action to postpone compliance until the administrative dispute resolution process is complete. This is necessary to avoid prejudice to the responsible entity's interests while the matter is under review and prevents the waste of resources that would occur, were a responsible entity to initiate changes that might be rendered unnecessary by any change in the requirement as a result of review. DTSC has no basis for concluding that there will be abuse of this mechanism to delay compliance with requirements imposed by DTSC. DTSC will endeavor to resolve disputes quickly to avoid as much delay as is possible.

Although the decisions are stayed, copies of all disputes and requests for review filed with DTSC are made available on DTSC's website, as called for in section 69501.5(a)(9). Further, information regarding the chemical/product combinations that resulted in the listing of the product as a Priority Product with a Chemical(s) of Concern will be also available on DTSC's website. Interested stakeholders will be informed of the hazard posed to both human health and/or the environment.

As stated earlier, each responsible entity will define the scope of the AA they wish to undertake. As such, it is impractical to issue a single regulatory response for each Chemical(s) of Concern/Priority Product combination. The regulatory responses will be dictated by the findings of each AA.

The Pre-Manufacture Notification (PMN) required under the federal Toxic Substances Control Act (TSCA) and Title 40 of the Code of Federal Regulations section 720.3 does not create a logistical limitation in conducting an AA, pursuant to the proposed Article 5 nor does it require additional time be taken into account. A pre-manufacture notice must be submitted to the U.S. EPA if the manufacturer intends to import or use any new chemical substance which is not on the TSCA Inventory or otherwise excluded from notification.

TSCA excludes certain substances from Pre-Manufacture Notification and provides exemption for others. Substances manufactured solely for use as pesticides, food, food-additives, drugs, or cosmetics, tobacco and tobacco products, nuclear source materials, firearms and ammunition, impurities, byproducts which have no commercial use, non-isolated intermediates, and new chemical substances manufactured solely for export are statutorily excluded. Substances imported or manufactured/used for/in research and development, test-marketing, low volume exemption, polymers, or low release and exposure all qualify for exemptions from the Pre-Manufacture Notification requirements. Further, the notification is not due until 90 days before the manufacturer

begins to manufacture or import a new chemical substance for a commercial purpose—meaning ready for distribution, or 30 days for a low volume exemption or low release and exposure, and 45 days before manufacture or importation under test-marketing.

Substantive changes to provisions regarding submittal dates have not been made. In response to the above and related comments, as well as streamlining efforts, these provisions have been moved to section 69505.1(b)(1)(A) (January 2013).

§ 69505.1(d)(1) Extensions to Deadlines for AA Reports

Comments: 55-12, PH3-4

Comments Summary:

The above comments expressed concerns with the provisions that allow responsible entities to request an extension to the due date for the Preliminary AA Report and/or Final AA Report. The provisions allow up to ninety (90) days extension for the submittal of either or both, provided the request is submitted sixty (60) days before the applicable due date for the report. The following concerns were expressed with these provisions:

- The regulations allow for alternate deadlines for different entities performing AAs for the same Chemical(s) of Concern/Priority Product combinations, resulting in competitive inequities that should not be permissible;
- The regulations should have the same deadlines for all to enable appropriate and consistent regulatory responses;
- The procedures for seeking extensions could be retained, but an extension granted for one company for a particular AA step would need to be extended to all entities subject to the same AA for the same Chemical(s) of Concern/Priority Product; and
- If DTSC does not grant time extensions, the product manufacturer has no choice but to opt out and take the product off the market or face the repercussions of a failure to comply. This represents a loss in sales revenue to California businesses.

Response:

Consistent with stakeholder input, the regulations do not mandate an outcome from the AA but instead allow manufacturers to select from a range of alternatives. As such, the regulations have built in flexibility to accommodate to the extent practical, without unnecessarily delaying the process indefinitely, the varying needs of responsible entities manufacturing the vast range of consumer products covered under these regulations.

The proposed regulations provide responsible entities with an opportunity to request an extension to the due dates for submittal of the Preliminary AA Report and/or Final AA Report in section 69505.1(c)(1) (January 2013). Section 69505.7(k)(1)(B) of the proposed regulations allows responsible entities the opportunity to request a due date greater than the default 12 months from the Preliminary AA Report to the submittal of the Final AA Report (January 2013). A responsible entity may request a due date that is up to twenty-four (24) months from the date DTSC issues a notice of compliance for the Preliminary AA Report, or thirty-six (36) months if the additional time is necessary to conduct further safety and/or performance testing on multiple alternatives. Extension requests must comply with the substantive and administrative requirements of sections 69505.1(c)(1) through (3) or 69505.7(k)(1)(B). DTSC has discretion to grant or deny these extension requests based on its review of the basis for the particular request.

As stated earlier, each responsible entity will define the scope of the AA they wish to undertake; as such, it is impractical to issue the same deadline beyond the Preliminary AA Report. Similarly, it is impractical to impose a single regulatory response for each Chemical(s) of Concern/Priority Product combination. The regulatory responses will be dictated by the findings of each AA.

Substantive changes to provisions regarding submittal dates have not been made. In response to the above and related comments and streamlining efforts, these provisions have been moved to section 69505.1(c) (January 2013).

§ 69505.1(e) Certified Assessors

Comments: 47-26, 57-59, 68-29, 72-2, 101-39, 131-6

Comments Summary:

The above comments expressed concerns with the provisions specifying that two (2) years after the effective date of the regulations, a certified assessor must be used to conduct and prepare the AA Reports submitted to DTSC. In summary, the comments expressed the following concerns:

- Incentives should be implemented that recognize companies who voluntarily seek “safer” alternatives and should serve as the primary tool used to promote safer alternatives or green chemistry innovation without the need for a third-party approach;
- Academic training cannot provide enough knowledge for a person to be able to either conduct or lead a robust AA;

- The professional experience cited is not enough and cannot be substituted for postgraduate work;
- Significant experience is required for formulators;
- Need flexibility to accept the qualifications of certified assessors from around the globe;
- Five (5) to ten (10) years of minimum experience working as a formulator or processing engineer should be the minimum experience required;
- What evidence does DTSC have that there will be enough certified assessors available by that date and that their services can be procured at reasonable costs;
- The requirements for a certified assessor in subpart (e) should be removed;
- The two (2) year implementation is unworkable;
- If the provision are kept, allow that the AAs for the first round of Priority Products do not require a certified assessor; and
- If DTSC is reviewing all AAs to ensure compliance with this section, it is not clear what role the certified assessor will serve in assuring the quality and thoroughness of the AAs.

Response:

In response to comments regarding the provisions contained in Article 8 Accreditation Bodies and Certified Assessors have been deleted. Conforming changes to this major change have been made throughout Article 5 to address the need for stakeholder confidence and quality assurance.

Persons preparing and carrying out an AA and preparing AA Reports are no longer required to be certified to conduct one and may be performed in-house by the responsible entity or through contract with a consultant, by a trade association and/or collaborative.

§ 69505.1(f) Previously Prepared AA

Comments: 68-3, 68-30, PH13-8, PH25-1

Comments Summary:

The above comments expressed concerns with the provisions that allow responsible entities to submit a previously prepared AA Report to comply with all or part of the requirements in Article 5. In summary, the following concerns were expressed:

- There is no requirement that there is an agreement between the preparer of an AA that has already been conducted and an entity who wishes to use it to submit its own AA;
- The second entity will not have to sustain the same economic burden to generate data; and
- Cradle to cradle certification builds on the AA process and provides a platform for getting to the new materials and products. Our optimization plan is close to the requirements outlined in AB 1879 and goes one step further to incentivize continuous improvement.

Response:

While DTSC understands the concern that an entity may make use of another entity's work, the contractual agreement between one responsible entity and another party, consortium and/or trade association is outside the scope of these regulations. DTSC is aware that companies otherwise not affiliated with one another find ways to build off work done by other than the particular company itself in other contexts; this program is no different in that regard. Please refer to the response provided under section 69505.1(c)(1) Consortium and/or Collaborative for further details.

The regulations intentionally do not endorse a specific life cycle analysis tool or process. Responsible entities are free to use any life cycle assessment tool, provided they meet the submittal dates and meet the substantive requirements of Article 5.

In response to the above comments, comments related to section 69505.1(c)(1) and to clarify and streamline the requirements, the provisions under this subsection have been moved and combined under section 69505.1(a)(3) (January 2013).

§ 69505.1(g) Chemical of Concern Removal Notification

Comments: 5-83, 5-124, 5-125, 5-162, 7-17, 36-97, 36-98, 36-99, 66-39, 68-8, 80-12, 80-13, 106-3

Comments Summary:

The above comments expressed concerns with section 69505.1(g), which allows a responsible entity to submit a Chemical of Concern Removal Notification, if the responsible entity removes the Priority Product and it no longer contains the Chemical of Concern, without adding a substitute chemical. While the comments generally supported the provision, some comments suggested additional scenarios be included in

the notification and/or the notification be expanded or broaden and the reporting requirements lessened. In summary, the comments expressed the following:

- This is an overly burdensome and large information request that manufacturers will be required to prepare, and DTSC will be required to process with little or no benefit to the environment;
- If the manufacturer reformulates the product, no further reporting should be due;
- A simple notification with the contact information and a statement that the product no longer contains a Chemical of Concern should be adequate;
- Without receiving notification, neither the public nor DTSC will be able to assess the true and complete impact of these regulations, which may come under budgetary scrutiny or attack in the future;
- The prohibition of all chemical substitutions is too restrictive because a manufacturer would not have a substitute chemical to replace the function of the original Chemical of Concern making this provision unworkable;
- The regulations do not encourage companies to reformulate products without using a Chemical of Concern. As such, a reformulation would almost always require a substitute chemical to replace the same function as the original Chemical of Concern;
- There are many examples of other reliable and credible ways to demonstrate conformance, including supply chain declarations and internal process controls;
- If DTSC is going to require testing to demonstrate compliance, it is incumbent on DTSC to specify which tests are acceptable to show compliance; and
- Regarding the requirement for the responsible entity to submit notification of the measures it will take to “ensure the product that contained the Chemical(s) of Concern is no longer placed into the stream of commerce in California,” it is important to protect environmental justice communities since companies often dump old products into dollar or discount stores located in poorer communities.

Response:

As stated in the ISOR, section 69505.1(g) is intended to provide an incentive to responsible entities to elect to remove the Chemical(s) of Concern that are not necessary for the product performance or function or when a readily available safer alternative exists, without being required to undergo the process of conducting an AA. The provision allows reformulations, redesigns, or replacements to occur without unnecessary DTSC oversight when the reformulated product does not contain any Chemical(s) of Concern or a substitute chemical and, hence, does not pose a risk of a “regrettable substitute.” Responsible entities may elect to substitute other chemicals to

replace the function of the Chemical(s) of Concern; however, depending on the chemical being substituted a responsible entity *may* be required to prepare an AA. As discussed, below, a responsible entity may substitute Chemical(s) of Concern with a replacement chemical that is not on the list of Candidate Chemicals, or a Candidate Chemical that is already in use, in lieu of the Chemical(s) of Concern, to manufacture the same product and not be required to conduct an AA. The AA process in the regulations requires that any alternative chemical substitutes be scrutinized, in order to avoid selecting an alternative that is equally or more harmful than the Priority Product.

Notifications are necessary to provide DTSC information regarding the Priority Products and responsible entities that elect to remove a Chemical(s) of Concern. Without a notification, DTSC would not have a means to identify the Priority Products that have been reformulated, making compliance confirmation and enforcement unworkable. The notification provides a means to identify the responsible entities and the Priority Products to ensure that those products may be tested and determined to be free of the Chemical(s) of Concern that is/are the basis for the product being listed as a Priority Product.

At the onset, DTSC will develop guidance materials to address the preparation of the AA, and examples of how to demonstrate compliance with threshold requirements, if applicable. Responsible entities may use supply chain declarations, third-party chemical management certifications, and internal process controls; however, the data demonstrating compliance with any threshold must be provided with the appropriate notifications and/or AA Reports. As the program matures, DTSC may recommend product-specific testing to demonstrate compliance.

In response to comments related to exemptions in this and other related sections—such as Chemical Removal Notification and AA Threshold notification—the exemption provisions have been amended. All provisions related to exemptions have been moved to section 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis, and section 69505.3 Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (January 2013). These sections are briefly discussed below.

Chemical or Product Removal or Replacement Notifications

The proposed regulations dated July 2012 were amended. Under the amended provisions, an AA is not required for a Priority Product if the manufacturer submits one of the following notifications by the due date for the Preliminary AA Report (or by the due date for the Final AA Report if a Preliminary AA Report has already been submitted):

- A Chemical Removal Intent and/or Confirmation Notification, certifying that the Chemical(s) of Concern will be/have been removed from the product without the use of any replacement chemical(s);
- A Product Removal Intent and/or Confirmation Notification, certifying that the manufacturer will cease or has ceased fulfilling orders for the product from persons selling or distributing the Priority Product in California;
- A Product-Chemical Replacement Intent and/or Confirmation Notification, certifying that the Chemicals(s) of Concern will be or have been removed from the product and any replacement chemical meets one of the following criteria:
    - The replacement chemical is not on the list of Candidate Chemicals; or
    - The replacement chemical is a Candidate Chemical that is already in use—in lieu of the Chemical(s) of Concern—to manufacture the same product by the same or a different manufacturer.

An Intent Notification must be followed by submission of a Confirmation Notification within ninety (90) days or by the due date for the Preliminary AA Report (or Final AA Report), whichever is later.

Alternatives Analysis Threshold Notification

A responsible entity is also exempted from conducting an AA, pursuant to Article 5, if a product that is listed as a Priority Product does not exceed the applicable AA Threshold and the manufacturer of the product submits an AA Threshold Notification to DTSC.

An AA Threshold is available for a manufacturer's Priority Product only if the Chemical(s) of Concern are present in the product solely as contaminants, and the concentration of the Chemical(s) of Concern(s) does not exceed the Practical Quantitation Limit (PQL) for the chemical(s). If during the product prioritization process, DTSC determines that an AA Threshold is needed for a particular intentionally added chemical in a particular product, this can be addressed in the rulemaking for that Priority Product listing. That is, DTSC has reserved the right to establish specific AA Thresholds on a case-by-case basis for intentionally added chemicals and to set an AA Threshold higher than the PQL for contaminants.

The regulations specify the information that must be included in an AA Threshold Exemption Notification, including the source of the contaminant Chemical(s) of Concern(s). The notification must identify the PQLs for the Chemical(s) of Concern and the methods used to determine the PQL(s). The manufacturer is required to notify DTSC if the information in the AA Threshold Exemption Notification significantly changes or the product no longer meets the criteria for an AA Threshold Exemption.

§ 69505.1(h) Relevant Information and Public Input

Comments: 11-42, 26-5, 29-18, 68-31, 72-4, 72-7, 72-19, 72-20, 73-10, 114-10, PH17-6, PH19-2, PH32-6

Comments Summary:

The above comments express concerns and/or request clarification on the requirements of section 69505.1(h), which specifies that a responsible entity conducting an AA under Article 5 shall consider all relevant information on DTSC's website, including any public comments received. While the regulations called for the inclusion of public input, the mechanisms for input were not explicit in the regulations. In addition, concerns related to the inclusiveness of the materials posted on DTSC's website were expressed. In summary, the following concerns were expressed:

- Need the public's ability to engage in this process and have transparency and opportunity to assess the AA Reports;
- Seems excessive to require that responsible entities must summarize in their AA Reports how they have made use of information made available on DTSC's website;
- DTSC is best suited to know what materials on its website are appropriate for a particular Alternatives Assessment; they should specify them to the responsible entity who prepares the AA and delete subsection (h);
- Manufacturers should not be expected to subject their critical business decisions to external entities;
- Manufacturers ultimately perform market research to assess consumer preference;
- Communication channels provide an opportunity to engage directly with those using the products, give consumers a forum to ask questions about appropriate use, and provide comments on the products;
- The quality of stakeholder engagement and input, substantiated by valid scientific principles, is imperative to appropriate stakeholder communication/involvement;
- Environmental justice, occupational concerns, and related social considerations should be integrated into many of the product development steps;
- The AAs are being completed by manufacturers who have an interest in the status quo;
- There are a number of "crowd-sourcing type" tools to engage a larger community of experts and other stakeholders, including the U.S. government website (www.challenge.gov) where a problem is put out to the public for solutions; and

- Although the reports will be public, there is no process to provide public comment or formal comment period.

Response:

As stated earlier, *Establish Process with Open Debate or Peer Review*, DTSC recognizes the benefits of open, transparent dialogue and, input from stakeholders will not only improve the quality in the AA Reports submitted for DTSC review but also improve stakeholder confidence. While the July 2012 proposed regulations contained opportunities for public comment and input, the proposed regulations have been modified to expand the opportunities for public involvement. The proposed regulations have been amended to include opportunities for public input regarding AAs. DTSC will post on its website and send to individuals on the electronic mailing list(s) a notice regarding the availability for public review and comment of each Final AA Report, or Abridged AA Report submitted to DTSC. (April 2013)

The regulations reflect the authorizing legislation, which specifies the type of information that can be claimed as trade secret. While the proposed regulations do not require that all critical business decisions be released to external entities, they do require that information related to hazard traits for chemicals be made public. For a more detailed discussion on masking of trade secret information, please refer to the discussion under former Article 10 Trade Secret Protection in this Response to Comments document, now numbered as Article 9 in the proposed regulations (January 2013).

In addition, the provisions have been modified to make specific the fact that the guidance materials on DTSC's website should be considered to the extent applicable. It is not DTSC's intent that all guidance materials must be reviewed and summarized in the AA Report that is submitted by the responsible entity. Each responsible entity is to take the information, to the extent practical, and use the information to guide them in the preparation of the AA that they submit. For example, if AAs posted on DTSC's website are determined to be deficient for failing to comprehensively address a requirement, and subsequent AAs made available address those deficiencies, the responsible entity is to make use of that recent information and submit an AA Report that is as comprehensive as possible.

The proposed regulations allow responsible entities to complete their own AA, and submit the Final AA Report. The responsible entity selects the alternative that works best for them, taking into account public health and the environment life cycle impacts, consumer needs, economic impacts, compliance with all local, state and federal laws and regulations, as well as regulatory responses that they will be subject to as a result

of their selection. As such, the status quo may not be in the best interest of most responsible entities.

The thirteen criteria in Health and Safety Code section 25253(a)(2) comprise the contents of an AA, which requires the evaluation of Chemicals of Concern in consumer products and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a Chemical of Concern during a product's life cycle (*i.e.*, from raw material extraction through materials processing, manufacture, distribution, use, repair and maintenance, to disposal or recycling). To the extent that environmental justice, occupational concerns, and related social considerations are identified as relevant factors in the AA, they will be addressed.

DTSC recognizes the benefit in the use of tools to engage a larger community of experts and other stakeholders, including the U.S. government website to solicit the public for solutions. To the extent that these tools provide DTSC benefit in developing guidance materials, DTSC may make use of these during implementation.

In response to the above comments and overarching input received on Articles 5 and 8, DTSC has revised the proposed regulations to include public review and comment of Final AA Reports to make use of stakeholder input. The amended provisions are in section 69505.8 (April 2013).

§ 69505.1(i) Department's Timely Review of AA Reports

Comments: 47-21, 68-28, 68-32

Comments Summary:

The above comments expressed concern with section 69505.1(i) which specifies that DTSC's failure to make a compliance determination by the time frame specified in section 69505.6 does not constitute an approval of the AA Reports. In summary, the following concerns were expressed:

- The proposed regulations lack criteria on what constitutes compliance and how the AA will be judged by DTSC;
- DTSC gives itself unrestrained authority to determine compliance in any way and at any time it wants; and
- The regulations should specify the consequences of DTSC's failure to react within the required deadline rather than specifying what this failure does not mean.

Response:

While DTSC will make every attempt to meet the review periods specified, the provision prevents the de facto—and potentially harmful—approval of a Preliminary AA Report or Final AA Report that does not comply with the applicable requirements of Health and Safety Code section 25253 or Article 5 in the event DTSC is unable to act within the 60-day time frame due to resource limitations or other reasons.

In response to the above and other related comments, DTSC amended section 69505.9 to include the review criteria (January and April 2013). In addition, in response to streamlining the above, the referenced provisions of this section 69505.1(i) are now in section 69505.1(e) (January 2013).

§ 69505.2 Analysis of Priority Products and Alternatives

§ 69505.2(a)(1) Two Stage Alternatives Analysis

Comments: 5-29, 7-17, 68-34, 72-24, 72-25, 72-26, 107-57, 107-58, 124-29, 124-11, PH13-8, PH16-7

Comments Summary:

The above comments expressed concern with section 69505.2(a)(1), which specifies that the AA must be conducted in two stages. In summary, the following concerns were expressed:

- To alleviate the burden and to cut down on the number of AAs that must be completed, the regulations should allow responsible entities to:
  1) Submit a chemical removal notification;
  2) Allow companies to collaborate;
  3) Allow responsible entities to use third-party chemical management certifications;
- A life cycle screening exercise can be used before going into a complete International Standards Organization (ISO)-compliant life cycle assessment;
- There should also be consideration of unintended impacts should resource volumes increase due to demand for a successful alternative;
- AA should not stifle innovation but instead promote and encourage the development and use of safer alternatives and foster the concepts of green chemistry, while also protecting intellectual property rights and trade secrets;
- Incorporate green chemistry thinking and screen potential new ingredients for severe hazard “show stoppers” as a preliminary step to narrow the field of

potential candidate ingredients to those that show promise for further assessment;

- The framework must provide the opportunity for a manufacturer to fully demonstrate the safety of a Priority Product as an initial step before proceeding with an analysis of acceptable alternatives;
- “No change” is an equally probable conclusion for a Priority Product after a risk-based evaluation of hazard, use, and exposure;
- While consumer acceptance is acknowledged, performance should not be compromised;
- The fundamentals of the process are routinely executed as part of industry's ongoing research and development, and product improvement;
- The key to innovation and better meeting consumer needs, expectations, and preferences is the ability for manufacturers to draw on a variety of existing evaluation and decision-making tools and approaches for developing products;
- Safety—protecting public health and the environment—is an inherent component of the product design process;
- Concepts that leverage existing practices in the product development paradigm should form the basis of a practical and meaningful regulatory framework for alternatives assessment; and
- DTSC has not documented any feasibility analysis or "beta test" to examine whether the required work can be conducted at all in order to estimate the costs and necessary time frame for conducting an AA and whether these costs are proportionate.

Response:

As is reflected in the companion Economic and Fiscal Impact Statement Form 399 and the ISOR, there are unknowable and unknown costs that will be experienced by responsible entities. For a more detailed discussion on the economic and fiscal impacts, refer to the accompanying Form 399 and supporting documents.

The proposed regulations are among the first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals and are viewed as a possible national model for chemical reform. The rulemaking is, in effect, a preemptive strategy that reduces the use of toxic substances in the design of products and industrial processes with the aim of creating safer and sustainable products that do not threaten human health or persist in the environment. The use of fewer hazardous substances leads to healthier air quality, cleaner drinking water, and a safer workplace. The rulemaking also promotes transparency by compelling chemical manufacturers to provide sufficient information for

businesses, consumers, and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products.

The proposed regulations provide ample and sufficient opportunities for Responsible Entities to condense and/or minimize the amount of work that must be undertaken, all while meeting the criteria and intent of AB 1879. Under the proposed rule, responsible entities are allowed to submit a Chemical Removal Notification it they meet the specified requirements. In response to comments received, the instances under which a Chemical Removal Notification may be submitted have been expanded. Please refer to section 69505.1(g) Chemical of Concern for Removal Notification of this Response to Comments document for further details.

If a responsible entity does not meet the requirements for submitting a Chemical Removal Notification, they are then afforded four options to choose from for meeting the requirements of Article 5. A responsible entity may choose to:

(1) Conduct a two staged AA—that is a first and second stage followed by the corresponding Preliminary and Final AA Report;
(2) Conduct an Abridged AA;
(3) Conduct an alternate AA process that meets the requirements of Article 5; or
(4) Submit a previously completed AA.

In addition, responsible entities are allowed to collaborate. A group of responsible entities (whether large, medium, or small) may work together to offset the costs of performing an AA on their own, but it is not required under the proposed regulations. Finally, responsible entities may also employ the services of a third-party chemical management certificate program to meet all or part of the requirements, further offsetting the costs of performing an AA, as required in the proposed regulations. Responsible entities may employ third-party organizations to assist them in early screening efforts for alternatives to the Chemical(s) of Concern. Third-party chemical management organizations can provide responsible entities with resources and materials to make decisions that consider performance, as well as human health and environmental impacts. For instance, if Candidate Chemicals, as defined in Article 1 and specified in Article 2, are not already included in third-party chemical management organization's lists of chemicals to avoid, they may begin to target these chemicals and begin to seek alternatives to those chemicals that are application-specific, prior to these chemicals being prioritized as Chemical(s) of Concern.

As indicated in the ISOR, the proposed regulations contain requirements that are not new. The requirements parallel popular life cycle assessment tools for evaluating

and/or taking inventory of the impacts of products or services. The criteria included in the proposed regulations are commonly taken into account by manufacturers who are faced with balancing choices and making tradeoffs—when re-manufacturing a product—to address a consumer or market need or demand. The AA process in the regulations is consistent with commonly used life cycle assessment tools and do not require an ISO compliant process.

The thirteen (A) through (M) criteria listed in statute in Health and Safety Code section 25253(a)(2) are embodied in the regulations and collectively address the life cycle impacts (*i.e.*, from raw material extraction through materials processing, manufacturing, distribution, use, repair and maintenance, to disposal or recycling) associated with the Priority Product or any alternative(s) considered. The requirements specified in the proposed regulations are consistent with commonly used principles in product assessment and reformulation and, thus, should not stifle innovation but instead promote and encourage the development and use of safer alternatives.

As expanded on in responses to comments regarding section 69505.3 Alternatives Analysis First Stage, the responsible entity may screen potential new ingredients for severe hazard “show stoppers” as a preliminary step to narrow the field of potential candidate ingredients to those that show promise for further assessment. Further, the framework allows the opportunity for a manufacturer to fully demonstrate the safety of a Priority Product as an initial step as part of the analysis of acceptable alternatives. A responsible entity may choose to keep the Priority Product if, upon evaluation, the responsible entity determines and demonstrates—after a risk-based evaluation of hazard, use, and exposure—that the impacts may be mitigated through the appropriate regulatory responses.

Consumer acceptance may be taken into account during the first stage but is not required until the second stage. The regulations do not require that the manufacturer compromise performance or any safety requirements inherent to the Priority Product. However, any criteria that are used at arriving at the selection of alternatives for further evaluation (and the final alternative that is selected) must be supported in the Preliminary and Final AA Reports.

While a feasibility study or beta test has not been conducted, DTSC has incorporated sufficient narrowing in scope to the Priority Products that could be named, to allow for this sort of testing without unnecessarily delaying the process. As indicated in the ISOR and section 69503.6(b) (January 2013), the Initial Priority Products List shall include no more than five (5) Priority Products. The purpose in narrowing the number of Priority Products required to undergo an AA in the first round is to help DTSC and responsible

entities to learn by doing and resolve any flaws or issues with the requirements. During the initial three (3) year period, DTSC will determine what works well and what could be improved. DTSC may then modify the regulations accordingly. An advantage to this approach is that consumer products that are currently of high concern can be immediately subjected to the requirements to expedite a move to safer alternatives while simultaneously creating the framework for others to follow.

In response to the above comments and overarching input received on Articles 5 and 8, DTSC has revised the proposed regulations to eliminate the certified assessor program (January 2013).

§ 69505.2(b) Abridged Alternatives Analysis

Comments: 17-3, 29-18, 66-40, 76-53

Comments Summary:

The above comments expressed concern with section 69505.2(b), which specifies that a responsible entity may conduct an Abridged AA. In summary, the following concerns were expressed:

- No art material manufacturer can afford the expense of the DTSC process to find an alternative for a product with a limited customer base, when these same companies have sought to discover alternatives for more than a century that will satisfy the demands of some professionals;
- It is critical that DTSC allows public comment on Abridged AA Reports before they are finalized, and that DTSC be given authority to require first and second stages, as well as enact regulatory responses in response to deficient Abridged AAs;
- If an acceptable alternative is determined to not be “available or feasible” during the first stage of the AA, a responsible entity should not have to complete the cumbersome second stage;
- Thresholds for “available or feasible” are not specified nor is guidance provided; and
- A responsible entity should be allowed to submit an Abridged AA Report without first going through the first stage process if they rely on information from other regulatory entities or trusted bodies to show that there are no viable alternatives.

Response:

The provisions in section 69505.2(b) are intended to assist responsible entities by providing a mechanism to move toward research and development, when it is evidently

clear that suitable alternatives are not available. The provisions are not to circumvent or bypass the intent and goals of AB 1879, which are to find safer alternatives to reduce or limit exposure to Chemicals of Concern.

As further detailed under section 69505.1(c)(3) Alternatives Analysis Timelines of this Response to Comments document, the goals and intent of the first stage and subsequent Preliminary AA Report are to establish the goals and scope of the AA. Information for preparation of the Preliminary AA Report can be collected from any reliable source and does not require specific testing or analysis. The first stage and the corresponding Preliminary AA Report, alone, do not address all of the criteria specified in Health and Safety Code section 25253. Therefore, responsible entities must comply with step 1 of the second stage to address all of the criteria, and allow a responsible entity to move into the appropriate regulatory responses while awaiting the development of a safer alternative.

The terms “functionally acceptable,” “technically feasible,” and “economically feasible” are defined in section 69501.1(a) (January 2013) and are narrative in nature and do not create a prescriptive standard. Narrative standards allow programs to evolve rather than to remain stagnant and quickly outdated and are necessary given the scope of these regulations.

In response to the above comments and overarching input received on Articles 5 and 8, DTSC has revised the proposed regulations to eliminate the certified assessor program (January 2013). Instead, DTSC has included provision for public review and comment of Final AA Reports to make use of stakeholder input (April 2013). This should serve as something of a check and balance on AA integrity and quality. The amended provisions for Abridged AA Reports are in section 69505.4(b) (January 2013).

§ 69505.2(c) Alternate Alternatives Analysis

Comments: 7-23, 29-16, 55-8, 55-13, 66-36, 68-33, 72-10, 91-11, 129-12

Comments Summary**:**

The above comments expressed concern with section 69505.2(c), which allows responsible entities to use an alternate AA process to comply with the process specified in sections 69505.3 and 69505.4, provided specific requirements are met. In summary, the following concerns were expressed:

- Amend proposed regulations to include the use of an open source AA/state sponsored AA in lieu of or in combination with an alternative process AA;

- Not all methodologies to perform an assessment are of equal caliber; therefore, DTSC should allow for public input into the guidance materials when they are posted and the alternative process AA work plan;
- Clear and consistent criteria should be established for the sources of data that will be collected and used;
- The more you drive towards a cookie cutter approach the less likely you will have real outcomes; and
- A responsible entity's own AA process should not be in conflict with guidance provided under section 69505.

Response:

For the reasons explained in the discussion to *Establish a State Sponsored AA or Open Source AA* that option was dismissed—that is, the process is costly to taxpayers and yields little or short term gains. DTSC recognizes that not all AAs will be of equal caliber, and will review the AAs submitted for compliance with the requirements of Article 5. DTSC has included four options for responsible entities to comply with the requirements of Article 5. DTSC is in no way proposing a one-size fits all nor a cookie cutter approach to conducting AAs. Regardless of the approach that a responsible entity elects to take, the Preliminary and Final AA Report, Abridged AA Report, or Alternate AA Work Plan must be submitted for review.

The data submitted to substantiate the findings of the Preliminary and Final AA Report, Abridged AA Report, or Alternate AA Work Plan will be reviewed and evaluated to determine the extent to which that data relied upon is reliable information.

In response to the above comments and overarching input received on Articles 5 and 8, DTSC has revised the proposed regulations to include public review and comment on Final AA Reports to make use of stakeholder input (April 2013). The amended provisions are in section 69505.4(c) (January 2013).

§ 69505.2(c)(3)(C)2 Work Plan for Product Introduced into Stream of Commerce in California

Comment: 68-33

Comment Summary:

In summary, the above comment expressed that the provisions in this subsection are somewhat confusing as they seem to allow new Priority Product(s) containing Chemical(s) of Concern to be placed into the stream of commerce in California, even

after the products have been listed as Priority Products, responsible entities have already conducted their AAs, and DTSC has already imposed a regulatory response (which might actually be a ban or an obligation to replace a Chemical of Concern). This provision should, therefore, be limited until such time that DTSC has imposed a regulatory response for a given Priority Product.

Response:

Given that each responsible entity will undertake an AA of the complexity and rigor that it determines appropriate, it is anticipated that the regulatory responses that are imposed will differ. This provision is intended to address those instances in which a consumer product meeting the description of the Priority Product is first placed into the stream of commerce *after* the listing has occurred. Given that it is impossible to predict the frequency in which this will occur, the provision allows for the responsible entity to enter into the process by providing the alternate process that they used in conducting the AA for the product. The time frames that are afforded, while streamlined, allow for an extension similar to that of a two staged AA. The provision is now found in section 69505.4(c)(1)(D) (January and April 2013).

§ 69505.2(d) Selection of Different Safer Alternatives

Comments: 66-42, 66-43, 76-24, 76-54, 124-21, PH28-2

Comments Summary:

The above comments expressed concerns with or requested clarification of section 69505.2(d), which allows a responsible entity to select a different alternative from the one identified as the selected alternative in the Final AA Report, provided specified requirements are met. In summary, the following concerns were expressed:

- It is not clear who will be ultimately responsible for a product's material content if a manufacturer disagrees with the certified assessor;
- This subpart allows the manufacturer to assume that responsibility, but it is not clear why it may want to do this if a certified assessor has already made a recommendation;
- This section should be eliminated, and 69505.4(c) and 69505.5(j)(2) should be modified to allow multiple alternatives to the Chemical of Concern;
- The only criteria for eliminating an alternative from consideration should be evidence of significant burden shifting;
- Consideration must be given to risk and exposure, impact of the substitution on other safety characteristics and trade-offs;

- Unclear how will DTSC approve research and development plans under this part and section 69505.3; and
- If the revised Final AA Report must be submitted to DTSC sixty (60) days prior to placing the product in the stream of commerce, what is the responsibility of the manufacturer if the proposed selected alternative is already in the stream of commerce?

Response:

The responsible entity, whether the AA is conducted in-house or through contract with another entity, ultimately has the responsibility for the content of the AA reports and any changes that the Priority Product undergoes. The provisions governing certified assessors have been deleted and are, therefore, no longer applicable.

The provisions under this section are options that remain available to responsible entities. The regulations do not specify outcomes; therefore, a wide range of alternatives are allowed to be considered, dismissed, and later reconsidered. As such, this provision allows a responsible entity to change the selected alternative and then re-submit to DTSC the information that led to the change in a revised Final AA Report. The revised Final AA Report is to document the change made, allow DTSC to revise the regulatory responses, if appropriate, and ensure compliance with the revised conditions. The sixty (60) days is comparable to the time provided to DTSC to review a Final AA Report and should be sufficient to ensure compliance. While the proposed regulations do not require that one alternative be selected over another, it is quite feasible that any burden shifting that is observed may be addressed through additional regulatory responses being imposed.

Work plans and/or research and development plans will be reviewed in accordance with the criteria specified in section 69505.7(k). For further discussion, refer to section 69505.5(k)(1)(A) Work Plan and Implementation Schedule of this Response to Comments document.

In response to overarching comments on Article 5, the provisions are now found in section 69505.4(e) (January 2013).

§ 69505.3 Alternatives Analysis: First Stage

§ 69505.3(a) Use of Term Chemical(s) of Concern

Comments: 5-115, 5-126, 5-163, 57-61, 66-44

Comments Summary:

The above comments expressed concern with section 69505.3(a), which establishes a naming convention for ”Chemicals of Concern,” as it pertains to the section. The comments expressed that there is an ambiguity throughout the regulations when the term “Chemical(s) of Concern” is used. In summary, the comments expressed the following:

- Delete the reference to “Chemicals of Concern,” it is not necessary;
- Using the same term, depending on when referenced in the regulations, is confusing; and
- By referring to “Chemical(s) of Concern” in this section to mean the chemical that is the basis for the Priority Product being listed makes the use of this term unclear in other sections. What is meant by Chemical(s) of Concern in those other sections?

Response:

The term “Chemical(s) of Concern,” when used throughout this article, means the chemical(s) in the Priority Product that is/are the basis for a product being listed as a Priority Product. In response to the above and other related comments, as well as streamlining efforts, the above provision has been deleted.

§ 69505.3(b)(1) Step 1: Identification of Product Requirements and Function of Chemical(s) of Concern

Comments: 7-20, 17-2, 36-100, 41-19, 66-45, 72-6, 72-15, 72-16, 72-21, 107-61, 109-16

Comments Summary:

The above comments expressed concern with or requested clarification of section 69505.3(b)(1), which specifies the first of five steps establishing the process for conducting a Preliminary AA. The first step requires the identification of product requirements and function of the Chemical(s) of Concern. The product requirements and the function or role that the Chemical(s) of Concern plays in the Priority Product is fundamental to knowing the alternatives that can or cannot be considered. In summary, the following points were made:

- The use of third-party chemical management certifications should be allowed to be incorporated into the AA process;
- A chemical may have multiple functions in a product and may require multiple changes in ingredients and manufacturing to adequately satisfy those functions;

- There should be a recognition that alternatives need to be “technologically and commercially feasible”;
- Most manufacturing entities will be largely dependent upon materials suppliers for information regarding potential alternatives to specific chemicals;
- The expectation that a “functionally acceptable” alternative encompasses consumer acceptability, compliance with legal requirements, and delivers a finished product that meets or exceeds performance of the original Priority Product must be specified in regulations;
- “Performs sufficiently well,” per section 69501.1(a)(31)(B), is not an acceptable criterion for a functionally acceptable alternative because the weak language suggests a lower or mediocre level of product performance and some level of trade-offs;
- A selected alternative must have acceptable or enhanced performance while reducing or eliminating the potential for harm via reasonable and foreseeable routes of exposure from a product;
- While green chemistry can contribute to achieving greater sustainability, green chemistry programs must recognize the interplay between hazard and exposure rather than take an extreme precautionary approach; and
- The responsible entity must identify all legal requirements associated with the use of the product and may not likely have this information.

Response:

This provision makes specific the first criterion that a responsible entity must take into account in evaluating alternatives for the Priority Product and is consistent with the authorizing legislation within Health and Safety Code section 25253(a)(2)(A). As stated in the ISOR, the responsible entities must evaluate, and later summarize in the Preliminary AA Report, the role of the Chemical(s) of Concern in meeting the performance, technical feasibility, and legal requirements of a Priority Product to adequately evaluate potential alternatives. This information ensures an informed and appropriate comparison of product function criteria between the Chemical(s) of Concern and potential alternatives.

While the regulations do not require the use of third-party chemical management certifications and/or third-party organizations, DTSC appreciates the cost savings that these organizations may play in addressing AA development under the proposed regulations. Responsible entities may employ third-party organizations to assist them in early screening efforts for alternatives to the Chemical(s) of Concern. Third-party organizations can provide manufacturers with resources and materials to make decisions that consider product performance as well as human health and

environmental impacts. For instance, if Candidate Chemicals, as defined in Article 1 and utilized in Article 3, are not already included in third-party organizations' lists of chemicals to avoid, they may begin to target these chemicals and begin to seek alternatives to those chemicals that are application-specific, prior to these chemicals being prioritized as Chemical(s) of Concern.

The term "functionally acceptable," as defined in section 69501.1(a)(35) (January 2013), requires that the alternatives meet all applicable legal requirements, and that the alternative performs the function of the original product sufficiently well so that it can be reasonably anticipated that consumers will accept the product. Performance and efficacy standards are covered in the defined term, and must be considered in the first stage of the AA. Responsible entities must ensure that an alternative complies with all legal requirements for the product. In addition, a responsible entity must consider the performance desired by consumers.

Stakeholders engaged in the development of the proposed regulations have repeatedly recognized that there will be trade-offs between the Priority Product and the alternatives. Further, stakeholders have consistently stated that adverse health and/or environmental impacts should not be compromised at the expense of economic impacts. For example, leaded paint required reapplication every twenty years, while unleaded paint requires reapplication every ten years. While there is a notable difference in performance, the removal or reduction of human health and environmental impacts is significant.

Section 69501.1(a) defines "technically feasible" and "economically feasible," and covers "technically and commercially" feasible. The proposed regulations address a wide range of consumer products, and it is, therefore, impractical to establish performance criteria.

The proposed regulations do not require that a responsible entity select a specific alternative; however, the regulatory responses will be commensurable with the risks posed and impacts requiring mitigation. In response to other comments on Article 5, as well as streamlining efforts, the provisions of this section have been moved to section 69505.5(a) (January 2013).

§ 69505.3(b)(2) Step 2: Identification of Alternatives

Comments: 7-18, 36-64, 39-10, 40-13, 41-19, 66-46, 66-47, 72-5, 72-13, 91-6

Comments Summary:

The above comments expressed concern with or requested clarification of section 69505.3(b)(2), which specifies the second of five steps in the process for conducting a first stage AA. The second step in performing a Preliminary AA requires that the responsible entity identify alternatives, as defined in section 69501.1(a), which meet the function, performance, and legal requirements of the Priority Product. In summary, the following comments were expressed:

- Add, modify, or delete regulatory text to make requirements more explicit, remove ambiguity, and/or remove redundancy;
- Manufacturers should regularly evaluate the life cycle maturity of their products that may dictate the extent to which a product is re-engineered or redesigned;
- Add explicit language providing that "If a responsible entity concludes that eliminating or reducing the concentration of the Chemical(s) of Concern in the Priority Product is not immediately feasible, they should then seek to reduce or restrict the potential for release of the Chemical(s) of Concern, leading to human or environmental exposures," as an interim action until a less or non-hazardous alternative is developed;
- When comparing products, one may see an environmental benefit in one category at the expense of another;
- Indicators of potential exposure may be useful in initial screening or prioritization efforts, but additional information such as use patterns, levels in products above an appropriate threshold and product forms should inform the exposure evaluation;
- Potential for exposure will help identify and eliminate alternatives that may likely adversely contribute to significant exposure through use;
- The regulations need to be very clear that this is about defining alternatives for safer chemical selection and minimizing the potential releases and exposures for Chemical of Concern throughout the life cycle;
- The regulations require that alternatives must "eliminate or reduce the concentration" of the Chemicals of Concern in the product but does not provide any threshold for this; and
- Concern with the requirement that a manufacturer shall consider alternatives posted for consideration by DTSC.

Response:

While DTSC cannot compel a responsible entity to regularly evaluate the life cycle impacts of the products that they manufacturer prior to being listed as Priority Products, regular evaluations will dictate the extent to which a product will require re-engineering or redesign to address any human health or environmental impacts. During stage one

and the corresponding Preliminary AA Report, the goal, scope and range of alternatives being considered in the AA is established. It is during the subsequent second stage that alternatives to the Chemicals of Concern and environmental benefits may be observed at the expense of another. However, it is these differences between the alternatives that become relevant factors that must be further evaluated during the second stage. As stated in the ISOR, during the second stage and the Final AA Report the relevant factors are refined, compared, and assessed.

During the second step of the first stage, responsible entities identify alternatives, as defined, that could meet the Priority Product's requirements such as function, performance, etc. A responsible entity must conduct research and evaluate available information that identifies existing possible viable alternatives for consideration in the AA. This research and evaluation must include, but is not limited to, information posted on DTSC's website. It may be premature to eliminate alternatives during the first stage because additional information such as use patterns and final concentrations of alternative chemicals in a product may not be known. As such, the proposed regulations do not require that alternatives be further considered if preliminary data suggests similar adverse human health and environmental endpoints. However, if the alternatives demonstrate an improvement in one or more adverse human and environmental endpoints, a responsible entity may elect to further evaluate those alternatives in the second stage AA. The proposed regulations seek incremental improvements.

At the completion of the second stage and preparation of the Final AA Report, if a responsible entity concludes that eliminating or reducing the concentration of the Chemical(s) of Concern in the Priority Product is not immediately feasible, regulatory responses will be required to reduce or restrict the potential for release of the Chemical(s) of Concern—through a combination of regulatory responses until a less or non-hazardous alternative is developed. The Chemical(s) of Concern and the Priority Products in which they are contained will be product-chemical specific; consequently, including thresholds in the proposed regulations is impractical.

In response to the above and other related comments, this section has been streamlined to remove the repetitive reference to "eliminate or reduce the concentration of Chemical(s) of Concern" and "alternative" within the same provision. Further, in response to concerns regarding the requirement that a manufacturer must consider alternatives posted on DTSCs website, the requirements have been modified to more accurately reflect that a "responsible entity shall research and evaluate available

information." In response to other comments in Article 5 and streamlining efforts, the revised provisions have been moved to section 69505.5(b) (January 2013).

§ 69505.3(b)(3) Step 3: Initial Screening of Alternatives

Comments: 5-84, 5-114, 5-164, 72-13, 76-55, 118-6, 129-13, 124-21, PH32-7

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.3(b)(3), which specifies the third of five steps in the process for conducting a Preliminary AA. The third step requires a responsible entity to conduct an initial screening of alternatives. In summary, the following concerns were expressed:

- Add, modify, or delete regulatory text to make requirements more explicit and remove ambiguity and/or redundancy;
- The provisions do not allow eliminating alternatives based upon economic, consumer acceptance, or performance considerations;
- The guidance documents should address the question of what is considered an unacceptable alternative because there are many ways to balance different health and environmental impacts;
- Require a simple conceptual model with the Preliminary AA work plans under section 69505.3;
- Elimination of an alternative on the basis of only public health or environmental impacts is ill-advised. Those two types of impacts (by definition) do not include consideration of exposure. Thus, one could eliminate an alternative simply based on hazard traits; when in fact, the exposure profile is such that it is inherently safer than the Priority Product;
- DTSC is limiting the data that will be considered in the AAs by inclusion of the "Ability to cause or contribute to adverse effects" because it is an extremely high burden of proof that is contrary to the statute; and
- Any alternative identified by the responsible entity that poses an equal or greater adverse impact as the Priority Product should be retained in the First Stage AA and discussed in the Preliminary AA Report;

Response:

As stated in the ISOR, this provision makes specific that for the alternatives that include replacement of a Chemical of Concern with another chemical, the Preliminary AA Report must include a comparison of the adverse public health and environmental impacts associated with each chemical being considered as a possible alternative to the

Chemical(s) of Concern in the Priority Product. Comparison of the alternative chemical with the Chemical of Concern's adverse impacts on public health and the environment is of significance in that it is undoubtedly the cause for the listing of the Chemical of Concern and Priority Product. Chemicals that are subsequently evaluated to replace a Chemical of Concern should have "overall" less adverse impacts on public health and the environment.

While the proposed regulations used the terms "potential" or "ability to cause" in Article 3, as part of the prioritization process, that same terminology has not been used in Article 5. The focus of the AA conducted under Article 5 is to quantify and/or qualify the adverse public health and environmental impacts. However, in response to comments in related sections in Articles 2 and 3 the term "potential," previously in earlier versions of the proposed regulations, has been reinstated. It is consistent with Health and Safety Code sections 25253(a)(2) and (3), which mandate that in establishing an identification and prioritization process that at a minimum the "potential" for exposure to a chemical in a consumer product, and "potential" effects on sensitive subpopulations be included. For a more detailed discussion on the appropriateness of the use of the term "potential," please refer to the discussion of Causation at the end of this document.

The provisions have been modified to more accurately reflect that a responsible entity *may* eliminate from further consideration alternatives that have the potential to pose equal or greater adverse impacts than posed by the Chemicals of Concern in the Priority Product. A responsible entity may continue to evaluate alternatives that demonstrate less overall adverse impact than the Priority Product does.

The evaluation during the first stage conducted as part of Step 3 requires that the responsible entity evaluate if the alternatives being considered would have a material contribution to one or more adverse impacts associated with the Chemical(s) of Concern, and/or one or more of the replacement chemicals under consideration. If the responsible entity is considering alternatives that involve removing or reducing the concentration of the Chemical(s) of Concern and using one or more alternative replacement chemicals, quantitative and qualitative information and analytical tools must be used to quantify or qualify the adverse impacts.

The corresponding Preliminary AA Report must include the information that was collected and compared. The requirements in section 69505.7(g)(1) require that the information be presented in a matrix or other summary format that provides a clear visual comparison among the chemical alternatives being considered and their associated adverse impacts (April 2013). The summary may include a conceptual

model that illustrates the routes of exposure being contemplated and evaluated and/or being dismissed if the information and analytical tools that is being used demonstrates that a particular route of exposure may be dismissed. The tools and information that is used must be included in the Preliminary AA Report that is submitted to DTSC.

Further, the provisions in section 69505.5(d)(2) (January 2013) specify that the responsible entity *may* eliminate from further consideration in the AA any alternative replacement chemical(s) that it determines has/have the potential to pose adverse impacts equal to or greater than those posed by the Chemical(s) of Concern, the proposed regulations do not mandate that these alternatives be eliminated.

As stated earlier, guidance materials may be developed to be product-specific if DTSC determines that is appropriate and useful. Similarly, if DTSC determines it is appropriate to develop guidance materials that balance different human health and environmental impacts, it will do so during implementation.

While the provisions do not allow a responsible entity to eliminate an alternative based on economic issues, consumer acceptance, or performance considerations as part of step three, it is allowed as the subsequent step four.

Any alternative that is evaluated and eliminated or retained must be summarized and included in the Preliminary AA Report per section 69505.7(j)(1).

In response to other related comments and overall streamlining, the provisions section 69505.3(b)(3) are now in section 69505.5(d) (January and April 2013).

§ 69505.3(b)(4) Step 4: Consideration of Additional Information

Comments: 5-114, 26-11, 72-18, 72-23, 74-46, 76-56, 114-11, 118-5, 118-7, 126-6

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.3(b)(4), which sets out the fourth of five steps in the process for conducting a Preliminary AA. The fourth step allows a responsible entity to consider other relevant information and data not specifically requested or identified in section 69505.3(b)(1) through (3) and may include factors being considered in the second stage of the AA as part of its evaluation in the first stage AA. In summary the following points were made:

- Add or modify regulatory text to make requirements more explicit;

- Early identification of exposure pathways is important and must be included in the Preliminary AA Report so that any inadvertent omissions or inaccuracies can be addressed at the beginning of the AA process;
- Trade-offs, inclusively of economic trade-offs, must be understood and considered before moving forward to avoid unintended consequences;
- Social benefits and consumer acceptance are inherent in the demand for the products and must be included in the evaluation of any alternatives;
- Each manufacturer must be given the latitude to leverage existing tools and approaches to evaluate alternative ingredients/components for their products, as appropriate;
- Allow for a gradual and measured implementation of appropriate or suitable alternatives to ensure that an alternative formulation meets legal requirements, especially when considering patent issues and other state and federal regulations;
- Any criteria should be valid for eliminating alternatives at this step; and
- Include a formal public comment and/or participation process for the Preliminary AA Report.

Response:

As stated in the ISOR, the fourth step allows a responsible entity to consider other relevant information and data not specifically requested or identified in section 69505.3(b)(1) through (3). Step four allows a responsible entity to include factors during the first stage that they believe may significantly influence the alternative that is selected for further evaluation. This provision provides responsible entities latitude in considering other factors that they consider relevant and significant in identifying viable alternatives. This includes economic, consumer acceptance, or performance considerations; however, those findings must be included in the Preliminary AA Report.

The first stage, and the corresponding Preliminary AA Report, is the first of two stages and does not require a feasibility check at this stage. A feasibility study—for example, economic evaluation, consumer acceptance, and phasing/implementation of a safer alternative into the marketplace—is more adequately placed under the second stage and the corresponding Final AA Report. Please refer to the Response to Comments under those sections. A responsible entity may include any criteria to narrow the number of alternatives in the first stage that move forward for more in-depth analysis during the second stage. The criteria used to narrow the number of alternatives must be included in the Preliminary AA Report. Further, a responsible entity may reconsider during the second stage an alternative that was dismissed in the first stage.

Trade-offs, inclusive of economic impacts, may not be fully understood during this early preliminary stage. However, if the responsible entity has sufficient information to fully understand the full impacts, that information may be used and included in the Preliminary AA Report. A responsible entity may use existing tools and approaches to scope and preliminarily evaluate alternative ingredients for their products, social benefits, and consumer acceptance—provided those tools are also included in the Preliminary AA Report. As stated in the ISOR, the first stage and corresponding Preliminary AA Report establish the goal, scope, and range of alternatives being considered in the AA. The exposure pathways are identified during this stage, it is during the subsequent second stage and Final AA Report that the relevant exposure pathways/factors are refined, compared, and assessed.

In response to the above and other related comments, the proposed regulations dated July 2012 have been amended to include a public review and comment of Final AA Reports in section 69505.8 to make use of stakeholder input (April 2013).

§ 69505.3(b)(5) Step 5: Identification of Next Steps

Comment: 76-57

Comment Summary**:**

The above comment expressed concern and requested clarification of section 69505.3(b)(5), which sets out the last step in the process for conducting a Preliminary AA. The comment expressed the view that the intended content of the work plan is not clear. DTSC should provide more specifics about the level of detail required for each work plan. For example, it would be helpful to clarify if is intended to be merely a schedule or if it must list activities and estimated milestone dates.

Response:

In response to the above and other related comments, as well as general streamlining efforts, the provisions in section 69505.5(k) have been modified. The revised provisions more specifically address the contents of the work plan and other interim milestones that must be achieved and reported on, if applicable, and are now found in section 69505.7(k) (January and April 2013).

Alternate Process to First Stage

Comment: 76-7

Comment Summary:

In summary, the above comment stated that the proposed regulations should be modified to add the establishment of a DTSC-led AA program during the second stage. Once a chemical is added to the Chemical(s) of Concern list and determined by DTSC to be present in Priority Products for which an AA must be conducted, DTSC must facilitate the performance of an AA for the major use(s) of that Chemical(s) of Concern in the Priority Products. The state sponsored AA must be open to participation by any interested stakeholder including manufacturers, distributors, retailers, non-governmental organizations, academic institutions, manufacturer consortia, trade associations, and individuals. The comment further states that:

- DTSC must ensure the AA is conducted such that it meets the requirements of Article 5;
- Participation in a DTSC-led AA must not limit a responsible entity from performing a separate AA as described in Article 5; and
- Participants in a DTSC-led AA must be subject to data call-ins by DTSC, pursuant to completing the AA with provisions for protection of trade secrets per section 69510.

Response:

Although the section number cited in the comment directed the comment for inclusion during the second stage AA, the content of the comment is more closely aligned with the first stage AA. The recommendations are closely aligned with the comments expressed suggesting a state sponsored AA. As discussed earlier, DTSC does not have the funding or staffing to develop a state sponsored AA. DTSC is not making any changes to the regulation in response to these comments. Please refer to the discussion under Establish a State Sponsored AA or Open Source AA of this Response to Comments document for details on the limitations of a state sponsored AA.

§ 69505.4 Alternatives Analysis: Second Stage

§ 69505.4(a)(1) Step 1: Identification of Factors Relevant for Comparison of Alternatives

Comments: 5-165, 5-166, 9-100, 39-24, 39-30, 64-13, 66-48, 68-34, 72-12, 73-14, 74-55, 74-56, 129-14

Comments Summary:

The above comments expressed concern with or requested clarification of section 69505.4(a), which sets out the first of five steps in the process for conducting the Final AA. The first step during the second stage is the identification of factors that are

relevant for an in depth comparison. In summary, the following concerns were expressed:

- Add or modify regulatory text to make requirements more explicit;
- Guidance needs to be developed to quantify demonstrable contributions, demonstrable differences, and how the factors are to be weighed or not;
- The range of factors to be analyzed during the second stage of the AA is extremely broad, which makes it very difficult to conduct the analysis within reasonable cost and time. For many parameters, it will be virtually impossible to find the required data, and this will be even more complicated if products are manufactured in third world countries;
- The use of quantitative analysis tools like quantitative structure/activity relationship models should be allowed to facilitate comparison. There are a number of widely accepted tools for filling data needs, including the use of molecular similarity, read across, and a number of computational methods. Adequately validated tools should be utilized during the hazard data gathering phase;
- It is not clear what recourse, if any, the manufacturer has if DTSC or the certified assessor second guesses the manufacturer;
- The AA should focus on relevant factors and set aside irrelevant ones which will have limited-to-no significant and meaningful impact on the outcome;
- The use of the word “demonstrable” inappropriately implies that even the slightest impact or change would be relevant;
- In the same spirit of AB 1879, with the goal of significantly reducing adverse impacts, “demonstrable” should be replaced with “significant.” Significant is an appropriate term and is used as a standard in numerous other places in the proposed regulations; and
- What criteria will be used to judge when an alternative makes a “demonstrable contribution” to one or more adverse public health, environmental, waste, end-of-life, and/or materials and resource consumption impacts of the Priority Product?

Response:

As stated in the ISOR, the principal goal of the second stage and subsequent Final AA Report is to further evaluate the alternatives identified in the first stage. The second stage of the AA and companion Final AA Report requires the collection and use of available information and tools to identify the relevant factors and an evaluation of those factors to qualify or quantify the impacts posed by the alternatives being evaluated. The second stage simultaneously addresses the thirteen statutory (A) through (M) criteria in Health and Safety Code section 25253(a)(2) and multimedia life cycle factors.

Relevant factors are those factors that materially contribute to the adverse effects of the product and will have material differences in the impacts observed between the alternatives being considered and the Priority Product. If, for example, the Priority Product and the alternatives being considered all have the same amount and type of environmental impact, those impacts need not be further evaluated. If, however, the Priority Product was prioritized for its adverse air impacts because of its green-house gas emissions and the alternatives being considered have varying degrees of reduction in green-house gas emissions, those factors are relevant and must be further evaluated.

The number and types of products that the regulations will address dictate that guidance documents be developed for product types and/or sector-specific consideration to address weighting factors, and/or the appropriate use of specific quantitative analysis tools like quantitative structure/activity relationship models. The regulations do not restrict the use of any available tools or models. However, any tools and/or models used must be included and summarized in the Preliminary and/or Final AA Report, as appropriate.

DTSC will not second guess the manufacturer, and DTSC will review the AA Reports for compliance with the requirements of Article 5. The responsible entity has the ultimate and final decision on what alternatives are further evaluated and implemented as the safer alternative. DTSC, however, may impose regulatory responses it determines to be appropriate to mitigate any human health and environmental impacts that remain after the responsible entity selects an alternative or decides to retain the Priority Product.

The proposed regulations do not weight subparagraphs (A), (B), or (C) and are all relevant for all comparisons of the Priority Product and alternatives considered. While the proposed regulations do not require responsible entities to fill all data gaps during the second stage, that requirement may be imposed as part of the regulatory response. Manufacturers, whether located in the U.S. or in third world countries, may collaborate to gather the required data to offset costs. However, the scope of the factors being analyzed and reported during the second stage of the AA and corresponding Final AA Report may make it increasingly difficult to work with multiple manufacturers, consortia, or other collaborative.

In response to the above comments, the term “demonstrable” has been deleted and the term “material” contribution inserted in its place. While “significant” is used in other places in the proposed regulations, the use of “significant” in the context of evaluating relevant factors is not desirable. DTSC does not want responsible entities to struggle

with which factors are “significant” or not. Use of the term “significant” could potentially create long-term compliance issues. “Significant” was deleted from earlier versions of the proposed regulations because it is not as well understood and is inherently vaguer than “demonstrable” or “material” contribution. DTSC agrees that the use of the word “demonstrable” inappropriately implies that even the slightest impact or change would be relevant, which is not the desired intent.

”Material” contribution, as is used in the proposed regulations dated January and April 2013, gets at a contribution that is important or substantial enough to influence or affect an outcome. ”Material” better captures the notion that not every provable or confirmable contribution (*i.e.*, a “demonstrable” one) is important. “Material,” in effect, means that something is either qualitatively and/or quantitatively important to the outcome. The connotation of a material contribution is one that is noteworthy and meaningful. As such, it is a good term to distinguish relevant factors that makes a material contribution from one that does not. Further, “material” is a term that is commonly used and well-understood in many legal contexts.

In response to the above and related comments, as well as streamlining efforts, the provisions have been moved to section 69505.6(a) (January 2013).

§ 69505.4(a)(2)(A) Multimedia Life Cycle Factors Relevant for Comparison

Comments: 1-9, 9-88, 9-89, 11-43, 36-106, 40-6, 40-10, 57-62, 73-15, 74-54, 74-57, 74-58, 81-4, 126-6, 129-16

Comments Summary:

The above comments expressed concern with section 69505.4(a)(2)(A), which requires that the responsible entity collect and use available information on the multimedia life cycle impacts and chemical hazards for chemical ingredients known to be in the Priority Product and the alternatives being considered. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit, and constrain the scope of AAs;
- The multimedia life cycle impacts and chemical hazards assessment should be limited to the Chemical(s) of Concern in the Priority Product that are the subject of the alternatives assessment and not all ingredients in the product, which vastly expands the scope of the AA;
- "Extraction of raw materials" should be added to the life cycle impacts listed;

- Not all studies are equal—a tool for scoring the reliability of toxicology studies is necessary;
- The emphasis on evaluation of full life cycle is important;
- Expanding the focus to a comprehensive analysis of all chemicals found in the product would divert resources from the real purpose of the AA, significantly extend the time necessary for AA completion, and put the green chemistry program in jeopardy of never achieving its objectives of significantly reducing adverse impacts to public health and the environment;
- DTSC should at least explicitly require that AAs consider the effects of switching to an alternative on the opportunities to make beneficial use of recycled materials;
- The list of impacts is confusing and overlapping—each term here should be clearly defined;
- Manufacturers are required to disclose the full composition of their product; however, per section 69501.1(a)(33), they cannot claim confidential business information protection unless the chemicals are totally hazard free;
- Manufacturers' proprietary compositions will be publicly disclosed, resulting in a large transfer of intellectual property to foreign competitors;
- The hazard constraints on what can be claimed as a trade secret need to be narrowed;
- It will be difficult to obtain product exposure information relating to manufacturing, use, storage, transportation, and end-of-life management practices, as well as the locations of these practices;
- It becomes increasingly difficult to monitor the exact movement of products once they are sold to distributors and to primary and secondary retailers;
- The regulations establish a process for evaluating chemical concerns in consumer products (and their potential alternatives) to determine how to best limit exposure or to reduce the level of hazard posed by Chemicals of Concern, which seems to imply a focus on hazard reduction, while the "(A) through (M) criteria" list for the life cycle impact assessment encompasses a much broader range of endpoints;
- Most consumer products find their way to a landfill or recycle stream at the end of their useful life. It is impractical for a manufacturer to know that location at the time of production or sale;
- End-of-life management practices are predisposed by municipalities in which the products reach the end of their useful life a manufacturer would clearly know that location at the time of production or sale; and

- The regulations should hold regulated entities accountable only for information that it can reasonably be expected to obtain.

Response:

In response to the above comments, the provisions in this section were modified to make more explicit that the scope of the AA is restricted to the Chemicals of Concern and any chemical in the alternatives that differ from the chemicals in the Priority Product. That is, if multiple chemicals are added to replace one Chemical of Concern in a product, then those chemicals must be included in the AA (January 2013).

The terms used in section 69505.4(a)(2)(A) are defined in section 69505.1(a). As stated in the ISOR, the definitions make a distinction between “materials and resource consumption impacts” as that term is used in section 69505.5(c)(2)(E) and ”manufacturing costs” included in the subsequent section 69505.6(a)(3) (January and April 2013). It is important to maintain this distinction to be consistent with the intent and goals of AB 1879. Extraction of raw materials is included under the term “materials and resource consumption” as defined in section 69501.1(a)(45) (January 2013) and includes all life cycle impacts.

The guidance materials that may be developed for product types and/or sector-specific consideration may address weighting factors and/or the appropriate use of specific quantitative analysis, if appropriate. The regulations do not restrict the use of any available tools or models. However, any tools and/or models used must be included and summarized in the Preliminary and/or Final AA Reports, as applicable.

The evaluation required during the second stage AA is consistent with the intent and goals of AB 1879 and emphasizes an evaluation of the full life cycle of a Priority Product or the alternatives to it that are being considered. If a responsible entity uses recycled material as its feedstock, and the resulting product contains contaminants that are later listed as a Chemical(s) of Concern/ Priority Product, the responsible entity may include in its evaluation the ramifications of switching to a feedstock that is virgin material. The regulations do not require a particular outcome of the AA; however, the responsible entity for a Priority Product must evaluate if an alternative exists and the human health and/or environmental impacts associated with those alternatives. This section does not specifically require that an analysis consider whether switching to an alternative might eliminate the use of a recycled raw material stream and the attendant loss of environmental benefits. However, this can be considered and included pursuant to section 69505.6(c) Consideration of Additional Information (January 2013).

In addition, the provisions do not require that a responsible entity identify the “location” of where manufacturing, use, storage, transportation, or final disposal at a landfill is identified. The proposed regulations require that the above-mentioned activities be taken into account when evaluating the Priority Product against a number of alternatives. For example, if a manufacturer produces a Priority Product that requires handling as a hazardous waste at the end of its useful life while the alternatives are not hazardous at the end of their life, the multimedia comparison must address the divergent impacts.

Consistent with Health and Safety Code section 25253(a)(2) of the authorizing legislation, the proposed regulations require a process that takes into account the life cycle impacts and economic impacts of the Priority Product and potential alternatives using life cycle assessment tools. End-of-life management has typically fallen on municipalities, and costs have been passed on to the public, taxpayers, and/or government; DTSC believes it was the intent of the Legislature to depart from this paradigm.

Health and Safety Code section 25257(f) specifies that the trade secret provisions do not apply to hazardous [sic] trait submissions for chemicals and chemical ingredients. DTSC is not authorized to narrow the scope on the information that may be claimed trade secret. The proposed regulations address trade secret issues in Article 9 of the January 2013 version of the regulations (previously Article 10 in the July 2012 version). While manufacturers must disclose the full composition of their products to DTSC, they may claim trade secret protection for certain pieces of information. This protects that information from being disclosed to the public. The reader is directed to the detailed discussion of trade secret provisions for more information on this topic.

§ 69505.4(a)(2)(B) Product Function and Performance Factors Relevant for Comparison

Comments: 57-62, 72-3, 74-62, 107-67, 129-15

Comments Summary:

The above comments expressed concern with section 69505.4(a)(2)(B), which requires that the responsible entity identify the principal and manufacturer-intended uses or applications, the functional and performance attributes, and the applicable legal requirements for the Priority Product. In summary, the following concerns were expressed:

- When conducting AAs, “commercial viability” of each alternative should be evaluated;
- There are a number of elements in the AA Report that a consortium of companies, a public-private partnership, or a trade association would not be permitted to discuss, evaluate, and report on because of federal antitrust restrictions. Among those restrictions are the communication or exchange of confidential competitive information (69505.4(a)(2)(B)1. and 2.), discussion of prices of ingredients or products and internalized costs to businesses (section 69505.4(a)(2)(B)3. and (C)), and discussion of business plans (section 69505.4(c));
- Make consumer acceptance explicit among the factors listed in section 69505.4(a)(2)(B); and
- This subsection calls for the determination of whether there exists a technically and economically feasible alternative. Since this section deals only with technical performance and not economic performance, this subsection should focus on technical feasibility only. We recommend that technical and economic feasibility be separated into two definitions.

Response:

In response to the above comments and general streamlining efforts, the provisions have been modified and are now in section 69505.6(a)(2) (January and April 2013). Editorial changes were made in sections 69505.6(a)(2)(A) and (B). However, a more substantive change was also made in section 69505.6(a)(2)(C), to decouple the terms technical and economically feasibility. The corresponding changes were made in section 69501.1(a) under definitions; to be “functionally acceptable,” as well as “technically feasible” and “economically feasible” are distinct and separate terms (January and April 2013).

Section 69505.6(a)(2)(A) through (C) specifies the “minimum” functional and performance attributes that must be evaluated (January and April 2013). At a minimum, a responsible entity must consider and include in the Final AA Report information on:

(A) The useful life of the Priority Product, and that of the alternatives under consideration;
(B) The function and performance of each alternative relative to the Priority Product and other alternatives under consideration; and
(C) Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.

Information regarding “commercial viability” and “consumer acceptance” as requested by the comments may be included but is not required. The responsible entity may elect to include other factors it determines influence the selection of an alternative provided that information is included in the Final AA Report.

As noted in responses to comments related to the first stage of the AA and the corresponding Preliminary AA Report, while the provisions allow for responsible entities to contract, form a consortium, collaborative, or other similar partnership to assist them in complying with the requirements specified in Article 5, they are not required to do so. Therefore, DTSC does not agree that the provision creates antitrust problems. Manufacturers may choose to join or form a collaborative and /or consortium or independently comply with the requirements and submit their work to DTSC within the time frames allotted.

Any contractual arrangements between competing businesses and any contractors, a collaborative, and/or consortium must address issues regarding release of trade secret information—whether that arrangement takes place pursuant to these regulations or any other regulatory scheme. The regulations do not change this sort of arrangement. Consultants frequently work for multiple clients and are privy to trade secret information. This concern is typically addressed by the use of nondisclosure agreements between the responsible entities, their consultants, and/or their clients.

§ 69505.4(a)(2)(C) Economic Impacts

Comments: 1-5, 5-30, 11-44, 36-108, 39-31, 66-49, 73-16, 73-17, 74-59, 74-60, 74-62, 76-23, 76-24, 76-59, 95-7, 101-33, 107-69, 118-12, 138-18

Comments Summary:

The above comments expressed concern with section 69505.4(a)(2)(C), which requires that the responsible entity evaluate and compare the economic impacts of the Priority Product and the alternatives being considered. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit and constrain scope of AAs;
- Specify a methodology or provide guidance to be used in carrying out the economic analysis;
- Require an economic analysis only when a responsible entity is seeking continued usage of the Chemical(s) of Concern and that no analysis is required otherwise;

- Economic impacts should be eliminated, as this will be well beyond the expertise of most responsible entities;
- The information may be relevant to DTSC with respect to a regulatory response; however, DTSC should find a more appropriate means of generating this data;
- Cost impacts need to explicitly include externalized costs related to public health, occupational health, and the environment which will be borne by society and the taxpayer stemming from the life cycle factors cited in section 69505.4(a)(2)(A);
- Cost impacts to the public and private institutions and society at large must be considered inclusive of health care due to injury or illness, job loss, and other costs borne by society at large;
- Delete “marketing costs,” as there will be a huge range in level of marketing among responsible entities such as “boutique” nail polish and other salon product manufacturers;
- The economic impacts in subpart (a)(2)(C) do not include research and development costs of using new materials, as well as performance and other testing;
- A manufacturer‘s operating margin is not a good choice as a criterion for the definition and determination of a technically and economically feasible alternative;
- The proposed regulations should additionally allow the responsible entity to also consider the availability of the “functionally acceptable” alternative, affordability, and the cost to produce the product;
- Government and not industry is responsible for making public policy decisions;
- More clear and concrete criteria need to be established by which the regulated entity understands what is required to satisfy this provision;
- Economic impact analyses, as described here, are extremely difficult to perform and add little to DTSC’s ability to select appropriate regulatory actions;
- Accounting for all projected direct and indirect cost impacts during the life cycle of the product, and the alternatives being considered, include, among others, costs to government agency, public, waste, and end-of-life management costs—which is so wide and far-reaching that it becomes nebulous and completely unclear how a manufacturer might account for these in any sort of standardized and broadly acceptable way;
- This is far too broad and complex an undertaking for almost any business, as most would be hard pressed to even provide estimates for all the factors involved. More importantly, there is insufficient agreement on the methodologies and scope to be used to deliver useful, reproducible results—and even those results will only be estimates; and

- Consider more deeply the costs associated with mitigating water pollution impacts after they occur under section 69505.4(a)(2)(C).

Response

Consistent with Health and Safety Code section 25253(a)(2)(M) of the authorizing legislation, the proposed regulations require a process that takes into account the economic impacts of the Priority Product and potential alternatives using life cycle assessment tools. The economic impacts must address the impacts across the life cycle (*i.e.*, from raw materials extraction through materials processing, manufacture, distribution, use, repair or maintenance, and disposal or recycling) associated with the Priority Product or any alternative(s) considered. The requirements specified in the proposed regulations are consistent with commonly used principles in product assessment and reformulation. While externalized costs may have been traditionally passed on to the public, taxpayers, and/or government, DTSC believes it was the intent of the Legislature to depart from this paradigm. This view is consistent with the statutory requirement that economic impacts be considered as part of the AA.

As indicated in the ISOR, the proposed regulations contain requirements that are not new. The requirements parallel popular life cycle assessment tools for evaluating and/or taking inventory of the impacts of products or services. The criteria included in the proposed regulations are commonly taken into account by manufacturers who are faced with balancing choices and making tradeoffs, when re-manufacturing a product, to address a consumer or market need or demand. The AA process in the regulations is consistent with commonly used life cycle assessment tools and does not require an ISO compliant process. While manufacturers may have traditionally focused on economic impacts, as it pertained to their bottom line or profits, the proposed regulations require that a responsible entity take into account the long-term impacts associated with a Priority Product and the alternatives that are considered.

While the capacity to assess or monetize externalized costs may currently be lacking, the proposed regulations create a demand for this capacity; and, as the program matures and is further addressed through guidance documents, this need will be met.

Consistent with Health and Safety Code section 25253(a)(2)(M), an economic impact analysis is required under all instances, whether a Priority Product is retained or a safer alternative is selected. Externalized costs including, public health, environmental costs (e.g., costs associated with mitigating water pollution or costs related to special handling at the end of a product's useful life), and costs associated with government agencies to manage the Priority Product as a waste requiring special handling must be included.

However, if the responsible entity elects to retain the Priority Product, the economic impact must include the internal cost impacts in the Final AA Report.

While research and development costs are not specifically called out in this provision, they may be included as part of the internal economic costs that a responsible entity considers.

In response to the above comments and general streamlining efforts, this section has been modified two include two tiers and is now in section 69505.6(a)(3) (January and April 2013).

The first tier must be addressed whether the Priority Product is retained or an alternative is selected. Section 69505.6(a)(3)(A) requires that the responsible entity evaluate, monetize, and compare the relevant exposure pathways and life cycle segments the impacts of the Priority Product and the alternatives on:

1. Public health and environmental costs; and
2. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.

Section 69505.6(a)(3)(B), the second tier, requires that if the responsible entity's alternative selection decision to retain the Priority Product is based in whole or in part on internal cost impacts, this decision must be explained in the Final AA Report. The Final AA Report must include a quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs (January 2013).

§ 69505.4(b) Step 2: Comparison of Priority Product and Alternatives

Comments: 5-127, 5-128, 29-19, 66-50, 68-34, 74-54, 74-61, 76-22, 76-60, 107-70, 129-17

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.4(b), which is the second of the five steps in the process for conducting a Final AA. The second step requires that the responsible entity use available information and analyses to evaluate and compare the Priority Product and each of the alternatives being considered. The provisions detail eight (8) criteria that must be identified and included in the Final AA Report. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit and/or constrain scope of AAs;
- Items 1-8 should be expanded on to include weighting criteria or deleted because they are too prescriptive;
- Need guidance using life cycle impact assessment multimedia models on how to weigh relevant criteria;
- Use of tools will provide important information but will not be conclusive regarding the final decision or assessment; and
- Weighting of the factors involved will have a significant effect on the outcome, and only the technical expertise of the manufacturer and assessor will be able to adequately weigh factors in the assessment.

Response:

In response to the above comments, the provisions formerly in section 69505.4(b)(1) through (8) have been deleted. DTSC has determined that any weighting of factors would be more appropriately addressed through guidance materials. The remaining provisions are now located in section 69505.6(b) (January and April 2013). Guidance materials that may be developed for product types and/or sector-specific consideration will address weighting factors and/or the appropriate use of specific quantitative analysis, if appropriate.

As indicated earlier, the number and types of products that the regulations will address dictate that guidance documents may be developed for product types and/or sector-specific considerations to address weighting factors and/or the appropriate use of specific quantitative analysis tools like quantitative structure /activity relationship models, if appropriate. That is, it cannot effectively be done in regulation. The regulations do not restrict the use of any available tools or models. However, any tools and/or models used must be included and summarized in the Preliminary and/or Final AA Report.

§ 69505.4(c) Step 3: Alternative Selection Decision

Comments: 11-45, 76-20, 76-61, 124-21, PH28-2

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.4(c), which is the third of five steps in the process for conducting a Final AA. The third step requires that the responsible entity select an alternative based on the comparative analysis that was conducted in step two. If the decision is to retain the

Priority Product, the responsible entity must include the information that led to this decision. In summary, the following concerns were expressed:

- This is a business decision and should be eliminated as it is inappropriate and impractical for responsible entities to be incorporating their business plans in an AA Report;
- The real issue with the AA is the absence of an explicit standard for a responsible entity to choose or reject an alternative or for DTSC to reject the responsible entity's choice;
- Comparative analyses are much easier to do than a full-fledged analysis of each alternative;
- There will be considerable uncertainty of any quantitative value, thus making determination of the alternative with the lowest adverse effects difficult to ascertain. If uncertainty ranges overlap, it would be difficult to determine the alternative with the lowest adverse impacts, and this should be acknowledged;
- The purpose of the second stage is to identify any significant burden shifting that would be expected to occur if an alternative were widely adopted, and potentially to use that information as a basis for deciding that an alternative is acceptable;
- Alternatives that do not pose an equal or greater risk of adverse impacts should be considered acceptable;
- Replace "the alternative" with "the three best alternatives" to allow DTSC to make much more sensible regulatory choices that maximize protection of public health and the environment;
- Responsible entities are forced to select and implement a single alternative to a Chemical(s) of Concern in a Priority Product, notify DTSC if another alternative is later used, and requires that DTSC approve replacements; and
- By forcing a single alternative to be chosen and by inserting DTSC into the selection process, the following issues are created:
    - Potentially forces the use of an inappropriate or sub-optimal solution since DTSC does not have subject matter experts on staff;
    - Creates the risk that environmentally preferable alternatives not be adopted because they are not fully developed; and
    - Fails to take full use of the supply chain to find innovation solutions.

Response:

The responsible entity has the ultimate and final decision on what alternatives are further evaluated and implemented as the safer alternative. A responsible entity may elect to carry more than one alternative forward for additional research and development; however, it is not required. The proposed regulations specify the

minimum threshold for what must be done as part of the AA. DTSC does not select or mandate that a specific alternative be selected, it is a business decision reserved for the responsible entity. Further, responsible entities may continue to evaluate as many alternatives as they choose but may eliminate from further consideration any alternative that poses greater or more adverse impacts than the Priority Product. However, DTSC believes that by narrowing the number of alternatives that are moved forward, costs incurred by the responsible entity may be significantly reduced. As such, the scenarios envisioning that DTSC may impose inappropriate or sub-optimal solutions and thus create prevent environmentally preferable alternatives from being adopted, is unfounded. Again, this is because DTSC is not selecting the alternative—the responsible entity is. Responsible entities are free to continue to make full use of the supply chain to find innovative solutions.

DTSC will impose the regulatory responses it determines are necessary to mitigate any human health and environmental impacts, regardless of how many alternatives were advanced for further evaluation. If a responsible entity submits a Final AA Report selecting an alternative, and later reconsiders another alternative, the Final AA Report must be amended to include the new alternative. DTSC does not “approve” the new alternative, but rather ensures that the appropriate regulatory responses are put in place to address any impact from the selected alternative.

Changes in response to the above comments were not deemed necessary.
In response to general streamlining efforts, the provisions are now found in section 69505.6(d) (January 2013).

§ 69505.4(d) Step 4: Consideration of Additional Information

Comments: 76-62

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.4(d), which is the fourth of five steps establishing the process for conducting a Final AA. The fourth step allows a responsible entity to consider other relevant information and data not specifically requested or identified in section 69505.4(b), and may include factors being re-considered from the first stage of the AA as part of its evaluation in the second stage AA. In summary, the following concern was expressed:

- Subpart (d), considering additional information, should be performed before an alternative is selected (currently subpart (c)).

Response:

In response to the above comment, this provision has been moved to more appropriately be included prior to the selection of an alternative. The provision is now found in section 69505.6(c) (January 2013).

§ 69505.4(e) Step 5: Identification of Next Steps

Comment: 76-63

Comment Summary:

The above comment expressed concern or requested clarification of section 69505.4(e), which is the last step in establishing the process for conducting an AA and completing the Final AA Report—containing the evaluation that was conducted and submitted to DTSC for review. The comment requests that the section be simplified such that the Final AA Report content requirements are all in one place.

Response:

In response to the above and other related comments, the substantive provisions in section 69505.5 have been retained and streamlined, and are now contained in section 69505.7 (January and April 2013).

Create a Process to Deselect a Priority Product

Comment: 107-68

Comment Summary:

In summary, the above comment requests a process to “declassify” a Priority Product once the AA process and subsequent regulatory response implementation result in definitive results. DTSC should narrow its focus to product-chemical combinations that truly contribute to significant adverse public health and environmental impacts, and an AA would be beneficial and would improve the safety profile for public health and the environment. When definitive results have been achieved, DTSC should declare success and move on to other Priority Products and not leave the “Priority Product” designation attached to a manufacturer’s product. The value chain may perceive the persistence of such a moniker as cause for de-selection or other undesirable market pressures.

Response:

As indicated in the ISOR, the proposed regulations are consistent with Health and

Safety Code section 25252 of the authorizing legislation. The prioritization processes in Articles 2 and 3 focus on Candidate Chemicals that have adverse impacts on public health and the environment. When consumer products are identified as the source of exposure to the Candidate Chemical(s), those products may be listed as Priority Products containing Chemical(s) of Concern (January 2013). They are prioritized, at a minimum, by the following factors:

(1) The volume of a chemical in commerce in California;
(2) The potential for exposure to a chemical in a consumer product; and
(3) Potential effects on sensitive subpopulations, including infants and children.

The goals and intent of AB 1879 are to find alternatives to Chemicals of Concern to reduce adverse public health and environmental impacts, regardless of whether alternatives have been identified or not. Priority Products will be listed with the Chemical(s) of Concern, their hazard traits, and if applicable, whether the entire product or components of the products are under scrutiny. It is not certain, at the onset of the program, that Priority Products will be listed by brand names. Thus, if a household cleaning product containing a Chemical of Concern is named a Priority Product, household cleaning products containing those Chemical(s) of Concern will be of concern. As such, it is impractical to create a delisting process. However, if a similar cleaning product is manufactured that does not contain the Chemical(s) of Concern the product will not be a Priority Product. DTSC is making no changes to the regulation.

§ 69505.5 Alternatives Analysis Reports

§ 69505.5(a)(1)-(5) General Provisions Applicable to AA Reports

Comments: 5-129, 5-167, 9-56, 11-46, 36-76, 36-94, 66-51, 129-18

Comments Summary:

The above comments expressed concern with section 69505.5(a)(1) through (5), which contain the general provisions that all AA Reports must comply with. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit;
- The responsible entity is required to provide sufficient information, which is not defined for the Final AA Report, for DTSC to determine the appropriate regulatory response. The responsible entity cannot know what information is sufficient for DTSC to make a decision. This requirement is unnecessary and inconsistent with the statute and should be eliminated from the regulations;

- DTSC must develop specific guidelines for masking strategies as part of the AA guidance published at the adoption of these regulations; and
- The language should be modified to clarify that DTSC has the authority to substantively review the AA Report.

Response:

"Sufficient," as is used in the proposed regulations, has the same meaning as the commonly understood meaning "of a quantity that can fulfill a need or requirement" and does not require defining under the regulations. Health and Safety Code section 25253(b) requires that DTSC may take a range of regulatory responses upon completion of an AA, and this section of the regulations is, therefore, not inconsistent with the authorizing legislation. In response to the above comments, DTSC has amended the provisions to make more specific the requirement that sufficient information must be provided in order for DTSC to determine compliance with the substantive and administrative requirements of Article 5, or the selection of the appropriate regulatory responses, and the appropriate due date for submission of the Final AA Report or final Abridged AA Report. The new provisions are found in section 69505.7(a)(2) (January 2013). In accordance with section 69505.9 of the proposed regulations, DTSC will review the AA Reports and Alternate Process AA Work Plans for compliance with the substantive and administrative requirements of Article 5 (January and April 2013).

Unlike conducting an AA, which is a new and rapidly emerging field, DTSC did not see the need in the drafting of the regulations to commit to drafting guidance materials regarding masking of trade secret information—to the extent masking is authorized under section 69510(g) (renumbered to 69509(g) in January 2013). Many industries may already be familiar with masking strategies, such as preparing disclosures to comply with securities laws or voluntarily describing confidential technology to prospective business partners. As such, DTSC will not be amending the regulations in response to these comments. Nonetheless, DTSC is certainly willing to work with interested parties during the implementation of the regulations if they seek assistance from DTSC in complying with this provision. For additional discussion on trade secret protection, please refer to Article 10 of this Response to Comments document.

§ 69505.5(a)(6) Alternatives Analysis Reports Made Public/Public Input

Comments: 9-56, 11-42, 29-18, 36-93, 36-94, 36-96, 68-31, 72-4, 72-19, 72-20, 73-10, 110-1, 126-4, PH17-6, PH32-6

Comments Summary:

The above comments expressed concern with section 69505.5(a)(6), which requires that responsible entities maximize the amount of information that is contained in the Preliminary and Final AA Reports, which can be made available to the public, while maintaining legitimate trade secrets. In summary, the following concerns were expressed:

- Absent public input, the public is unlikely to have confidence in the decisions made by the program since the responsible entities have a vested interest in the outcome of the AA;
- DTSC should rely on the public, as well as a manufacturer's competitors, to ensure that the AA is factual and represents a good faith effort to reduce the use of toxic chemicals;
- Without reasonable limits on the information that can be claimed as confidential in AA Reports, there is no way for the public to maintain its critical role as watchdog over this important part;
- Since regulatory responses are based on the content of AA Reports, it is essential that there be a mechanism for the public to register questions or objections to information in the Preliminary and Final AA Report, the Abridged AA Report and/or the Alternate Process Work Plan;
- A publicly available executive summary of both the Preliminary AA Report and Final AA Report should be accompanied by a public comment period before DTSC accepts the findings of either document;
- A formal comment period provides greater transparency, ensures higher quality AAs, and leads to better results since stakeholders may provide insights that may be overlooked by both certified assessors and DTSC staff;
- Proposed product stewardship plans for end-of-life management of products should be posted to DTSC's website and DTSC should invite public comment prior to approval of the plans; and
- All notices, public comments, and correspondence with stakeholders should be posted on DTSC's website.

Response:

In response to the above comments and comments related to public input in general, DTSC amended section 69505.1(h). The text of section 69505.1(h) in the July 2012 proposed rule is now found in section 69505.1(d) Consideration of Information. The responsible entity preparing the AA must take into account "relevant" information and technical assistance provided by DTSC (January and April 2013).

As stated in the ISOR, per Health and Safety Code section 25257(f), information related to hazard traits for chemicals and chemical ingredients may not be claimed trade secret. For a more detailed discussion on trade secret claims, refer to Article 10 of this Response to Comments document. Sufficient information must be provided in the reports that allow for public comment and review.

As stated in the ISOR and per section 69501.5(b)(9) (April 2013) of the proposed regulations, copies and links to product stewardship plans, exemptions from end-of-life management programs, and copies of annual end-of-life reports will be posted on DTSC's website.

In response to the above comments and overarching input received on Articles 5 and 8, DTSC has revised the proposed regulations to include public review and comment of Final AA Reports, as well as a notice of proposed regulatory response determinations to make use of stakeholder input (January and April 2013).

§ 69505.5(a)(6)(A) Trade Secret Information in AA Reports

Comments: 1-9**,** 9-56, 36-94, 36-76

Comments Summary:

The above comments expressed concern with section 69505.5(a)(6)(A), which specifies that responsible entities claiming trade secret status for information in an AA Report must provide a redacted AA Report for public review and comment. In summary, the following concerns were expressed:

- The language in section 69505.5(a)(6)(A) is vague—there are no clear steps that companies should take to ensure that they meet these provisions;
- The disclosure requirements may put confidential information at risk. The cruxes of the proposed regulations are to address "Chemical(s) of Concern" in specific "Priority Products." DTSC's authority to require the disclosure of all known chemical ingredients in the alternative that differs from the original composition will put confidential information regarding new uses of chemicals and new products at risk;
- Disclosure of the new alternative formulation or composition of the chemicals in the selected alternative is outside of the scope of the regulations and, thus, is outside of DTSC's statutory authority to require; and
- Many industries are already familiar with such masking strategies, such as preparing disclosures to comply with securities laws or voluntarily describing

confidential technology in initial approaches to prospective business partners, even under confidentiality agreements.

Response:

DTSC respectfully disagrees with the comment that it is not clear how trade secret information is to be addressed in AA Reports. The proposed regulations devote an entire article to the procedures that a person asserting a trade secret claim must follow (see Article 10, July 2012). Unlike conducting AAs, which is a new and rapidly emerging field, DTSC did not see the need in the drafting of the regulations to commit to drafting specific guidance materials regarding masking of trade secret information—to the extent masking is authorized under section 69510(g) (renumbered to 69509(g) in January 2013). Nonetheless, DTSC is certainly willing to work with interested parties during the implementation of the regulations if they seek assistance from DTSC in complying with this provision.

The proposed regulations specify the applicable criteria, procedures, and time lines that must be followed when claiming trade secret protection. The proposed regulations reflect the authorizing legislation, which specifies the type of information that can be claimed as trade secret. The provisions protect valid trade secret claims but at the same time require that a useful range of data be included, establishing the basis for decision. However, per Health and Safety Code section 25257(f), information related to hazard traits for chemicals and chemical ingredients may not be claimed trade secret. Sufficient information must be provided in the reports that allow for public comment and review.

While manufacturers must disclose the full composition of their product to DTSC, they may claim trade secret protection for certain pieces of information. The proposed regulations do not require that all critical business decisions—such as new alternative formulation or composition—be released to external entities, only information related to hazard traits for chemicals must in virtually every case be made public. This protects that information from being disclosed to the public. The reader is directed to the detailed discussion of trade secret provisions for more information on this topic. For a more detailed discussion on masking of trade secret information, please refer to the discussion under Article 10 in this Response to Comment document, now numbered as Article 9 in the proposed regulations (January 2013).

§ 69505.5(d) Responsible Entity and Supply Chain Information

Comments: 5-85, 5-131, 5-168, 9-42, 11-47, 36-77, 36-101, 57-63, 57-64, 68-35, 76-64, 86-23, 91-12, 109-18

Comments Summary:

The above comments expressed support, concern, or requested clarification of section 69505.5(d) regarding supply chain information. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to narrow requirements;
- The information requested will help the market operate more efficiently;
- The supply chain information is simply too broad that can be a vast listing, it is also overly burdensome and complicated for complex articles;
- The information is not necessary for an environmental health and safety alternatives assessment;
- The requirement that the name and contact information of all persons to whom the manufacturer or importer directly sold the Priority Product in California must be submitted to the agency is both impractical and unnecessary;
- It is very likely that the manufacturer will not have much of this information, which will require that responsible entities gather and provide the name and contact information for all parties who purchased products within the last 12 months—a task that will require hours of manpower;
- Sensitive and confidential business information should not be required or narrowed significantly;
- Retail sales information is often proprietary and goes beyond the statutory authority of DTSC, particularly if it occurs outside of the State of California or via the internet;
- There is lack of clarity in disclosure of the location(s) of manufacturing plants and/or the proximity to sourced materials;
- The chemical industry and the broader manufacturing industries are operating globally, a chemical (or an alternative) can easily be sourced from another country it is not necessary to know the source of source materials;
- The need for information pertaining to a manufacturer's proximity to recycled materials that influence the type and/or amount of a Chemical(s) of Concern in the Priority Product has not been substantiated; and
- How will trade secrets and confidential business information be properly protected during the public review and report process of the AA?

Response:

As stated in the ISOR, discussing section 69501.2 Duty to Comply and Consequences of Non-Compliance, the primary responsibility to comply falls on the manufacturer of a Priority Product; however, if a manufacturer fails to comply, the responsibility falls on the importer, retailer, or assembler of the consumer product. A "responsible entity," as defined, means any manufacturer, importer, retailer, or assembler of the consumer product. (Note: the term "assembler was added in April 2013.) For a more detailed discussion on the hierarchy of these responsibilities, refer to the FSOR Article 1.

Given that a vast number of the consumer products placed into the stream of commerce in California are done so by someone other than the actual manufacturer of the product, the duty to comply in the proposed regulations is not entirely placed on the manufacturer. DTSC's ability to implement the directives of Health and Safety Code sections 25252 and 25253 requires that DTSC be able to compel and enforce compliance with the requirements of these regulations in California. As such, the proposed regulations are similar to the duty to comply approach embodied in other California statutes and regulations that impose requirements on products that are sold in California but manufactured both in-state and out-of-state (for example, California's Toxics in Packaging Prevention Act, found in Health and Safety Code Division 20, Chapter 6.5, Article 10.4).

If a responsible entity for a Priority Product fails to comply with the requirements of Article 5, the Priority Product may not be offered for sale or distributed in California commerce. Disclosure of sales outlets, as defined, is required to be provided in the Final AA Report and in various notifications set out in the regulations. The disclosure/notification of retail sales outlets is necessary to provide DTSC information regarding the locations of where the Priority Products or their alternatives are destined to be distributed in California. Without disclosure/notification DTSC would not have a means to identify the Priority Products that have been reformulated, making compliance confirmation and enforcement unworkable. The disclosure/notification provides a means to identify the responsible entities and the Priority Products to ensure that those products may be tested and determined to be free of the Chemical(s) of Concern that is/are the basis for being listed.

If the information being requested under this provision is claimed to be trade secret, the responsible entity may redact that information from the Preliminary and Final AA Report, the Abridged AA Report, and/or the Alternate Process AA Work Plan. If DTSC concurs with the trade secret claim, the information may remain redacted from those reports. For a more detailed process related to trade secret claims, please refer to Article 10 of

this Response to Comments document. The trade secret provisions have been moved to Article 9 of the proposed rule (January 2013).

Throughout the public comment period, stakeholders have repeatedly expressed that the lack of control along the supply chain makes it impossible for manufacturers to know all chemical ingredients in some of the raw materials used to manufacture their products. Numerous stakeholders expressed that without requiring the specified information, most manufacturers would not be able to influence major supply chain players on their own nor to catalyze an increase in the type of information that is provided throughout the supply chain. Many stakeholders have expressed this information is needed for a real transition to sustainability and will help the market operate more efficiently. Nonetheless, other stakeholders have expressed that the supply chain is global and that, provided the specifications are made outside of these provisions, the market will meet the demand without potentially compromising confidential business information.

In light of the above information, DTSC has modified the provisions and has deleted the "manufacturer's proximity to recycled materials that influence the type and/or amount of a Chemical(s) of Concern in the Priority Product" from the proposed regulations (January 2013). DTSC believes that the responsible entities are the best suited to demand the specifications for the raw materials along the supply chain, and it is not necessary to include those provisions in the proposed regulations. The proposed regulations will create the necessary demand for disclosure between the manufacturer and its supply chain without specifying it in regulation. In response to the above comments and other general streamlining efforts, the provisions are now found in section 69505.7(d) (January 2013).

§ 69505.5(e) Product Information

Comments: 5-130, 11-48, 30-4, 66-61, 138-23

Comments Summary:

The above comments expressed support, concern, or requested clarification of section 69505.5(e) regarding product information. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit;
- The State of California cannot extend its authority beyond its borders;
- The disclosure of the Chemicals of Concern that are the basis for listing, plus all other Chemicals of Concern, is unnecessary;

- Material safety data sheets or safety data sheets should be added to the lists of information that must be provided to be consistent with other state regulations and take advantage of existing information; and
- The Globally Harmonized System (GHS) is changing how manufacturers present information about their products. Material safety data sheets will be called "safety data sheets."

Response:

In response to the comments related to DTSC's authority to extend its authority beyond its borders and disclosure requirements for Chemical(s) of Concern, please refer to the response immediately above under section 69505.5(d) Responsible Entity and Supply Chain Information, for a more detailed response on the duty to comply.

The proposed regulations have been amended to include the Globally Harmonized System (GHS) "safety data sheets." Responsible entities may comply with the requirement by using either or both the Material safety data sheets or safety data sheets.

In response to streamlining efforts these provisions have been streamlined and moved to section 69505.7(e) (January 2013).

§ 69505.5(f) Scope and Comparison of Alternatives

Comments: 36-48, 39-16, 66-52, 72-8, 72-9, 72-22, 114-10, 121-7

Comments Summary:

The above comments expressed concern, or requested clarification of section 69505.5(f) regarding the scope and comparison of alternatives. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit;
- It is not possible, in all cases, to present a matrix or even an easily-understood visual comparison;
- Very complex AAs may not lend themselves to one particular type of information format;
- DTSC should add language to ensure that AAs do not rely on outdated and inadequate occupational exposure limits in the development of a safer alternative chemical or product;
- Improve public involvement process and revise the wording from "presented in matrix" to "summarized in matrix";

- Any comparative assessment methodology that relies solely on hazard can be grossly misleading and may result in unintended consequences;
- The hazard assessment should focus on the collection of hazard information for the chemical(s) being evaluated and any potential alternatives; and
- It may be possible to characterize an alternative based on the hazard information, but it is premature to eliminate an alternative solely on this basis without consideration of the use, exposure, performance, availability, and other relevant factors.

Response:

As stated in the ISOR, the responsible entity may consider, retain, drop, and/ or reconsider an alternative to address the public health and/or environmental impacts from the Priority Product. The regulations do not require or specify an outcome of the AA. To address this overarching concern expressed regarding the July 2012 proposed regulations, companion provisions have been amended to more explicitly state that a responsible entity retains this latitude. Provisions regarding identification of alternatives in the first stage and corresponding Preliminary AA have been modified in section 69505.5(b)(1)(A) (January 2013).

Responsible entities are allowed to collect the hazard information for the chemicals under evaluation and retain, drop, and/ or later reconsider these chemicals. The proposed regulations allow for incremental improvements and, therefore, do not disallow the use of a chemical that exhibits a hazard trait. It is anticipated that virtually all chemicals will exhibit a combination of hazard traits. The goal, however, is to reduce and, to the extent practical and feasible, eliminate the overall impacts.

Given that the proposed regulations are narrative in standard and not prescriptive, it is not necessary to include language to ensure that outdated inadequate information is not used. The regulations provide the criteria with narrative standards that must be addressed to complete an AA. While the regulations contain the criteria and procedures, the guidance materials will guide preparers in performing the AAs (*i.e.*, sources of information, trends or emerging technologies, etc.).

The proposed regulations do not require that the AA rely solely on hazard; instead, information regarding hazard endpoints must be collected for the Chemical(s) of Concern, and any alternatives being considered must be further evaluated. The proposed regulations also do not require that alternative(s) be dismissed entirely based on the hazard information. Instead, the responsible entity is to take the hazard information and conduct a thorough evaluation throughout the life cycle to determine

differences between the Priority Product and the alternatives being considered. This is intended to identify the trade-offs and to allow the responsible entity to select the alternative that has the least impacts or at a minimum, makes an incremental improvement.

In response to the above comments and other streamlining efforts, these provisions have been streamlined to remove repetitiveness and clarify that that information may be provided in a matrix or other summarized format that provides the reviewer with an easily understood visual comparison of the chemicals and their adverse impacts. The new provisions are found in section 69505.7(g) (January 2013).

§ 69505.5(g) Scope of Relevant Comparison Factors

Comments: 29-20, 66-53

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.5(g) regarding the scope of relevant comparison factors. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit;
- The regulations provide safer products to individuals residing in California; however, DTSC is required to consider the adverse impacts due to exposures to the Chemical(s) of Concern in consumer products during its life cycle;
- Determining the relevant comparison factors is a somewhat subjective exercise and depends greatly on technical expertise and knowledge of the industry being assessed; and
- It is not clear what will happen if DTSC disagrees with the weighting and comparison of the factors.

Response:

As indicated in the ISOR, the proposed regulations are consistent with Health and Safety Code section 25252. The prioritization processes in Articles 2 and 3 focus on Candidate Chemicals that have been listed on specified authoritative lists as having adverse impacts on human health and the environment.

When consumer products are identified a source of the Candidate Chemical(s), those products may be listed as Priority Products containing Chemical(s) of Concern. The products are prioritized by the following factors, at a minimum:

(1) The volume of a chemical in commerce in California;

(2) The potential for exposure to a chemical in a consumer product; and
(3) Potential effects on sensitive subpopulations, including infants and children.

The goals and intent of AB 1879 are to find alternatives to a Chemicals of Concern to reduce adverse public health and environmental impacts in California.

The AAs conducted under Article 5 will address the life cycle impacts of products containing Chemical(s) of Concern. The responsible entity selects the alternative that works best for it taking into account human health and the environment life cycle impacts, consumer needs, economic impacts, compliance with all local, state and federal laws and regulations, and regulatory responses that they will be subject to as a result of their selection.

DTSC agrees that relevant comparison factors, weighting of the factors, and their associated trade-offs may be subjective and may depend on technical expertise. As such, DTSC has determined that comparison and weighting of relevant factors would be more appropriately addressed through guidance materials than in these regulations. Guidance materials that may be developed for product types and/or sector-specific considerations will address weighting factors, and/or the appropriate use of specific quantitative analysis, if appropriate.

In response to the above comments and other streamlining efforts, these provisions have been moved to section 69505.7(f) (January 2013).

§ 69505.5(h) Methodology

Comments: 40-12, 40-14, 91-13 PH19-2

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.5(h) regarding methodologies that a responsible entity may use in conducting the AA to meet the requirements of Article 5. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit;
- Life cycle assessment results are subject to a great amount of uncertainty, especially if a lack of primary databases resulting in a need to rely on secondary sources;
- ISO standards call for a validation process, which adds time and costs;

- The methods and data on which the analysis is based should be complete enough that the analysis can be reproduced by other competent analysts;
- Certainty in the AA process comes from achieving and clearly demonstrating the desired outcomes, not from checking the boxes in a meaningless process or blindly applying models, scoring, and checklists; and
- Guidance is necessary on how to use models.

Response:

The provisions contained in the proposed regulations allow responsible entities flexibility in the use of tools and methodologies. However, responsible entities must include in the AA work plan and AA Reports a description of the analysis tools, models, or software used. The proposed regulations do not require the AA be ISO compliant. Therefore, additional time and expense will not be required to render the AA ISO compliant. In addition, DTSC has drafted the requirements in Article 5 to be flexible enough to achieve a useful and meaningful outcome from the AA. The requirements are not “check box” by any means. Rather, the regulations establish a broad baseline for what analysis a responsible entity should conduct and in what logical sequence.

As stated in the ISOR, the AA Report must identify and describe the analytical tools, model, and software used to conduct the AA, inclusive of any limitations. In addition, the AA Reports must identify the use of published methodologies and/or guidelines, and any deviation from those methodologies and/or guidelines. The information requested ensures that the methods used and data on which the analysis is based is completely summarized so that the results can be verified and/or audited by other competent analysts.

While DTSC is committed to developing guidance materials to assist responsible entities in complying with the requirements of Article 5, it has not envisioned preparing guidance materials regarding use of specific models. To the extent appropriate and useful, DTSC may provide guidance on the use of models. In addition, DTSC is willing to work with interested parties during the implementation of the regulations if they seek assistance from DTSC in complying with these provisions.

Changes in response to the above comments have not been made. Due to other streamlining efforts, these provisions have been moved to section 69505.7(h) (January 2013).

§ 69505.5(i) Supporting Information

Comments: 11-49, 57-65, 68-36, 72-11, 72-12, 74-63, 107-71

Comments Summary:

The above comments expressed concern, or requested clarification of section 69505.5(i) regarding supporting information that is submitted with the AA Reports. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit;
- This section appears to attempt to identify data gaps that might exist and should be more explicit;
- A list of other chemical ingredients in products is not necessary for the successful analysis of the Chemical of Concern and its alternatives, and it is not the intent of the statute;
- Selection of data sources should be consistent with internationally recognized definitions for reliable information; and
- The quality of the data reported will dictate its utility.

Response:

The provisions under this section are intended to include information and not just strictly identify data gaps. In theory, information might be exchanged as its relevance might be broadly applicable. The context in how a responsible entity "translates" the information for its own use and preparation of the AA is crucial and required to be submitted. Based on the information, compilation, and evaluation, unique data gaps may be identified. Uncertainties in the information (inclusive of the data gaps) must be considered in carrying out the first and second stage AA and must be identified in the corresponding AA Reports.

Responsible entities are required to summarize the information that was reviewed and considered, inclusive of information on AAs included on DTSC's website, in the AA Reports submitted for review. Responsible entities are not required to fill the data gaps.

In response to the above comments, the provisions in section 69505.5(i)(2)(C), which specified that a list of all chemical ingredients required to be identified for the product and its alternative during the conduct of the AA, have been deleted.

In addition, due to other streamlining efforts, these provisions have been moved to section 69505.7(i) (January 2013).

§ 69505.5(j) Selected Alternatives

Comments: 1-9, 11-50, 11-51, 41-18, 57-66, 66-54, 68-37, 76-21, 76-58, 76-65, 87-9, 107-59, 107-71

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.5(j) regarding the selection of the final alternative(s). In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit;
- Support retaining the original Chemical(s) of Concern as the baseline for all first and second stage comparisons;
- It is unnecessary for a responsible entity to identify and describe the selected alternative in the Final AA Report to effectuate the regulations, including the regulatory response from DTSC;
- The intent of the statute is not ingredient disclosure for Priority Products; rather, the regulations should remain consistent with the statute and focus on assessment of the identified Chemicals of Concern and their alternatives, not all chemicals within a product;
- DTSC lacks the authority to "approve" whether a particular product is permitted to be on the market;
- When AAs can identify multiple alternatives that would be acceptable, with respect to the impacts to human health and the environment, there is no benefit to artificially restrict Chemical(s) of Concern replacements to a single alternative; and
- DTSC must not create a regulatory AA process in which DTSC compares manufacturers' AA Reports and chooses a particular alternative to mandate across the industry.

Response:

The proposed regulations do not require, nor has DTSC ever envisioned, reviewing all AA Reports submitted for a particular Priority Product and imposing a single AA approach and/or regulatory response on all responsible entities. DTSC will evaluate the AA Reports on their own merits to establish compliance with procedural and substantive requirements. A manufacturer has met its statutory obligation when it completes and submits an adequate AA within the mandated time line. The responsible entity retains the final say in the choice of the most technologically and commercially feasible alternative. DTSC will not "approve" whether a particular product is permitted on the market. DTSC will impose the appropriate regulatory responses to mitigate any

adverse human health and environmental impacts, as a result of the responsible entity's selection.

In response to the concern that the focus of the AA has expanded from the Chemical(s) of Concern to all chemicals ingredients in the alternatives, DTSC has modified the language to explicitly require that only the Chemical(s) of Concern that was the basis for listing as a Priority Product and its replacement chemical(s) must be included in the AA Reports. Full ingredient disclosure of the selected alternative selected is not required.

It is essential that the responsible entity identify and describe the selected alternative in the Final AA Report to effectuate the regulations. Without this information, it would be impossible to select the most appropriate range of regulatory responses. The proposed regulations do not restrict a responsible entity to consider only one alternative; a responsible entity may elect to select more than one alternative to further evaluate, consider, and select as its alternative(s). The proposed regulations establish the minimum criteria; however, a responsible entity is free to do as much as they have the capacity for. That is, the responsible entity may evaluate and ultimately select more than one alternative to the Chemical(s) of Concern in the Priority Product.

Changes in response to the above comments have not been made. Due to other streamlining efforts, these provisions have been moved to section 69505.7(j) (January 2013).

§ 69505.5(j)(2)(C) Final AA Selected Alternative(s)

Comments: 11-51, 41-18, 57-66, 68-37, 76-65

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.5(j)(2)(C) regarding the selection of the final alternative(s). In summary, the following concerns were expressed:

- The regulations should be focused on the Priority Product and Chemical(s) of Concern combination and alternatives selected;
- This section significantly impacts innovation and inhibits reformulation due to the limitations on confidential business information claims;
- The selected alternative would most likely be confidential business information, but responsible entities cannot claim confidential business information unless totally hazard free;

- DTSC inadvertently creates a strong incentive for responsible entities not to select an alternative and to maintain the Priority Product, as it seems they then do not have to comply with this obligation; and
- This section should be modified to allow multiple alternatives to be found to be acceptable. As long as the alternatives do not pose an equal or greater risk of adverse impacts and there is no significant burden shifting, they should all should be considered acceptable. This section should be modified to reflect that a single solution is not required.

Response:

In response to the concern that the focus of the AA has expanded from the Chemical(s) of Concern to all chemicals ingredients in the alternatives, DTSC has modified the language to explicitly require that only the Chemical(s) of Concern that led to the listing of the product as a Priority Product and their replacement chemicals must be included in the AA Reports (January 2013).

The regulations reflect the authorizing legislation, which specifies the type of information that may not be claimed as trade secret and, by implication, what information may not. While the proposed regulations do not require that all critical business decisions be released to external entities, they do (consistent with Health & Safety Code section 25257(f)) require that information related to hazard traits for chemicals are made public. If the information being requested under this provision is claimed to be trade secret, the responsible entity may redact that information from the Preliminary and Final AA Report, the Abridged AA Report, and/or the Alternate Process AA Work Plan. If DTSC concurs with the finding, the information may remain redacted from those reports. For a more detailed discussion of the criteria and processes related to trade secret claims, please refer to Article 10 in this Response to Comment document. Article 10 is now numbered as Article 9 in the proposed regulations (January 2013).

While the provisions are written in the singular— namely, the ”selected alternative”—a responsible entity may elect to select more than one alternative to further evaluate, consider, and select as its alternative(s). The proposed regulations establish the minimum criteria; however, a responsible entity is free to do as much as they have the capacity for. That is, the responsible entity may evaluate and ultimately select more than one alternative to the Chemical of Concern(s) in the Priority Product.

DTSC disagrees that an incentive is being created to retain the Priority Product. The prospect of multiple regulatory responses being imposed on a Priority Product, while simultaneously being displayed on DTSC’s Website, provides an incentive to select an

alternative(s), if feasible. Responsible entities will be driven to select alternatives that not only reduce adverse impacts to human health and the environment but are economically advantageous so as to not lose markets shares.

Changes in response to the above comments have not been made. Due to other streamlining efforts, these provision have been moved to section 69505.7(j)(2)(C) (January 2013).

§ 69505.5(k) Next Steps

Comments: 5-169, 19-30, 22-3, 26-8, 66-55, 73-12, 74-49, 74-50, 74-51, 74-52, 76-8, 107-62, 107-64, 107-65, 109-6, 127-13

Comments Summary:

The above comments expressed concerns or requested clarification of section 69505.5(k), which procedurally specifies the deadlines by when a responsible entity is to complete the AA Reports. While many of the comments expressed in this section were repeated verbatim by some parties, others expressed slight variations to those concerns that were more specific to this section. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to expand time lines and/or make more flexible;
- The proposed regulations currently imposes time lines for responsible entities that could put them in violation of already existing requirements that hold precedence over the authority of the Safer Consumer Products Regulations;
- If the time frames are lengthy and allow too much flexibility, environmental impacts from products will not be quickly addressed;
- We urge DTSC to revise the proposed regulations so that time frames throughout the process are specific and as short as possible, while still allowing for reasonable public comment periods;
- There are clear cases where industry-wide efforts have been shown to be the best way to address substitution;
- Little to no time is included to do further experimental research to evaluate a particular alternative or to create a consortium or public-private partnership approach to accomplishing the AA work;
- The allowed time to complete an AA should be extended to at least three years—U.S. EPA may request additional data generation during review of a Pre-Manufacture Notification that could extend the time necessary;

- DTSC should include language in these sections that recognizes the many compliance schedules will be measured in years not months;
- Industry has already completed the “easy” alternative substitutions. A new AA will require several steps that illustrate the complex, lengthy process a manufacturer undertakes to identify and implement a functionally acceptable and commercially viable alternative;
- Substitution of a single Chemical of Concern may require multiple substitute alternatives if the Chemical of Concern performs different functions within the product formula matrix;
- Rather than specifying the maximum extension an entity can receive to complete the AA Reports, DTSC should grant extensions based upon a petition that demonstrates the need for additional time to enable Priority Products, whose safety and performance are regulated by other state or federal laws, to complete safety and performance testing requirements; and
- A case-specific schedule, taking into account testing and certification procedures, is necessary rather than the one-size-fits-all approach embodied in the current proposed regulations.

Response

To reduce repetitiveness, please refer to the response to comments under section 69505.1(c)(3) Alternatives Analysis Timelines and section 69505.1(c)(1) Consortium and/or Collaborative of this Response to Comments Document. The aforementioned sections address timing, the use of a consortium, collaborative and/or similar partnership, and the impracticability of a “one-size fits all” approach. In addition, the above sections address the amount of time allotted and the lack of potential conflict with U.S. EPA’s Pre-Manufacture Notification.

As indicated in the above mentioned sections, the regulations provide18 months or more to complete the first stage AA and corresponding Preliminary AA Report, depending on the Priority Product. The proposed regulations provide the responsible entity twelve (12), twenty-four (24), or thirty-six (36) months of gathering and compiling the data to complete the second stage AA and submit the Final AA Report. As such, responsible entities are afforded two and a half years for a simple substitution and three and a half or four and a half years for complex substitutions or products, without taking into account the additional extensions that are afforded.

Responsible entities may request a total of two ninety (90) day extensions: 1) one during the first stage and corresponding Preliminary AA Report; and 2) one during the second stage and corresponding Final AA Report. If a responsible entity requested an

extension during both stages and DTSC granted them, the total time would range from three years for a simple substitution to four or five years for more complex substitutions. In addition, the proposed regulations do not require that the alternative replacing the Priority Product be available for market distribution or that all research and development be completed by the time the Final AA Report is submitted.

If we took the example of phosphates in automatic dishwashing products, the aforementioned time lines would be more than sufficient to form a consortium, collaborative, and/or similar partnership AND perform the analysis and submit the Final AA Reports. Phosphate replacement required four to five different chemicals depending on the formulation), and the initial replacement was accomplished in three years.[6] DTSC acknowledges that each product and industry is different but believes that the time frames specified, especially with the ability to request extensions, is sufficient for a meaningful AA to be completed.

In response to the above and other related comments, the provisions have been streamlined, and are now under section 69505.7(k)(1) (January and April 2013).

§ 69505.5(k)(1)(A) Work Plan and Implementation Schedule

Comments: 55-11, 76-66, 76-67, 107-63

Comments Summary:

The above comments expressed concerns, or requested clarification of section 69505.5(k)(1)(A), which specifies that the work plan and implementation schedule must specify the proposed submission date for the Final AA Report and the Final AA Report must be submitted within 12 months after DTSC issues a notice of compliance for the Preliminary AA Report. In summary, the following concerns were expressed:

- The work plan and implementation schedule must specify the proposed submission date for the Final AA Report;
- The intended content of the work plan is not clear and more specifics about the level of detail required for each work plan should be provided. These details should be added to this section and included in the FSOR; and

[6] Proctor and Gamble, Grocery Manufacturers Association

- If the deadline for submission of Preliminary AA Reports will be the same for all responsible entities, any extension granted for one responsible entity should apply to all responsible entities.

Response:

The contents required to be included in the Preliminary AA Report are necessary to ensure that a Priority Product has been adequately scoped, prior to beginning the second stage of the AA. In addition, the Preliminary AA Report must include a work plan that identifies the proposed implementation schedule for further assessing viable alternatives, including collected data if determined necessary to complete the AA. The information required establishes the basis under which the AA will be performed and informs DTSC and other parties of the intended scope of the AA and/or AA work plan. In response to these comments, the language in section 69505.5(k)(1) has been streamlined and amended to be more descriptive of the process that will be used to identify the factors and associated pathways and life cycle segments that are relevant and will be compared during the second stage (January and April 2013).

In addition the deliverable and requirements have been amended. The work plan and implementation schedule in the Preliminary AA Report must specify the proposed submission date for the Final AA Report and must ensure that the Final AA Report or progress report, if applicable, will be submitted to DTSC no later than twelve (12) months after DTSC issues a notice of compliance for the Preliminary AA Report. If DTSC approves an extended due date, under section 69505.9(b)(4), the responsible entity must provide a yearly progress report per section 69505.7(k)(1)(A), until the Final AA Report is submitted (January and April 2013). The first yearly progress report must be submitted no later than twelve (12) months after DTSC issues a notice of compliance for the Preliminary AA Report. To ensure the responsible entity is making tangible progress and to ensure compliance, each progress report must include:

1. Preparer information, specified in section 69505.7(c);
2. Priority Product information, specified in section 69505.7(e);
3. A summary of achievements since the last progress report;
4. A summary and discussion of issues that have arisen, as well as their resolutions;
5. A summary of work that is pending; and
6. An assessment of whether the milestones in the schedule set forth in the Preliminary AA Report or Alternate Process AA Work Plan are anticipated to be completed on time and any contingency plans to ensure timely completion.

As elaborated in the response to comments in section 69505.1(c)(3) Alternatives Analysis Timelines, it is impractical to impose the same deadline for all second stage AAs and the corresponding Final AA Report because the scope of the AA will differ from manufacturer to manufacturer. Changes to reflect this comment have not been made.

In response to overarching comments related to Article 5, the provisions have been moved to section 69505.7(k)(1) (January and April 2013).

§ 69505.5(k)(1)(B) Final AA Report Submittal Extensions

Comments: 15-6, 19-30, 57-67, 68-4, 68-7, 74-52, 74-64, 74-65, 76-8, 76-67, 76-68, 76-70, 107-63, 107-72, 107-73, 109-6, 127-13

Comments Summary:

The comments above expressed concern or requested clarification of section 69505.5(k)(1)(B), which specifies that the responsible entity may request an extension for submittal of the Final AA Report, not to exceed twenty-four (24) months after DTSC issues a notice of compliance for the Preliminary AA Report. While many of the comments expressed in this section were repeated verbatim by some parties, others expressed slight variations to those concerns that were more specific to this section. In summary, the following comments were made:

- The amount of time provided for submission of the Final AA Reports should be proportional to the number of alternatives to be assessed, as well as the complexity of the product being studied;
- Deadlines and extensions for submission of AA Reports may not be the same for all related responsible entities;
- The time line for the preparation of Preliminary and Final AA Reports must be flexible enough to accommodate the time that manufacturers will need to work the necessary issues up and back down the impacted supply chain, to assess and implement potential component redesigns in the context of globalized logistics;
- Smaller companies often do not have the “pull” to affect changes in the supply chain;
- Innovation requires resources (*i.e.*, people, finances, and equipment) and time (anywhere from months to years), depending on the size of the project and the complexity of the product; and
- In the absence of a reasonable multi-year time line, the program will simply collapse under its own unsustainable weight.

Response

To reduce repetitiveness, please refer to the response to comments under and section 69505.1(c)(1) Consortium and/or Collaborative and section 69505.1(c)(3) Alternatives Analysis Timelines. The aforementioned sections address timing, the use of a consortium, collaborative and/or similar partnership, and the impracticability of a "one-size fits all" approach.

While all Preliminary AA Reports are due on the same due date, the scope set out in the Preliminary AA Report will dictate the due date for the Final AA Report. Despite making the same Priority Product, each responsible entity may decide the number of alternative(s) it will consider, evaluate, and retain for further evaluation. The proposed regulations do not impose a particular outcome nor do they require that all responsible entities adopt the same alternative(s); as such, it is impractical to impose the same deadlines and/or regulatory responses. As elaborated in the response to section 69505.1(c)(3) Alternatives Analysis Timelines it is impractical to impose the same deadline for all second stage AAs and the corresponding Final AA Reports because the scope of the AAs will differ from manufacturer to manufacturer.

As indicated in the response for section 69505.5(k) Next Steps, sufficient time has been built into the process to allow for adequate planning, scoping, data collection, and in-depth evaluation of alternatives—ranging from simplex to more complex AAs. If a responsible entity takes the amount of time allowed and requests the two extensions that are provided under section 69505.1(c), the AA Reports will be completed in either three years for a simple substitution or four to five years for more complex substitutions.

DTSC recognizes the current limitations small to medium-sized manufacturers or manufacturers in third world countries may have in affecting changes in the supply chain. However, the proposed regulations will create a demand internationally for less harmful chemicals, as evidenced by the size and types of comments received from international stakeholders, thereby making the change to safer alternatives more effective. In addition, the regulations do not necessarily require chemical substitution if that is not a feasible alternative. Therefore, in this sense, the regulations already acknowledge limitations on the ability of suppliers to affect changes in the supply chain.

In addition, DTSC recognizes that there will be economic impacts as a result of the proposed regulations. As documented in the Economic and Fiscal Impact Statement (Form 399) submitted with the proposed regulations, there will be an unquantifiable cost to industry, consumers, and taxpayers in implementing the regulations. It is also important to note that there is currently an unquantifiable cost that is passed on to

Californians through added health care and or added taxes as a result of not addressing impacts from consumer products that have human health and environmental impacts. For further details on the types of costs and jobs that may be created, please refer to Economic and Fiscal Impact Statement in this Response to Comments document.

In response to the above and other related comments, all language relating to products' contents, beyond the Chemical(s) of Concern that was/were the basis for the listing, have been deleted. That is, the scope of the chemicals that must be reviewed as part of the AA has been reduced to the Chemical(s) of Concern that led to the listing as a Priority Product, and alternatives to the Chemical of Concern(s).

§ 69505.5(k)(2) Final AA Report Implementation

Comment: 57-67, 74-64, 74-65, 76-68, 107-72, 107-73

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.5(k)(2), which specifies the contents of an implementation plan following the completion of the AA Report. In summary, the following points were made:

- Add, delete, or modify regulatory text to expand time lines and/or make more flexible;
- This section should be modified to allow for an entity to submit a proposed transition plan and to suggest regulatory responses but not require them to do so;
- This provision should be expanded to include international laws as well. Since companies operating within the U.S. often make and market products for all of North America, compliance with Mexico and Canada's requirements may also be necessary (*e.g.*, a New Substance Notification);
- The manufacturer's proposed regulatory response should focus on the outcome related to the specific Chemical of Concern/Priority Product pair that drove the AA;
- All language relating to a Priority Product's contents, beyond the Chemical of Concern that was the basis for the listing, should be deleted from this article;
- A responsible entity "may" propose a regulatory response, but this seems to presuppose that a regulatory response requirement will be forthcoming from DTSC;
- Clarify the identification of regulatory responses that may be suggested by the implementation plan;

- Add “significant” to “adverse public health and environmental impacts” to indicate an appropriate threshold consistent with CEQA;
- An AA Threshold level under which no regulatory response is required should be included;
- Different regulatory responses for different responsible entities create the appearance of impropriety and potential corruption as differing responses are awarded to entities based on hidden criteria; and
- The lack of clarity in this section implies that product information and end-of-life considerations (if hazardous waste) will be automatically required for all alternatives or Priority Products.

Response:

The responsible entity selects the alternative that works best for it while taking into account human health and the environment life cycle impacts, consumer needs, economic impacts, compliance with all local, state and federal laws and regulations, and regulatory responses that it will be subject to as a result of the selection. With all due respect, it is not necessary to include a provision that Canada’s or Mexico’s requirements be addressed in California. It is also not necessary to include “significant” to indicate a threshold consistent with CEQA. The proposed regulations, while broadly applicable, are a distinct program from CEQA. For a more detailed discussion on the use of “significant” in the context of evaluating relevant factors, please refer to section 69505.4(a)(1) Step1 Identification of Factors Relevant for Comparison of this Response to Comments document.

At the completion of the AA report, the responsible entity may, for example, determine that it will retain the Priority Product on the market for two years, until an alternative can be selected. Because the alternative is, in effect, the Priority Product, the responsible entity must implement the regulatory responses that DTSC determines are necessary to mitigate public health and environmental impacts. If public health impacts were the cause for the Priority Product to be listed, then it is likely that information to consumers will be required in the interim. Similarly, if the selected product has end-of-life impacts because it must be managed as a hazardous waste at the end of its useful life, then the responsible entity will be required to put in place a product stewardship plan for the selected alternatives or retained Priority Product. The responsible entity may take into account the reason a Priority Product was listed to determine which of the regulatory response(s) could potentially address human health and environmental impacts, and propose those to DTSC for consideration.

The implementation plan may also include the identification of any regulatory response(s) that the responsible entity wishes to propose. The responsible may identify and recommend regulatory responses that would best limit the exposure to, or reduce the level of, adverse public health and environmental impacts posed by any Chemical(s) of Concern. DTSC, however, retains the authority to either approve the regulatory responses, adjust the regulatory response and or require additional regulatory responses.

As stated earlier, the requirements of Article 5 do not apply if the Priority Product contains a Chemical of Concern below the AA Threshold exemption criteria and, consequently, a regulatory response would also not apply. An AA Threshold is available as a default for a Priority Product only if the Chemical(s) of Concern are present in the product solely as contaminants, and the concentration of the Chemical(s) of Concern(s) does not exceed the practical quantitation limit for the chemical(s). DTSC may specify an AA Threshold for intentionally added chemicals or set the AA Threshold higher than the PQL for contaminants on a case-by-case basis. (§69503.5(c) April 2013) However, if a Priority Product exceeds the AA Threshold, an AA is required and, in accordance with Health and Safety Code section 25253(b), the regulatory response(s) DTSC determines are necessary will be required, upon the completion of the AA.

In response to the above and other related comments, all language relating to products' contents beyond the Chemical(s) of Concern that was/were the basis for the listing have been deleted. That is, the scope of the chemicals that must be reviewed as part of the AA has been reduced to the Chemical(s) of Concern that led to the listing as a Priority Product and alternatives to the Chemical of Concern(s) (January 2013).

§ 69505.6 Department Review and Determinations for AA Reports

§ 69505.6(a)(1) Review of Preliminary AA Reports

Comments: 66-41, 66-56, 68-38, 72-27, 76-69, 129-19

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.6(a)(1), which contains DTSC's review process. In summary, the following points were made:

- Add or modify regulatory text;

- It would seem that this section obviates the need for certified assessors in Article 8. If DTSC is reviewing all AAs to ensure compliance with this section, it is not clear what role the certified assessor will serve in assuring the quality and thoroughness of the AAs;
- The time frame for DTSC to review an AA Report (60 days) and also the time frame for responsible entities to redress deficiencies (60 days) seems excessively short against the background of the complexity of the work required;
- Final decisions should focus on whether alternatives are safer for human health and the environment, meet consumer needs, comply with all local, state and federal laws and regulations, and address significant life cycle impacts;
- There will not be a single best alternative that works for every manufacturer of a given product, and governments must not impose such requirements;
- The language should be modified to clarify that DTSC has the authority to substantively review the AA Report; and
- It is unclear how DTSC will approve research and development plans under this part and section 69505.3.

Response:

In response to numerous comments related to the provisions in Article 8 Accreditation Bodies and Certified Assessors, Article 8 has been deleted and the corresponding changes have been made in other impacted sections. Conforming changes to this major change have been made throughout Article 5 to address the need for stakeholder confidence and quality assurance regarding AAs. Persons preparing and carrying out an AA and compiling AA Reports are no longer required to be certified in order to conduct one, and AA Reports may be performed in-house by the responsible entity or through contract with a consultant, by a trade association, and/or collaborative.

DTSC will review the Preliminary and Final AA Reports, Abridged AA Reports, AA work plans, and/or implementation plans, as well as research and development plans for compliance with the substantive requirements in Article 5. To address the concerns raised, the proposed regulations have been amended to include more specific criteria in section 69505.7(k)(1) and 69505.9 (January and April 2013).

In reviewing AA Reports and Alternate Process AA Work Plans for compliance with the substantive and administrative requirements of this article, DTSC shall consider:

1. Whether the AA Report or Alternate Process AA Work Plan was submitted timely;

2. Whether, and to what extent, the responsible entity considered and addressed all applicable provisions of this article pertaining to the preparation and submittal of an AA Report or Alternate Process AA Work Plan, whichever is applicable;
3. Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable; and
4. Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA Report were determined using reliable information.

DTSC has allocated sixty (60) days for a substantive review of the Preliminary and Final AA Reports, Abridged AA Reports, and AA work plans. In the event that the review cannot be completed within that time frame, DTSC will notify the responsible entity that the report is still under review. In the notice, DTSC will specify the date by when the review can be expected to be completed. If the review cannot be completed because the report is deficient, the report will be determined to be deficient and returned to the responsible entity. The responsible entity is then granted no more than 60 days to revise and complete a Preliminary or Final AA Report, Abridged AA Report, or AA work plan. DTSC believes this a reasonable amount of time given that the responsible entity is only addressing portions of the AA that are minor. If the AA Report require substantive changes that may not be addressed in (60) days, the AA Report will be rejected and other requirements, to cease placing the Priority Product in California commerce, will be triggered.

As stated earlier, the responsible entity selects the alternative that works best for it taking into account: human health and the environment life cycle impacts, consumer needs, economic impacts, compliance with all local, state and federal laws and regulations, and regulatory responses that they will subject to as a result of their selection. DTSC will not impose a “one-size fits all” regulatory response for different selected alternatives to the same Priority Product.

The amended provisions of this subsection have split and are now found in sections 69505.7(k)(1) and 69505.9 (January and April 2013).

§ 69505.6(a)(2)(A) Notice of Deficiency on Preliminary AA Report

Comment: 129-20

Comment Summary:

Add a new subsection to clarify that DTSC may modify the Preliminary AA Report in the event that the responsible entity fails to comply with the notice of deficiency.

Response:

DTSC will review plans for compliance with the substantive requirements in Article 5, and if the Preliminary AA Report is determined to be deficient, DTSC will note the deficient sections and request that the responsible entity address the deficient areas within the time frame specified. No changes have been made in response to this comment.

The provisions of this subsection moved to 69505.9(b)(2)(A) (January and April 2013).

§ 69505.6(b)(1) Review of Final AA Report

Comments: 19-31, 29-21, 47-19, 129-21, 129-22, 133-2

Comments Summary:

The above comments expressed concern or requested clarification of section 69505.6(b)(1), which contains DTSC's review process. In summary, the following points were made:

- Add, delete, or modify regulatory text to make requirements more explicit;
- Based on industry trade secret concerns, it is likely that many AAs will be conducted independently, resulting in numerous findings or regulatory responses based on any one company's determination of "safer";
- The language should be modified to clarify that DTSC has the authority to substantively review the Final AA Report;
- Add a new subsection to clarify that DTSC may modify the Final AA Report in the event that the responsible entity fails to comply with the notice of deficiency; and
- How does a company perform an adequate AA?

Response:

Please refer to the response to comments under section 69505.6(a)(1) review of Preliminary AA Reports for the criteria DTSC will use to review the Final AA Reports as well as the corresponding changes made in response to these comments.

DTSC will review AA Reports for compliance with the requirements in Article 5, and if the AA Report is determined to be deficient, DTSC will note the deficient sections and request that the responsible entity address the deficient areas within the time frame specified. Responsible entities addressing the requirements in Article 5 will likely complete and prepare (for review) adequate AAs. It is likely that many AAs will be conducted independently and each result in divergent results, specific to the responsible

entity's business plans. The regulatory responses that will be required will be tailored in accordance to the adverse human health and environmental impacts of the alternative selected.

No changes have been made in response to this comment. The provisions of this section were moved to 69505.9(c)(1) and review criteria were added to 69505.9(a) (January and April 2013).

§ 69505.6(c)(1) Compliance with Article

Comments: 5-132, 5-170, 15-6, 57-68, 68-7, 73-20, 133-2, 138-17

Comments Summary:

The above comments expressed concern, or requested clarification on section 69505.6(c)(1), which details the process by which DTSC will review and approve/disapprove Final AA Reports or make a determination of ongoing review. In summary, the following concerns were expressed:

- Add, delete, or modify regulatory text to make requirements more explicit;
- Take into account the economic impacts upon small businesses, and ensure that the regulatory response adheres to the most cost-effective options;
- The imposition of regulatory responses have the potential of making products unacceptable to consumers or imposing such cost that a manufacturer may cease making the product available in California;
- The consequences of imposing substantial cost or forcing the withdrawal of products for sale in California are so significant that the various regulatory responses should be imposed only under circumstances that are necessary to carry out the purposes of the underlying statute; and
- Explicitly state that the goal is the removal of toxic substances, re-design of processes, etc., and that other measures are less effective steps that may be necessary on an interim or short-term.

Response:

DTSC will review the Preliminary and Final AA Reports, Abridged AA Reports, AA work plan and/or implementation, as well as research and development plans, for compliance with the requirements in Article 5. To address these concerns, the proposed regulations have been amended to include more specific criteria in section 69505.7(k)(1) and 69505.9 (January and April 2013).

As stated earlier, AB 1879 does not authorize DTSC to exempt small to medium-sized manufacturers. As such, the regulations intentionally do not carve out provisions for small to medium-sized manufacturers or manufacturers in third world countries. All manufacturers are subject to the same requirements as manufacturers located in the U.S. Regulatory responses placed on Priority Products will be based on the public health and environmental impacts that the alternative or the Priority Product poses if an alternative is not selected, and not the size of the manufacturer. The proposed regulations establish the minimum requirements that must be met by manufacturers of Priority Products that contain Chemical(s) of Concern. However, responsible entities may elect to achieve more aspirational goals as a result of their own initiative or public demand, which do not need to be specified in the regulations.

As a result of the proposed regulations, manufacturers are more likely to make safer alternative(s) currently available in Europe and Canada more widely available in the U.S. and, at a minimum, in California. Despite California's recent fiscal woes, according to the U.S. Department of Commerce's estimates, California's gross domestic product was $1.89 trillion, which puts California as the world's eighth largest economy in 2009. Since the 1970s, California has ranked as the 7th largest world economy, except for a couple of years in 1984 and 1985, when California was the 5th largest economy in the world.[7] Further, as evidenced by the comments received on the proposed regulations, the regulations will create a demand that will be met by many manufacturers worldwide, who want to continue to have presence in the California market.

The provisions of this section were amended and moved to 69505.9(c)(3) Notice of Disapproval (January and April 2013.)

§ 69505.6(e) Notices Issued by DTSC

Comment: 36-78

Comment Summary:

All notices issued by DTSC should also be posted on DTSC's website.

Response:

[7] http://econpost.com/californiaeconomy/california-economy-ranking-among-world-economies February 03, 2011

Pursuant to section 69501.5(a), all notices of compliance, notices of deficiencies, and/or notices of disapproval or ongoing review will be posted on DTSC's website.

No changes have been made in response to this comment.

This section was moved to 69505.9(e) (January and April 2013).

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ARTICLE 6. REGULATORY RESPONSES

Support / Object Article 6

Comments: 36-58, 36-115, 39-7, 39-25, 41-45, 69-25, 74-67, 114-5, 121-4, 129-23, 138-16, PH34-6

Comments Summary:

The above comments expressed support or general concern/objection to the provisions in Article 6. The provisions in Article 6 clarify, interpret, and make specific the provisions in Health and Safety Code section 25253(b) of the authorizing legislation. More specifically, this article identifies the process and general sets of circumstances that will give rise to specific regulatory responses, while preserving the necessary flexibility to implement appropriate regulatory measures on a case-by-case basis.

Comments expressing support for various provisions included the following provisions:

- Section 69506(a), which provides guiding principles in selecting regulatory responses;
- Section 69506(b), which requires that the Department of Toxic Substances Control (DTSC) give preference to regulatory responses that provide the greatest level of inherent protection;
- Section 69506.2(a) and (b), which require that responsible entities fill information gaps when requested by DTSC;
- Section 69506.7, which requires that a responsible entity invest in research and development if a safer alternative does not exist; and
- Section 69506.8, which requires that manufactures establish and fund an end-of-life management program.

The comments expressing general concern with the provisions in Article 6 stated that the July 2012 proposed regulations continue to be intrusive, onerous, and potentially destructive to companies doing business in California and the general California economy. Additionally, there is so much flexibility in the regulatory responses that it lacks specificity and thus clarity, and the regulations do not provide sufficient standards for decisions by DTSC and in several cases exceeds the authority provided in statute.

Comments objecting to various provisions in Article 6 objected to the following provisions:

- Section 69506(a), which allows DTSC to imposed different regulatory responses to different manufacturers of the same product depending on the outcome of the Alternatives Analysis (AA);
- Section 69506.7, which requires that a responsible entity invest in research and development if a safer alternative does not exist;
- Section 69506.8(d), which allows a manufacturer to request an exemption to the end-of-life management program;
- Section 69506.10(a), which requires that the manufacturer apply for an exemption in lieu of it being automatic; and
- Section 69506.11(b), which allows DTSC to consider the degree to which a Priority Product is already regulated and modify regulatory response accordingly.

Response:

As stated in the Initial Statement of Reasons (ISOR), Article 6 delineates and clarifies the provisions of Health and Safety Code section 25253(b), which specifies that "the regulations adopted pursuant to this section shall specify the range of regulatory responses that the department may take following the completion of the Alternatives Analysis."

Further, as stated in the ISOR, in specifying the criteria for and the operation of the regulatory responses, DTSC fulfilled the legislative intent for Health and Safety Code section 25253(a)(1). This section sets forth the purpose of the AA process, the first step leading to the imposition of a regulatory response, as "to determine how best to limit exposure or to reduce the level of hazard posed by a Chemical of Concern." Health and Safety Code section 25255(a) states that the overall goal of the authorizing statute is "significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches."

Section 69506 identifies the overarching principles that will guide DTSC in selecting from among the broad array of permissible regulatory responses. This increases the predictability of such responses for all stakeholders; helps guide DTSC program implementation staff, and increases the consistency of regulatory decision-making. As such, not only is this provision not in conflict with statute, but it is necessary to effectuate the statement of goals in Health and Safety Code section 25255: "[T]he goals of this Article . . . [are] significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of these impacts to

the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches."

Specific changes to the proposed regulations have not been made to address the above-mentioned comments. Where appropriate, changes have been made in the above-mentioned provisions to address comments that were directed to the specific provisions and are discussed in the corresponding section. Further, DTSC respectfully disagrees that the provisions of Article 6 fail to meet the clarity standard within the Administrative Procedure Act (APA). DTSC has purposefully drafted the provisions to give DTSC discretion to craft a regulatory response that is appropriate for different scenarios. But this does not mean that the regulations fail the clarity standard. The comment appears to conflate the concepts of clarity and certainty. See discussion of the clarity standard under Procedural, Legal, and Overarching Issues in this Response to Comments document. Those responses apply here as well. DTSC further disagrees that any of the unspecified provisions of Article 6 exceed DTSC's authority. DTSC is not making any changes to the regulations in response to these comments.

§ 69506 Regulatory Response Selection Principles

§ 69506(a) Need for Regulatory Response

Comments: 5-116, 5-171, 29-4, 29-7, 41-56, 57-69, 76-71, 95-4, 107-74, 126-5, 126-7, 129-23

Comments Summary:

The above comments expressed concern for or requested clarification of section 69506(a), which requires that DTSC identify and require the implementation of regulatory responses designed to protect public health and the environment, and maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible. In summary, the following concerns were raised:

- Amend regulatory language to make more explicit that regulatory responses are limited to the Chemical(s) of Concern in the Priority Product or the selected alternative at the completion of the Alternatives Analysis (AA);
- This section conflicts with the statutory provision in section 25253 and should be revised to more clearly reflect the intent of the statute;
- A different regulatory response for different responsible entities for the same Priority Product creates a situation ripe for claims of impropriety by DTSC with regard to different treatment for different entities;
- An "alternative of least concern" may be patented;

- DTSC should ensure the regulations provide a level playing field by stating that all AAs for the same Chemical(s) of Concern will be reviewed by DTSC at the same time, and that DTSC will issue a single public policy decision with the most appropriate regulatory response;
- The provision has a clear preference for substitution with an acceptable alternative rather than first applying equally due consideration that a Priority Product may be completely safe as it currently exists with no change; and
- The regulations should also confirm that DTSC is authorized to take a regulatory response on the basis of an approved AA, a disapproved AA, or an AA developed by or modified by DTSC.

Response:

DTSC respectfully disagrees that any of the provisions in Article 6 conflict with Health & Safety Code section 25253 of the authorizing legislation. DTSC has specifically followed the content and structure of section 25253 in drafting Article 6. In the absence of any specific provisions that are alleged to be in violation of section 25253, DTSC cannot provide any further information in response to this comment.

As discussed in the ISOR and response to comments in Article 5, the complexity of the AA proposed by the responsible entity will dictate the due date for the Final AA Report, which in turn dictates the due date for the regulatory response and any applicable notifications. DTSC disagrees that applying differing regulatory responses on seemingly similar products at the completion of the AA creates an un-level playing field for the following reasons. First, each responsible entity when conducting the AA will select the range of alternatives that are most appropriate to address the complexities of its own Priority Product. Second, DTSC will not necessarily impose a particular outcome (*i.e.*, require a reformulation or replacement product). As such, it is highly unlikely that DTSC may impose an alternative that is patented or that DTSC is inclined to favor substitution over the Priority Product. DTSC's focus after completion of the AA is on addressing any impacts posed by the Priority Product and/or selected alternative(s) with the appropriate range of regulatory responses. Finally, since the market is driven by consumer demand, this will motivate responsible entities to select alternatives with the least amount of adverse impacts on public health or the environment. This will, in turn, affect the nature of the regulatory responses DTSC may impose.

Upon completion of the AA, DTSC will specify the regulatory response(s) necessary to address the impacts posed by the Priority Product or the alternative(s) selected. If upon the second review of the Final AA, it is determined to be out of compliance, the Final AA

Report will be disapproved and the responsible entity notified to comply with the requirements of section 69501.2. The responsible entity must cease placing the Priority Product into the stream of commerce in California. If the responsible entity is a retailer, the retailer must cease ordering the Priority Product. DTSC will not amend the Final AA Report but will post the name of the responsible entity and the applicable Priority Product on its website pursuant to section 69501.5.

In response to the above and other related comments, the provisions of this section have been modified to more explicitly state that one or more regulatory responses may be identified and that the regulatory responses are limited to the Chemical(s) of Concern in the Priority Product Priority Product and/or its replacement chemicals in the selected alternative(s) (January and April 2013).

§ 69506(b) Inherent Protection Preference

Comment: 9-25, 11-52, 29-22, 36-23, 36-112, 39-7, 41-56, 42-19, 57-69, 68-5, 73-21, 95-4, 107-74, 114-5, 114-16, 114-17, 114-18, 118-14, 121-4, 126-5, 138-16, PH20-4

Comments Summary:

The above comments expressed concern with or requested clarification of section 69506(b), which specifies that in selecting regulatory responses, DTSC will give preference to regulatory responses providing the greatest level of inherent protection. The provision further defines “inherent protection” as “avoidance or reduction of adverse impacts, exposures and/or adverse waste and end-of-life effects that is achieved through the redesign of a product or process, rather than through administrative or engineering controls designed to limit exposure to, or the release of, a Chemical of Concern or replacement Candidate Chemical in a product.” In summary, the following points were made:

- This section conflicts with Health & Safety Code section 25253 and should be revised to more clearly reflect the intent of the statute;
- The “avoidance or reduction of adverse impact or exposure” by Chemical(s) of Concern in a product coupled with the use of the term “ability” throughout the proposed regulations means that *potential* hazards cannot be considered by DTSC in identifying Chemical(s) of Concern, by alternatives assessors comparing alternatives to Chemical(s) of Concerns or, ultimately, by DTSC in fashioning a regulatory response;
- The use of the “ability” standard of causation in the proposed regulations is illegal under AB 1879;

- The selection principles need to be modified to include a time line to make timely action a priority; and
- Preventing the use of toxic substances in products is the most effective means to deal with a hazard, containing and controlling are much less effective measures.

Response:

DTSC respectfully disagrees that this provision conflicts with section 25253. As stated in the ISOR, in specifying the criteria for and the operation of the regulatory responses, DTSC addressed the legislative intent and mandate embodied in Health and Safety Code section 25253(a)(1), which establishes the purpose of the AA process, the steps leading to the imposition of a regulatory response—"to determine *'how best'* to limit exposure or to reduce the level of hazard posed by a chemical of concern."

As with all mandates imposed on regulatory agencies by the Legislature, agencies are granted discretion in how to implement the statute. The authorizing legislation grants DTSC discretion in determining "how best" to limit exposure or reduce the level of hazard posed by a Chemical of Concern. In addition, Health and Safety Code section 25255(a) states that the overall goal of the authorizing statutes is "significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches."

The "use of alternatives of least concern," as specified in the proposed regulations, is consistent with the goals and mandate of authorizing legislation, which allows a range of regulatory responses to be required that would "best limit exposure to or reduce the level of hazard posed by the Chemical(s) of Concern."

The responsible entity selects the alternative that works best for it while taking into account public health and the environment life cycle impacts, consumer needs, economic impacts, compliance with all local, state, and federal laws and regulations. The regulatory responses that will be required are dictated by the alternative selected. As such, it is impractical to include a time line in regulation. However, in assigning a due date for one or more regulatory responses DTSC will take into account the complexity of implementing the regulatory response.

Please refer to the discussion of Procedural, Legal, and Overarching Issues in this Response to Comments document for clarification on the use of the terms "potential," "ability to," and the causation standard in general.

In response to the above and other related comments, section 69506(b) was amended and the text "impact or exposures" was replaced with "impact, exposures and/or adverse wastes and end of life effects." In addition the text "replacement Candidate Chemicals" has been included which effectively requires that a responsible entity take into consideration how best to limit exposure to or the release of these chemicals if used to replace the Chemical(s) of Concern.

§ 69506(c) Factors in Selecting a Regulatory Response

Comments: 9-44, 26-9, 26-10, 36-53, 37-13, 42-19, 42-20, 44-9, 66-57, 114-14, 114-15, 114-16, 114-17, 121-5, 121-6, 125-6, 138-22

Comments Summary:

The above comments expressed support, concern, or requested clarification of section 69506(c), which delineates five factors, *actual effectiveness*, *relative cost-effectiveness, administrative and other burdens, unique or additional burdens, and ease and efficacy of enforcement,* that DTSC may consider in selecting the most appropriate regulatory response(s). In summary, the following concerns were raised:

- Amend regulatory text to require that DTSC must weigh all five criteria before making a decision to avoid selecting an ineffective, expensive, burdensome, unenforceable regulatory response;
- The negative impacts to the natural environment/ecosystem should be considered;
- Costs and other burdens incurred by other government agencies, non-profit stewardship organizations, and certain other private businesses that manage wastes should be considered when selecting a regulatory response;
- DTSC must use its best judgment to choose options that, on the whole, produce effects that it considers less significant in endangering public health;
- Appreciate the inclusion of a cost-effectiveness consideration in 69506(c)(2); however; concerned that DTSC will not have the information necessary to do an effective cost-benefit analysis of the regulatory response; and
- Include the impact on communities (*e.g.*, neighbors, employees, suppliers) connected to the manufacture of a product and ways to mitigate anticipated adverse impacts on those communities.

Response:

DTSC respectfully disagrees that it is necessary to address all five of the criteria specified in section 69506(c)(1) through(5) in making a decision to avoid the selection of

an ineffective, expensive, burdensome, unenforceable regulatory response (July 2012). The criteria enumerated and the factors specified may not be relevant or applicable in each case.

The criteria make clear that DTSC's selection of regulatory responses may, when appropriate, be guided by its determination of:

(1) the overall benefits of the regulatory response to protection of public health and the environment;
(2) cost impacts on responsible entities who must implement regulatory responses; and
(3) public agency costs associated with the Priority Product or alternative product at end-of-life.

Further, DTSC's regulatory response selection may be based in part on pragmatic considerations relating to the ease and burdens of implementation and enforcement.

In response to the above comments, section 69506(c) has been modified to delete the terms "any or all" to more accurately reflect that DTSC may take into account the factors specified without unnecessarily including those terms. Inclusion of the terms added confusion rather than clarity. In addition, to streamline the provisions, the factors for selecting a regulatory response have been categorized under either:

1) Public health and environmental protection;
2) Private economic interests of responsible entities; or
3) Government interest in efficiency and cost containment (January and April 2013).

Each of these factors, in turn, contains three criteria that may be evaluated, to the extent practical, in arriving at the most appropriate regulatory response. Hence, the term "may" was used here to indicate that these criteria and factors may not be relevant or applicable in each case (January and April 2013).

In addition, DTSC amended section 69506(c) for better organization and clarity. That is, the principal purpose and effect of the changes was to insert headings for the types of factors DTSC may consider and to appropriately group these factors under the appropriate headings—i.e. "Public health and environmental protection," "Private economic interests of responsible entities," and "Government interest in efficiency and cost containment." Other non-substantive changes were also made to streamline the drafting. However, none of the changes made in January 2013 affect the actual operation of this provision. More specifically, these factors were optional for DTSC's consideration in the July 2012 version of the proposed regulations, and they remain optional. These factors were included to give DTSC additional discretion to consider

general public policy criteria over and above the specific criteria for regulatory response selection in sections 69506.1 through 69506.8. Those sections have mandatory criteria for DTSC to consider in the selection of the various regulatory responses. If resources permit, and it is appropriate, DTSC may then also consider these additional broad public policy factors in section 69506(c). But given the specific, tailored criteria in sections 69506.1 through 69506.8, it will not be necessary for DTSC to consider these section 69506(c) factors in every case (January and April 2013).
The categories of selection factors and the various criteria contained within each of those factors should allow DTSC to consider the timeliness in which regulatory responses can be implemented and simultaneously take into account adverse ecological impacts and costs to responsible entities and other public agencies. DTSC anticipates that as the program matures, information that is currently viewed as nonexistent or marginally acceptable will gradually become more available and of higher quality because of the demand that the proposed regulations will create. As such, effective cost-benefit analysis of regulatory responses will become more common.

While the provisions do not specifically call out for impacts on neighboring communities, employees, etc., they are included by the use of the term “sensitive subpopulations” as it is defined in former section 69501.1(a)(58), now section 69501.1(a)(64). Sensitive subpopulations means subgroups that comprise a meaningful portion of the general population that are identifiable as being at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait and/or toxicological endpoint, including, but not limited to, infants, children, pregnant women, and elderly individuals. “Sensitive subpopulations” also include persons at greater risk of adverse health effects when exposed to chemicals, because they are either individuals with a history of serious illness or greater exposures to chemicals, or workers with greater exposures to chemicals due to the nature of their occupation (January and April 2013).

While in selecting the appropriate regulatory responses, DTSC may not particularly focus in on neighboring communities and/or employees because that may not be the life cycle impact that caused the Priority Product to be listed, impacts at these locations may be indirectly addressed.

In response to the above comments, the provisions have been modified to address the above-mentioned criteria. In addition, the provisions have been streamlined and regrouped for simplicity (January and April 2013).

§ 69506.1 Applicability and Determination Process

§ 69506.1(a) Applicability of Regulatory Responses

Comments: 5-111, 5-181, 19-12, 19-20, 55-15, 55-21, 68-39, 76-9

Comments Summary:

The above comments expressed concern with section 69506.1(a), which specifies when regulatory responses will be applied. The following concerns were expressed:

- Regulatory responses should not apply to historic products or replacement products;
- Regulatory responses should not apply to any product for which prototype building, testing, and validation has not been completed and for which necessary regulatory approvals have not been obtained;
- Regulatory responses should apply only to products, and the service parts for products, manufactured during the course of the manufacturer's normal product manufacturing cycle (*e.g.*, model or model year) that begins after the effective date of the regulatory response, taking into account lead-time necessary for manufacturers to implement the regulatory response(s);
- The ability of DTSC to enact different regulatory responses for different responsible entities in relation to the same Priority Product is fundamentally unfair; and
- What will DTSC do in the case of diverging or conflicting results of alternatives assessments for the same/similar products and Chemical(s) of Concern?

Response:

Regulatory responses will apply to any product placed into the stream of commerce in California that is:

1) An alternative selected at the completion of the Final AA Report under section 69505.4(c);
2) A Priority Product for which an alternative is not selected; or
3) A Priority Product that will remain in commerce in California pending development and distribution of a selected alternative.

The regulatory response applies to the Priority Product not the prototype undergoing testing and validation. As such, the scenario that products undergoing development should be exempt from regulatory responses is not necessary.

Section 69501(a) and (b) specifies the consumer products, as defined, that these regulations applies to or that are exempt. While the July 2012 proposed regulations made use of the term ”historic product” to refer to products that are no longer being manufactured, that term has been deleted. The term “historic product” created unnecessary confusion and potentially created conflicts with other provisions of the proposed regulations (January and April 2013).

Products that are excluded in section 69501 from the requirements of Chapter 55, such as products that are no longer being manufactured after the Priority Product listing, are not subject to any of the requirements of the regulations. Therefore, they are not captured by the AA requirements of Article 5 or the regulatory responses of Article 6. Therefore, an exemption in Article 6 is not only unnecessary, but inserting one would create unnecessary confusion. If a product that is no longer being manufactured is prioritized because it poses a public health and/or environmental impact, any replacement to that product that is newly manufactured is not exempt from Chapter 55.

As discussed in the ISOR, responses to comments in Article 5, and in response to comments under *section 69506(a) Need for Regulatory Response*, the complexity and diverging results of the AA proposed by the responsible entity dictates the due date for the Final AA Report and the due date and types of regulatory responses that will apply to the Priority Product. More regulatory responses may be required of a responsible entity that fails to select an alternative and retains the Priority Product than may be required of a responsible entity who selects an alternative with minimal public health and environmental impacts. It is the only practical and meaningful way to implement a program that is not command and control but instead promotes innovation and is flexible enough to accommodate technological advances.

Changes in response to the above comments were not made. However, in response to related comments section 69506.1 was amended to remove any reference to sections 69506.5, 69506.6, 69506.7, 69506.9 and 69506.10 as section sections 69506.3 and 69506.10 were deleted and corresponding changes made (January and April 2013).

§ 69506.1(b) Regulatory Response Determination Process

Comments: 44-10, 55-14, 55-21, 68-39, 86-24

Comments Summary:

The above comments expressed concern with section 69506.1(b), which specifies that prior to issuing a final regulatory response determination notice under sections 69506.5, 69506.6, 69506.7, 69506.9, and/or 69506.10, DTSC will notify all known responsible

entities for the product of the proposed regulatory response(s), and make the proposed regulatory response determination notice available on its website for public review and comment. The section further states that DTSC will hold one or more public workshop(s) to provide an opportunity for oral comment on the proposed regulatory response determination and send notice of the workshop to individuals on the electronic mailing list(s). In summary, the following concerns were expressed:

- The public notification and input process only applies to some regulatory responses (namely use restriction, product bans, engineering and administrative controls, research and development grants and reevaluation of regulatory responses), and it should be included for product information for consumers and end-of-life management;
- What authority does DTSC have to decide that some regulatory responses will be subject to the public notice requirements and others will not; and
- The 45-day comment period seems too short to comment for companies outside of California, particularly if English is not their first language.

Response:

As stated in the ISOR, most of the regulatory responses will need to be customized on a case-by-case basis in light of the nature and the uses of the individual products. In response to the above comments and other related comments on applicability, the provisions in section 69506.1(b) have been amended to address exceptions to the applicability of Article 6. The amended provisions of section 69506.1(b) specify that if the manufacturer submits a Removal or Replacement Confirmation Notification to DTSC prior to implementing the regulatory response that would otherwise apply, Article 6 will not apply. This is a logical exception to the requirements of Article 6 should a manufacturer elect to Remove a Priority Product from California commerce or if the manufacturer elects to replace the Chemical(s) of Concern with a chemical that is not a Chemical(s) of Concern, not on the Candidate Chemicals list, or is a Candidate Chemical that is/are already in use to manufacture the same product by the same or another manufacturer (January and April 2013).

In addition, the provisions of section 69506.1(b) related to public review and comment have been moved and are now in sections 69506.1(c) and (d). The provisions limiting public review and comment on only some of the regulatory responses have been deleted. The amended provisions specify that after DTSC issues a notice of compliance or a notice of disapproval for a Final AA Report or an Abridged AA Report a notice must be issued within ninety (90) days. The notice will be sent to all known

responsible entities for the product and will be made available on DTSC website for public review and comment (January and April 2013).

The proposed regulations state that, at a minimum, a forty-five (45) day comment period will be afforded. Depending on the complexity of the Priority Product under review, the comment period may be greater than forty-five (45) days. DTSC believes that given the prior notice to interested parties and the general public of the Priority Product(s) undergoing an AA, the time frame allowed is sufficient to gain meaningful input without unduly delaying the process. In addition, the regulations have intentionally not created any special exemptions or conditions for manufacturers outside of California. This was done so as not to put manufacturers in California at a disadvantage. DTSC also recognizes that there may be some instances in which the manufacturer operating outside of California may not speak English as their first language. Despite this situation, section 69501.3(b) requires that all documents submitted to DTSC be in the format specified and in English. This is necessary so as not to burden California taxpayers with having to pay for translations services. DTSC believes the burden is appropriately placed on the manufacturers to seek and hire individuals that can assist them with meeting all of the requirements.

In response to the above comments and related comments, the provisions have been modified to remove any reference to specific regulatory responses from being subject to public review and comment since all regulatory responses are subject to a public comment period and making an unnecessary distinction was only creating confusion. In response to the above comments, other related comments, and general streamlining efforts, the provisions have been modified and are now in sections 69506.1(c) and (d) (January and April 2013).

§ 69506.1(c) Public Input in Regulatory Response Process

Comments: 5-172, 37-14

Comments Summary:

The above comments expressed concern with section 69506.1(c), which states that after review and consideration of public comments DTSC will finalize and send to known responsible entities the final regulatory response determination notice. Further, DTSC may respond to some or all public comments received. In summary, the following concerns were expressed:

- Delete regulation text allowing for public comment;

- Remove permissive language not requiring DTSC to respond to all comments;
- If the objective is to provide meaningful input, DTSC should be required to respond to all comments; and
- This approach results in robbing the public of meaningful participation and robbing DTSC of critical and important information regarding proposed responses.

Response:

DTSC understands the concern with affording the public an opportunity to review and comment on the proposed regulatory responses, which is why DTSC has included a public comment period. DTSC fully intends to consider public input as it imposes regulatory responses. DTSC, however, is concerned with the use of limited resources if it were compelled to respond to all comments. Instead, DTSC has reserved the right to respond to some or all public comments. While DTSC is not compelled to respond to all comments, DTSC anticipates that it will respond to some or all of the comments, when DTSC determines that it is appropriate to do so. The regulatory text ensures that DSC considers all public comments received prior to finalizing its determination, while retaining the latitude to determine which comments warrant a response. This latitude is necessary to maximize the effective use of DTSC's limited resources.

Substantive changes have not been made in response to the above comments. In response to other related comments and general streamlining efforts, the provisions have been split into two and moved into sections 69506.1(d) Public Input and 69506.1(e) Notice of Final Determination (January and April 2013).

§ 69506.1(e) Due Date for Regulatory Responses

Comment: 55-14, 66-58

Comments Summary:

The above comments expressed concern with section 69506.1(e), which specifies that in assigning a due date for a regulatory response, DTSC will consider the complexity of implementing the regulatory response. In summary, the following concerns were expressed:

- The regulated entities should be given a minimum of one year after the receipt of the final regulatory response determination notice to implement the regulatory response;
- This section should include a minimum time line for when a regulatory response will be required to be implemented;

- Given the complexity and significance of the regulatory response options at DTSC's disposal, regulated entities should be given a minimum of one year of the receipt of the final regulatory response determination notice to implement the regulatory response;
- This time line should increase depending on the severity of the regulatory response selected; and
- At least twenty-four (24) months must be provided for completion of the prototype process.

Response:

The amount of time that a responsible entity will have to implement a regulatory response is dependent on the regulatory response(s) that are applicable. While the proposed regulations allowed a responsible entity to comply with some regulatory responses within 12 months -- providing product information to consumers; product sales prohibition; or end-of-life management requirements, other regulatory responses allowed for a case by case determination. It is important to note that a responsible entity may be subject to multiple regulatory responses and would be simultaneously required to comply with some regulatory responses within one year and others that are due at a later date. As such, the proposed regulations were amended to delete the reference to the 12 month period and instead allow for a case by case determination for all regulatory responses (January and April 2013).

The regulations provide ample opportunity for prototype building and testing without the need to further delay implementing regulatory response(s) to mitigate any adverse human and environmental impacts. Former section 69505.5(k)(2)(A) and (B), now section 69505.7(k)(2)(A) and (B) provides responsible entities an opportunity to propose the amount of time necessary to implement the selected alternative and propose any applicable regulatory responses. If a Priority Product will remain in the market, pending prototype building and testing of a safer alternative, then the appropriate regulatory response(s) must be in place during that period—such as product information for consumers under section 69506.3; while prototype building and testing is conducted under former section 69506.9, now section 69506.8 Advancement of Green Chemistry and Green Engineering (January and April 2013).

In response to other related comments and streamlining efforts, the provisions have been moved to section 69506.1(g) (January and April 2013).

§ 69506.2 AA Report Supplemental Information Requirements

§ 69506.2(a) Supplemental Information for Selection of Regulatory Response(s)

Comments: 5-86, 5-117, 5-173, 11-53, 19-43, 36-118, 41-22, 57-70, 66-59, 68-40, 74-68, 107-75

Comments Summary:

The above comments expressed concerns with section 69506.2(a), which specifies that DTSC may at any time require a responsible entity to provide any supplementary information to the Final AA Report that DTSC determines is necessary to select and ensure implementation of one or more regulatory responses that may be imposed under this Article. In summary, the following concerns were expressed:

- Amend regulations text to make standards that will be used more explicit and/or require that request for further information must be made within one year of approval of Final AA Report;
- This provision is broad and contrary to DTSC's indication that its intent is not to require the generation of information in order to fill data gaps;
- This section should be clarified to specify the boundaries of DTSC's authority;
- Without guidance on what kind of information could be requested, this could represent significant time and money being allocated to developing potentially unnecessary data;
- If requests for additional information are made, they should concern all entities and not only individual ones;
- If one responsible entity has already provided the information, DTSC could increase efficiency by using it and require all others to participate in the costs of the first one for generating the information, rather than requiring them to produce the same information again; and
- A responsible entity should not be required to continuously generate more and more information.

Response:

In response to the above comments, section 69506.2(a) has been modified to more explicitly reflect the intent and goals of Health and Safety Code section 25253(b)(2). The statute authorizes DTSC to impose a requirement to provide additional information needed to assess a Chemical of Concern and its potential alternative. Consistent with the goals and intent of the authorizing legislation, the proposed regulations do not require that data gaps be filled during the Alternative Analysis process. However, if

information is necessary to supplement the Final AA Report in order for DTSC to select the appropriate regulatory response, further information may be required from the responsible entity.

As discussed in the ISOR, the response to comments in Article 5, and *section 69506(a) Need for Regulatory Response*, the complexity of the AA proposed and undertaken by the responsible entity dictates the due date for the Final AA Report and the due date and types of regulatory responses that will apply to the Priority Product or the alternative that is selected. A responsible entity that elects to fill more data gaps earlier in the process than its competitors will be less likely to be required to fill data gaps as a regulatory response. While responsible entities are encouraged to participate in and/or form a consortium, collaborative, and/or similar partnership to offset costs, it is not required. Each responsible entity or someone on their behalf must ensure the data requirements specific to their Priority Product are submitted by the deadlines specified. Please refer to the discussions under Article 5 related to Establish a State Sponsored AA or Open Source AA under Alternate Process to Article 5 and Consortium and/or Collaborative in section 69505.1(c)(1) of this Response to Comments document which address some of the limitations of these approaches.

In response to the above comments, the provision has been modified to streamline and simplify the requirement and make it more explicit when the requirement will or will not be triggered (January and April 2013).

§ 69506.2(b) Information for Revision of Regulatory Response(s)

Comments: 5-117, 19-44

Comments Summary:

The above comments expressed concerns with section 69506.2(b), which specifies that DTSC may at any time require a responsible entity to obtain or develop, within a time frame specified by DTSC, information to fill one or more of the information gaps identified in the Final AA Report if DTSC determines this information is needed to re-evaluate the initial regulatory response(s) imposed. In summary, the following concerns were expressed:

- Amend regulation text to make conditions more explicit and/or require a request within one year of approval of Final AA Report; and
- "There are no criteria as to what is “necessary” and no limits as to what will guide DTSC’s actions in this area.

Response:

In response to the above comments and related comments under section 69506.2(a) Supplemental Information for Selection of Regulatory Response, a companion provision, the provisions have been amended. While the regulations do not require that data gaps be filled as part of the AA conducted in Article 5, data gaps that are necessary in order for DTSC to select the appropriate regulatory response(s) will be required to be filled by the responsible entity.

The amended text allows DTSC to revise the initial regulatory responses if the data gaps that are addressed demonstrate that revision to the regulatory responses is appropriate. Any proposed revision to the regulatory responses will be subject to public comment.

In response to the above comments, the provision has been modified to streamline and simplify the requirements and make more explicit when the requirement will or will not be triggered (January and April 2013).

§ 69506.3 No Regulatory Response Required

Comments: 11-54, 41-23, 41-29, 66-60, 73-22, 74-69

Comments Summary:

The above comments expressed concerns with section 69506.3, which specifies that no regulatory response under sections 69506.4 through 69506.10 will be required if DTSC determines for the selected alternative that no regulatory response is necessary to prevent or limit adverse public health or environmental impacts. In summary, the following concerns were expressed:

- This section fails to provide adequate standards and lacks clarity as to when a regulatory responses is not necessary;
- It is not clear how this section relates to the product sales prohibition (section 69506.6) and end-of-life management (section 69506.8) response options; and
- This section provides that no regulatory response is required if DTSC determines that no regulatory response is necessary to prevent or limit adverse public health and environmental impacts which are redundant.

Response:

Conceptually, this provision was intended to address instances where there was “evidence of absence” of adverse public health and environmental impacts. This

requirement would address those instances where further action would not be required per Health and Safety Code section 25253(b)(1). However, the provision created more confusion rather than clarity. In response to the above comments and other related comments, the provision has been deleted. Corresponding changes in other related sections have been made to more clearly articulate when specific regulatory responses are triggered. Thus, the absence of meeting the specified criteria for any of the enumerated regulatory responses is the circumstance in which no regulatory response may be imposed (January 2013 and April 2012).

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§ 69506.4 Product Information for Consumers

§ 69506.4(a)(1) Applicability of Product Information for Consumers

Comments: 5-14, 5-87, 5-118, 5-174, 12-10, 12-11, 41-28, 44-11, 57-71, 74-70, 74-71, 107-76

Comments Summary:

The above comments expressed concern with section 69506.4(a)(1), which requires that information be provided to consumers if the responsible entity retains the Priority Product or if the Priority Product will remain in commerce pending research and development and distribution of a safer alternative. In summary, the following concerns were expressed:

- Some of the regulatory responses are expressly provided in the statute, but some are not, such as labeling and end-of-life management requirements;
- This section applies to all products going through the AA process, seems unnecessary and could lead to information saturation for consumers on a wide scale;
- Information on a product label about the Chemical of Concern while an AA is in progress, when that information will be available to consumers through website or telephone access, is unnecessary;
- It requires that information be provided for the whole of a product, as opposed to the component(s) and/or homogeneous material(s) within a component in the product that are the focus of the regulations;
- The large Chemicals of Concern list means that most products regulated under this section will require extensive labeling;
- It is unclear whether DTSC has considered how that requirement will interfere with existing labeling regulations that already strain limited label space, especially for smaller-sized products;

- DTSC's suggested alternatives (an accessible manual or point of sale posting) are inflexible given the sheer variety of products that may be subject to alternatives assessments over the years; and
- The presence of the "except" provision in sections 69506.6 and 69506.8 creates an ambiguity as to why that provision is not also included in sections 69506.4, 69506.5, and 69506.7.

Response:

The intent and goals of Health and Safety Code section 25253(b)(3), which authorizes DTSC to impose a "requirement on labeling or other type of consumer product information," are to provide consumers with information on how best to limit their exposure or to reduce the level of hazard posed by a Chemical of Concern. DTSC has explicit authority to apply this regulatory response. The proposed regulations make specific how DTSC intends to implement the requirement to provide consumer information.

In response to the above and other comments related to the scope of this requirement, the proposed regulations have been amended to make specific when the requirements apply. The requirement to provide information to consumers is not triggered until after AA has been completed. The regulatory responses apply to the Priority Product if an alternative is not selected and Priority Products in California commerce, pending development and distribution of an alternative and the selected alternatives that contain any replacement Candidate Chemical(s), formerly called Chemicals of Concern, as defined in Article 2 (January and April 2013).

In response to numerous comments related to the definition of the term "homogenous material(s)," a companion definition to the term "Priority Product" used in this section, the previous definition of "homogenous materials" has been deleted and corresponding sections of the regulations modified to clarify the pertinent requirements. "Homogeneous materials" is not defined as a subset of the term "component." As detailed in the ISOR and in responses to comments related to Article 3, the Priority Product, as listed under the criteria and procedures in Article 3, could be the entire product or components of a larger product. The final list of Priority Products, made available pursuant to former section 69503.4, now section 69505.3, will provide the level of detail necessary to inform manufacturers which product or component is listed as the Priority Product and subject to the AA requirements. As such, the proposed regulations do not apply to a whole product if only a component(s) of the product was listed (January and April 2013).

As discussed in the ISOR and in the response to comments under Article 2, the Candidate Chemicals list, formerly referred to as Chemicals of Concern list, in earlier versions of the proposed regulations, is comprised of chemicals that exhibit hazard traits and/or an environmental or toxicological endpoints. Consumer products containing the Candidate Chemical(s) will be prioritized based on:

1) Volume in commerce;
2) Propensity for exposure; and
3) Exposure to sensitive subpopulations.

The Candidate Chemical(s) identified in the Priority Products will become the Chemical(s) of Concern in Article 3. Researchers looking for innovative formulations may refrain from using chemicals on the Candidate Chemicals list and/or Chemicals of Concern list as they have been determined to exhibit hazard traits and/or environmental endpoints.

The prioritization processes in Articles 2 and 3 apply to those products that contain Candidate Chemicals that are prioritized because of existing concerns. Those Priority Products containing Chemical(s) of Concern will be subjected to the requirements of conducting an AA in accordance with Article 5, and consequently subject to regulatory responses in accordance with Article 6. Informing the public of the ongoing concerns related to the use of the Priority Product or its alternative is consistent with the intent and goals of AB 1879.

Article 1 has a hierarchical duty to comply that first falls on the manufacturer of the Priority Product, then on the importer of the Priority Product, and finally on the retailer or assembler of the Priority Product. If a manufacturer fails to comply with the information requirements, DTSC will notify *known* importers and/or retailers and assemblers of the Priority Product and post on DTSC' website the manufacturer's failure to comply status. Retailers, however, must cease ordering the Priority Product from manufacturers, who continue to use Chemical(s) of Concern in the Priority Product that have failed to comply with the requirements. The requirements in the proposed regulations do not obligate a retailer to continue selling a Priority Product. If the manufacturer fails to make the information more accessible or labor intensive for the retailer, inclusive of Priority Products that require too much signage, a retailer may elect to cease selling that product.

DTSC has taken into account the constraints on labeling requirements and, as a result, the proposed regulations requiring information of ongoing concerns be shared with the public does not equate to labeling. Information can be provided on a manufacturer's

and an importer's website where a consumer can obtain additional information about the product, any adverse impacts associated with the product as identified in the AA Report, and proper end-of-life disposal or management of the product. In addition, the proposed regulations allow a responsible entity to satisfy the requirements by making the information available to consumers by posting the information in a prominent place on the manufacturer's website and providing information at the point of sale. Information at the point of sale may be accomplished by either posting information in a prominent place or providing the information in the packaging. The size, type, and place where the Priority Product is offered for sale must be taken into account when providing information to consumers. Please refer the discussion under *section 69506.4(a)(1)(A)-(F) Required Product Information for Consumers* below for details on the information that must be provided.

In response to overarching comments related to Article 6, the provisions in sections 69506.3 and corresponding provisions have been deleted. The provisions of section 69506.4 are now found in section 69506.3. In addition, the provisions related to Product Information to Consumers have been amended to include headings to make the requirements more visible (January and April 2013).

§ 69506.4(a)(1)(A)-(F) Required Product Information for Consumers

Comments: 5-88, 5-175, 57-71, 57-72, 57-74, 57-73, 66-61, 68-42, 68-41

Comments Summary:

The above comments expressed concern with section 69506.4(a)(1)(A) through (F), which requires the following information be provided to consumers:

A) Manufacturer's name and importer's name;
B) Brand name(s) and product name(s), and description of the product;
C) A list of, and common names for all Chemicals of Concern known to be in the product, and known hazards traits for those chemicals, based on available information;
D) Any safe handling procedures needed to protect public health or the environment during the useful life of the product, including precautions that consumers may take to prevent or limit exposure to the Chemical(s) of Concern;
E) Identification of any end-of-life management requirements specified by law, and any existing end-of-life management program(s) for the product; and
F) The manufacturer's website address and the importer's website address where the consumer can obtain additional information about the product, the adverse public health and/or environmental impacts associated with the product as

identified in the AA Report for the product, and proper end-of-life disposal or management of the product. In summary, the following concerns were expressed:

- What is meant by description of the product in (a)(1)(B);
- The manufacturer may not even have available information such as (a)(1)(C);
- List of Chemical(s) of Concern should be limited to the Chemical(s) of Concern that caused the Priority Product listing in the first place;
- The provision in (a)(1)(E) is unnecessary and the statute does not authorize imposition of financial guarantees or compensation to retailers, local governments, and others and should be deleted;
- The importer information requested in (a)(1)(F) may be considered confidential business information;
- The manufacturer/retailer should not be liable if the consumer uses a product inappropriately and causes issues based on some unknown use;
- Lack of clarity of what information would suffice for industrial purposes;
- It would also be very difficult to fit this much information on the product packaging, and retailers will not voluntarily provide a placard at the point of sale;
- The physical labeling of products is an outdated and inefficient solution that makes little sense for many types of products; and
- There is more flexibility to add more detailed context to a website to help a consumer understand the reason for and meaning of communicated information required by these regulations than there is with a small product label with limited space.

Response:

The standards in section 69506.4(a)(1)(A) through (F), now 69506.3(b)(1) through (7), are not prescriptive but narrative and afford responsible entities the opportunity to comply with the requirements in a variety of methods that are tailored to their specific needs. For example, the “description” of the product in former section 69506.4(a)(1)(B),is not uniquely defined in the regulations. As such, the commonly understood use of the term “description” may be used, meaning a written account, representation, or explanation of the product may be provided.

In response to the above and overarching comments related to the Chemicals of Concern list, section 69506.4(a)(1)(C) has been amended. The list of and common names for the Chemicals of Concern in the product and/or any replacement Candidate

Chemicals and their known hazards traits and/or environmental or toxicological endpoints must be included in the information provided to consumers.

Section 69506.4(a)(1)(D) is not prescriptive but narrative in nature. Thus, this allows the responsible entity to comply with the requirement to provide "any safe handling procedures needed to protect public health or the environment during the useful life of the product, including precautions that consumers may take to prevent or limit exposure to the Chemical(s) of Concern" in a number of ways. A Safety Data Sheet, which would be in alignment with the Globally Harmonized System (GHS), would suffice for industrial products. In addition, manufacturers may provide additional information on their website provided the required information in the regulations is included.

As part of the AA conducted under section 69505.6(a)(2)(B), the responsible entity must take into account the principle uses of a product, as intended by the manufacturer. The product information requires the inclusion of information related to any safe handling procedures needed to protect public health or the environment during the useful life of the product, including precautions that consumers may take to prevent or limit exposure to the Chemical(s) of Concern. Further, the provisions require the identification of any end-of-life management requirements specified by law, and any existing end-of-life management program(s) for the product, to inform consumers and prevent and/or minimize misuse and or improper disposal of the Priority Product or its alternative. The manufacturer is in the best position to know this information and to appropriately convey it to consumers of the manufacturer's products. The provisions in 69506.4(a)(1)(D) will remain largely unchanged. However, the provisions are now in section 69506.2(b)(5).

Health and Safety Code section 25253(b)(7) authorizes DTSC to impose a requirement "for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product." DTSC has explicit authority to apply this regulatory response. The proposed regulations make specific how DTSC intends to implement the requirements. Given the impact numerous consumer products have placed on other parties such as state and local governments, not for profit organizations, and in some instances retailers, a comprehensive end-of-life management program consisting of "responsible disposal of the consumer product" must include some level of information being conveyed to the consumer of the products to ensure the program's success. As such, the provisions in section 69506.4(a)(1)(E), placing information requirements on the responsible entity will remain unchanged.

If a manufacturer and/or importer asserts a claim that their website address is confidential business information, as requested under section 69505.4(a)(1)(F), referred

to as trade secret under the proposed regulations, the responsible entity may submit its request to DTSC per the requirements of Trade Secret Protection, formerly Article 10 (July 2012) and Article 9 thereafter.

As indicated under the discussion under section 69506.4(a)(1) Applicability of Product Information for Consumers, above, information to consumers does not equate to labeling.

In response to overarching comments related to Article 6, the provisions in sections 69506.3 and corresponding provisions have been deleted. The provisions of section 69506.4 are now found in section 69506.3 (January and April 2013).

§ 69506.4(a)(2) Chemicals of Concern are Below AA Threshold

Comment: 57-75

Comment Summary:

The above comment expressed concern with section 69506.4(a)(2), which specifies that if a product contains *no* Chemical(s) of Concern above the applicable AA Threshold then section 69506.4(a)(1) does not apply. In summary, the following concern was expressed:

- There is a lack of clarity between this section and the previous section if a Priority Product contains a Chemical of Concern below the AA threshold. This section appears to be in conflict with section 69506.4(a)(1)(C) which indicates that this section does apply.

Response:

In response to the above comment and other comments related to the AA Threshold, this provision has been deleted.

§ 69506.4(b) Communication to Consumers

Comments: 36-49, 37-15, 37-16, 41-63, 42-21, 57-71, 57-76, 86-25, PH7-2

Comments Summary:

The above comments expressed concern with section 69506.4(b), which specifies that a responsible entity must satisfy the production information requirements of section 69505.4(a) by making the required information available to consumers, in easily seen, legible, and understandable formats by:

1) Posting the information in a prominent place on the manufacturer's website and the importer's website; and
2) Posting the information at the point of sale and providing the required information on the product packaging or in accompanying written material that is accessible without breaking the product seal.

In summary, the following concerns were expressed:

- These sections allow a product manufacturer to provide required consumer information either on the product packaging *or* "posting the information in a prominent place at the point of retail display";
- The current proposed language provides manufacturers with the option to provide disclosures either on the product packaging or on an accessible manual or to shift the product disclosure burden to retailers by requiring the posting of signs at the point of retail display;
- Retailers are not provided the opportunity to comment on any product information posting requirement proposed by manufacturers;
- If the manufacturer picks the retail point of display option, it will result in an unmanageable amount of signage at the store level;
- Different manufacturers of similar products could lead to potential posting of dozens of signs per Priority Product;
- There is no indication what "prominent" means;
- It is entirely unworkable for DTSC to mandate additional required disclosures absent a grocery retailer's agreement to participate in that kind of consumer education;
- The noticing requirements would inherently require an increase in product packaging and/or posting of additional signage at point of sale and will contribute to increased waste and energy consumption;
- The ISOR indicates that lack of clarity is meant to foster flexibility;
- The additional information required will dwarf pricing, product size/weight, and other information that is legally required;
- It is unclear if DTSC has considered how that requirement will interfere with existing labeling regulations that already strain limited label space—especially for smaller-sized products;
- The suggested alternatives (an accessible manual or point of sale posting) are inflexible given the sheer variety of products that may be subject to AAs as the program proceeds;

- Any requirement for labeling should be twenty-four (24) months to allow sufficient time for appropriate distribution throughout commerce and allow a sell through provision for existing inventory;
- Point of sale posting is inherently difficult. Most retailers are not equipped to handle additional posting of information that is not covered by product labeling;
- Manufacturers should not be liable if a retailer fails to execute a point of sale posting;
- This measure is impractical given the number retail outlets potentially impacted;
- Labeling is the standard approach; recommend removal of the provision to post information at point of sale display;
- Concerned with the different approaches the manufacturers can take for the same Priority Product which can create possible confusion for consumers; and
- Product information for consumers, as specified in this section, also needs to be made available to workplaces.

Response:

For a more detailed explanation of statutory authority, the applicability of Product Information for Consumers and required contents please refer to the discussions under *section 69506.4(a)(1) Applicability of Product Information for Consumers*, and section *69506.4(a)(1)(A) through (F) Required Product Information for Consumers* of this Response to Comment document.

While the authorizing legislation explicitly requires that the manufacturer be required to manage the product at the end of its useful life, the other regulatory responses are not explicitly limited to the manufacturer. The proposed regulations allow a responsible entity, namely the manufacturer, to choose to comply with the requirements by a combination of approaches; however, the retailer retains the authority to cease offering the Priority Product for sale or the alternatives to it. The proposed regulations do not require “Stock Keeping Unit” be provided.

The proposed regulations require that the responsible entity, post on its website, in a prominent place, legible, and in an understandable format the information required in section 69505.4(a)(1)(A) through (F) and may either put the information on the product packaging if appropriate, *or* post the information in a prominent place at the point of retail display. Given that “prominent” has not been specifically defined in the proposed regulations, the term has its commonly understood meaning that the information must be noticeable and obvious. It cannot be obscure, remote, or otherwise difficult to see or read.

These provisions take into account that it may not always be practical to include all of the information on the product itself or at the point of sale and provide the necessary flexibility for manufacturers to make a case-by-case determination. The sizes of the product or the store logistics, however, are not valid reasons for failing to inform consumers of the hazards that any given Priority Product or its alternative may pose. Stakeholders have consistently expressed the need for information to consumers, which will drive the change to safer products. DTSC recognizes that informing consumers may initially create added packaging leading to incrementally more waste. However, as the program matures, responsible entities, as a result of market pressures, will find creative alternatives to move away from this approach and still inform consumers.

Retailers, along with other members of the public, will be afforded numerous opportunities to comment and voice their product-specific concerns commencing with the Priority Product/Chemical of Concern Prioritization. In addition, the Final AA Report or Abridged AA Report, whichever is applicable, which contain the implementation plan for the regulatory response(s) will be subject to public comment, followed by a public notice of the Proposed regulatory responses. Retailers wishing to participate in the selection of final regulatory response(s) must stay involved and engaged to ensure that any store-specific concerns are not overlooked by the responsible entities when selecting the most appropriate means of communicating information to consumers. It is impractical and unworkable to include this level of detail in regulatory language.

The manufacturer is not held responsible if a retailer fails to execute a point of sale posting; however, the manufacturer must provide DTSC with a list of the importers and/or point of sale outlets where the Priority Product or its alternative is sold in California for distribution.

To the extent that the Priority Product and/or its alternative are used in a workplace, the information will be provided with the sale of the product. Information related to use restrictions—the proper use and/or handling at the end of its useful life applies—must be contained with the sale of the product and if applicable, may carry requirements that workplace information be made available. It is a case-by-case determination.

DTSC respectfully disagrees that the ISOR states that lack of clarity fosters flexibility. As stated in the ISOR and FSOR this section is necessary to ensure that, in all cases, the information is easily seen, legible, and understandable to the consumer. Product information that does not meet these standards is unlikely to achieve the objective of this regulatory response as explained above. This provision ensures that the required information is useful to the consumer and is made readily available and visible to the

consumer prior to purchase. In addition, the provision provides the necessary flexibility to the responsible entity in deciding how to comply with the requirement so as to accommodate the wide variability (for example, shape, size, structure and packaging) among the range of product types that may be subject to this regulatory response. This provision also reflects the reality that with respect to certain product types, on-product label requirements may be preempted by federal law, necessitating other means of providing the required information to consumers prior to purchase. This section is necessary to provide a reasonable mechanism for making the information available to consumers prior to product purchase so that consumers can make an informed purchasing decision taking into account the information listing in section 69506.3(b).

In response to the above and related comments the proposed regulations have been amended to delete the reference to the 12 month period and instead allow for a case by case determination for all regulatory responses. DTSC will specify in the final regulatory response determination, following public comment, the time frame by when the various regulatory responses must be complied with (January and April 2013).

In response to overarching comments related to Article 6, the provisions in section 69506.3 and corresponding provisions have been deleted. The provisions previously in section 69506.4 are now found in section 69506.3 (January and April 2013).

§ 69506.5 Use Restrictions on Chemical(s) of Concern and Consumer Products

Comments: 5-89, 5-119, 5-176, 11-55, 11-56, 41-24, 41-29, 44-12, 47-30, 54-11, 66-62, 74-72

Comments Summary:

The above comments expressed concern with section 69506.5, which allows DTSC to impose restrictions on the use of one or more Chemicals of Concern in a selected alternative or in a Priority Product for which an alternative is not selected or restrictions on the use of the product itself to reduce the ability of the product to contribute to or cause adverse public health and/or environmental impacts. In summary, the following concerns were expressed:

- Delete or amend the provisions because they go beyond the authority conveyed in the authorizing legislation and are wholly unnecessary to effectuate its intent;
- The provisions do not provide a standard as to when these restrictions may be imposed and confers unfettered and arbitrary discretion on DTSC;
- DTSC appears to be giving itself authority to regulate commerce in ways that are not related to the statute's purposes;

- The imposition of use restrictions is common under regulatory schemes as Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the regulations need to provide a process that will allow for possible mitigation scenarios and/or the development of additional substantiating data;
- It is not clear how restrictions on the use of consumer products can be enforced; and
- Clarify why this section does not include the provision, "except as provided in section 69506.3."

Response:

The intent and goals of Health and Safety Code section 25253(b)(4), which authorizes DTSC to impose a "restriction on the use of the Chemical of Concern in the consumer product," are to limit exposure or to reduce the level of hazard posed by the Chemical(s) of Concern by taking into account the best available approaches. DTSC has explicit statutory authority to apply this regulatory response. The proposed regulations make specific how DTSC intends to implement the statute.

As stated in the ISOR, a *use restriction* may apply to one or more Chemicals of Concern in a selected alternative, within the Priority Product, if an alternative is not selected or in the use of the product if it is determined that a restriction is the best approach to limit adverse impacts to public health and/or the environment. This includes waste and end-of-life effects.

Health and Safety section 25251 and Article 1 of the proposed regulations specify the applicability and scope of these regulations. A pesticide as defined in section 12753 of the Food and Agricultural Code or of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is exempt. FIFRA controls pesticide distribution, sale, and use. Under FIFRA, all pesticides must be registered (licensed) by the U.S. EPA. Registration assures that pesticides will be properly labeled and, if used in accordance with specifications, they will not cause unreasonable harm to the environment. Use of each registered pesticide must be consistent with use directions contained on the label or labeling. Restricted-use pesticides are limited to use by pesticide applicators who are certified or to people under the supervision of a certified applicator. The use restrictions envisioned under the proposed regulations are similar, albeit on a smaller scale, to the use restrictions under FIFRA which restricts whom can purchase and/or use restricted pesticides. Again, though these use restrictions would not apply to pesticides due to their exempt status under these regulations.

Use restrictions on Chemicals of Concern and Priority Products may well turn out to be a companion regulatory response, if determined to be necessary, with Product Information for Consumers. Enforcement and/or compliance will be assured through the audit provisions contained in Article 8, formerly Article 9, to ensure information provided to consumers is on the manufacturer's website is being posted at the point of sale or is in the packaging material with the product and meets the information requirements (January and April 2013).

Conceptually, section 69506.3 was intended to address the instances where the evidence demonstrated absence of adverse public health and environmental impacts; however, the provision created more confusion than clarity. In response to the above and other related comments, the provisions previously in section 69506.3 have deleted and corresponding changes made (January and April 2013).

In response to overarching comments related to Article 6, Use Restrictions on Chemicals and Consumer Products have been moved to section 69506.4 (January and April 2013).

§ 69506.5(b) Restrictions on the Settings in Which a Product May be Sold or Used

Comments: 37-17, 47-30

Comments Summary:

The above comments expressed concern with section 69506.5(b), which allows DTSC to impose restrictions on the settings in which a product may be sold or used if one or more Chemicals of Concern is in the selected alternative, or in a Priority Product for which an alternative is not selected. In summary, the following concerns were expressed:

- A retailer should not be given a competitive advantage by being allowed to sell products a competitor is not; and
- This provision gives DTSC authority to regulate commerce in ways that are not related to the statute's purposes.

Response:

Use restrictions on Chemicals of Concern and Priority Products will apply to the chemical and/or the product not the retail center. DTSC will not allow nor disallow the sale of a Priority Product or an alternative by one retailer and not another unless one retailer has complied with the requirement of Article 5 and the other has not. If the manufacturer fails to comply with the requirements of Article 5, the product cannot enter

into the stream of commerce in California. This provision does not give DTSC authority to regulate commerce in ways that are not related to the statute's purposes. In fact, this type of regulatory response is expressly set out in the authorizing legislation (Health and Safety Code section 25253(b)(4)).

In response to overarching comments related to Article 6 and streamline efforts, Use Restrictions on Chemicals and Consumer Products have been moved to section 69506.4 (January and April 2013).

§ 69506.5(d) Restrictions on Who May Purchase and/or Use a Product

Comment: 37-18

Comment Summary:

The above comment expressed concern with section 69506(d), which specifies that a use restriction on Chemicals of Concern and Priority Products may include a restriction on who may purchase and/or use a product. In summary, the following concern was expressed:

- A grocery retailer should not be penalized for inadvertent or occasional sales that may occur to unauthorized populations;
- Grocery retailers should be given notice of any alleged sales violation and afforded an opportunity to engage in retraining of employees when human error is involved before penalties apply;
- In addition, it should be made clear that grocery retailers are not responsible for monitoring end use of a product; and
- Grocery retailers cannot and should not be held responsible beyond the point of sale.

Response:

Use restrictions on who may purchase and/or use the Chemical of Concern(s) and the Priority Products that contain them will apply to the chemical and/or the product. The retail center, to the extent relied upon to meet the requirements, will have to verify that the person making the purchase meets the requirements if any apply, such as meeting the age requirement and or has received the training and is licensed to make the purchase if deemed necessary.

This requirement is no different than is currently required of persons wishing to purchase "professional beauty supplies" for in home use. There is no requirement that the retailer monitor the end use of a product. In response to overarching comments

related to Article 6, Use Restrictions on Chemicals and Consumer Products have been moved to section 69506.4 (January and April 2013).

§ 69506.5(e) Requirements for Training of Product Purchasers and/or Users

Comments: 37-19

Comment Summary:

The above comment expressed concern with section 69506(e), which allows DTSC to impose restrictions involving the training of purchasers or end users.
In summary, the following concerns were expressed:

- Impossible for retailers to accommodate this requirement if it applies to them; and
- Clarify what the requirements are on the retailer.

Response:

Use restrictions on Chemicals of Concern and Priority Products will apply to the chemical and/or the product. The retail center, to the extent relied upon to meet the requirements, will have to verify that the person making the purchase has received the training and is licensed to make the purchase if deemed necessary. This requirement is no different than is currently required of persons wishing to purchase “professional beauty supplies” for in home use. If a retailer chooses to lock products requiring training before purchase, they may do so, although it is not required. Similarly, there is no requirement that the retailer conduct the training. The retailer of a product that has a use restriction on the chemical regarding to whom the product may be sold to must comply only with that requirement. A retailer may stop offering for sale products that have use restrictions if the retailer believes the requirement is too burdensome.

In response to overarching comments related to Article 6, Use Restrictions on Chemicals and Consumer Products have been moved to section 69506.4 (January and April 2013).

§ 69506.5(f) Other Use Restrictions

Comment: 37-20

Comment Summary:

The above comment expressed concern with section 69506(f), which allows DTSC to impose other restrictions that reduce the amount of any Chemical of Concern(s) in a Priority Product or reduce the ability of the Priority Product to contribute to or cause an

exposure to the Chemical(s) of Concern. In summary, the following concern was expressed:

- The regulations must ensure that any "other" use restrictions are, at a minimum, feasible, affordable, and effective.

Response:

The provisions contained elsewhere in Article 6, namely sections 69506 and 69506.1, Regulatory Response Selection Principles and Applicability and Determination Process, coupled with the above provisions, will ensure that any future restriction are feasible, affordable, and effective.

In response to overarching comments related to Article 6, Use Restrictions on Chemicals and Consumer Products have been moved to section 69506.4 (January and April 2013).

§ 69506.6 Product Sales Prohibition

§ 69506.6(a) AA Thresholds

Comments: 11-57, 41-25, 57-78, 74-73

Comments Summary:

The above comments expressed concern with section 69506.6(a), which specifies that a product sales prohibition does not apply to a product that contains any Chemical of Concern below the applicable AA threshold level. In summary, the following concerns were expressed:

- There is lack of clarity with the exemption for a product that does not contain any Chemical(s) of Concern above the AA Threshold provision;
- This requirement should only apply to the Chemical(s) of Concern that are the basis for listing as a Priority Product; and
- There may not be tests available for determining the presence of a particular material in a product, making these determinations and enforcement challenging.

Response:

The July 2012 proposed regulations envisioned an AA Threshold exemption that required responsible entities to submit analytical data demonstrating that the Priority Product did not contain the Chemical(s) of Concern above the threshold. The AA Threshold Exemption applied to both intentionally and non-intentionally added

Chemicals of Concern. If the Priority Product is retained as the selected alternative or the alternative selected contains Chemical(s) of Concern at or below the AA Threshold exemption level established for the Priority Product, if one was established, the product would be exempt from further regulatory responses; that is, the product sales prohibition would not be applied.

In response to comments related to the AA Threshold exemption, the exemption has been deleted from Article 3, and placed in Article 5 where it more appropriately aligns with the requirements related to Chemical and/or Product Removal Notifications. The AA Threshold Exemption in section 69505.3 exempts a responsible entity from conducting an AA pursuant to Article 5 if a product that is listed as a Priority Product meets the criteria for an AA Threshold exemption and the manufacturer of the product submits an AA Threshold Exemption Notification to DTSC (January and April 2013).

The provisions related to AA Threshold have been deleted from this section. In response to overarching comments related to Article 6, Product Sales Prohibition has been moved to section 69506.5 (January and April 2013).

§ 69506.6(b) & (c) Notification that a Safer Alternative Exists

Comments: 11-57, 37-21, 41-25, 42-22, 44-13, 57-77, 57-79, 74-73, 109-19

Comments Summary:

The above comments expressed concern with section 69506.6(b) and (c), which specifies that if DTSC determines and notifies the responsible entity that there is a safer alternative that does not contain a Chemical of Concern and that is both functionally acceptable and technically and economically feasible, the responsible entity must cease placing the product into the stream of commerce in California within one (1) year, unless the notification specifies a shorter period of time. In summary, the following concerns were expressed:

- Amend regulatory text to clarify or make requirements more explicit;
- The text “unless the notification specifies a shorter period of time” leaves open the possibility that unworkable time frames could be provided and specific criteria should be provided;
- The graveness of this regulatory response means DTSC should only be permitted to do so after significant deliberation and satisfying a high standard of due process;
- This mechanism should not be invoked unless significant adverse impacts are identified that make it necessary to protect public health and the environment;

- This mechanism should only be invoked with a rulemaking which allows for public review and comment;
- A sales prohibition is only appropriate in the circumstances set out in subsection (b);
- DTSC should not specify which chemical ingredients should be used in products; and
- DTSC should not be empowered to determine and/or require that a safer alternative chemical should be used in the Priority Product.

Response:

As stated in the ISOR and in Article 5, as part of the Alternatives Analysis, a responsible entity may retain the Chemical of Concern in the Priority Product as one of the alternatives considered and may choose to keep the Priority Product as its final alternative. Conceptually, the July 2012 proposed regulations contemplated that after conducting research and development, safer alternative(s) would be identified by some responsible entities of similar Priority Products. DTSC would then take this information into account and notify the other responsible entities to either modify their Final AA Report to consider other alternatives and/or cease placing the Priority Product in the stream of commerce in California. However, in response to the above comments, the provisions have been modified and the companion provisions of section 69506.10, Regulatory Response Selection and Re-Evaluation, have been deleted (January and April 2013).

The revised language in the proposed regulations effectively requires that if the products sales prohibition is applied on a Priority Product, the regulatory response must be applied at the onset—meaning following the public comment period of the Final AA Report and draft regulatory response(s), regulatory responses will be required. Regulatory responses will not be re-evaluated and new ones applied at a later date. The product sales prohibition may be applied if sufficient information is received during the public comment process that demonstrates safer alternatives exist without the need for the Chemical of Concern(s) and/or adverse human and environmental impacts are of high enough concern that despite the absence of a safer alternative, the product must be prohibited to mitigate ongoing adverse public health or environmental impacts. Information related to the safety and performance of a consumer product may be submitted during the AA process and, for consideration by DTSC, prior to the regulatory response(s) being selected.

In response to concerns related to DTSC specifying shortened or compressed periods of time to remove a Priority Product from the stream of commerce in California, those

provisions have been deleted. Narrative standards are included to allow DTSC and the responsible entities to take into account the complexity of a Priority Product being removed from the stream of commerce in California in setting the time line for compliance (January and April 2013).

In response to overarching comments related to Article 6, Product Sales Prohibition provisions have been moved to section 69506.5 (January and April 2013).

§ 69506.6(d)(1) Notification Product May No Longer be Placed into the Stream of Commerce in California

Comments: 4-17, 11-57, 36-117, 37-22, 41-25, 42-23, 42-24, 42-25, 44-13, 57-80, 66-63, 109-19

Comments Summary**:**

The above comments expressed concern with section 69506.6(d)(1), which specifies that if DTSC determines and notifies the responsible entity that a product containing a Chemical of Concern may no longer be placed into the stream of commerce in California, notwithstanding that there are no currently identified safer alternatives that are both functionally acceptable and technically and economically feasible, the responsible entity must cease placing the product into the stream of commerce in California within one (1) year, unless the notification specifies a shorter period of time. In summary, the following concerns were expressed:

- Bans should only be done if legally permissible, in very rare cases where “imminent hazard” is observed and appropriately balance public safety, economic, and societal impacts;
- There may be a need for recall of product already sold;
- The potential stockpiling of upcoming prohibited products at some intermediate stage in the marketing of a Chemical of Concern and/or Priority Product should be addressed;
- Additional language should be added here to ensure that phased-out products, with a consumer label or not, are not dumped into discount stores and low-income areas;
- Subsection (d) contains no standards as to when DTSC would issue a notification prohibiting the sale and enables DTSC to impose unfettered and potentially arbitrary discretion;
- Given the severe effect of banning an entire type of product where no alternative exists, the standards placed on DTSC should be much higher; and

- How can DTSC make a determination that a product is so dangerous that it must be removed from the stream of commerce, absent acceptable alternatives, while existing consumer protection and public health regulators would not already have authority to do so?

Response:

As stated in the ISOR and pursuant to section 69506.1, prior to issuing or modifying the regulatory response(s) applied to any Priority Product, DTSC will notice and inform all known responsible entities for the product and make the proposed regulatory responses available on its website for public review and comment. Once a regulatory response is applied, it will not be re-evaluated or new ones applied, unless the Priority Product is re-listed and after public comment received, new regulatory responses applied. This approach ensures that factors such as public safety, economics, and societal impacts are adequately balanced and the concerns of stakeholders are voiced and addressed. Product sales restrictions apply to the product regardless of where the product is sold in California. As such, language specific to discount stores and low-income areas is not necessary.

As stated in the ISOR, the goals and intent of the proposed regulations are to compel the quest toward safer alternatives. As such, it is likely that there will be instances where safer alternatives do not readily exist but the impacts of the Priority Product are so compelling that a product sales prohibition must be applied. Different regulatory agencies have different mandates such as protection of air, water, or public health but seldom a comprehensive mandate to address all media and impacts simultaneously. The approach in Health and Safety Code sections 25251 through 25257.1 that make up the authorizing legislation is the first comprehensive approach taken thus far in the California. Products that have impacts in all media or various stages of their life cycle but whose impact are not comprehensively addressed or seen because of the divergent mandates on multiple agencies will now be evaluated across the life cycle of the product and in all media to more accurately account for the total impacts of the product.

As stated in the ISOR, if a product is adequately regulated and/or it does not pose adverse public health and environmental impacts, it will not get prioritized. However, if a product is not adequately regulated and public health and/or environmental impacts are observed, it may get prioritized. Generally, existing regulatory frameworks address a single medium or a discrete subpopulation and fail to take into account the life cycle impacts which yield a false low impact. The proposed regulations are more comprehensive and will begin to demonstrate that when impacts are combined across the life cycle, impacts that were seen as marginal are in fact of higher concern.

Section 69506.6(b) provides that, in making a determination, DTSC would consider the exposure pathways and the ability to contribute to or cause adverse public health impacts and/or environmental impacts associated with an alternative product or the Priority Product. In response to overarching concerns regarding the use of the term " ability to" in lieu of "potential," the provisions have been amended, and the term "ability to" has been deleted and "potential" inserted in its place (January and April 2013).

In response to overarching comments related to Article 6, the provisions in Product Sales Prohibition have been moved to section 69506.5 (January and April 2013).

§ 69506.7 Engineered Safety Measures or Administrative Controls

§ 69506.7(a) Engineered Safety Measures or Administrative Controls: Applicability

Comments: 36-61, 41-30

Comments Summary:

The above comments expressed concern with section 69506.7(a), which allows DTSC to impose requirements that control access to or limit exposure to Chemical(s) of Concern in a selected alternative product, or a Priority Product for which an alternative is not selected, to reduce the likelihood of adverse public health and/or environmental impacts. In summary, the following concern was expressed:

- This section, like sections 69506.4 and 69506.5, does not contain the provision "except as provided in section 69506.3" and creates ambiguity;
- Engineered safety measures or administrative controls should be considered an interim action until a more sustainable solution is found; and
- While there is little DTSC can do about this, people do not always follow the engineering and administrative controls listed in warning labels.

Response:

Conceptually, section 69506.3 was intended to address the instances where the evidence demonstrated absence of adverse public health and environmental impacts; however, the provision created more confusion than clarity and it has therefore been deleted.

While DTSC concurs that there may be instances where engineering or administrative controls may be interim measures, there may be instances where it is the only feasible

means of preventing human and/or environmental impacts and, thus, is an appropriate permanent regulatory response. DTSC is mindful that individuals may not always follow the engineering and/or administrative controls listed on warning labels. Please refer to the discussions under *section 69506(a) Need for Regulatory Response*; *section 69506(b) Inherent Protection Preference*; and *section 69506(c) Factors in selecting a Regulatory Response*, of this Response to Comments document, for details on the principles that DTSC will employ in the selection of the most appropriate regulatory responses.

In response to numerous comments related to the revision of regulatory responses without the opportunity for stakeholder and/or public comment, a companion provision in section 69506.10 has been deleted.

In response to overarching comments related to Article 6, Engineering Safety Measures or Administrative Controls has moved to section 69506.6 (January and April 2013).

§ 69506.7(b) Engineered Safety Measures or Administrative Controls: Criteria

Comments: 5-120, 5-177, 11-58, 39-6, 66-64, 74-74, 101-34

Comments Summary:

The above comments expressed concern with section 69506.7(b), which allows DTSC to impose engineering or administrative controls that either integrally contain the Chemical(s) of Concern within the structure of the product or limit exposure to the Chemical(s) of Concern to control access to or limit exposure to Chemical(s) of Concern in a selected alternative product, or a Priority Product for which an alternative is not selected, to reduce the likelihood of adverse public health and/or environmental impacts. In summary, the following concerns were expressed:

- Amend and/or delete language to narrow scope—it is unnecessarily strict;
- Engineering or administrative controls should be implemented to reduce real human health or environmental risks and the analysis necessary to make such determinations should be included;
- When engineering or administrative controls are necessary to control exposures, responsible entities should be required to completely eradicate the use of their Chemical(s) of Concern by seeking other and safer alternatives;
- This mechanism should be allowed only as interim action to protect public and/or environmental health until such safer alternatives can be developed;
- Use the term “accessibility” rather than “integrally contain” as there are defined tests for accessibility, making it a more objective standard for compliance;

- There needs to be thresholds for presence, as Chemicals of Concern, metabolites, or others may be naturally occurring or have multiple metabolites. Simply requiring "presence" is too ambiguous of a standard to be useful here; and
- DTSC has the power to redesign a product and it does not have the expertise to redesign products.

Response:

As stated earlier in section 69506.7(a) Engineered Safety Measure or Administrative Controls, there may be instances where engineering or administrative controls may be the only feasible means of preventing human and/or environmental impacts.

Controlling and/or eliminating the hazards through engineering safety measures could include permanent workplace modifications or redesign of the product to limit public and/or environmental exposures that could lead to adverse impacts. Engineering measures may be coupled with administrative controls that could include training or information dissemination for maximum effectiveness. For example, a Priority Product might be required to be placed behind a store counter for sale, or dispensed only by an informed intermediary who can explain relevant risks to purchasers (forms of administrative control). As another example, a product might be required to have a childproof cap or other packaging designed to deter improper use. This provision is necessary to make specific the provisions of Health and Safety Code section 25253(b)(6), which authorizes DTSC to regulate a Priority Product by "[i]mposing requirements that control access to or limit exposure to the chemical of concern in the consumer product."

Just as DTSC will not dictate an outcome of the AA, it will also not redesign products. The responsible entity elects to either comply with the requirements of Article 5 and 6 or take the product out of the stream of commerce in California. DTSC has the authority in appropriate cases to require the responsible entity for a Priority Product to make changes to the product to "control access to or limit exposure to the Chemical of Concern in the consumer product" (Healthy and Safety Code section 25253(b)(6)).

In response to the above concerns, reference to the term "integrally contain" has been deleted from this section. As stated in the ISOR, reliable information will be used to prioritize products containing Chemicals of Concern; those products are a priority because they have been linked to exposure to the Chemical(s) of Concern. It is impractical to include a threshold for Chemical(s) of Concern above which engineered safety measures or administrative controls would be triggered in the proposed

regulations given the varying complexities and types of products covered by the regulations. The determination of when an engineering control and/or administrative control are the best approach to limit an exposure must be done on a case-by-case basis.

In response to overarching comments related to Article 6, the provisions in Engineering Safety Measures or Administrative Controls have been moved to section 69506.6 (January and April 2013).

§ 69506.8 End-of-Life Management Requirements

Comments: 5-90, 5-91, 5-93, 12-12, 12-14, 12-15 27-3, 37-23, 37-26, 42-26, 44-14, 44-15, 44-18, 56-5, 57-81, 68-43, 104-5, 107-77, 124-8, 136-6, PH35-2, PH35-3

Comments Summary:

The above comments expressed general concerns with section 69506.8, which implements Health and Safety Code section 25253(b)(7) of the authorizing legislation. That statutory provision authorizes DTSC to impose a requirement on manufacturers to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product. In summary, the following concerns were expressed:

- End-of-life management requirements must be amended to conform with the enabling statute, which requires the obligation to be placed solely on manufacturers;
- The requirement for an end-of-life program as called for in the proposal is excessive, unnecessary, questionable, and duplicative of responsibilities of other state agencies;
- Manufacturers are required to develop, fund, and manage an end-of-life stewardship program for their products that generate hazardous waste;
- The statute does not authorize imposition of financial guarantees or compensation to retailers, local governments, and others;
- This mechanism is pre-empted by the federal Resource Conservation and Recovery Act (RCRA), as it conflicts with many of RCRA' s provisions, and RCRA occupies the field where these issues of end-of-life for hazardous waste management are concerned;
- Provide an exemption to manufacturers of selected consumer products if they are subject to another end-of-life management program;
- Build flexibility into the existing provisions that would allow for opt-out by individual companies or industries that can demonstrate that a recycling system

is in place or that they have voluntarily implemented their own effective take-back or recycling programs;

- The vast majority of pharmaceuticals in the environment are from human use and metabolites of medicines—not from the improper disposal of medicines;
- The end-of-life management program seems impossible to meet for individual companies, in particular for manufacturers that are small or medium enterprises and/or located in third world countries, and can probably only be achieved if DTSC establishes a rule applicable to (a range of) products that would apply to all responsible entities to create this jointly;
- In the light of the high costs involved, this regulatory response could amount to a disguised ban on marketing the product in California;
- If end-of-life management is already regulated in California, or by the federal government, it is duplicative to include such management in a regulatory response required under this Chapter;
- DTSC should acknowledge that certain other regulatory programs, combined with this Chapter, will provide complete life cycle management of the exposure risks for Chemicals of Concern in Priority Products in California;
- The regulations are not legally defensible;
- It is unclear how a manufacturer might be able to prove that an end-of-life management program is not feasible under subsection (d). How does this affect products that are hazardous waste as sold, but are no longer considered hazardous after complete use by the consumer; and
- How does this section impact local and state waste disposal sites without being burdensome and cost prohibitive?

Response:

In response to the above comments, the regulatory text has been amended to explicitly reflect that end-of-life requirements fall on the manufacturer of the Priority Product or of the alternative that is selected.

As stated in the ISOR and in Article 1, the authorizing legislation exempts certain products from the statutory scheme and the implementing proposed regulations. As such, prescription drugs are not subject to the proposed regulations. Further, section 69501(b)(2) exempts from the regulations any product that is statutorily exempted from the definition of “consumer product.” DTSC does not have the authority to exempt other consumer products that are not statutorily exempted. However, flexibility is included in the proposed regulations in section 69506.8(c), which allows a manufacturer to submit to DTSC an existing end-of-life management program for review. If an existing program achieves the same results of the a program that would be required by this

section, the existing program may be substituted and/or amended to the extent necessary to comply with the requirements of this section.

As indicated above, DTSC does not have the authority to exempt products or entities beyond what is authorized in statute, inclusive of small to medium enterprises or manufacturers located oversees. As stated in the response to comments in section 69505.2, Analysis of Priority Products and Alternatives, a beta test or feasibility study has not been conducted. However, the narrowed focus of the Priority Products in the first years of implementation will allow DTSC to address limitations with the overall program and address them in the out years. In addition, the proposed regulations adequately accommodate responsible entities forming a consortium, collaboration, or other similar partnerships to offset costs and minimize duplication of efforts.

The proposed regulations are consistent with the goals and intent of Health and Safety Code section 25253. Health and Safety Code section 25253(b)(7) expressly authorizes DTSC to impose a requirement “for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product.” The proposed regulations make specific how DTSC intends to implement the provision. It would be difficult to believe that an end-of-life management program consisting of “responsible disposal of the consumer product” would not include some level of financial compensation to address impacts experienced by the entities typically relied upon to ensure proper disposal of a product at the end of its useful life.

The ability to require an end-of-life management program for products that must be managed as hazardous wastes in California at the end of their useful life does not conflict with RCRA. RCRA expressly authorizes state hazardous waste management schemes that are broader in scope and more stringent than the federal RCRA program. The State of California, namely DTSC, is authorized by U.S. EPA to implement the California hazardous waste management program in lieu of RCRA. In addition, RCRA excludes certain solid wastes from the definition of hazardous waste. Household hazardous wastes, for example, are excluded from the definition of “hazardous waste” because of their ubiquitous volume. As such, regulating household hazardous waste has historically fallen on state and local governments who then transfer the burden of paying for these programs to taxpayers. As stated in Health and Safety Code section 25255, “the goals of this Article [include] significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches.”

As stated in the ISOR, the requirements of this section apply to products that are required to be managed as hazardous waste at the end of the product's life. The requirements of this section are necessary to build on, but do not duplicate or conflict with, existing regulatory requirements for products that must be handled as hazardous wastes at the end of their useful life. For many of these products, there are no end-of-life management programs in place, whether mandatory or voluntary. This places a logistical burden and financial hardship on local and state agencies and ultimately, taxpayers to provide for management of these products at the end of their useful lives.

Additionally, the lack of an adequate end-of-life management program often leads to illegal end-of-life disposal practices that result in adverse public health and environmental impacts. As an example, only a small fraction of Californians dispose of their mercury-containing compact fluorescent light (CFL) bulbs at a hazardous waste collection facility, as is required by law. This regulatory provision is necessary to address the situations in which comprehensive product stewardship programs are most likely to be appropriate under these regulations, to specify the elements that must be included in a DTSC-mandated product stewardship program. These provisions are based on guidance provided by the Association of State and Territorial Solid Waste Officials, the California Department of Resources Recycling and Recovery, and the California Product Stewardship Council. These provisions are meant to address both the environmental impact of Priority Products, and the fiscal impacts of waste management on local and state governments and taxpayers. These provisions provide a comprehensive yet flexible method for managing products that may have significant adverse impacts on public health and the environment if not properly managed at end-of-life.

In response to overarching comments related to Article 6, End-of-Life Management Requirements have moved to section 69506.7 (January and April 2013).

§ 69506.8(a)(2) Applicability of End-of-Life Management Requirements

Comments: 12-16, 26-6, 36-115, 37-25, 37-27, 43-1, 44-17, 51-1, 52-1, 57-81, 62-1, 66-65, 66-66, 66-70, 77-1, 89-1, 90-1, 107-77, 110-1, 111-1, 114-4, 114-17, 116-1, 118-8

Comments Summary:

The above comments expressed concern with section 69506.8(a)(2), which requires that a manufacturer for a selected alternative, or a Priority Product for which an alternative is not selected, that is sold or otherwise made available to consumers as a

finished product and is required to be managed as a hazardous waste in California at the end of its useful life, shall within one (1) year fund, establish, and maintain an end-of-life management program for the product and ensure that information required by section 69506.4 is provided for the product. In summary, the following concerns were expressed:

- Add language to include public comment from stakeholders prior to approval of product stewardship plans and post them on DTSC's website;
- The automatic requirements for end-of-life management are crucial to ensure proper handling of Priority Products at the end of their useful life;
- These requirements will also encourage manufacturers to incorporate innovation into their designs to create greener products;
- Comprehensive product stewardship plans are very significant undertakings—logistically, financially, and otherwise—that should not be imposed absent careful consideration of all factors delineated in section 69506(c);
- Responsible parties should also be required to estimate the lifetime of the applicable products they are managing and provide DTSC with a copy of their product stewardship plan;
- Many companies are engaging in research and development to achieve the goals specified in the end-of-life requirement independent of the mandates in these regulations and should be given credit for their efforts; and
- The one year time frame given in this subsection to fund, establish and maintain an end-of-life program is far too short for entities to implement the complex take-back schemes envisioned by this section;

Response:

In response to the above comments and comments received on Article 5, DTSC has revised the proposed regulations to include public review and input of Final AA Reports and Abridged AA Reports. (April 2013) After issuing a compliance or disapproval determination for the Final AA Report or Abridged AA, whichever is applicable, DTSC will issue a proposed notice of determination and notify all responsible entities for the product and individuals on the electronic list, related to this chapter, regarding the determination and availability of the proposed regulatory response determination. The proposed regulatory response determination will be made available on DTSC's website for public review and comment. DTSC will hold one or more public workshops to provide the opportunity for comment on the proposed regulatory response determination.

The anticipated useful life of Priority Products and/or their alternatives will be established as part of the AA process established in Article 5 and, consequently, it is not necessary to amend the provisions in Article 6 to address this concern. The end-of-life management requirements and the respective product stewardship plan will be required if the Priority Product or its alternative has an end-of-life impact that requires to be treated as a hazardous waste at the end-of-life. A proposed notice of determination will be made available to all known responsible entities of the product and individuals on the electronic mailing list. If an entity is actively engaged in conducting research and development to address issues regarding end of life those efforts will undoubtedly pay off when it comes to implementing the product stewardship plan. Given the time lines to conduct the AA and public review periods for the proposed regulatory response, manufacturers will have sufficient time to fully consider, evaluate and implement a product stewardship plan. Adding additional time will unnecessarily continue the delay of expediting the process to safer alternatives.

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the provisions of section 69506.8(a) have been amended and are now under section 69506.7(a) provisions related to roles and responsibilities have been streamlined and are now under section 69506.7(b) (January and April 2013).

§ 69506.8(a)(2)(A)3. Product Stewardship Plan: Roles and Responsibilities

Comments: 19-37, 37-24, 37-25

Comments Summary:

The above comments expressed concern with section 69506.8(a)(2)(A)3, which requires that a responsible entity, namely the manufacturer, include in the product stewardship plan the roles and responsibilities for manufacturers, importers, retailers, consumers, and government throughout the life cycle of the product and identification of retailers who have agreed to participate in the program. In summary, the following concerns were expressed:

- It is imperative that if responsibilities are contemplated beyond those authorized by Health and Safety Code section 25253(b)(7) (*i.e.*, beyond manufacturers) that importer and/or retailer participation be entirely voluntary;
- Responsibility for developing end-of-life programs, state, and local infrastructure programs and all related costs should be included;

- Product stewardship plans should assign responsibility all along the supply chain including all intermediate suppliers as well as the consumer;
- If consumers are not assigned some responsibility in DTSC's regulatory approach then all the upfront work to encourage sustainable approaches will be negated;
- If the final manufacturer is responsible for all aspects of end-of-life management, there is no incentive for all players along the supply chain to invest in green design and development;
- Language appears to leave the door open for a manufacturer to create a plan that imposes responsibilities on importers and grocery retailers without the advice and, most importantly, consent of those parties; and
- The stewardship plan calls for grocery retailers to accept hazardous waste for in-store recycling or disposal purposes, even though grocery retailers may be unable to do so without violating the stringent requirements for licensed food facilities.

Response:

Health and Safety Code section 25253(b)(7) assigns responsibility for end-of-life management to manufacturers with the stated goal, per Health and Safety Code section 25255, "of significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches."

The development of the product stewardship plan, if it is to be successful, must be developed in coordination with impacted stakeholders which includes the manufacturer, importers, retailers, consumers, and government throughout the life cycle of the product. Any responsibilities placed on any entities, that the manufacturer is relying on such as the infrastructure established by government, or information along the supply chain including retailer, and dependence on consumers, to ensure a successful program, must be addressed by the manufacturer. While the regulations do not compel a retailer to participate in a take back program, the manufacturer must take into account which parties it is relying upon to ensure success of the program whether it achieves cooperation from the retailer or not. Grocery retailers are not required to accept hazardous waste under the proposed regulations.

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the

provisions related to roles and responsibilities have been streamlined and are now under section 69506.7(b)(2)(C) (January and April2013).

§ 69506.8(a)(2)(A)5. Product Stewardship Plan: Applicable and Relevant Requirements

Comments: 41-32, 41-33, 41-34, 109-20, 130-2, 136-6, PH35-1

Comments Summary:

The above comments expressed concern with section 69506.8(a)(2)(A)5, which requires that a manufacturer, include in the product stewardship plan end-of-life management information, including the steps that will be taken to ensure compliance with all applicable federal and State of California and local laws and that addresses any adverse multimedia impacts. In summary, the following concerns were expressed:

- The proposed regulations will potentially be in conflict with the Public Resources Code, which requires municipalities to develop strategies for achieving the State goal of 75% recycling rate; and
- Putting the programs in the hands of manufacturers may provide problems for municipalities who are currently developing strategies for recycling that do not rely on manufacturers.

Response:

The proposed regulations have provisions specifically designed to address applicable and relevant federal and/or state goals and/or mandates. The requirements under the stewardship plan will help meet those goals. Under this provision, the responsible entity, namely the manufacturer, is explicitly directed to take into account any federal and/or state goals in developing its product stewardship plan.

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the provisions related to applicable and relevant federal and state requirements have been streamlined and are now under section 69506.7(b)(2)(E) (January and April 2013).

§ 69506.8(a)(2)(A)6. & 7. Product Stewardship Plan: Resource Requirements

Comments: 5-121, 5-178, 19-39, 48-1, 95-8, PH10-5

Comments Summary:

The above comments expressed concern with sections 69506.8(a)(2)(A)6. and 7., which require that a responsible entity, namely the manufacturer, include in the product stewardship plan the anticipated resources needed to implement and sustain the plan, including identification of any third-party product stewardship organization collecting and administering a fee to fund the stewardship program and/or any financial guarantee to insure a sustainable end-of-life management program for the product. In summary, the following concerns were expressed:

- The provisions allowing for imposition of the financial guarantee, "collecting and administering a fee to fund the stewardship program," compensation to retailers collecting used products should be eliminated, as they are not authorized by statute;
- Responsibility should be placed on all responsible parties, including state and local government, for creating the needed public infrastructure, and consumers for following safe and sustainable disposal practices;
- The financial guarantee language for sectors that have demonstrated effective programs in this area should be removed;
- Concerned that "financial assurance" is unclear and may not provide the level of assurance that would be adequate; and
- The regulatory responses should be revised to be practical, and tailored to address the Chemical(s) of Concern in the Priority Product.

Response:

As stated in the ISOR and in the discussion under *section* 69506.8(a)(2)(A)3 Product Stewardship Plan Roles and Responsibilities, these requirements are necessary for DTSC to assess the financial assumptions under which the plan is being developed and to ensure that responsibility for financing the product stewardship program is appropriately assigned to the manufacturer.

Through AB 1879, Legislature authorized "imposing requirements for the manufacturer to manage the product at the end of its useful life" and the ability to require financial assurance is implicit in this grant of authority and reasonably necessary to effectuate the statute.

This provision makes the manufacturer responsible for addressing the implications that its product places on the market throughout the product's life cycle, including ultimate disposition at the end of product's useful life. By placing this responsibility on the manufacturer, instead of requiring local governments to fund collection and recovery programs for discarded products, the product stewardship program will force internalization of the costs of collection and disposal or recovery, so those costs are

borne jointly by the producer and the consumer (*i.e.*, the parties deriving direct benefit from the product's sale) rather than passed on to taxpayers.

In response to the above comments, the provisions in section 69506.8(a)(2)(A)7.b. related to "financial guarantee" have been amended to eliminate reference to Article 8 of Chapter 14. The remaining narrative provisions have be retained.

In response to overarching comments related to Article 6, the provisions of sections 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the provisions related to resource requirements in the product stewardship plan have been streamlined and are now under section 69506.7(c)(2)(F) (January and April 2013).

§ 69506.8(a)(2)(A)8. Product Stewardship Plan: Performance Goal Requirements

Comment: 41-32, 41-34, 48-2, 109-20, 130-2

Comments Summary:

The above comments expressed concern with section 69506.8(a)(2)(A)8., which requires that a responsible entity, namely the manufacturer, include in the product stewardship plan the program performance goals, which shall be quantitative to the extent feasible, for increasing the capture rate of covered products at the end-of-life and increasing recyclability. In summary, the following concerns were expressed:

- Recyclability is not the same as increasing recycling rate—both should be included;
- Given the potentially low Chemical(s) of Concern threshold limits and the liability associated with marketing a product containing a Chemical(s) of Concern, a manufacturer may move to virgin materials to mitigate their business risk; and
- Demand for recycled material may decline and meeting CalRecycle's 75% recycling goal may be difficult or impossible to meet.

Response:

DTSC concurs with the recommendation to include both recyclability and recycling and has amended the proposed regulations. As indicated in the discussion under *section 69506.8(a)(2)(A)5 Product Stewardship Plan*, the requirements in the proposed regulations specifically call for and require that applicable and relevant goals and mandates be addressed. Consequently, these regulations should not detrimentally affect any goals and/or mandates placed by federal and/or other state requirements.

In response to comments related to the AA Threshold exemption, those provisions have been moved from Article 3 into Article 5 where they more appropriately align with the requirements related to Chemical and/or Product Removal Notifications. The AA threshold exemption in section 69505.3 exempts a responsible entity from conducting an AA pursuant to Article 5 if a product that is listed as a Priority Product meets the criteria for an AA threshold exemption and the manufacturer of the product submits an AA threshold exemption Notification to DTSC (January and April 2013).

The revised language specifies that an AA threshold exemption is only available as a default for a manufacturer's Priority Product if the Chemical(s) of Concern are present in the product solely as contaminants and the concentration of the Chemical(s) of Concern does not exceed the practical quantitation limit (PQL) for the chemical(s). If during the product prioritization process DTSC determines that an AA Threshold is needed for a particular unintentionally added chemical in a particular product or that the AA Threshold should be higher than the PQL for a contaminant, this can be addressed in the rulemaking for that Priority Product listing. DTSC is mindful that any limits on contaminants may ultimately play a role in the amount of recycled content used as feed stocks. The provisions in the proposed regulations address provided DTSC sufficient latitude to address this during implementation should the amount of recycling become a concern (January and April 2013).

In response to overarching comments related to Article 6, the provisions of sections 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the provisions related to stewardship plan performance goals and responsibilities have been streamlined and are now under section 69506.7(c)(2)(H) (January and April 2013).

§ 69506.8(a)(2)(B) Product Stewardship Plan: Coordination Requirements

Comments: 5-122, 37-23, 37-28, 42-27, 44-16

Comments Summary:

The above comments expressed concern with section 69506.8(a)(2)(B), which requires that a responsible entity, namely the manufacturer, include in the product stewardship plan for collecting and, if applicable, the recycling of the product. The plan must be developed in consultation with California retailers and owners/operators of prospective collection sites. The collection program must include the collection mechanisms and/or compensation to retailers and other persons who agree to administer or participate in the collection program. In summary, the following concerns were expressed:

- Amend text to make it voluntary for third parties and place all requirements on manufacturers;
- Participation on the part of entities beyond those outlined in Health and Safety Code section 25253(b)(7) should be entirely voluntary and reimbursable;
- Health and Safety Code section 25253(b)(7) requires manufacturers to manage products at the end of their useful life, and there should be no requirement that retailers participate in collection programs;
- The proposed regulations would allow a manufacturer to require in-store collection of hazardous waste and refuse to reimburse a grocery retailer for their expenses in dealing with those substances inside a licensed food facility;
- Retailers should be reimbursed for financial burdens associated with participation in a collection program; and
- There is a conflict between the regulatory language and the ISOR which may just be a drafting error in the regulations. The current language in the regulations reads *one or both. The ISOR states that both a collection mechanism AND compensation to persons participating in the program should be provided.*

Response:

As stated in the ISOR, the establishment of an effective and robust collection infrastructure is an essential element of an end-of-life management program. For many products, this will require establishing collection sites that are operated by businesses other than the manufacturer. This provision provides responsible entities that may be out of state the flexibility to establish a program to be implemented by an entity that is willing to administer the program on their behalf.

As discussed under *section 69506.8(a)(2)(A)3 Product Stewardship Plan Roles and Responsibilities*, an effective product stewardship plan requires the coordination of efforts of stakeholders along the life cycle of a product. Failure on the part of any of the stakeholders along the life cycle of the product, whether it be the manufacturer, importers, assemblers, retailers, consumers and government, compromises the success of the program and places an additional burden on the others. Nonetheless, the regulations do not compel participation in end-of-life management programs for any entity other than the manufacturer, given the constraints of the authorizing legislation.

The proposed regulations require that the product stewardship plan include coordination activities and written identification and documentation of retailers and or assemblers who have agreed to participate in the program. While the proposed regulations do not compel the retailers to participate in a take back program, the proposed regulations do require that the manufacturer in preparing its product stewardship plan take into account

the stakeholders that will participate to ensure the infrastructure is in place. The proposed regulations do not authorize the manufacturer to compel the retailer to collect hazardous waste.

In response to the above and other comments received on the proposed regulations dated January 2013, the provisions in the regulations have been amended to remove the requirements specifying that both a collection mechanism and compensation to persons participating in the program should be provided.

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the provisions related to have been streamlined and are now under section 69506.7(c)(3) (January and April 2013).

§ 69506.8(a)(2)(C) Product Stewardship Plan: Availability Requirements

Comment: 48-3

Comment Summary:

The above comments expressed concern with section 69506.8(a)(2)(C), which requires that a responsible entity, namely the manufacturer, provide its product stewardship plan to DTSC for review and approval, post a copy of the product stewardship plan on its own website and provide a link to the posting to DTSC for posting on DTSC's website. In summary, the following concern was expressed:

- DTSC should carefully consider whether more specific language in the proposed regulations is necessary to ensure quality plans are submitted. An example of a quality plan is Carpet America Recovery Effort's (CARE) plan submitted to CalRecycle. CARE is a stewardship organization for carpets. This plan can be found on the following website: http://www.calrecycle.ca.gov/EPR/Carpet/default.htm#Stewardship

Response:

DTSC has consulted with and taken into account the recommendations provided by CalRecycle and other interested stakeholders in developing the provisions contained in this section. The salient parts contained in the above-mentioned stewardship plan include:

- Contact information;

- Participants;
- Scope;
- Performance Goals and Activities;
- Solid Waste Management Hierarchy;
- Collection Systems;
- Market Development;
- Financing Mechanism;
- Education and Outreach;
- Program Performance Measurement;
- Stakeholder Consultation; and
- Audits are all reflected in the proposed regulations.

DTSC has given the product stewardship plans careful consideration and does not believe that additional changes to the regulations are necessary to ensure that quality plans are submitted.

In response to overarching comments related to Article 6, the provisions of sections 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the provisions related to product stewardship plan availability have been streamlined and are now under section 69506.7(c)(4) (January and April 2013).

§ 69506.8(a)(2)(D) Product Stewardship Plan: Annual Requirements

Comments: 48-4, 48-5, 66-67

Comments Summary:

The above comments expressed concern with section 69506.8(a)(2)(D), which requires that the responsible entity, namely the manufacturer, ensure that a report is provided to DTSC annually from the date the end-of-life management program is required to be implemented. The report must include, by total tonnage, the quantity of products placed into the stream of commerce in California over the previous one-year period and the quantity of products recovered over the same one-year period. In summary, the following concerns were expressed:

- Report should mirror what is required in the plan;
- Multiple programs with different due dates for their annual reports may be administratively challenging;

- The information on state sales and recycling is likely not available. Most sales are done through distributors, and manufacturers have no way to track what is sold in state; and
- For durable products, especially, which have lifespans of several years, the amount of goods recovered in a given year will have no relation to the amount of goods sold, which could give the impression to DTSC that a program is performing poorly when in fact it is not.

Response:

The report requested under this provision is an annual report and not an amendment to the product stewardship plan. In an effort to minimize costs, the product stewardship plan, unless revised, does not need to be submitted annually as it is not anticipated to change from year to year. The report must include, by total tonnage, the quantity of products placed into the stream of commerce in California over the previous one-year period and the quantity of products recovered over the same one-year period which is expected to fluctuate from year to year.

DTSC understands that all of the information may not be initially available; however, the proposed regulations will create the demand for the information and as the program matures the information will become more readily available. While the information will be reported on an annual basis, the information can be easily extrapolated for consumer products with lifespans of several years, where the amount of goods recovered in a given year will have no relation to the amount of goods sold. DTSC is mindful of these instances.

In response to overarching comments related to Article 6, the provisions of sections 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the provisions related to annual requirements for product stewardship plans have been streamlined and are now under section 69506.7(c)(5) (January and April 2013).

§ 69506.8(b) End-of-Life Management Collaboration

Comment: 86-26

Comment Summary:

The above comment expressed concern with section 69506.8(b), which allows the responsible entities, namely the manufacturers, to form a third-party product stewardship organization, funded by participating manufacturers and other responsible

entities, to provide local services to collect, recycle, or otherwise appropriately manage covered products at the end-of-life. In summary, the following concerns were expressed:

- Rather than require that each manufacturer fund, establish, and maintain a management system for end-of-life, the state should fund such activity. There will be chaos at the products' end-of-life if each company tries to have its own and different system.

Response:

As stated in the ISOR, the provisions provide the necessary flexibility for responsible entities to collaborate with other responsible entities to implement an end-of-life management program. The flexibility and critical mass that may result from collaboration are intended to incentivize the creation of effective end-of-life programs than would occur if a manufacturer was required to act independently.

For the reasons cited in the discussion under section 69506.8 End-of-Life Management Requirements, it is imperative that manufacturers fund, establish, and maintain the product stewardship plan, not government. The authorizing legislation clearly envisions and authorizes that the manufacturers ultimately have the responsibility for the end-of-life effects of their products and that manufacturers be responsible for implementing these efforts. A state-funded end-of-life management program places a logistical burden and financial hardship on local and state agencies, and ultimately taxpayers, to provide for management of these products at the end of their useful lives. The proposed regulations provide ample opportunity for responsible entities to form a consortium, collaborative, or similar partnership to offset costs.

In response to overarching comments related to Article 6, the provisions of sections 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the provisions related to end-of-life management collaboration have been streamlined and are now under section 69506.7(b) under the heading Manufacturer Collaboration Option (January and April 2013).

§ 69506.8(c) Alternative End-of-Life Management Program

Comments: 37-29, 41-32, 41-34, 44-19, 74-75, 107-77, 109-20, 130-2, 136-6, PH35-1

Comments Summary:

The above comments expressed concern with section 69506.8(c), which requires that a responsible entity, namely the manufacturer, subject to the requirements of this section, may request DTSC's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program required by this section. A manufacturer may not substitute an alternative end-of-life management program for the program specified in this section unless it receives advanced written approval from DTSC. In summary, the following concerns were expressed:

- Establish criteria under which DTSC would consider approving an "alternative" end-of-life program other than that specified in the proposed regulations;
- A manufacturer subject to the end-of-life requirements may request DTSC's approval to substitute an alternative end-of-life program that essentially achieves the same thing that is outlined in the regulations; however, the manufacturer must seek written approval; and
- Existing regulations should include product stewardship programs that have been determined by regulatory authorities to provide adequate protection.

Response:

As stated in the ISOR, this provision provides the necessary flexibility to responsible entities to use innovative and/or customized approaches to address the end-of-life management concerns associated with their products. Without this provision, responsible entities would be required to follow the same end-of-life management program that may or may not suit their individual needs. However, DTSC must review the alternative end-of-life management plan to ensure the plan meets the requirements of Article 6.

As discussed under section 69506.8(a)(2)(C) Product Stewardship Plan Availability Requirements, stakeholders were consulted in the development of the proposed regulations. It is not necessary, nor advisable, to include existing product stewardship plans as part of the proposed regulations because those plans may or may not address the goals of this program. However, as the product stewardship plans are prepared and made available they will be posted on DTSC's website, which may be used as guidance if appropriate.

In response to overarching comments related to Article 6, the provisions of sections 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69505.7. In addition, the provisions related to alternate end-of-life management programs have been streamlined and are now under section 69506.7(d) (January and April 2013).

§ 69506.8(d) Exemption from End-of-Life Management Program Requirements

Comments: 5-92, 5-179, 12-17, 19-38, 36-116, 57-81, 66-68

Comments Summary:

The above comments expressed concerns with section 69506.8(d), which specifies that a responsible entity, namely the manufacturer, may request an exemption from the requirement to provide an end-of-life management program by demonstrating to DTSC's satisfaction in the Final AA Report that an end-of-life management program cannot feasibly be implemented for the product. In summary, the following concerns were expressed:

- There are no standards or clear criteria for obtaining the exemption;
- Add language that a manufacturer otherwise subject to the requirements of this section shall be exempt from an end-of-life management regulatory response if the manufacturers participating in an end-of-life management program or extended producer responsibility program that is currently required pursuant to a different California statute or regulation;
- An exemption for end-of-life management of low volume products should be provided;
- It is not clear what is meant by "demonstrating to the Department's satisfaction" that an end-of-life program cannot be feasibly implemented for the product or what criteria DTSC will use to assess whether any additional program is needed at all; and
- This provision will surely lead to claims that end-of-life programs are not feasible and DTSC would then have the job of deciding if the manufacturer had adequately "demonstrated" its claim.

Response:

As indicated in earlier discussions, DTSC does not have the authority to exempt products nor the entities that manufacture them beyond what is authorized in statute. Please refer to the discussion under section 69506.1 Applicability and Determination Process for details on the existing exemptions.

As discussed under section 69506.8(a)(2)(A)5 Product Stewardship Plan, responsible entities must consider goals and/or mandates imposed by other regulatory frameworks. To the extent that other regulatory frameworks address the life cycle impacts of the Priority Product or its alternative inclusive of the end-of-life impacts, the Priority Product may be exempt from additional end-of-life requirements under these provisions. DTSC,

however, retains the authority to review requests for exemptions to ensure that the goals and intent of authorizing statute are complied with.

Responsible entities must submit a request for an exemption from the regulatory responses containing the information specified in section 69506.11(b). If DTSC grants the exemption based on information contained in section 69506.11(b)(6), DTSC may require the implementation of a modified regulatory response that resolves any conflict. Further, DTSC may rescind an exemption if it determines that the facts or assumptions that it relied upon in granting the exemption are no longer valid.

As discussed in the ISOR and in the response to comments under Article 3, consumer products containing Candidate Chemicals will be prioritized based on:

1) Volume in commerce;
2) Propensity for exposure; and
3) Exposure to sensitive subpopulations.

The Candidate Chemical(s) identified in the Priority Products will become the Chemical(s) of Concern in Article 3. If a Priority Product is truly a “low volume” product, meaning not manufactured at high volumes to make an impact, it is not very likely that it will be prioritized. It is important to note that “low volume” by multiple manufacturers could equate a meaningful volume in commerce.

As stated in the ISOR, DTSC anticipates that this provision will be invoked infrequently, but it is necessary because there may be products that would otherwise be subject to the requirements of section 69506.8 for which an end-of-life management program cannot feasibly be implemented. This may be because of some unique characteristic of, or circumstance associated with, the product. DTSC is mindful that it may not regulate products in a manner that is duplicative of or conflicts with existing regulations. This provision acknowledges and accommodates that prohibition. However, the mere fact that a manufacturer is participating in another extended producer responsibility program does not necessarily mean that DTSC is prohibited from subjecting the manufacturer to an end-of-life program under these regulations. That is because the other program may not have the same objective or scope, it may not be compulsory, and it may not pose any conflict with this program.

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted. Provisions related to end-of-life management requirements have been moved to section 69506.7. In addition, the

provisions related to exemption from end-of-life management program requirements have been streamlined and are now under section 69506.7(e) (January and April 2013.

§ 69506.9 Advancement of Green Chemistry and Green Engineering

§ 69506.9(a)-(d) Advancement of Green Chemistry and Green Engineering

Comments: 5-180, 11-59, 36-119, 41-26, 41-35, 41-65, 41-66, 57-82, 66-69, 68-44, 74-76, 76-72, 107-78, 109-17

Comments Summary:

The above comments expressed concern with section 69506.9, which specifies that DTSC may require a manufacturer, who concludes that no safer alternative is available, to initiate a research and development project or fund a challenge grant pertinent to the Priority Product that uses green chemistry and/or green engineering principles. In summary, the following concerns were expressed:

- Amend proposed language to make criteria and/or standards more specific as to when DTSC will invoke requirement;
- Requirement should only be invoked when “no feasible safer alternative exists”;
- The listing of a Chemical of Concern in Article 2 will discourage researchers looking for innovative new formulations to make products last longer, function in different or improved ways, or to enhance other environmental characteristics from looking at any of the Chemical(s) of Concern listed on DTSC’s list;
- It is unclear if DTSC has reached out to the academic or private research community to better understand the potential downsides of the failure to include a research and development exemption;
- How will research and development be monitored and enforced and will there be penalties for non-compliance;
- A manufacturer might not have the resources to undertake such project or might believe that such projects are not likely to be successful;
- A manufacturer should always have the option of discontinuing manufacture of the Priority Product;
- How will the amounts be determined that a responsible entity will have to provide? As a share/percentage of overall sales? How will the DTSC avoid discriminatory treatment of different responsible entities;
- Legal protections must be in place to ensure ownership of the intellectual property;
- The requirement to initiate a research and development project or fund a challenge grant where a safer alternative does not exist raises significant

confidentiality issues and issues of ownership of intellectual property in a market where the products have important and significant chemistry-based differences;

- Some companies are engaging in research and development to achieve the goals specified in subparts (a) through (d), independent of the mandates in these regulations. These companies should be given credit for their independent efforts as it relates to this regulatory response; and
- Do not support the possible requirement to conduct research and development projects or fund a green chemistry challenge grant for Priority Products where no alternative chemical is selected because it is essentially a tax on manufacturers.

Response:

In response to the above comments, the provisions in section 69506.9 have been modified to more explicitly reflect the intent and goals of Health and Safety Code section 25253(b)(8), which authorizes DTSC to impose a requirement to fund green chemistry challenge grants where no feasible safe alternative exists (January and April 2013).

When a manufacturer concludes that no safer alternative to its Priority Product is functionally acceptable and technically and economically feasible, or a manufacturer selects an alternative that reduces but does not eliminate the use of the Candidate Chemical(s) in the product, DTSC may require the manufacturer to initiate a research and development project or fund a challenge grant pertinent to the Priority Product that uses green chemistry and/or green engineering principles to:

(i) Design a safer alternative;
(ii) Improve the performance of a safer alternative;
(iii) Decrease the cost of a safer alternative; and/or
(iv) Increase the market penetration of a safer alternative.

If, for example, after completing the first stage of the AA, the responsible entity determines a functionally acceptable alternative does not exist, the responsible entity may submit an Abridged AA. However, even if the manufacturer concludes that no viable alternative currently exists, they may be required to conduct a research and development project or fund a green chemistry challenge grant for the product. This is consistent with the goals and intent of statute. The proposed regulations do not require that the data gaps be filled during the AA process in Article 5; however, if information or research is necessary it may be required as a regulatory response. The manufacturer, however, reserves the right and option of discontinuing the manufacturing of the Priority Product and/or introducing it into the stream of commerce in California.

The Final AA Report must contain an implementation plan and schedule inclusive of the implementation of any regulatory responses that are applied. The proposed regulations have been modified in section 69505.7(k)(1)(A) to include annual progress reports for any regulatory response that will take longer than twelve (12) months to complete. The fact that DTSC may require a manufacturer to fund a challenge grant is not a tax. Rather, it is one of the expressly authorized outcomes upon the completion of an AA. A "tax" is a term of art under California Constitutional provisions and interpretive case law. The funding of a grant, in certain limited circumstances authorized by the Legislature and these regulations, does not meet the definition of a "tax" (January and April 2013).

As discussed under Article 5, forming a consortium, collaborative, or other similar partnership is accommodated in the regulations but is not required. A manufacturer subject to conducting research and development may undertake the effort on its own or form a consortium, collaborative or other similar partnership. The decision is up to the manufacturer. For the same reasons cited under Article 5, contractual business arrangements between responsible entities and any contractors, a consortium, collaborative, or other similar partnership must address and release of confidential business information or intellectual property. As such, the amounts, shares, and percentage of conducting a joint venture are outside of the scope of these regulations. The regulatory response provisions do not compel the sharing or release of any intellectual property under this program. Nor do they affect the status of any information under intellectual property regimes (*e.g.*, trademark, copyright, and patent law).

As discussed in the ISOR and in the response to comments under Article 2, the Candidate Chemicals list (formerly referred to as Chemicals of Concern list) is comprised of chemicals that exhibit hazard traits and/or environmental or toxicological endpoints and meets the specified criteria. Consumer products containing Candidate Chemicals will be prioritized based on:

1) Volume in commerce;
2) Propensity for exposure; and
3) Exposure to sensitive subpopulations.

The Candidate Chemical(s) in the Priority Products will become the Chemical(s) of Concern in Article 3. Researchers looking for innovative formulations should rightfully be discouraged from using chemicals on the Candidate Chemicals list and/or Chemicals of Concern list, as they have been determined to exhibit hazard traits and/or environmental endpoints.

Responsible entities actively engaged in conducting research and development to address alternatives to the use of Candidate Chemicals and/or Chemicals of Concern may be “ahead of the curve” when it comes to implementing this regulatory response should their product be listed as a Priority Product. Specific credits or exemptions are not included in the proposed regulations as they are not authorized.

While the provisions under this section do not explicitly reference the request for an exemption from a regulatory response, responsible entities may submit a request under former, section 69506.11, now 69506.9. As stated in the ISOR, a product is exempt from the requirements of article 6, if the responsible entity requests and DTSC grants an exemption (January and April 2013).

The responsible entities must submit a request for an exemption from the regulatory responses containing the information specified in former section 69506.11(b), now 69506.9(b). If DTSC grants the exemption based on the information provided, DTSC may require the implementation of a modified regulatory response that resolves any conflict. Further, DTSC may rescind an exemption if it determines that the facts or assumptions that it relied upon in granting the exemption are no longer valid (January and April 2013).

In response to overarching comments related to Article 6, the provisions of sections 69506.3 and 69506.10 have been deleted and corresponding changes have been made. Provisions related to Advancement of Green Chemistry and Green Engineering have been moved to section 69506.8 (January April 2013 2013).

§ 69506.10 Regulatory Response Selection and Re-Evaluation

§ 69506.10(a) Regulatory Response Selection and Re-Evaluation

Comments: 5-94, 5-95, 5-123, 5-181, 11-60, 37-30, 37-31, 41-27, 42-28, 44-20, 47-28, 47-29, 55-20, 66-71, 73-23, 73-24, 74-66, 74-77, PH12-8

Comments Summary:

The above comments expressed concern with section 69506.10(a) and (b), which allow DTSC to impose one or more regulatory responses to situations others than those specified in sections 69506.2 and 69506.4 through 69506.9 and may periodically re-evaluate any regulatory response imposed to determine if changes are needed based upon changed circumstances or information identified since a regulatory response was selected. In summary, the following concerns were expressed:

- Amend or delete the provisions to make requirements more explicit, establish criteria, and provide more certainty;
- These provisions could mean that a responsible entity invests significant capital in undertaking a regulatory response imposed by DTSC only to be told that DTSC has changed its mind and would instead like to impose a different regulatory response;
- There should be a point where the responsible entity is deemed to have complied with its obligations under the rules and the process is concluded;
- If new evidence of a concern appears, the product and chemical combination should once again go through a meaningful product chemical prioritization process;
- A “no further action" provision should be added to the regulations;
- If a Priority Product is indeed subject to the regulatory treadmill as a result of the current proposal, it will kill innovation by diverting company resources to continuously assess a product that is already safe and preventing the development of other improvements in safety, cost, and sustainability;
- “Definitive results” would be a successful criterion, without the need for further regulation of the alternative;
- This section seems to remove any of the constraints or certainty imposed by earlier sections; and
- How will regulatory responses apply to interim products and their service parts, thereby generating uncertainty in the regulated community?

Response:

In response to the concerns expressed above and related concerns on public input expressed under other regulatory responses, the provisions of this section have been deleted. Given that data gaps are not required to be filled as part of the AA process conducted under Article 5 but are instead filled as a regulatory response under Article 6, DTSC anticipated that as a result of data gaps being filled, new information could potentially lead it to either remove a regulatory response or impose additional regulatory response; hence, the flexibility in the proposed provisions.

In response to the above and related comments under section 69506.2(a) Supplemental Information for Selection of Regulatory Response, the provisions have been amended. While the regulations do not require that data gaps be filled as part of the AA conducted in Article 5, data gaps that are necessary to select the most appropriate range of regulatory responses will be required to be filled by the responsible entity. The amended text allows DTSC to revise the initial regulatory responses only if the data gaps that are addressed demonstrate revision to the regulatory responses is

appropriate. Any revision to the regulatory responses will be subject to public comment (January and April 2013).

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted.

§ 69506.11 Exemption from Regulatory Response Requirements

§ 69506.11(a) & (b) Request for Exemption from Regulatory Response

Comments: 5-96, 5-182, 9-113, 9-114, 11-61, 11-62, 12-13, 41-37, 41-38, 41-39, 41-40, 41-57, 56-3, 57-83, 57-84, 57-85, 66-72, 74-78, 74-79, 74-80, 101-35, 107-79, 109-3, 129-24, PH5-4

Comments Summary:

The above comments expressed concern with sections 69506.11(a) and (b), which specify that a product may be exempt from the requirements of sections 69506.4 through 69506.10, if the responsible entity submits a timely request containing the information specified and DTSC grants the request. The request must include contact information, information identifying and describing the product, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, and information that demonstrates to DTSC's satisfaction that either or both:

(1) The required regulatory response would conflict with a requirement of another State of California or federal regulatory program or a treaty or international trade agreement in such a way that the responsible entity could not reasonably be expected to comply with both requirements. In this situation, DTSC may require implementation of a modified regulatory response that resolves the conflict; and/or
(2) The required regulatory response substantially duplicates a requirement of another State of California or federal regulatory program or a treaty or international trade agreement without conferring additional public health or environmental protection benefits.

In summary, the following concerns were expressed:

- Amend or delete provisions so that a request for an exemption is not necessary and/or provide exemptions to certain products;
- The provisions ignored the fact that Health and Safety Code section 25257.1(b) prohibits DTSC from superseding the regulatory authority of any other

department or agency, even if it provides additional public health or environmental protection because it supersedes the other agency's regulatory program;

- The statute specifically precludes DTSC from requiring a regulatory response where either of these two scenarios occurs;
- DTSC should have presumably already completed the determination of conflicting or duplicative regulatory programs and the responsible entity should automatically be exempt from these requirements;
- The statute does not impose the burden on the responsible entity to apply for an exemption;
- A responsible entity should be able to request and receive an exemption for compliance with international law, such as Restriction of Hazardous Substances Directive or Registration, Evaluation, Authorisation and Restriction of Chemicals;
- The provisions grant DTSC the authority to require specific e*xtended producer responsibility* components that were intentionally left out of AB 1343[8], allowing a back door way for CalRecycle and DTSC to push PaintCare towards a government run, command and control extended producer responsibility program that the agencies could not get passed in the Legislature;
- The Food and Drug Administration's New Drug Application process should obviate the need for inclusion in the regulations and subsequent burden of the exemption process; and
- An exemption should not be available if the exemption is inconsistent with the principles established in section 69506. For example, take the case of federal or state regulations that address an adverse public health impact through engineering controls even though a safer alternative exists. The preference in section 69506 for inherent protection should prevent issuance of an exemption in that case.

Response:

Please refer to the discussion under section 69506.1 Applicability and Determination Process, of this Response to Comments document for details on the applicability and exclusions under this Chapter.

[8] AB 1343, Chaptered 2009, an act to add Chapter 5 (commencing with Section 48700) to Part 7 of Division 30 of the Public Resources Code, relating to solid waste.

The very provision of the authorizing legislation that the commenters cite, Health and Safety Code section 25257.1(c), is the reason that DTSC included the exemption provision from the requirement to carry out a regulatory response. While the statute does not specifically mandate that DTSC require manufacturers to apply for an exemption, discretion is granted to agencies to determine how best to implement the requirements of a mandate by the Legislature. In this case, DTSC has determined it needs to know the nature and extent of any conflict or duplication to know if an alternate regulatory response may be tailored and effectuated.

As stated in the ISOR and response to comments in Articles 2 and 3, the Candidate Chemicals list, formerly referred to as Chemical(s) of Concern in earlier versions of the proposed regulations, is comprised of chemicals that exhibit hazard traits and/or environmental or toxicological endpoints and meets the specified criteria detailed in those Article. Consumer products containing Candidate Chemicals will be prioritized based on:

1) Volume in commerce;
2) Propensity for exposure; and
3) Exposure to sensitive subpopulations and the Candidate Chemical(s) in the Priority Products.

Section 69503.2 contains the factors that DTSC will take into account in prioritizing products that are listed as Priority Products as mandated through Health and Safety Code sections 25251 through 25257.1. Section 69503.2(a)(3) includes the evaluation of other regulatory programs DTSC will consider. DTSC will take into account the scope of other State of California and federal laws and treaties and international agreements under which the Priority Product or the Candidate Chemical(s) in the product is/are regulated. In addition, DTSC will consider the extent to which these other regulatory requirements address and provide adequate protections with respect to the same potential adverse public health and environmental impacts, exposure pathways, and adverse waste and end-of-life effects.

Section 69505.1(f) allows a responsible entity to submit a previously prepared AA, whether it is prepared by the responsible entity or by another entity through a consortium, collaborative, or other similar partnership. To the extent materials and/or reports that are prepared and submitted to comply with the Restriction of Hazardous Substances Directive or Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), they may be resubmitted to DTSC provided they address the provisions of Article 5. The reports that are submitted to DTSC must meet the

administrative and substantive requirements of Article 5. The requirements under Article 6, however, are different in that they pertain to mitigation impacts in California.

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted. The provisions related to Exemption from Regulatory Response Requirements have been moved to section 69505.9 (January and April 2013).

§ 69506.12 Regulatory Response Report and Notifications

§ 69506.12(a) Supply Chain Regulatory Response Report and Notifications

Comments: 5-183, 5-184, 11-64, 44-21, 57-86, 66-73, 68-45, 68-46, 74-81, 86-27, 107-80

Comments Summary:

The above comments expressed concern with section 69506.12(a), which requires a responsible entity subject to a regulatory response under Article 6, except for the regulatory responses specified in sections 69506.2 and 69506.9, to ensure that a notice is sent to all retailers who sell a Priority Product in California, informing the retailers of the applicability of the regulatory response to the product. The notice must be sent within thirty (30) days after receiving a final regulatory response determination notice, under section 69506.1, after DTSC issues a notice of compliance for a Final AA Report for a product subject to sections 69506.4 or 69506.8. In summary, the concerns expressed included the following:

- Amend language to make applicability more specific;
- Health and Safety Code section 25253 does not include notification to the retailers as a regulatory response nor does it authorize DTSC to impose such a reporting requirement;
- Responsible entities should be required to send notice only to those to whom they “directly” sell;
- The timing for such notification also needs to be lengthened, as such notifications will be a burdensome task;
- This subsection implies that different responsible entities will get different regulatory responses imposed for the same (or similar) Priority Product(s). It would seem more logical that DTSC informs all retailers and publishes general rules about one identical regulatory response applicable to all responsible entities in a non-discriminatory way; and

- This provision establishes burdensome reporting requirements for responsible entities and even more so for DTSC itself, as the number of products and regulatory responses concerned could easily run into the hundreds after a few years and would grow continuously over time.

Response:

As stated in the ISOR, the notification requirements in this section are only necessary in the case of those regulatory responses that may have a direct or immediate impact on retail inventory, so that retailers can assess whether there are any actions they need, or wish to take, in light of the regulatory response. This provision does not apply with respect to the regulatory responses requiring a research and development project, challenge grant, or providing additional information and submitting a new AA, as these regulatory responses do not have the potential to have a direct or immediate impact on retailers. DTSC has included this provision, though not expressly authorized, because DTSC has determined that this notification is reasonably necessary to ensure that the program is effective.

Further, as discussed in the ISOR, the provisions in this section are necessary to:

(i) Hold responsible entities accountable for timely implementation of required regulatory responses and, if applicable, their selected alternative products;
(ii) Ensure that retailers are made aware of regulatory responses that affect the products they sell; and
(iii) Ensure that DTSC is kept apprised of the implementation status of required regulatory responses and selected alternative products.

As discussed in the ISOR, in response to comments in Article 5, and in response to section 69506(a) Need for Regulatory Response, the complexity of the AA proposed by the responsible entity dictates the due date for the Final AA Report and the due date and types of regulatory responses that will apply to the Priority Product. More regulatory responses may be required of a responsible entity that fails to select an alternative and retains the Priority Product than may be required of a responsible entity who selects an alternative with minimal public health and environmental impacts. It is the only practical and meaningful way to implement a program that is not command and control but instead promotes innovation and is flexible enough to accommodate technological advances.

As stated in this response to comments in section 69505.2 Analysis of Priority Products and Alternatives, the narrowed focus of the Priority Products in the first years of

implementation will allow DTSC to address limitations with the overall program and address them in the out years.

In response to the above concerns, the provisions have been modified to require that the notification be provided by the manufacturer to entities that the manufacturer directly sells the product to (January and April 2013).

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted. The provisions related to Regulatory Response Report and Notifications have been moved to section 69506.10 (January and April 2013).

§ 69506.12(b) Contents of Regulatory Response Report and Notifications

Comment: 37-32

Comment Summary:

The above comment expressed concern with section 69506.12(b), which specifies that the notice required under section 69506.12(a) include the specified information inclusive of the date by when the regulatory response should be completed. In summary, the following concerns were expressed:

- The due date for compliance in section 69506.12(b)(5) to be communicated in the regulatory response report and notifications should be no sooner than 180 days from the date of the notice; and
- The factors outlined in section 69506(c)(1) through (5) should be taken into account in determining the due date.

Response:

Former section 69505.5 (k)(2)(A) and (B), now section 69505.7(k)(2)(A) and (B) provides responsible entities an opportunity to propose the amount of time necessary to implement the selected alternative and propose any applicable regulatory responses. Please refer to the discussion under section 69506.12(b) Contents of Regulatory Response Report and Notifications for details on the need for timely submittals.

The factors in section 69506 are guiding principles and will be taken into account. However, in establishing a due date, the complexity of the AA Report and findings will dictate the due date for the regulatory responses.

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted. The provisions related to Regulatory Response Report and Notifications have been moved to section 69506.10 (January and April 2013).

§ 69506.12(c) Notification to DTSC on Regulatory Responses

Comments: 66-74

Comments Summary:

The above comments expressed concerns with the provisions in section 69506.12(c), which require that the responsible entity notify DTSC upon completing implementation of the required regulatory response(s) and, if applicable, upon completing development and introduction into the California marketplace of the selected alternative. The notification must include information describing how the regulatory response(s) was/were implemented. If requested by DTSC, the responsible entity shall provide periodic implementation status reports regarding the selected regulatory response(s). The information provided to DTSC under this subsection shall also be posted on the website of the responsible entity. In summary, the following concern was expressed:

- Noticing DTSC is unnecessary; DTSC should assume and confirm compliance as needed, by requesting compliance documentation.

Response:

Please refer to the discussion under *section 69506.12(b) Contents of Regulatory Response Report and Notifications,* of this Response to Comments document, for details on the need for timely DTSC notification.

In response to overarching comments related to Article 6, the provisions of section 69506.3 and 69506.10 have been deleted. The provisions related to Regulatory Response Report and Notifications have been moved to section 69505.10 (January and April 2013).

ARTICLE 7. DISPUTE RESOLUTION PROCESSES

§ 69507 Dispute Resolution

Comment: 36-120

Comment Summary:

The above comment expresses support for the language that responsible entities lose their right to further pursue administrative disputes if they do not follow the specified procedures.

Response:

DTSC appreciates this support. No changes were made in response to this comment.

Comment: 36-120

Comment Summary:

The above comment suggests that when a dispute is filed, DTSC should make the rationale and the status of the dispute public, along with a summary of why the chemical/product combination was prioritized and a current update about how the dispute is being resolved in order to prevent frivolous disputes.

Response:

DTSC respectfully disagrees. The procedure proposed by the comment would require additional resources on the part of DTSC. DTSC is concerned about the efficient and effective functioning of the program and does not want to introduce additional steps that will lead to delay. Disputes may arise from many steps of the regulations' implementation and will not solely be related to the prioritization process. A requirement to publish statements of rationale and status for every dispute could unduly burden DTSC's resources, especially when dealing with disputes for minor issues that could otherwise be quickly addressed. DTSC is making no changes to the regulations in response to this comment.

Comment: 37-33

Comment Summary:

The above comment notes that responsible entities that make a technical error in the dispute resolution process would be deprived of an administrative and judicial review of

their dispute. The commenter suggests a revision of the section to allow judicial review if failure to comply with the administrative processes is the result of technical errors, inadvertent action or inaction, or circumstances beyond the control of the responsible entity.

Response:

DTSC respectfully disagrees. Initially, DTSC notes that it is not clear what is meant by "technical errors." But, more importantly, the requirements for filing a Request for Review under the formal dispute resolution procedures are extremely modest. Responsible entities must only include a statement of the reasons supporting the request and, as applicable, a showing that the determination is based on (a) erroneous facts, assumptions, approaches, or conclusions of law; and/or (b) a policy judgment that DTSC should, in its discretion, reconsider. The requirements for a request for informal dispute resolution are even less burdensome. Responsible entities should not have any issues complying with the administrative process. In addition, the principal purpose of establishing an accessible administrative dispute resolution process is so that affected parties make use of it—as opposed to sleeping on their rights and then engaging in time-consuming and expensive judicial processes. Therefore, it would be unproductive and inefficient to weaken the need for exhaustion of administrative remedies in order to pursue judicial remedies. DTSC is making no changes to the regulations in response to this comment.

Comments: 37-22, 37-34, 66-75, 107-82

Comments Summary:

Two of the above comments suggest that DTSC's authority to eliminate the right to resolve disputes is not apparent in Health and Safety Code sections 25251 through 25253. DTSC has eliminated this right for disputes arising from actions imposed under Articles 2, 4, and 10.

Two other comments note that it is unclear why Articles 2, 4, and 10 are not subject to dispute resolution. Commenters suggest having dispute resolution for all articles as the only other remedy is injunctive relief, which is not preferred over informal arbitration.

Another comment suggests a change allowing all articles to have an administrative dispute process to narrow the scope of dispute and exhaust administrative remedies prior to the judicial review process.

Response:

DTSC acknowledges that there is no express authority in Health and Safety Code sections 25251 through 25253 for the elimination of the dispute resolution process for actions arising under specific Articles of these regulations (nor is there express authority for any sort of dispute resolution process). However, agencies have implicit authority to develop regulatory programs that are efficient, effective, and workable. The dispute resolution process, as outlined in these regulations, has been tailored by DTSC to make the program function as envisioned by Health and Safety Code sections 25251 through 25253. DTSC has eliminated the right for dispute resolution for decisions arising from those articles where such an allowance would unduly burden the program and limited resources within DTSC.

The Initial Statement of Reasons (ISOR) discusses why Articles 2, 4, and then 10 (now Article 9 as of January 2013) are not subject to the dispute resolution procedures. For Article 2, the ability of a responsible entity to challenge the basic determination of what is and is not a Candidate Chemical could bring the whole program to a halt. Identification of a chemical as a Candidate Chemical does not place any burdens on responsible entities for those chemicals. Article 4 creates the petition process. If one could enter the dispute resolution process regarding an adverse decision made on a petition, DTSC could become overwhelmed and unable to administer the program due to extreme overlap and delay in these two processes. Lastly, Article 9 (as of January 2013, formerly Article 10) sets out the trade secret provisions and time frames. The article, in effect, has a stand–alone process for pursuing relief. Further, DTSC could not carry out its duties under the Public Records Act if it could not release records caught up in dispute resolution. DTSC is concerned about the efficient and effective functioning of the program and does not want to introduce additional steps that will lead to delay. DTSC is making no changes to the regulations in response to these comments.

Comment: 42-31

Comment Summary:

The above comment suggests that the dispute resolution process is unclear and unnecessarily limited. Example of the lack of clarity: the ISOR and the regulations do not align; and regulations says the responsible entity may lose the right to administrative dispute resolution, while the ISOR says the responsible entity may lose administrative and judicial dispute resolution.

Response:

DTSC respectfully disagrees. It is unclear what inconsistency the commenter is referring to. Section 69507(b) indicates that a responsible entity's failure to avail itself of the procedures in Article 7 for disputes subject to the article constitutes a waiver of its right to further review of the disputed issue, either administratively or judicially, because the responsible entity has failed to exhaust its administrative remedies. This is consistent with the common law doctrine of exhaustion. If the dispute for which relief is sought is excluded under Article 7, judicial review is the only available remedy. DTSC is making no changes to the regulations in response to this comment.

Comment: 42-31

Comment Summary:

The above comment suggests that the dispute resolution policy is in conflict with State law regarding exhaustion of administrative remedies.

Response:

DTSC respectfully disagrees. Article 7 lays out the procedures for administrative remedies available under the regulations, thus clarifying how exhaustion of administrative remedies is achieved. Section 69507(b) indicates that a responsible entity's failure to avail itself of the procedures in Article 7 for disputes subject to the article constitutes a waiver of its right to further review of the disputed issue, either administratively or judicially, because the responsible entity has failed to exhaust its administrative remedies. This is consistent with the common law doctrine of exhaustion. If the dispute for which relief is sought is excluded under Article 7, judicial review is the only available remedy. DTSC is making no changes to the regulations in response to this comment.

Comment: 42-31

Comment Summary:

The above comment suggests that the 30-day time frame for disputing an action is too short.

Response:

DTSC respectfully disagrees. The time frame was already increased from fifteen (15) days in response to prior comments. The requirements for the filing of a request for dispute resolution are extremely modest. That is, there are no required forms or specified contents for the petition. DTSC must be mindful of public comments pointing

out that the time lines in these regulations are too protracted. DTSC is making no changes to the regulations in response to this comment.

Comment: 74-82

Comment Summary:

The above comment notes that the dispute resolution process does not apply to the decisions made by DTSC under Articles 2, 4, and 10. Disputes in those cases must be taken up in a judicial proceeding.

Response:

Comment noted.

Comments: 74-85, 74-86

Comments Summary:

The above comments suggest that the effect of failing to pursue one of these dispute resolution processes is unclear. Does DTSC propose that the failure to pursue an administrative dispute resolution preclude the responsible entity from seeking review of DTSC's decision in court?

Response:

Section 69507(b) clearly indicates that a responsible entity's failure to avail itself of the procedures in Article 7 for disputes subject to the article constitutes a waiver of its right to further review of the disputed issue, either administratively or judicially, because the responsible entity has failed to exhaust its administrative remedies. If the dispute for which relief is sought is excluded under Article 7, judicial review is the only available remedy. DTSC is making no changes to the regulations in response to these comments.

§ 69507.1 Informal Dispute Resolution Procedures

Comment: 11-65

Comment Summary:

The above comment suggests that the party bringing disputes should be allowed to choose to follow the formal or informal dispute resolution process, and all DTSC decisions should be permitted to follow the formal dispute resolution process. The

processes would be sequential with the option of an informal review occurring before a formal review.

Response:

DTSC respectfully disagrees. By providing for both informal and formal dispute resolution processes for specific provisions, the article tailors the manner of review to the urgency of resolving the particular issue under review while allowing for the most efficient allocation of DTSC resources. DTSC is concerned about the efficient and effective functioning of the program and does not want to introduce additional steps that will lead to delay. DTSC is making no changes to the regulations in response to this comment.

Comment: 11-66

Comment Summary:

The above comment suggests that failure to select a particular dispute resolution option should not preclude other administrative or non-administrative review of a DTSC decision.

Response:

DTSC respectfully disagrees. Article 7 lays out the procedures for administrative remedies available under the regulations, thus clarifying how exhaustion of administrative remedies is achieved. Section 69507(b) indicates that a responsible entity's failure to avail itself of the procedures in Article 7 for disputes subject to the article constitutes a waiver of its right to further review of the disputed issue, either administratively or judicially, because the responsible entity has failed to exhaust its administrative remedies. This is consistent with the common law doctrine of exhaustion. If the dispute for which relief is sought is excluded under Article 7, judicial review is the only available remedy. DTSC is making no changes to the regulations in response to this comment.

Comment: 44-22

Comment Summary:

The above comment suggests that clarification is needed for the relationship of informal dispute resolution with judicial review. Usually, failure to exhaust administrative remedies precludes judicial review.

Response:

DTSC respectfully disagrees. Section 69507(b) clearly indicates that a responsible entity's failure to avail itself of the procedures in Article 7 for disputes subject to the article constitutes a waiver of its right to further review of the disputed issue, either administratively or judicially, because the responsible entity has failed to exhaust its administrative remedies. If the dispute for which relief is sought is excluded under Article 7, judicial review is the only available remedy. DTSC is making no changes to the regulations in response to this comment.

Comments: 66-76

Comments Summary:

The above comments suggest that thirty (30) days is too short for disputing action, as it might take a responsible entity that long to realize they are involved and decide to dispute a point. Comment suggests at least ninety (90) days be provided to bring a dispute.

Response:

DTSC respectfully disagrees. The time frame was already increased from 15 days in response to prior comments. The requirements for the filing of such a request are extremely modest. That is, there are no required forms or specified contents for the petition. DTSC must be mindful of public comments pointing out that the time lines in these regulations are too protracted. DTSC is making no changes to the regulations in response to these comments.

Comments: 74-83, 74-84, 107-81

Comments Summary:

One comment notes that informal review applies to all but three of the regulatory responses. Several comments suggest that all regulatory responses should be subject to formal dispute resolution. Another comment suggests that disputes regarding end-of-life management issues should be resolved through formal dispute resolution instead of informal.

Response:

In response to concerns about dispute resolution related to regulatory responses, DTSC has amended the formal dispute resolution provisions. As indicated in the January 2013 proposed version of section 69507.3, *all* disputes regarding a decision made by DTSC under Article 6 (regulatory responses) shall be governed by the formal dispute resolution procedures set forth in sections 69507.4 through 69507.6 (emphasis added).

§ 69507.3 Formal Dispute Resolution Procedures

Comment: 42-32

Comment Summary:

The above comment suggests that Article 7 should be deleted and DTSC should work with interested parties to develop a replacement policy.

Response:

DTSC respectfully disagrees. These proposed regulations, and the included dispute resolution process, have undergone extensive public scrutiny in the form of both public workshops, a public hearing, and two formal notice and public comment periods. The resulting policy is the result of careful consideration of the concerns of interested parties. DTSC is making no changes to the regulations in response to this comment.

Comment: 42-32

Comment Summary:

The above comment suggests that the 30-day time frames are too short due to the volume of information that must be submitted. This is particularly hard on retailers, and hard without the facts and assumptions used by DTSC.

Response:

DTSC respectfully disagrees. The requirements for filing a Request for Review under the formal dispute resolution procedures are extremely modest. Responsible entities must only include a statement of the reasons supporting the Request for Review and as applicable, a showing that the determination is based on: (a) erroneous facts, assumptions, approaches, or conclusions of law; and/or (b) a policy judgment that DTSC should, in its discretion, reconsider. Additionally, proposed regulatory responses shall be noticed and include a public input phase. The notice will include DTSC's rationale for the proposed regulatory response. After consideration of public comments, DTSC's final regulatory response determination shall include the rationale, information, and information sources supporting DTSC's determination. DTSC is making no changes to the regulations in response to this comment.

§ 69507.4 Time Lines for Requests for Review

Comment: 57-87

Comment Summary:

The above comment recommends adding a periodic review period of five (5) years for a completed Alternatives Analysis (AA) to address the situation in which a problem arises during implementation and it turns out DTSC's decision was ill advised.

Response:

While this is not specifically a comment regarding dispute resolution, DTSC nonetheless offers this response. DTSC does not issue decisions approving or denying AA Reports. AA Reports are products prepared by responsible entities. Thus, AAs are not appropriately subject to a review cycle of any length by DTSC. Therefore, DTSC is not making any changes to the regulations in response to this comment.

§ 69507.5 Contents of Requests for Review

Comment: 37-35

Comment Summary:

The above comment suggests that the authority to eliminate the right to resolve disputes is not apparent in Health and Safety Code sections 25251 through 25253, specifically, the limitation on requests for review of circumstances where DTSC based a decision on an error.

Response:

DTSC acknowledges that there is no express authority in Health and Safety Code sections 25251 through 25253 for the elimination of the dispute resolution process. However, agencies have implicit authority to develop programs that are efficient, effective, and workable. The dispute resolution process, as outlined in these regulations, has been tailored by DTSC to make the program function as envisioned by Health and Safety Code sections 25251 through 25253. There is no limitation on requests for review of circumstances where DTSC has based the decision on an error. Rather, section 69507.5 requires that a Request for Review filed under section 69507.4 must include a statement of the reasons supporting the Request for Review, and as applicable, a showing that the determination is based on: (a) *erroneous facts, assumptions, approaches, or conclusions of law;* and/or (b) a policy judgment that DTSC should, in its discretion, reconsider (emphasis added). This does not mean that Requests for Review filed under section 69507.4 are limited to those circumstances described in section 69507.5(a), but merely that those are among the types of circumstances that would make a Request for Review appropriate. This is borne out by the inclusion of the phrase "as applicable" in the text introducing subsections (a) and (b)

of section 69507.5. DTSC is making no changes to the regulations in response to this comment.

§ 69507.6 Department Procedures for Requests for Review

Comment: 7-24

Comment Summary:

The above comment suggests that DTSC should not be able to deny a request for review of a dispute. This undermines the safeguard of review.

Response:

DTSC respectfully disagrees. Once DTSC has denied review of a dispute, the responsible entity is free to seek judicial review. In addition, a contrary result would lead to unnecessary expense and delay for responsible entities and DTSC. DTSC is making no changes to the regulations in response to this comment.

Comment: 36-104

Comment Summary:

The above comment suggests that 180 days for DTSC to specify its decision on the merits of a Request to Review is too long since DTSC will have already had sixty (60) days to consider whether to grant a review or not. This should be changed to ninety (90) days.

Response:

DTSC respectfully disagrees. DTSC is mindful of public comments pointing out that the time lines in these regulations are too protracted, but DTSC must be realistic about its resources and the effective implementation of this program when setting time lines. DTSC is making no changes to the regulations in response to this comment.

Comment: 107-83

Comment Summary:

Since thirty (30) days is a relatively short window of time, it is critically important that the responsible entity clearly understands when the clock begins. Does the clock begin to run upon mailing or upon receipt?

Response:

Section 69507.4 indicates that a responsible entity must submit a Request for Review to DTSC within thirty (30) days of *receiving* a final regulatory response determination notice from DTSC under Article 6. Subsequently, the 30-day clock begins to run upon receipt of the decision that would be subject to dispute. DTSC is not making any changes to the regulations in response to this comment.

Comment: 107-83

Comment Summary:

If a decision is posted on the website, will there be an alert to the responsible entity?

Response:

As specified in section 69507.6(a), decisions made under section 69507.6 will be subject to an order either granting or denying the request for review or a notice of ongoing review. DTSC is not making any changes to the regulations in response to this comment.

Comment: 107-83

Comment Summary:

The above comment suggests that section 69507.6(b)(1) needs more specificity: what sort of time line can a responsible entity expect for compliance with DTSC response to a Request for Review?

Response:

DTSC respectfully disagrees. The time line for compliance will vary depending on the nature of the compliance requirements being imposed. This section must allow DTSC flexibility when crafting requirements based on the wide range of potential regulatory responses. DTSC is making no changes to the regulations in response to this comment.

Comment: 107-83

Comment Summary:

The above comment suggests that DTSC needs to clarify the scope/intent of the "stayed during pendency on an administrative dispute."

Response:

As discussed in the ISOR, any disputed requirement imposed by DTSC is suspended while the administrative dispute is pending, thus allowing the party disputing the DTSC action to postpone compliance until the dispute resolution process is complete. This avoids prejudice to the responsible entity's interest while the matter is under review and prevents the waste of resources that would occur were a responsible entity to initiate changes that might be rendered unnecessary by any change in a departmental requirement as a result of review. DTSC is making no changes to the regulations in response to this comment.

ARTICLE 8. ACCREDITATION BODIES AND CERTIFIED ASSESSORS

Comments: 1-6, 7-21, 7-22, 7-25, 9-43, 11-67, 36-85, 36-86, 36-87, 40-7, 40-16, 47-23, 57-88, 58-1, 66-6, 66-38,66-77, 66-78, 66-79, 68-11, 73-26, 73-30, 76-12, 76-13, 76-14, 76-15, 76-16, 76-17, 76-18, 76-73, 84-4, 86-28, 87-10, 91-15, 101-4, 101-38, 107-84 114-6, 119-4, 124-32, 124-33, 127-10, 131-7, 131-8, 131-9, 136-11, PH4-3, PH4-5, PH33-6, PH36-3

Comments Summary:

The above comments express concerns with the provisions in Article 8 specifying the requirements for accreditation bodies and certified assessors. In summary, the following concerns were expressed:

- Delete the provisions; they are unnecessary, cumbersome, and costly;
- The requirement to hire an outside certified assessor or train in house staff to perform an Alternatives Analysis (AA) is superfluous and will not yield higher quality AAs;
- The provisions are not necessary to achieve the goals and objectives of AB 1879;
- The provisions will have the unintended consequence of delaying the assessment of products, as well as compromise innovation and ultimately economic growth;
- The manufacturer should not be allowed to perform its own AA because the outcome could easily be gamed;
- AAs are already conducted by persons with the necessary expertise to adequately complete an assessment;
- Building the capacity to have sufficient certified assessors in the various sectors will delay innovation and hinder time frames;
- There will be added costs to both industry and the Department of Toxic Substances Control (DTSC) without any tangible benefits;
- The program will create numerous legal issues regarding product formulations that must be made known to the certified assessor;
- The rigor of the assessments should be ensured through DTSC's use of audits, as specified in the proposed regulations;
- To achieve the desired outcome of good science, innovative thinking, and the use of expert judgment, DTSC must develop guidelines on how to conduct AAs; and
- DTSC may reject inadequate, incomplete, or erroneous AA Reports—making the certified assessor program unnecessary.

Response:

As expanded on in the Initial Statement of Reasons (ISOR), the accreditation and certification program was intended to create the capacity—and simultaneously improve the quality of—the AAs submitted for DTSC review. In turn, this would improve stakeholder confidence in the AAs. While conducting an AA, as described in the proposed regulations is new, the concepts are not. Manufacturers have historically conducted internal evaluations/assessments to evaluate performance of one design or formulation over another. However, manufacturer's assessments have typically been focused on internal costs. The proposed regulations, on the other hand, require that a manufacturer conducting an AA address the criteria specified in Article 5, which takes into account the life cycle impacts of the product. Typically, life cycle impacts have not been addressed in internal evaluations. Hence, current practitioners, while experienced, will be required to address impacts not typically taken into account. Further, the regulations previously specified that persons designated as accreditation bodies, bodies tasked with training persons, and persons performing and preparing the Alternatives Analysis meet specified educational background and professional experience.

The added costs to both industry and DTSC, coupled with the potential that the provisions may have the unintended consequence of redirecting efforts and thus delaying the assessment of products without ensuring quality AAs, led DTSC to consider adopting the regulations without the accreditation and certification program. Although adopting these regulations without a certification process could potentially increase the amount of time required for DTSC's review of the work that is submitted, DTSC nonetheless believes that the preferred course at this time is to delete the provisions. In the early years of implementation of these regulations, focused outreach and training on AAs by DTSC will be a necessary component. This is true regardless of whether the regulations are adopted with or without a certification program, thereby yielding little cost savings to the state by including a certification program. The use of existing outreach programs such as factsheets, mailers, and workshops to disseminate information and guidelines related to AAs will ensure consistency in the quality and rigor of the AAs without necessitating a certification program.

Due to DTSC's commitment to launch a practical and meaningful program, and in response to the numerous comments received, the provisions in Article 8 establishing accreditation bodies and certified assessor requirements have been deleted. Conforming changes have been made throughout the proposed regulations that address some of the programmatic issues, formerly addressed through Article 8. The

review process contained in Article 5, coupled with the audit provisions formerly in Article 9 and now in Article 8 (January 2013), will provide DTSC sufficient oversight of the work products that are submitted. In addition, DTSC anticipates working more closely with responsible entities in developing and amending AAs. Responsible entities may conduct and prepare an in-house AA and the associated reports without becoming or necessitating the use of a certified assessor. Public review of Final AA Reports have been included in the proposed regulations to make use of stakeholder input (April 2013). DTSC will learn from the first years of implementation and adopt, if necessary, future regulations in the out years to address any training or educational requirements.

Comments: 29-23, 36-88, 36-90, 58-1, 76-13, 76-16, 76-19, 76-74, 87-10, 124-33, 131-9, PH4-4

Comments Summary:

The above comments expressed concerns with the provisions in Article 8 that specified the requirements for accreditation bodies and certified assessors and recommended the article be modified with one of the following:

- Create a fund—which manufacturers are required to pay into and that is administered by DTSC—to hire one or more AA experts to conduct the AA or for DTSC to conduct itself;
- Deem an entity (such as the Cradle to Cradle Institute) certification process functionally equivalent to its AA;
- Establish a peer review process in lieu of the certified assessor program;
- Allow responsible entities to self-certify;
- Allow small companies an alternative process that lets in-house experts conduct the AA without necessitating certification;
- Create an independent third-party verification of AA Reports;
- Reduce the program to a simple computer based training module with a challenge test; and
- Ensure that the accreditation is International Organization for Standardization (ISO) compliant such that certification can be readily achieved outside of California boundaries by professional with relevant education and experience.

Response:

As indicated in the ISOR, in developing these regulations to be practical, meaningful, and legally defensible, DTSC considered and evaluated various alternatives that would:

1) Minimize the cost to the State;

2) Create the capacity while simultaneously advance the principles of green chemistry;
3) Ensure only persons with the relevant education and experience are permitted to perform and prepare AAs; and
4) Create public confidence in the results obtained in the AAs that are prepared and submitted.

As indicated in the ISOR, in addition to the requirements set out in Article 8, DTSC considered the following alternatives in lieu of—or in combination with—Article 8:

- Status quo (*i.e.*, no certification);
- Third party verification; and
- Peer review process.

The recommendations suggested have either been previously considered and are discussed in the ISOR and/or are not legally defensible.

As indicated in the ISOR, a third party verification requirement for an AA would require that once a responsible entity has completed its AA, it would then submit the AA Reports to the third party organization to ensure compliance with the requirements of Article 5. The third party verification structure would necessitate some level of qualification and licensing of third parties capable of successfully completing the assessment. That is, additional qualification requirements—beyond those set out in Article 8—would be necessary.

A peer review process would require that, upon completion of the AA, a responsible entity would submit the AA for review to one or more peers to ensure compliance with the requirements of Article 5. Given that some of the information contained in the AA may well be a trade secret, submitting the AA to peer reviewers may be problematic. At a minimum, there would seem to be complexities related to confidentiality agreements. DTSC anticipates that responsible entities would want to submit their AAs to peer reviewers in redacted form. This, in turn, could make it difficult for the peer reviewer(s) to conduct their evaluations.

Under a “pro bono” or “voluntary” peer review scenario, selection of the peer reviewers would be at the discretion of the responsible entity. DTSC has determined it would be extremely difficult, if not impossible, to establish in regulation a voluntary peer review process. Under a “mandatory” peer review scenario, the requirements to qualify as a peer reviewer could be in regulation, similar to the regulations in Title 16, California Code of Regulations, Article 6, governing peer review for professional and vocational

peer reviews. While those regulations pertain to peer review work performed by certified public accountants, to be meaningful and ensure public trust, the provisions contained in Article 8 would need to closely parallel those requirements. In fact, many of those requirements closely align with the requirements in Article 8 of these regulations.

The regulations do not prevent a responsible entity from soliciting peer reviews prior to the submittal of its AA Reports to DTSC. A mandatory peer review process would contain many of the same provisions in Article 8 and would require some administration by DTSC. That is, DTSC would be compelled to provide administrative and logistical support to the peer reviewers. DTSC's experience has been that such support is time-consuming and expensive.

In summary, the other alternatives considered were rejected for one or more of the following reasons:

- Costs to the State to implement the program in a practical and meaningful way;
- Costs to regulated entities to implement;
- Delays in reviews and/or impediments to innovation;
- Duplicative process and review, with little or no added value; and/or
- Potential to create distrust in AA findings.

The legislation authorizing DTSC to adopt these regulations does not authorize DTSC to create and administer a fund which manufacturers are required to pay into in order to cover costs for AA development. Creating and administering a computer-based training module, as suggested in one comment, would require substantial costs to the State and is thus cost-prohibitive.

In revising the regulations, DTSC evaluated and considered including an additional level that would create an ISO compliant program. Due to the additional and unpredictable and potentially significant costs to industry and the state, the program was deleted. In the first years of implementation DTSC will assess the quality of the AA submitted for review and approval and the need for and the type of certification program in the out years, if necessary. Conforming changes have been made throughout the proposed regulations that eliminate the need to include Article 8.

§ 69508 Qualification and Certification for Assessors

Comments: 21-6, 34-12, 36-89, 40-8, 40-9, 41-20, 57-60, 68-10, 68-47, 73-25, 73-27, 73-28, 73-29, 74-87, 74-88, 74-90, 76-11, 76-19, 76-73, 76-74, 84-4, 91-14, 107-85, PH4-3, PH4-4, PH4-5, PH33-6

Comments Summary:

The above comments express concern with the provisions that specified the criteria to ensure that certified assessors possess the educational background, sufficient training, and qualifications to perform an AA and to provide a disciplinary mechanism for deviations from standards of the program or of professional conduct. In summary, the following concerns were expressed:

- Many of the professionals that develop products have years of expertise and advanced degrees in chemistry or engineering; additional certification requirements for these highly trained professionals is unwarranted;
- Those currently conducting AAs may not qualify under the proposed requirements or would require certification and would thus delay the process;
- Companies should be using their most qualified and knowledgeable staff to conduct the AA even if they are not in California or do not maintain certified status;
- The accreditation and qualification requirements are so rigorous that it will delay the development of safer alternatives;
- The qualification requirements for assessors grossly underestimate the training, skills, and experience required;
- Academic knowledge in various fields—without experience in formulation, processing, or manufacturing—can highly compromise the results of the AA;
- The requirements do not include knowledge of patent and antitrust laws, which could compromise product formulations;
- The requirements are at odds with product-specified expertise, required to improve product performance efficacy, function, and cost of replacing a Chemical of Concern (COC);
- The requirements create a disadvantage to out-of-state entities and persons seeking accreditation or certification;
- The requirements are very strict and rigorous, which may limit the number of certified assessors, leading to a high fee for responsible entities;
- In-house experts possess the necessary knowledge, skills, and expertise to lead AAs and should not be required to become certified assessors;
- The professional experience required under the proposed regulations is not enough to allow one to be fully aware of all the intricacies of formulating products;

- Five (5) to ten (10) years of professional experience should be required;
- Global companies will likely have to rely on professionals outside of the U.S., and the regulations make it difficult for those entities to be accredited and/or certified;
- The expectation to have one individual in charge of all aspects is far too ambitious. A product requires the melding of many different skills to complete a reformulation;
- Two years of experience is not sufficient to know all the "ins and outs";
- Support for the requirement of twenty (20) hours of continuing education, with two (2) hours being dedicated to professional ethics;
- Support for the provision that a certified assessor may not be responsible and/or in charge of conducting the AA if the certified assessors have an ownership interest in the responsible entity whose product is the subject of the AA; and
- A certified assessor should have no permissible equity on a product that is subject to the AA and thus the $10,000 limit threshold should be eliminated.

Response:

While some comments expressed support for the provisions related to the qualifications for accreditation bodies and certified assessors, numerous concerns were expressed on both ends of the spectrum. That is, while some expressed the view that requirements were too rigorous, others expressed the view that the requirements were not sufficient enough to ensure quality AAs. Some comments suggested discrete amendments to correct or address the identified flaws in the proposed regulations. However, in response to overarching comments related to Article 8, numerous changes have been made throughout the proposed regulations to eliminate the requirements in Article 8. Hence, this has eliminated the issues related to the qualification of accreditation and certified assessors. Responsible entities may continue to use their in-house experts, without requiring them to obtain additional training and/or certifications. In the first years of implementation, DTSC will assess the quality of the reports being submitted and the need for and type of certification program in the out years, if necessary. Conforming changes have been made throughout the proposed regulations that eliminate the need to include Article 8.

§ 69508.1 Qualifications for Accreditation Bodies

Comments: 36-91, 36-92, 70-10, 74-87, 74-89, 76-19, 76-74

Comments Summary:

The above comments expressed concern or support for the provisions that specified the criteria, experience, and/or subject areas of proficiency that must be met by an entity

wishing to be designated as an accreditation body. In summary, the following comments were expressed:

- Support for the requirement that accreditation bodies demonstrate expertise in public health, and request that “pollution prevention” and “maternal and child health” be reinstated;
- Support for the provision which required that accreditation bodies demonstrate professional ethics;
- Accreditation bodies should be held accountable for the quality of assessors and work product produced by the assessors;
- DTSC should have the ability to challenge the accreditation body;
- Broad skills and knowledge are necessary to conduct AA across the extremely broad spectrum of products that are covered;
- Exposure assessment has been omitted but should be included and is an important field of expertise;
- The requirements should be modified and reduced so that accreditation bodies are not limited to California Universities;
- The list of teaching competencies for accreditation bodies should include basic statistics and methods for critically evaluating scientific studies; and
- “Critical evaluation” is only included for epidemiology studies, but should be included for all others as well.

Response:

In response to overarching comments related to Article 8, numerous changes have been made throughout the proposed regulations to eliminate the requirements of Article 8; hence, eliminating the issues related to the qualification of accreditation and certified assessors. Responsible entities may continue to use their in-house experts, without requiring them to obtain additional training and/or certifications. In the first years of implementation, DTSC will assess the quality of the reports being submitted and the need for and type of certification program in the out years, if necessary. Conforming changes have been made throughout the proposed regulations that eliminate the need to include Article 8.

§ 69508.3 Accreditation Body Designation Process

Comment: 36-79

Comment Summary:

The above comment supports the provision in section 69508.3(e) which states that an accreditation body may not claim trade secret protection for its general admission process, curriculum, and educational approach.

Response:

Comment noted. In response to overarching comments related to Article 8, the Article has been deleted; and corresponding changes, if appropriate, have been made in Article 5.

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ARTICLE 9. AUDITS

§ 69509 Audit of Materials Submitted to the Department and Regulatory Responses

Comment: 11-68

Comment Summary:

The comment asserted that Article 9 lacks clarity in its purpose and consequences. The comment asserted that subparagraph (b)(3) implies DTSC will be auditing the business decisions of a company and making sure they make the "right" choice and (b)(3)should be eliminated. The comment asked DTSC to amend the regulations to indicate the standards against which the audited documents are being compared.

Response:

DTSC respectfully disagrees. As stated in the Initial Statement of Reasons (ISOR), Article 9 describes the process that DTSC may administer to ensure the accuracy and integrity of actions performed under the regulations and of documents submitted to DTSC under the regulations. It is essential that DTSC have a mechanism through which these actions and documents can be verified as complete and satisfactory, in order to ensure the efficient functioning of the Safer Consumer Products program. Article 9 provides a non-exhaustive list of the types of actions and documents that are subject to the audit process and details how the process will function. The audit process is meant to ensure that submittals are accurate and reliable. An evaluation under the audit process will depend on the nature of the document or action being considered; therefore, DTSC cannot provide specific standards against which documents and actions will be compared. DTSC disagrees with the assertion that subparagraph (b)(3) is unnecessary for the effectuation of the statute, as well as the implication that DTSC will be auditing the business decisions of a company. DTSC must be able to evaluate a responsible entity's implementation of a selected alternative in order to ensure that the program is accomplishing its goals, and responsible entities are complying with the regulations. No changes have been made to the regulations in response to this comment.

Comment: 74-91

Comment Summary:

The comment noted that DTSC audits, particularly in early implementation, would help to increase the credibility of the Alternative Analysis (AA) process as well as improve consistency.

Response:

Comment noted.

ARTICLE 10. TRADE SECRET PROTECTION

§ 69510 Assertion of a Claim of Trade Secret Protection

Note: The section numbers from the July 2012 version of the regulations have been retained for clarity in the headings, the summary of comments, and the Department of Toxic Substances Control's (DTSC) responses. However, since the July 2012 version, the proposed regulations were amended in January 2013. Those amendments included the deletion of Article 8 in its entirety. Therefore, the sections that were in Article 10 in the July 2012 version are in Article 9 in the January 2013 and April 2013 version of the proposed regulations. DTSC has also provided the new section numbers, where necessary, for additional clarity.

Comment: 36-73

Comment Summary:

DTSC is not providing any broad new leadership on transparency and trade secrecy. Transparency of information is important for accountability, public confidence in the program, and the ability of the program to affect the market.

Response:

DTSC agrees with the commenter that transparency of information, with respect to the contents of Alternatives Analyses (AA) and otherwise, is important. Because AB 1879 (Ch. 559, Stats. 2008, "the authorizing legislation" or "AB 1879") expressly incorporates the definition of a trade secret from the state's Uniform Trade Secrets Act (UTSA, Cal.CA Civ. Code § 3426 et seq.); however, DTSC cannot by regulation depart from the existing state substantive law of trade secrecy. DTSC has instead endeavored to provide leadership in the area of trade secret substantiation, a procedural matter, to ensure that trade secrecy claims are properly justified. DTSC believes this is important to public confidence in the program, as described more fully in the response to comments regarding the benefits of requiring up-front substantiation of trade secrecy claims. DTSC is not making any changes to the regulations in response to this comment.

Comments: 1-10, 17-8

Comments Summary:

DTSC's regulations modify the legal definition of a trade secret and fail to provide protections available under state and federal law.

Response:

DTSC respectfully disagrees that the regulations modify the legal definition of a "trade secret." Section 69501.1(a) ("Definitions") provides at paragraph (66) (January 2013) that a "'trade secret' means 'Trade secret' as defined in Civil Code section 3426.1(d)," thereby expressly incorporating the preexisting state-law definition of trade secret contained in the UTSA. The commenters have not identified which specific state or federal protections for trade secrets are alleged to be abridged by Article 10 of the regulations. To the extent that commenters are concerned that not all types of confidential business information may be claimed as trade secrets; however, that matter is addressed below. DTSC is not making any changes to the regulations in response to these comments.

Comments: 1-12, 5-97, 5-98, 12-18, 27-4, 41-47, 57-89, 57-96, 64-15, 66-80, 86-8, 86-29, 87-11, 124-13, 124-34, 167-1

Comments Summary:

This article should provide protection for a broader range of information by addressing confidential business information ("CBI"), which includes not only trade secrets but also commercial or financial information that is privileged or confidential. This includes, for example, information such as customer lists, supply chain relationships, and a responsible entity's research and development plans. One commenter recommends that to address this concern, DTSC add a definition of "Confidential Business Information" to Article 1 that enumerates the types of information protectable on the basis of commercial sensitivity.

Response:

DTSC agrees with the commenters that many types of commercial information including, but not limited to, those identified by commenters may be commercially sensitive, and should be eligible for protection from public disclosure where the need for secrecy is adequately justified. Sometimes, this type of sensitive non-technical information is described as "CBI" and distinguished from more technical information, such as a product's chemical formula, that is described as a "trade secret." The UTSA makes no such distinction, however, in that it encompasses not only technical matters such as "a formula, pattern, compilation, program, device, method, technical, or process," but also any "information" that has independent economic value by virtue of its secrecy, and is the subject of reasonable efforts to maintain that secrecy. (Cal. Civil Code, § 3426.1(d).)

The Restatement (Third) of Unfair Competition, the authoritative treatise on trade secrecy, confirms that the UTSA's definition of trade secrecy is broad enough to encompass "any information that can be used in the operation of a business or other enterprise" that has the required attributes of independent value and secrecy. (*Id.* at § 39 ["Definition of a Trade Secret"].) For this reason, DTSC believes it is unnecessary to define CBI as a category separate from other forms of trade secrets. DTSC also believes it is undesirable, because it is not possible to create an exhaustive list of all species of information that might legitimately be claimed as CBI, and thus a supplemental definition could in fact operate as an unintended limitation. DTSC construes its proposed regulations to authorize the assertion of trade secrecy claims for both technical information and CBI as long as these classes of information conform to the definition of a "trade secret" set out in the UTSA that is incorporated into these regulations. Therefore, DTSC is not making any changes to the regulations in response to these comments.

Comment: 74-92

Comment Summary:

Names, concentrations, and properties of ingredients in formulas are the result of investments in innovation and will inevitably be claimed as trade secrets.

Response:

DTSC disagrees that all of the product attributes listed will inevitably be claimed as trade secrets for all product types. DTSC notes that the majority of product ingredients in, for example, foods, pesticides, and cosmetics, and to a lesser extent, personal care products and household cleaning products, are conspicuously indicated on product labels (whether because legally compelled or otherwise). Further, functional descriptors (*e.g.*, "surfactant or "colorant") are often publicly disclosed on product labels or labeling whether or not legally required. This occurs notwithstanding that all these products' compositions may arise in the first instance as a result of "investment in innovation."

Nevertheless, to the extent that any name, concentration, or property of an ingredient in a formula is asserted to be trade secret, the regulations authorize a responsible entity to make and justify such a claim to DTSC, subject to the limitations in Health and Safety Code section 25257(f), as implemented through section 69510(f) (renumbered to section 69509(f) (January 2013)). Accordingly, DTSC is not making any changes to the regulations in response to this comment.

Comments: 109-7, 109-8, 109-11, PH5-6

Comments Summary:

DTSC should provide "categorical protection for those chemical ingredients in tires that are trade secrets."

Response:

DTSC respectfully declines the commenter's request. As a policy matter, DTSC sees no principled basis upon which to exempt categorically the ingredients in one specific consumer product category (tires) from public disclosure, while subjecting manufacturers of all other consumer products to the requirement to justify trade secrecy claims. Further, commenter's proposal is somewhat circular. Clearly, not all ingredients in tires may properly be characterized as trade secrets. For example, as the name of comment submitter Rubber Tire Manufacturers Association makes plain, the fact that "rubber" is an ingredient in tires is manifestly non-secret, as is the fact that the manufacture of the synthetic rubber used in tires involves the combining of butadiene and styrene. (See: https://www.rma.org/about_rma/rubber_faqs/.) Thus, it is incumbent on manufacturers to identify and justify the specific ingredients and/or manufacturing process information that are asserted to be trade secret, whereupon they may qualify for protection from public disclosure. DTSC is not making any changes to the regulations in response to these comments.

Comment: 124-31

Comment Summary:

Requiring companies to make their AA Reports publicly available—even in redacted form—will force companies to give up proprietary work and knowledge associated with the reports' preparation.

Response:

DTSC respectfully disagrees, and indeed believes that any other approach would violate the authorizing legislation. The authorizing legislation both allows claims for trade secrecy (Health and Safety Code section 25257(a)), and provides that "[i]information not identified as a trade secret . . . *shall be available to the public* unless exempted from disclosure by other provisions of law." (Health and Safety Code section 25257(c); emphasis added.) By permitting submitters to create full copies of AAs for DTSC use and redacted copies for public use, the implementing regulations honor both the trade secrecy and public transparency instructions in the authorizing legislation.

DTSC also does not believe that provision of redacted copies of AAs necessarily compromises submitters' intellectual properly. Manufacturers and other business entities are required by numerous state and federal laws to prepare and publicly disclose reports that at least indirectly reveal "work" and "knowledge" of company operations, ranging from environmental impact reports mandated by the California Environmental Quality Act (CEQA), to reports documenting all material risks associated with a stock offering under federal securities law. DTSC's Safer Consumer Products Regulations give companies wide latitude to redact sensitive information in AA Reports, so long as redactions can be justified on the basis of genuine trade secrecy.

In addition to the legal justifications for DTSC's approach, DTSC believes that the approach represents sound policy. Allowing companies to keep AAs fully confidential, as the commenter proposes, would undermine public confidence in DTSC's regulatory program. This is because only the submitter and DTSC would be privy to information regarding a matter in which the public has a strong and legitimate interest: production of safer consumer products. It would also deprive DTSC of the benefit of public input regarding potentially viable alternatives—and in particular, those not considered by the submitter—and potentially suitable regulatory responses.

As a final matter, there is an independent public interest in "securing the benefits of vigorous competition" by allowing "competitors and others to exploit information and skills in the public domain." (Restatement (Third) of Unfair Competition at § 39(b) ["doctrinal development"].) Such information sharing promotes the goal of broad dissemination of safer consumer product technologies, rather than restricting them to niche markets. DTSC is not making any changes to the regulations in response to this comment.

Comment: 109-11

Comment Summary:

DTSC should recognize that a Chemical of Concern in a Priority Product may itself be a trade secret and create a confidential process to consider such information.

Response:

DTSC respectfully disagrees, and indeed believes that the commenter's suggestion would render AB 1879 a nullity. That statute requires DTSC to identify "those chemicals or chemical ingredients in consumer products that may be considered as being a Chemical of Concern" (Health and Safety Code section 25252(a)), to evaluate "potential alternatives" to such chemicals (*Id.* at section 25253(a) (1)), and to select from a "range

of regulatory responses" to the Chemical(s) of Concern in the product under evaluation. (*Id.* at section 25253(b).) None of these actions can be undertaken if manufacturers are not required to make known that their product is in fact subject to regulation as a Priority Product because it contains one or more Chemicals of Concern. Further, it is unclear how the use of a specific Chemical of Concern in a particular type of consumer product could be both known to and identified by DTSC and of sufficient public concern to warrant a Priority Product listing, and yet qualify as a trade secret.

§ 69510(a) Substantiation Requirements

Comments: 36-74, 36-80, 107-91, 138-4

Comments Summary:

The requirement that responsible entities provide adequate justification for trade secret claims is appropriate and necessary to ensure that such claims are not asserted frivolously. We fully support a requirement for upfront substantiation of trade secret protection claims. Trade secret claims should be as transparent as possible.

Response:

DTSC appreciates the support and agrees that the requirement of up-front justification of trade secrecy claims is a hedge against unwarranted or mistakenly asserted claims. Illegitimate claims of trade secrecy are not a mere hypothetical but are a well-documented phenomenon, particularly with respect to chemical information submitted to the U.S. EPA pursuant to the Toxic Substances Control Act (TSCA). As described in one Governmental Accountability Office (GAO) report on TSCA's deficiencies:

> *EPA officials told us that some claims of confidential business information may be unwarranted, but challenging the claims is resource-intensive. . . . [A] 1992 EPA study indicated that problems with inappropriate claims were extensive. This study examined the extent to which companies made confidential business information claims, the validity of the claims, and the impact of inappropriate claims on the usefulness of TSCA data to the public. . . . EPA officials also told us that the agency does not have the resources that would be needed to investigate and challenge claims to determine the number that are inappropriate. . . . The EPA official responsible for initiating challenges to confidentiality claims told us that EPA challenges about 14 such claims each year and that the chemical companies withdraw nearly all of the claims challenged.*

(U.S. GAO, *Chemical Regulation: Observations on Improving the Toxic Substances Control Act,* Dec. 2009, at pp. 10-11.) By requiring up-front substantiation of confidentiality claims under the Safer Consumer Products Regulations, DTSC hopes to discourage over-claims in the first instance and reduce the burdens on DTSC of challenging any illegitimate claims. DTSC is not making any changes to the regulations in response to these comments.

Comment: 138-4

Comment Summary:

DTSC should ensure that the trade secrecy provisions do not undermine workplace communication requirements of the Cal/OSHA Hazard Communication Standard.

Response:

DTSC appreciates the commenter's concerns and does not believe that the regulations affect, much less undermine, any preexisting disclosure obligations. Where workplace hazard information is already required to be disclosed to workers under state occupational health law and regulations, such as through provision of Material Safety Data Sheets, a responsible entity could not make the threshold showing that such information is legally authorized to be held as a secret. DTSC is not making any changes to the regulations in response to this comment.

Comments: 1-10, 1-11, 5-13, 5-99, 5-103, 5-107, 7-27, 11-8, 11-69, 11-70, 12-19, 12-20, 12-21, 38-9, 56-6, 57-94, 57-95, 59-14, 61-9, 64-15, 66-81, 73-31, 73-32, 92-7, 95-9, 105-9, 106-4, 107-86, 107-87, 125-9, 136-10, 139-9, PH15-4

Comments Summary:

Numerous industry commenters objected to DTSC's overall approach to trade secrecy in Article 10 and to some or all of the substantiation requirements in section 69510(a). Some commenters contended that the regulatory features criticized are unlawful, while others characterized them as merely undesirable. Commenters' heavily overlapping general comments can be collectively summarized, and are addressed below:

<u>Comment:</u>

The information required to substantiate the legitimacy of a trade secrecy claim goes beyond what is authorized by AB 1879.

<u>Response:</u>

DTSC respectfully disagrees. When a person provides information to DTSC that is identified as trade secret, AB 1879 expressly allows DTSC to request "support for the claim that . . . information is a trade secret." (Health and Safety Code section 25257(a).) AB 1879 neither identifies what types of information would constitute such "support" nor constrains DTSC's selection of substantiation criteria. Further, as other commenters' suggestions of alternative substantiation regimes in federal regulations implicitly acknowledge, substantiation requirements are generally a feature of implementing regulations rather than statutes.

Comment:

The requested information is irrelevant, unnecessary, and excessively costly to produce. DTSC should only require information that is absolutely essential to implement the regulations.

Response:

For the reasons described in the Initial Statement of Reasons (ISOR) and below, DTSC believes the substantiation information requested is both relevant and necessary to making trade secrecy determinations. The criteria enumerated in regulation are all relevant, but no one of them is dispositive, as to information's trade secret status.

No commenters appeared to have concern with the requirement that a submitter identify the person asserting a trade secrecy claim (section 69510(a)(1)), and briefly describe the nature of the information subject to the claim (section 69510(a)(2)). To the extent that information required by sections 69510(a)(3) through (a)(10) is unavailable, inapplicable to the type of trade secret claimed, or excessively costly to produce, the claimant's submission may explain why this is the case.

Comment:

Substantiation requirements should be tied to California trade secrecy law, as reflected in the UTSA, by focusing DTSC's inquiry on whether information (1) has independent economic value because it is not known to others (*i.e.*, is secret), and (2) is the subject of reasonable efforts to maintain secrecy.

Response:

California trade secrecy case law states plainly that "[a]n exact definition of a trade secret is not possible" (*Futurecraft Corp. v. Clary Corp.* (1962) 205 Cal.App.2d 279); that "[t]he issue of whether information constitutes a trade secret is a question of fact" (*In re Providian Credit Card Cases* (2002) 96 Cal.App.4th 292), and that merely

labeling information "trade secret" does not establish that the information fits this description. (*Morlife, Inc. v. Perry* (1997) 56 Cal. App.4th 1514.) DTSC has therefore identified those factors that would permit it to make an informed judgment as to whether claimed trade secret material is in fact so.

The substantiation requirements in DTSC's regulations are closely tied to the UTSA's focus on the existence of independent economic value attributable to secrecy, and the efforts made to maintain that secrecy. Section 69510(a)(6) [estimation of value of information to claimant and competitors], section 69510(a)(7) [estimated money/effort expended to develop trade secret], and section 69510(a)(10) [description of the nature and extent of potential competitive harm from disclosure] go directly to the existence of economic value of a claimed trade secret.

Sections 69510(a)(3) [extent to which information is known in submitter's business/facility], 69510(a)(4) [extent to which information is known outside of submitter's business/facility], and 69510(a)(5) [submitter's measures taken to safeguard secrecy], and associated questions regarding the existence of nonexistence of nondisclosure agreements, go directly to determining the reasonableness of efforts to maintain secrecy.

The Restatement (Third) of Unfair Competition additionally makes clear, however, that "protection under the law of trade secrets terminates when the information becomes generally known or readily ascertainable by proper means" (*Id.* at § 39, Comment (f), p. 449). Therefore, DTSC also seeks, via section 69510(a)(8), information regarding the degree to which information could be properly acquired, duplicated, or reverse-engineered by others. The rationale for this provision is further described in the ISOR at page 201.

The remaining information requirements under section 69510(a) (renumbered to section 69509(a) (January 2013)) relate solely to the good-government goals of efficient administration of Article 10 (renumbered to Article 9 (January 2013)) (see discussion of sections 69510(a)(1) and 69510(a)(2) above, and discussion of (a)(11) below), and maximizing cross-agency consistency of trade secrecy determinations (section 69510(a)(9)).

<u>Comment:</u>

The ISOR does not sufficiently justify each item of information required to substantiate a trade secrecy claim, in potential derogation of Government Code section 11346.2(b)(1).

Response:

DTSC respectfully disagrees. The ISOR describes, and justifies with respect to state statute, legal treatise, and trade secrecy law, every specific item of justificatory information required to be submitted to DTSC in support of a trade secrecy claim. (See ISOR at pages 199-201.) The Government Code provision cited by the commenter requires, in relevant part, that an agency ISOR for a regulation's adoption must include "[a] statement of the specific purpose of each adoption, [. . .] the problem the agency intends to address, and the rationale for the determination by the agency that each adoption, [. . .] is reasonably necessary to carry out the purpose and address the problem for which it is proposed." (Gov. Code § 11346.2(b)(1).) DTSC's ISOR fulfills this requirement.

Comment:

The justificatory information requested may not be easy to calculate/goes beyond what companies can reasonably be expected to know/often cannot be assigned a dollar value/is more cumbersome than necessary.

Response:

As described above and below, DTSC believes that the information required in section 69510(a) (renumbered to section 69509(a) (January 2013)) is both consistent with the existing law of trade secrecy, and necessary to insure that confidentiality claims are sufficiently supported by submitters to permit fair evaluation by DTSC. There is no requirement that all claims of value be monetized or otherwise asserted with precision; the commenter is correct that this may in many instances be beyond what a company can know, or may be highly speculative. As a legal matter, however, the existence of a trade secret requires that the claimed secret information confer "independent economic value, actual or potential" that is attributable to secrecy. (Cal. Civ. Code § 3426.1(d).) The submitter must, therefore, make some effort to characterize the value derived from preventing disclosure of the information at issue.

Comment:

Given that chemical identity generally cannot be claimed as trade secret under DTSC's regulations, there is no need for such a lengthy and burdensome substantiation exercise.

Response:

DTSC respectfully disagrees with the commenter's premise. As described more fully above, responsible entities may under these regulations assert trade secrecy claims for numerous types of information other than ingredient identity including, for example, technical information about product manufacture or business information often referred to as "confidential business information" (CBI). In addition to serving as a hedge against unwarranted claims, the requirement of up-front substantiation will assist DTSC in timely responding to Public Records Act requests. This is due to the fact that DTSC will have a significantly better understanding of the basis for a confidentiality claim at the time it receives an information request than under a regime in which submitters provide minimal information until their trade secrecy claim is challenged.

Comment:

The substantiation questions involve DTSC in judging the value of one company's innovative approach against another company's.

Response:

DTSC does not believe that this is a fair reading of section 69510. There is nothing in the regulations to suggest that DTSC will compare and contrast companies and pick favorites, rather than evaluating the merits of each company's justificatory information in support of a trade secrecy claim.

Comment:

DTSC does not have legal authority to decide how to weigh innovation versus maximizing of public information.

Response:

Common law doctrines and the modern statutory law of trade secrecy reflect the dual truths that protecting trade secrets "insures an incentive to invest in the creation of intangible assets and prevents the potential unjust enrichment . . . from the appropriation of an investment made by another," while at the same time, "exclusive rights in intangible trade values can impede access to valuable information and restrain competition [,]. . . thus deny[ing] to the public the full benefits of valuable ideas and innovations by limiting their distribution and exploitation." (Restatement (Third) of Unfair Competition, § 38, Comment (b), at p. 409.) AB 1879 also reflects the tension between these goals, in permitting the assertion of trade secrecy claims (Health and Safety Code section 25257(a)), recognizing a need to assess their validity (*Id.*), and restricting their application where the public interest in disclosure is strongest. (Health and Safety Code section 25257(f).) DTSC's regulations simply

implement the statute's instruction to recognize the legitimacy of more than one type of societal goal.

Comment:

DTSC has too much discretion to accept or reject a trade secrecy claim.

Response:

Health and Safety Code section 25257(d) states that "the [D]apartment shall determine whether or not . . . information claimed to be a trade secret is to be released to the public," making clear that a submitter's designation of information as "trade secret" does not control. Any regulator to which claimed confidential information is submitted must necessarily have discretion to determine the legitimacy of that claim. Because determination of the existence of a trade secret is not a mechanical exercise susceptible to creation of robotic protocols, the enumeration of the substantiation requirements for trade secrecy claims will assist submitters in understanding the totality of criteria DTSC will use in assessing the existence of trade secrets, thereby promoting transparency and discouraging arbitrariness. The availability of judicial review of DTSC's determination acts as an independent check on DTSC's exercise of its discretion.

Comment:

DTSC should model its substantiation regulation on the federal regulation at 49 Code of Federal Regulations, part 512, which has more modest substantiation requirements.

Response:

There is a diversity of substantiation regulations across agencies with respect to trade secrecy claims and, thus, there is no one set of substantiation criteria that DTSC could adopt that would precisely mirror all other agencies' approaches to trade secret justification. The commenter has not presented any compelling reasons for DTSC to adopt the criteria of the National Highway Traffic Safety Administration (NHTSA) at 49 C.F.R. part 512, but not adopt those used (*e.g.*, by the U.S. Environmental Protection Agency under the Emergency Planning and Community Right-to-Know Act at 40 C.F.R. part 350).

Although DTSC has not taken the commenter's suggestion to adopt NHTSA's regulations wholesale, it notes substantial similarities between NHTSA's approach and that of DTSC's regulations. For example, both regimes require up-front substantiation of all confidentiality claims rather than imposing this requirement post-

hoc and case-by-case (see 49 C.F.R. § 512.8); both regimes require an explanation of why information is, and how it has been kept, secret (see 49 C.F.R. § § 512.8(c)(1) and (c)(4)); and the NHTSA regulations in some instances require submitters to both characterize the "harmful effects of disclosure," and to explain "why the effects should be viewed as substantial." (49 C.F.R. § 512.8(c)(2).)

Comment:

DTSC's substantiation requirements threaten innovation, may lead manufacturers to abandon California markets out of fear of intellectual property loss, and may threaten U.S. businesses in a global marketplace by forcing excessive disclosure.

Response:

DTSC believes commenters' contentions are speculative and exaggerated. As one of the world's ten largest economies, California represents a vast consumer product market that few manufacturers are likely to forgo simply because they must justify (not forsake) certain trade secret claims. DTSC is not making any changes to the regulations in response to these comments.

§ 69510(a)(5)-(10) Generally

Comment: 107-92

Comment Summary:

Only the criteria in paragraphs (1) and (2) are consistent with UTSA requirements. The criteria in paragraphs (6) through (10) diverge from the UTSA, exceed statutory authority, and are not legally defensible.

Response:

DTSC respectfully disagrees. As described above, the multiple justificatory criteria in section 69509(a) (January 2013) address matters of value and secrecy, which are the core attributes of a trade secret under the UTSA. These criteria are both consistent with the existing law of trade secrecy, and with the new authority conferred on DTSC by AB 1879, which expressly provides that DTSC may require "support for the claim that . . . information is a trade secret." (Health and Safety Code section 25257.)

§ 69510(a)(6) Value

Comments: 7-28, 57-90, 76-75, PH11-2, PH11-6

Comment Summary:

There is no statutory basis for needing estimated value of a trade secret to the claimant and competitors. Further, determining value is an enormous undertaking, and value information will be difficult for DTSC to evaluate because any particular number could have widely different importance to companies of different size. Inclusion of this criterion suggests that "if the value is more than X," DTSC will consider it to be trade secret.

Response:

DTSC respectfully disagrees that there is no need for DTSC to elicit information regarding a claimed trade secret's value. The legal definition of a "trade secret" hinges on existence of something with "*independent economic value*, actual or potential" that is attributable to secrecy. (Cal. Civ. Code § 3426.1(d); emphasis added.)

There is no suggestion in the regulations that DTSC intends to create a bright-line rule that "if the value is more than X," a trade secret exists, and to do so would run contrary to trade secrecy law. As the Restatement (Third) of Unfair Competition states, "A trade secret must be of sufficient value in the operation of a business . . . to provide an actual or potential economic advantage over others who do not possess the information. The advantage, however, need not be great. It is sufficient if the secret provides an advantage that is more than trivial." (*Id.* at § 39, Comment (e), at p. 430.) Submitters of claimed trade secret information are encouraged, by section 69509(a)(10) (January 2013), to contextualize any value and other information they provide with respect to their company and/or industry. DTSC is not making any changes to the regulations in response to these comments.

§ 69510(a)(7) Investment

Comments: 57-91, 76-75, PH11-3

Comments Summary:

The amount of money and effort expended to develop trade secrets has no relevance to a trade secrecy determination-serendipitous discoveries do occur. This information is also unnecessary to determining whether information derives economic value by virtue of being secret.

Response:

DTSC respectfully disagrees that money and effort expenditures are irrelevant to trade secrecy determinations. The Restatement (Third) of Unfair Competition states plainly that the value of information claimed as a trade secret must be shown, and may be

established directly or circumstantially. "Direct evidence relating to the content of the secret and its impact is clearly relevant. *Circumstantial evidence of value is also relevant, including the amount of resources invested . . . in the production of the information* . . . ." (*Id.* at § 39, Comment (e), p. 431; emphasis added.) The commenter's observation that serendipitous discoveries do occur does not undermine the thrust of the Restatement, which provides: "Although a trade secret may consist of information discovered fortuitously, a significant expenditure of time, money, or effort in the production of information is evidence of value." (*Id.* at § 39, Comment (e), p. 446.) DTSC is not making any changes to the regulations in response to these comments.

§ 69510(a)(8) Discoverability

Comments: 36-81, 57-92, 82-8, PH11-4

Comments Summary:

Discussion of the ease with which chemical identity is or is not discoverable through reverse engineering or otherwise is not relevant or necessary. Further, explaining whether and how something could be reverse engineered provides competitors a road map for so doing. One commenter disagreed, finding this requirement essential for substantiating a trade secret claim.

Response:

DTSC respectfully disagrees that the ease of discoverability of a claimed trade secret is irrelevant to substantiation. As explained in the ISOR, determination of whether information is "readily ascertainable through proper means" (Restatement (Third) of Unfair Competition, Comment (f), p. 432), which are well established in the chemical-identity context to include reverse engineering, is central to the trade secrecy inquiry. The ISOR provides statutory and case law authority for this proposition, and the corresponding inclusion of subsection 69510(a)(8) (renumbered to section 69509(a)(8) (January 2013)) in the regulations. As the Restatement additionally makes clear, however, the mere theoretical possibility of reverse engineering does not defeat a trade secrecy claim; where such information acquisition would be "difficult, costly, or time-consuming" (Restatement at Comment (f), p. 432), the case for trade secrecy protection is strongest. DTSC appreciates that the commenter fears that addressing criterion in section 69510(a)(8) might provide a road map for competitors, however, and expects that submitters may wish to address the reverse-engineering issue in a confidential (redacted) portion of its submission. DTSC is not making any changes to the regulations in response to these comments.

§ 69510(a)(10) Cost and Risk to Industry

Comment: 57-93

Comment Summary:

A description of the nature and extent of harm from public disclosure is unnecessary to a trade secrecy determination.

Response:

DTSC respectfully disagrees. Description of the nature and magnitude of harm from disclosure—whether or not strictly able to be monetized—is one means of establishing the "independent economic value, actual or potential" that is attributable to secrecy, as required by the UTSA. (Cal. Civ. Code § 3426.1(d).) Section 69510(a)(10) (renumbered to 69509(a)(10) (January 2013)) also provides an opportunity for submitters of claimed trade secret information to contextualize any value and other information they provide with respect to their company and/or industry. DTSC is not making any changes to the regulations in response to this comment.

Comment: 115-4

Comment Summary:

It is possible that the information called for in sections 69510(a)(5) through (a)(10) would be cost justified in some instances, but DTSC should make this determination on a case-by-case basis.

Response:

DTSC does not believe it would be practical to tailor substantiation requirements on a case-by-case basis and further believes this approach would be wasteful of scarce program resources. Rather, to the extent that particular information substantiation elements are inapplicable, impossible, or cost-prohibitive for a submitter to obtain in a given instance, DTSC expects the submitter to be able to explain that fact in its submittal. DTSC will evaluate the legitimacy of a trade secrecy claim based on the totality of circumstances, and no one substantiation criterion is dispositive. DTSC is not making any changes to the regulations in response to this comment.

Comment: PH11-1

Comment Summary:

The substantiation requirements stem from the UTSA, which authorizes those whose trade secrets have been misappropriated to bring lawsuits to seek relief. It is not DTSC's role to address misappropriation.

Response:

DTSC's regulations do not purport to address misappropriation, which, as the commenter indicates, is instead a matter for the courts. DTSC's substantiation requirements overlap with the inquiry that a court would make in certain misappropriation cases, however, insofar as both have as their touchstone the substantive law of trade secrecy. DTSC is not making any changes to the regulations in response to this comment.

Comments: 41-48, 92-7

Comments Summary:

When DTSC rejects a trade secrecy claim, substantiation information submitted in connection therewith can be used by a competitor to damage a Responsible Entity's business. It is dangerous for DTSC to have absolute discretion to make a decision about a trade secrecy claim.

Response:

Whenever trade secret claims are asserted to an agency that has public disclosure obligations, someone must ultimately be the arbiter of whether such claims are justified under the law of trade secrecy. The Safer Consumer Product regulations do not give DTSC unchallengeable discretion to make such a determination. Rather, the regulations themselves implicitly establish some limits on DTSC's discretion. That is, DTSC's review and decision-making regarding trade secret claims are guided and informed by the criteria in section 69509(a) (January 2013), which specify the required substantiating information that must be provided to DTSC. In addition, the regulations empower a submitter to obtain a second opinion, via judicial review, before any claimed-sensitive information may be released. DTSC is not making any changes to the regulations in response to these comments.

Comments: 2-1, 2-2, 2-3, 2-4, 2-5

Comments Summary:

The regulations provide insufficient protection for classified information, especially with respect to the types of highly sensitive information handled by defense contractors. This poses a potential conflict with federal law.

Response:

The regulations have been modified to address this concern. Section 69509(c)(1) now provides that complete documentation regarding claimed trade secrets need not be provided to DTSC "where expressly prohibited by federal law" (January 2013).

Comment: 107-92

Comment Summary:

The regulations provide no direction as to how a manufacturer may assert a trade secrecy claim when it is bound by a nondisclosure agreement (NDA) with a raw material supplier.

Response:

The regulations have been modified to address this concern. Section 69509(c)(1) now provides that complete documentation regarding claimed trade secrets need not be provided to DTSC "where expressly prohibited . . . by a nondisclosure agreement whose relevant text is provided to the Department" (January 2013).

Comment: 73-32

Comment Summary:

Article 10 [now renumbered as Article 9 (January 2013)] of DTSC's regulations will "arguably" result in exchange of competitively sensitive information among competitors, exposing them to liability under antitrust laws.

Response:

The commenter has not clearly explained how the requirement that a submitter justify trade secrecy claims will result in collusive behavior among competitors in derogation of antitrust laws. This scenario seems particularly unlikely in view of a submitter's ability, under DTSC's regulations, to justify its trade secrecy claim(s) in a confidential document. Further, commenter has provided no examples of how long-standing substantiation provisions in the confidentiality regulations of other agencies, such as U.S. EPA or NHTSA (as described above), have resulted in antitrust liability. DTSC is not making any changes to the regulations in response to this comment.

Comments: 11-71, 41-49, PH11-7

Comments Summary:

A company's general counsel is unlikely to have the substantive knowledge to assess whether a trade secrecy claim is justified. DTSC should eliminate the requirement of signature by the general counsel. DTSC should also eliminate the statement that the signature must be provided "under penalty of perjury"; only the Legislature has the authority to determine which acts constitute a crime.

Response:

The regulations do not require the signature of general counsel, but instead permit signature by any "executive with knowledge of the preparation of the substantiating information." (See section 69509.9(a)(11) (January 2013), previously numbered 69510(a)(11).) DTSC believes that it is reasonable to require a high-level company official to exercise due diligence in insuring that trade secrecy claims asserted are legitimate. DTSC has, however, eliminated the requirement that documents containing information claimed to be trade secret be certified under penalty of perjury (January 2013).

Comments: 9-66, 9-67, 9-68, 9-69, 54-12

Comments Summary:

Rather than requiring provision of confidential and redacted copies of information supporting a trade secrecy determination in all cases, the regulations should require that no confidential information should be submitted in support of a trade secrecy claim in the first instance. This is particularly important given the risk of accidental disclosure. Non-redacted versions should only be required where DTSC shows necessity, or upon judicial determination.

Response:

DTSC does not believe the commenter's proposal is practical, because the nature of the information required to be submitted by way of substantiation is inherently sensitive. In DTSC's judgment, it is unlikely that it could make an informed judgment about the legitimacy of a trade secrecy claim absent the level of detail that can generally only be provided in a confidential submittal. Although risk of accidental disclosure inheres in any regime requiring submission of confidential information to a regulator and safeguards against such disclosure are critical, this is properly addressed with practices followed during implementation rather than in regulatory construction. DTSC is not making any changes to the regulations in response to this comment.

Comments: 10-8, 54-3, 54-12, 56-6, 57-89, 73-18

Comments Summary:

DTSC will not have the resources to process, adjudicate, and manage the large volumes of information reported under this article. DTSC also lacks personnel trained in managing confidential information on a routine basis. DTSC needs stronger safeguards to protect confidential information, such as information security systems, employee protocols, and training. The Department of Pesticide Regulation (DPR) has systems for managing confidential information that could be a useful model.

Response:

Several commenters have stated or implied that DTSC has no experience or protocols with respect to handling competitively sensitive information. This is incorrect. DTSC has experience receiving and protecting trade secret information in the context of regulated parties' hazardous waste handling and disposal activities (see Health and Safety Code section 25173), and specific statutory provisions both govern DTSC's sharing of such information with authorized parties, and impose criminal liability for the knowing or willful dissemination of protected information. (See Health and Safety Code section 25358.2.) DTSC additionally has written policies that alert employees to the importance of maintaining trade-secret confidentiality and identify applicable laws and regulations. (See *DTSC Policy for Conducing Inspections,* Enforcement and Emergency Response Program*,* dated Jan. 30, 2009, at p. 21; see also *DTSC Public Records Act Policy*, dated Oct. 8, 2003, at pp. 8-9.)

Some commenters have recommended that DTSC examine the DPR's systems for managing confidential information, such as the confidential statements of formula associated with state-level pesticide registrations. DTSC does expect to consult with other agencies that handle confidential information in the consumer product regulatory context in tailoring its information protection systems and employee training to present needs.

Information management systems, and associated DTSC staff resources, are best dealt with as implementation rather than regulatory matters. Resources available to DTSC for specific programs have varied and will inevitably vary through time. Further, by expanding or contracting the number of products identified as Priority Products, DTSC has the ability to keep information management needs within DTSC's management capacity. DTSC is not making any changes to the regulations in response to these comments.

Comments: 10-8, 10-9

Comments Summary:

DTSC should be mindful of the World Trade Organization's TRIPS Agreement, which requires WTO members to protect confidential information.

Response:

DTSC is aware of the WTO TRIPS Agreement, which is a multilateral agreement regarding intellectual property protection. DTSC believes that Article 10 (since renumbered to Article 9 (January 2013)) is fully consistent therewith. The commenter has not identified any specific conflict between DTSC's regulations and the United States' ability to fulfill TRIPS Agreement obligations. DTSC is not making any changes to the regulations in response to these comments.

Comments: 12-22, 57-96

Comments Summary:

The trade secrecy provisions conflict with the statutory instruction in Health and Safety Code section 25253 to create an easy-to-use process with simplified tools for use by manufacturers and other actors throughout the product supply chain.

Response:

The commenters' assertion appears to pertain to the portion of Health and Safety Code section 25253 providing, *inter alia,* that DTSC shall "devise simplified and accessible tools" that actors throughout the product supply chain can use "to make consumer product manufacturing, sales, and purchase decisions." (Health and Safety Code section 25253(c) [emphasis added].) It is unclear how supplying a legal definition of "trade secrets" (in Article 1) or specifying the substantiation requirements therefor (in Article 9 (January 2013)), might have bearing on the types of private-actor "decisions" contemplated by Health and Safety Code section 25253(c), or what "tools" the commenters seek to have DTSC provide in this regard. It appears, rather, that the Legislature intended such "tools" to be created for a context of use other than trade-secrecy delineation. DTSC believes, however, that by enumerating each item required to be submitted in support of a trade secrecy claim (see section 69509(a)(1) through (a)(12) (January 2013)) and establishing clear protocols for document marking and redaction, DTSC has created an "easy-to-use process" for asserting a claim of confidentiality. DTSC is not making any changes to the regulations in response to these comments.

Comments: 107-88, 107-89

Comments Summary:

The public right-to-know agenda has unfairly characterized consumer product manufacturers as “hiding” important information as secrets. Our company provides substantial formulation information to customers who contact us. However, companies must balance their transparency actions with the critical need to protect confidential information in a global marketplace.

Response:

DTSC appreciates that some companies provide substantial product composition information to consumers through voluntary disclosure initiatives. The extent of such disclosures varies widely across manufacturers and product types. DTSC’s regulations reflect the balance struck in AB 1879 among provisions designed to insure intellectual property protection (such as Health and Safety Code section 25257, permitting the assertion of trade secrecy claims), and those designed to increase the availability of ingredient and toxicity information in the marketplace (such as section 25253(b)(3), indicating that DTSC may wish to invoke as a regulatory response to a product “requirements on the labeling or other consumer product information”). DTSC is not making any changes to the regulations in response to these comments.

Comments: 36-95, 91-16

Comments Summary:

DTSC should provide incentives for full public transparency, including disclosure of all ingredient identities. For example, manufacturers could get a streamlined review process in exchange for forgoing all trade secrecy claims.

Response:

DTSC is sympathetic to the thrust of commenters’ suggestions but declines to adopt them at this time. The notion that DTSC should incentivize complete transparency as to product ingredients and otherwise, such as by accelerating DTSC review processes for documents with no claimed trade secrets, presupposes that maintaining confidentiality of any product-related information is inherently against the public interest. DTSC believes this is a contestable proposition, because manufacturers may be more inclined to invest in the development of safer product chemistries and product designs in the first instance if they are guaranteed a period of confidentiality and exclusive use of their innovations, be these new chemicals development or use of unconventional raw material sources or supply chains. That said, as DTSC’s regulatory program evolves, DTSC will be receptive to any streamlining suggestions that are likely to have the

overall effect of accelerating the introduction of safer consumer products in California. DTSC is not making any changes to the regulations in response to these comments.

§ 69510(c) Documentation

Comments: 2-6, 2-7

Comments Summary:

Conflicts between DTSC regulatory requirements and federal law may arise when a defense contractor is required to provide Classified Information to DTSC. The Commenter proposes the addition of a new definition to Article 1 for "Classified Information," and a corresponding set of protections from disclosure for this information.

Response:

DTSC appreciates the issue raised by the commenter and has chosen to address it through a substantive change to the trade secrecy article of the regulations rather than as a definitional matter in Article 1. The January 2013 revisions to the regulatory section governing trade secrecy provide, at section 69509(c)(1), that persons asserting a claim of trade secret protection need not provide DTSC with a complete copy of the documentation that includes the information for which trade secret protection is claimed where to do so would be "expressly prohibited by federal law." On this basis, classified information whose release is proscribed on the basis of national security interests, or other information required by federal law to be kept secret, would not be required to be disclosed to DTSC.

§ 69510(e) Provision of Separate Copies

Comment: 115-5

Comment Summary:

To reduce costs for responsible entities, DTSC should determine on a case-by-case basis whether a redacted version of a document containing trade secrets must be provided rather than requiring this in all instances.

Response:

As described above, AB 1879 mandates that all information that is not claimed as trade secret is expressly required to be publicly disclosed. (See Health and Safety Code section 25257(c).) Thus, it is appropriate for the regulations to require categorically that responsible entities provide a redacted, publicly available version of documents

containing asserted trade secrets. DTSC is not making any changes to the regulations in response to this comment.

Comments: 66-82

Comments Summary:

Where submission of trade secret information is necessary to justify a trade secrecy claim, there is a feedback loop of submissions to DTSC.

Response:

Section 69509(e) provides that where substantiation of a claim of trade secrecy requires submittal of justificatory information that is itself trade secret, the submitter must provide the justificatory information to DTSC in both full and redacted forms. The regulations also make clear, however, that this submittal "shall not itself require further documentation." (*Ibid*.) Thus, there is a maximum of two rounds of submissions contemplated, not an infinite feedback loop. DTSC is not making any changes to the regulations in response to these comments.

Comments: 7-26, 41-51, 66-7

Comments Summary:

Even redacted documents will divulge confidential information through context. DTSC has failed to protect confidential business information through this provision.

Response:

As described above, the regulations provide for two rounds of confidential submissions to DTSC to ensure that submitters can present the details of their trade secrecy claim(s) to DTSC without compromising confidential content. Because the submitter has ultimate authorial control over documents submitted to DTSC, and the types of information that may be claimed as trade secret under Article 9 (January 2013) are broad, the submitter should be capable of drafting documents that, when redacted, avoid divulging genuinely confidential information. DTSC is not making any changes to the regulations in response to these comments.

Comments: 7-26, 36-82, 41-50, 56-6, 74-95

Comments Summary:

Several commenters noted that making redacted copies of documents available at the "discretion" of DTSC (section 69510(c)(2)) is inconsistent with section 69501.5(b)(6) of

the regulations, which provides that DTSC “shall” post enumerated documents on DTSC’s website. Some of these commenters objected to the requirement to provide redacted copies. Others supported this requirement and said that such documents should be uniformly available, rather than available at DTSC's "discretion."

Response:

The regulations have been amended to address the internal inconsistency noted by commenters. Section 69509(c)(2) now omits mention of DTSC “discretion,” and the provisions of section 69501.5(b)(6) control the availability of enumerated documents (January 2013). The need for provision of redacted copies, and the rationale for making these publicly available, is described more fully above.

§ 69510(f) Hazard Trait Submissions

Comment: 36-83

Comment Summary:

AB 1879 prohibits a claim of trade secrecy for health, safety, or environmental information; the fact that this is made explicit in the statute reflects the importance of making this information publicly available. Chemical identity information associated with a hazard trait submission is required to make the submission meaningful.

Response:

DTSC agrees with the commenter that the plain text of AB 1879 indicates the importance the Legislature placed on public disclosure of information relevant to the health, safety, and environmental effects of chemicals and chemical ingredients, notwithstanding the existence of potentially competing private interests. AB 1879 states that Health and Safety Code section 25257, which generally permits parties to designate information to DTSC as trade secret, “does not apply to *hazardous trait submissions for chemicals and chemical ingredients* pursuant to this article.” (Health and Safety Code section 25257(f) [emphasis added].”

As explained in the ISOR, DTSC and commenters have assumed that the phrase “hazardous trait submissions” contains a typographical error and is intended to read “hazard trait submission,” the term used in companion bill SB 509. (Ch. 560, Stats. 2008.) DTSC agrees with the commenter that identification of the “chemicals and chemical ingredients” to which a particular “hazard[] trait submission” pertains is necessary to maximize the public utility of the information in that submission, while recognizing that the submission might have some, more limited value without full

chemical-identity disclosure. DTSC is not making any changes to the regulations in response to this comment.

Comments: 11-5, 109-9, PH11-5

Comment Summary:

It is inconsistent with AB 1879 to require disclosure of the chemical associated with a hazard trait. For many years, TSCA has separated the two.

Response:

DTSC disagrees that the California Legislature intended, or that the state's consumers and environment would be well served by, replication of TSCA's approach to confidential information. The commenter is correct that under TSCA, manufacturers have frequently used generic descriptors in lieu of precise chemical identities when submitting health and safety studies and other chemical-related information to U.S. EPA. DTSC's Safer Consumer Products Regulations intentionally depart from and improve upon this decades-old federal approach for three reasons:

1. U.S. EPA has itself acknowledged significant problems with TSCA's approach to confidentiality and specifically urged that statutory reform must include the following principle: "Data relevant to health and safety should not be claimed or otherwise treated as CBI." (U.S. EPA, "Essential Principles for Reform of Chemicals Management Legislation," Principle No. 5, available at: www.epa.gov/oppt/existingchemicals/pubs/principles.html [accessed March 1, 2013].)
2. TSCA's approach to confidential information has been widely criticized by third parties as antiquated and inadequate. As described above, a recent GAO report identified problems with unwarranted confidentiality claims under TSCA, as well as difficulties in making chemicals information publicly available and sharing it across government agencies.
3. AB 1879 was drafted more than 30 years after TSCA and against a backdrop of criticism of TSCA's approach to confidential information, including information in documents describing health and environmental effects of chemicals. AB 1879 uses different statutory language from TSCA in identifying the type of information that must be publicly disclosed in this regard. (*Compare* Health and Safety Code section 25257(f) *with* 15 U.S.C. § 2613(b).)

All of these factors suggest that the California Legislature intended DTSC to learn from, rather than perpetuate, the problems with TSCA's approach to confidential information. DTSC is not making any changes to the regulations in response to these comments.

Comments: 124-35, 124-36

Comments Summary:

DTSC's determination to require disclosure of specific chemical identity in connection with hazard traits is problematic and exceeds the scope of AB 1879. DTSC's regulations fail to distinguish between "hazard traits," which are specific hazards, such as corrosivity or ignitibility, and "chemical identities," which are a separate type of information different from hazard traits.

Response:

As describe above and below, DTSC disagrees with the commenter regarding the need for chemical identity disclosure as a matter of policy. As to the commenter's claim that DTSC's regulatory approach exceeds the scope of AB 1879, DTSC disagrees as a matter of statutory interpretation.

AB 1879 states that trade secrecy protection does not extend to "hazard[]trait submissions for chemicals and chemical ingredients" (Health and Safety Code section 25257(f)), but does not define the phrase "hazard trait submissions." This phrase is susceptible of more than one reasonable interpretation. DTSC believes that the definition of "hazard trait submission" in Article 1, section 69501.1(a)(37) (January 2013), to subsume chemical identity, is a reasonable one. It effectuates the Legislature's intention to maximize the public availability of information related to the health, safety, and environmental attributes of specific chemicals that have been studied with respect to specific, potentially deleterious effects. DTSC believes that the Legislature's specific reference to "chemicals and chemical ingredients"—rather than a mere statement that "hazard trait submissions" must be provided to the public—tethers the hazard trait(s) studied to the subject chemicals in a manner that presupposes their essential linkage.

The commenter has also presented a false dichotomy between "hazard traits" and "chemical identities," by omitting a key statutory term—"*submission.*" A "hazard trait *submission*" to DTSC logically encompasses both information about one of more hazard traits and information about the chemical(s) to which they pertain. DTSC is not making any changes to the regulations in response to these comments.

Comments: 9-58, 9-59, 115-6

Comments Summary:

DTSC's regulatory definition of "hazard trait submission" conflicts, or arguably conflicts, with the UTSA. AB 1879's statement that Health and Safety Code section 25257 does not apply to hazard trait information means simply that the hazard trait submissions are excluded from the specific procedures governing trade secrets found in that section and that the UTSA governs instead.

Response:

DTSC respectfully disagrees with commenters' legal interpretation, which relies on a statutory reading that is both circular and illogical. The UTSA is the background state law against which AB 1879 was enacted. As a more recent statute enacted by the same sovereign, AB 1879 may supplant any UTSA provision that it expressly negates or with which it conflicts.

The first subsection of section 25257—subsection (a)—confirms the general applicability of the UTSA to information confidentiality claims under AB 1879. Subsection (b) expressly authorizes sharing of trade secret information across public agencies where it is "relevant and necessary" and information confidentiality is maintained.

Subsection (c) goes beyond matters addressed by the UTSA in compelling public disclosure, in specifying that "[t]he fact that information is claimed to be a trade secret is public information." Subsection (d) is largely ministerial and dictates procedures for confidentiality determinations and public information release. Subsection (e) goes beyond matters addressed by the UTSA in compelling disclosure to DTSC, in providing that "[t]his section does not authorize a person to refuse to disclose to the department information required to be submitted to the department pursuant to this article" (*i.e.*, private parties may not maintain secret information vis-à-vis DTSC).

Section 25257(f) contains a carve-out from trade secrecy eligibility, stating that "[t]his section does not apply to hazard[] trait submissions for chemicals and chemical ingredients pursuant to this article."

As a structural matter, commenter's argument that the UTSA controls hazard trait submissions is nonsensical, because this would render 25257 subsection (f) complete surplusage: subsection (a) of section 25257 already establishes that the UTSA will generally define the scope of information that may be claimed trade secret, and subsection (f) is clearly intended as a limitation on this general principle.

As a substantive matter, commenter's suggestion that hazard trait submissions are merely meant to be exempt from the procedural instructions in 25257 subsections (b)

through (e) is highly implausible, as this would make “hazard[] trait submissions” *less* amenable to disclosure than other types of information rather than *more* so: there would be no explicit duty for private parties to provide such information to DTSC (subsection (e)), no express ability to share hazard-trait information across agencies (subsection (b)), and no duty for DTSC to inform the public of the existence of a trade secrecy claim (subsection (c)). Given that a core purpose of SB 509 and AB 1879 is to *increase* the availability of information about chemicals’ hazard traits—and that even TSCA, for all its acknowledged flaws, forces more disclosure of health and safety information than of other types of information—commenters’ interpretation is not legally supportable. DTSC is not making any changes to the regulations in response to these comments.

Comments: 9-60, 11-72, 41-41, 41-42, 41-52, 41-53, 73-33, 74-93, 74-96

Comments Summary:

Section 69510(f) (renumbered to 69509(f) (January 2013)) goes beyond or “arguably” goes beyond the authorizing statute, by requiring chemical identity information, not just "hazardous [sic] trait submissions," the term used in statute. This amounts to a modification of trade secrecy law.

Response:

DTSC respectfully disagrees. As described above, AB 1879 post-dates the UTSA; to the extent the two state statutes diverge, AB 1879 controls, and any modification of trade secrecy law has been effected by the Legislature rather than DTSC.

The statutory phrase “hazard[] trait submission” is undefined by AB 1879 or SB 509. As described above, DTSC has defined this phrase in regulation to include chemical identity. DTSC believes this statutory interpretation is objectively reasonable, because a “submission” logically encompasses both information about particular “hazard[] trait(s)” examined, and the chemicals to which they pertain. DTSC also believes this interpretation comports with AB 1879 and companion bill SB 509, which collectively manifest a goal of increasing the availability of hazard trait information with respect to individual chemicals in commerce.

DTSC also notes that there is no limiting principle to the alternative interpretation implicitly urged by commenters. That is, under their argument, the statutory purpose would be fulfilled if a hazard trait submission stated simply: “In this study, ‘Chemical X’ was found to demonstrate the hazard traits of carcinogenicity, reproductive toxicity, and aquatic toxicity.” Such a submission would provide near-zero useful information to the

public, in obvious tension with the transparency-promoting provisions of AB 1879. DTSC is not making any changes to the regulations in response to these comments.

Comments: 9-57, 9-60, 9-61, 9-62, 9-65, 74-93, 74-94, 74-97, 109-10

Comments Summary:

With respect to chemical identity in particular, DTSC's regulations over-reach, and could hinder innovation by disincentivizing research into safer alternatives. Chemical identity is extremely valuable intellectual property, and requiring its disclosure makes no sense; manufacturers will jeopardize their ability to file patents if they are forced to disclose an unpatented alternative.

Response:

Commenters' concerns regarding the need for intellectual property protection for safer product innovation through the patent system is valid. DTSC has modified the regulations in response to these comments. The concern is addressed in new section 69509(g), which allows time-limited masking of the precise chemical that is the subject of a hazard trait submission where a patent application is pending for the chemical or its use in a specified product (January 2013).

Comments: 9-63, 9-64, 9-65, 74-93, 82-7, 107-90

Comment Summary:

Health and safety studies are meaningful to the public if structurally descriptive generic names are used. These may even lead to retrieval of more journal literature than more specific searches. Other nations have provided for more intellectual property protection for chemical identity.

Response:

DTSC acknowledges that the degree of protection for chemical identity varies across regulatory regimes, both foreign and domestic. DTSC disagrees with commenters' premise, however, which is that the most property-protective regime should govern here. DTSC's regulatory approach to chemical identity disclosure reflects learning from the four decades of experience under TSCA regarding how best to balance the public interest in chemical identity information and vigorous promotion of competition against the interest of a particular innovator in maintaining chemical identity secrecy.

While DTSC agrees that structurally descriptive generic names of chemicals have some utility, these names are rarely precise enough to permit efficient research, and provision

of precise chemical identity information will unquestionably increase the public utility of information provided in hazard trait submissions. By way of analogy, if one is searching for a particular book, it is significantly more efficient to be handed its call number than to be given access to the Library of Congress with no further information. Simply put, retrieving “more . . . literature” is not a reasonable measure of utility.

DTSC believes that maximizing the availability of information about specific chemicals and their hazard traits—or absence thereof—is particularly critical in the absence of any pre-market approval process for such chemicals in the majority of consumer product applications within DTSC’s regulatory purview. Such information access will enable universities, government agencies, and others to make informed decisions and to perform research to fill data gaps. DTSC is not making any changes to the regulations in response to these comments.

Comment: 66-83

Comment Summary:

It is overbroad to require disclosure of chemical identity in connection with a hazard trait (*e.g.*, “irritation”) for which it is not being assessed.

Response:

DTSC will consider a wide array of hazard traits when selecting Priority Products, identifying Chemicals of Concern, and determining appropriate regulatory responses following an alternatives assessment. Because all hazard traits identified by the Office of Environmental Health Hazard Assessment (OEHHA) are potentially relevant to DTSC’s implementation of, and stakeholder participation in, the Safer Consumer Products regulatory program, DTSC believes that chemical identity disclosure is relevant with respect to all hazard traits addressed in submissions to DTSC. DTSC is not making any changes to the regulations in response to this comment.

§ 69510(g) Chemical Identity Masking When a Patent is Pending

Comments: 57-98, 66-84, 107-93

Comment Summary:

Section 69510(g) provides no clarification as to what constitute a "new use" for a chemical proposed as an alternative to a Chemical of Concern. It is also unclear as to how "substantially safer" will be determined.

Response:

DTSC has substantially modified former section 69510(g) in response to comments on it. As revised and renumbered, the analogous regulatory section (69509(g)) omits the concepts of “new use” or “substantially safer” (January 2013).

Comments: 107-93, 115-6

Comments Summary:

Because section 69510(f) is unauthorized by statute, sections 69510(g) and (h) also should not be adopted. Limited exceptions do not ameliorate the over-reach of requiring chemical identity disclosure in the first instance.

Response:

For the reasons described above, DTSC believes that its definition of a “hazard[] trait submission” to encompass chemical identity information comports with the plain language and intent of AB 1879. The trade secrecy implications of this definition are explained in section 69510(f) (since renumbered to section 69509(f) (January 2013)). Former 69510(g), now section 69509(g), has been substantively changed in response to stakeholder input, as described below (January 2013). Former 69510(h), now renumbered as section 69509(g)(2), is necessary to provide information to the public that is both accurate and protective of information allowed to be kept confidential (January 2013).

Comments: 11-73, 36-69, 36-70, 36-71, 107-90, 107-91

Comments Summary:

Some commenters stated that former subsection 69510(g), an exception to the otherwise general rule that chemical identity may not be claimed trade secret, is both legally invalid and unwise policy. They stated that AB 1879’s required disclosure of health and safety information necessarily includes chemical identity information to make the disclosure meaningful. These commenters urged that should DTSC retain any exception to the rule that chemical identity is an integral part of a hazard trait submission. The exception should be that only chemicals not chosen as an alternative to a Chemical of Concern may remain undisclosed, and that such a secrecy claim should be time-limited and periodically reevaluated. Other commenters urged, to the contrary, that the strong disclosure-forcing aspect of DTSC’s regulations with regard to ingredient identity will pose problems for manufacturers faced with the new “first to file” patent rule in the U.S. Some commenters recommended eliminating this provision altogether.

Response:

In light of helpful stakeholder input on this topic from all sides, DTSC has substantially revised the contours of the limited exception from chemical identity disclosure with respect to hazard trait submissions. The new exception, contained in section 69509(g) (January 2013), permits time-limited masking of precise chemical identity where a patent for the subject chemical is pending. In so doing, DTSC has recognized the need to incentivize manufacturers to invest in safer product chemistries by protecting their intellectual property in the time while a patent application is pending, whether or not any new chemical will be immediately contained in an alternative to a Priority Product that is brought to market in California. At the same time, DTSC has recognized the public interest in knowledge of the specific chemistries of products that may in future result in exposures to Californians and their environment, and therefore believes that chemical-identity protection should be limited to the time necessary to secure patent protection.

Comment: 57-97

Comment Summary:

Given the broad definition of “hazard trait submission” in the regulations, very little will information will be able to be claimed as trade secret.

Response:

DTSC respectfully disagrees. Information concerning adverse safety, health, and environmental effects associated with specific chemicals is but a fraction of the information likely to be submitted to DTSC pursuant to the Safer Consumer Products Regulations. Significant technical information about a chemical or product that does not relate to safety/health/environmental attributes is potentially protectable as trade secret, as is all manner of CBI, as discussed more fully above.

Comments: 101-40, 107-95

Comments Summary:

It is unclear how trade secrets will be handled by certified assessors and accrediting bodies, which are not discussed in the trade secrecy article. Trade secrecy protection needs to extend to their review of confidential material.

Response:

DTSC appreciates the concerns raised by this comment. The issue raised is now moot, as certified assessors and accrediting bodies (discussed in former Article 8) are no longer part of the proposed regulatory scheme.

§ 69510.1 Department Review of Claims of Trade Secret Protection

Comment: 57-99

Comment Summary:

The commenter has proposed multiple drafting changes to this section, many of which are minor stylistic revisions, such as a proposal to change the finding of documentation "insufficiency" to a finding of documentation "incompleteness."

Response:

DTSC declines to adopt the proposed edits, which it does not believe are necessary or add clarity to the regulations.

Comment: 115-7

Comment Summary:

Section 69510.1 should contain a provision allowing for the return of information to the submitter when DTSC disagrees with the submitter's claim, so that a company may opt out of sales in California if necessary to protect information recognized as trade secret information elsewhere.

Response:

DTSC understands the commenter's concern but does not believe Health and Safety Code section 25257 authorizes DTSC to withhold from the public already-submitted documents determined not to be trade secret. Further, DTSC is not familiar with any regulatory regime adopted by any sovereign that adopts the commenter's suggested approach. DTSC believes, however, that the theoretical scenario posited is unlikely to arise in practice, in that it presupposes that: (a) information is already recognized as trade secret elsewhere, a factor that would be identified in an information submittal to DTSC pursuant to section 69510(a)(9) (renumbered to section 69509(a)(9) (January 2013)); (b) the claimed trade secret is so important that the submitter is willing to forgo all California product sales to protect it, yet is unable to justify its secret status to DTSC adequately; and (c) the submitter is unwilling to seek judicial review of DTSC's determination, or a court upholds DTSC's view. DTSC is not making any changes to the regulations in response to this comment.

§ 69510.1(a) Review of Support for Trade Secret Designation

Comment: 107-91

Comment Summary:

The regulations should contain a commitment by DTSC to review trade secrecy substantiation submissions.

Response:

Due to resource limitations, it is impractical for DTSC to commit to a specific time frame for reviewing trade secrecy substantiation submissions. This is best addressed as an implementation rather than regulatory issue, particularly because information submitters are not prejudiced by any DTSC delay in review of trade secrecy claims. DTSC is not making any changes to the regulations in response to this comment.

Comments: 5-97, 5-98, 119-5

Comment Summary:

The regulations do not specify how DTSC intends to ensure that trade secrets are actually protected. This is especially important with respect to formulas held by small companies.

Response:

DTSC understands the need for protection of private parties' trade secrets and indeed believes this is critical for all companies, regardless of size. DTSC believes this is properly addressed as an implementation and operational issue, rather than through regulation. This is particularly so because specifying precise protocols in regulation may act as an impediment to fine-tuning and improving such protocols through experience. DTSC is not making any changes to the regulations in response to these comments.

Comment: 36-84

Comment Summary:

DTSC should inform the public when companies' trade secret claims have been approved so that the public knows when complete information about a chemical is not available.

Response:

AB 1879 provides that "[i]information not identified as a trade secret . . . shall be available to the public unless exempted from disclosure by other provisions of law," and that "[t]he fact that information is claimed to be a trade secret is public information."

(Health and Safety Code section 25257(c).) DTSC's implementing regulations further require, at section 69509(d) (January 2013), that a party asserting a trade secrecy claim conspicuously mark "trade secret" on each document page that contains purported trade-secret information. Therefore, any member of the public requesting access to particular information will be able to determine whether s/he is receiving "complete information" about a given chemical, regardless of whether DTSC has reviewed or approved a trade secrecy claim. In light of resource constraints and competing program priorities, however, DTSC does not believe it would be practical to commit to the additional administrative step of affirmatively notifying the public whenever a particular trade secrecy claim has been approved. DTSC is not making any changes to the regulations in response to this comment.

§ 69510.1(b) Additional Information Requirements

Comments: 5-133, 5-185, 66-85

Comments Summary:

The 30-day period within which to seek judicial review of a DTSC finding that a substantiation submittal is noncompliant with Article 10 (since renumbered to Article 9 (January 2013)) should be changed to sixty (60) days. It is unlikely that a manufacturer will be able to respond or file a court action in thirty (30) days.

Response:

Section 69510.1(b) (renumbered to section 69509.1(b) (January 2013)) is a procedural requirement that a responsible entity supply supplemental justificatory information regarding a trade secret to DTSC in a specified time frame. DTSC believes that thirty (30) days is sufficient time for the submitter to file a legal action challenging any DTSC determination that the requested information has not been timely submitted. Commenters have not justified why the determination of whether such information has, in fact, been provided is so complex that a relevant complaint would take more than thirty (30) days to prepare. DTSC is not making any changes to the regulations in response to this comment.

§ 69510.1(c) Notice to Submitter

Comments: 5-133, 5-185

Comments Summary:

The 30-day period within which to seek judicial review of DTSC's denial of a claimed trade-secret designation should be changed to sixty (60) days.

Response:

Section 69510.1(c) (renumbered to section 69509.1(c) (January 2013)) provides a submitter of claimed trade-secret information with thirty (30) days to challenge judicially any DTSC determination that such information does not meet the substantive criteria for trade secrecy, and will be considered a public record subject to disclosure. This regulatory provision tracks Health and Safety Code 25257(d)(3), which states that DTSC need only provide a submitter of claimed trade-secret information "30 days' notice prior to the public disclosure of the information." DTSC believes that thirty (30) days is sufficient time to file a court challenge to release of information, because by definition the potential plaintiff will already have compiled evidence that it believes sufficient to justify its confidentiality claim. Commenters have not explained why the presentation of such already-compiled evidence in a court pleading requires more than thirty (30) days. DTSC is not making any changes to the regulations in response to these comments.

Comment: 107-94

Comment Summary:

In section 69510.1(b)(1)(D) (renumbered as section 69509.1(b)(1)(C) (January 2013)), DTSC should specify a uniform time frame within which submitters must provide any additional information necessary to permit a trade secrecy determination.

Response:

Because both the amount of supplemental information that DTSC requests from submitters and the ease or difficulty of preparing same may vary widely on a case-by-case basis, DTSC believe that all parties will be better served by tailoring the response time to the nature of the identified task(s). Accordingly, DTSC declines to amend section 69510.1(b)(1)(D) as suggested.

Comment: 107-94

Comment Summary:

In section 69510.1(b)(1)(D)(2) [now renumbered as 69509.1(b)(2) (January 2013)], deadlines should be tied to recipient's signature of a certified mail receipt rather than to the sending date, as delivery times may vary.

Comment:

The minor fairness issue raised by the commenter must be weighed against the administrative difficulty for DTSC of tracking letter-receipt rather than actual correspondence dates, and the additional postal costs for DTSC if return receipts are required in all instances. For these reasons, DTSC has declined to amend this section as requested.

§ 69510.1(d) Judicial Review

Comment: 107-94

Comment Summary:

The regulations should recognize that a submitter may seek judicial review by filing an action for any type of relief appropriate under the law, not just a preliminary injunction or declaratory relief.

Response:

The judicial review provision of the regulations, section 69510.1(d) (now renumbered as 69509.1(d) (January 2013)), mirrors AB 1879's statement that a person seeking to protect claimed trade-secret information may maintain a court action "for a declaratory judgment that the information is subject to protection . . . or for a preliminary injunction prohibiting disclosure of the information to the public." (Health and Safety Code section 25257(d)(3).) To the extent that a submitter of claimed trade secret information contends that more expansive legal remedies remain available, that party may attempt convince a court that the Legislature did not intend to foreclose additional forms of judicial relief. DTSC is not making any changes to the regulations in response to this comment.

PROCEDURAL, LEGAL, AND OVERARCHING ISSUES

The following comments were not necessarily directed to any particular section(s) of the proposed regulations. Rather, the comments are of an overarching nature and are directed to the regulations in general or concepts embedded throughout the regulations. Thus, they are summarized and responded to here rather than as part of a particular section or Article within the proposed regulations.

Support

Comments: 8-1, 8-2, 19-2, 19-3, 26-1, 29-1, 32-1, 35-1, 36-32, 45-1, 89-3, 114-1, 126-1, 128-1, 138-1, 138-2, 138-15, 32-1, 140-1, 142-1, 143-1, 144-1, 146-1, 147-1, 148-1, 149-1, 150-1, 151-1, 153-1, 155-1, 156-1, 157-1, 160-1, 161-1, 162-1, 164-1, 165-1, 166-1, 168-1, 169-1, 170-1, 171-1, 174-1, PH17-8, PH20-5, PH21-4, PH22-4, PH24-1

Comments Summary:

All of the above comments expressed support for the general concepts and content of the regulations.

Response:

DTSC notes and appreciates the support for the regulations expressed in these comments. DTSC is making no changes in response to these comments.

Antitrust Issues

Comments: 5-45, 5-46, 12-1, 12-2, 78-5

Comments Summary:

The comments point out that the regulations allow—or even encourage—consortia to work together in developing and conducting a single Alternatives Analysis (AA) and related reports and/or cooperating in the development of an end-of-life program as a regulatory response. The comments then assert that such coordinated activity could be a violation of antitrust laws and, therefore, DTSC should amend the regulations to extend protections to regulated entities working in coordination from being deemed in violation of antitrust laws.

Response:

DTSC notes that the regulations do not compel the formation of consortia or any other cooperative arrangements. The regulations merely make it clear that such

arrangements are permissible under these regulations, where specified. The regulations do not compel any behavior that would constitute a violation of antitrust laws. Nor does DTSC have the authority to confer immunity or create a defense for violation of antitrust laws and requirements. Regulated entities choosing to work in coordinated fashion with other regulated entities must comply with myriad other laws and requirements in the course of doing therefore, including antitrust laws. Accordingly, DTSC is not making any changes to the regulations in response to these comments.

Requests for Exemption(s)

Comments: 4-7, 5-48, 5-124, 9-108, 9-116, 13-9, 13-10, 13-11, 13-12, 13-13, 13-14, 19-42, 20-4, 20-5, 20-6, 20-7, 23-1, 23-5, 23-8, 25-1, 25-2, 25-3, 25-4, 25-5, 25-6, 25-7, 25-8, 25-9, 25-10, 25-11, 25-12, 25-13, 38-10, 46-3, 56-1, 56-2, 56-4, 57-11, 59-3, 60-6, 60-7, 69-1, 69-2, 69-3, 69-4, 69-5, 69-6, 69-7, 69-8, 69-9, 69-10, 69-11, 69-12, 69-13, 69-14, 69-15, 69-16, 69-17, 69-18, 69-19, 69-20, 69-21, 69-22, 69-23, 69-24, 69-25, 81-3, 101-10, 101-11, 101-12, 101-13, 101-14, 107-10, 109-2, 109-3, 109-4, 115-3, 122-2, 122-4, 122-5, 122-6, 122-7, 124-25, 130-1, 130-3, 132-1, 132-2, 132-4, 132-5, 152-1, PH5-2

Comments Summary:

The above comments all request that DTSC grant a particular product a partial or complete exemption from the regulations. The comments request an exemption based on the view that the products identified are regulated under another state and/or federal regulatory scheme in a manner that obviates the need for regulation under these regulations. More specifically, the commenters assert that for various reasons, the products mentioned do not warrant regulation under DTSC's Safer Consumer Products Regulations. The comments go on to state that regulatory authority over the products is inconsistent with Health and Safety Code section 25257.1 of the authorizing legislation. That provision precludes DTSC from adopting regulations that conflict with or duplicate existing regulatory schemes that regulate product categories in a manner that is consistent with the protection of public health and safety and the environment afforded by these regulations. (Comments discussing preemption, regulatory conflict, and duplication are also summarized and responded to later in these responses to comments.)

The comments also included, in some cases, extensive descriptions of the existing regulatory schemes under which the various regulated entities operate. These include, but are not limited to the airlines/aviation industry, over-the-counter pharmaceuticals, tire manufacturers, and food packaging products. The comments also assert that DTSC

lacks the ability to regulate these industries in an informed and productive manner. Many commenters point out the benefits of the particular product that they manufacture or sell. Finally, some commenters urged DTSC to restore the "upfront exemption" for products already adequately related, as was the case with earlier versions of these regulations.

Response:

The authorizing legislation at Health and Safety Code section 25251 defines the universe of "consumer products" that will be subject to the regulations adopted by DTSC, pursuant to Health and Safety Code section 25252 and 25253, among other key provisions of the authorizing statute. The statutory definition of "consumer product" expressly excludes certain products that would otherwise meet the general description of "consumer product." For instance, as defined, dangerous drugs, dental restorative materials, food, pesticides, and certain packaging (other than for food) are all permanently excluded from the definition of "consumer product." The Legislature crafted an exhaustive list of products that were rendered exempt from the regulations authorized and mandated by these statutes. This was done by virtue of the content of Health and Safety Code section 25251's exclusions from the definition of "consumer product" and, thus, from the reach of these regulations.

Under well-established principles of the proper exercise of rulemaking authority granted to administrative agencies, the implementing regulations may neither expand nor contract the scope of the authority conferred by the authorizing statute. Here, DTSC is being urged to shrink the scope of the statute by adopting exemptions that were not set out in the authorizing statute. DTSC has no authority to limit the reach of the statute by drafting such exemptions when the Legislature did not confer such authority.

In addition, DTSC notes that the statutory prohibition invoked by these comments as the express or implied basis of their request for exemption is Health and Safety Code section 25257.1(c). That provision reads: "The department [DTSC] shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this Article [Article 14, of Chapter 6.5, of Division 20 of the Health and Safety Code]." Two important limitations in this text are applicable here.

First, the prohibition in Health and Safety Code section 25257.1(c) is against regulating "product categories" that are already regulated, and there are no specific product categories that will be regulated under these regulations. Rather, these regulations are "process regulations." In order to create a process that achieves the goals of the

authorizing legislation, DTSC has determined that the regulations must assess product-chemical combinations, rather than broad product categories. That is, consistent with the mandates in the authorizing legislation, the regulations establish a process for the identification and prioritization of chemicals and products containing them that must be analyzed to determine if they can be made in a manner that reduces the risks posed by them.

Second, the prohibition is against conflicting or duplicative regulations when a product category is already regulated "consistent with the purposes of" Article 14. Article 14 in its totality establishes an identification, prioritization, and analysis process for chemicals in products based on the risks posed throughout the entire life cycle of the product. See, for example, Health and Safety Code section 25253(a)(2). This provision sets out a full life cycle of the product as the basis for comparing the current product to possible alternatives. None of the comments established that the particular product discussed was regulated throughout the entire life cycle of the product. This is a separate, substantive basis for denying these requests for exemption—in addition to the fact that DTSC lacks the legal authority to do so.

Nonetheless, the commenters should note that pursuant to Health and Safety Code section 25257.1 and proposed section 69501(b)(3)(A) of these regulations (January 2013), DTSC does not intend to implement the regulations in a manner that conflicts with existing State and/or federal regulations. More specifically, proposed section 69501(b)(3)(A) specifies that the requirements of these regulations do not apply to a consumer product that DTSC determines is regulated by state or federal programs that collectively address the same public health and environmental threats and exposure pathways that would otherwise be the basis for the chemical being listed as a Chemical of Concern or the product being listed as a Priority Product and that are at least as protective as the provisions of this program that otherwise would apply.

These regulations implement the prohibition in Health and Safety Code section 25257.1, without DTSC exceeding its authority by the adoption of exemptions beyond those set out in the authorizing legislation. As DTSC implements the proposed regulations, it will consider information and justification that any person provides to DTSC that is relevant to a determination that a particular chemical or product qualifies for the exclusion in proposed section 69501(b)(3)(A) (January 2013). Finally, DTSC notes that there are additional balancing criteria in Article 3 that allow DTSC to consider the extent to which a product is already regulated, even if such regulation is not co-extensive with this program. Those provisions are discussed in detail under Article 3.

Therefore, DTSC declines to adopt any of the partial or complete exemptions urged by the above comments.

Technical Barrier to Trade

Comments: 5-23, 5-47, 10-1, 10-2, 10-6, 10-7, 10-10, 13-15, 13-16, 57-10, 66-5, 67-1, 85-1, 86-1, 86-3, 101-9, 124-12

Comments Summary:

The above comments all claim that to one degree or another, the proposed regulations constitute a barrier to international trade. One area in particular claimed to constitute a technical barrier to trade was the accreditation body/certified assessor program. There was also a request that regulated entities under this regulatory program be allowed to use internationally recognized test methods to demonstrate compliance with these regulations. Some of the above comments more specifically assert that the proposed regulations meet the definition of a “technical barrier to trade,” as that term is defined and used by the World Trade Organization (WTO) in examining various state, federal, and international regulatory regimes for compliance with trade agreements ratified by member states and enforceable by the WTO. Finally, one commenter urged DTSC to re-notice later regulations that identify certain products as “Priority Products” under the WTO process at the time DTSC adopts those implementing regulations.

Response:

As a threshold matter, DTSC notes that there is nothing in the Safer Consumer Products Regulations that facially or implicitly discriminates against foreign-made products. To the contrary, DTSC’s regulations apply equally to domestically produced and imported consumer products that are offered for sale in California. DTSC has, however, through the U.S. Trade Representative (USTR), publicly notified its regulations to WTO nations for international review and comment and has benefitted from the input of the European Union, in particular, in formulating its present regulations. This noticing of DTSCs regulations occurred pursuant to the USTR’s formal determination that the regulations constitute “technical regulations” within the meaning of the Technical Barriers to Trade (TBT) Agreement entered into by signatories of the General Agreement on Tariffs and Trade (GATT).

The terms “technical regulation” and “technical barrier to trade” are used synonymously in the TBT Agreement context to denote national regulations imposed by WTO member nations or their political subdivisions that, while wholly lawful exercises of sovereignty, may have the consequence of increasing the cost and/or difficulty of conducting

international trade. The TBT Agreement explicitly recognizes that a sovereign's legitimate regulatory objectives include protection of health and the environment. (TBT Agreement, paragraph 2.) It further states that "whenever a technical regulation is prepared, adopted, or applied for one of the legitimate objectives explicitly mentioned in paragraph 2 of the Technical Barriers to Trade Agreement "*it shall be rebuttably presumed not to create an unnecessary obstacle to international trade*" (*id.*, Article 2.5; emphasis added). Because these regulations manifestly advance California's legitimate interest in protection of health and the environment, they are presumptively valid under international trade law.

Further, the proposed regulations would operate in a manner similar to that of numerous public health and environmental regulatory programs related to consumer products that are specific to California. California has its own regulatory programs that govern, for example, chemical exposure warnings (Proposition 65), lead in plumbing fixtures, lead in jewelry, and toxics in packaging. In addition, the California Air Resources Board (CARB) has extensive regulations that govern the sale and use of various consumer products that may have adverse impacts on air quality. None of these regulatory programs has been deemed an unnecessary barrier to international trade.

In addition, these regulations do not specify product content or impose other technical requirements on products. Rather, these framework regulations merely set up a process for the identification and prioritization of chemicals and products containing them, and performing an AA to identify safer substitutes for products identified as Priority Products.

Several commenters stated that the accreditation body/certified assessor program was particularly problematic for foreign companies, and could impose unequal burdens on them that would inhibit international trade. In response to these comments, criticisms of the same requirements from commenters on non-trade matters, and DTSC's reexamination of the issue, the accreditation body/certified assessor provisions and requirements have been eliminated from the regulations.

In addition, the regulations do not prescribe any particular test or laboratory methodologies for determining compliance with these regulations, instead they use narrative standards throughout. In many cases, document quality is assured by requiring that it be based on "reliable information," as defined. Regulated entities under this program are therefore authorized to rely on test data gathered or generated for purposes of compliance with another regulatory program, including the chemicals regulatory program(s) of foreign nations.

DTSC cannot ascertain at this time whether the USTR will designate later regulations identifying various products as “Priority Products” as technical regulations when adopted. However, DTSC will work with the USTR to comply with all legal obligations it has as a WTO member and TBT Agreement signatory.

Additionally, as stated elsewhere, DTSC will be implementing its regulations so as to avoid duplication and potential conflicts with existing regulatory programs, as is required by section 69501(b)(3)(A) (January 2013) and related provisions in Article 3 of the regulations. For all of the above reasons, DTSC declines to make any further changes to the proposed regulations to address these comments.

Interstate Commerce

Comments: 5-23, 5-47, 74-6

Comments Summary:

The above comments all claim that the regulations unreasonably interfere with interstate commerce in violation of the Commerce Clause of the U.S. Constitution. That clause grants the U.S. Congress the exclusive authority to regulate interstate commerce. One commenter asserted that DTSC lacked the authority to establish “new rules of the game.” This phrase was used in a report describing fiscal and economic effects of the proposed regulations.

Response:

For reasons similar to those identified in DTSC’s response to comments claiming that the violations constitute an unnecessary and therefore unlawful barrier to international trade, DTSC respectfully disagrees with the comments. The proposed regulations are limited to those consumer products placed into the stream of commerce in California and treat all consumer products equally, regardless of their place of manufacture. Again, this regulatory approach to having California-specific standards applicable to the sale of products in California is nothing novel or unique.

There are countless such state-specific regulatory regimes, as discussed in DTSC’s response above. As also discussed above, DTSC will implement the regulations in a manner consistent with Health and Safety Code section 25257.1 and proposed section 69501(b)(3)(A), both of which preclude DTSC from having a regulatory program that regulates consumer products in a manner that conflicts with or duplicates the provisions and protections of the authorizing statute. For all of these reasons, DTSC disagrees that the regulations as proposed, or as they will be implemented, violate the Commerce

Clause of the U.S. Constitution. Accordingly, DTSC is making no change in response to these comments.

Preemption

Comments: 4-1, 4-2, 4-3, 4-4, 4-5, 4-6, 4-7, 4-8, 4-9, 41-43, 87-4, 127-2, 127-3

Comments Summary:

All of the above comments contend that unspecified provisions of federal law or various specific federal regulatory programs (*e.g.*, the Federal Aviation Act, the Federal Food, Drug and Cosmetic Act, the National Highway Traffic Safety Act, or the Toxic Substances Control Act) preempt the proposed regulations. Some of the commenters provided an explanation of the general legal concepts embodied within the concept of preemption, including the various types of preemption that the courts have applied to different state legal requirements. Other commenters described in some detail the nature and extent of regulations to which they are subject under existing federal regulatory regimes.

Response:

DTSC respectfully disagrees that the proposed regulations are preempted by any of the named federal regulatory programs or any other programs. The focus, purpose, and reach of the proposed regulations are distinct from any of the federal regulatory schemes mentioned in the comments. In essence, the comments seek an exemption for certain products from the proposed regulations (*e.g.,* tires, airplanes, and over-the-counter medications) on the grounds that the proposed regulations are preempted by federal law. Such an approach would exceed DTSC's authority to create exemptions beyond those set out in the authorizing statutes. In addition, DTSC can find no federal regulatory program that preempts the proposed regulations. None of the federal regulatory schemes discussed expressly states that it preempts the entire subject matter field, and thereby forecloses additional regulation under a state's police powers for protection of public health and the environment. No official from any of the discussed federal agencies has informed DTSC that the particular agency views its program as preempting this program.

As discussed in response to earlier comments dealing with requests for exemption and international trade implications within this section, DTSC will implement the regulations in a manner consistent with the provisions of Health and Safety Code section 25257.1 and section 69501(b)(3)(A) (January 2013), both of which prevent DTSC from running a regulatory program that is duplicative of or in conflict with another state or federal

regulatory program. As also discussed above, DTSC will be determining the potential applicability of section 69501(b)(3)(A) (January 2013) to the proposed identification of chemicals and/or products under these regulations. DTSC is making no change in response to these comments.

Duplication/Conflict with Other Regulatory Programs

Comments: 2-5, 3-7, 3-8, 5-1, 5-8, 5-9, 5-15, 5-16, 5-17, 5-74, 9-117, 11-10, 11-63, 12-14, 13-8, 14-7, 14-8, 20-1, 20-2, 22-4, 23-3, 23-4, 23-6, 31-6, 34-2, 34-3, 34-13, 35-2, 40-3, 41-31, 41-44, 41-71, 47-1, 55-24, 57-8, 57-19, 60-1, 60-2, 60-3, 60-4, 60-5, 64-14, 66-24, 69-31, 73-34, 73-35, 73-36, 74-1, 74-2, 74-8, 78-2, 81-7, 86-6, 96-2, 101-5, 101-36, 101-37, 104-4, 107-7, 107-8, 107-9, 107-77, 122-3, 124-7, 127-1, 127-4, 127-5, 130-4, 131-2, 131-5, 136-5, 136-7, 136-8, 136-9, 152-2

All of the above comments claim to one extent or another that DTSC misapplied Health and Safety Code section 25257.1. Similarly, the comments state that DTSC created too narrow an exclusion for products already adequately regulated and/or assert that a particular product is, or should be, outside of the reach of the proposed regulations because the regulation of the enumerated products by these regulations would violate Health and Safety Code section 25257.1(c). Again, that section of the authorizing legislation precludes DTSC from regulating consumer products in a manner that conflicts with or is duplicative of existing regulation of the products under state or federal laws or regulations. One comment notes that DTSC should, in addition to consideration of other applicable laws, consider the existence of voluntary agreements by which entities that produce a Chemical of Concern have established a commitment with regulators to phase out the manufacture or importation of a particular Chemical of Concern. Recently, U.S. EPA has entered into a number of such agreements.

It should be noted that the text of section 25257.1(c) has been significantly amended from the July 2012 version that was the subject of these comments. More specifically, the prior text did not create an outright exemption from these regulations for products already subject to state and/or federal regulation in a manner that addressed the same harms and to the same extent as these regulations do. It should also be noted that the comments and concepts addressing requests for exemption and preemption are interrelated with the comments and concepts addressed here. Therefore, those comments and responses are applicable here to the extent they overlap with the substance of the comments dealing with regulatory duplication or conflict.

Response:

As stated above in response to several earlier comments, DTSC is proposing to adopt new section 69501(b)(3)(A) (January 2013) that will clarify, interpret, and make more specific the provisions of Health and Safety Code section 25257.1. Again, during implementation of the regulations, DTSC will be accepting information germane to making a determination of whether or not a given product meets the terms of section 69501(b)(3)(A) (January 2013), and is thus not subject to the substantive requirements of these regulations. Quite simply, there is no need or ability in these present, process-oriented regulations to identify every possible consumer product that may qualify for the exclusion in section 69501(b)(3)(A) (January 2013).

There are countless unknown products covered by an array of state and/or federal requirements that may or may not satisfy the terms of section 69501(b)(3)(A) (January 2013). As a result, DTSC declines to carve out any such suggested products from these regulations until the implementation stage. At that point, DTSC will be in a position to collect, review, and analyze information relevant to a determination under section 69501(b)(3)(A) (January 2013). As discussed above, however, DTSC will not then be carving out exclusions *in regulations* for categories of products that are included within the authorizing statute. Rather, it will be implementing these regulations in a manner that is consistent with Health & Safety Code section 25257.1(c) and section 69501(b)(3)(A) (January 2013). Similarly, entities are free to submit information to DTSC showing that they have entered into a voluntary agreement with regulators to phase out the manufacture or importation of a particular Chemical of Concern, and DTSC will consider this information as appropriate during the prioritization process.

In addition, and in response to some of the above public comments, DTSC notes that the provision specifying the criteria for determining whether or not a product is outside of these regulations as already adequately regulated is directly tied to the terms and purpose of the authorizing legislation. More specifically, section 69501(b)(3)(A) (January 2013) requires that the product be regulated by one or more agencies in a manner that covers “the same potential adverse impacts, potential exposure pathways and potential adverse waste and end-of-life effects that could otherwise be the basis for a product being listed as a Priority Product; and provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product were listed as a Priority Product.”

This standard for determining that one or more regulatory programs duplicates the program is consistent the Legislature’s instruction to DTSC, which is: “The department [DTSC] shall not duplicate or adopt conflicting regulations for *product categories* already regulated or subject to pending regulation *consistent with this Article* [14].” (Health and

Safety Code section 25257.1(c); emphasis added.) As discussed in response to earlier comments, this statutory language is noteworthy for two reasons. First, it does not prohibit all overlapping or arguably duplicative regulations; rather, it prohibits such regulation if a product is already regulated or subject to pending regulation "consistent with the purposes" of Article 14. Article 14 is the entire statutory "Green Chemistry" (Safer Consumer Products) program. It consists, in part, of mandating life cycle thinking, examination of multimedia impacts, and inducing a transition to safer consumer products. Thus, it is concerned with the regulation of a product with respect to numerous types of potential impacts on human health, wildlife, and the environment—a far broader sphere of concern than encompassed by most regulatory programs. Second, the prohibition in section 25257.1(c) extends only to "product categories." DTSC is not presently proposing any specific "product categories" for regulation through this process-oriented regulation. It has instead left the determination of products subject to regulation to later implementation stages. DTSC is not making any changes to the regulations in response to these comments.

Administrative Procedure Act Issues

DTSC's Compliance with Administrative Procedure Act's Standards for Review

Comments: 4-18, 5-2, 9-1, 9-15, 9-31, 9-70, 11-1, 38-2, 38-4, 41-12, 41-54, 41-55, 42-1, 42-2, 42-30, 47-3, 47-31, 59-5, 87-2, 105-5, 125-2, 139-11, PH15-1, PH15-2

Comments Summary:

All of the above comments assert that various unspecified or vaguely specified provisions within "the regulations" violate one or more of the criteria specified in the Administrative Procedure Act (APA) that must be met by the agency adopting regulations. More specifically, the comments claim that the proposed regulations fail one or more of the following standards that are used by the Office of Administrative Law to approve or disapprove of regulations: authority, clarity, consistency, non-duplication, and necessity. (See Government Code sections 11349 and 11349.1.) Note: comments related more specifically to the clarity standard, and the charge that the regulations do not represent the least burdensome approach, are addressed separately in later parts of this Response to Comments document. A few comments summarized some of the statutory, regulatory, and case law standards dealing with the APA, and stated that DTSC must comply with the APA.

In addition, some comments expressed the opinion that the regulations have been developed using a piecemeal process; that details will be developed through an evolving series of vaguely described processes, which will have a major impact on the

regulated community; and that all such later-coming steps must be taken in compliance with the APA.

Response:

As noted immediately above, the comments summarized and responded to here are not directed to any one provision or portion of the proposed regulations. Thus, it is difficult, if not impossible, to know which aspect of the regulations is alleged to violate the APA criteria for properly adopted regulations. (To the extent comments objected to a particular provision in the regulations, those comments are summarized in a discussion of the specific section and responded to in the same manner.) But, in general, DTSC drafted the regulations to carry out the purpose and implement the provisions of the authorizing legislation. DTSC drafted the proposed regulations to be fully compliant with the APA, including the standards mentioned above. DTSC respectfully disagrees with the comments that the regulations do not comply with the requirements of the APA. DTSC does agree with the comment that it must comply with the APA, and it has done so.

In addition, DTSC issued a Revised Initial Statement of Reasons (ISOR) that further elaborates on the statements of necessity that were included in the ISOR that DTSC first issued. While DTSC firmly believes the first version of the ISOR fully complied with the APA, it nonetheless issued a Revised ISOR so that interested parties could have a fuller understanding of the rationale and necessity for each provision. That Revised ISOR is separately addressed elsewhere in this Response to Comments document.

DTSC disagrees that it has done anything unlawful in the adoption of these regulations. It is true that DTSC has undertaken various steps and processes under the APA at various times—as is expressly authorized under the APA. DTSC has attempted to stage timing and flow of information, as well as process steps so that interested parties are not overwhelmed and can fully participate. In addition, DTSC has taken steps not required under the APA, and has provided time for public comment on documents beyond that required by the APA. For example, DTSC has, in some instances, provided comment periods longer than the APA-mandated minimum. In addition, DTSC disagrees that the proposed regulations describe an evolving series of vaguely described processes. Rather, DTSC has spelled out in fine detail, and explained in a 200+ page ISOR how the regulations will be implemented. DTSC notes that some of the provisions in the regulations employ a narrative standard; this is not the same thing as the standards being vague. (See first and Revised ISOR for full discussion of narrative standards.)

In addition, DTSC has specified in these regulations that it will take later action to implement this program by adopting more focused regulations under the APA. That step is the identification of Priority Products. While agencies do not always bind themselves to take specific future action under the APA, DTSC nonetheless chose to make this public commitment. This was done to provide more clarity and certainty to the regulated community about how one important aspect of these regulations will be implemented. (See section 69503.5(a)(2) (January 2013).) The fact that DTSC has committed itself in regulations to comply with the APA when listing Priority Products also means that DTSC will be analyzing economic impacts related to those listings. Along these same lines, DTSC will comply with the APA for implementation of any aspect of these regulations that is subject to the APA. Accordingly, DTSC declines to make any changes to the proposed regulations in response to these comments.

Comments: 3-1, 3-2, 9-1, 9-70, 11-1, 14-5, 38-8, 47-5, 47-34, 59-6, 61-2, 65-5, 66-2, 66-3, 92-3, 94-3, 96-7, 99-2, 104-1, 104-3, 105-3, 105-8, 124-6, 125-3, 125-8, 136-1, 139-8, 152-3, PH10-1, PH15-1, PH15-2, PH27-1, PH31-1

Comments Summary:

All of the comments assert that the regulations did not provide an acceptable level of certainty to regulated entities that must comply with the regulations. The commenters also claim that the fact that the regulations do not have an “objective framework” means that they fail the “Clarity” standard under the APA. Some of the above comments also state that there will be implementation and compliance challenges that result in the regulations failing the APA’s clarity standard. In addition, some of the comments state that there are no criteria by which DTSC can determine what a “safer” product is, and they claim is a violation of the clarity standard. The comments do not point to any specific provision which they claim violates the clarity standard. Rather, the criticism is leveled at “the regulations” as a whole. Finally, some of the comments directly or indirectly allude to the fact that some of the provisions of the regulations employ a narrative standard.

That is, some commenters felt that because the identification and prioritization processes did not use “objective” criteria, they must not comply with the clarity standard. These comments urged DTSC to abandon the narrative standard that DTSC uses in various places, and to substitute a more formulaic, numerical, or weight-of-evidence approach.

Response:

DTSC initially notes that the various criteria used throughout the identification and prioritization of chemicals in consumer products is discussed at length in the Comments and responses to comments dealing with Articles 2 and 3. Thus, the reader is directed there for a more detailed response regarding the "narrative standard" regulatory framework/lack of objective criteria comments that concern the identification and prioritization processes.

DTSC respectfully disagrees that the regulations do not comply with the APA clarity standard in Government Code section 11349(c). In addition, DTSC notes the fact that one cannot read the regulations and predict with complete certainty how all aspects of the regulations will play out when implemented is not a failure of the clarity standard. Rather, the commenters are really arguing that there is a lack of "certainty" to some of the regulations. While predictability and certainty are aspects of regulatory schemes that may be desirable in the abstract, they are not APA standards that must be met in order for the regulations to be valid and lawful. In addition, there are competing values that are not well served by an exclusive focus on predictability and certainty. For instance, flexibility and ease of implementation are important values that may be undermined by application of by rigid, formulaic, numerical approaches. Thus, DTSC adopted a more scientifically appropriate and flexible approach that outlines factors and criteria that DTSC will consider but without putting a rank order on the importance of these considerations or criteria. Accordingly, DTSC is not making any changes in response to these comments.

Comment: 5-70

Comment Summary:

The commenter asserts that the list of Chemicals of Concern in the July 2012 version of the regulations (Candidate Chemicals list in the January 2013 version) is vague and does not put interested parties on notice of what chemicals are included. The comment goes on to claim that if the list of chemicals is not available during the public comment period, the future process for listing chemicals must comply with the APA.

Response:

DTSC respectfully disagrees that the list of Candidate Chemicals is vague. More specifically, DTSC has given very precise descriptions of which lists of chemicals issued by one or more authoritative organizations constitute the Candidate Chemicals subject to these regulations. Each of the 23 lists of chemicals and the criteria within them, if applicable, that led to a chemical being a Candidate Chemical is clearly set in regulations text. In addition, the basis for selecting each of these lists, a description of

the work processes used by the authoritative organizations, and lengthy explanations are set out in the ISOR for each of these lists. DTSC does not see the connection between these lists purportedly being vague and DTSC's prospective obligations to comply with the APA when adding chemicals to the Candidate Chemicals list. Nonetheless, if DTSC undertakes additions to the Candidate Chemicals list in a manner that constitutes a "regulation," as defined in the APA, DTSC will comply with the APA in doing so. DTSC is not making any changes to the regulations in response to this comment.

Comment: 41-15

Comment Summary:

The comment states that DTSC's deletion of previously proposed language regarding the relationship between a Chemical of Concern and a Priority Product has created uncertainty about whether an AA could be required for a product for some reason other than the presence of a Chemical of Concern.

Response:

The language in section 69503.5(a)(1) was revised in the January 2013 version to more clearly specify that it is the Chemical of Concern-product combination that constitutes the Priority Product. In addition, the reader is directed to the discussion of comments and responses related to Article 3. The discussion there, related to the identification of Priority Products, is applicable here is as well. DTSC is not making any changes to the regulations in response to this comment.

Comments: 5-36, 5-37, 5-38, 5-101, 5-102, 9-3, 134-3, 134-4, 134-5, 134-6, 134-7, 134-8

Comments Summary:

These comments claim that DTSC did not give meaningful consideration to alternatives to these regulations. One comment claimed that DTSC ignored many of the substantive comments provided by the commenter and others. In addition, a completely new alternative approach to adopting regulations to implement the authorizing legislation is proposed.

Response:

DTSC respectfully disagrees that it did not give meaningful consideration to alternatives to these regulations. DTSC's "Consideration of Alternatives" includes three distinct alternatives. In addition, DTSC considered other alternatives —Other Options

Considered in Earlier Proposed Versions of the Regulations— an umbrella term that captures numerous prior iterations and variations of these proposed regulations. DTSC has been extremely solicitous in seeking input to shape these regulations, going back as far as 2009. For example, DTSC convened numerous meetings of the statutorily established Green Ribbon Science Panel (GRSP) to seek the GRSP's advice and recommendations about how to craft these regulations. The GRSP met several times over the course of 2009-2011. In addition, DTSC convened various subcommittees of the GRSP. Here too, the subcommittees met in open session numerous times to provide DTSC advice and recommendations about how to draft these regulations. In addition, DTSC convened various public workshops and held dozens of meeting with interested parties. All of this was done to consider these regulations and alternatives to them.

Two other points are relevant here. First, the provisions in the authorizing legislation direct DTSC to adopt regulations that:

(1) Establish a process for the identification and prioritization of chemicals in products;
(2) Establish a process for the evaluation of alternatives to those harmful chemicals in order to limit exposure and reduce the level of hazard posed by a Chemical of Concern; and
(3) Specify the range of regulatory responses that DTSC may impose following the completion of the second process — an AA (Health and Safety Code sections 25252 and 25253).

This level of specificity in the direction from the Legislature on how to proceed means that there were far fewer alternatives to the current regulations that were eligible for consideration as complying with the authorizing legislation's mandates than would otherwise be the case. Finally, as several commenters have pointed out, this is approximately the eighth or ninth iteration of these proposed regulations that DTSC has considered and pursued, dating back to 2009. This, too, shows that DTSC has given meaningful consideration to alternatives to these regulations.

As for ignoring any public comments regarding these regulations, DTSC respectfully disagrees with the assertion that it did so. In addition to the Response to Comment 9-1, DTSC notes that all comments have been considered. Many, many changes have been made in response to these comments. The number and nature of changes made in the January 2013 version is striking for how willing DTSC was to make a number of major changes at this stage of regulatory development. The fact that a comment was not accepted does not mean that it was ignored. It means that after review and

consideration, the comment(s) was/were ultimately not accepted as the best approach for DTSC and all other regulated entities.

With respect to the completely new proposal, see discussion of this alternate regulatory scheme under the discussion of comments regarding Article 5: Alternatives Analysis. Therefore, DTSC notes that there was no discussion of any of these new concepts during the three-year-plus discussion of how DTSC might adopt regulations to carry out the authorizing legislation. DTSC cannot justify wholesale abandonment of its carefully considered and fully vetted proposal at the eleventh hour for this unknown approach suggested by one commenter only. There has been no support offered for this proposal by any other interested party. Simply put, there is no credible reason for pursuing this approach at this point. Therefore, DTSC is not making any changes to the regulations in response to these comments.

Comments: 5-50, 5-51, 5-52, 5-53, 5-100, 5-104, 5-105, 19-34, 23-7, 55-25

Comments Summary:

All of the above comments contend that the ISOR released by DTSC in conjunction with the July 2012 version of the regulations does not comply with the requirements of the APA for an ISOR. Some of the comments do not indicate which specific provisions or portions of the ISOR are purportedly defective. Rather, these comments simply assert that the DTSC did not include sufficient description of the purpose or necessity of unspecified provisions of the regulations. Comment 5-100 contends that the ISOR for then Article 10 (now Article 9 (January 2013))—dealing with the issue of trade secrets—lacked necessary justification. Finally, Comments 19-34 and 5-50 through 5-53 contend that references in the ISOR to catalytic converters in automobiles as potentially being subject to these regulations is in excess of DTSC's authority.

Response:

DTSC respectfully disagrees that its ISOR in conjunction with the July 2012 version of the regulations does not comply with the APA. DTSC notes that there was extensive justification of each provision of the Article within the regulations addressing trade secrets. This explanation and rationale extend all the way to the paragraph level within each section dealing with trade secrets. In addition, DTSC provided an overall basis and rationale for the Article as a whole. DTSC issued a Revised ISOR (to be discussed in greater detail below) that removed all references to catalytic converters. Therefore, no further changes to the ISOR or the proposed regulations will be made in response to these comments.

Comments: 5-31, 5-32, 5-33, 5-34, 5-35

Comments Summary:

Each of these comments asserts that the guidance DTSC is going to prepare and publish regarding the conducting of AAs by responsible entities will be an "underground regulation" in violation of the APA. Thus, the comments go on to claim that any guidance DTSC may develop to assist responsible entities in preparing an AA must be adopted through a rulemaking. The comments recap the definition of what constitutes a "regulation," as defined by the APA. The comments further state that any such guidance needs to be publicly vetted and the subject of feedback before becoming effective, in part, because the guidance material may alert the regulated community to issues related to the regulations. Accordingly, the comments also seek additional public comment time on the regulations themselves.

Response:

DTSC respectfully disagrees. Quite simply, there is no basis in law or in fact for assuming or concluding that guidance materials not yet written will inevitably constitute "underground regulations." DTSC understands and appreciates the difference between enforceable regulatory requirements and non-binding guidance to the regulated community. DTSC is planning to draft guidance materials in response to suggestions and requests from the GRSP and numerous other interested parties that it do so. In addition, DTSC is informally working with other states, U.S. EPA, and interested parties in developing the guidance material. Guidance will not be static but will be dynamic. Thus, it can be responsive to the needs and wants of responsible entities. Contrary to the implications of the above comments, development of guidance materials will not limit the ability of interested parties to comment on proposed guidance regarding AAs. The guidance is a separate non-APA undertaking from writing regulations. DTSC will not extend the public comment period for the regulations due to this separate non-APA process. DTSC is not making any changes to the regulations in response to these comments.

Comments: 10-8, 15-3, 19-1, 20-3, 24-5, 34-1, 46-4, 59-15, 59-16, 66-1, 83-5, 86-7, 120-1, 154-1, 158-1, 163-3, PH10-8, PH30-2

Comments Summary:

The comments point out some of the burdens placed on responsible entities under these regulations. They make generalized claims that the regulations are burdensome and include discussion of some of the specific burdens. One of the specific burdens mentioned is the requirement to have various notifications signed by a corporate officer.

There is some very general discussion of the costs of this program. Some comments contend that the regulations are not workable. It is not clear, but there may be an implication intended by these comments that DTSC cannot appropriately make the finding that there is no less burdensome manner to carry out this program.

Response:

DTSC considered all public comments received during the extensive pre-APA outreach and input activities, as well as during the APA public comment periods in order to reduce burdens on regulated entities to the extent feasible. DTSC has made significant changes from the pre-APA proposed regulations to the initially noticed regulations and from the July 2012 proposed regulations to the January 2013 proposed regulations—in response to public comments received. Many of these changes reduce the burdens that would otherwise have been placed on the regulated community when compared to earlier versions. DTSC did not accept all of the commenters' suggestions because DTSC concluded that the rejected suggestions would not accomplish the required program in a manner that was as efficient, effective, and scientifically sound.

Just a few of the many changes DTSC made to lessen the burdens placed on the regulated community are:

- Eliminating the accreditation body and certified assessor programs;
- Streamlining and sequencing the AA process; and
- Introducing numerous "off-ramps" from the AA process.

In addition, DTSC notes that the very nature of the authorizing legislation is to impose burdens on manufacturers and other responsible entities. That is, the authorizing legislation creates new broad authority in DTSC to regulate consumer products by making manufacturers of those products responsible for analyzing their content to see if the risk posed by the presence of harmful chemicals therein may be reduced or eliminated. Again, there is no way that such a program could exist without the imposition of burdens on those affected.

As stated above, however, DTSC has endeavored to reduce to the fullest extent possible the amount of burden imposed, while still accomplishing the purpose and goal of the authorizing legislation. As for the specific example of a corporate officer's signature on certain documents, DTSC has made this requirement flexible. That is, it may be satisfied by the signature of an "authorized representative" of the company. Thus, corporate officers need not be the individuals satisfying this requirement. (See section 69501.3(a) (January 2013).) Discussion of the economic impacts of this

program is included in a separate discussion regarding DTSC's Form 399 and related concepts elsewhere in this document.

DTSC is convinced that the changes discussed above, as well as others, along with the overall approach it is taking will result in the regulations being workable. Accordingly, DTSC declines to make any changes to the proposed regulations in response to these comments.

Comment: 19-51

Comment Summary:
The comment claimed that the lack of transparency in how DTSC is addressing comments from the public comment periods. The comment goes on to state that DTSC does not indicated why changes were made.

Response:

DTSC respectfully disagrees. In the first version of the ISOR and in the Revised ISOR DTSC provided an explanation and rationale for each provision within the regulations. In addition, it is this Response to Comments document that is the appropriate mechanism for indicating to interested parties what changes are being made and why suggested changes are or are not being made. In addition, in the Final Statement of Reasons, DTSC will explain the final version of the regulations and the reasons why they were written the way they were. Therefore, this also gives interested parties an understanding of the regulations and DTSC's thinking about them. DTSC is making no change to the regulations in response to this comment.

Comment: 31-4

Comment Summary:

The comment states that it is conceivable that special interest groups, as well as those with a political agenda to target certain products or chemicals that they perceive to be unsafe, could hijack the regulations. The comments goes on to say that in order for the regulations to avoid regulatory gridlock, the process of chemical and product prioritization must be clear, transparent, and relatively straightforward.

Response:

DTSC respectfully disagrees. It does not see any basis for claiming that the regulations could be "hijacked" by special interest groups to target certain products. DTSC has adopted the regulations in an open, transparent, and inclusive fashion. The criteria for selecting Priority Products in Article 3, as well as the open and public process by which

they are selected, ensures that the process will not be hijacked. More specifically, DTSC has set out various scientific criteria that it will be using to select Priority Products, and it will comply with the APA in doing so. This allows for robust public participation. See discussion of Article 3 Comments for more information. DTSC is making no change in response to this comment.

Comment: 41-36

Comment Summary:

The comment contends that DTSC has done nothing to simplify the regulations or make them more accessible. The comment goes on to say that the fact that DTSC puts much information about the implementation of the regulations on its website means it will be difficult for consumers to sift through, and urges the information available to be clear, focused, and easy to understand.

Response:

DTSC respectfully disagrees that is has done nothing to simplify the regulations or make them more accessible. DTSC has defined all key regulatory terms; made the AA process a series of logical, specified steps and stages; and committed to publishing guidance for conducting AAs. DTSC is confident that consumers will want to have access to the types of information it is committing to posting on its website. DTSC also believes that it can post the relevant information in a manner that is understandable and usable by interested parties, including consumers. The reader is directed to the Response to Comments 9-1, 9-70, and 41-12 for further responsive information. DTSC is not making any changes to the regulations in response to this comment.

Comments: 31-3, 42-30, PH31-3

Comments Summary:

The comments state that the regulations do not indicate how later actions taken to implement the regulations will interact with the APA, including the imposition of regulatory responses under Article 6.

Response:

DTSC is not necessarily required in this rulemaking to specify whether later actions it takes to implement the regulations must be undertaken as regulations subject to the APA. Nonetheless, DTSC has specified that it will comply with the APA in the listing of Priority Products. (See section 69503.5(a)(2) (January 2013).) In addition, DTSC notes that if at the time it imposes regulatory responses, it does so in a manner that

constitutes a “regulation,” as defined in the APA, it will comply with the APA. But DTSC is not able at this time to forecast with precision whether the regulatory responses will or will not be subject to the APA. DTSC has amended the regulations to specify it will follow the APA in selecting Priority Product, but it is making no further changes to the regulations in response to these comments.

Comment: PH18-2

Comment Summary:

The comment claims that any product that uses any Chemical of Concern (now Candidate Chemical) is thrust into a bureaucratic labyrinth. It goes on to say that DTSC’s underlying impulse seems to be to declare these chemicals to be off limits and to discourage society from safely harnessing them.

Response:

DTSC respectfully disagrees. There are no duties triggered by merely having a Candidate Chemical in one’s product. No duties are triggered by the use of Candidate Chemicals unless and until they are identified as Chemicals of Concern in conjunction with a Priority Product. It is the authorizing legislation that subjects Chemicals of Concern in products to an AA; the regulations merely implement this provision of the legislation. In addition, DTSC does not believe that these regulations will discourage society from safely harnessing Candidate Chemicals. Rather, there will be incentives to better understand and make better use of all chemical ingredients in products and incentives to reduce the overall harm posed by products. DTSC is making no changes to the regulations in response to this comment.

Comments: 41-10, PH30-1

Comments Summary:

The comments claimed that the title of the regulations—“Safer Consumer Products” Regulations—was fear mongering. Another comment contended that the regulations were premised on the idea that products are not safe. The comment goes on to point out voluntary efforts by companies to improve product safety. One commenter notes his earlier support for the regulations, but claims as currently drafted they give too much discretion to DTSC.

Response:

DTSC respectfully disagrees that the title “Safer Consumer Products” is fear-mongering. This is an accurate title for the goals and purposes of the authorizing legislation and

these regulations. This, or something very similar, has been the title for this effort for the past three-plus years. In so naming its regulations, DTSC does not imply that all consumer products are unsafe; rather, it implies that this program will help to promote **safer** products for consumers. DTSC will address in a separate summary of comments and responses below the notion that DTSC has too much discretion under these regulations. DTSC agrees that some forward-thinking companies engage in an ongoing quest for better and safer products. However, this effort is by no means universal or systematic—as demonstrated by the fact that the Legislature felt compelled to enact, and the Governor signed, two bills designed to improve the safety of consumer products. The purpose of this program is to systematize and expand the search for safer products. Thus, DTSC is making no change in response to these comments.

Comment: PH33-7

Comment Summary:

The comment claims that there has been insufficient examination of the legal implications of this rule. The comment goes on to claim there will be some implications for Proposition 65 lawsuits, the California Environmental Quality Act (CEQA), APA, and product liability issues.

Response:

Initially, DTSC must note that it is not sure what the commenter means by insufficient examination of legal issues. As for Proposition 65 implications, these regulations do not add any chemicals to the Proposition 65 list. Therefore, they cannot impose any additional burdens under Proposition 65. On the contrary, these regulations borrow from the Proposition 65 list of chemicals as part of the Candidate Chemicals listing provisions. In addition, DTSC is complying with CEQA and the APA in adopting these regulations. Therefore, DTSC is making no change to the regulations in response to this comment.

Comments: 98-1, 98-2, 98-3

Comments Summary:

The comments claim that DTSC incorrectly assumes that untested products are safe and DTSC should never assume that untested products are safe. In addition, the comment goes on to point out that many products have not been reviewed by various public health agencies.

Response:

DTSC respectfully disagrees. DTSC has made no assumption that untested products are safe. The Priority Product provisions in Article 3 of the regulations apply to all consumer products not otherwise excluded from this program. The definition of "consumer product" does not exclude untested products. For further discussion of how DTSC will take into account the nature and extent of information about a product as part of prioritization, see the discussion of Article 3. DTSC is making no changes to the regulations in response to these comments.

Conflicts with Authorizing Legislation and Other Statutory Schemes

Comments: 9-11, 9-13, 9-115, 10-3, 15-2, 24-5, 68-6, 86-4, 87-3, 87-4, 115-1, 124-25, 127-4

Comments Summary:

The comments make some generalized claims that the regulations do not conform to the authorizing legislation; some comments state that DTSC has exceeded its authority. In addition, there are some claims that the regulations conflict with various state regulatory schemes—including the Uniform Trade Secrets Act, the Public Records Act, and Cal/OSHA provisions. Similarly, there are comments that the regulations conflict with various federal statutory/regulatory schemes—including, but not limited to, the federal Toxic Substances Control Act (TSCA), the Consumer Product Safety Improvement Act, and Department of Transportation rules. There is also a claim that the definition of "person" in the regulations is beyond the scope of authority conferred in the authorizing legislation. One comment states that the regulations exceed the legislative intent. Another contends that the regulations do not comport with the federal government's "smart regulation" policy. An additional comment claims that DTSC does not have authority over workplace exposures to chemicals.

Response:

DTSC respectfully disagrees. DTSC firmly believes that the regulations are consistent with the goals, purpose, and scope of the authorizing statute and that DTSC can effectively and efficiently implement the regulations. In addition, DTSC disagrees that the regulations conflict with any of the state or federal regulatory schemes cited by the comments. No examples of actual conflicts were provided—commenters merely asserted the existence of conflicts, without concretely identifying any inconsistent or conflicting provisions between any other laws and these regulations. As discussed in great detail under the heading of Duplication/Conflict above, DTSC intends to implement the regulations in a manner that poses no conflict with any other state or

federal regulatory scheme, and it has drafted these regulations in a manner that poses no conflict.

The definition of the term "person" is consistent with the use of that term in various places in the Health & Safety Code, including the Chapter and Article that are the authority for these regulations. (Division 20, Chapter 6.5, Article 14.) Therefore, DTSC sees nothing in the authorizing legislation that would preclude DTSC's program from extending to workplace exposures. More specifically, the very broad statutory definition of "consumer product" implicitly extends to workplace exposures traceable to products. Finally, DTSC disagrees that these regulations do not comply with the "smart regulation" policy of the United States, while noting that DTSC is not directly bound by this policy since it is not an arm of the federal government. Nonetheless, DTSC believes these regulations do comply with that policy. Accordingly, DTSC is not making any changes to the proposed regulations in response to these comments.

Causation Standard

Comments: 36-19, 36-20, 36-21, 36-22, 36-24, 36-25, 36-26, 36-27, 36-28, 36-29, 129-1, 138-13

Comments Summary:

All of these comments contend that DTSC's use of the phrase "ability to cause…" [various types of harm or exposure] as the causation standard for a chemical to be identified and prioritized as a Chemical of Concern was ill advised and even in conflict with the authorizing legislation. Various reasons were offered in support of the idea that the phrase "ability to cause" was inappropriate in these regulations. The use of this new phrase in other places in the regulations was also objected to by these commenters, and a contention was made that it conflicted with the standards for listing chemicals used by many of the authoritative organizations whose lists were included in the Article 2 Process for Identifying Candidate Chemicals (January 2013). Prior iterations of the proposed regulations had used the term "potential" in virtually every instance in which the phrase "ability to cause" was now being used. The comments sought a return to the use of the term "potential" in those places in which "ability to cause" was used.

Response:

In response to these comments and its own reconsideration of these issues, DTSC has returned to the use of the term "potential" in the January 2013 version of the regulations. Along these same lines, DTSC has introduced the concept of a chemical's ability to "cause or contribute to" (harmful results) to better capture how certain chemicals work

and can lead to certain endpoints of harm that result. In addition, DTSC notes that the term “potential” has now been defined. This, too, was in response to comments that the term was too vague or unbounded. (See section 69501.1(a)(51)(A) (January 2013).) Due to this change in terminology, the other objections to the use of the phrase “ability to cause” are now rendered moot. DTSC is making no changes to the January 2013 version of the regulations in response to these comments.

Due Process

Comments: 5-18, 5-19, 5-20, 5-21, 5-22, 42-29, 47-24, 47-25, 57-1, PH10-2

Comments Summary:

The comments object to the fact that DTSC has not included in these regulations the guidance material that DTSC intends to publish regarding AA. The comments contend that the inability to comment on these guidance documents is a deprivation of due process and all that documents critical to implementation must be adopted under the APA. The comments assume that one or more critical implementation documents will have requirements that place these regulations in jeopardy. These documents include: the Chemicals of Concern list, the first proposed Priority Products list, and the AA guidance documents. Other comments claim that DTSC’s use of a narrative standard—as opposed to a quantitative standard—constitutes a denial of due process. One comment contends that the issuance of separate notices by DTSC for various documents relied on by DTSC and placed in the rulemaking file was a violation of due process. Finally, some comments contend that the fact that these regulations build on the related regulations duly adopted by the Office of Environmental Health Hazard Assessment (OEHHA) is a due process violation.

Response:

DTSC notes that there is extensive discussion of the guidance materials it intends to develop and publish in Response to Comments 5-2, 5-31, 5-32, 5-33, 5-34, and 5-35 above in the discussion of APA objections. In addition, DTSC discussed its continued compliance with the APA in Response to Comment 5-18. That is, all documents developed as part of the implementation of these regulations that are subject to the APA will be adopted through a rulemaking under the APA. With respect to the Chemicals of Concern list, DTSC notes that the list of Candidate Chemicals in section 69502.2 (January 2013) puts responsible entities on notice of the fact that these chemicals may become Chemicals of Concern. More importantly, however, a Candidate Chemical may become a Chemical of Concern only after DTSC identifies the chemical in the Priority

Product as part of a rulemaking undertaken in conformance with the APA. (See section 69503.5(a)(2) (January 2013)).

The objection to the development of the Priority Products list is also addressed by the discussion immediately above. That is, Priority Products are identified via an APA rulemaking. Once more, the guidance materials DTSC develops to assist responsible entities in conducting AAs will not be a "regulation," as defined under the APA. Rather, the guidance materials are intended to be a tool to assist responsible entities in carrying out their duties under these regulations. DTSC rejects the implication that all guidance materials are ipso facto "underground regulations"—as does case law interpreting the APA—or that all guidance material an agency may ever want to develop must be done simultaneously with, and as part of, an APA rulemaking.

DTSC respectfully disagrees with the contention that a narrative standard for the evaluation of chemicals and products to determine which of these will be further prioritized is a violation of due process—*i.e.*, that the use of this standard is void for vagueness. DTSC notes there is extensive discussion above regarding the clarity/certainty issue that is related to this discussion. The reader is directed to that discussion in response to these comments as well. In addition, DTSC reiterates the fact that just because one cannot predict with certainty how particular regulatory provisions will be applied at a later date does not mean that those provisions are void for vagueness. One can tell from reading the regulations what the applicable standards are.

DTSC respectfully disagrees that the separate issuance of various notices and other documents relevant to the rulemaking process is a violation of due process. Rather, interested parties are given numerous, specific opportunities for notice and comment on the various documents released by DTSC. DTSC can only imagine the outcry if it were to have released the numerous reports and notices all at once and given interested parties only one opportunity to review and comment on them. In addition, DTSC notes that it has at all times complied with Government Code section 11347.1. That APA section expressly authorizes the placement of additional materials into the rulemaking file so long as the adopting agency provides at least fifteen (15) days' notice of the new study, report, or similar document.

As for the complaint about the earlier adopted OEHHA regulations being partially incorporated into these regulations as constituting a due process violation, DTSC is perplexed. In effect, all interested parties had at least two opportunities to comment on the content of the OEHHA regulations. That is, there was due process in the form of notice and comment when OEHHA adopted its regulations, and again with DTSC's

adoption of these regulations—to the extent that they incorporate some of OEHHA's regulations. The tie-in between the two sets of regulations was mandated by the Legislature in the authorizing legislation. DTSC can see no due process violation by virtue of its compliance with the authorizing legislation. Accordingly, DTSC is not making any changes to the regulations in response to these comments.

Enforceability

Comments: 19-45, 19-46

Comments Summary:

These comments question DTSC's ability to enforce these regulations. More specifically, they express concern that there could be "level playing field" problems if companies that do not comply with these regulations go undetected and unpunished. This would reward non-compliance and be unfair to those companies that do comply. There was special concern raised for the initial notification that a company must make to identify itself as a responsible entity for a Priority Product. More specifically, the commenter stated there was a good possibility that many companies would not comply with this notification and, thus, would evade the duty to perform an AA. Therefore, there was concern as to the adequacy of DTSC's resources to implement and enforce this program.

Response:

Under Division 20, Chapter 6.5 of the Health and Safety Code, DTSC has authority to enforce these regulations and prosecute violations. That is, Article 14, within Chapter 6.5, is the authorizing legislation for these regulations. In turn, Chapter 6.5 has provisions that establish administrative, civil, and criminal penalties for specified violations of provisions of Chapter 6.5 or regulations adopted under that Chapter. Therefore, violations of the authorizing legislation and these regulations are subject to robust existing enforcement authority.

DTSC intends to use its own personnel and resources, and to collaborate with other states, the GSRP, academic institutions, non-governmental organizations, and other interested parties to implement these regulations. DTSC has entered into a Memorandum of Understanding (MOU) with U.S. EPA along these lines to allow for an effective and efficient use of resources between the two agencies in carrying out related programs. DTSC also intends to use its audit functions, set out in Article 8 of these regulations, to ensure enforcement of the proposed regulations. DTSC has extensive experience enforcing complex regulatory requirements including, but not limited to, their

Hazardous Waste Management Program. For all these reasons, DTSC is confident that it has the capacity to oversee this program and pursue violations of it. Accordingly, DTSC is making no changes to the regulations in response to these comments.

Marginal Health Gains

Comments: 13-17, 83-2, 94-7, 96-3, 125-4

Comments Summary:

These comments contend that the regulations will result in marginal health gains for Californians. The comments also contend that the program will result in a large and expensive bureaucracy.

Response:

DTSC respectfully disagrees with these comments. The Legislature, Governor and DTSC, as well as many other interested parties, believe that this program could be a groundbreaking example of the notion that "an ounce of prevention is worth a pound of cure." That is, DTSC believes that there will be important improvements in both public health and the environment from the voluntary or compulsory reduction or elimination of the use of harmful chemicals in consumer products from the adoption of these regulations.

While such gains in public health and environmental protection may be difficult to measure with any precision, such anticipated improvements were the premise of the authorizing legislation, and commenters have presented no evidence that the Legislature's factual premise was misguided. In addition, DTSC was not given any additional funding or staff to implement this program. Therefore, for the present time at least, DTSC disagrees that these regulations require a large and costly bureaucracy. Accordingly, DTSC is making no change to the regulations in response to these comments.

Regulations Place Too Much Discretion in DTSC

Comments: 14-5, 31-2, 38-3, 41-36, 59-6, 61-2, 66-2, 66-3, 92-3, 94-3, 99-2, 104-3, 105-3, 125-3, 139-3, PH13-1

Comments Summary:

These comments all object to the amount of discretion that DTSC reserves to itself in the implementation of these regulations. More specifically, the comments contend that DTSC has reserved discretion for itself at virtually every turn and has not given the

same amount of flexibility or discretion to regulated entities. Some of the comments state or imply that the amount of DTSC discretion actually causes a clarity problem for the regulations. Some of the comments take issue with the narrative standard that the regulations employ for the identification and prioritization of chemicals and products.

Response:

DTSC respectfully disagrees that it has vested too much discretion in itself. It is true that at many points in the regulations DTSC reserves discretion to itself in how to make various decisions under the regulations. This is necessary so that DTSC has the flexibility to make the best implementation decisions when carrying out its duties, particularly in light of the very broad range of consumer products potentially subject to DTSC regulation, as well as the corresponding range in, differences among, and issues that might arise with respect to their regulation. Flexibility is not inconsistent with clarity, as at least one comment seems to imply. In addition, DTSC notes that the narrative standard used to identify Chemicals of Concern and Priority Products is necessary and appropriate. Use of a weighting or ranking system would bog DTSC down in unnecessary complexity and arguments regarding the relative harm of various chemicals and products, and/or the relative importance of certain types of harms, such as human cancer versus wildlife impacts or water quality degradation.

Therefore, the discretion that DTSC vests in itself is not unfettered or unlimited. To the contrary, the discretion is limited to applying the various criteria that are specified regarding how to evaluate chemicals and products for further prioritization as Priority Products, in reviewing AAs, and in imposing regulatory responses. Again, DTSC needs the flexibility to tailor its decisions to the particular facts without being hamstrung by rigid criteria.

Due to the overlap with related comments, the reader is directed to the Response to Comments 5-2, 9-70, 11-1, 38-2, 41-12, 42-29, 47-31 and 87-2. These comments and responses are relevant to the comments discussed here and are incorporated herein by reference. DTSC is not making any changes to the regulations in response to these comments.

The Regulations are Not Risk-Based and/or Science-Based

Comments: 9-4, 9-31, 31-1, 40-1, 74-3, 94-1, 95-1, 95-10, 103-5, 105-1, 107-1, 107-4, 107-25, 125-1, 135-1

Comment Summary:

The comments contend that DTSC's Safer Consumer Products program is not "science-based" or that it is not "risk-based." One comment urges a greater focus on risk, harm, and exposure. Some of the comments complain of a lack of scientific rigor at key decision points; others claim the program should be simpler and that the program will lead to the de-selection of products.

Response:

DTSC respectfully disagrees with the notion that its regulations are not science-based or risk-based. As is directed by the authorizing legislation, DTSC has made use of the prior work of other scientific bodies and agencies. This is most obvious in the development and inclusion of the 23 lists of chemicals that make up the universe of Candidate Chemicals. DTSC has also harnessed the scientific work of OEHHA in its development of hazard trait information. The salient provisions of OEHHA's regulations may be found in these regulations. In addition, the entire identification and prioritization schemes for chemicals and products are based on an evaluation of potential risks and exposures. (See Article 3 comments and responses for detailed information regarding chemical and product identification and prioritization.)

DTSC also disagrees that there is a lack of scientific rigor at key points. DTSC assumes from other related comments that this comment is addressing the narrative standard that DTSC uses to prioritize products. Again, a narrative standard is a non-weighted, non-ranking system of evaluating risk. See the discussion above regarding the rationale for DTSC's use of a narrative standard. Such an approach is certainly a scientifically valid and rigorous one, even if it is not purely objective.

DTSC has striven to make the program simpler and has incorporated life cycle analysis tools and thinking. (See Article 5 comments and responses for detailed information regarding life cycle analysis.) DTSC anticipates the fact there may be some product de-selection based on the presence of Candidate Chemicals in products. Given that all of these chemicals have already, by definition, been identified as posing a concern by one or more scientific agencies or bodies, such market de-selection is presumably already occurring independent of DTSC's actions. DTSC cannot predict how much more product de-selection will result from these regulations. For all of these reasons, DTSC is making no change to the regulations in response to these comments.

The Regulations Need to Be Harmonized with Other Laws or Programs

Comments: 12-1, 59-4, 86-5

Comments Summary:

The comments urge DTSC to have its definitions track more closely with the definitions of the same terms when used in various federal regulatory schemes. They further note that the regulations are quite different from the European REACH (Registration, Evaluation, Authorization, and Restriction of Chemical substances) program. There is also an implication that the regulations should be modified to more closely align with the REACH program.

Response:

DTSC respectfully disagrees that the regulations need to be modified to more closely track other federal or international programs. The commenters are correct that these regulations diverge from federal regulatory programs and REACH. But those differences are due in very large part to the nature and scope of the program that was dictated by the authorizing legislation. That is, no federal program has the same structure or approach as this program, nor does the REACH program. Further, the federal regulatory scheme and REACH do not have a mutually consistent structure. The definitions, and all other provisions in these regulations, were drafted to effectuate the specific authorizing legislation that underpins this program. Therefore, it is impossible to compare this program provision by provision with other programs and expect uniformity. For these reasons, DTSC is making no change to the regulations in response to these comments.

Scope of the Regulations is Too Big, Costly and Difficult for DTSC to Administer

Comments: 9-6, 9-8, 9-9, 9-12, 13-17, 19-1, 22-2, 24-5, 31-2, 33-5, 34-17, 38-1, 41-1, 59-2, 83-1, 83-2, 83-5, 87-1, 92-1, 93-3, 94-1, 96-1, 96-4, 96-6, 105-10, 107-3, 122-1, 125-1, 139-1, 163-1, PH10-8, PH12-1, PH15-3, PH24-5

Comments Summary:

All of the above comments contend that the regulations are too big in scope and/or too costly for the regulated entities and DTSC and/or that the program will be too difficult for DTSC to administer. These comments are related and in addition to, the comments discussed elsewhere in this document regarding:

- The burdensome nature of the regulations;
- The allegedly trivial health gains that will result from the regulations; and
- Those that question whether the regulations are practical, meaningful, and legally defensible.

Thus, the responses to those comments are applicable here as well.

The comments essentially claim that the regulations are simply too broad in scope. Some go on to say that the regulations need to be of a logical scope, efficient, and transparent. Other comments are based on the contention that the definition of "consumer product" is too broad and, therefore, this program is too broad. Some claim that the regulations are far in excess of what is needed in the initial phases or what DTSC can support. Others contend that DTSC's regulations should focus on products which are alleged to have the greatest human health impact—household cleaners, personal hygiene products, and children's products. Some comments expressed agreement with the concept of the program being limited to five Priority Products at the initial stages of this program.

Response:

DTSC respectfully disagrees with the above comments regarding the scope, expense, and ability to administer the regulations. Due to the related comments mentioned above, the reader is directed to those responses as well. In addition, DTSC notes the following. The scope of the regulations is directly dictated by the scope of the authorizing legislation. More specifically, the definition of "consumer product" in the authorizing legislation is quite broad, and includes all products other than the six classes of products that are expressly excluded. (See Health and Safety Code section 25251.) Accordingly, DTSC is not in a position to reduce the scope of the authorizing legislation through regulation. The Legislature did not confer authority on DTSC to expand or contract the scope of the consumer product categories subject to these regulations.

The legislative terms and intent being effectuated by these regulations were deliberately broad in scope. The program was intended by the Legislature to be a groundbreaking, comprehensive program that addresses the content of "consumer products," as defined. That is what DTSC has done with these regulations. Accordingly, DTSC disagrees with the comments suggesting that the program extend only to certain classes of products (*e.g.*, household cleaners, personal hygiene products, or children's products). DTSC also notes that it has crafted the regulations to address no more than five Priority Products during the initial stages of implementation. DTSC also notes that many comments supported this limitation. This approach will allow DTSC to focus its resources, learn by doing, and allow for relatively few consumer products to have to undergo an AA in the early years of this program. This approach will go a long way toward addressing concerns about DTSC's staffing and other resource limitations. DTSC firmly believes it can manage a program of this modest scope in the near term.

Over time, DTSC may identify fewer or more Priority Products, as its resources permit and experience indicates is appropriate.

DTSC acknowledges that regulated entities will incur expenses in complying with these regulations; that is, the nature of the authorizing legislation and these implementing regulations. The authorizing legislation mandates a program that requires regulated entities to evaluate their products to see if they may be made safer by the reduction or elimination of Chemicals of Concern, and that evaluation—the AA—may be time-consuming and expensive. This will, of course, vary with the type of product being evaluated and the extent of the AA performed. DTSC has worked to reduce expenses and burdens of this program. For example, it eliminated the accreditation bodies and certified assessors program, it has created numerous off-ramps from the obligation to perform an AA, and allowed for collaboration in the preparation of AAs. However, the authorizing legislation mandates consideration of a large number of factors in AAs, DTSC may not, by regulation, override this legislative instruction.

DTSC also points out that it has drafted provisions to limit the number of components or products themselves that are “complex durable goods,” as defined, to prevent such components or products from having to undergo AAs too frequently. Again, DTSC made this change in response to earlier comments from interested parties and to facilitate implementation. Finally, DTSC notes that the regulations do focus on exposure, risk, and likelihood of harm. (See Article 3 for detailed discussion of evaluation criteria for chemicals in products that are prioritized as Priority Products.) For all of these reasons, DTSC is making no changes to the regulations in response to these comments.

Regulations are not Practical, Meaningful, and Legally Defensible

Comments: 41-11, 59-8, 61-1, 61-4, 92-2, 94-2, 94-4, 96-5, 105-2, 107-4, 125-5, 139-2, 139-5, 139-11

Comments Summary:

These comments assert that the regulations fall short of DTSC’s stated goal that they be practical, meaningful, and legally defensible. The comments go on to say that each step in the regulatory process must be necessary, clear, and consistent but claim that serious error is compounded with each successive step in the regulations when the preceding actions are themselves defective. Some commenters assert that DTSC must make a comprehensive response to these problems and not just a piecemeal fix of one or two industry concerns.

Response:

DTSC respectfully disagrees that the regulations fall short of DTSC's stated goal that the regulations be practical, meaningful, and legally defensible. DTSC has worked tirelessly to respond to stated concerns by numerous interested parties to make the regulations ever more practical, meaningful, and legally defensible. For example, DTSC has built on existing lists of chemicals that have already been identified by other authoritative entities as problematic; DTSC has provided off-ramps from the obligation to conduct an AA in appropriate situations; it has eliminated the accreditation bodies and certified assessors programs to reduce cost for regulated entities, and made countless other changes to improve the practicality and enhance the beneficial impact of these regulations. DTSC has also made various modifications to the proposed regulations in response to objections based on legal principles. These include, but are not limited to:

- The elimination of an omnibus regulatory response provision;
- An exemption for products manufactured in California solely for use outside of California; and
- The recognition of the role of patent law in the application of trade secret provisions.

DTSC has kept the initial scale of the program quite modest to be practical. That is, the program is initially limited to no more than five (5) Priority Products. But the criteria on which the initial Priority Products are selected are based on scientific principles related to risk and exposure to chemicals. DTSC does not know what purported errors the regulations are premised on that are then purportedly compounded at each successive step, so it is difficult, if not impossible, for DTSC to respond to this vague allegation. However, DTSC notes that each step of the regulations has been crafted to be true to the letter and spirit of the authorizing legislation and to achieve the standards of practical, meaningful, and legally defensible. Finally, since these comments are related to and overlap with the comments regarding clarity, certainty, and the burdensome nature of the regulations, the responses to those comments are applicable here, too. For the reasons stated above, DTSC is making no changes to the regulations in response to these comments.

CALIFORNIA ENVIRONMENTAL QUALITY ACT

Category #1 – Objections to the Notice of Exemption

Comments: 5-5, 5-40, 6-1, 6-3, 6-10, 6-12, 6-14, 6-20, 6-21, 6-22, 6-23, 6-24, 6-25, 6-26, 6-27, 6-28, 6-30, 11-12, 41-58, 54-1, 55-1, 57-2, 74-9, 73-39, 73-41, 136-12, PH29-1, PH29-2

Comments Summary:

The Notice of Exemption (NOE) is not sufficient to satisfy DTSC's obligations under the California Environmental Quality Act (CEQA). The common sense exemption is not appropriate. DTSC did not perform a meaningful environmental review in utilizing the common sense exemption. DTSC does not and cannot support the common sense exemption with substantial evidence. DTSC is wrong in determining CEQA does not apply at this stage and DTSC is improperly avoiding and/or deferring CEQA analysis.

Response:

These comments object to DTSC's proposed use of the exemption in section 15061(b)(3) of Title 14 of the California Code of Regulations (CEQA Guidelines), which applies to projects where there is no possibility that the activity in question may have a significant effect on the environment. Based on the comments DTSC received, it has elected not to pursue the exemption in section 15061(b)(3) but maintains that the proposed regulations fall within the list of exempt categories or classes of projects that have been determined by the State Resources Agency not to have a significant effect on the environment and, therefore, further environmental review is not necessary. (See *Apartment Assn. of Greater Los Angeles v. City of Los Angeles* (2001) 90 Cal.App.4th 1162 [agency not required to conduct initial study before declaring project exempt from CEQA review].) DTSC is considering public comments received during the second public comment period for these regulations and expects to revise its Draft Notice of Exemption accordingly and release its Final Notice of Exemption at or about the same time as it files its final rulemaking package with the Office of Administrative Law. DTSC is not making any changes to the regulations in response to these comments.

Comments: 6-21, 6-22, 6-23

Comments Summary:

The statutory exemption and CEQA Guidelines are unrelated to the rulemaking as they pertain to agency actions that establish "rates, tolls, fares and charges" for five specific

actions. It is expected that DTSC will respond by stating it meant to claim a statutory exemption under Public Resources Code, § 21080(b)(8). However, the criterion for this exemption cannot be satisfied given the scope of the regulations.

Response:

DTSC mistakenly cited section 21080(b)(8) of the Public Resources Code as the basis for its Notice of Exemption. The correct citation is section 15061(b)(3) of the CEQA Guidelines. As stated, however, based on the comments received, DTSC has elected not to pursue the exemption in section 15061(b)(3). Please see the first response in Category #1 – Objections to the Notice of Exemption. DTSC is not making any changes to the regulations in response to these comments.

Comment: 6-30

Comment Summary:

Commenter asserts that the ruling in *Davidon Homes v. City of San Jose* (1997) 54 Cal.App.4th 106 requires that DTSC must provide the support for its decision that the project falls under the common sense exemption, before the burden shifts to the challenger. According to commenter, DTSC's Draft NOE fails to provide support for using the common sense exemption and therefore the burden does not shift to the public.

Response:

See the first response in Category #1 – Objections to the Notice of Exemption.

Because DTSC has elected not to use the common sense exemption, this comment is no longer relevant. Therefore, DTSC is not making any changes to the regulations in response to these comments.

Category #2 – Potential Environmental Impacts of the Proposed Regulations

Comments: 5-43, 6-7

Comments Summary:

The regulations will cause or compel the use of alternative substances; the impacts of which are unknown. CEQA requires DTSC to inform itself about the supply of potential alternatives if it were to push for alternatives.

Response:

As DTSC understands these comments, they assert that the proposed project currently before DTSC—a set of process-oriented regulations that establish the framework to guide future rulemakings addressing specific chemicals, products, and alternatives—will impact the environment at the present time because DTSC may—but is not presently—compelling the use of alternatives substances.

It is correct that ultimately the goal of the regulations is to promote public health and the environment by "introducing a set of rules that will create a discovery process that will change how manufacturers produce their products and generate new information about the chemical content of products" and "by lessening our use of toxic chemicals." (Executive Summary, Economic Analysis; and California Environmental Protection Agency, DTSC, News Release, T-06-12, July 27, 2012. http://www.dtsc.ca.gov/PressRoom/upload/News-Release-T-06-12.pdf.)

However, upon adoption, the regulations do not restrict the use of any chemicals or products or compel the use of any alternatives. DTSC agrees that at a later stage(s) of implementation of these process regulations, when its actions may lead to direct or indirect effects on the environment which may be evaluated, DTSC must consider the need for further environmental review.

In addition, the Alternatives Analysis that responsible entities must perform for their Priority Products will ensure that the environmental impacts of any alternatives are known and minimize any possibility that the regulatory response selected by DTSC will result in additional adverse environmental impacts. DTSC will consider the need to conduct appropriate environmental review when chemical- and product-specific regulations are proposed. That is, the regulations require DTSC to identify Priority Products that contain Chemicals of Concern by way of a rulemaking subject to the Administrative Procedure Act. (See section 69503.5(a)(2) of the January 2013 version of the regulations.) The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Comments: 6-6, 6-7, 6-36, 6-38, 6-39, 57-4

Comments Summary:

The potential for end-of-life management requirements and anticipated increase in hazardous waste disposal must be evaluated to be certain there are not feasible, less environmentally detrimental alternatives. DTSC must perform an analysis of impacts caused by the elimination and disposal of existing products. The regulations may cause

a huge surge in waste streams. DTSC must consider the impacts of the need to expand existing facilities to accommodate more manufacturing.

Response:

DTSC is well aware of the need to analyze reasonably foreseeable impacts of its action under CEQA. Under CEQA, an indirect physical change requires evaluation only if it is reasonably likely to occur. (CEQA Guidelines, § 15064, subd. (d)(3).) At this point in the rulemaking, however, the impacts from potential end-of-life management issues, increased hazardous waste disposal, and the need to expand existing facilities are too speculative to be considered reasonably foreseeable. (*Ibid.)* As discussed in the response immediately above, the adoption of these process regulations will not result in the imposition of any requirements on any chemicals or products. Accordingly, it is entirely speculative at this point to know if any of the products later identified as Priority Products under a different rulemaking process will be subject to end-of-life management requirements and what the adverse environmental impacts, if any, might be from that action. DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because the agency is using a Notice of Exemption for this rulemaking does not foreclose the agency from conducting future environmental review when appropriate.

C**omments:** 6-8

Comment Summary:

The regulations will stall the introduction of new, safer products. The absence of desirable consumer products in California could result in major shifts in global supply chain logistics, increased travel, reduced sales tax revenues, and environmental justice concerns.

Response:

The purpose of the authorizing legislation and these regulations is to promote public health and protection of the environment. The regulations establish a process for DTSC to oversee and manage a process in which responsible entities rigorously evaluate the chemicals in consumer products and analyze viable alternatives to the most harmful chemicals. To that end, DTSC believes that the regulations will result in newer, safer products that will move consumers away from chemicals that pose the greatest risk and foster replacement with chemicals that have lower risks.

To the extent that this comment raises economic and social concerns, under CEQA “economic and social changes resulting from a project shall not be treated as significant

effects on the environment." [CEQA Guidelines § 15064, subds. (e)(f)(6), 15131, 15358.]). Economic and social changes may be considered under CEQA, if they also produce changes in the physical environment. (See *Friends of Davis v. City of Davis* (2000) 83 Cal.App.4th 1004, 1019-1021.) At this point, any indirect changes to the physical environment caused by economic or social factors are too speculative to analyze and are outside of CEQA's scope.

Comment: 6-13, 6-31, 6-32, 6-33, 13-1, 73-41

Comments Summary:

DTSC cannot support the statement that there will be no physical changes to the environment resulting from DTSC's adoption of regulations that specify a process for identifying and prioritizing Chemicals of Concern in consumer products. It isn't credible for DTSC to claim there will be no environmental impacts. It is not credible for DTSC to conclude that (1) there is no possibility of significant environmental effect due to the rulemaking, and (2) evaluation of such impacts is infeasible or impossible at this stage of the program's development. DTSC characterizes the rulemaking as a four-step, iterative process, but only begins to (does not fully) consider the results of the above four-step process.

Response:

DTSC does not claim that the regulations will not impact the environment. In fact, as pointed out by commenters, the purpose of the regulations is ultimately to benefit the physical environment, protect public health, and minimize harm from the most dangerous chemicals in consumer products. However, at this juncture, the regulations merely establish the process to guide DTSC's implementation of the authorizing legislation. DTSC is well aware of the need to analyze reasonably foreseeable impacts of its actions under CEQA. Under CEQA, an indirect physical change may be considered only if it is reasonably likely to occur. (Guidelines, § 15064, subd. (d)(3).) At this point in the rulemaking, the impacts to the environment are too speculative to be considered reasonably foreseeable. (*Ibid.)* DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because the agency filed a Notice of Exemption at this rulemaking does not foreclose the agency from conducting environmental review when appropriate in the future.

Comment: 6-34

Comment Summary:

DTSC believes the regulations will result in “new materials” and “new processes” as stated in its raft NOE. These effects are more likely to occur at steps 3 (Alternatives Analysis) and 4 (regulatory response). Commenter suggests that voluntary redesign or reformulation may occur as early as Step 2 (identifying the Priority Products) and that DTSC must analyze these potential impacts at the present time.

Response:

As DTSC understands this comment, it asserts that the proposed project currently before DTSC—a set of regulations that will establish the framework to guide future rulemakings addressing specific chemicals and products—will impact the environment because as yet undefined future regulations for unidentified specific chemicals and products might require “new processes” or “new materials,” which, in turn, might impact the environment. DTSC does believe that ultimately the regulations when implemented will result in “new materials” and “new processes,” but the exact nature of these new materials and processes are dependent on future actions that cannot be known at the present time. DTSC agrees with commenter that these impacts will more likely occur at step 3 and step 4.

DTSC will consider the need to conduct appropriate environmental review when chemical-specific and product-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Comment: 6-35, PH29-4

Comment Summary:

The direct effects of redesigning and reformulating Priority Products (whether voluntary or mandatory) are foreseeable. Commenter states that a redesigned or reformulated product is likely to require raw materials that are less easy to obtain, require more difficult or intensive manufacturing process, or result in a less effective product.

Response:

As DTSC understands this comment, it asserts that the proposed project currently before DTSC—a set of regulations that will establish the framework to guide future rulemakings addressing specific chemicals and products—will impact the environment because as yet undefined future regulations for unidentified specific chemicals and products might require a reformulation that may in turn make raw materials more difficult to obtain or require more intensive manufacturing processes. The impacts of

reformulation on the environment will differ depending on what chemicals and which products are being reformulated, and the exact nature of these changes are dependent on future actions that cannot be known at the present time. Under CEQA, an indirect physical change may be considered only if it is reasonably likely to occur. (Guidelines, § 15064, subd. (d)(3).) At this rulemaking stage, the impacts from reformulation and redesign are far too speculative to be considered reasonably foreseeable. (*Ibid.)*

DTSC will consider the need to conduct appropriate environmental review when chemical-specific and product-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Comment: 6-36

Comment Summary:

As a regulatory response, a manufacturer could be required to implement an end-of-life management program, which could require the establishment of collection centers throughout California. Collected consumer products would require special handling.

Response:

As DTSC understands this comment, it asserts that the proposed project currently before DTSC—a set of regulations that will establish the framework to guide future rulemakings addressing specific chemicals—will have impacts on the environment because as yet undefined future regulations for unidentified specific chemicals might require an end-of-life management program, which in turn might require collection centers as a program element.

Under CEQA, an indirect physical change may be considered only if it is reasonably likely to occur. (Guidelines, § 15064, subd. (d)(3).) At the point of this rulemaking, the potential environmental impacts that might result from hypothetical future regulations for specific chemicals and products are far too speculative to be considered reasonably foreseeable. (*Ibid.)* It is even more speculative to engage in conjecture about which of these as- yet unspecified chemicals and products, if any, might require end-of-life management requirements. The framework regulations currently proposed by DTSC do not control the details of future chemical-specific and product-specific regulations. Moreover, even assuming that end-of-life management programs will be required, the impacts any such programs will vary depending on the product involved and on how the

responsible entity develops and implements the product stewardship plan for a given Priority Product.

DTSC will consider the need to conduct appropriate environmental review when chemical-specific and product-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Comment: 6-37

Comment Summary:

Indirect effects of listing Chemicals of Concern and Priority Products will include the desire to avoid costly alternatives assessment process, perceived increase in product liability if sales continue during assessment process, heightened public concern, and avoidance or aversion of Chemicals of Concern or Priority Products.

Response:

As DTSC understands this comment, it asserts that the proposed project currently before DTSC—a set of regulations that will establish the framework to guide future rulemakings addressing specific chemicals and products—will have the indirect effect of encouraging consumers to avoid certain products containing chemicals under evaluation.

CEQA is concerned with physical changes in the environment and under CEQA "economic and social changes resulting from a project shall not be treated as significant effects on the environment." [CEQA Guidelines § 15064, subds. (e)(f)(6), 15131, 15358.]). Economic and social changes may be considered under CEQA, if they also produce changes in the physical environment. (*See Friends of Davis v. City of Davis* (2000) 83 Cal.App.4th 1004, 1019-1021.) To the extent that commenter raises impacts which appear to be purely economic and/or social, they may be outside of CEQA's scope.

However, at the point of this rulemaking, the impacts proposed by commenter (heightened public concern, anticipatory avoidance of products, etc.) are far too speculative to be considered reasonably foreseeable. (*Ibid.)* DTSC will consider the need to conduct appropriate environmental review when chemical-specific and product-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting

environmental review when some other more specific regulatory action is proposed in the future.

Comment: 6-38

Comment Summary:

There are possible indirect impacts if replacement parts are not available for a consumer product already in commerce. For example, if a manufacturer of automobile replacement parts ceases to produce certain parts rather than redesign them, consumers will be faced with no means to repair their vehicles which could lead to a large increase in vehicles scrapped in California.

Response:

As DTSC understands this comment, it asserts that the proposed project currently before DTSC—a set of regulations that will establish the framework to guide future rulemakings addressing specific chemicals and products—will impact the environment because as yet undefined future regulations for unidentified specific chemicals and products might eliminate replacement parts currently in the marketplace, which in the case of automobiles, may lead to a large increase in vehicles scrapped in California. Under CEQA, an indirect physical change to the environment shall be considered only if it is reasonably likely to occur. (Guidelines, § 15064, subd. (d)(3).) At the point of this rulemaking, the potential impact described above is far too speculative to be considered reasonably foreseeable. (*Ibid.)* Further, as discussed in responses to comments above, it is not yet known if any of the Priority Products will *ever* be a an automobile part, much less which part of an automobile. Accordingly, no one can forecast at this point of process regulations adoption that there will be automobile replacement parts shortages and increased scrapping of automobiles in California. This entire chain of "analysis" is really speculation heaped on speculation.

DTSC will consider the need to conduct appropriate environmental review when chemical-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Comment: 6-39, 13-1, 57-4

Comments Summary:

Commenter suggests that the public and retailers may spontaneously dispose of existing Chemicals of Concern and Priority Products in commerce, causing a surge in products being directed to landfills. Also recycling of these products and paper products will diminish.

Response:

Under CEQA, an indirect physical change may be considered only if it is reasonably likely to occur. (Guidelines, § 15064, subd. (d)(3).) At the point of this rulemaking, the impacts from reformulation and redesign of as yet unidentified chemicals and products are far too speculative to be considered reasonably foreseeable. (*Ibid.)* The impacts of reformulation on the environment will differ depending on what chemical and which product are being reformulated. Again, those chemicals and products will not and cannot be known until they are identified as part of a Priority Products rulemaking at a later stage of implementation of these regulations.

DTSC will consider the need to conduct appropriate environmental review when chemical-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Comment: 6-42

Comment Summary:

Commenter alleges the following impacts are foreseeable.

Table CEQA-1. Example of Foreseeable Significant Environmental Impacts

Environmental Factor	Foreseeable Effect of Regulations
Air Quality	•Construction and operational activities from new facilities and/or expansion of existing facilities will result in localized and regional increases in dust, criteria pollutant emissions, and air toxics emissions in excess of thresholds of significance. •New or modified manufacturing processes for Chemicals of Concern and/or Priority Product alternatives could create objectionable odors.
Greenhouse Gas Emissions (GHG)	•Construction and operational activities of new expanded or modified facilities will result in GHG emissions in excess of thresholds of significance. •New and or substitute raw materials for Chemicals of Concern and/or

	Priority Product alternatives have associated life cycle GHG emissions in excess of thresholds of significance. •New or modified manufacturing processes producing Chemicals of Concern and/or Priority Product alternatives are more energy- intensive, resulting in an increase in GHG emissions that exceeds a threshold of significance.
Hazards and Hazardous Materials	• New and/or modified manufacturing processes create new streams of hazardous materials as a result of either removing Chemicals of Concern from Priority Products or from more complex manufacturing techniques required under alternatives assessment. •Mandated end-of-life procedures create new (or consolidated) waste streams that require enhanced handling procedures and/or special disposal sites. •Listing of Chemicals of Concern or Priority Products triggers voluntary disposal of such chemicals or products by the public, thus increasing the occurrence of Chemicals of Concern in normal waste streams. •Manufacturers voluntarily substitute listed Chemicals of Concern with non-listed chemicals outside of the DTSC's alternatives assessment process to avoid further regulation.
Hydrology and Water Quality	• New and/or modified manufacturing processes are more water-intensive or create additional industrial wastewater volumes as a result of either removing Chemicals of Concern from Priority Products or from more complex manufacturing techniques required under Alternatives Assessment.

Response:

Under CEQA, an indirect physical change may be considered only if it is reasonably likely to occur. (Guidelines, § 15064, subd. (d)(3).) At this point in the rulemaking, the impacts to air quality, greenhouse gas emissions, hazardous wastes and water quality are far too speculative to be considered reasonably foreseeable. (*Ibid.)* The impacts of reformulation on the environment will differ wildly depending on what chemical(s) and which product(s) are being reformulated. As discussed above in several responses to comments, those chemicals and products are not known at this time.

DTSC will consider the need to conduct appropriate environmental review when chemical-and product-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Comment: 6-56, 6-57, 6-58, 6-59, 6-60, 6-61, 6-62, 6-63, 6-64

Comments Summary:

Commenter provided examples of cases in which product substitutes without Alternatives Analysis resulted in adverse environmental impacts, such as MTBE as a substitute for tetraethyl lead in reformulated gasoline, and replacement of perchloroethylene with VOC-based dry cleaning solvents. Commenter provided examples in which an Alternatives Analysis revealed that some of the chemicals under consideration for replacement posed greater harm than the original chemical. These included: an alternatives assessment on flame retardants used in printed circuit boards, an alternatives assessment on nonylphenol ethoxylates used in surfactants, bisphenol A (BPA) alternatives in thermal paper, flexographic ink substitutes, wire and cable insulation and jacketing, and finally desk top computer displays.

Commenter states that the Alternatives Analysis on these potential replacement chemicals or processes revealed that not all the alternatives were more environmentally beneficial than the original product.

Response:

The regulations establish a rigorous Alternatives Analysis process, which is designed to ensure that any regulatory actions taken are well reasoned and will benefit the environment and promote public health. As stated in the Initial Statement of Reasons, Health and Safety Code section 25253(a)(2) requires these regulations to establish a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. The process must include life cycle assessment tools that take into consideration, but are not limited to, all of the following:

(A) Product function or performance.
(B) Useful life.
(C) Materials and resource consumption.
(D) Water conservation.
(E) Water quality impacts.
(F) Air emissions.
(G) Production, in-use, and transportation energy inputs.
(H) Energy efficiency.
(I) Greenhouse gas emissions.
(J) Waste and end-of-life disposal.
(K) Public health impacts, including potential impacts to sensitive subpopulations, including infants and children.
(L) Environmental impacts.

(M) Economic impacts.

The thirteen, (A) through (M), criteria listed in statute are embodied in the regulations and collectively address the life cycle impacts (*i.e.*, from raw material extraction through materials processing, manufacture, distribution, use, repair and maintenance, and disposal or recycling) associated with the Priority Product or any alternative(s) considered.

The thirteen criteria of section 25253(a)(2) comprise the contents of an Alternatives Analysis, which requires the evaluation of Chemicals of Concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a Chemical of Concern. Collectively, the required evaluation of these impacts throughout the life cycle of the Priority Product and for any alternative being considered, works to prevent the selection of a regrettable substitute. This evaluation of hazards posed by the Chemical(s) of Concern in the Priority Products as well as any potential alternatives is the essence of the Alternatives Analysis and is grounded in the notion of avoiding regrettable substitutes.

Comment: 41-61

Comment Summary:

Commenter suggests that companies will stop using recycled materials today before Chemicals of Concern are selected because of the fact that they cannot control the recycled material stream. For example, if DTSC selects BPA as a Priority Product and cash register receipts contain trace amounts of BPA, this could lead to a decrease in the use of post-consumer recycled fiber and result in more waste going to landfills as a result of an increased use of virgin materials to make paper products.

Response:

Under CEQA, an indirect physical change may be considered only if it is reasonably likely to occur. (Guidelines, § 15064, subd. (d)(3).) At the point of this rulemaking, the impact described above is not reasonably likely to occur. (*Ibid.)* See responses to comments above discussing the unknown nature of the chemicals and products that may become subject to the requirement to conduct an Alternatives Analysis under later implementation stages of these regulations only. The impact on companies' recycling practices will vary tremendously depending on what chemicals and which products are under review. This entire comment consists of conjecture and speculation.

DTSC will consider the need to conduct appropriate environmental review when chemical-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Comment: 41-62

Comment Summary:

Companies will desire purer virgin feedstock which will, in turn, require greater energy and produce greater waste. For example, if DTSC were to select carbon black as a Chemical of Concern, a colorant used in inks, and there was the possibility that trace amounts of carbon black may end up in recycled content, this would encourage companies to use virgin plastics instead of using recycled products.

Response:

Under CEQA, an indirect physical change may be considered only if it is reasonably likely to occur. (Guidelines, § 15064, subd. (d)(3).) At the point of this rulemaking, the impact described above is not reasonably likely to occur. (*Ibid.)* As shown by the commenter, the impact on companies' recycling practices will vary depending on what chemicals and which products are under review. As with other similar comments above, this comment engages in wild conjecture and speculation.

DTSC will consider the need to conduct appropriate environmental review when chemical-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Comment: 41-64

Comment Summary:

Compact fluorescent lights are energy efficient but contain measureable amounts of mercury. DTSC's regulations may ban this lighting option for consumers in California if mercury is a chemical that is banned under the regulations.

Response:

As DTSC understands this comment, it asserts that the proposed project—a set of regulations that establish the framework to guide future rulemakings addressing specific

chemicals and products—will create a conflict for California consumers if DTSC were to hypothetically ban mercury in compact fluorescent light bulbs. Under CEQA, an indirect physical change may be considered only if it is reasonably likely to occur. (Guidelines, § 15064, subd. (d)(3).) At the point of this rulemaking, the impact described above is not reasonably likely to occur. (*Ibid.)* As shown by commenter, any impact to the environment will vary depending on what chemicals and which products are under review. As with other similar comments above, this comment engages in wild conjecture and speculation.

DTSC will consider the need to conduct appropriate environmental review when chemical-specific regulations are proposed. The fact that DTSC is relying on a Notice of Exemption for this rulemaking does not foreclose the agency from conducting environmental review when some other more specific regulatory action is proposed in the future.

Category #3 – Initial Study and Programmatic Environmental Impact Report (EIR) Required

Comment: 5-39

Comment Summary:

The July 2012 proposal has the real potential to result in “direct physical change[s] in the environment” and/or “reasonably foreseeable indirect physical change[s] in the environment” and an initial study and programmatic environmental impact report must be completed prior to adoption of the July 2012 proposal.

Response:

This comment objects to DTSC’s use of the exemption in section 15061(b)(3) of the CEQA Guidelines and contends that because the regulations will result in “direct physical change[s] in the environment” and/or “reasonably foreseeable indirect physical change[s] in the environment,” DTSC must perform an initial study and programmatic environmental impact report before adopting the regulations. Based on the comments received, DTSC has elected not to pursue the exemption in section 15061(b)(3). But DTSC maintains that the proposed regulations fall within the list of exempt categories or classes of projects that have been determined by the State Resources Agency not to have a significant effect on the environment and therefore, further environmental review is not necessary. (See *Apartment Assn. of Greater Los Angeles v. City of Los Angeles* (2001) 90 Cal.App.4th 1162 [agency not required to conduct initial study before declaring project exempt from CEQA review].)

DTSC is well aware of the need to analyze reasonably foreseeable impacts of its regulatory activities under CEQA, including the present rulemaking. Indeed, the purpose of the proposed regulations is ultimately to benefit the physical environment, protect public health, and minimize harm through redesign, reformulation, manufacturing process redesign, phase-out of harmful chemicals and/or removal of harmful chemicals in consumer products. However, at this point in the rulemaking, the alleged impacts of reformulation and redesign on the environment are too speculative to be considered reasonably foreseeable. (See CEQA Guidelines, § 15064, subd. (d)(3).) The proposed regulations merely "establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a Chemical of Concern." (Health and Saf. Code § 25252, subd. (a).) Because the impacts of reformulation will differ depending on what chemical and which product may be reformulated or otherwise modified (in addition to any other action that may be taken as a result of the Alternatives Analysis), the speculative concerns about future actions by regulated entities are too vague and imprecise at this juncture for any meaningful environmental assessment. (See *Laurel Heights Improvement Assn. v. Regents of University of California* (1988) 47 Cal.3d 376, 398; *Kaufman & Broad-South Bay, Inc. v. Morgan Hill Unified School Dist*. (1992) 9 Cal.App.4th 464, 475–476.) DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because DTSC is proceeding with a Notice of Exemption at this rulemaking does not foreclose the agency from preparing a programmatic environmental review if and when it is appropriate in the future.

Comment: 5-41

Comment Summary:

A CEQA analysis is required prior to adoption and should be conducted in a programmatic EIR to ensure DTSC considers broad policy alternatives and program wide mitigation measures at a time when the agency has the greatest ability to deal with cumulative impact problems.

Response:

Please see DTSC's Response to Comment 5-39. DTSC further notes that the Alternatives Analysis embedded in the regulations is designed to protect the environment by analyzing the human and environmental impacts of the Chemical(s) of Concern in the Priority Product as well as any other alternative being considered before any changes to the current product are made. As stated in the Initial Statement of Reasons, Health and Safety Code section 25253(a)(2) requires these regulations to

establish a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. The process must include life cycle assessment tools that take into consideration, but are not limited to, all of the following: product function or performance; useful life; materials and resource consumption; water conservation; water quality impacts; air emissions; production, in-use, and transportation energy inputs; energy efficiency; greenhouse gas emissions; waste and end-of-life disposal; public health impacts, including potential impacts to sensitive subpopulations, including infants and children; environmental impacts; and economic impacts. Collectively, the required evaluation of these impacts throughout the life cycle of the Priority Product and for any alternative being considered, works to prevent the selection of a regrettable substitute.

Comment: 5-42

Comment Summary:

A programmatic document will also play an important role in establishing a structure within which future reviews and related actions can most effectively be conducted.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: 5-4

Comment Summary:

"It is critically necessary for the Department to conduct a programmatic analysis now, so that it can make any modifications to the July 2012 Proposal that are necessary to address potentially significant environmental impacts and can analyze reasonable and feasible alternatives to specific provisions of the July 2012 Proposal . . . before the regulations are adopted and enforced."

Response:

Please see DTSC's Response to Comment 5-39. DTSC further notes that the Alternatives Analysis embedded in the regulations is designed to protect the environment by analyzing the human and environmental impacts of the Chemical(s) of Concern in the Priority Product as well as other chemical alternatives being considered before any changes to the current product are made.

Comment: 5-6

Comment Summary:

"DTSC attempts to limit the scope of the environmental review required by CEQA to DTSC's own administrative activities, thereby ignoring any 'reasonable and foreseeable' activities that might occur as a result of DTSC adopting the July 2012 proposal. DTSC implies that the 'project' consists merely of DTSC's 'intellectual evaluation and analysis' (*i.e.*, Department employees administering the program in an office environment). However, in its Economic Analysis, its Initial Statement of Reasons and in public statements, the Department states that it anticipates a growth in green business and overall growth in jobs. The Department also asserts that having a large list of Chemicals of Concern ('COCs') will serve as a signal to the market to switch out of these chemicals to other product ingredients. If these potential changes are reasonably foreseeable enough to justify the purported economic benefits of the July 2012 proposal, then the potential impacts of said changes must be analyzed under CEQA and in the multimedia analysis that is required under the Statute."

Response:

To the extent this comment objects to DTSC's use of the common sense exemption, please see the first response in Category #1 – Objections to the Notice of Exemption.

With respect to the comment that potential impacts of purported economic benefits must be analyzed under CEQA, DTSC responds that under CEQA "economic and social changes resulting from a project shall not be treated as significant effects on the environment." [CEQA Guidelines § § 15064, subds. (e)(f)(6), 15131, 15358.]). Economic and social changes may be considered under CEQA, if they also produce changes in the physical environment. (*Friends of Davis v. City of Davis* (2000) 83 Cal.App.4th 1004, 1019-1021.) At this point, any indirect changes to the physical environment caused by economic or social factors are too speculative to analyze and are outside the scope of CEQA. Again, as stated in response to several comments above, the mere fact that DTSC anticipates various unspecified changes in the market in response to the adoption of these regulations does not mean that DTSC has sufficient information to engage in a meaningful evaluation of potential environmental impacts under CEQA. None of the discussion in DTSC's economic impact analysis (Std. 399) or in any of its public statements can be accurately characterized as standing for the proposition that DTSC knows which chemicals or what products may be subject to further regulation—much less that DTSC knows what the environmental consequences would be from such selection.

Comment: 6-9

Comment Summary:

DTSC should suspend finalization of the regulations until a CEQA initial study can be performed followed by the appropriate level of CEQA review, which is a program EIR.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: 6-11

Comment Summary:

The regulations contain no mechanism to ensure compliance with CEQA at the project level. A key issue is DTSC's failure to avoid compliance with CEQA from a programmatic standpoint.

Response:

Please see DTSC's Response to Comment 5-39.

Comments: 6-15, 6-16

Comments Summary:

The potential impacts should be disclosed at this time via a Programmatic EIR. See CEQA Guidelines sections 15168(a)(3) and 15164.

Response:

Please see DTSC's Response to Comment 5-39. DTSC further notes that the commenter mistakenly cites to section 15164 of the CEQA Guidelines, which discusses the use of an addendum to a previously certified EIR or negative declaration, not program EIRs.

Comment: 6-17

Comment Summary:

DTSC must abandon the approach of deferring CEQA and suspend further action until an Initial Study is performed, which will show that a programmatic EIR is required and that future project level CEQA review of DTSC's subsequent actions will be required as described in section 15152 of the CEQA Guidelines.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: 6-18

Comment Summary:

The AB 32 Scoping Plan is an example of how California regulatory agencies need to address the requirements imposed by CEQA. The AB 32 Scoping Plan and its Appendices provide all of the information required to assess the environmental and public health impacts of the AB32 program including, but not limited to, assessments of how technical and economic factors may create adverse impacts.

Response:

Please see DTSC's Response to Comment 5-39. Unlike the AB 32 Scoping Plan, DTSC's proposed regulations merely "establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a Chemical of Concern." (Health and Safety Code § 25252, subd. (a).) DTSC is well aware of the need to analyze reasonably foreseeable impacts of its regulatory activities under CEQA. However, at this point in the rulemaking, the alleged impacts of reformulation and redesign on the environment are too speculative to be considered reasonably foreseeable. (See CEQA Guidelines, § § 15064, subd. (d)(3).) Indeed, the impacts of reformulation will differ depending on what chemicals and which products may be reformulated. As stated, DTSC's regulations merely establish the process by which DTSC must now move forward in order to comply with the authorizing legislation. DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because DTSC is proceeding with a notice of exemption at this rulemaking does not foreclose the agency from preparing a programmatic environmental review if and when it is appropriate in the future.

Comment: 6-19

Comment Summary:

The CEQA analysis for the Scoping Plan is programmatic and looks at the broader environmental and public health impacts of a regulatory structure. ARB could have argued that the Scoping Plan was exempt from CEQA as an intellectual exercise and that there could never be action taken pursuant to AB 32 that would result in adverse environmental or public health impacts. In addition to the Program EIR, specific actions implementing the Scoping Plan are subject to project level CEQA.

Response:

Please see DTSC's Response to Comment 5-39. Unlike the AB 32 Scoping Plan, DTSC's proposed regulations merely "establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a Chemical of Concern." (Health and Safety Code § 25252, subd. (a).) DTSC is well aware of the need to analyze reasonably foreseeable impacts of its regulatory activities under CEQA. However, at this point in the rulemaking, the alleged impacts of reformulation and redesign on the environment are too speculative to be considered reasonably foreseeable. (See CEQA Guidelines, § 15064, subd. (d)(3).) Indeed, the impacts of reformulation will differ depending on what chemicals and which products may be reformulated. As stated, DTSC's regulations merely establish the process by which DTSC must now move forward in order to comply with the authorizing legislation. DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because DTSC is proceeding with a notice of exemption at this rulemaking does not foreclose the agency from preparing a programmatic environmental review if and when it is appropriate in the future.

Comment: 6-29

Comment Summary:

All of DTSC's rationale for the common sense exemption applies to "project," not 'programmatic' impacts, which is the purpose of a Programmatic EIR.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: 6-40, 6-41

Comments Summary:

DTSC should conduct an Initial Study and further environmental review. We believe the Initial Study will show that there are numerous potentially significant environmental impacts and that a Program EIR must be prepared.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: 19-47

Comment Summary:

The California Environmental Quality Act (CEQA) requires that DTSC prepare an in-depth Environmental Impact Report (EIR) before adopting any proposed regulations. An exemption to this requirement may be granted only if the requesting agency demonstrates that there is no potential for significant adverse effects on public health or the environment. In posting a draft Notice of Exemption on its website, DTSC has indicated its intent to assert that there will be no significant adverse effect on public health or the environment. Given the very nature of these regulations and the extent to which they will fundamentally impact California's environmental and public health, it is clear that there will be significant impacts. As we have indicated in our comments, we believe that these regulations have the potential to drive premature and potentially harmful chemical substitution choices. We have raised concerns that consumer safety could be jeopardized by limitations on products and components that ensure both performance and safety standards are met.

We believe this rulemaking does not qualify for a statutory exemption under CEQA and support the more extensive comments in this area submitted by the Alliance of Automobile Manufacturers.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: 34-14

Comment Summary:

CCEEB concurs with other commenters that a complete California Environmental Quality Act (CEQA) analysis is legally required and should be performed on this proposed regulation.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: 41-60

Comment Summary:

DTSC argues that it did not conduct environmental review at this stage because potential impacts are too speculative and CEQA analysis should not be conducted until later in process. DTSC has not used its best efforts to make a thorough investigation and has deferred environmental review to a future date. However, future environmental review does not excuse DTSC from adequately analyzing reasonably foreseeable

significant environmental effects of the project and deferring the analysis to a later environmental review document. An investigation would find that there is substantial evidence of knowable potential impacts even at this stage in the regulatory process.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: 57-3

Comment Summary:

The regulations have real potential to result in "direct physical change[s] in the environment and or reasonably foreseeable indirect physical changes in the environment." Therefore, an initial study and programmatic EIR must be completed before adoption of the July 2012 proposal.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: PH10-3

Comment Summary:

DTSC should have prepared a master EIR to compare the reasonably foreseeable changes in the environment.

Response:

Please see DTSC's Response to Comment 5-39.

Comment: PH29-3

Comment Summary:

The ISOR states that, based on the economic analysis, the regulations may result in the creation of jobs. The Economic Analysis states the regulations will fundamentally change how and where consumer products are manufactured with many of those impacts occurring in California. This contradicts the CEQA requirement to analyze reasonably foreseeable fiscal changes in the environment. Impacts identified in the economic analysis that have potential adverse environmental impacts include increases in energy consumption due to new production of processes and product distribution systems that could result in increased greenhouse gas emissions.

Response:

DTSC is well aware of the need to analyze reasonably foreseeable impacts of its regulatory activities under CEQA, including the present rulemaking. Indeed, the purpose of the proposed regulations is ultimately to benefit the physical environment, protect public health, and minimize harm through redesign, reformulation, manufacturing process redesign, phase-out of harmful chemicals and/or removal of harmful chemicals in consumer products. However, at this point in the rulemaking, the alleged impacts of reformulation and redesign on the environment, as well as any other possible actions that manufacturers may take as a result of an Alternatives Analysis, are too speculative to be considered reasonably foreseeable. (See CEQA Guidelines, § § 15064, subd. (d)(3).) The proposed regulations merely "establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a Chemical of Concern." (Health and Safety Code § 25252, subd. (a).) Because the impacts of reformulation, or any other possible action taken by manufacturers, will differ depending on what chemical(s) and which product(s) may be reformulated or otherwise modified. The speculative concerns about future actions by regulated entities are too vague and imprecise at this juncture for any meaningful environmental assessment. (See *Laurel Heights Improvement Assn. v. Regents of University of California* (1988) 47 Cal.3d 376, 398; *Kaufman & Broad–South Bay, Inc. v. Morgan Hill Unified School Dist*. (1992) 9 Cal.App.4th 464, 475–476.) DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because DTSC is proceeding with a notice of exemption at this rulemaking does not foreclose the agency from preparing a programmatic environmental review if and when it is appropriate in the future.

Further, under CEQA, "economic and social changes resulting from a project shall not be treated as significant effects on the environment." [CEQA Guidelines § 15064, subds. (e)(f)(6), 15131, 15358.]). Economic and social changes may be considered under CEQA if they also produce changes in the physical environment. (*Friends of Davis v. City of Davis* (2000) 83 Cal.App.4th 1004, 1019-1021.) At this point, any indirect changes to the physical environment caused by economic or social factors are too speculative to analyze and are outside the scope of CEQA.

Comment: PH29-5

Comment Summary:

DTSC's position is fundamentally at odds with the normal rulemaking process. See ARB's AB32 scoping plan as a great one for DTSC to follow.

Response:

Please see DTSC's Response to Comment 5-39. Unlike the AB 32 Scoping Plan, DTSC's proposed regulations merely "establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a Chemical of Concern." (Health and Safety Code § 25252, subd. (a).) DTSC is well aware of the need to analyze reasonably foreseeable impacts of its regulatory activities under CEQA. However, at this point in the rulemaking, the alleged impacts of reformulation and redesign on the environment, in addition to other actions that manufacturers may take as a result of an Alternatives Analysis, are too speculative to be considered reasonably foreseeable. (See CEQA Guidelines, § 15064, subd. (d)(3).) Indeed, the impacts of reformulation will differ depending on what chemical(s) and which product(s) may be reformulated or otherwise modified or whether the Priority Product is retained as is. As stated, DTSC's regulations merely establish the process by which DTSC must now move forward in order to comply with the authorizing legislation. DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because DTSC is proceeding with a notice of exemption at this rulemaking does not foreclose the agency from preparing a programmatic environmental review if and when it is appropriate in the future.

Comment: 136-12

Comment Summary:

Many commenters have expressed concern that the proposed Safer Consumer Products Regulation has failed to satisfy all requirements of the California Environmental Quality Act (CEQA). WSPA shares those concerns as well.

Response:

Please see the first response in Category #1 – Objections to the Notice of Exemption.

Category #4 – Uncategorized

Comment: 6-2

Comment Summary:

DTSC's position that the regulations are exempt from CEQA does not comport with the intent of the Legislature in enacting CEQA. Under Public Resources Code section 21001, subdivision (f), government agencies must develop standards and procedures to protect environmental quality. Under Public Resources Code section 21001, subdivision (g), government agencies must consider qualitative factors as well as

economic and technical factors and long-term benefits and costs, in addition to short-term benefits and costs and alternatives to the proposed action.

Response:

Please see DTSC's Response to Comment 5-39. DTSC understands that the primary goal of CEQA is the protection of the environment and that environmental quality is a statewide concern. DTSC does not claim that the regulations will not impact the environment. In fact, the purpose of the regulations is ultimately to benefit the physical environment, protect public health, and minimize harm from dangerous chemicals in consumer products. However, at this juncture in the rulemaking, the regulations merely establish the process by which DTSC must oversee the work of manufacturers as they rigorously evaluate the chemicals in consumer products and analyze viable alternatives to the harmful chemicals. To that end, DTSC believes that the regulations will result in newer, safer products that will move consumers away from chemicals that pose the greatest risk and foster replacement with chemicals that have lower risks.
DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because DTSC is proceeding with a notice of exemption at this rulemaking does not foreclose the agency from preparing a programmatic environmental review if and when it is appropriate in the future. To the extent that this comment raises economic concerns, under CEQA, "economic and social changes resulting from a project shall not be treated as significant effects on the environment." [CEQA Guidelines § 15064, subds. (e)(f)(6), 15131, 15358.]). Economic and social changes may be considered under CEQA if they also produce changes in the physical environment. (*Friends of Davis v. City of Davis* (2000) 83 Cal.App.4th 1004, 1019-1021.) At this point, any indirect changes to the physical environment caused by economic or social factors are too speculative to analyze and are outside the scope of CEQA.

Comment: 6-4

Comment Summary:

Regulations create a massive program with the potential to alter the availability, composition and nature of consumer products. The Legislature intended this to be subject to CEQA. DTSC has acknowledged that the regulations will affect the environment. Regulations should not be adopted absent consideration of the factors in the CEQA provisions (mentioned above).

Response:

Please see DTSC's Response to Comment 5-39. DTSC does not claim that the regulations will not impact the environment. In fact, the purpose of the regulations is ultimately to benefit the physical environment, protect public health, and minimize harm from the most dangerous chemicals in consumer products. However, at this juncture in the rulemaking, the regulations merely establish the process by which DTSC must rigorously evaluate the chemicals in consumer products and analyze viable alternatives to the most harmful chemicals. To that end, DTSC believes that the regulations will result in newer, safer products that will move consumers away from chemicals that pose the greatest risk and foster replacement with chemicals that have lower risks.

DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because DTSC is proceeding with a notice of exemption at this rulemaking does not foreclose the agency from preparing a programmatic environmental review if and when it is appropriate in the future. To the extent that this comment raises economic concerns, under CEQA "economic and social changes resulting from a project shall not be treated as significant effects on the environment." [CEQA Guidelines § 15064, subds. (e)(f)(6), 15131, 15358.]). Economic and social changes may be considered under CEQA, if they also produce changes in the physical environment. (See *Friends of Davis v. City of Davis* (2000) 83 Cal.App.4th 1004, 1019-1021.) At this point, any indirect changes to the physical environment caused by economic or social factors are too speculative to analyze and are outside the scope of CEQA

Comments: 6-43, 6-44, 6-45, 6-46, 6-47, 6-48, 6-49

Comments Summary:

DTSC's claims that the regulations will satisfy CEQA on a project level are incorrect because the Alternatives Analysis process is not CEQA equivalent. The Alternatives Analysis overlooks numerous environmental factors that must be evaluated under CEQA. And for those environmental factors that do require review, the review under CEQA is more rigorous and comprehensive. DTSC's process requires some level of disclosure of "adverse environmental impacts" but these impacts are defined only in a cursory manner that sidesteps the concept of a "threshold of significance" found in CEQA where thresholds are set by public agencies responsible for resources based on existing environmental standards. Further, under CEQA, public agencies have the ability to review and comment on analyses and significance determinations and so does the public and CEQA provides for the application of enforceable mitigation measures. In contrast, the DTSC process is closed to other resource agencies and the public. Determinations of adverse environmental impacts are left primarily to the responsible

entity, with review oversight by DTSC. There is a decided advantage for responsible entities to identify significant environmental impacts with product alternatives, to the end that they are not required to implement those alternatives. Therefore, the DTSC process is not a substitute for CEQA and the only appropriate course of action is for DTSC to suspend its effort to finalize the regulations until an Initial Study can be performed to determine the appropriate level of review, which is to prepare a Program EIR.

Response:

Please see DTSC's Response to Comment 5-39. DTSC is not claiming that the Alternatives Analysis is CEQA equivalent, but rather that the regulations contain procedures for protection of the environment. The Alternatives Analysis embedded in the regulations is designed to protect the environment by analyzing the human and environmental impacts of the Chemicals of Concern in the Priority Product as well as any alternative being considered. DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because DTSC is proceeding with a Notice of Exemption at this rulemaking does not foreclose the agency from preparing a programmatic environmental review if and when it is appropriate in the future.

Comment: 41-59

Comment Summary:

CEQA broadly applies to an agency's discretionary approval of a project, which includes adoption of regulations that may have a significant impact on the environment. DTSC has failed to assess the negative environmental impacts that will likely result from implementation of the proposed regulations.

Response:

Please see the first response in Category #1 – Objections to the Notice of Exemption.

Comment: 57-2

Comment Summary:

A NOE is not appropriate here and DTSC must complete the CEQA process. Because the regulations are designed to reduce adverse public health and environmental impacts, it is DTSC's responsibility to show the benefit of the regulations.

Response:

Please see the first response in Category #1 – Objections to the Notice of Exemption.

DTSC agrees that the purpose of the regulations is ultimately to benefit the physical environment, protect public health, and minimize harm from the most dangerous chemicals in consumer products. To that end, DTSC believes that the regulations will result in newer, safer products that will move consumers away from chemicals that pose the greatest risk and foster replacement with chemicals that have lower risks. But, at this juncture in the rulemaking, the regulations merely establish the process by which DTSC must oversee the manufacturer as it rigorously evaluates the Chemicals of Concern in Priority Products and analyzes viable alternatives to these harmful chemicals. DTSC will consider the need to conduct appropriate environmental review when implementing the regulations. Simply because DTSC is proceeding with a Notice of Exemption at this rulemaking does not foreclose the agency from preparing a programmatic environmental review if and when it is appropriate in the future

Comment: PH34-5

Comment Summary:

It is essential this program explicitly follow APA and CEQA requirements.

Response:

DTSC agrees and notes that the proposed regulations do comply with the requirements of the APA and CEQA. See detailed discussion of APA compliance in the section of this Response to Comments document that specifically addresses APA issues.

Comment: 73-40

Comment Summary:

While DTSC claims that the proposed regulations are exempt from CEQA because the structure of the regulations will ensure that there are no adverse environmental impacts associated with any action taken, the proposed regulation contains no mechanism that will ensure compliance with CEQA even at the "project" level. DTSC acknowledged that the regulations would have short and long-term impacts.

Response:

Please see the first response in Category #1 – Objections to the Notice of Exemption.

THE CALIFORNIA ENVIRONMENTAL POLICY COUNCIL ACTION

Comments: 5-44, 6-50, 6-51, 6-52, 6-53, 6-54, 6-55, 57-5, 57-6, PH29-6

Comments Summary:

The comments object to the fact that DTSC has neither conducted a multimedia life cycle evaluation of the regulations, as is required by the authorizing legislation, nor been excused from this requirement by the California Environmental Policy Council (Council), as is allowed by the authorizing legislation. The comments note that DTSC cannot rely on the determination from the Council in 2010 that the regulations did not have to undergo a multimedia life cycle evaluation. Some of the comments go on to critique the validity of the Resolution adopted by the Council in 2010, which stated that the regulations would not pose a significant adverse risk to public health or the environment and that they were, therefore, exempt from the duty to perform a multimedia life cycle evaluation. One commenter objected to the timing of the Council's review of the regulations, suggesting that stakeholders were deprived of a meaningful public comment period.

Response:

DTSC respectfully disagrees with each of these comments and will explain why in detail below. However, before doing that, DTSC wishes to provide a bit of background information about the Council and its duties in connection with these regulations.
The Environmental Policy Council is a creature of statute and is composed of the Cal/EPA Secretary, DTSC's director and the director or chair of the following entities: the Department of Pesticide Regulation, OEHHA, the Department of Resources Recycling and Recovery (Cal/Recycle, as successor agency to the California Integrated Waste Management Board), CARB, and the State Water Resources Control Board.
The authorizing statute for these regulations requires that either DTSC prepare a multimedia life cycle evaluation of the regulations, or the Environmental Policy Council conclusively determine that the regulations will not have any significant adverse impact on public health or the environment. (Health and Safety Code § 25252.5(a) and (f).)

An Environmental Policy Council meeting was held on February 28, 2013. At that time, the Council accepted oral and written public comments on the issue of whether or not, following an initial evaluation of the regulations, it could conclusively make the determination set out in Health and Safety Code § 25252.5(f). The July 2012 regulations were the subject of the Council's review and determination. At the meeting, the Council unanimously adopted a resolution that contained the following determination:

"NOW, THEREFORE BE IT RESOLVED that the Council, following an initial evaluation of the proposed regulations, conclusively determines that the regulations will not have any significant adverse impact on public health or the environment."

Accordingly, these regulations were exempted from the requirement that they undergo a multimedia life cycle evaluation.

Responses to specific comments regarding the Environmental Policy Council: As the quoted text demonstrates, most of the comments are rendered moot by the fact that the Council was reconvened, voted, and conclusively determined that the regulations did not pose a significant adverse effect on public health or the environment. In addition, DTSC notes that it did prepare a staff report that demonstrated that it met the basis for being exempted from the multimedia life cycle evaluation. (See Health and Safety Code section 25252.5(f).) DTSC also disagrees with the comments questioning the validity of the Council's actions in 2010. But since those actions are moot in terms of relevance to these regulations, DTSC will not rebut each criticism of the Council's action in 2010.

Finally, DTSC is baffled by the notion that submitting the regulations to the Council at the time that it did deprived stakeholders of a meaningful comment period. Again, the Council considered a formally proposed rulemaking undertaken under the APA. Therefore, interested parties had a public comment period specific to the Council's actions on February 28, 2013, in addition to the following public comment periods that DTSC has provided for:

- The July 2012 version of the regulations;
- The revised Initial Statement of Reasons;
- The January 2013 version of the regulations; and
- The External Scientific Peer Review Reports.

DTSC believes there have been ample opportunities for meaningful public comment at each stage of the proceedings. For these reasons, DTSC is not making any changes to the regulations in response to these comments.

ECONOMIC AND FISCAL IMPACT STATEMENT GENERAL

Form 399 and Economic and Fiscal Impact Statement Does Not Comply with the Administrative Procedure Act

Comments: 5-3, 5-24, 5-25, 5-26, 5-27, 5-28, 6-5, 6-6, 9-7, 10-4,13-2, 13-3, 14-1, 14-2, 17-10, 19-48, 19-49, 19-50, 22-1, 22-11, 38-11, 41-66, 47-2, 47-4, 47-5, 47-6, 47-7, 47-9, 47-32, 47-33, 57-7, 57-9, 73-37, 73-38, 74-10, 78-1, 95-5, 135-2, 135-5, 139-10, PH8-1, PH8-2, PH8-3, PH8-4, PH8-8, PH31-2

Comments Summary:

The above comments assert that the Department of Toxic Substances Control (DTSC) failed to comply with the Administrative Procedure Act (APA) because DTSC failed to attach a meaningful and thorough analysis of the Economic and Fiscal Impact of the Safer Consumer Products Regulations. DTSC indicated the economic and fiscal impact of the regulations was unknown. Some comments specifically state that DTSC failed to comply with Senate Bill 617 (Ch. 496/Stats. 2011) that established new requirements for conducting Economic and Fiscal Impact Statements. In general, the comments state that:

- DTSC fails to provide an analysis of “potential for adverse impact on California businesses”;
- DTSC fails to provide an analysis of the impact of the regulations on the competitiveness of California’s businesses;
- DTSC fails to provide a meaningful cost analysis—either cost-benefit or cost-effectiveness;
- DTSC fails to assess the impact on California jobs;
- DTSC fails to provide an analysis of the impact on key industries or businesses;
- DTSC fails to provide an assessment on the impact to housing costs;
- DTSC fails to assess the costs of reporting requirements required by the regulations;
- DTSC has only completed a “Preliminary” economic analysis, and must provide a “Final” analysis for public review and comment before adopting the regulations;
- DTSC fails to provide alternatives to the regulations and the costs of those alternatives compared to the regulations;
- DTSC fails to provide a complete fiscal impact to State government; and
- DTSC fails to assess the impact of the regulations on local governments.

Response:

DTSC respectfully disagrees with these comments. As part of its Initial Notice of Rulemaking and Initial Statement of Reasons (ISOR), DTSC completed a Standard Form 399 Economic and Fiscal Impact Statement (Std. Form 399) for the Safer Consumer Products Regulations. DTSC included three attachments to supplement the Std. Form 399. The first attachment provided supplemental information to the responses on the Std. Form 399. The second attachment was an Economic Analysis of the Regulations prepared by an outside contractor. The third attachment provided a more detailed explanation of the costs to the State. It is true that DTSC was not able to provide a dollar amount for the estimated economic and fiscal impact to businesses and government. However, the attachments to the Std. Form 399 provided factors that would impact the costs to businesses and government. Further, DTSC indicated in the Std. Form 399 that the regulations would likely qualify as "major regulations." The Std. Form 399 indicates a major regulation would cost business enterprises more than $10 million. Senate Bill 617, which took effect January 2012, changed a major regulation to one costing business enterprises more than $50 million. In the first attachment to the Std. Form 399, DTSC provided a few examples of costs businesses might incur for one aspect of the regulations. One example estimated the cost for this one aspect of the regulations, conducting Alternatives Analyses (AA), as $110 million for 100 businesses. The Std. Form 399 plus the attachments together constitute DTSC's compliance with its obligations under the APA.

More importantly, DTSC provided as much information as possible in response to the questions on the Std. Form 399. In Attachment 1 to the Std. Form 399, DTSC expanded on its response of "Unknown" for the total number of businesses impacted, explaining it did not "include an estimate of the number of businesses impacted by the regulations or the total costs to the private sector because it is not possible, due to the nature of the regulations to make those estimates until implementation is under way." Under the January 2013 version of the regulations as well as the current version of the proposed regulations (April 2013), DTSC will comply with all of the requirements of the APA whenever it lists Priority Products. (See section 69503.5(a)(2) (January 2013)). The Safer Consumer Products Regulations only specify and describe the processes that DTSC will use to list Priority Products, the requirements that responsible entities must follow if one of their products is listed as a Priority Product, and the actions DTSC may take once businesses conduct Alternatives Analyses of their Priority Products. In other words, these proposed regulations do not impose any obligations or mandatory duties on any businesses. That one fact is responsible for most, if not all, of the tremendous limitations on DTSC's ability to predict with any certainty the economic impacts of the former proposed regulations being adopted. Once a Priority Product is listed many of the unknowable factors that prevented DTSC from identifying the number

of businesses impacted or the costs to businesses to comply with the regulations will be better defined, and DTSC will be able to prepare a more quantitative economic and fiscal impact statement instead of the qualitative economic and fiscal impact statement prepared for the July 2012 proposed regulations. Further, as pointed out above, the economic and fiscal impact statement will be required since the Priority Product listing process will comport with the APA.

Finally, DTSC's Std. Form 399, Economic and Fiscal Impact Statement was marked "Preliminary" because DTSC was waiting to finalize the Std. Form 399 until after the regulations were in their final form. By waiting until the regulations were in final form, any changes to the regulations that would have an effect on the Economic and Fiscal Impact Statement could be incorporated into a final Std. Form 399 and its attachments. Significant changes to the proposed regulations were made in January 2013 and April 2013 that had major impacts on the Std. Form 399. As a result, DTSC issued a revised Std. 399 for a 15-day public comment period. The revised Std. 399 reflected the changes made to the proposed regulations, as well as fixing an inaccurate statement concerning reporting that was in the "Preliminary" Std. Form 399.

DTSC is making no change to the regulations in response to these comments.

Comments: 9-2, 13-3, 14-2, 22-11, 47-8, 99-3

Comments Summary:

These comments urge DTSC to withhold submitting the Safer Consumer Products Regulations to the Office of Administrative Law until DTSC completes an economic analysis on the regulations complying with SB 617, as was requested in correspondence between members of the Legislature and the Governor.

Response:

On October 1, 2012, certain members of the Legislature sent the Governor a letter expressing concern over the economic analysis of the Safer Consumer Products Regulations prepared by DTSC and requesting that DTSC delay resubmitting the regulations to the Office of Administrative Law until after an economic analysis on the regulations complying with SB 617 was completed and submitted for review and comment by the parties impacted by the regulations. On November 9, 2012, DTSC received a letter signed by Senator Rubio and several other legislators stating that based on the October 5, 2012 letter from DTSC in which DTSC committed to conduct an economic analysis when a Priority Product was listed, Senator Rubio and the other signers were no longer seeking a delay in the regulations.

The proposed Safer Consumer Products Regulations require DTSC to complete the APA process for each Priority Product listing. As discussed above, this ensures that a more focused and quantitative economic and fiscal impact assessment will be conducted on the specific products—Priority Products—subject to the requirement that they undergo an Alternatives Analysis. That is the first opportunity and most appropriate point in the adoption/implementation of these regulations that an economic and fiscal impact assessment may be conducted that provides more specific dollar figures. DTSC is making no change to the regulations in response to these comments.

ESTIMATED PRIVATE SECTOR COST IMPACTS

Number and Type of Businesses Impacted

Comments: 9-28, 22-1, 47-3, 47-8, PH3-1, PH3-5, PH9-1, PH30-4, PH33-2

Comments Summary:

These comments express concern that DTSC has not provided an estimate of the number and type of businesses impacted.

Response:

DTSC agrees that it did not provide a numerical value for the number of businesses impacted. DTSC also did not state specific industries that would be impacted. However, DTSC did describe the businesses or entities that were required to comply with the regulations (manufacturers, importers, and retailers of consumer products that became listed as Priority Products). In addition, DTSC described what requirements the regulations would place on businesses. DTSC explained that it could not estimate the number of businesses or types of businesses impacted until the regulations were implemented. That is, DTSC could not estimate the number or types of businesses impacted until DTSC listed specific products as Priority Products that must undergo an Alternatives Analysis. Under the revised proposed regulations, DTSC will go through the formal rulemaking process when it lists a Priority Product. At that time, DTSC will be able to estimate the number of businesses and types of businesses that will be impacted. DTSC would expect that it may be able to refine the number and types of businesses impacted based on comments received from affected parties during the rulemaking process. DTSC is making no change to the regulations in response to these comments.

Number or Percentage of Total Businesses Impacted that are Small Businesses

Comments: 9-30, 22-2, 34-4, 41-2, 47-3, 47-8, 79-1, 95-5, 101-6, 101-7, 101-8, 135-2, 159-1, 172-1, PH7-3, PH30-4

Comments Summary:

These comments expressed concern that the number of small businesses impacted was not identified, that the regulations would overwhelm small businesses in the worst economic times, and that DTSC had not identified the true impact on small and medium-sized businesses or made considerations in the regulations to assist small businesses with compliance with the regulations.

Response:

DTSC is unable to quantify the number of small businesses impacted for the same reason that it was unable to quantify the total number of businesses impacted. Until the Priority Product(s) are identified, DTSC cannot accurately estimate the number of businesses impacted that are small businesses. Since DTSC will be going through the rulemaking process each time a Priority Product is identified, under the revised proposed regulations, DTSC would have more information available and would be able to provide an estimate of the number of small businesses impacted.

Creating exemptions for small to medium-sized businesses is not authorized under Health and Safety Code sections 25251 through 25257.1, the authorizing legislation. The regulations have options that any business, including small and medium businesses, may avail themselves of that may help to reduce cost. A group of manufacturers or other “responsible entities,” whether large, medium or small, may work together to offset the costs of performing an AA on their own and achieve a common goal. Businesses are allowed to use an already prepared AA, if it meets their needs. The requirement for AAs to be performed by certified assessors has been eliminated from the regulations. Businesses that are not manufacturers will not be required to comply with regulatory responses imposed by DTSC for engineered safety measures/administrative controls, end-of-life management requirements, and the advancement of Green Chemistry and Green Engineering. (See discussion of Article 6 Regulatory Responses for a detailed discussion of this issue.)

Further, when deciding whether to list a product-chemical combination as a Priority Product, DTSC may also consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible. Proposed section 69501.1(a)(29) (January 2013) of the regulations defines “economically feasible” to mean “an alternative product or replacement chemical does

not significantly reduce the manufacturer's operating margin." By including the "economic feasibility" of a readily available safer alternative as potential criteria for listing a product-chemical combination, DTSC has the ability to consider whether the negative economic impacts would outweigh the public health and environmental benefits of listing a product-chemical combination.

A business may decide during the AA to retain the Priority Product based in whole or in part on internal cost impacts; however, this decision must be explained in the Final AA Report. The Final AA Report must include a quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs. If a business does decide to retain the Priority Product, DTSC must consider economic feasibility—among other factors—in determining a regulatory response it may impose, if any, on the business.

Requiring both the business entity and DTSC to look at the economic feasibility of proposed actions should help balance cost impacts on businesses with the public health and environmental benefits of the actions. DTSC is making no change to the regulations in response to these comments.

Number of Businesses that will be Created or Eliminated/Number of Jobs that will be Created or Eliminated

Comments: 14-4, 34-4, 41-2, 41-75, 47-7, PH30-3, PH33-2

Comments Summary:

These comments express concerns that compliance with the regulations is so costly or creates such burdens that it will drive businesses/jobs out of California; small and medium-sized businesses will not be able to absorb the costs of compliance and will go out of business; the regulations will cause a disincentive for businesses to come to California; and Attachment 2, "Economic Analysis of California's Green Chemistry Safer Consumer Products Regulations," contradicts itself when it states impacts will be minimal because most manufacturing takes place out of California, yet California business will have an advantage in gaining market share.

Response:

DTSC has combined the responses to this series of comments because the concepts are related and DTSC's response is similar. DTSC acknowledges that as these regulations are implemented and Priority Products are listed through the APA process, businesses will incur costs. However, the adoption of these regulations and the

implementation of them will not just impact businesses in California; they will impact manufacturers in other states and countries. The primary responsibility for implementing the regulations is with the manufacturer of the Priority Product, regardless of the place of manufacture, and many manufacturers are located outside of California.

Many of the comments failed to acknowledge that these regulations have the potential for creating new businesses or jobs. While the regulations no longer require the use of a certified assessor businesses and individuals capable of performing Alternatives Analyses will be in demand and these regulations may well stimulate growth of businesses/jobs in these areas. These regulations may also stimulate growth and innovation in the production of “green” products. The Economic Analysis attached to the Std. Form 399 projected that California businesses might have an advantage over non-California businesses in producing “green products” due to the educational level of the California workforce, the presence of many academic institutions, and the access to capital in California.

DTSC respectfully disagrees that Attachment 2 to the Std. Form 399 is contradictory about its statements concerning California businesses and job creation. In Attachment 2, Section 4.2 “Regulation’s impact on existing California employment” predicts that the regulations will have the largest impact on the chemical industry. Section 4.2 provides data on the size of the chemical industry in California compared to the national statistics and the data show that California has relatively few chemical manufacturing jobs. Section 4.5, “Regulations’ impact on future job creation in California,” identifies factors that will provide an advantage to existing California businesses to gain market share by producing new “greener” products in response to the regulations, as was briefly discussed above. DTSC is able to envision a scenario in which an existing California business would cease producing a Priority Product, thus requiring a reduction in jobs, yet at the same time develop a new product(s) without the specific chemical/product combination increasing customer demand and thus resulting in the creation of new jobs.

At this time, any estimates of business creation/elimination or job creation/elimination are speculative, since no Priority Products have been listed. As Priority Products are identified, DTSC may well discover additional information for the specific products to address the number of businesses or jobs that have the potential to be created or eliminated. Accordingly, at the time DTSC lists Priority Products, and conducts another economic and fiscal impact analysis as part of the rulemaking process for the listings, DTSC will be in a much better position to provide a more quantitative and detailed analysis. DTSC is making no change to the regulations in response to these comments.

Geographic Impact of the Regulations

Comment: PH3-6

Comment Summary:

Comment requests that the initiative and the publication of the final regulation be postponed until DTSC can adequately assess the economic impact of implementation on businesses both inside and outside of California and stakeholders are allowed to comment.

Response:

DTSC concurs that implementation of this regulation will impact businesses both inside and outside of California. However, DTSC has no requirement under the APA to assess the economic impact on businesses outside of California. Other responses in this section cover the economic impact to businesses inside California. DTSC is making no change to the regulations in response to this comment.

Ability of California to Compete with Other States/Regulation Will Slow California's Economic Recovery

Comments: 6-8, 41-2, 74-7, 135-3, PH7-3, PH8-3, PH27-1, PH31-4, PH33-1

Comments Summary:

These comments express general concern that implementation of these regulations will impact California's ability to compete, decrease sales, decrease tax revenues; or that implementation will slow California's economic recovery.

Response:

These regulations impact both businesses inside and outside California. The requirement on the Std. Form 399 is to address whether the regulation will make it more difficult for California businesses to compete with other states by making it more costly to produce goods and service here. DTSC has met this requirement and concluded that these regulations should not make it more costly for California businesses to compete because these regulations would equally impact the cost of producing goods both within and outside of California. In an article by Bergeson, Lynn L., "Dreaming no longer: California issues draft safer consumer products regulations," Environmental Quality Management, Volume 21, Issue 3, pages 81-91, Spring 2012, the author concludes that "…implementation of the Green Chemistry Initiative will have impacts far beyond the borders of California. Because the state represents such a big market, manufacturers

will likely conform their overall consumer-product specifications to California's regulatory criteria. The alternative—maintaining one set of product specs for California, and another set for other markets—is commercially infeasible and legally risky."

Since the proposed regulations were originally released in July 2012, DTSC has streamlined many of the processes required by the regulations and, thus, reduced the related costs on businesses that would be incurred during such steps. DTSC is very aware of the difficult economic times faced by all sectors of California's economy. It has drafted the regulations with this awareness in mind. Tremendous flexibility has been built into the regulations to accommodate businesses' concern about the burdens the regulations impose. Information-gathering requirements, as an example, have been revised to limit costs incurred, while still providing DTSC will information it needs to make the regulations work. DTSC is making no change to the regulations in response to this comment.

ESTIMATED COSTS

What are the Total Statewide Costs that Businesses and Individuals May Incur to Comply with This Regulation Over its Lifetime?

Comments: 22-7, 31-3, 34-1, 38-11, 40-2, 41-2, 41-72, 41-73, 41-75, 57-9, 74-11, 135-2, 139-10, 163-2, 173-1, PH7-3

Comments Summary:

These comments express concern that: the regulations are too costly to businesses and taxpayers; that the regulations are generally too burdensome; that DTSC's Economic and Fiscal Impact Statement downplays the costs associated with the loss of trade secrets; DTSC does not acknowledge the high costs of reporting and data collection; and higher short-run costs are not justified by lower longer-run costs.

Response:

DTSC acknowledges that implementation of these regulations will be costly. However, DTSC believes that the benefits will outweigh the costs. DTSC has not been able to place a dollar value on the cost of implementing the entire Safer Consumer Products program. Better estimates of the costs and benefits will be made when DTSC goes through the rulemaking process for listing of the Priority Products. These regulations are necessary to implement Assembly Bill 1879 (Ch. 559, Stats. 2008), which requires DTSC to adopt regulations to establish processes to provide for safer consumer products.

DTSC respectfully disagrees that the "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products," Attachment 2 to Std. Form 399, downplays the costs associated with the loss of trade secrets. On page 15 of Attachment 2, the author acknowledges that trade secrets are valuable, and that losing trade secrets would be very costly for firms especially those companies that have made enormous up front research and development investments to design a product. DTSC agrees with the author's conclusion that the probability of a firm losing trade secrets is low and that the regulations include substantial trade secret protections to limit the possibility that trade secrets would be violated.

DTSC also disagrees that the author of the Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products," Attachment 2 to Std. Form 399, justifies higher short-run costs by lower longer-run costs. The author states that firms are likely to overestimate the long-run costs of implementing the Safer Consumer Products program. In the long run, firms can make adjustments for the regulations, unlike in the short-run. "The net effect of this enhanced "flexibility" is that long run regulatory compliance costs are likely to be much lower than short run costs." DTSC is making no change to the regulations in response to these comments.

If the Regulation Imposes Reporting Requirements, Enter the Annual Costs a Typical Business May Incur to Comply with These Requirements

Comment: PH8-3

Comment Summary:

The comment expresses concern that Section one of the Std. Form 399 fails to note this regulation will impact complex competitiveness and imposes significant reporting requirements, contradicting the assessment in Attachment 2 of that very same filing.

Response:

DTSC's response on Attachment 1 to the Std. Form 399 was that not all businesses would be required to report. However, DTSC inaccurately stated that the regulations did not require *any* annual reporting. There are instances when annual reporting will be required. Annual reporting, when required, would only occur upon adoption of Priority Products regulations. DTSC disagrees that there are any statements in Attachment 2, "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products," that conflict with DTSC's response on Attachment 1 regarding reporting. Section 3.1, "Cost of testing and reporting for Priority Products," is the only section where reporting is included in Attachment 2. However, this section only discusses the

costs of testing products, not preparing reports, and thus DTSC disagrees that this section contradicts DTSC's statement in Attachment 1.

Implementation of these regulations will require significant amounts of information and/or reports from some of the responsible entities. DTSC did note that responsible entities for Priority Products would have to conduct AAs and submit the appropriate reports to DTSC.

DTSC provided information on a range of costs for conducting AAs in the preliminary Std. Form 399. Below is a more complete list of the information, reports, or notifications required of responsible entities for Priority Products. This reporting will be required when DTSC proposes Priority Products regulations. At that time, DTSC will have to provide estimates for the reporting.

Chemical and Product Information

The regulations require that DTSC obtain information necessary to implement the regulations. DTSC is to obtain that information from existing sources in the public domain, through the purchase of information in the public domain, or DTSC may request any business to provide any existing or generate new chemical or product information. DTSC may send correspondence directly to businesses from which it seeks information or it may post call-in requests on its website requiring all businesses with the information to provide it to DTSC. Businesses are not required to provide existing or generate new chemical or product information. If businesses do not provide or generate the information, DTSC will place their names on a Failure to Comply List. At this time, DTSC does not know what specific information it needs and what is available in the public domain. DTSC cannot estimate the cost to businesses if they decide to comply with any potential request. Because businesses do not have to provide the information, it is reasonable to assume that information, either existing or generated specifically in response to a request, will be provided if it makes business sense.

Alternatives Analyses

There are several different types of AA Reports a responsible entity may be required to prepare depending upon the option the responsible entity selects for compliance with the AA requirement. The following is a list of the types of reports that could be required: Preliminary AA Report, Abridged AA Report, Alternate Process Work Plan, or Previously Completed AA Report, Final AA Report, AA Report Addendum, or Annual Progress Reports for completion of Final AA. Note: DTSC does not mean to imply that any one responsible entity for a Priority Product would have to comply with all of these

reporting requirements. Rather, DTSC is indicating that there is quite a menu of options for reporting compliance from which responsible entities may select.

Notifications

Priority Product Notifications—all responsible entities for Priority Products must submit this information.

Notifications required if responsible entity elects one of the following options (January 2013). (These notifications require providing significant amounts of information and data.):

- Chemical Removal Intent and/or Chemical Removal Confirmation Notification;
- Product Removal Intent and/or Product Removal Confirmation Notification;
- Product-Chemical Replacement Intent and/or Product-Chemical Replacement Confirmation Notification; or
- AA Threshold Notification.

The notifications above would only be required if a responsible entity chose to:

1) Remove a Priority Product from the market;
2) Remove the Chemical of Concern from the Priority Product without the replacement of other chemicals;
3) Replace the Chemical of Concern in the Priority Product with another chemical(s), as defined in the regulations; or
4) Demonstrate that the Chemical of Concern is only in the Priority Product as a contaminant and only at levels consistent with DTSC's AA Threshold limit.

Information and reporting pursuant to regulatory responses (January 2013):

1. Information to fill data gaps;
2. Information for consumers;
3. Product sales prohibition (no safer alternatives exist)—responsible entity has to provide information pursuant to section 69506.5(b)(2) to DTSC upon receipt of such a notice. Exemptions to sales prohibitions may be granted if responsible entity complies with other requirements;
4. End-of-life management requirements—product stewardship plans and annual reports after implementation;
5. Advancement of green chemistry and green engineering—research and development information;

6. Regulatory response exemption request—responsible entity must show that the regulatory response imposed conflicts or duplicates another State or federal agency requirement or a treaty;
7. Regulatory response notification to supply chain (required for all but two of the regulatory responses); and/or
8. Notification to DTSC that regulatory response has been implemented (DTSC may require subsequent reports).

DTSC may require a responsible entity to implement a regulatory response, item numbers one (1) through six (6) above. With each of these regulatory responses, a responsible entity would have to provide the information requested. If a responsible entity is required to implement a regulatory response, the responsible entity may also have to complete the notifications identified in item numbers seven (7) through eight (8) above. Not all responsible entities will be required to implement regulatory responses. However, the list above is provided to identify potential reporting requirements that some responsible entities may be required to comply.

In addition to the above reports, if a responsible entity chooses to dispute a DTSC decision or submit a trade secret claim, additional information is specified in the regulation that must be provided. Finally, responsible entities have to retain specific information in the event DTSC chooses to audit compliance with the regulations.

DTSC is making no change to the regulations in response to this comment. However, DTSC will be modifying Attachment 1 to the Std. Form 399 to more fully describe the reporting requirements that will be required of responsible entities when the Priority Products are listed.

ESTIMATED BENEFITS

Briefly Summarize the Benefits that May Result from these Regulations and Who will Benefit

Comments: 41-76, 41-77

Comments Summary:

The comments disagree with the analysis of the social benefits that may occur from these regulations. They point out that the “Economic Analysis of California’s Green Chemistry Safer Consumer Products Regulations” states there is a “fundamental uncertainty” on how the regulations will be implemented; thus, there is uncertainty that any benefits will occur, that the regulations create a disincentive for development of

safer products, and that consumers do not necessarily make healthier choices based on the availability of better information.

Response:

DTSC respectfully disagrees with the comments that benefits of the regulations are at risk because of the uncertainties in the regulations. DTSC did not quantify the benefits that would occur from the regulations for the same reason that it did not quantify the costs of the regulations. Without knowing which Priority Products that DTSC will identify, any quantitative prediction of costs or benefits of the regulations are highly speculative. DTSC took the approach of providing a qualitative analysis of the factors impacting costs and benefits.

DTSC also disagrees that the regulations will create a disincentive for innovation. The regulations directly require responsible entities to review their Priority Products to identify alternatives to make those products safer. Further, by identifying the Candidate Chemicals in the regulations, manufacturers have an opportunity as they are developing new products or modifying existing products to determine if the Candidate Chemicals are necessary and remove them or reduce their use in advance of DTSC potentially listing the product as a Priority Product.

DTSC will be listing the Priority Products in separate regulations. When those regulations are proposed, DTSC will have more specifics to enable it to quantify the benefits of the regulations as well as the costs. DTSC is making no change to the regulations in response to these comments.

ALTERNATIVES TO THE REGULATION

List Alternatives Considered and Describe Them. Summarize the Total Statewide Costs and Benefits from this Regulation and Each Alternative Selected.

Comments: 9-5, 9-29, 31-5, 47-7, 59-16, 61-3, 74-8, 95-2, 105-4,139-10, PH8-7

Comments Summary:

These comments, many of which cited the California Foundation for Commerce and Education's (CFCE), "The Consumer Impact of California's Green Chemistry Initiative," by Andrew Chang & Company, LLC, expressed concerns that the large costs of the regulations, which the CFCE report estimates to be cumulative costs of $170 billion over 25 years, greatly exceed the benefits—cumulative benefits of $21.1 billion over 25 years—as estimated in the CFCE report. In addition, some comments expressed concerns that DTSC did not adequately identify and assess the costs of alternatives.

Response:

DTSC respectfully disagrees with the comment that it did not provide sufficient information regarding the alternatives to the regulations in Attachment 1 to the Std. Form 399. Attachment 1 to the Std. Form 399 includes over two pages of information on the alternatives DTSC considered. As with the regulation, DTSC was unable to quantify the cost to implement the alternatives due to the number of unknowable factors just as DTSC was unable to quantify the actual costs of implementing the regulation.

Many of the comments cited the cost of the regulations prepared by the California Foundation for Commerce and Education (CFCE). CFCE calculated estimates for a Best Case, Optimistic Case, and Potential for Adversity Case. Costs were estimated based on:

- Cost of compliance (25th, 50th, or 75th percentile of costs estimated in literature review of the European Union's (EU) Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) Program;
- Cost of switching (25th, 50th, or 75th percentile of costs estimated in literature review of case studies of chemical switching); and
- Portion of market impacted (quotient of number of products DTSC estimates will be Priority Products [85] divided by number of chemicals produced in the U.S. [6,759] {low}, midpoint of low and high, quotient of number of products DTSC estimates will be Priority Products [85] divided by the number of chemicals produced in California [251] {high}).

In the Potential for Adversity Case, CFCE estimates that the Safer Consumer Products Regulations will cost $7.8 billion in the 25th year of implementation with cumulative costs over 25 years of $173.0 billion, cumulative benefits of $21.1 billion, with a loss of 103,000 jobs in Year 25 and 123,000 jobs at the high point. In the Optimistic Case, which CFCE says is the most likely, costs in Year 25 are $2.1 billion, cumulative costs over 25 years are $46.1 billion, cumulative benefits of $21.1 billion, with a loss of 28,000 jobs in Year 25 and 32,000 jobs at the high point.

DTSC is unclear as to how the CFCE economic model could accurately predict the costs of implementing the entire Safer Consumer Products program including all the Priority Product listings over a 25-year period based on the variables in their model.

DTSC believes that in order to provide any credible dollar estimate of the costs of the Safer Consumer Products Regulations, at a minimum, values for the following variables, which were not available to either DTSC or CFCE would be needed (note: these factors

do not include any data needed to estimate benefits of replacing the Priority Product, the "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products," Attachment 2 to the Std. Form 399 also identifies variables needed to estimate a dollar value):

- Number of Priority Products;
- Number of Chemicals of Concern in the Priority Products;
- Number of manufacturers of the Priority Product(s);
- Availability of alternatives;
- Availability of chemical data to the manufacturers on the Chemical(s) of Concern and the its replacement;
- Operating cost to produce the Priority Product(s) with the Chemical of Concern;
- Process or capital cost of producing the Priority Product(s) with the Chemical of Concern;
- Change in the production cost of implementing the selected alternative. (Are capital costs needed to change the production line? Are cost of chemical inputs higher?);
- Change in the characteristics of the product that would impact the operating cost (more or less labor needed to produce the product, more or less energy to produce the product);
- Change in the attributes of the product due to the change in the product composition that would impact the downstream user (for example, the change in the durability of a consumable product—Priority Product would have to be replaced every 6 months with labor costs of 15 minutes at $20 an hour; alternative products would have to be replaced every 5.5 months with labor costs of 15 minutes at $20 an hour);
- Number of units sold currently;
- Number of units expected to be sold after the change (the availability of alternatives on the market to the downstream user); and
- Elasticity of demand for the product by consumers.

To predict the cost of compliance, CFCE has assumed that DTSC's Safer Consumer Products program would be between the 25th and 75th percentile of the estimated costs of the EU's REACH Program. CFCE states that DTSC's Safer Consumer Products program is much larger than REACH. However, DTSC respectfully disagrees with that assessment. The costs included for REACH in the CFCE estimates include the cost to businesses to collect, test and submit data for all substances used per year of 1 ton or more, the fees paid by the businesses, costs of businesses to switch to safer substances if a substance is restricted, costs passed on to consumers and the cost

European Chemicals Agency. The REACH Program is much broader in scope than the Safer Consumer Products program. The REACH Program impacts thousands of chemicals used in the EU, including substances in articles (or products). The Safer Consumer Products program only impacts a small number of consumer products that DTSC identifies as Priority Products and the initial list is further limited to five (5) Priority Products. Further, the European Chemicals Agency is significantly larger than DTSC's Safer Consumer Products program with more staff (a recent fact sheet indicated that the European Chemical Agency had 500 staff members excluding enforcement, scientific and expert committees), a larger information technology budget, and a larger budget for administration. Therefore, estimating the economic cost of DTSC's Safer Consumer Products program as a percentage of the cost of the entire REACH program is comparing apples to oranges. It should also be noted that the EU's initial Extended Impact Analysis showed that the benefits of REACH outweighed the cost of the program. Below is a brief overview of the REACH program:

REGISTER: Register any substance of one (1) ton or more per year manufactured or imported into the EU, which includes providing data on the properties of the substance including an assessment of the hazards and potential risks. The registration data requires entities to test their substances. Registration of substances is being phased-in through 2018. To date, the European Chemicals Agency has received over 33,000 data reports on over 8,000 different substances. In 2013, the European Chemicals Agency is expecting 6,000 more data packages. More importantly, this registration is required of substances in articles (products) if certain requirements are met (whether the substance is intended to be released and if the quantity of substance in the article exceeds one ton per year produced or imported by one entity). In its "Guidance on requirements for substances in articles, Version 2, April 2011 (Reference ECHA-11-G-05-EN, April 2011), the European Chemicals Agency provided an example of a situation where a producer of a t-shirt containing a fragrance would be required to register the fragrance substance in the t-shirt.

EVALUATION: The European Chemicals Agency and its member states then evaluate the chemical information submitted on the Registration documents to determine if any of the substances pose a risk to human health or the environment. Evaluation focuses on a review of the testing data submitted by the registrants, compliance check of the information, and substance evaluation. The European Chemicals Agency may request an entity to provide additional information. After evaluation, if the substance still poses a risk, then the EU can request that the substance be classified and labeled, prepare a proposal to identify the substance as a Substance of Very High Concern, prepare a proposal to restrict the substance, or refer for actions outside of REACH.

AUTHORIZATION: Substances proposed as a Substance of Very High Concern go through an evaluation process. The first step is listing on the Candidates List of Substances of Very High Concern. Once listed on the Candidates List, European entities have specific notification responsibilities to customers about the substance, the substance in a mixture or the substance in an article. Exporters to the EU do not have the same requirements, but EU Importers do have some responsibilities. Substances on the Candidate List are then evaluated to determine if they should be listed as requiring Authorization. Once a substance is on the Authorization List (Annex XIV), entities wishing to use the substance must submit an Authorization request. Once an authorization is received, the European Chemicals Agency prepares a risk assessment and socio-economic analysis. The European Commission decides whether to grant the authorization to use the substance.

RESTRICTION: Restrictions limit or ban the manufacture, placing on the market or use of certain substances that pose an unacceptable risk to human health and the environment. The European Chemicals Agency evaluates whether the suggested restriction is the appropriate measure to reduce the risk to human health and the environment. The European Chemicals Agency balances the pros and cons of the restriction for society, based on the information provided by proposals and the comments received. The committee analyzes the health and environmental benefits, the associated costs and other socioeconomic impacts of the restriction. If approved, the restriction is submitted to the European Commission where it will be adopted if not opposed.

Under the proposed Safer Consumer Products Regulations, DTSC may request information from businesses on any chemical or product. Businesses are not required to provide the information. Once DTSC prepares a Priority Products list, the list will be submitted as a separate rulemaking under the APA. At that time, DTSC will have more information and many of the unknowable items in the current Std. Form 399 will be known and DTSC will be able to provide a more thorough analysis of the economic impacts and benefits of implementing the Priority Product List.

Responsible entities are only required to implement the Safer Consumer Products process when the Priority Product list is adopted. Once the Priority Product is listed, responsible entities are required to notify DTSC, conduct an AA to determine if there are any feasible alternatives to the Chemical of Concern, and implement the alternative and regulatory responses required by DTSC, if any. The AA required by the Safer Consumer Products process is very similar to the Authorization process in REACH,

except that responsible entities may have to spend more time collecting data that they would have already had to collect under the Registration process of REACH. The "Restriction" aspect of REACH is similar to the some of the regulatory responses DTSC may require a responsible entity to implement. Like the REACH program, DTSC has to evaluate the economic feasibility of implementing regulatory responses as part of its determination regarding which regulatory response, if any, to impose.

While there are some similarities in certain aspects of the REACH and Safer Consumer Products programs, the scope of the Safer Consumer Products program is significantly smaller than REACH. The entire Safer Consumer Products program is focused on chemicals in consumer products while REACH is focused on the substance. DTSC must identify a chemical-product combination as a Priority Product before a responsible entity is required to take actions under the Safer Consumer Products program. REACH does not have to make a determination that the presence of substance in a product is an issue. Rather, if a business is producing or importing a substance in an article (product) that is intended to be released and the total volume of the substance in the articles produced or imported exceeds 1 ton per year per business, the producer/importer is required, with some exceptions, to prepare a registration document for the substance. In addition, if a substance is on the Candidate List of Substances of Very High Concern, there are certain situations where businesses that produce or import articles (products) containing that substance are required to notify the EU. DTSC is making no change to the regulations in response to these comments.

Comment: 36-111

Comment Summary:

This comment expressed concerns that industry statements of the cost (loss of jobs) of the regulations are too high and that the societal benefits (health and worker productivity and creation of jobs) are understated.

Response:

DTSC concurs with the comment that estimates of job losses by the industry commenters that cite to and rely on the CFCE report appear to be too high and that the societal benefits are understated. DTSC believes that when the Priority Product Listing regulations are submitted for public comment that DTSC will have better information on potential impacts to jobs as well as the benefits of the proposed regulations. DTSC is making no change to the regulations in response to this comment.

Comments: PH20-1, PH20-2, PH24-6, PH24-7

Comments Summary:

These comments expressed concern that the Std. Form 399 did not adequately quantify the benefits of the regulations to waste water treatment plants believing that the cost to treat wastewater to remove chemicals is much higher than the cost to industry to address the chemical before it is released.

Response:

DTSC concurs with the comments that the environmental benefits in the preliminary Std. Form 399 and its attachments did not adequately address all potential benefits of the regulations. DTSC acknowledges that the cost to remove contaminants from the environment, in this case wastewater, is likely much higher than the costs to remove the contaminants from products. DTSC will be in a better position to estimate the economic benefits of the Priority Products listings when those regulations are adopted, as DTSC will have information on the potential for the Chemical of Concern to impact the environment. DTSC is making no change to the regulations in response to these comments.

Rulemaking Law Requires Agencies to Consider Performance Standards as an Alternative, if a Regulation Mandates the Use of Specific Technologies or Equipment or Prescribes Specific Actions or Procedures. Were Performance Standards Considered to Lower Compliance Costs?

Comment: 59-15

Comment Summary:

The comment expressed concerns that the Safer Consumer Products Regulations force all manufacturers of a given product to utilize a favored technology, thereby eliminating the California consumer's right to choose.

Response:

DTSC respectfully disagrees that the Safer Consumer Products procedures require that manufacturers of a Priority Product utilize a favored technology. The Safer Consumer Products Regulations do not mandate any specific technologies or equipment. The Safer Consumer Products Regulations do prescribe specific actions or administrative procedures to which responsible entities of Priority Products must adhere. However, the Safer Consumer Products Regulations provide a great deal of flexibility on how the actions are to be performed. In the AA process, responsible entities are responsible for identifying the functional, performance, and legal requirements of the Priority Product

that must be met by the potential alternatives to the Chemical of Concern. The responsible entity selects the alternative(s), if any, to replace the Priority Product. It is possible that two different responsible entities of a similar Priority Product will select different alternatives, if any. DTSC does not have the authority to approve the alternative. Once the responsible entity selects the alternative, DTSC has the authority to mandate regulatory reforms, if any, to protect health and the environment. In general, performance standards are not applicable to these regulations. DTSC is making no change to the regulations in response to this comment.

FISCAL IMPACT STATEMENT

Fiscal Effect on Local Government

Comments: 118-11, PH20-1, PH20-2, PH24-6, PH24-7

Comments Summary:

These comments expressed concern that DTSC did not adequately assess the costs to local communities of exposure to harmful chemicals and the ecological impacts that occur. In addition, the comments expressed concern that DTSC did not adequately assess the cost to local communities of removing chemicals from wastewater. With over 300 wastewater treatment plants, costs to remove chemicals through wastewater treatment are in the billions of dollars.

Response:

In preparing the Std. Form 399, DTSC focused on the potential cost to local agencies from changes in the cost of Priority Products. DTSC did not evaluate the costs local communities were currently incurring due to the presence of chemicals in the local community, such as costs to remove chemicals from wastewater at wastewater treatment plants as such an analysis would be purely speculative until DTSC identified Priority Products. When the Priority Product Listing regulations are going through the rulemaking process, DTSC will work with local agencies to get input on any costs that they may be incurring due to the presence of the Chemical of Concern in the local environment. DTSC is making no change to the regulations in response to these comments.

Fiscal Effect on State Government

Comments: 9-26, 9-27, 59-2, 59-7, 139-4, PH8-3, PH8-5, PH8-6

Comments Summary:

These comments expressed concern that: DTSC has underestimated the costs to implement the program, the costs are in excess of DTSC's resources, implementation would create a huge government program, and DTSC would require $9 million to $27.2 million annually for next six (6) years to implement the program.

Response:

DTSC has redirected $6.2 million in existing funding to implement the Safer Consumer Products program. DTSC received approval from the Legislature and the Governor through the adoption of the Budget Act to make this redirection. DTSC acknowledged in Attachment 1 to the Std. Form 399 that the budget was a conservative amount based on a limited Priority Products list. DTSC further indicated that as it gained experience in implementing the regulations, resource needs could change as the Priority Products list expands and as DTSC identifies improvements and efficiencies. DTSC is making no change to the regulations in response to these comments.

Comment: 36-1

Comment Summary:

This comment expressed concern that DTSC did not have sufficient resources to implement the program and should be given additional funds.

Response:

DTSC appreciates the concern raised in the comment. As DTSC gains experience with the program, resources needs could change as the Priority Products list expands and as DTSC identifies improvements and efficiencies. DTSC is making no change to the regulations in response to this comment.

OTHER ECONOMIC AND FISCAL IMPACT STATEMENT COMMENTS

Economic Analysis is Biased Toward Industry

Comments: 41-66, 41-67, 41-68, 41-69, 41-70, 74-11

Comments Summary:

The comments express concerns that Attachment 2 to the Std. Form 399 negatively portrays industry with unsubstantiated generalizations that characterize industry as "profit seeking" with "agendas" based on the supposition that industry does not take responsibility for and knows little of the composition and safety of its products.

Response:

DTSC agrees that the statements above were included in Attachment 2 to the Std. Form 399. However, DTSC disagrees that the economic analysis was biased towards industry or that some of the generalizations negatively portrayed industry. For example, DTSC does not agree that the term "profit seeking" is a negative portrayal of industry. commercial enterprises exist to make a profit and businesses that sell stock want to maximize profits for their shareholders. "Profit seeking" is a neutral statement of fact. The author writes in plain English making the "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products" much more readable for the lay person. DTSC is making no change to the regulations in response to these comments.

Regulations Allow Regulators to Pick Winners and Losers

Comments: 41-74, 41-85

Comments Summary:

The comments express concern that the regulations allow DTSC to pick businesses that will benefit from the regulations at the expense of businesses that will be harmed by the regulations.

Response:

DTSC disagrees that the regulations "pick" winners and losers. There is no requirement that responsible entities select a safer alternative. Each responsible entity decides, based on the AA, what the best course of action is for itself after considering the factors that must be considered during the analysis. DTSC acknowledges that as Priority Products lists are adopted, businesses will be required to adapt to a new environment, and current business practices may need to change. On page 5 of the "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products" under the heading, "Incentives for innovation and eliminating the barriers to market efficiency," the author says that some firms will lose sales because they produce a product containing a Chemical of Concern while other firms will gain sales because they make a comparable but safer product and these are not social costs of the regulations but a shift of sales from one business to another. On page 11, the author states that there is "ample evidence from the industrial organization literature that through a competitive process firms adapt to new circumstances that they face." DTSC is making no change to the regulations in response to these comments.

Flawed Comparison of the Regulations to the European Union's REACH Program

Comments: 41-78, 41-79, 41-85, 74-11

Comments Summary:

These comments express concern that parallels drawn in the "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products" between REACH and the proposed regulations are inaccurate and that the author lacks and understanding of REACH and thus any mitigation of the economic impacts of proposed regulations based on these flawed assumptions should be negated. As a specific example, the comments express concern that DTSC's regulations allow concentration limits to be set on a case-by-case basis as opposed to REACH where 1.0% and 0.1% de minimis concentrations are applied. Thus, the assumption that compliance with REACH will equal compliance with the proposed regulations and would mitigate the economic impact is incorrect.

Response:

DTSC respectfully disagrees that there are significant parallels drawn between DTSC's implementation of the Safer Consumer Products Regulations and the REACH program in the "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products" or that compliance with REACH equals compliance with the Safer Consumer Products Regulations. In fact, as stated on page 11 of "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products," the author did not rely on the REACH program in identifying the factors that affect the economic impact of DTSC's regulations:

> "A second approach for generating predictions about a new regulatory program is to use statistical estimates of the effects of similar past regulatory efforts to extrapolate about the consequences of this new regulation. Unfortunately, from a research perspective, the draft AB 1879 regulations represent a unique law that has not been implemented elsewhere. While Europe started its REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulations in 2007, we do not have a sufficiently long history of regulatory compliance with these types of regulations to be able to statistically estimate how different firms adapt to similar regulations. We have carefully searched for relevant past cases, and we will below discuss examples that we believe speak to the likely consequences of these regulations but we are not aware of any regulatory actions that are closely similar to this specific regulatory action."

DTSC is making no change to the regulations in response to these comments.

Comment: 41-80

Comment Summary:

The only requirement to comply with REACH with respect to Substances of Very High Concern in the import of articles into Europe is to provide information to the consumer, upon request, about the presence of the Substance of Very High Concern if it is above a level of 0.1%.

Response:

DTSC acknowledges this comment. DTSC would also like to note that there are also conditions under which a notification to the European Chemicals Agency is required when an article contains a substance listed on the Candidate List for Substances of Very High Concern. However, DTSC does not see how the comment applies to the Economic and Fiscal Impact Statement prepared by DTSC. DTSC is making no change to the regulations in response to this comment.

Comment: 41-81

Comment Summary:

Only EU manufacturers of articles containing Substances of Very High Concern are required to obtain authorization for that use. This creates an advantage for the non-EU manufacturers of articles containing Substances of Very High Concern, as they do not have to apply for an authorization to use the Substances of Very High Concern and, further, they can freely import the Substances of Very High Concern containing article into the EU.

Response:

DTSC concurs that non-EU manufacturers of articles containing Substances of Very High Concern do not have to comply with the REACH regulations. However, the importer, who is established in the EU, may have information and notification requirements under REACH. DTSC believes this statement has been made to distinguish REACH requirements with the proposed regulations where non-California manufacturers would have the primary responsibility for complying with the Safer Consumer Products Regulations. Other entities would be required to respond if the non-California manufacturer does not comply. By requiring both California and non-California manufacturers to comply with the SCP regulations, DTSC is not conveying an advantage to non-California manufacturers, thereby ensuring a level playing field for industry. DTSC is making no change to the regulations in response to this comment.

Comment: 41-82

Comment Summary:

The REACH framework allows for the demonstration for of the negative exposure even where Substances of Very High Concern may be known to be present in a finished article. This is in stark contrast to the proposed regulations where the mere presence of a substance in a product is presumed to result in exposure and triggers an AA.

Response:

DTSC respectfully disagrees that the mere presence of a Candidate Chemical in a product is presumed to result in exposure and triggers an AA. Proposed section 69503.2(a) (January 2013) requires that any consumer product must meet both of the following criteria before it may be identified as a Priority Product: there must be a potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and there must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

DTSC does not see how the comment applies to the Economic and Fiscal Impact Statement prepared by DTSC. DTSC is making no change to the regulations in response to this comment.

Comment: 41-83

Comment Summary:

The comment expresses concern that the Economic Impact Analysis includes a presumption that “drop-in” alternatives are readily available from within the European market. The comment also expresses concern that the proposed regulations do not provide similar shared responsibility by the end user as is provided under REACH and that this responsibility under REACH plays a significant role in mitigating human and environmental exposure concerns.

Response:

DTSC respectfully disagrees with the comment that DTSC’s economic analysis presumes that “drop-in” alternatives are readily available from within the European market. The only instance where the Economic Analysis of California’s Green Chemistry Regulations for Safer Consumer Products uses the term “drop-in” is when referring to “drop-in” or “add-on” technologies (see page 17) available to re-engineer production processes. The availability of such technologies would lower compliance

costs. There is no mention of the technologies being available from the EU. DTSC is making no change to the regulations in response to this comment.

Comment: 41-84

Comment Summary:

The comment expresses concern that REACH is a risk-based approach versus the strictly hazard-based approach that is contemplated by the proposed regulations. REACH allows a hazardous substance to be retained in a product if, over the life cycle of the product, the risk of exposure to the hazardous substance is acceptable.

Response:

DTSC respectfully disagrees with this comment. As stated in the Response to Comment 41-82 above, DTSC must demonstrate that there is a potential for exposure to the Candidate Chemical before DTSC may list a product as a Priority Product. Further, DTSC's regulations are not the same as the REACH regulation; thus, requirements under DTSC's regulations will be different from REACH. DTSC is making no change to the regulations in response to this comment.

MISCELLANEOUS

Comments: 5-49, 19-52, 22-11, 23-2, 29-6, 55-2, 57-21, 78-7, 80-1, 85-2, 87-2, 87-12, 107-2, 113-1, 125-10, 133-1

Comments Summary:

The above listed comments either summarize the comments that have been included in a comment letter or incorporate the comments of another entity's comment letter by reference.

Response:

Because all of the substantive comments that these comments are summarizing or incorporating have been responded to separately in this document, DTSC is not providing any additional response to these comments. Any additional responses would be completely redundant. DTSC is not making any changes to the regulations in response to these comments.

Comments: 11-11, 40-4

Comments Summary:

These comments pertain to the External Scientific Peer Review (ESPR):

- The ESPR entities should be familiar with the context of the regulations and have experience with regulation implementation;
- The questions presented to the ESPR entities should be released for public comment before submission to the reviewers; and
- The regulations could benefit from independent peer review by a broader scientific organization.

Response:

These comments are repetitive of comments submitted during the public comment period for the ESPR. For responses to these comments, please refer to the response to comments on the External Scientific Peer Review for the July 2012 proposed regulations.

Comment: 15-7

Comment Summary:

The regulations should encourage voluntary actions toward product improvement and innovation, rather than imposing mandatory requirements.

Response:

DTSC believes that the regulations do encourage voluntary innovation, as well as requiring specific actions with regard to some products. More specifically, the use of a Candidate Chemicals list as an interim step before the listing and prioritization of Chemicals of Concern in Priority Products allows for more informed voluntary innovation. That is, a product manufacturer may well decide to evaluate the presence of Candidate Chemicals in its products even if these chemicals have not been identified as Chemicals of Concern in any of its products.

Having a robust list of chemicals that may become subject to more compulsory innovation evaluation (*i.e.,* an AA) allows manufacturers to move forward on their own, knowing which chemicals may later become subject to DTSC oversight. DTSC also notes that the authorizing legislation envisions a compulsory program to advance the issue of safer consumer products on a more systematic basis. Of course, nothing in these regulations prevents manufacturers from taking additional voluntary innovative measures on their own. Therefore, DTSC is not making any changes to the regulations in response to this comment.

Comment: 34-15

Comment Summary:

The comment states that DTSC should review product liability laws to determine the level of potential state liability because of an unanticipated product malfunction due to a state mandated product change. The comment goes on to say that DTSC must be mindful of its liabilities at the Stringfellow Superfund Site arising from state-mandated actions.

Response:

DTSC is well aware of the existence and application of product liability laws. DTSC respectfully disagrees that it may incur any liability for an unanticipated product malfunction due to a DTSC mandated product change. As discussed throughout the regulations, the ISOR and the Response to Comments documents, DTSC does not mandate the outcome of the AAs. (See Article 5 for a complete discussion of this concept.) In addition, any regulatory responses DTSC may impose after the completion of an AA would be done under DTSC's police powers in general and the authorizing legislation in particular. Thus, various immunities and defenses apply to these actions. In addition, DTSC notes that it was not found liable at the Stringfellow Superfund Site, the State of California was. But, much more importantly, liability under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) for a siting decision of a hazardous waste landfill back in the 1950's has no relevance to DTSC's potential liabilities, if any, under this program. Accordingly, DTSC is not making any changes to the regulations in response to this comment.

Comment: 34-16

Comment Summary:

The comment contends that the insertion of State employees into a decision-making role in the choice of chemicals used by private industry raises many issues regarding qualifications, readiness, and appropriateness of this approach.

Response:

DTSC agrees that it must have staff assigned to this program that are capable and qualified, just as it must to effectively administer any of its programs. But DTSC respectfully disagrees that its staff will be the decision-maker regarding which chemicals are used in products. As has been pointed out throughout the rulemaking process, including in this Response to Comments document, it is the responsible entity for a Priority Product that determines whether or not to retain the Chemical(s) of Concern that led to the listing as a Priority Product, or what chemical(s) or engineering solutions, if

any, should be used as substitutes. While it is true that DTSC retains the ability to impose a regulatory response following the completion of the AA, this authority is clearly conferred by the authorizing legislation. Therefore, DTSC is not making any changes to the regulations in response to this comment.

Comment: 36-2

Comment Summary:

The commenter notes that DTSC's limited ability to create a requirement for a minimum data set for all chemicals in commerce under its existing authority is a critical shortcoming of the proposed program. Building a "no data, no market" mechanism into California's regulatory structure is a big job that remains to be undertaken, and is another key task for the Legislature in order to fill the data gaps outlined in the 2006 report "Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation."

Response:

DTSC respectfully disagrees, and believes it is too early to say whether there is a need for additional legislation to expand DTSC's authority to gather data about all chemicals in commerce. The proposed regulations have not yet entered the implementation stage, and DTSC cannot anticipate how the data gathering provisions that are included in the proposed regulations will succeed or fail at that time. DTSC is not making any changes to the regulations in response to this comment.

Comment: 40-2

Comment Summary:

The commenter notes that the regulations must avoid reaching an end product that is heavily bureaucratic, and/or unreasonably controlling or rigid. The regulations must be user-friendly.

Response:

DTSC agrees that the regulations must retain sufficient flexibility to address a variety of situations and outcomes. With this in mind, DTSC has crafted a regulatory program that allows for the maximum degree of flexibility. The regulations allow the responsible entities to perform the Alternatives Analysis of a scope that they select and to propose an acceptable alternative based on their own research and knowledge of their products. DTSC is not making any changes to the regulations in response to this comment.

Comment: 141-1

Comment Summary:

This comment referred to "Dugway Proving Grounds UTAH United States Test & Evaluation Command" and how Veterans Claims say it never existed. The comment also referred to the existence of Tabun and mustard in some location, and asserted they were exempt from DTSC's laws.

Response:

DTSC was unable to respond to this comment, as it was unrelated to the regulations and too vague to understand.

Comment: 145-1

Comment Summary:

This comment pointed to an error in the public notice for this comment period, where a miscalculation led to a statement that a new chemical is put on the market every 2.6 seconds, instead of 2.7 chemical per day.

Response:

DTSC appreciates this comment and has noted that error.

Comment: PH15-5

Comment Summary:

The commenter contends that its prior comments recommending changes to the regulations were not made.

Response:

DTSC has made countless changes to the regulations in response to individual and collective stakeholder comments. As the scope and number of changes from the July 2012 to January 2013 demonstrates, DTSC has given careful consideration to all comments it has received as part of the rulemaking process. DTSC does not know which specific comments were being referenced, but it has given good faith consideration to all comments. The fact that a comment did not lead to a change in the regulations does not equate to a comment being ignored. DTSC has sound reasons for accepting and rejecting the comments received. As a result, DTSC is not making any changes to the regulations in response to these comments.

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