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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 April 10, 2013. The proposal was available for comment for 15 days, with the public comment period closing on April 25, 2013. For a list of commenters and response to comments received on the proposed regulations dated July 2012 and January 2013, please refer to the July 2012 and January 2013 Response to Comments documents, respectively.

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 January 30, 2013 version of the proposed regulations.

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.

A total of 48 letters commenting on the revised proposed regulations released on April 10, 2013 were received. A list of commenters in alphabetical order, their affiliations, and the number assigned to their correspondence is 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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15	Chemical Industry Council of California	10
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18	Computers for Classrooms (Furr, Pat)	1
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31	Koch Industries	9
32	Minnesota Computers for Schools	1

	Name of Entity	Number of Comments
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34	Outdoor Power Equipment Institute	1
35	PC Rebuilders & Recyclers (PCRR)	3
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38	Procter & Gamble Company	8
39	Quint, Julia	1
40	Renew Computers Inc.	1
41	Rubber Manufacturers Association	19
42	San Francisco Estuary Institute	6
43	Sierra Club California	2
44	TechSoup Global (Brown, Stephen)	1
45	TechSoup Global (Lynch, Jim)	1
46	Toy Industry Association	8
47	Unilever	6
48	Worksafe	6

ACRONYMS

AA	Alternatives Analysis
APA	Administrative Procedure Act
Cal/OSHA	California Occupational Safety and Health Administration now known as Department of Industrial Relations (DIR)
COC	Chemical of Concern
DTSC	Department of Toxic Substances Control
EC	European Commission
EPA	Environmental Protection Agency (U.S.)
FSOR	Final Statement of Reasons
GHS	Globally Harmonized System
ISOR	Initial Statement of Reasons
OEHHA	Office of Environmental Health Hazard Assessment
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
U.S.	United States

ARTICLE 1. GENERAL

Article 1 establishes the applicability of the regulations, definitions, duty to comply responsibilities, procedures for information submittals, requests for information, and the information that will be available on the Department of Toxic Substances Control's (DTSC) website.

Support for Amendments in Article 1

Comments: 3-3, 8-4, 8-29, 20-11, 25-3, 25-4, 26-2, 26-24, 27-5, 27-7, 27-8, 27-9, 37-2, 46-4

Comments Summary:
The above comments express support for the following amendments:

- Section 69501(c) – the proposed section improves the proposed regulations and prohibits DTSC from superseding other state and federal regulations;
- Section 69501.1(a)(12) – the definition has expanded the applicability of the Alternative Analysis (AA) Threshold Exemption to include intentionally-added chemicals and the definition now includes section 69503.5(c) which allows DTSC to be able to set a case-by-case AA Threshold;
- Section 69501.1(a)(44) – the definition of "manufacturer" is a positive refinement. The principal entity responsible for performing the Alternatives Analysis (AA) should be the entity that "specifies the use of a chemical" in a product, and not any entity with the capacity to do so;
- Section 69501.1(a)(53) – the revised definition of "Priority Product" further clarifies that it refers to the product-chemical combination. This is important to help avoid an inappropriate designation for a product from the same category that does not utilize the Candidate Chemical as an ingredient;
- Section 69501.1(a)(57) – the revision to the definition of "reliable information" shifts the criteria for evaluating such information to be more broadly applicable to any information considered in the product-chemical prioritization process;
- Section 69501.1(a)(59) – the definition of "Replacement Candidate Chemical" regarding cases where the increase of an existing component in a formulation could be considered a replacement chemical provides further clarification;
- Section 69501.5(a)(3) – the posting of decisions on exemptions is positive; and
- Section 69501.5(b)(7) – The postings of public comment facilitated by DTSC will improve the AA process.

Response:

DTSC acknowledges the support offered by these commenters. There are no changes required to the proposed regulations in response to these comments.

§ 69501(b)(3) Non-Duplication

Comments: 8-23, 8-24, 8-25, 25-1, 26-24, 37-4

Comments Summary:
The provisions as revised do not yet provide a clear exemption for consumer products already regulated at the state or federal level, as required by the authorizing legislation. The comments suggest the following:

- The current proposed language should be replaced with a straightforward and clear exemption for consumer products that are regulated by one or more federal and/or California State regulatory program(s);
- The language should not include end-of-life effects as a criterion for this exemption because it narrows the applicability of this exemption; and
- DTSC continues to maintain complete discretion to determine whether its regulation "would provide equivalent or greater protection."

Response:
The comments are not directed to a change made to the regulations in the April 2013 version of the proposed regulations. DTSC notes that these comments are have been addressed in the "Procedural, Legal, and Overarching Issues" section of the July 2012 January 2013 Response to Comments documents. Please see the discussion of Duplication/Conflict with Other Regulatory Programs in those documents.

DTSC is not making any change to the regulations in response to these comments.

Section 69501(b)(2) & (b)(3) July 2012 version of regulations

Comments: 8-28, 20-10, 26-25

Comments Summary:
A previous version of the proposed regulations (July 2012) included language stating that the regulations do not apply to products that are manufactured or stored in

California solely for use outside of California or products that are used only to manufacture a product exempted from the definition of "consumer product" specified in Health and Safety Code section 25251. These provisions should not have been moved to sections 69503.3(b)(4)(B) and 69503.3(b)(4)(C) as product prioritization factors. The language should be restored due to the following concerns:

- Commenters remain concerned that deleting the clauses will lead to confusion regarding the scope of the regulations; and
- This approach appears to be an attempt to circumvent the very exclusions provided for in section 69501.

Response:
These comments relate to a previous version of the regulations and do not address a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments have been addressed in Article 1 of the July 2012 and January 2013 Response to Comments documents.

These provisions were removed from section 69501 and were moved to section 69503.4(b)(4)(B) and (C) as factors for prioritizing product-chemical combinations. Thus, there are now complete exemptions in Article1 and prioritization criteria in Article 3 based on the nature and extent of existing regulations for consumer products.

DTSC is making no changes to the regulations in response to these comments.

§ 69501(c) Harmonization

Comment: 20-11

Comment Summary:
This provision rephrases Health and Safety Code section 25257.1(b). The commenter is concerned about being consistent with Health and Safety Code section 25257.1(b) and (c). The comments suggests that an additional clause should be added to the regulatory provision so that the regulations may not be interpreted or implemented in a way that duplicates requirements imposed by other state or federal agencies.

Response:
This comment relates to a previous version of the regulations and is not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that this comment has been addressed in Article 1 of the January 2013

Response to Comments document. Please see the discussion of "Harmonization" under section 69501(c) in that document.

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

§ 69501.1 Definitions
§ 69501.1(a)(new) Move "Complex Durable Product"

Comments: 8-19, 17-11

Comments Summary:
Move the definition of "complex durable product" that is now in section 69503.5(d)(2) to new section 69501.1(a)(23), and renumber subsequent sections accordingly.

Response:
These comments relate to a previous version of the regulations and are not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes the following:

- The definition was not moved to the definitions section because it is germane only to the requirements for listing Priority Products in section 69503.5 in the April 2013 version of the regulations.

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(new) Add "Associated chemicals "

Comments: 42-2, 42-3

Comments Summary:
DTSC should establish a definition for "associated chemicals" to include degradates, metabolites, and reaction products of Candidate Chemicals and use the phrasing "Candidate Chemical and/or associated chemicals" consistently throughout the regulations. Inconsistent use of phrases to describe candidate and associated chemicals may inappropriately limit implementation of the regulation.

Response:
The definition of "chemical" means "an organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or

in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any degradate, metabolite, or reaction product of a substance with a particular molecular identity…." Degradates, metabolites, and reaction products are already included; thus, adding a new definition for "associated chemicals" is not necessary. This suggested new definition would also require the term "Chemicals of Concern" to be renamed "Chemicals of Concern and Associated Chemicals of Concern," which would make the language more cumbersome to follow.

DTSC is making no change to the regulations in response to these comments.

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

Comments: 8-12, 8-47, 10-2, 10-7, 17-3, 17-4

Comments Summary:
Although section 69506.1(f)(4) does not address replacement parts specifically, this provision could potentially provide regulatory certainty regarding the availability of these parts. Section 69506.1(f)(4) could be applied to Priority Products that are replacement parts from any particular regulatory response requirement on a case-by-case basis. However, this provision still does not properly address the treatment of repair, maintenance, and refurbishment parts. DTSC should provide for a clear and complete exclusion for replacement parts to maintain the "forward-looking" nature of the regulations, and not focus on products placed in the stream of commerce prior to the implementation of a selected regulatory control.

Replacement parts for complex durable goods are critical and present some unique challenges as described below:

- Replacement parts for complex durable goods must remain available for years, even for products that are no longer being manufactured;
- Frequently, replacement parts must meet specific legal requirements and/or regulatory approvals or certifications. It is not possible to simply substitute newly designed parts—not without substantial investment of time and resources. Further, such efforts would drain resources from other efforts to "green" current and future products currently or imminently entering commerce;
- The lead time necessary for product design, development, and validation of complex durable goods is on the order of years, not months or weeks, and certainly not in the short time frames contemplated by these regulations;

- With the multi-tiered, multi-faceted global supply chain inherent in the assembly of complex durable goods, replacement parts may be available only from overseas manufacturers. Such manufacturers may not provide redesigned replacement parts to fulfill demand for a single market (*i.e.*, California);
- The new definition of "assembler" takes DTSC further from its goals and introduces uncertainty about how these regulations apply to replacement parts and repair facilities; and
- Many of these repair and maintenance items are generated from recycled or reused vehicle components. Including these types of products in the regulations could ultimately create more waste, increase energy use, and potentially further damage the environment.

Response:
These comments relate to a previous version of the regulations and are not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments have been addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of Exemption Request for Replacement Parts under section 69501.1(a)(24)(B) in that document.

DTSC would like to provide a courtesy response as clarification regarding the concern that the regulations will result in detrimental impacts on the environment. In addition, DTSC respectfully disagrees with the comments and offers this additional response as a courtesy to the commenters:

First, DTSC will proceed through rulemaking for the adoption of the Priority Products; thus, there will be an opportunity for public comment on issues related to the listing. If there are detrimental impacts resulting from the listing of a Priority Product, these impacts will be compared to the adverse impacts caused by the proposed Priority Product. Prioritization as a Priority Product means the product contains Chemical(s) of Concern, it is present in commerce in California in high volume, and there is a propensity for exposure resulting from the product. Second, if the Priority Product is listed, what is required is the preparation of an AA to find an alternative. The optimum goal of an AA is to find a "safer alternative" for the Priority Product that does not pose regrettable substitutes.

When conducting an AA, the responsible entity may demonstrate detrimental environmental impacts of the alternatives being considered and elect to retain the Chemical of Concern in a product. That is, a responsible entity is not required to eliminate the Chemical of Concern as the outcome of the AA. However, the Priority

Product may be subject to regulatory responses depending on the outcome of the AA. At the time of the regulatory responses, there will be opportunity to account for products that are manufactured after the effective date of the Priority Product listing, but before the date of the regulatory response determination notice under section 69506.1(f). Again, this will allow for consideration of factors, such as useful life, supply chain issues, lead-time and others.

DTSC is making no changes to the regulations in response to these comments.

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

Comment: 30-1

Comment Summary:
The definition of "adverse public health impacts" includes "occupational health," which is outside the scope of "consumer products." The sentence, "Public health includes occupational health [ ]" should be deleted.

Response:
This comment relates to a previous version of the regulations and is not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that this comment was addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of "Adverse Public Health Impacts" under section 69501.1(a)(6) in that document.

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

§ 69501.1(a)(12) "Alternatives Analysis Threshold" or "AA Threshold"

Comment: 22-4

Comment Summary:
Worldwide, chemical management programs and regulations incorporate a de minimis regulatory threshold below which no action is required. Washington State's Children's Safe Products Act implementing regulations and Maine's revised Toxic Chemicals in Children's Products Law use the practical quantitation limit (PQL) as a regulatory threshold. This threshold only applies for intentionally added chemicals; contaminants are regulated at 100 parts per million.

Response:
The comment relates to a provision that changed from the previous iteration of the proposed regulations, but the comment is not related to the change made. Nonetheless, DTSC notes that this comment was addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of "Alternatives Analysis Threshold" under section 69501.1(a)(12) in that document.

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

The regulations were revised in the April 2013 version to allow the opportunity to set product-chemical specific thresholds in section 69503.5(c). See Responses to Comments in sections 69503.5(c), and 69505.3 of this April 2013 Response to Comment document for additional discussions regarding the AA Threshold.

§ 69501.1(a)(15) "Assemble" and (16) "Assembler"

Comments: 1-2, 1-3, 1-4, 1-5, 1-6, 2-6, 8-13, 8-14, 8-22, 9-7, 10-3, 10-4, 10-5, 10-6, 10-7, 10-8, 17-2, 17-5, 17-7, 17-8, 17-10, 22-8, 27-3, 27-6, 34-1, 35-1

Comments Summary:
The revised definition of "assemble" adds "repair, maintenance, refurbishment, and alterations" to the scope of "assemble," and expands the scope of responsible entities. The above comments urge that repair, maintenance, and refurbishment-based (repair/maintenance) entities and parts retailers should be exempted from the regulations as responsible entities. Concerns regarding this definition are as follows:

- The definition of "assemble" is problematic –
  - The definition is broad, and the distinction between a manufacturer and an assembler is confusing;
  - This definition varies with manufacturers' conventional understanding of the term "assemble" and by reference "assembler"; and
  - The definition introduces additional uncertainty about how the regulations will apply to replacement parts and repair facilities.
- The proposed regulation should be aimed at the manufacturing processes. The regulations should not target service entities, such as repair and maintenance. Repair and maintenance entities should not face the same potential consequences as manufacturers;

- Repair and maintenance entities and parts retailers are ill-equipped to fulfill the requirements of any responsible entity within the "duty to comply" hierarchy created by the regulation –
    - These repair and maintenance entities are not involved in developing products and are not able to specify or control substances within those products;
    - Repair and maintenance entities and parts retailers are, for the most part, small businesses that will struggle to adhere to the burdensome inventory reporting standards, and the potential regulatory response process;
    - The definition could inadvertently subject anyone repairing, refurbishing, maintaining, or making non-material alterations to the rule—even a consumer at his/her own home;
    - Products may be required to be maintained; and non-material alterations, such as adding a software application, would subject all owners of such equipment with the duty to comply, as outlined in section 69501.2; and
    - Repair/maintenance entities' only recourse may be to stop purchasing parts, which will put them out of business. This will have an enormous economic impact and may drive maintenance jobs out of California.
- Covering the repair and refurbishment of products that were potentially not in scope when they were manufactured would be environmentally counterproductive –
    - Creating barriers to the refurbishment and reuse of products could lead to even more Priority Products entering the waste stream if serviceable products are not maintained through their entire service life. Wasting valuable resources produces a negative impact on the environment; and
    - Repair/maintenance entities help reduce emissions of greenhouse gases and toxic pollutants by maintaining the performance of products. Components are reused which result in a reduced depletion of resources.

Response:
The proposed regulations (April 2013) define "assemble" 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." This definition directly ties into the definition of "assembler" in proposed section 69501.1(a)(16), and effectively allocates the secondary burden of compliance on any person who performs an activity covered under the definition of "assemble."

The definitions of “assemble” and “assembler” in the regulations were meant to provide regulatory relief to entities that do not manufacture a product but simply use the Priority Product to create a new product. The definition of “assemble” has been revised to include repair/maintenance activities. This amended definition of “assemble” in the regulations (April 2013) now results in the term “assembler” to include persons that repair, refurbish, maintain, or make non-material alterations. This makes it clear that persons that provide these services do not fall within the definition of “manufacturer.” Manufacturers are subject to more substantive requirements under the regulations than are assemblers. Assemblers have certain “off-ramps” from the requirement to conduct an AA that manufacturers do not have. Repair facilities will be considered “assemblers” if they perform repair/maintenance activities using a Priority Product.

Because including repair/maintenance activities may not conform to the common understanding of “assemble,” DTSC has defined this term in the regulations. This revised definition (April 2013) does not address replacement parts. Replacement parts are not exempt from the regulations; thus, this definition does not have any impact on the applicability of the AA to replacement parts.

DTSC agrees that the proposed regulations should not subject repair/maintenance entities (assemblers) to the same potential consequences as manufacturers. The regulations do not assign the principal responsibility for compliance to assemblers. In response to comments received for the January 2013 version of the regulations, DTSC revised the definition of “assemble” to address repair, refurbishment, and product maintenance. This provision allows repair/maintenance entities (assemblers) to be treated in a manner similar to retailers, not manufacturers.

Retailers and assemblers may not be involved in developing products; thus, completing an AA may not be a viable option for them. The regulations allow retailers and assemblers to defer to the manufacturers and the importers who have the principal duty to comply. However, if it is critical for a business to continue to use, sell, or distribute a Priority Product, and neither the manufacturer nor importer has conducted the AA, there is an option for the assembler (or retailer) to take on the responsibility for the AA. DTSC expects that this will not be the preferred compliance method. If a manufacturer or importer complies with the duty to conduct an AA, there will be no additional requirements on the assemblers or retailers. Furthermore, there are no inventory reporting standards for “assemblers” or for “retailers.” Maintaining good inventory records is a good business practice but not required by these regulations. “Assemblers” and “retailers” are generally not subject to the regulatory response process, unless they have submitted an AA for a Priority Product and comply with the regulatory response.

However, if a manufacturer does the AA but then fails on the regulatory response, retailers or assemblers would have to implement the regulatory response or stop ordering.

[Note: Section 69501.2(a)(1)(C) prohibits DTSC from requiring any responsible entity other than the manufacturer to comply with regulatory responses under section 69506.6, Engineered Safety Measures and Administrative Controls; section 69506.7, End-of-Life Management Requirements; and section 69506.8, Advancement of Green Chemistry and Green Engineering.]

The regulations will not apply to individuals doing their own home repairs because the homeowners are the end users, and it is understood that the end user does not typically place the Priority Product into the stream of commerce in California (section 69501(b)(1)). Even when an end user sells a Priority Product, the end user is not subject to the regulations. Under section 69501.1(a)(24)(C), the regulations allow an individual to resell a Priority Product and be exempt from the definition of "consumer product" and, thus, the regulations.

The regulations would not apply to software used to maintain a product. First, a software application would not contain a Candidate Chemical. However, it may be possible that the media used to install a software application could be a potential Priority Product, if it were prioritized in accordance with the factors in Article 3. In this scenario, the manufacturer of the media would be the primary responsible entity subject to the duty to comply requirements as outlined in section 69501.2, and the entity (assembler) that uses the Priority Product (media) to install new software would have responsibilities as the assembler under the regulations.

When a Priority Product is listed, an assembler and retailer may continue to purchase, use, sell, and distribute the Priority Product if the manufacturer or importer complies with the requirement to conduct an AA or otherwise comply with Article 5. Two situations would require an assembler or a retailer to stop ordering a Priority Product. The first situation is when the manufacturer and importer fail to comply with the requirements in Article 5 and the assembler and retailer also decline to conduct an AA. The second is when the manufacturer or importer has completed an AA and a sales ban of the Priority Product is imposed as the regulatory response. In the first situation, only if the manufacturer and the importer of a Priority Product fail to comply with the regulations is the assembler or the retailer in a position to either comply with the AA requirements or cease ordering the Priority Product. If the assembler or retailer chooses to cease ordering the Priority Product in lieu of completing an AA, 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. The second situation that would require an assembler or retailer to stop ordering a Priority Product would be if a product sales prohibition under section 69506.5 were imposed on the Priority Product as a regulatory response.

As for the potential impacts on the environment, DTSC does not agree that there will be significant environmental impacts due to the early disposal of consumer products due to amended definition. The definition of "assemble" does not prohibit the reuse or the repair of a product. This definition clarifies that repair/maintenance entities (assemblers) have a secondary responsibility similar to those of a retailer. The definition should not cause the early disposal of products that would have remaining useful life through reuse or repair. Repair/maintenance entities (assemblers) will be allowed to use replacement parts if the manufacturer or the importer complies with the regulations and will be allowed to continue to provide service if alternatives to the Priority Product are available for repair and maintenance.
Repair/maintenance entities (assemblers) may help reduce emissions of greenhouse gases and toxic pollutants or allow for the reuse of components, which results in a reduced depletion of resources. Nevertheless, if a Priority Product has been listed it is because there is concern regarding the product's adverse public health or environmental impacts.

DTSC is making no changes to the regulations in response to these comments.

Comments: 1-1, 8-21, 17-6

Comments Summary
The current definition of "assemble" is inconsistent with DTSC's previous versions of the regulations and the Initial Statements of Reasons (ISOR). The ISOR and the revised ISOR emphasized the need to exclude repair and maintenance of existing products. Furthermore, it is an inappropriate expansion of authority under AB 1879 to include entities that provide repair, maintenance, and refurbishment-based services in the hierarchy of entities with a Duty to Comply.

Response:
DTSC acknowledges that the current definition (April 2013) is inconsistent with the ISOR language which addresses the provisions in the July 2012 version of the proposed regulations. The definitions of "assemble" and "assembler" were added to the regulations in the January 2013 version; thus, creating this secondary responsibility for "assembler" under the duty to comply would not have been included in the ISOR.

Again, the ISOR describes and explains the provision in the original version of the proposed regulations. It would be impossible for the ISOR to describe provisions that had not yet been drafted. In addition, the definitions of "manufacture" and "import"; and, by reference, "manufacturer" and importer" have been revised. In addition, these amendments are not reflected in the ISOR. DTSC will be preparing a Final Statement of Reasons (FSOR) that will include a description and explanation of all of these changes and the necessity for them. DTSC does not agree that including entities that place Priority Products into the stream of commerce is an inappropriate expansion of its authority under AB 1879.

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 have no presence in California, DTSC has no practical, and in most cases no legal, ability to compel those 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, Chapter 6.5, 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.

DTSC is making no changes to the regulations in response to these comments.

Comments: 8-15, 8-16, 8-17, 17-10

Comments Summary:
The above comments express general concerns regarding the revisions made to the language for the definitions of "assemble" and "assembler." The comments support adding the definition of "assembler," decoupling "assembler" from "manufacturer," and then clarifying in section 69501.2(a)(1)(A) that the manufacturer has the principal duty to

comply. However, taken together, these changes do not provide the needed relief for the complex durable goods assembler and, instead, create multiple paths of regulatory uncertainty. The definitions for “assemble,” “consumer product,” “complex durable product,” “importer,” and “manufacturer” need revision to achieve the goal of providing gradation of responsibilities with regard to fulfillment of the various sections of the proposed regulations. The definitions need additional clarification to create these clear lines of separation for products with complex supply chains.

The only limited scenario in which this complicated combination of definitions and exclusions would allow an automobile assembler to fall under the definition of “assembler” would be if the assembler:

- Assembled components into a product in the U.S.;
- Acquired all components from a U.S. manufacturer;
- Did not import the components of the product or assembled product from out of the country (otherwise they would be an importer); and
- Did not stipulate any component specifications (*e.g.*, safety requirements, performance, functionality, durability, etc.)—otherwise, they would be a manufacturer.

Response:
These comments relate to a provision that has changed from the prior iteration of the regulations, but the comment is not directed to the change made. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of “assemble,” “assembler,” “component,” “import,” “importer,” “manufacture,” “manufacturer,” under section 69501.1 and Duty to Comply under section 69501.2 in that document.

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(20)(A) “Chemical”

Comment: 23-2

Comment Summary:
Comment would like to underline that the comments expressed previously and in particular the deviation from the definition of chemical substance from the international standard set in the United Nations Globally Harmonized System have not been addressed.

Response:
This comment relates to a previous version of the regulations and is not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that this comment was addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of "Chemical" under section 69501.1(a)(20)(A) in that document.

§ 69501.1(a)(20)(B) "Molecular identity"

Comment: 4-2

Comment Summary:
The commenter questions the definition of "molecular identity" in the revised proposed regulations. Would any variation in the properties listed in the definition give rise to a new molecular identity? This definition may require guidance to understand which properties and "states of matter" are relevant under what conditions for the purposes of making hazard and exposure determinations. "Physicochemical properties and structure" would cover all of the factors, obviating the need for these elaborate factors.

Response:
This comment relates to a previous version of the regulations and is not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that this comment was addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of "Molecular Identity" under section 69501.1(a)(20) in that document.

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

§ 69501.1(a)(24)(A) "Consumer product"

Comments: 8-22, 10-8, 17-9

Comments Summary:
Activities that include repair, refurbishment, and maintenance of vehicles and/or motor vehicle parts retailers should be exempt from the proposed regulations. The definition of "consumer product" should be revised to exclude replacement parts used to repair, refurbish, or maintain existing consumer products.

Response:
These comments relate to a previous version of the regulations and are not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that this comment was addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of Exemption Request for Replacement Parts section 69501.1(a)(24)(B) in that document. There is additional discussion regarding the activities to repair, refurbish, maintain, or make non-material alterations in this document under section 69501.1(a)(16).

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

§ 69501.1(a)(29) "Economically feasible"

Comments: 11-1, 11-2, 14-5, 48-5

Comments Summary:

There are continuing concerns regarding the current language defining "economically feasible." The definition is problematic for the following reasons:

- The definition essentially gives a responsible entity the freedom to opt out of replacing a Chemical of Concern by simply stating that its operating margin will be significantly reduced;
- The DTSC definition of "economically feasible" is not supportive of public review of AAs. A key criterion in the evaluation of alternatives may be blocked from public review by confidential business information claims;
- The definition of economic feasibility complicates any effort on the part of industry consortia to submit AAs since competitors will not want to share this information—assuming the sharing of such information among competitors is even legal;
- DTSC needs to ensure that "economically feasible" goes past the company's bottom line and accounts for externalized costs that are part of what these regulations are designed to reduce; and
- It is not clear how a "significant" reduction is defined or how will it be measured and validated. Does DTSC expect to audit a responsible entity's internal documents to compare profit margins?

Comments suggest the following revisions:

- The definition should be amended. "'Economically feasible' means that an alternative product or replacement chemical is commercially available for a similar functional use in similar products does not significantly reduce the manufacturer's operating margin"; or
- DTSC should use a variation of the United Kingdom Health and Safety at Work Act's definition of "economically feasible." The phrase "as far as reasonably possible" has a specific legal meaning and is used in legislation around the world to deal with the economic feasibility of dealing with hazards.

Response:
These comments relate to a previous version of the regulations and are not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the July 2012 Response to Comments document. Please see the discussion of Technically and Economically Feasible under section 69501.1(a)(59)(B) in that document.

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(30) "End-of-life"

Comments: 16-1, 18-1, 19-1, 32-1, 33-1, 35-2, 40-1, 44-1, 45-1

Comments Summary:
The "end-of-life" definition will subject all used goods to regulatory responses under section 69506.7 end-of-life requirements. The provision as currently written may actually impede the reuse of products (notably computers) that could still have a great deal of practical useful life. Please amend this language that would keep firms from reusing donated systems and help ensure that reusable equipment can be reclaimed for its highest and best use.

- Current text: "End-of-Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs first." The above comments request that the final word be changed from "first" to "last."

Response:
These comments relate to a previous version of the regulations and are not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the July 2012

Response to Comments document. Please see the discussion of "end-of-life" under section 69501.1(a)(26) in that document. There is also additional discussion regarding the activities to repair, refurbish, maintain, or make non-material alterations in this document under section 69501.1(a)(16).

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(38) "Import"

Comment: 14-8

Comment Summary:
The current definition states that "Import" does not include ordering a product manufactured outside of the U.S. if the product is ordered from a person located in the U.S. This means that anyone located in the U.S. could order a product manufactured abroad and this by itself would exempt the product.

- Comment suggests the following language, "'Import' does not include ordering a product manufactured outside of the United States if the product is ordered from a person located in the United States solely for use in that person's workplace if that product is not sold or distributed by that person to others."

Response:
This comment relates to a previous version of the regulations and is not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that this comment was addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of "import" under section 69501.1(a)(38) in that document. Finally, as a point of clarification, this definition does not exempt products from the regulations. This provision defines what is considered "import" and by reference who is considered an "importer" for purposes of establishing the hierarchy of the duty to comply for the various responsible entities.

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(39) "Importer"

Comments: 8-20, 17-11

Comments Summary:
If the goal of the responsible entity hierarchy is to ensure that the most knowledgeable entity conducts the AA, then the regulations in their current form fail to achieve it. The comments urge DTSC to add a sentence to this definition that will exempt complex durable product assemblers.

Response:
These comments relate to a previous version of the regulations and are not directed to a change made to the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of "assemble," "assembler," "component," "import," "importer," "manufacture," "manufacturer," under section 69501.1, and Duty to Comply under section 69501.2 in that document. There is also additional discussion regarding "assemble" and activities to repair, refurbish, maintain, or make non-material alterations in this document under sections 69501.1(a)(15) and (16).

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(43) "Manufacture"

Comments: 8-22, 10-8, 17-8

Comments Summary:
The above comments recommend restoring the language found in the July 2012 version of the proposed regulations by revising the definition of "manufacture" to exclude the following:

- Acts that meet the definition of "assemble";
- Repair or refurbishment of an existing consumer product;
- Installation of components to an existing consumer product; or
- Making non-material alterations to an existing consumer product.

Response:
These comments relate to a previous version of the regulations and are not directed to a change made in the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the January 2013

Response to Comments document. Please see the discussion of “assemble,” “assembler,” “component,” “import,” “importer,” “manufacture,” “manufacturer,” under section 69501.1, and Duty to Comply under section 69501.2 in that document. There is also additional discussion regarding “assemble” and activities to repair, refurbish, maintain, or make non-material alterations in this document under sections 69501.1(a)(15) and (16).

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(44) “Manufacturer”

Comments: 2-5, 3-3

Comments Summary:
The comments approve of the revisions to the definition of “manufacturer.” The principal entity responsible for performing the AA should be the entity that “specifies the use of a chemical” in a product and not any entity with the capacity to do so. However, the comments urge further clarification and refinement by changing the term product to “Priority Product” in the definition.

Response:
DTSC appreciates the support for the amended language. The substantive requirements of the regulations apply to Priority Products, as established in section 69501. The use of the term “product” is consistent with the other definitions of responsible entities. Furthermore, in Article 6 of the regulations, “manufacturer” may mean a manufacturer of an alternative product, so the definition should not be restricted to only the manufacturer of a Priority Product.

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

§ 69501.1(a)(52) “Practical Quantitation Limit” or “PQL”

Comment: 22-4

Comment Summary:
Worldwide chemical management programs and regulations incorporate a de minimis regulatory threshold below which no action is required. Washington State's Children's Safe Products Act implementing regulations and Maine's revised Toxic Chemicals in

Children's Products Law use the PQL as a regulatory threshold. This threshold only applies for intentionally added chemicals; contaminants are regulated at 100 parts per million.

Response:
This comment relates to a previous version of the regulations and is not directed to a change made in the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that this comment was addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of "Alternatives Analysis Threshold" under section 69501.1(a)(12) and "Practical Quantitation Limit" under section 69501.1(a)(52) in that document.

DTSC is making no change to the regulations in response to this comment.

§ 69501.1(a)(57) "Reliable information"

Due to the many comments that were received that related to previous versions of the proposed regulations, the three different versions of the definition of "reliable information" are provided below:

July 2012

(52) "Reliable information" means a scientific study or other information that is one or more of the following:

(A) Published in a scientifically peer reviewed report or other literature;
(B) Published in a report of the United States National Academies;
(C) Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or
(D) Conducted, developed, submitted, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes.

January 2013

(57) "Reliable information" means information that is trustworthy based on the following:

(A) The level of rigor attendant to the generation of the information, including, where relevant, the use of quality controls;
(B) The degree to which the information has been independently reviewed by qualified disinterested parties;
(C) The degree to which the information has been independently confirmed, corroborated, or replicated; and/or

(D) With respect to a scientific study, the fact that the study meets both of the following criteria:

1. The study was:
   a. Published in a scientifically peer reviewed report or other literature;
   b. Published in a report of the United States National Academies;
   c. Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or
   d. Conducted, developed, submitted, prepared for, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes.

2. 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.

April 2013

(57) "Reliable information" means a scientific study or other scientific information that meets the criteria in subparagraphs (A) and (B):

(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 the Department. [Note: Underlined text indicates text added for the first time in the April 2013 version of the proposed regulations.]

§ 69501.1(a)(57)(A) Scientific Study or Other Scientific Information Criteria

Comments: 5-3, 22-14, 26-10, 47-2

Comments Summary:
All of the sources mentioned in the definition are appropriate for making proper and robust decisions. These include deliberative scientific bodies that review the information in studies and judge weight-of-evidence and other factors, such as the

National Academies and reports from government agencies. Their assessments and conclusions can be considered reliable.

However, the comments above do not agree with the proposed changes to the definition of "reliable information." Concerns regarding this revision include the following:

- The only information defined as reliable information would be "a scientific study or other scientific information";
- There are many other kinds of information outside of this definition that could be important in the regulatory process that would not be subject to the same level of scrutiny. For example, data on product market volumes or use of products by consumers should not be excluded;
- The public should be given the opportunity to challenge the reliability of any study upon which DTSC relies for its regulatory decisions;
- The definition establishes reliable information as de facto that which emanates from several sources independent of the quality of that information; and
- Not all scientific studies are designed to determine conclusions based on robust test designs with appropriate controls. They can just as easily be designed to show that a hypothesis has merit (*i.e.*, a proof of principle evaluation) and warrants further, more robust study designs.

Response:
The regulations have narrowed the definition of reliable information to include scientific studies or information only. The term "reliable information" is used most importantly to define the term "potential," which is used extensively throughout the regulations. The term "reliable information" is also used in the regulations to define the type of information that may be used to add chemicals or chemical lists to the Candidate Chemicals List or to remove chemicals or chemical lists from the Candidate Chemicals List, to prioritize product-chemical combinations, to verify the conclusions of an AA Report, and to impose engineered safety measures or administrative controls as a regulatory response. In all these instances, the regulations are written to ensure that the decisions that are made are science-based.

The regulations do not preclude the use of non-science information or the use of information that is not "reliable information" for implementation of these regulations. The use of non-science information, such as statewide sales by volume, statewide sales by number of units, and/or intended product use, can be considered as exposure factors in evaluating Candidate Chemicals in the product (section 69503.3(b)(1)). The petition process for identification and prioritization of chemicals and products in Article 4 does

not require “reliable information” to be included in the petition. Reliable information was not made a requirement in this section because there are no regulatory consequences to persons that submit a petition.

The last three comments relate to a provision that changed from the prior iteration, but the comment is not directed to a change made in the April version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the July 2012 and January 2013 Response to Comments documents. Please see the discussion of “Reliable Information” under section 69501.1(a)(52) in the July 2012 Response to Comments document and section 69501.1(a)(57) in the January 2013 Response to Comments document.

DTSC is making no changes to the regulations in response to these comments.

As a point of clarification, the definition in all versions of the regulations (July 2012, January 2013, and April 2013) has required that reliable information be a scientific study or other information. “Other information” was changed to “other scientific information” in the revised proposed regulations (April 2013).

Organization for Economic Cooperation and Development Manual

Comments: 5-6, 5-8, 47-3

Comments Summary:
The need for a mechanism to judge the reliability of studies is widely recognized by federal agencies and in international forums. As a result, the Organization for Economic Cooperation and Development (OECD) has developed a globally accepted method for rating the quality and reliability of studies. DTSC should use the principles found in the OECD Manual for evaluating whether data is reliable for the purposes of the regulations.

Response:
The suggestion to include the OECD Manual in the revised proposed regulations (April 2013) as criteria to judge the reliability of studies was addressed in Article 1 of the January 2013 Response to Comments document. However, as a clarification, DTSC is providing the following response:

First, there are many new and valuable methods of assessing chemical toxicity, for which there are no official guidelines from OECD or other institutions. Because the guideline methods in the OECD Manual are limited to specific tests, they do not include

more recent scientific procedures or methodologies that have been accepted in the general scientific community. Nor do they include some important older procedures that are accepted in the scientific research community. While following established quality control and quality assurance guidelines is a good step towards establishing confidence in a study, simply following guidelines does not ensure that the study objectives were met. DTSC will evaluate these types of scientific studies, on a case-by-case basis, to determine whether they are acceptable for purposes of these regulations.

Second, the OECD's Guidelines for Testing of Chemicals, Series on Principles of Good Laboratory Practice and Compliance Monitoring, and Manual for Investigation of 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.

DTSC is making no change to the regulations in response to these comments.

Weight of Evidence

Comments: 4-3, 15-4, 25-5, 26-12, 26-14, 36-5

Comments Summary:
While the revisions to this definition are positive, they still fall short of calling for a full "weight of the evidence" determination in the application of such information. The standard of merely relying on "other scientific information" without being obligated to consider the weight of scientific evidence leaves open the possibility of decisions being founded upon conclusions that would be undermined if a full consideration of available science were conducted. DTSC should ensure that the best scientific judgment of the State of California is brought to bear, and that dictates consideration of the full range of available information. In summary:

- If DTSC fails to exercise measured judgment in evaluating current science, it will have effectively abdicated that responsibility;
- Not utilizing a weight of evidence approach violates standard scientific protocols used in other regulatory programs and will preclude the potential for California Green Chemistry's program from building a reputation as a meaningful, science-based program; and
- There is an absence of emphasis on a weight-of-evidence evaluation of information and on ensuring decisions are driven by conclusions from the most

relevant and highest quality studies. This issue could be addressed by adding the following points into this section of the regulations or into the FSOR:

- "In evaluating information to make decisions and substantiate conclusions about "the ability of the chemical to contribute to or cause adverse public health and/or environmental impacts," DTSC, responsible entities, and stakeholders should be guided by the following principles:
- All evaluations—determining Candidate Chemicals, petitions, Priority Products, AA Thresholds, AAs, and regulatory responses—must rely on the best available scientific information regarding possible adverse impacts and exposures of substances, and employ consistent, objective methods and models to derive realistic determinations of adverse impacts at environmentally relevant levels of exposure;
- Transparent criteria must be established upfront and then consistently applied throughout the evaluation process to identify studies, and to evaluate their quality, relevance, and reliability; and
- All evaluations must be based on a framework that takes into account and integrates all relevant studies while giving the greatest weight to information from the most relevant and highest quality studies.

Response:
These comments relate to a previous version of the regulations and are not directed to a change made in the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of "Reliable Information" under section 69501.1(a)(57) in that document.

Also, DTSC appreciates the suggestion for how to write the FSOR but will not be including the suggested language in the FSOR. The suggested language uses the term "must," which would mean that these principles are required to be adhered to. That would be inappropriate for the FSOR document. Only the regulations text may impose binding requirements on regulated entities. Furthermore, the regulations have been written to allow the maximum flexibility to address a wide variety of possible information gaps; it is counter to the regulations to stipulate that uniform criteria must be developed and used.

DTSC is not making any change to the regulations in response to these comments.

§ 69501.1(a)(57)(A), (B), and (C) (January 2013)

Comments: 4-3, 5-7, 22-13, 26-9, 26-11, 26-13

Comments Summary:
The previous version of the regulations (January 2013) had criteria for the quality of the information (previously section 69501.1(a)(57)(A), (B), and (C) in the January 2013 version of the regulations). The revised proposed regulations no longer have these criteria in this definition, but have moved this criteria to section 69503.2(b)(1)(C) in the April 2013 version of the proposed regulations. Section 69502.2(b) incorporates by reference the criteria in section 69503.2(b)(1(C). The previous positioning made the concept of information quality operative across the entire regulations. Removing this provision from "reliable information" suggests that DTSC, responsible entities, and/or stakeholders need not consider information quality in their actions and decisions under any other section of the regulations—a position that seems completely out of step in these science-based regulations. The information quality provisions included a requirement that the information be independently confirmed, corroborated, or replicated. A sound definition of "reliable information" that includes independent review and independent confirmation or replication would enhance the scientific credibility of the complex regulatory proposal.

The commenters recommend that the data quality criteria be restored to the definition of "reliable information" and that all evaluations under the regulations be based on a framework that takes into account and integrates all relevant studies while giving the greatest weight to information from the most relevant and highest quality studies.

Response:
The definition of "reliable information" is used in the regulations to define "potential," which is used extensively throughout the regulations, to specify the type of information that can be used to add or remove chemicals or chemical lists from the Candidate Chemicals list (Article 2), to prioritize product-chemical combinations (Article 3), to verify the conclusions of an AA Report (Article 5), and to impose engineered safety measures or administrative controls as a regulatory response (Article 6).

DTSC disagrees that moving the provisions for the quality of the information from the definition section (previously section 69501.1(a)(57)(A), (B), and (C) in the January 2013 version of the regulations) into Article 2 and Article 3 suggests that DTSC, responsible entities, and/or stakeholders need not consider information quality in their actions and decisions under any other section of the regulations. The provisions for the quality of information criteria (sections 69502.2(b)(3) and 69503.3.2(b)(1)(C)) require that the information be independently confirmed, corroborated, replicated, and

independently reviewed still apply to chemical and product-chemical prioritization. Furthermore, the definition of “reliable information” is restricted to scientific studies or scientific information, but the regulations, in their entirety, do not preclude the use of non-science information for implementation of these regulations, such as section 69503.3(b)(1) for the market presence of a product.

It is also important to clarify that there may be valid scientific studies or other scientific information that may not meet the “reliable information” definition, but would be relevant and important to consider for these regulations. For instance, a manufacturer may have a scientific study or scientific information on animals, humans, or mechanistic data relevant to a chemical that does not meet the criteria described in sections 69501.1(a)(57)(A)(1) through (4). In this situation, a manufacturer may choose to submit this information to DTSC. In so doing, the scientific study or information will meet the criterion in section 69501.1(a)(57)(A)4; that is, it is “conducted, developed or submitted” to DTSC. The second condition is dependent on DTSC’s acceptance of the scientific studies or information.

The scientific community and public policy makers have taken steps to increase the confidence or reliability in study results by establishing quality control and quality assurance guidelines, which allow for informed decision-making. In reviewing the scientific study for acceptance as reliable information, DTSC will evaluate whether the scientific study provided was conducted according to generally accepted principles, including testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to guideline methods, for example, OECD Guidelines for Testing of Chemicals, Series on Principles of Good Laboratory Practice and Compliance Monitoring, and Manual for Investigation of High Production Volume Chemicals.

DTSC will not be moving the quality of information criteria back to the definition of “reliable information” because there is a vast and informative scientific literature, produced by academic institutions, which that could not be considered under these regulations because it did not conform these criteria.

DTSC will not be making any changes in response to these comments.

§ 69501.1(a)(57)(A)1 Published in a Scientifically Peer Reviewed Report

Comments: 5-4, 20-12, 22-10, 22-11, 25-9, 47-2

Comments Summary:
The provision that allows “reliable information” that is “published in a scientifically peer reviewed report or other literature” is excessively broad and undefined. The comments recommend that this provision’s scope be improved to ensure confidence in the underlying science and avoid the appearance of arbitrary decisions. Issues that were stated in these comments are as follows:

- Information “(p)ublished in scientifically peer reviewed reports or other literature” may not lead to the scientifically robust analyses;
- “Other literature” is too open-ended and could include significant amounts of unreliable and non-scientifically generated information;
- Peer reviewed studies could be subject to significant bias by virtue of the credentials of the peer reviewers chosen;
- Information “published in scientifically peer reviewed reports or other literature” is problematic because it is well established that individual published peer reviewed studies may be unreliable;
- Information “published in scientifically peer reviewed reports or other literature” will include everything from all other sources as “reliable information,” which is scientifically inaccurate and has the potential to drive controversy into a program that is intended to be science-based;
- The requirement for peer reviewed studies will disallow any well-designed and implemented studies that have not been published in peer reviewed literature; and
- These standards may be intended to negate inclusion of non-published information from industry. It is our expectation that the state's scientists will be in a position to judge the scientific merit of such information per these regulations.

Response:
These comments relate to a previous version of the regulations and are not directed to a change made in the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of “Reliable Information” under section 69501.1(a)(57) in that document.

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(57)(A)4 Accepted by Governmental Agencies

Comments: 22-12, 31-1, 36-4

Comment Summary:
The definition of “reliable information” has been amended to provide some clarification as to how scientific information submitted to DTSC will be reviewed or relied upon as part of an AA. The changes to the definition would broaden the criteria for what constitutes “reliable information” to include information that was developed or prepared for any international, federal, state, or local regulatory agencies for compliance purposes. This change also appears to clarify that reliable information may be scientific information prepared by industry scientists. DTSC should clarify that the information contemplated by section 69501.1(57)(A)(4) would include such information developed or commissioned by industry.

Conversely, another comment cautions that studies “conducted, developed, submitted, prepared for, or reviewed and accepted by an international, federal, state or local agency” or that published reports by any international, federal, state or local agency” that implement laws governing chemicals are not necessarily reliable merely by virtue of the agency conducting those activities.

Response:
These comments relate to a previous version of the regulations and are not directed at a change made in the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of “Reliable Information” under section 69501.1(a)(57) in that document.

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(58) “Reliable information demonstrating… chemical”

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

Comments Summary:
The definition of “Reliable information demonstrating the occurrence or potential occurrence of exposures to a chemical” is problematic due to the following issues:

- The definition includes a determination of the sources as reliable, independent of the actual reliability of any specific studies;
- The definition inappropriately limits this definition to chemicals that are persistent and bioaccumulative. Many chemical contaminants, particularly those commonly detected in wastewater, may not be considered persistent or accumulative by

traditional definitions, but are instead considered 'pseudo-persistent' because of their continuous release to aquatic environments –

- o The definition should be improved by eliminating the inappropriately narrow focus on persistent and bioaccumulative compounds; and
- o The definition should be expanded or clarified to include the presence or detection of the chemical in the environment.

Recommended changes are provided using the underline and strikeout conventions observed in the latest version of the Safer Consumer Products regulations:

- (58)(A) Monitoring data that shows the chemical or its degradation products, metabolites, or reaction products to be any of the following:

  1. Present in household dust, indoor air, or drinking water, or on interior surfaces;
  2. Present in, or released from, products used in or present in homes, schools, or places of employment;
  3. Present, or accumulative or persistent in the environment; or
  4. Present or, accumulative in aquatic, avian, animal, or plant species.

- (58)(D) Exposure or environmental modeling that indicates one or both of the following:

  1. Exposure point concentration(s) associated with adverse impacts; or
  2. Environmental presence or accumulation of a chemical.

Response:
These comments relate to a previous version of the regulations and are not directed to a change made in the April 2013 version of the proposed regulations. Nonetheless, DTSC provides the following response as a courtesy to the commenters.

In the ISOR, DTSC explains that the terms "reliable information" and "reliable information demonstrating the occurrence or potential occurrence of exposures to a chemicals" will together ensure that DTSC uses information that is reliable. Sources of scientific studies and scientific 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. The definition of "reliable information demonstrating the occurrence or potential occurrence of exposures to a chemicals" (section 69501.1(a)(58)) 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.

The definition does not limit itself to chemicals that are persistent and bioaccumulative. Section 69501.1(a)(58)(A) allows for monitoring data for drinking water or data that shows the chemicals are released from products used in or present in homes, schools, or places of employment to serve as "reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical." Section 69501.1(a)(58)(D) allows for exposure or environmental modeling and section 69501.1(a)(58)(E) allows for monitoring data for solid waste, wastewater, biosolids, or storm water streams. All of these sources are tied to a release of a consumer product and potential exposures.

As for the suggested language, in section 69501.1(a)(58)(A), the term "chemical," as defined in proposed section 69501.1(a)(20)(A), already includes a chemical's degradation products, metabolites, or reaction products. It is unnecessary to restate what is included in the definition of "chemical." In section 69501.1(a)(58)(D), the exposure point concentrations associated with adverse impacts address the presence of chemicals. For example, if copper is found in a body of water, modeling studies may be undertaken to determine the sources of the chemical. There would also be an associated exposure point concentration for aquatic toxicity that would indicate the potential for adverse ecological impacts or adverse water quality impacts.

DTSC is making no changes to the regulations in response to these comments.

§ 69501.1(a)(59)(B) Chemicals Present in the Priority Product

Comments: 8-32, 17-22, 20-13, 27-7

Comments Summary:
This section in the revised proposed regulations (April 2013) defines "Replacement Candidate Chemical" and "replacement chemical" completely opposite to its original meaning. Does DTSC mean that a chemical that is present at a higher concentration than other chemicals in the Priority Product would be considered as a potential replacement chemical? In light of the significant impact of this definition on implementing the proposed regulations and, particularly, the AA process to be undertaken by responsible entities, DTSC must revise this definition. The following recommendations were made to amend this definition:

- The definition must be revised to make its meaning clear and must provide the public with a further opportunity to comment on the revised definition;

- DTSC must explain its rationale in detail and provide illustrations of its application in the FSOR; and
- This provision should be improved to consider risk-based determinations, which account for multiple chemicals being required to replace the function of a single chemical or potential increased exposure of a "less toxic" replacement.

Response:
The revised definition (April 2013) of "Replacement Candidate Chemical" in section 69501.1(a)(59)(B) clarifies that an increase of an existing chemical in a Priority Product is considered a replacement chemical. The January 2013 version and April 2013 version of the definition of "Replacement Candidate Chemical" are set out below:

- "'Replacement Candidate Chemical' or 'replacement chemical' means a Candidate Chemical or other chemical, whichever is applicable, that replaces, or is under consideration to replace, the Chemical(s) of Concern, in whole or in part, in an alternative to the Priority Product, and that is one of the following:

  (A) A chemical that is not present in the Priority Product; or
  (B) A chemical that is present at a lower concentration in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern." (January 2013); and

- "'Replacement Candidate Chemical' or 'replacement chemical' means a Candidate Chemical or other chemical, whichever is applicable, that replaces, or is under consideration to replace, the Chemical(s) of Concern, in whole or in part, in an alternative to the Priority Product, and that is one of the following:

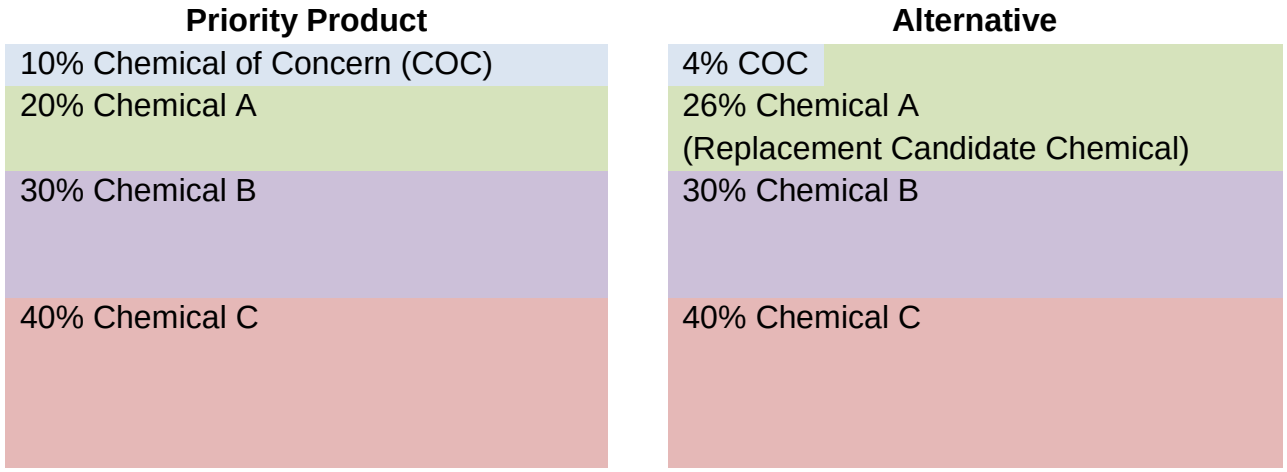
  (A) A chemical that is not present in the Priority Product; or
  (B) A chemical that is or would be present in the alternative at a higher concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern." (April 2013)

For example, assume there is a Priority Product (see Figure 1) that has the Chemical of Concern at a 10% concentration. A replacement Candidate Chemical may be a chemical that is not present in the Priority Product that completely replaces or reduces the concentration of the Chemical of Concern in the Priority Product. However, the replacement Candidate Chemical may also be a chemical that is currently included in the Priority Product. The alternative being considered is a formulation that reduces the concentration of the Chemical of Concern down to 4%, but there is a need to increase the concentration of an existing chemical in the product, "Chemical A," to make the

formulation functionally acceptable. Chemical A also meets the definition of a Replacement Candidate Chemical. Section 69501.1(a)(59)(B) may not apply to all situations; this provision may be more applicable for formulations or homogenous materials. DTSC will explain its rationale in detail and provide illustrations of its application in the FSOR.

Figure 1 is a graphic representation of a replacement Candidate Chemical that is or would be present in the alternative at a higher concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern. The replacement Candidate Chemical in this figure is "Chemical A."

Figure 1. Graphic Representation of a Replacement Candidate Chemical



This provision will not be revised to consider risk-based determinations. The AA provisions allow risk-based determinations to account for multiple chemicals being required to replace the function of a single chemical or potential increased exposure of a "less toxic" replacement.

DTSC is making no change to the regulations in response to these comments.

§ 69501.1(a)(61) "Retailer"

Comment: 10-8

Comment Summary:

The comment recommends that activities including repair, refurbishment, maintenance of vehicles and motor vehicle parts retailers be exempted from the proposed regulation by revising the definition of "retailer" to exclude *entities selling only products intended for the repair, maintenance, or refurbishment of motor vehicles as defined in California Vehicle Code § 415(a) through (c).*

Response:
These comments relate to a previous version of the regulations and are not directed to a change made in the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in section 69501.1(a)(15) and (16) of this document.

DTSC is making no change to the regulations in response to these comments.

§ 69501.1(a)(62) "Safer alternative"

Comments: 8-37, 8-38, 8-39, 8-40, 8-41

Comments Summary:
DTSC did not address the definition of "safer alternative" in the April 2013 version of the regulations. The comments above express concerns about the additional burden this places on the manufacturer and the limitations it imposes on the universe of chemicals that may be considered as candidates for replacing Chemicals of Concern.

First, it creates an overly broad universe of determinations that need to be made by the manufacturer. A manufacturer must now assess not only the relative hazards and exposure of the chemical in the product but also with the manufacturing process itself. Requiring a comparison to other products beyond the Priority Product requires information that may well be trade secret or proprietary and unavailable. The second and equally troublesome concern is that DTSC has also narrowed the universe of chemicals that a manufacturer may consider when looking for viable alternatives. The regulations should use the definition found in the July 2012 version of the proposed regulations, thereby deleting the Candidate Chemicals from the definition of "safer alternative."

Response:

These comments relate to a previous version of the regulations and are not directed to a change made in the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments were addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of "Safer Alternatives" under section 69501.1(a)(62) in that document.

DTSC is making no change to the regulations in response to these comments.

§ 69501.2 Duty to Comply
§ 69501.2 General

Comment: 30-2

Comment Summary:
The total lead time through supply chain to produce a consumer product is quite long, and each portion of the supply chain is always keeping some amount of inventory at each stage. The comment recommends that regulations imposed on a Priority Product should allow sufficient time for depleting existing inventories of the product to avoid unnecessary disposal of materials and half-products, which may cause another kind of environmental impact.

Response:
This comment relates to a provision changed from the prior iteration, but the comment is not directed to a change made in the April 2013 version of the proposed regulations. . This same comment was previously submitted and was responded to in the Response to Comments document for the July 2012 version of the proposed regulations. Please see section 69501.2 Duty to Comply of that document for further discussion.

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

§ 69501.4 Chemical and Product Information

§ 69501.4(a)(2) Information Gathering: Scope of Products and Chemicals

Comments: 4-4, 20-14

Comments Summary:
The proposed regulations provide DTSC with authority to request information from any product or chemical manufacturer, importer, retailer, or assembler even for consumer

products specifically excluded from the authorizing legislation and regardless of whether these chemicals or products are subject to the regulations. It is questionable whether DTSC currently has authority under Health and Safety Code sections 25252 through 25255, and 25257 to require these information requests. The Legislature clearly did not intend to grant DTSC with such unlimited discretion and authority. Comments recommend that DTSC eliminate proposed section 69501.4(a)(2).

Response:
The proposed regulations were revised in the April 2013 version to clarify that this provision does not apply to consumer product specifically excluded from the authorizing legislation—and by extension—these regulations. The remainder of this comment relates to a provision that was changed, but the comment is not directed to the change made. This comment was addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion of Chemical and Product Information under section 69501.4(a)(2) in that document.

DTSC is making no change to the regulations in response to this comment.

§ 69501.5 Availability of Information on DTSC's Website

§ 69501.5(a) Website Postings Requiring Noticing

§ 69501.5(a)(3)(A) Exemption Determinations

Comment: 20-15

Comment Summary:
Commenter is concerned about the inclusion of the website posting of exemption determinations and rescissions of exemption determinations in section 69501.5. It is unclear about the benefit of posting this information and recommends removal of these provisions.

Response:
Section 69501.5 specifies a list of documents that DTSC will post on its website. In order to implement these regulations, making 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. Exemption determinations will be DTSC decisions that are open for public review and are one of many of the required documents that will be posted for transparency.

§ 69501.5(b) Additional Website Postings

§ 69501.5(b)(3) Priority Product Information

Comment: 12-3

Comment Summary:
Section 69501.5(b)(3) needs to be amended to ensure the removal from DTSC's website information such as the name and address of a company whose product was exempted from the AA process because the Chemical of Concern met the AA Threshold, or the company placed into the stream of commerce in California an alternative product pursuant to an approved Final AA that does not require a regulatory response.

Response:
The comment relates to a provision that was changed from the prior iteration, but the comment is not directed to the change made. Nonetheless, DTSC notes that this comment was addressed in Article 1 of the January 2013 Response to Comments document. Please see the discussion under section 69501.5 Availability of Information on DTSC's Website in that document.

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

ARTICLE 2. PROCESS FOR IDENTIFYING CANDIDATE CHEMICALS

Support for the Amendments in Article 2

Comments: 15-5, 25-6, 26-17, 26-18

Comments Summary:

These comments are in support of the provisions set out in Article 2 for identifying Candidate Chemicals. The provisions in Article 2 carry out the directives in Health and Safety Code sections 25252 and 25253 as well as the overarching legislative intent of the "Green Chemistry" statutes embodied in Health and Safety Code section 25255(a). Specific remarks from the commenters expressing support for section 69502.2(a) Candidate Chemicals Identification in Article 2 are as follows:

- Support the reference to the initial list of chemicals for consideration as the "Candidate Chemicals list" rather than "Chemicals of Concern"; and
- Support identification of a more focused subset of 230 Candidate Chemicals to be selected on the basis of the chemicals' hazard traits and exposure characteristics for the outset of the program through 2016 and suggest using a similar approach to identify focused Candidate Chemicals beyond 2016.

Response:
The Department of Toxic Substances Control (DTSC) acknowledges the support offered by these commenters. There are no changes required to the proposed regulations in response to these comments.

Article 2 specifies a process to identify chemicals 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 that 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. Previously "Candidate Chemicals" were known as "Chemicals of Concern" in the proposed regulations dated July 2012. Since then, the term "Chemicals of Concern" has been redefined and the term "Candidate Chemicals" has been used in the revised proposed regulations dated January 2013, and retained in the revised proposed regulations dated April 2013.

The commenters are referring to provisions in section 69503.6 for the initial list of Priority Products adopted prior to January 1, 2016. Section 69503.6(a) states that

DTSC may list a product-chemical combination as a Priority Product only if one or more Candidate Chemical(s) that is/are the basis for listing the product, meet one or more criteria specified in section 69502.2(a)(1) ***and*** meet one or more criteria specified in section 69502.2(a)(2).

As specified in Article 3, section 69503.5(a)(2), subsequent Priority Products lists must be established through rulemaking under the Administrative Procedure Act (APA) (commencing with Government Code section 11340). DTSC is making no changes to the regulations in response to these comments.

§ 69502.2 Candidate Chemicals Identification
§ 69502.2(a) Candidate Chemicals List

Comments: 14-4, 48-4

Comments Summary:
These commenters oppose the change in terminology from “Chemicals of Concern” to “Candidate Chemicals,” stating that this is a significant weakening of the regulations, and goes against the language of the statute. The commenters also state that these chemicals have been identified as hazardous by respected authoritative bodies and calling them "Chemicals of Concern" is scientifically accurate. They express concern that this revision could be misleading to the public of the potential threat posed by these chemicals and recommend that DTSC should modify these regulations to refer to the initial list of chemicals as “Chemicals of Concern.”

Response:
These comments relate to a previous version of the regulations and do not address a change made to the proposed regulations in the April 2013 version. Nonetheless, DTSC notes that these comments have been addressed in Article 2 of the January 2013 Response to Comments document. Please see the discussion on Candidate Chemicals Identification under section 69502.2(a) in that document. DTSC is making no changes to the regulations in response to these comments.

While DTSC respectfully disagrees with the commenter and is making no changes to the proposed regulations in response to this comment, DTSC would like to reiterate the response to this serious allegation. DTSC has met the intent of the authorizing legislation “to identify Chemicals of Concern” in the proposed regulations (January 2013 and April 2013). The regulatory requirements are initiated only when a Candidate

Chemical (previously known as COC) has been designated a Chemical of Concern (new definition as of January 2013) based on a product-chemical combination being prioritized and listed as a Priority Product. Thus, DTSC has amended the regulations to clearly effectuate the 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), first chemicals are identified as Candidate Chemicals. Then, a subset of these chemicals is further prioritized and identified as Chemicals of Concern based on evaluation and prioritization of product-chemical combinations as Priority Products. This is clearly consistent with the directives in Health and Safety Code section 25252(a), discussed above.

Potential

Comment: 9-6

Comment Summary:
This comment refers to the proposed regulations' (January 2013 and April 2013) use of the term "potential" in regard to additions of chemicals to the list of Candidate Chemicals. The commenter states that replacing the phrase "ability to cause harm" with "potential to cause harm" unnecessarily broadens the level of risk associated with a chemical and recommends that the definition should be narrowed to reflect a reasonable level of hazard a chemical poses when used as designed.

Response:
This comment relates to a previous version of the regulations and does not address a change made to the revised proposed regulations in the April 2013 version. Although DTSC has reviewed this comment and has determined that no regulatory change is necessary, DTSC offers the following clarification in response to this comment.

DTSC disagrees with the commenter's assertion that the use of the term "potential" unnecessarily broadens the level of risk associated with a chemical. 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 fulfilled 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 may 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. Thus, use of the term "potential" ensures the use of scientific rigor, which is generally desired.

"Potential" is defined in section 69501.1(a)(51) as "the phenomenon described is reasonably foreseeable based on reliable information." It is consistent with Health and Safety Code section 25252(a)(2) and (3), which mandate that in establishing an identification and prioritization process that, at a minimum, evaluate the "potential" for exposure to a chemical in a consumer product and "potential" effects on sensitive subpopulations be included.

On the other hand, "ability" refers to a chemical's inherent property to cause adverse impacts, which broadens the level of risk associated with a chemical. Therefore, the replacement of the phrase "ability to cause harm" with "potential to cause harm" has been retained in the revised proposed regulations (January 2013 and April 2013).

For a more detailed discussion on the appropriateness of the use of the term "potential," please refer to the discussion of Causation Standards in the July 2012 Response to Comments document. DTSC has reviewed this comment and has determined that no regulatory change is necessary.

Thresholds and Risk Assessment

Comments: 3-8, 20-16

Comments Summary:
These comments expressed concern that the proposed regulations do not attempt to provide prioritization of higher risk chemicals in consumer products, while many of the underlying lists incorporate threshold values based upon rigorous scientific determinations of risk. The commenters state that there is no indication that any thresholds or any risk determinations will be included in the Candidate Chemicals list preparation, considering that in the latest version of the regulations only contaminants may be exempted from consideration if they are a Chemical of Concern in a Priority Product at a concentration below the practical quantitation limit for the chemical.

Response:
These comments do not address a change made to the proposed regulations in the April 2013 version. Nonetheless, DTSC notes that these comments have been

addressed in Article 2 of the January 2013 Response to Comments document. Please see the discussion on Thresholds and Risk Assessment under section 69502.2(a) in that document. Please also refer to the discussion on Alternatives Analysis Threshold Notification in Article 5 of that document. DTSC is making no changes to the regulations in response to these comments.

Initial List of Candidate Chemicals

Comments: 15-6, 25-7, 30-5

Comments Summary:
These commenters object 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 and state that some of the lists do not seem to meet the criteria that would be applied to the addition of subsequent "lists" and quite a lot of chemicals are not scientifically proven to be hazardous. The commenters recommend that DTSC extend the scientific criteria for scientific rigor required for addition of chemicals to the list of Candidate Chemicals to all chemicals identified as a Candidate Chemicals, including those selected from authoritative organizations' lists for the initial list of Candidate Chemicals.

Response:
These comments do not address a change to the proposed regulations made in the January 2013 version. Nonetheless, DTSC notes that these comments have been addressed in Article 2 of the Response to Comments document for the January 2013 version of the proposed regulations. Please see the discussion on Potential and on Initial List of Candidate Chemicals under section 69502.2(a) in that document. DTSC is making no changes to the regulations in response to these comments.

List: Other Lists

Comment: 42-1

Comment Summary:
This commenter suggests that to significantly improve the ability of DTSC to identity chemicals potentially harmful to the California environment, the following lists should be added to the lists identified in section 69502.2(a) of the proposed regulations:

1. Stockholm Convention list of Persistent Organic Pollutants;

2. Chemicals listed by the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) as having health or environmental hazards;
3. Canadian Health Measures Survey Environmental Chemicals list;
4. Constituents of Emerging Concerns (CECs) recommended for initial monitoring by the California State Water Resources Control Board's Science Advisory Panel;
5. Oregon Priority Persistent Pollutant list; and
6. Washington Puget Sound Chemicals in Toxics Assessment list.

Response:
This comment does not address a change made in the April 2013 version of the proposed regulations. DTSC notes that a similar comment with other sources of chemical lists has been addressed in Article 2 of the July 2012 Response to Comments document. See discussion of List: Other Programs of that document.

Nonetheless, 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 at this time, as discussed below:

1) Stockholm Convention list of Persistent Organic Pollutants -

   The international community called for action to reduce and eliminate production, use, and releases of persistent organic pollutants. A strict international regime for initial lists of 12 persistent organic pollutants was established in the Stockholm Convention, with provisions for including additional chemicals on these lists. The original persistent organic pollutants were mainly pesticides and the new chemicals listed include four types of polybromodiphenyl ethers, alpha hexachlorocyclohexane, beta hexachlorocyclohexane, perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride and pentachlorobenzene. Pesticides are exempt from this program, while all other industrial chemicals are not unique to this list of chemicals and are already included in the initial list of Candidate Chemicals. Thus, inclusion of this list would add no new chemicals to the Candidate Chemicals list.

2) Chemicals listed by the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) as having health or environmental hazards -

   As the name suggests, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is a single internationally agreed upon system of chemical classification and hazard communication through labelling and Safety

Data Sheets. This system includes harmonized criteria for the classification of physical hazards, health hazards, and environmental hazards. Thus, it is a list of hazard statements for all of the hazardous chemicals. The goal of the GHS is to identify the intrinsic hazards of chemical substances and mixtures and to convey hazard information about these hazards. It would not be appropriate to include chemicals listed by the Globally Harmonized System of Classification and Labeling of Chemicals because this list applies to all of the chemicals in commerce.

3) Canadian Health Measures Survey Environmental Chemicals list -

The Canadian Health Measures Survey is a national survey that is being led by Statistics Canada, in partnership with Health Canada and the Public Health Agency of Canada, which collects information from Canadians about their general health. Through personal interviews and the collection of physical measurements, the survey is providing baseline data on indicators of environmental exposures, chronic diseases, infectious diseases, fitness, and nutritional status, as well as risk factors and protective characteristics related to these areas. This an ongoing survey that includes physical measurement factors such as height and weight, blood pressure, physical fitness, and lung function measures, as well as many measures based on blood and urine samples including environmental chemicals.

In January 2012, the Canadian Health Measures Survey began the third round of data collection; this includes sampling of indoor air and tap water for measurement of environmental chemicals. This sample collection is to be completed in 2013. This list of Canadian Health Measures Survey of Environmental Chemicals is a work in progress and, therefore, not appropriate for inclusion in the proposed regulations at this time.

4) Constituents of emerging concern (CECs) recommended for initial monitoring by the California State Water Resources Control Board's Science Advisory Panel -

CECs is a term used to include a broad range of unregulated chemical components found at trace levels in many of our water supplies, including surface water, drinking water, wastewater, and recycled water. The list of constituents of emerging concerns mostly includes pesticides and a few other industrial chemicals. Pesticides are exempt from this program, while all other industrial chemicals are not unique to this list of chemicals and already included in the initial list of Candidate Chemicals.

5) Oregon Priority Persistent Pollutant list -

In October 2009, the Oregon Department of Environmental Quality released the Final priority list of persistent pollutants with 118 toxic pollutants, divided into two categories that persist in the environment or accumulate in animals. All of the pollutants on the list have potential to cause harm to human health or aquatic life if they get into the water and thereby have the potential to pose a threat to Oregon's waters. Department of Environmental Quality continues to focus on strategic planning and measures that could be implemented by state and local governments, non-governmental organizations, businesses, industries, manufacturers, and individual citizens to reduce the presence of persistent pollutants in Oregon's waters. This is a onetime list of prioritized persistent pollutants compiled by the Oregon Department of Environmental Quality as directed by the 2007 Oregon Legislature in order to guide Oregon's pollution prevention efforts. The Oregon Priority Persistent Pollutants list is a static list that would not be appropriate for inclusion in this program as it does not meet the list selection criteria for the proposed regulations.

6) Washington Puget Sound Chemicals in Toxics Assessment list -

The Puget Sound Toxics Assessment focuses on 17 toxic chemicals and chemical groups due to their potential to harm the health of people, fish, and Puget Sound. Toxic chemicals enter the Puget Sound basin from many scattered and hard-to-control sources. Once released, toxic chemicals can affect the environment and human health. While there are thousands of chemicals in use today, scientists had to narrow the field to a manageable number of chemicals to study and to understand how other pollutants not included in the assessment may also behave in the environment. Chemicals in the Toxics Assessment include metals, polyaromatic hydrocarbons, petroleum-based compounds, flame retardants, phthalates, polychlorinated biphenyls and dichlorodiphenyltrichloroethane, dioxins, triclopyr, and nonylphenol. All of the chemicals are already included in the initial list of Candidate Chemicals from other source lists except triclopyr, which is an herbicide and, therefore, exempt from the proposed regulations under the pesticide exemption.

DTSC reiterates that revising the regulations is not necessary in order to add any chemical(s) or chemical lists as suggested by the commenter. Please see Article 4 provisions that allow stakeholders to petition DTSC to add to and also delete list of chemicals from the initial list of Candidate Chemicals. For all of the reasons stated above, DTSC is making no changes to the regulations in response to this comment.

European Commission Lists

Comments: 4-5, 5-9, 26-15

Comments Summary:
These comments refer to the citations for the "Candidate Chemicals" list sources in section 69502.2(a)(1). These commenters state that proper citation for section 69502.2(a)(1)(B), 69502.2(a)(1)(C), 69502.2(a)(1)(G) and 69502.2(a)(1)(I) should be "by the European Chemicals Agency." This agency has ultimate responsibility for both classification and Substances of Very High Concern regulations conducted under European Union laws.

Response:
These comments relate to a previous version of the regulations and do not address a change to the proposed regulations made in the January 2013 version. However, DTSC has reviewed these comments and declined to make any changes to the proposed regulations.

In the proposed regulations (July 2012) and the revised proposed regulations (January 2013 and April 2013 versions), section 69502.2(a)(1)(B), the list of chemicals classified as carcinogens, mutagens, and/or reproductive toxicants Categories 1A and 1B and section 69502.2(a)(1)(I), the list of chemicals classified by the European Commission (EC) as respiratory sensitizers Category, both refer to the “Regulation (EC) No 1272/2008 of the European parliament and of the council of 16 December 2008.[1]”

Section 69502.2(a)(1)(C), list of chemicals included as Category 1 endocrine disruptors in the candidate list of Substances of Very High Concern, and section 69502.2(a)(1)(G), chemicals included as persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, both refer to the “Regulation (EC) No 1907/2006 of the European parliament and of the council of 18 December 2006.[2]”

The European Union commented on the proposed regulations (July 2012) and revised proposed regulations (January 2013) to provide the correct citation. Furthermore, the

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF
[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF

European Chemicals Agency (ECHA) that implements the European Union's chemicals legislation also cites “by the European Commission” in the references for the above mentioned regulations.

Therefore, the revised proposed regulations (April 2013) retain the references as listed below:

- Section 69502.2(a)(1)(B) - Chemicals classified by the European Commission as carcinogens, mutagens, and/or reproductive toxicants Categories 1A and 1B in Annex VI to Regulation (EC)1272/2008;
- 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;
- 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; and
- Section 69502.2(a)(1)(I) - Chemicals classified by the European Commission as respiratory sensitizers Category 1 in Annex VI to Regulation (EC)1272/2008.

§ 69502.2(a)(1)(C) Category 1 Endocrine Disruptors

Comments: 4-6, 5-10, 25-14, 26-16

Comments Summary:
These comments refer to section 69502.2(a)(1)(C) list of Category 1 endocrine disruptors and state that that there is no process under Substances of Very High Concern categorization or in any other part of the Registration, Evaluation, Authorisation and Restriction of Chemical substances.(REACH) regulation for categorization of endocrine disrupting chemicals. Therefore, the commenters recommend that reference to “Category 1 endocrine disruptors” should be eliminated from the regulations.

Response:
DTSC has reviewed this comment and determined that no change is necessary to the proposed regulations in response to these comments.

Section 69502.2(a)(1)(C) of the proposed regulations references "Category 1" as a qualifying descriptor for the list of endocrine disruptors included in the initial list of Candidate Chemicals.

Under the European Union's REACH regulation, endocrine disruptors may be included under the authorization scheme if they are deemed to be Substances of Very High Concern (SVHC) according to Article 57(f). When the regulation was enacted in 2006, it was recognized that there was limited scientific knowledge about the effects of endocrine disruptors. Consequently, the European Commission is mandated reviewing the provisions of REACH regarding endocrine disruptors (Art 138 (7)) by June 1, 2013. Substances to which authorization will apply are listed in Annex XIV of REACH. Before a substance may be included on Annex XIV, it must be identified as a Substance of Very High Concern and placed on the Candidate List.

In December 1999, the European Commission adopted a Community Strategy for Endocrine Disruptors. The strategy addressed key requirements of further research and appropriate policy action; and recommended short, medium and long-term actions as discussed below.

Short term actions –
The Directorate-General for the Environment commissioned a series of studies in order to develop a coherent approach to establish a list of priority substances for further evaluation. The European Commission services developed a priority list of substances to be investigated further on the basis of their possible endocrine disrupting properties. This list of over 432 candidate substances, based on the proposals of various organizations and countries for suspected endocrine disruptors, has been subdivided into categories: Category 1, Category 2; and Category 3a, and 3b.

Category 1 - includes 194 substances with more or less comprehensive evidence of endocrine-disrupting effects in live animals and that are, therefore, prioritized for further evaluation of endocrine disrupting properties.

The Directorate-General for the Environment developed a database with the substances suspected of having the potential for endocrine disruption. The information that was used to establish a priority list has been made available through Directorate-General for the Environment's Endocrine Disruptor Website.[3] As of September 2010, the Joint Research Centre, Institute for Health and Consumer Protection has taken over the

[3] http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/endocrine_disrupters/eas_database

existing database with the results of the 2000-2007 studies from Directorate-General for the Environment, to develop it further as a Web-based Information System on Endocrine Active Substances.

Medium term actions –
There has been considerable activity within the European Union to develop criteria and testing strategies for identification of endocrine disruptors as a consequence of severe restrictions on substances identified as endocrine disruptors imposed by several pieces of legislation. The EC has recommended that exposure to multiple endocrine disruptors should be further addressed within relevant existing Community legislation.

Long term actions –
In accordance with Article 57 of the REACH regulation, substances:

- Having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or to the environment which give rise to a level of concern equivalent to that of categories 1A or 1B of carcinogenic, mutagenic and/or reproductive toxicants, or persistent bioaccumulative toxicants, or very persistent and very bioaccumulative substances; and;
- That have been identified on a case-by-case basis in accordance with the procedure set out in Article 59 of the Regulations…

…may be included in Annex XIV (List of Substances Subject to Authorisation), in accordance with the procedure laid down in Article 58 of the Regulation. As mentioned above, the European Commission is mandated to review the provisions of REACH regarding endocrine disruptors (Art 138 (7)) by 1 June 2013. For the reasons stated above, DTSC is making no regulatory changes in response to these comments.

§ 69502.2(a)(1)(I) European Union Respiratory Sensitizers

Comment: 20-17

Comment Summary:
This comment refers to the inclusion of Category I respiratory sensitizers in section 69502.2(a)(1)(I). The commenter states that all other lists included in the proposed regulations have been evaluated publicly on the basis of the criteria elicited in the Initial Statement of Reasons (ISOR), but this list has not been evaluated. Therefore, this list should not be included in the proposed regulations.

Response:
This comment relates to a previous version of the regulations and does not address a change made to the proposed regulations in the April 2013 version. Nonetheless, DTSC notes that this comment has been addressed in Article 2 of the January 2013 Response to Comments document. Please see the discussion on EU Respiratory Sensitizers under section 69502.2(a)(1)(I) in that document. DTSC is making no changes to the regulations in response to this comment.

§ 69502.2(a)(2)(D) 303(d) List Impaired Waterways

Comment: 20-18

Comment Summary:
This comment refers to the inclusion of pollutants from 303(d) of the federal Clean Water Act in section 69502.2(a)(2)(D). The commenter states that all other lists have been evaluated publicly on the basis of the criteria elicited in the ISOR and expresses the concern that this list includes chemicals/constituents already "managed" by water quality agencies. The commenter recommends that the 303(d) list should be removed from the proposed regulations.

Response:
This comment relates to a previous version of the regulations and does not address a change made to the proposed regulations in the April 2013 version. Nonetheless, DTSC notes that this comment has been addressed in Article 2 of the January 2013 Response to Comments document. Please see the discussion of the 303(d) List of Impaired Waterways under section 69502.2(a)(2)(D) in that document. DTSC is making no changes to the regulations in response to this comment.

§ 69502.2(b) Additions to the Candidate Chemicals List

Comments: 15-6, 25-7

Comments Summary:
These commenters state that same level of scientific rigor required for additions to the list of Candidate Chemicals, should also be mandated for consideration of chemicals on the initial Candidate Chemicals lists prescribed under these regulations.

Response:

These comments relate to a previous version of the regulations and do not address a change to the regulations made in the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that these comments have been addressed in Article 2 of the January 2013 Response to Comments document. Please see the discussion of "Potential" under section 69502.2(a) of that document. DTSC is making no changes to the regulations in response to these comments.

Comment: 30-4

Comment Summary:
This comment refers to section 69502.2(b) and suggested that additions to the Candidate Chemicals list should also consider chemical information required by other regulations such as European Union's REACH regulations, with the view to harmonize the approach.

Response:
These comments relate to a previous version of the regulations and do not address a change to the regulations made in the April 2013 version of the proposed regulations. Nonetheless, DTSC notes that this comment has been addressed in Article 2 of the July 2012 Response to Comments document. Please see the discussion under the heading "Harmonize" in Other Miscellaneous Comments section of that document. DTSC is making no changes to the regulations in response to this comment.

§ 69502.3 Candidate Chemicals List
§ 69502.3(a) Informational List

Comments: 11-3, 11-4

Comments Summary:
These comments refer to section 69502.3(a). The commenter suggests that DTSC should update the list of Candidate Chemicals at least every twelve (12) months to reflect changes to the underlying lists and warns that failure to do so will result in an outdated list.

Response:
These comments relate to a previous version of the regulations and do not address a change made in the April 2013 version of the revised proposed regulations. Nonetheless, DTSC notes that these comments have been addressed in Article 2 of the July 2012 Response to Comments document. Please see the discussion on Update the

List under section 69502.3(a) of that document. DTSC is making no changes to the regulations in response to these comments.

§ 69502.3(c) Public Notice of Proposed List Revisions

Comments: 30-3, 30-5

Comments Summary:
This commenter is concerned that the process to identify the Candidate Chemicals is quite dependent on DTSC's study and decision, considering that many chemicals are not scientifically proven to be hazardous. Commenter alleges that without holding stakeholder discussions and receiving all of the stakeholder opinions, the determination may not be considered fair. Also, the commenter states that the public comment period of forty-five (45) days sounds too short and suggests that the time frame specified in the European Union's REACH program should be considered.

Response:
These comments relate to a previous version of the regulations and do not address a change made in the April 2013 version of the revised proposed regulations. These comments have been addressed in Article 2 of the July 2012 Response to Comments document. Please see the discussion under section 69502.3(c) Public Notice of Proposed List Revisions of that document. DTSC is making no changes to the regulations in response to this comment.

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ARTICLE 3. PROCESS FOR IDENTIFYING AND PRIORITIZING PRODUCT-CHEMICAL COMBINATIONS

Support for the Amendments in Article 3

Comments: 3-9, 5-1, 6-1, 7-1, 7-3, 8-4, 8-26, 8-29, 15-7, 15-8, 20-1, 20-20, 20-21, 20-27, 22-9, 22-15, 24-3, 24-6, 25-4, 25-8, 25-10, 26-3, 26-19, 26-20, 27-2, 27-5, 27-10, 29-2, 36-6, 38-1, 46-4, 47-1

Comments Summary:
The above comments expressed support for the inclusion of the following amendments or retention of the specified 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 Candidate Chemicals in consumer products. Consumer products listed as Priority Products containing Candidate Chemicals (considered Chemicals of Concern when in a Priority Product) will be subject to the requirements in Article 5.

The comments expressed support for the following provisions:

- Section 69503, which changed the terminology to “Candidate Chemical” unless a product-chemical combination becomes listed as a Priority Product, and the focus on product-chemical combinations;
- Section 69503.2(a), which states the key prioritization principles that any product-chemical combination identified and listed as a Priority Product must meet;
    - Support for requiring both of the two criteria: potential for exposure and potential for that exposure to have significant or widespread impacts;
- Section 69503.2(b)(1)(C), inclusion of new language which specifies the standards that the Department of Toxic Substances Control (DTSC) will use to evaluate the quality of available information used to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects when identifying and prioritizing product-chemical combinations for potential listing as Priority Products;
    - Appreciate that DTSC has taken efforts to address weight of evidence in determining reliable information;
    - The changes to the current definition would shift the criteria for evaluating such information to be somewhat more broadly applicable to any information considered in a product-chemical prioritization, and additionally prescribe that such information is to be a “scientific study or other scientific information”;

- Section 69503.5(a)(2), which specifies that the Priority Products list shall be established and updated through rulemaking pursuant to the Administrative Procedure Act (APA);
- Section 69503.5(c), which specifies that DTSC may include on the Priority Products list an Alternatives Analysis (AA) Threshold concentration for any Chemical of Concern that is an intentionally added ingredient and an AA Threshold greater than the applicable practical quantitation limit (PQL) for any Chemical of Concern that is a contaminant; and
- Section 69503.6(b), which specifies that the initial final list of Priority Products shall include no more than five (5) Priority Products.

These supportive comments did not recommend any changes to the regulations; therefore, DTSC made no changes to the regulations in response to these comments.

§ 69503.2 Product-Chemical Identification and Prioritization Factors

Comment: 41-9

Comment Summary:
The above comment expressed concern with section 69503.2, which specifies the key prioritization principles and the identification and prioritization process that DTSC will employ in prioritizing products that contain Candidate Chemicals. In summary, the following concern was expressed:

- The risk of exposure to chemicals in tires is reduced or eliminated as the chemicals in tire formulations undergo a chemical reaction during the vulcanization or heating of a tire during the manufacturing process.

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised these issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC is making no change to the regulations in response to this comment.

§ 69503.2(a) Key Prioritization Principles

Comments: 9-6, 26-23

Comments Summary:
The above comments expressed concern with section 69503.2(a), which specifies two key prioritization principles that any product-chemical combination identified and listed as a Priority Product must meet:

(1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
(2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

In summary, the following concerns were expressed:

- The use of the word "potential" instead of "ability" unnecessarily broadens the level of risk associated with a chemical; and
- DTSC should eliminate the language "potential for exposure in quantities that would contribute to or cause adverse impacts."

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised these issues with respect to prior text of the proposed regulations, these issues are responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC is making no changes to the regulations in response to these comments.

§ 69503.2(b) Identification and Prioritization Process

Comments: 3-8, 3-10, 6-6, 20-19, 26-23, 29-3

Comments Summary:
The above comments expressed concern with section 69503.2(b), which specifies the process DTSC will follow to identify and list Priority Products. DTSC will evaluate product-chemical combinations to determine the potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects associated with the product-chemical combination by considering the factors in sections 69503.2(b)(1) and (b)(2). DTSC may, in its discretion, consider paragraph (b)(3). In summary, the following concerns were expressed:

- A commenter was disappointed that the proposed revisions do not attempt to provide prioritization of higher risk chemicals in consumer products;
- The proposed revisions lack quantitative, objective criteria for prioritization;

- DTSC should use risk-based approaches and utilize scientifically recognized methodologies by which to evaluate product-chemical combinations;
- There was concern about the non-quantitative, "narrative" process for product-chemical prioritization; and
- DTSC should use a scientifically based approach, and substances that exhibit the greatest hazards should be given priority (*i.e.*, carcinogens, developmental and reproductive toxins and persistent, bioaccumulative, and toxic (PBTs).

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised these issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC made no changes to the regulations in response to these comments.

§ 69503.2(b)(1)(A) Adverse Impacts and Exposures

Comments: 9-3, 9-4

Comments Summary:
The above comments expressed concern with section 69503.2(b)(1)(A), which specifies that DTSC will begin the product-chemical combination evaluation process by evaluating potential adverse impacts posed by Candidate Chemicals in products due to potential exposures during the life cycle of the products by considering one or more factors listed in sections 69503.3(a) and 69503.3(b). In summary, the following concern was expressed:

- If a product does not contribute to or cause widespread adverse public health and/or environmental impacts, it should be excluded from the prioritization process or be given special consideration and lower prioritization.

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised these issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC is making no changes to the regulations in response to these comments.

§ 69503.2(b)(1)(B) Adverse Waste and End-of-Life Effects

Comment: 9-5

Comment Summary:
The above comment expressed concern with section 69503.2(b)(1)(B), which specifies that DTSC may consider product uses, discharges, or disposals that have the potential to contribute to or cause adverse waste and end-of-life effects associated with the Candidate Chemical(s). In summary, the following concern was expressed:

- The regulations should only apply in instances where end-of-life issues are not being dealt with by existing market-based programs.

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised this issue with respect to the prior text of the proposed regulations, this issue is responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC is making no change to the regulations in response to this comment.

§ 69503.2(b)(1)(C) Availability of Information

Comments: 5-7, 15-4, 15-7, 22-16, 24-7, 25-5, 25-9, 26-9, 36-5

Comments Summary:
The above comments express concern with section 69503.2(b)(1)(C), which specifies that DTSC will consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects and specifies the criteria DTSC will consider to evaluate the quality of available information. In summary, the following concerns were expressed:

- There is no discussion on the use of a full “weight of evidence” determination in the evaluation of such information;
- There was a concern that these standards may be intended to preclude inclusion of non-published information from industry;

- There should be a requirement of a method that would show general acceptance by the scientific community;
- DTSC should remove “disinterested” from the criteria of a peer reviewer's independence and trustworthiness, and simply look to the education and experience of the reviewer;
- By extracting the factors for evaluating the quality of available information from the definition of “reliable information” and including them in sections 69502.2(b)(3) and 69503.2(b)(1)(C) DTSC inadvertently will restrict itself to consider these factors only in these instances and it should be considered in all aspects of the regulations; and
- These criteria were downgraded in the recent version of the regulations by removing the criteria from the “reliable Information” definition and moving them to this subsection.

Response:
In response to comments on the proposed regulations dated January 2013, DTSC amended section 69503.2(b)(1)(C) in the April 2013 version of the proposed regulations. Section 69503.2(b)(1)(C) was amended to make the criteria, previously in section 69501.1(a)(52) (July 2012) defining “reliable information” (since renumbered to section 69501.1(a)(57) (January 2013)), explicit in section 69503.2 of the proposed regulations. However, the prioritization process remains essentially unchanged. Section 69503.2(b)(1)(C) specifies that in evaluating the quality of the available information DTSC will consider, as applicable the following:

1. The level of rigor attendant to the generation of the information, including, when relevant, the use of quality controls;
2. The degree to which the information has been independently reviewed by qualified disinterested parties;
3. The degree to which the information has been independently confirmed, corroborated, or replicated;
4. The credentials and education and experience qualifications of the person(s) who prepared and/or reviewed the information; and
5. The degree to which the information is relevant for the purpose for which it is being considered by the DTSC.

The revisions do not in any way downgrade or diminish the process or criteria that DTSC will use in evaluating the information that is available. In response to concerns regarding weight of evidence and the use of available information to prioritize Candidate Chemicals and the consumer product that contain those chemicals, the provisions related to the review of the information were moved into Article 3, where the

requirements are directly applicable. DTSC included provisions regarding reliable information in sections section 69501.1(a)(57); 69502.2(b)(3) and 69503.2(b)(1)(C) of the proposed regulations to emphasize the criteria that DTSC would use in evaluating the quality of scientific information that is available. Section 69501.1(a)(57) sets out the criteria that must be met by the scientific study and/or information, while section 69503.2(b)(1)(C) was amended to set out the criteria that DTSC will use in evaluating the quality of the information that is available.

While the definition of "reliable information" is restricted to scientific studies or scientific information, the regulations, in their entirety, do not preclude the use of non-science information for implementation of these regulations. Information that would be considered not scientific such as statewide sales by volume, statewide sales by number of units, etc. while not scientific may be used to extrapolate the potential to exposure. In reviewing a report and/or study for acceptance as reliable information, and/or reviewing other information, DTSC will evaluate whether the report and/or study was conducted according to the criteria enumerated in section 69503.2(b)(1)(C).

The amendments do not change DTSC's direction regarding the "full weight of evidence." That approach would not be prudent, given the anticipated variability of available information, such as exposure data on chemicals and products, and would restrict DTSC from taking action when sufficient data is available to demonstrate a hazard. 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 continue to give full consideration to scientific studies and/or other scientific information that demonstrates evidence of potential harm, actual harm, potential exposure, and actual exposure in the prioritization process.

To the extent that non-published information from industry or any other interested party meets the criteria in section 69503.2(b)(1)(C), the information may be considered by DTSC as part of its evaluation of product-chemical combinations for potential listing as Priority Products. It is not necessary, and would be unworkable, to include in the proposed regulations a method that would show general acceptance by the scientific community. This standard would prevent DTSC from accomplishing the goals of these regulations.

DTSC respectfully disagrees that section 69503.2(b)(1)(C) should be amended and reference to "disinterested" (parties) removed from the criteria. The education and experience of the reviewer alone does not address potential conflicts of interest that would be germane to the findings in any given report or study that is conducted and/or

published. As such, “qualified disinterested” more appropriately captures those individuals whose work does not result in an actual conflict of interest or create the appearance of a conflict of interest. This, in turn, is necessary to preserve the integrity of this program and to engender public confidence in it.

For a more detailed discussion on Availability of Information, see section 69503.2(a)(2) of the July 2012 Response to Comments document and section 69503.2(b)(1)(C) of the January 2013 Response to Comments document.

DTSC is making no further changes in response to the above comments.

§ 69503.2(b)(2) Other Regulatory Programs

Comments: 9-1, 9-4, 15-1, 20-22, 20-24, 25-1, 25-15, 25-16, 30-6

Comments Summary:
The above comments expressed concern with section 69503.2(b)(2), which specifies that DTSC will consider the scope of other state and federal laws and applicable treaties or international agreements under which the product or the Candidate Chemicals in the product is/are regulated and the extent to which these other regulatory requirements address, and provide adequate protections. If further specifies that adequate protection must be 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. DTSC may list a product-chemical combination that is subject to one or more state or federal regulatory requirements only if doing so would meaningfully enhance protection of public health and/or the environment with respect to the same concerns that are the basis for listing. In summary, the following concerns were expressed:

- Home appliances are well-regulated by other entities, and these products should be consider low priority or be excluded from the regulations;
- The very narrow standard being imposed to justify deference to other regulatory programs is seriously flawed and could allow DTSC’s interpretation to intrude into other regulatory programs;
- These regulations cannot limit or supersede the authority of any other agency, nor may DTSC duplicate or adopt conflicting regulations for categories already regulated;
- This is not authorized by the underlying statute and goes beyond the delegated statutory authority specifically limited under Health and Safety Code section 25257.1(a) through (c);

- DTSC should exercise its discretion and not place additional burdens that appear to be in conflict with the authorizing legislation;
- There is regulatory overlap in which the presence of the product-chemical combinations will cause releases at homes, schools, workplace, and other locations, which could be under the authority or various regulatory agencies; and
- In addition to federal law and international agreements, other major areas' regulations (such as EU) should also be considered.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations (January 2013). None of the comments are directed to the changed text. (The phrase "and/or adverse wastes and end-of-life effects" was added.) To the extent that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 3 portion of the Response to Comments for the July 2012 and January 2013 versions of the regulations. More specifically, see discussion of sections 69503.2(a)(3) and 69503.3(b) in the July 2012 Response to Comments document and section 69503.2(b)(2) of the January 2013 Response to Comments document.

DTSC is making no changes to the regulations in response to these comments.

§ 69503.2(b)(3) Safer Alternatives

Comment: 20-26

Comment Summary:
The above comment expressed concern with section 69503.2(b)(3), which specifies that DTSC may consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible when deciding to list a product-chemical combination as a Priority Product. In summary, the following concern was expressed:

- Authorizing DTSC to use its judgment to determine whether a safer alternative exists when prioritizing product-chemical combinations allows DTSC to prioritize based on convenience rather than based on risk, presence of actual hazard, and routes of significant exposure for the hazard.

Response:

The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised this issue with respect to the prior text of the proposed regulations, this issue is responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC made no changes to the regulations in response to this comment.

§ 69503.3 Adverse Impacts and Exposure Factors

§ 69503.3(a)(1) Adverse Impacts: Evaluating Product-Chemical Combinations

Comments: 9-6, 20-19, 26-23, 29-3

Comments Summary:
The above comments expressed concern with section 69503.3(a)(1), which specifies that in evaluating product-chemical combinations for possible listing as Priority Products, DTSC must evaluate the potential for the Candidate Chemical(s) to contribute to or cause adverse impacts by considering one or more listed factors for which information is reasonably available. In summary, the following concerns where expressed:

- The use of the word “potential” instead of “ability” unnecessarily broadens the level of risk associated with a chemical;
- DTSC should use risk-based approaches and utilize scientifically recognized methodologies by which to evaluate product-chemical combinations; and
- DTSC should use scientifically based approach, and substances that exhibit the greatest hazards should be given priority (*i.e.*, carcinogens, developmental and reproductive toxins and PBTs).

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised these issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC made no changes to the regulations in response to these comments.

§ 69503.3(a)(2)(A) Adverse Impacts: Sensitive Subpopulations

Comment: 26-23

Comment Summary:
The above comment expressed concern with section 69503.3(a)(2)(A), which specifies that DTSC shall give special consideration to the potential of a Candidate Chemical a product to contribute to or cause adverse impacts to sensitive subpopulations. In summary the following concern was expressed:

- The comment opposed the use of the word “potential” instead of “ability.”

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised these issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC made no change to the regulations in response to this comment.

§ 69503.3(b) Exposures

Comment: 20-19

Comment Summary:
The above comment expressed concern with section 69503.3(b), which specifies that in evaluating product-chemical combinations for listing as Priority Products, DTSC must evaluate potential exposures to public health and the environment by considering one or more factors. In summary, the following concern was expressed:

- An undue emphasis is placed on “potential” rather than “actual” exposures.

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised this issue with respect to the prior text of the proposed regulations, this issue is responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

No changes have been made to the regulations in response to this comment.

§ 69503.3(b)(4)(B) Products for Use Solely Outside of California

Comment: 20-23

Comment Summary:
The above comment expressed concern with section 69503.3(b)(4)(b), which specifies that in prioritizing product-chemical combinations for exposure to the Candidate Chemical(s), DTSC will consider whether a product is manufactured, stored in, or transported through California solely for use outside of California. In summary, the following concern was expressed:

- The regulations exceed their authority by regulating a product that is manufactured, stored, or transported through California even when destined for use outside of California.

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised this issue with respect to the prior text of the proposed regulations, this issue was responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC made no changes to the regulations in response to this comment.

§ 69503.3(b)(4)(D) Use Types

Comments: 9-3, 20-24

Comments Summary:
The above comments expressed concern with section 69503.3(b)(4)(D), which specifies that in prioritizing products for exposure to Candidate Chemical(s), DTSC must take into account product uses or releases from use types such as household and recreational use, use by sensitive subpopulations, product use in homes, schools, workplaces, or other locations to the extent such information is reasonably available. In summary, the following concerns were expressed:

- Products that are used by a broad cross-section of users that do not contribute to or cause widespread adverse public health and/or environmental impacts should

be excluded from the prioritization process or be given special consideration and lower prioritization; and
- The regulations cause a regulatory overlap when a product's presence includes homes, schools, workplace and other locations; and
- How do the proposed regulations align with authorities of other regulatory agencies (*i.e.*, CaI/OSHA).

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised these issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC is making no changes to the regulations in response to these comments.

§ 69503.3(b)(4)(F) Containment of Candidate Chemical

Comment: 9-4

Comment Summary:
The above comment expressed concern with section 69503.3(b)(4)(F), which specifies that in prioritizing products for exposure to Candidate Chemical(s), DTSC will take into account how well a Candidate Chemical(s) is contained within the consumer product, including potential accessibility to and/or releases of the Candidate Chemical(s). In summary, the following concern was expressed:
- Any Candidate Chemical in a home appliance is likely part of a component contained within the appliance and should therefore be excluded from the scope of the regulation.

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised this issue with respect to the prior text of the proposed regulations, this issue is responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

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

§ 69503.4 Priority Product Work Plan

§ 69503.4(c) Revisions to Work Plans

Comment: 41-9

Comment Summary:
The above comment expressed concern with section 69503.4(c), which specifies that DTSC may revise an adopted work plan to include one or more additional product categories if necessitated by either being legally required to take action on a particular chemical and/or product prior to the expiration of the work plan or if DTSC grants a petition under section 69504.1. In summary, the following concern was expressed:

- This section should be revised to clarify that DTSC will revise the work plan to add or remove product categories in response to public comments.

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised this issue with respect to the prior text of the proposed regulations, this issue is responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

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

§ 69503.4(d) Public Input

Comment: 41-10

Comment Summary:
The above comment expressed concern with section 69503.4(d), which specifies that DTSC will hold one or more public workshop(s) to provide an opportunity for comments prior to issuing each work plan. In summary, the following concern was expressed:

- DTSC should amend the regulatory language to require that revisions to the work plan, to add or remove product categories, must be based on public comment provided at the workshop.

Response:

The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised this issue with respect to the prior text of the proposed regulations, these issues are responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

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

§ 69503.5 Priority Products List

§ 69503.5(a)(2) Priority Products List Established through Rulemaking

Comments: 12-2, 14-7, 20-2

Comments Summary:
The above comments expressed concern with section 69503.5(a)(2), which specifies that the Priority Products list must be established and updated through rulemaking pursuant to the Administrative Procedure Act (APA) and DTSC must hold one or more public workshop(s) to provide an opportunity for comment prior to issuing a proposed Priority Products list. In summary, the following concerns were expressed:

- Adopting the Priority Products list through the APA process will dramatically slow down the listing process;
- DTSC should list product-chemical combinations based on the criteria included in previous drafts of the regulations; and
- The regulations should include explicit articulation that DTSC will follow the APA process for future Priority Products lists without administrative exemptions.

Response:
Section 69503.5(a)(2) of the proposed regulations did not change in relevant part from the January 2013 to April 2013 version of the proposed regulations. While section 69503.2(a)(2) was amended by deleting the text “pursuant to” and inserting the text “under,” the function of the provisions remains the same. The above comments are not directed to a change made in the April 2013 version of the regulations. For a discussion of this topic, see Article 3 of the Response to Comments document for the January 2013 version of the proposed regulations.

DTSC is making no changes to the regulations in response to these comments.

§ 69503.5(b)(2)(B) Chemicals of Concern Designation in Priority Products

Comment: 8-27

Comment Summary:
The above comment expressed concern with section 69503.5(b)(2)(B), which specifies that 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. In summary, the following concern was expressed:

- The Priority Products list should only include one Chemical of Concern per listed Priority Product.

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised this issue with respect to the prior text of the proposed regulations, this issue is responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

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

§ 69503.5(c) Alternatives Analysis Threshold

Comments: 3-2, 6-1, 7-2, 7-3, 8-9, 8-31, 12-2, 15-8, 20-5, 20-27, 20-30, 24-4, 25-10, 31-4

Comments Summary:
The above comments expressed concern with section 69503.5(c), which specifies that DTSC may include on the Priority Products list an AA Threshold concentration for any Chemical of Concern that is an intentionally added ingredient and an AA Threshold greater than the applicable practical quantitation limit (PQL) for any Chemical of Concern that is a contaminant. In summary, the following concerns were expressed:

- DTSC should focus the resources of manufacturers on chemicals present in concentrations greater than the PQL, so that these expensive analyses are directed to those chemicals in concentrations above 0.1%;
- An AA Threshold is necessary for every product-chemical combination and contaminant;

- Thresholds should be based on risk posed by a Chemical of Concern and not simply whether it can be detected in a Priority Product;
- DTSC should focus solely on Chemicals of Concern that are intentionally added ingredients not contaminants;
- DTSC's approach to will discourage recycling if contaminants in recycled products trigger the requirement to conduct an AA;
- DTSC fails to specify a clear, scientific process to determine AA Threshold concentrations; the comment requests that DTSC provide the process details they will use to develop AA Thresholds;
- The proposed regulations are amended to exempt from the Priority Products list products with Chemicals of Concern that meet the AA Threshold provision;
- The proposed regulations do not establish a de minimis standard;
- There is a lack of guidelines or criteria to consider for raising the AA Threshold;
- Clarify that DTSC may consider public comments regarding the need for an AA Threshold and establish one in the final Priority Products list;
- It is possible there could be disclosure of confidential business information or trade secret information about methods or suppliers that would need careful consideration when manufacturers submit AA Threshold proposals;
- DTSC needs to clearly articulate the scientific and technical basis for the AA Threshold during the APA process; and
- How will DTSC manage multiple AA Threshold submissions for the same Chemical of Concern by different manufacturers suggesting different thresholds?

Response:
In response to comments on the January 2013 version of the proposed regulations, section 69503.5(c) was added to restore flexibility found in earlier versions of the proposed regulations. The amendment allows DTSC to determine, if appropriate, product-chemical specific AA Thresholds at the time the Priority Products are listed. That is, 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. Section 69503.5(c) and companion provisions in section 69505.3(a)(4)(A) and (B) effectively exempt a manufacturer from conducting an AA under Article 5 if a listed Priority Product does not exceed the applicable AA Threshold for a contaminant or for an intentionally added ingredient, if one is established, and the manufacturer of the product submits an AA Threshold Notification to DTSC.

A default AA Threshold is available 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 PQL for the chemical(s). If during the product prioritization process, DTSC determines that an AA Threshold is appropriate for a particular intentionally added Chemical of Concern in a particular product, this may be addressed in the rulemaking for that Priority Product listing. DTSC may also specify an AA Threshold concentration greater than the applicable PQL for any Chemical of Concern that is a contaminant. This provision was added to the April 2013 version of the regulations in response to public comments.

Setting AA Thresholds are necessary to ensure that in the face of limited resources and time constraints, DTSC does not have to establish a case-by-case AA Threshold for each Priority Product-Chemical of Concern, while giving DTSC the ability to do so when it determines a Priority Product-Chemical of Concern specific AA Threshold is warranted. This approach also avoids the potential for exempting from the AA and regulatory response processes a Priority Product-Chemical of Concern that presents concerns that need to be addressed but that would not be if the regulations set an across-the-board AA Threshold (e.g., 0.01% or 0.1%).

DTSC is cognizant that the PQL is media, product, and analytical method-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, in which continuous improvement is sought in the quest 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. DTSC believes that this approach strikes the proper balance between innovation and the search for safer consumer products.

At the outset of the implementation of this program, DTSC will develop guidance materials to address the conducting of the AA and preparation of the AA Reports. This may include examples of how to demonstrate compliance with AA Threshold requirements, if appropriate. Responsible entities may use supply chain declarations, third party chemical management certifications, and internal process controls to obtain data; however, the data demonstrating compliance with any threshold must be provided with the appropriate notifications and/or AA Reports specified in the regulations. The AA Threshold will be a case-by-case determination based on the presence of

contaminants in the particular Priority Product, the PQL, and criteria for the protection of public health and the environment.

DTSC may list Priority Products that contain Chemical(s) of Concern, whether the chemical(s) is/are intentionally added or a contaminant. The listing information will inform the responsible entities of the specific Priority Product(s) that is/are the focus of the AA. If a product contains Candidate Chemical(s) but is not listed as a Priority Product, there are no requirements applicable to the product under the proposed regulations. However, the manufacturer may elect to remove the Candidate Chemical(s) independently and no reporting requirements would be triggered. Once listed as a Priority Product, however, 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 PQL(s) 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 Notification significantly changes or if the product no longer meets the criteria for an AA Threshold, if applicable.

While DTSC agrees that the source of Chemical(s) of Concern, whether intentionally added or a contaminant, does not dictate the adverse impacts that the Chemical(s) of Concern may pose, it is important to maintain a distinction, to enable the identification of alternatives. DTSC retained the necessary latitude during the prioritization process that ensures progress made towards safer alternatives, while ensuring the latest technological advances are being reflected. 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 is mindful that any limits on contaminants may ultimately play a role in the amount of recycled content used as feedstock. The provisions in the proposed regulations provide sufficient latitude to address this during implementation should the amount of recycling become a concern.

In the instance where the Chemical of Concern is present in a particular manufacturer's Priority Product solely as a contaminant, the manufacturer can submit a notification under section 69505.3 for an AA Threshold exemption if the concentration of the Chemical of Concern in their product does not exceed the PQL. Providing a default AA Threshold for contaminant Chemicals of Concern is necessary because manufacturers do not always have knowledge of and/or control over factors (e.g., contaminants in raw materials or recycled materials) that may lead to the presence of the contaminant in their products – and so in many cases testing will be needed to determine if the Chemical of Concern is present in the product. As is discussed below, the PQL was

determined to be the most workable and appropriate AA Threshold for contaminants, at least as a default. In some cases, a higher AA Threshold may be appropriate for a contaminant Chemical of Concern, and section 69503.5(c) gives DTSC the latitude to address this situation as part of the Priority Product listing process.

If sufficient reliable information is available to appropriately establish an AA Threshold, one will be proposed, subjected to public review, and included in the Priority Products list. However, if information is not available to indicate that DTSC should deviate from the PQL along with the analytical methods, then the AA Threshold for contaminants will be the PQL for the Chemical(s) of Concern in the Priority Product. While there may be multiple PQL submissions for the same Chemical of Concern in a Priority Product by different manufacturers suggesting different quantitation limits, the magnitude of the diverging results will be taken into account and addressed at the appropriate stage of implementation; this includes, if necessary, during the selection of appropriate regulatory responses.

The regulations reflect the authorizing legislation, which specifies the type of information that may and 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. All AA Threshold Notifications will be posted on DTSC's website in accordance with section 69501.5(b)(3)(F)2 and will be posted in their redacted form. For a more detailed discussion on treatment of trade secret information under these regulations, please refer to the discussion under Trade Secret Protection in Article 10 of the July 2012 Response to Comments document and Article 9 in the January 2013 and April 2013 Response to Comments documents.

While the definition specifies that the PQL is the lowest concentration of a chemical that can be "reliably measured," there is a lower limit – that is the concentration at which instruments will detect the presence of a contaminant (e.g., a Chemical of Concern) with consistent confidence. If a chemical is detected at this lower level but cannot be reliably quantified this is commonly referred to as the method detection limit (MDL). This level can vary from laboratory to laboratory. The fact that the chemical concentration cannot be reliably quantified at these lower levels makes the MDL unsuitable for policy setting and/or regulatory decision-making. Similarly, there is a higher concentration than the PQL at which a chemical concentration may be quantified. However, because some chemicals (e.g., carcinogens) cause adverse impacts at very low levels, at or near zero, it is unsuitable to use higher levels of quantification for policy setting and/or regulatory decision-making. It is important to note that chemicals may have adverse impacts below levels that can be measured and/or quantified.

The concentrations between the PQL and MDL are real and provide indications of presence; however, because of the inability to reliably quantify contaminants at the MDL, the MDL is used as the starting point to establish a more reliable concentration — the PQL. There are two primary approaches to establish the PQL using the MDL: (1) the laboratory performance method; and (2) the multiplier method. In the laboratory performance method, through the application of statistical and scientifically acceptable methods, the MDL is used to extrapolate the PQL. In essence, this method establishes the PQL based on the performance of a representative number of laboratories that can reliably quantify the concentration using appropriate analytical methods. This method takes into account the practicability of laboratories quantifying the identified concentration. The multiplier method is based on multiplying the MDL by a factor ranging from three (3) through ten (10). This takes into account the variability and uncertainty that can occur at the MDL. The MDL multiplier method may be most suitable when a representative number of laboratories are not available to establish a more rigorous PQL. Historically, the laboratory performance method has been used to validate the PQLs that were developed using the MDL multiplier method.

The PQL, as defined in the proposed regulations, is consistent with U.S. EPA's approach and takes into account the quantitation limits, precision and biases, normal operations of laboratories, and the programmatic needs to have a sufficient number of laboratories available to conduct compliance monitoring. The PQL is, in effect, the point where an occurrence or presence of a contaminant (e.g., a Chemical of Concern) can be reliably quantified by most laboratories for specific chemical contaminants using day-to-day routine laboratory operating procedures.

In general, the use of the PQL as a point of departure is advantageous over a default de minimis threshold (e.g., 0.01% or 0.1%) that is applied across the board to all product-chemical combinations – because the PQL is the lowest quantifiable concentration, is medium- specific, can be achieved by a representative number of laboratories, and provides a uniform measurement of concentrations that can be adjusted as technological advances are made. As the laboratory methods and limit of detections are lowered due to advances in testing or analytical advancements, the PQL can be lowered, if necessary to address contaminants that have adverse effects at much lower concentrations.

For the reasons cited above, DTSC believes the PQL is the most protective default AA Threshold level for contaminants, while simultaneously taking into account the practicality of reliably detecting and confirming the quantifiable levels of specific contaminants. The use of a specific MDL-derived procedure for calculating the PQL

also provides a mechanism by which DTSC and stakeholders can recognize and take advantage of analytical technologies to re-evaluate method-specific and matrix specific PQL on an as-needed basis.

For a more detailed discussion on DTSC's rationale for dismissing the concept of a default threshold (*i.e.,* 0.01% and/or 0.1%, and the use of the term "de minimis"), see section 69505.3 of the January 2013 Response to Comments document.

DTSC is not making any further changes to the regulations in response to the above comments.

§ 69503.5(d) Complex Durable Products

Comments: 8-19, 8-46, 8-47, 8-48, 8-49, 17-11

Comments Summary:
The above comments expressed concern with section 69503.5(d), which establishes the provisions by which a complex durable product or its components may be listed as a Priority Product. In summary, the following concerns were expressed:

- Create a definition of "complex durable product" in section 69501.1(a)(23);
- DTSC has limited the number of components of a complex product that can be the subject of review at any given time;
- DTSC has attempted to address replacement parts by allowing themselves flexibility in the regulatory response options rather than providing an upfront exemption; and
- DTSC has made the regulations more complicated than necessary for simpler consumer products and inadequate to effectively assess and address complex durable goods such as automobiles.

Response:
Section 69503.5(d) of the proposed regulations did not substantively change from the January 2013 to April 2013 version. The provisions previously in section 69503.5(c) of the January 2013 version were moved to section 69503.5(d) to accommodate the provision related to the AA Threshold. But the substantive provisions remained the same. None of the above comments are directed to changes made in the April 2013 version of the regulations. For a discussion of this topic, see Article 3 of the Response to Comments document for the January 2013 version of the proposed regulations.

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

§ 69503.6 Initial Priority Products List

§ 69503.6(b) Size of the List

Comments: 8-26, 8-27

Comments Summary:
The above comments expressed concern with section 69503.6(b), which specifies that the final initial Priority Products list will include no more than five (5) Priority Products and that the list may identify more than one Chemical of Concern for each listed product. In summary, the following concerns were expressed:

- DTSC should only include one Chemical of Concern per listed Priority Product.

Response:
The regulatory text to which this comment is directed is unchanged since the prior iteration of these proposed regulations. To the extent that commenters timely raised the this issue with respect to the prior text of the proposed regulations, this issue is responded to in the Article 3 portion of the Response to Comments for the January 2013 version of the regulations.

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

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ARTICLE 4. PETITION PROCESS FOR IDENTIFICATION AND PRIORITIZATION OF CHEMICALS AND PRODUCTS

§ 69504.1 Merits Review of Petitions

Comments: 14-6, 48-6

Comments Summary:
These comments raised a concern that section 69504.1(b)(5) injects another layer of review into the program because it allows opponents to challenge entire lists of chemicals. The comments suggest removing the section, which requires a petitioner to show that the entity responsible for the list still conducts its scientific assessments of chemicals in a manner that is substantially equivalent to, or as rigorous as, the manner in which it conducted its scientific assessments at the time of the initial adoption of the regulations.

Response:
These comments do not relate to changes in the proposed regulations made in the January 2013 version. Thus, they are outside the scope of topics subject to public comments. For a discussion of this topic, see Article 4 of the Responses to Comments document for the January 2013 version of the proposed regulations. No changes have been made to the regulations in response to these comments.

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ARTICLE 5. ALTERNATIVES ANALYSIS

Support for the Amendments in Article 5

Comments: 3-4, 3-8, 4-8, 5-11, 5-12, 8-5, 8-7, 8-10, 8-33, 11-5, 15-10, 17-17, 22-18, 22-20, 25-12, 26-5, 26-21, 27-1, 27-11, 27-12, 27-13, 27-14, 27-15, 27-16, 27-17, 27-18, 27-19, 27-20, 27-21, 27-22, 29-1, 31-9, 37-2, 38-3, 41-1, 41-4, 46-2, 47-4, 47-5

Comments Summary:

The above comments expressed support for the provisions in Article 5 of the proposed regulations dated April 2013. Comments expressing support were made for inclusion of the following amendments or retention of the specified provisions:

- Sections 69505 through 69505.8, which authorize companies to conduct the Alternatives Analysis (AA), reaching their own decisions on any product changes and preserves other improvements;
- Section 69505.1(d)(2), which was deleted and replaced with section 69505.8;
- Section 69505.2(a)(2), which deleted the reference to Abridged AA Reports;
- Section 69505.4(b)(2), which was amended to reflect the changes to section 69505.5(c) related to the evaluation of the relevant factors during the first stage and corresponding Preliminary AA Report;
- Section 69505.5(c)(1)(A), which was amended to require that relevant factors be evaluated during the first stage and corresponding Preliminary AA Report;
- Section 69505.5(c)(3), which was amended to combine the exposure pathway determinations during the first stage;
- Section 69505.6(a)(1), which was amended and reference to evaluation of the relevant factors deleted and moved to section 69505.5(c);
- Section 69505.7(a)(1), which was amended which deleted reference to the various Reports;
- Section 69505.7(a)(4)(B), which was amended to delete reference to “masking” and replaced with “redaction”;
- Section 69505.7(g)(1), which was amended to clarify that the Preliminary AA Report and Abridged AA Report must include a matrix or other summary format that provides a clear visual comparison of the alternatives under consideration; and
- Section 69505.8, which was added to specify that DTSC will facilitate public comment review on the Final and Abridged AA Reports by determining which issues need to be addressed in an AA Report Addendum.

Response:

These supportive comments did not recommend any changes to the regulations; therefore, DTSC is made no changes to the regulations in response to these comments.

Comments Out of Scope

Comments: 2-12, 3-11, 6-3, 6-5, 6-5, 8-34, 8-35, 8-36, 11-6, 11-7, 17-24, 17-25, 17-23, 17-24, 20-31, 20-32, 20-33, 20-34, 20-35, 20-42, 20-43, 20-44, 20-45, 21-2, 23-2, 26-21, 30-7, 30-8, 30-9, 30-10, 36-3, 41-18, 41-16, 46-3

Comments Summary:

The above comments expressed general concerns with the proposed regulations or concerns with the following specific provisions in the proposed regulations dated April 2013:

- Section 69505, which specifies that before finalizing the initial list of Priority Products, DTSC must make available on its website guidance materials to assist persons in performing the AAs in accordance with Article 5;
- Section 69505.1(a) which specifies that the requirement to conduct an AA does not apply to a product for which the notification requirements have been met
- Section 69505.1(b), which specifies the requirements of the AAs and the time periods by when the Preliminary AA and/or Final AA Reports must be submitted;
- Section 69505.6(a)(3), which requires that the responsible entity evaluate and compare the economic impacts of the Priority Product and the alternatives being considered; and
- Section 69505.7(d)(3), which requires that the responsible entity include in the AA Report information about parties to whom the manufacturer or importer directly sold the Priority Product to in the last twelve (12) months.

Response:

The regulatory text to which these comments are directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised these issues with respect to the prior text of the

proposed regulations, these issues are responded to in the Article 5 portion of the July 2012 and January 2013 Response to Comments documents.

§ 69505.3 AA Threshold Notification in Lieu of Alternatives Analysis

Comments: 2-4, 3-1, 4-7, 5-2, 6-2, 7-2, 8-30, 9-8, 15-9, 17-12, 17-13, 17-14, 17-15, 17-16, 20-4, 20-28, 20-29, 22-2, 22-5, 22-6, 22-7, 22-17, 24-5, 25-11, 26-4, 28-2, 28-3, 31-2, 31-3, 31-4, 31-5, 36-7, 36-8, 38-2, 41-17, 46-5, 46-6, 46-7, 46-8

Comments Summary:

The above comments expressed concern with section 69505.3, which specifies that the requirements of Article 5 do not apply to a responsible entity's Priority Product if the manufacturer submits 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. In summary, the following concerns were expressed:

- Establish a clear de minimis threshold of 0.1% to allow industries to better focus their resources on finding replacements to the toxic ingredients;
- The practical quantitation limit (PQL) is an analytical term and in no way related to the potential harm that could be caused by chemicals present in products;
- DTSC should treat intentionally added chemicals and contaminants in a manner that incentivizes efforts to limit them throughout the manufacturing process;
- DTSC should lead the effort to identify appropriate methods for measuring contaminant Chemical(s) of Concern in products and determining the appropriate PQL;
- Use of a PQL gives DTSC the authority to mandate an AA simply because there is an ability to measure a small amount of a contaminant in a product;
- The thresholds that are set by DTSC should be based on risk posed by the Chemical(s) of Concern in the product and not simply whether the Chemical(s) of Concern can be detected in the Priority Product;
- DTSC has not provided the criteria by which it will develop AA Thresholds and should be transparent;
- The option of DTSC specifying an AA Threshold in section 69503.5(c) is a significant improvement; however, DTSC should determine the AA Threshold based upon scientifically valid risk-based determinations and utilize the underlying list(s) forming the basis for the Priority Product listing where the list establishes a de minimis level;

- The proposed AA Threshold is expensive, administratively difficult, and overly burdensome;
- We urge DTSC to adopt other federal and international regulations for this concept using precedent including, but not limited to: the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard requirements for development of Material Safety Data Sheets (MSDSs), U.S. Environmental Protection Agency's (EPA) Toxic Release Inventory (TRI) program, the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals Program (REACH), the European Union's Classification, Labeling and Packaging (CLP) Regulation and the United Nation's Globally Harmonized System for Classification and Labeling (GHS);
- DTSC has added the possibility of establishing an AA Threshold value greater than the PQL for Chemical(s) of Concern present both as contaminants and intentionally added substances;
- Should include a default AA Threshold Exemption of 0.1% for all chemicals, and allow for the default value to be lowered or raised based on sound scientific evidence;
- The default AA Threshold should apply to an individual chemical and should not apply to a group of chemicals that exhibit similar hazard traits or environmental/toxicological end points;
- Provide greater consistency with other states by exempting contaminants below a set de minimis level; and
- How will DTSC deal with different manufacturers of the same chemical, which may submit information documenting differing thresholds?

Response:

Section 69505.3(a)(4)(A) and (B) and a companion provision in section 69503.5(c) effectively exempt a manufacturer 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. An AA Threshold may be established by DTSC under section 69503.5(c) for an intentionally added ingredient. (There is no default AA Threshold for intentionally added ingredients.) Or the AA Threshold may be the PQL if the Chemical of Concern is a contaminant, which is the default AA Threshold for contaminants. DTSC may also set the AA Threshold higher than the PQL for a Chemical(s) of Concern that is a contaminant. (April 2013) In order for a manufacturer to avail itself of this AA Threshold exemption, it must submit a notification to DTSC that complies with section 69505.3(a)(4)(A) and (B).

DTSC considered in its earlier regulations proposal, dated September 2010, the use and concept of the term “de minimis” to harmonize the proposed regulations with the application of de minimis level concepts with numerous state, federal, and global regulations. It was crafted to serve as an “administrative convenience.” That is, the “de minimis” levels and concepts contemplated in earlier drafts of these regulations were never intended to define a level at which risks were negligible or unimportant. The term “de minimis” as is used in the European Union Restriction of Hazardous Substances (RoHS) Directive, REACH, and other programs is a reporting limit based on volume not risk. The overlapping and potentially conflicting uses of the term “de minimis” caused DTSC to reconsider the use of the term, and to instead create an independent term to minimize the mistaken assumption that the concentration equates to an acceptable level of risk. The proposed regulations dated July 2012 appropriately introduced the use of the term “Alternatives Analysis Threshold” and related Exemption Notification—that is, an exemption from the requirement to conduct an AA. In response to comments on the proposed regulations dated July 2012, the term was amended to “Alternatives Analysis Threshold Notification,” (January and April 2013).

An AA Threshold is available as a default for a manufacturer’s Priority Product only if the Chemical(s) of Concern is/are present in the product solely as contaminants, and the concentration of the Chemical(s) of Concern(s) does not exceed the 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 may be addressed in the rulemaking for that Priority Product listing. This option was added to the April 2013 version of the regulations in response to public comments. That is, DTSC has the authority to establish specific AA Thresholds on a case-by-case basis for intentionally added chemicals in Priority Products. If DTSC exercises this authority, it will do so at the time it lists Priority Products.

DTSC is cognizant that the PQL is media- and product-specific and that it will ultimately require that responsible entities account for any concentration of intentionally added Chemical(s) of Concern in their products. Despite the potential variability in the concentrations detected, the proposed regulations are aligned with and consistent with the goal and intent of AB 1879, in which 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 at lower levels are detected, assessments on whether they are of concern can be made. DTSC believes that this approach strikes the proper balance between innovation and safer consumer products.

At the onset, DTSC may develop guidance materials to address compliance with AA Threshold requirements, if applicable. The proposed regulations defines the AA Threshold as either the PQL for a Chemical of Concern that is present in a Priority Product solely as a contaminant; or the applicable concentration, if any, specified by DTSC under section 69503.5(c) (April 2013). That is, if DTSC prioritizes a consumer product for listing as a Priority Product due to the chemical(s) in the product, the volume in commerce, and/or the propensity for exposure to consumers, the responsible entity must conduct an AA or comply with one of the other options available under Article 5. Responsible entities may internally use supply chain declarations, third party chemical management certifications, and internal process controls to obtain data; 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. The AA Threshold will be a case-by-case determination based on the presence of contaminants, the PQL, and criteria for the protection of public health and the environment.

DTSC may list Priority Products that contain Chemical(s) of Concern, whether intentionally added or as a contaminant. This information will inform the responsible entities of the Priority Products that are the focus of the AA. If a product contains Candidate Chemical(s) but is not listed as a Priority Product, there are no requirements under the proposed regulations. However, the manufacturer may elect to remove the Candidate Chemical(s) independently and no reporting requirements are triggered. Once listed, however, the regulations specify the information that must be included in an AA Threshold Notification, including the source of the contaminant Chemical(s) of Concern(s). The notification must identify the PQL(s) 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 Notification significantly changes, or the product no longer meets the criteria for an AA Threshold Exemption.

While DTSC agrees that the source of Chemical(s) of Concern, whether intentionally added or a contaminant, does not dictate the adverse impacts that the Chemical(s) of Concern may pose, it is important to maintain a distinction, to enable the identification of alternatives. As the program matures and as responsible entities are more aware of the constituents in the products that they manufacture, this distinction will become of more importance in identifying and selecting alternatives. As such, the term “contaminant” as defined in section 69501.1(a)(26)(A) is necessary and will not be amended or deleted.

Section 69505.3(a)(4)(A) and (B) requires that the AA Threshold Notification include a statement that either (A) the Chemical(s) of Concern is only present as a contaminant and that it does not exceed the PQL for that Chemical of Concern; or (B) if the

Chemical(s) of Concern was intentionally added or DTSC set an AA Threshold other than the PQL for a contaminant, that the chemical does not exceed the AA Threshold established by DTSC under section 69503.5(c). These two paragraphs provide DTSC with necessary latitude during the prioritization process that ensures progress in made towards safer alternatives, while ensuring the latest technological advances are being reflected. If sufficient reliable information is available to appropriately establish an AA Threshold level, one will be proposed, subjected to public review, and included in the Priority Products list. However, if information is not available to indicate that DTSC should deviate from the PQL along with the analytical methods, then the AA Threshold for contaminants will be the PQL of the Chemical(s) of Concern in the listed Priority Product(s). Additionally, any Chemical(s) of Concern that is intentionally added to a Priority Product must be addressed.

DTSC is not making any further changes to the regulations in response to the above comments.

§ 69505.4 Alternatives Analysis Process and Options

§ 69505.4(b) Abridged AA Reports

Comments: 41-8

Comments Summary:

The above comments expressed concern with section 69505.4(b) of the proposed regulations dated April 2013, which specifies that a responsible entity may conduct an Abridged AA and sets out the requirements for this option. In summary, the following concerns were expressed:

- Responsible entities that submit an Abridged AA Report should not have to complete step 3 in the first stage of the AA—Identification of Factors Relevant for Comparison of Alternatives specified in section 69505.5(c);
- Responsible entities that determine based on available information that there are no technically feasible or functionally acceptable alternative chemicals for the Chemical(s) of Concern should not have to identify factors relevant for comparison of alternatives; and
- DTSC should exclude from the first stage of the AA (Step 3 for entities who submit an Abridged AA Report).

Response:
The Abridged AA Report provisions in section 69505.4(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 for a more in-depth evaluation. The provisions are not intended to circumvent or bypass the intent and goals of AB 1879, which is to find safer alternatives to reduce or limit exposure to Chemical(s) of Concern. Rather, they are but one means among many of pursuing the quest for safer products.

In response to related comments on the first and second stages of the AA, section 69505.4(b) was amended. Section 69505.4(b) of the proposed regulations dated April 2013 specifies that after completing the first five steps of the first stage AA and concluding that a functionally acceptable and technically feasible alternative is not available, the responsible entity may prepare an Abridged AA Report that summarizes the first stage findings *and* the relevant factors of the second stage specified in section 69505.6(a). Completing the first stage and portions of the second stage ensures that all thirteen criteria specified in statute are addressed prior to imposing regulatory responses.

Section 69505.7 specifies the content requirements for all AA Reports, including the Abridged AA Report. The Abridged AA Reports uniquely straddle the first and second stages of the AA to ensure that the data and information necessary to make an informed decision is considered evaluated, summarized, and submitted to DTSC.

Upon completion of the Abridged AA Report, responsible entities must then comply with, at a minimum, two regulatory responses: section 69506.3 Product Information for Consumers; and section 69506.8 Advancement of Green Chemistry and Green Engineering. Other regulatory responses may also be required until a safer alternative is identified. Given that the goals and intent of AB 1879 is to find safer alternatives, DTSC believes this is an appropriate incentive.

Please refer to the discussion under section 69505.5(c) below for more details on the requirements in step 3.

DTSC is not making any further changes to the regulations in response to the above comments.

§ 69505.5 Alternatives Analysis: First Stage

§ 69505.5(c) Step 3: Identification of Factors Relevant for Comparison

Comments: 5-11, 8-7, 8-33, 11-5, 22-18, 26-6, 27-1, 27-4, 27-14, 27-17, 39-1, 47-4

Comments Summary:
The above comments expressed concern or requested clarification of section 69505.5(c), which specifies the third of six steps in the process for conducting a Preliminary AA. The third step requires a responsible entity to identify factors that are relevant for comparison of the alternatives. In summary, the following concerns were expressed:

- There is probably no situation where all of the "A through M criteria" would have material differences among alternatives that are under consideration, and the reality is that in most cases there will probably only be a few relevant factors;
- While this change will create more work at the beginning of the process, we are hopeful that it will give DTSC the opportunity to provide guidance early on in the AA process rather than after the development of the Final AA Report;
- The Preliminary AA timeline is already shorter than is appropriate;
- Revisions made in the January 2013 version of the proposed regulations eliminated extensions for the Preliminary AA Report;
- DTSC should modify the second stage AA to eliminate duplicating analyses already conducted in the first stage of the AA;
- This amendment may require moving section 69505.6(a) to 69505.5(f); and
- The revisions in section 69505.5 appear to conflict with the existing information in section 69505.2 because replacement chemicals that are on the list of Candidate Chemicals that are already in use to manufacture the same product, in lieu of the Chemical of Concern, are exempt from AAs and could create a regrettable substitute of "N-methylpyrrolidone" for "methylene chloride" in paint strippers, even though safer, non-Candidate Chemicals are currently available in paint strippers.

Response:
Section 69505.5(c) of the proposed regulations dated January 2013 was amended in the April 2013 version to include the identification of factors relevant for comparison of alternatives as part of the first stage of the AA. Provisions previously in sections 69505.6(a)(1)(A) and (B), 69505.6(a)(2)(A) and 69505.6(a)(3) were moved to section 69505.5(c). The movement of the above-mentioned sections effectively requires that the responsible entity identify, during the first stage of the AA, the factors that are relevant for comparison as a result of a material contribution to one or more adverse public health and environmental impacts, adverse waste and end-of-life effects, and/or

materials and resource consumption. While the provisions moved, the requirements, for the most part, remained unchanged and are not new. Consideration and evaluation of the relevant factors is now done earlier in the process, which effectively refines the scope and goals of the AA being conducted—saving time and resources.

As required in earlier versions of the proposed regulations, the responsible entity must use available quantitative information—meaning information that is accessible or existing and not required to fill the data gaps and supplement it with qualitative information to identify the associated exposure pathways and life cycle segments that are relevant for comparison. The life cycle segments that are identified as relevant for comparison are then evaluated in the second stage of the AA in step 1; they are not duplicative.

DTSC is cognizant that the factors to be evaluated under the first stage may be expansive; however, it would be inappropriate in the regulations to narrow the scope of the factors that must be addressed. The narrowing must be done on a case-by-case basis that is product-specific and/or chemical-specific as the AA is conducted and the factors are evaluated by the responsible entity. The rationale used to narrow the factors and thus scope of the AA, must be summarized and included in the Preliminary AA Report that is submitted to DTSC.

DTSC respectfully disagrees that the timelines for the Preliminary AA are either shorter than appropriate or that the extensions were eliminated in the proposed regulations dated January 2013 and April 2013. The January 2013 version streamlined the requirements by including headings to improve readability, which also retained in the April 2013 version. Section 69505.1(c) titled “AA Report Due Date Extension” was previously in section 69505.1(d), and while there were editorial changes, the substantive provisions remained unchanged. As elaborated in the July 2012 Response to Comments under sections 69505.1(c)(3) and January 2013 Response to Comments under and 69505.1(c)(3)(A) and (B), the timelines afforded to responsible entities is sufficient given the activities conducted during the first stage and the information being required to be included in the Preliminary AA Report. The first stage of the AA and corresponding Preliminary AA Report involve the gathering, organizing, and evaluating of scientific and technical information necessary to decide whether a particular alternative is likely to be a potential alternative to the Chemical(s) of Concern. As such, it is not necessary to move section 69505.6(a) to section 69505.5(f).

The revisions in section 69505.5 do not affect how the provisions in section 69505.2 function. The provisions in section 69505.2 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 to the Chemical(s) of Concern 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 that was the basis for its listing and/or the Priority Product is taken out of the California market. It 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, by definition, does not pose a risk of a "regrettable substitute."

In addition, under section 69505.2, a responsible entity may substitute a 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 for the Priority Product, to manufacture the same product, and not be required to conduct an AA. The notifications and options afforded to responsible entities under section 69505.2 are not only an improvement from the status quo, but also ensure that the appropriate factors are being timely considered when looking for safer alternatives. In addition to the mandatory evaluation of Priority Products by responsible entities, the regulations provide an incentive for manufacturers to take the initiative to seek safer alternatives before their products are prioritized. The goal of the proposed regulations is not necessarily to prioritize every product and conduct an AA for each product but instead to promote incremental improvements across a broad spectrum of products. A manufacturer who takes the initiative to remove the Chemical(s) of Concern in its product is afforded opportunities to minimize the amount of DTSC oversight and/or avoid the requirement of conducting an AA under Article 5. The specified activities must be carried out by no later than the due date for the applicable AA Report and one of the following Intent Notifications followed by the Confirmation Notification must be submitted. For a more detailed discussion, refer to Article 5 in the January 2013 Response to Comments document.

DTSC is aware of the narrowed scope for the initial Priority Products list created by section 69503.6(a) of the proposed regulations dated January 2013 and April 2013. More specifically, for the initial list of Priority Products—and any revisions to it through January 1, 2016—only those chemical-product combinations that meet one or more criteria in sections 69502.2(a)(1) *and* (a)(2) may be prioritized. In short, these two provisions limit DTSC to identify products for the *Initial* Priority Product Work Plan only those chemicals that:

> i) Have a hazard trait or toxicological or environmental endpoint listed on one or more of the authoritative organization's chemical lists; *and*
> ii) Appear on an exposure or monitoring related chemical list.

This narrowing in scope of the proposed regulations is limited to the initial Priority Products list. Future work plans do not have this limitation. In part, the narrowed scope was done to enable DTSC and the regulated community to learn by doing. The example cites that because of the narrowed scope "the Candidate Chemical, N-methylpyrrolidone, a developmental toxicant, could be used as a replacement chemical for methylene chloride paint strippers, without conducting an alternatives analysis, even though safer, non-Candidate Chemicals are currently available in paint strippers." It is difficult to know whether responsible entities using methylene chloride would choose the safer non-Candidate Chemicals over N-methylpyrrolidone or vice versa, if methylene chloride in paint strippers were prioritized.

It is important to note, however, that the notification requirements apply to all replacement chemicals whether on the Candidate Chemicals list or not. DTSC is cognizant that replacement chemicals not on the Candidate Chemicals list may have health and environmental effects. Section 69505.2(b)(9)(F) specifies that the replacement chemical must meet one of two conditions. Either the replacement chemical is not on the Candidate Chemicals list or the replacement chemical is on the Candidate Chemicals list, but that chemical is already in use to manufacture the same product. In the latter case, DTSC will have had the opportunity during its prioritization process to evaluate available information and determine whether or not the chemical posed the same concern as the Chemical of Concern that was prioritized. In other words, if DTSC determines the hazard traits and endpoints are less toxic than those of the Chemical of Concern that is being prioritized, DTSC may decide not to list the chemical(s) as Chemical(s) of Concern that could end up serving as a replacement chemical.

DTSC is not making any further changes to the regulations in response to the above comments.

§ 69505.6 Alternatives Analysis: Second Stage.

§ 69505.6(a)(1) Adverse Impacts and Multimedia Life Cycle Impacts

Comments: 20-39

Comments Summary:
The above comment expressed concern with section 69505.6(a)(1), 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:

- DTSC must make a distinction between hazard, risk, and what is safe; and
- Any chemicals in the alternatives that are not on the Candidate Chemicals list should be exempt from consideration and analysis should be limited to only those chemicals that DTSC has identified as posing a potential "risk" to the user of the final product.

Response:
Section 69505.6(a)(2)(A) of the proposed regulations dated January 2013 was amended. The provisions of 69505.6(a)(2) were renumbered to section 69505.6(a)(1), and the provisions previously in section 69505.6(a)(2)(A) were moved to section 69505.5(c)(2) in response to comments on the January 2013 version of the proposed regulations. As discussed in section 69505.5(c) Step 3: Identification of Factors Relevant for Comparison of Alternatives, relevant factors must be identified as part of the first stage AA and corresponding Preliminary AA Report.

As stated in the ISOR, the first and second stages of the AA, and the corresponding Preliminary AA Report and Final AA Report, 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 and 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.

Consistent with Health and Safety Code section 25253(a)(1), the proposed regulations require that the process for evaluating Chemical(s) 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 Chemical(s) of Concern include the evaluation of alternatives. While the proposed regulations allow responsible entities to submit a Removal/Replacement Notification in accordance with section 69505.2, the notification must be submitted within specified timeframes consistent with the submittal of the Preliminary AA Report and/or Final AA Report. The options created under section 69505.2 are incentives to expedite the selection of safer alternatives without DTSC oversight. Section 69505.2(b)(9)(A) through (F) collectively require that the responsible entity evaluate the hazard traits and/or environmental or toxicological endpoints of the

replacement chemical(s), whether a Candidate Chemical or not. And in evaluating the replacement chemicals, the responsible entity must consider only replacement chemicals that exhibit fewer hazard traits and endpoints than those of the chemical it is replacing. The requirements provide a necessary and practical means of addressing the Chemicals of Concern that are prioritized and replaced with chemicals that are of less concern. Responsible entities that exercise this initiative are then not required to undergo a rigorous AA to select an alternative. Please refer to the discussion in January 2013 Response to Comments document under section 69505.2(a) Applicability for more details on Removal/Replacement Notifications.

Exempting alternatives based solely on the fact that the chemical(s) is/are not on the Candidate Chemicals list is counter to the goals of AB 1879; however, the above-mentioned removal notification provides the necessary incentives to a manufacturer for expediting the quest for safer alternatives. At the same time this approach ensures the hazard traits of replacement chemicals are meaningfully evaluated. If a replacement chemical exhibits hazard traits equal to or greater than the Chemical of Concern, whether on the Candidate Chemicals list or not, that information must be included in the applicable Removal/Replacement Notification and/or the Preliminary and Final AA Report that is conducted and, if necessary, the appropriate regulatory responses required. A manufacturer may submit a Chemical Removal/Replacement Notification in lieu of conducting an AA, as discussed in the January 2013 Response to Comments under section 69505.2(a) Applicability, if after commencing the AA, it determines that it can meet the criteria specified.

DTSC respectfully disagrees that a distinction in the regulations between hazard, risk, and what is safe is necessary. In addition, this would not be prudent. Under the prioritization process in 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. Those Candidate Chemicals identified in the Priority Products become the Chemical(s) of Concern and may be identified by the Chemical Abstracts Service (CAS) number and/or the chemical family group, or other naming convention that DTSC determines is most appropriate and protective. As such, the proposed regulations do focus on the chemicals that DTSC has identified as posing a potential “risk” to the user of the final product and are thus subject to the AA. Further, the proposed regulations provide ample opportunity to evaluate the hazards and select alternatives that best limit exposure to or reduce the level of hazard posed by a Chemical of Concern through reformulation, reengineering, or regulatory responses. The proposed regulations are not intended to replace conventional risk assessments or to quantify and “assess health impact based on actual exposure.” Rather, the proposed

regulations are intended to prevent exposures and minimize them to the maximum extent practical.

DTSC is not making any further changes to the regulations in response to these comments.

§ 69505.7 Alternatives Analysis Reports

Comment: 8-36

Comment Summary:
The above comment expressed that while the commenter appreciates DTSC's efforts in providing structure, the proposed regulations should continue to allow flexibility for the preparation of the AA in designing the appropriate summary of information in section 69505.7 Alternatives Analysis Reports.

Response:
While DTSC made minor conforming changes to the provisions in section 69505.7 to reflect changes in other companion provisions, the function and requirements of section 69505.7 remain the same. Responsible entities are still afforded multiple options under section 69505.4 Alternatives Analysis Process and Options to conduct an AA and prepare and submit the applicable AA Reports.

DTSC is not making any further changes to the regulations in response to these comments.

§ 69505.7(a)(4)(B) Requirements Applicable to AA Reports and Trade Secret

Comments: 8-10, 20-40, 20-46, 30-10, 41-16, 47-6

Comments Summary:
The above comments expressed concern with section 69505.7(a)(4)(B) of the proposed regulations dated April 2013, which specifies that the responsible entity must maximize the scope of information in the AA Reports that can be made available to the public while maintaining protection of legitimate trade secret information. In summary, the following concerns were expressed:

- Increased visibility of AA Reports complicates trade secret claims;

- Even with this revised language changing “masking” to “redaction,” we still see significant issues with the potential to disclose business confidential information. This could jeopardize a company's ability to innovate and compete in an open marketplace;
- DTSC should be the only group which can review and assess the full AA Reports, since it is required to maintain business confidentiality and cannot disclose confidential business information contained in a company's submission;
- The general public will not be able to understand, in the depth required, all the technical and economic information which leads the manufacturer to the best decision in the AA process; and
- Because companies do not want to divulge information, which it considers confidential, to the general public and thus, to their competitors, the public AA Reports will be subject to considerable redaction and therefore have limited utility.

Response:
Section 69505.7(a)(4)(B) was amended. Reference to the term “masking” was deleted and “redaction” was inserted. DTSC respectfully disagrees that the revised text increases the AA Reports’ visibility, thereby compromising trade secret information. The proposed regulations specify the applicable criteria, procedures, and timelines that must be followed when claiming trade secret protection. The proposed regulations reflect the authorizing legislation, which specifies the type of information that may be claimed as trade secret. (This is done by implication. That is, all information other than that expressly precluded from by the authorizing legislation is eligible for a claim of trade secrecy—subject, of course, to DTSC’s review and concurrence.) 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-making under the regulations. However, pursuant to Health and Safety Code section 25257(f), information related to hazard traits for chemicals and chemical ingredient may not be claimed as 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 every instance 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. See Article 10

of the July 2012 Response to Comments document and Article 9 of the January 2013 and April 2013 Response to Comments documents.

In response to related comments regarding public review and comments, the proposed regulations have been modified. The proposed regulations dated April 2013 deleted the provision providing for public comment on the Preliminary AA Report and the Alternate AA Work Plan. The Final AA Report and Abridged AA Report are now subject to public review and comment (April 2013). In addition, DTSC is now responsible for reviewing the public comments and determining which issues, if any, must be further addressed by the responsible entity based on the public comments. If public comments are provided and DTSC determines they raise legitimate issues that need to be addressed in the AA Report, DTSC will notify the responsible entity of the issues it must address in an addendum to the Final AA Report or Abridged AA Report. The amended provisions are found in section 69505.8.

DTSC is not making any further changes to the regulations in response to these comments.

§ 69505.8 Public Comments on AA Reports

§ 69505.8(a) Public Notice of Opportunity for Comment

Comments: 6-7, 11-8, 12-1, 17-18, 17-21, 20-37, 20-48, 22-19, 31-6, 31-7, 31-9, 38-3, 4-1, 4-4, 41-5, 41-6, 41-7

Comments Summary:
The above comments expressed concern or requested clarification of section 69505.8(a), which provides an opportunity for public comment on AA Reports. Upon receipt of a Final AA Report and/or Abridged AA Report, DTSC will post on its website and send to persons on its electronic mailing list, notice of the availability of the reports mentioned above. In summary, the following points were made:

- This section is extremely problematic and has the potential to violate important intellectual property rights which may allow competitors access to trade secrets and confidential information;
- This new section would likely have the unintended consequence of placing American and, more particularly, California companies in the untenable position of having to disclose their most economically valuable trade secret product

formulations in a manner which ultimately would place those trade secrets in the hands of foreign competitors;

- Add in public review and comment on the Preliminary AA Reports, as they are a critical step in the AA process, including the identification of alternatives as well as the screening out of possible alternatives;
- Public comment after a Final AA Report has been submitted, rather than after submission of the Preliminary AA Report, could negatively impact business planning cycles and delay the launch of safer alternatives;
- The procedure of requiring the responsible entity to respond to public comments is not a lawful under the Administrative Procedure Act (APA) and is contrary to Health and Safety Code section 25253(c) (requiring that tools for evaluating chemicals of concern be in a form that "allows ease of use and transparency of application");
- The proposed public comment process at the end of the AA process will add more uncertainty and will increase the resources and time to necessary to finalize AAs—with as-yet-unknown benefits, if any;
- Public comment on AA Reports are not likely to provide significant improvement to the AA process since the majority of the public will not be familiar with the manufacturing processes, design demands, legal requirements, and market pressures that go into the development and design of a product;
- DTSC is abandoning its role as the governing authority and placing it in the hands of the public which creates the potential for anticompetitive issues and numerous legal complications;
- Public comments should be eliminated from the regulatory compliance obligation for responsible entities;
- DTSC should outline the specific criteria that will be used to evaluate the public comments and identify the methodology for determining which comments DTSC will require responsible entities to address as part of an amended AA Report; and
- It is unclear how a public commenter can adequately consider a redacted AA, especially when comments are directed at provisions within the redacted portion of the AA. Will the manufacturer be forced to divulge proprietary information, confidential business information or trade secrets by responding to or acknowledging the question?

Response**:**
In response to comments and concerns related to public comments and the responsible entity's obligation to examine and subsequently respond to the comments, the provisions previously in section 69505.1(d)(2) of the January 2013 version of the proposed regulations were moved to section 69505.8 under "Public Comments on AA

Reports." Section 69505.8(a) requires that upon receipt of a Final AA Report or an Abridged AA Report, DTSC must post on its website, and send to persons on the electronic mailing list(s) that DTSC establishes related to these regulations, a notice regarding the availability of the pertinent report for public review and comment. In its notice, DTSC must specify the comment period, provide a link to the location on DTSC's website where a copy of the Final AA Report or Abridged AA Report may be viewed, and specify the methods for submitting comments on the Report. The comment period must be no less than forty-five (45) days from the date the notice of availability of the Final AA Report or Abridged AA Report is posted or the date the notice is sent to persons on the electronic mailing list(s), whichever is the later date. DTSC will take into account the Priority Product and the scope of the Final AA Report or Abridged AA Report in establishing review periods longer than forty-five (45) days.

The regulations reflect the authorizing legislation, which specifies the type of information that may not be claimed as trade secret and, by implication, that which may be claimed as such. 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. All AA Reports posted on DTSC's website in accordance with section 69501.5(a)(6) will be in their redacted form.

All responsible entities, whether based in California or not, wishing to introduce or to continue to make available a Priority Product or its alternative into California commerce are subject to the requirements in Article 5. As such, the argument that American and, more particularly, California companies are in the untenable position of having to disclose their most economically valuable trade secret product formulations in a manner that ultimately would place those trade secrets in the hands of foreign competitors is unfounded. Foreign competitors are also subject to the requirements of Article 5.
For a more detailed discussion on treatment of trade secret information under these regulations, please refer to the discussion under Trade Secret Protection in Article 10 of the July 2012 Responses to Comments document and Article 9 in the January 2013 and April 2013 Response to Comments documents.

As a result of the amendments made to related sections, all references to the Draft and Final Abridged AA Report have been deleted. In addition, the Preliminary AA Report, Abridged AA Report, and Alternate Process AA Work Plan will not be subject to public comment; however, they will be posted on DTSC's website, in accordance with section 69501.5. Interested stakeholders may review Preliminary AA Reports, Abridged AA Reports, and Alternate Process AA Work Plans, and may submit comments on the Final AA Reports when they are submitted to DTSC. DTSC believes this is an appropriate balance between keeping stakeholders informed and involved, while ensuring progress

is made towards safer consumer products. Given the scope of Removal/Replacement Notifications and AA Threshold Notifications in lieu of conducting an AA, DTSC believes it would not improve the quality of the program to subject these notifications to public comment. Accordingly, DTSC has not included them among the reports subject to public comment. The Final AA Report and the Abridged AA Report are subject to public comment.

The procedure of requiring the responsible entity to respond to public comments on an AA Report prepared in accordance with Article 5 is not covered under the APA. Nor is it contrary to Health and Safety Code section 25253(c). The APA governs the process by which regulations must be adopted, these proposed regulations being one example. The act allows the public to participate in the adoption of state regulations in order to ensure that the regulations are clear, necessary, and legally valid. The AA Reports are not regulations and are, therefore, not subject to the APA. DTSC is unclear how the review of the AA Reports is purportedly in conflict with Health and Safety Code section 25253(c) requiring that tools for evaluating chemicals of concern be in a form that "allows ease of use and transparency of application."

DTSC made no further changes to the regulations in response to the above comments.

§ 69505.8(b) Department Review of Public Comments

Comments: 8-6, 20-36, 20-38, 20-47, 36-9

Comments Summary:
The above comments expressed concern or requested clarification of section 69505.8(b), which specifies that DTSC will review the public comments received and notify the person that submitted the Final AA Report and/or Abridged AA Report of those issues that DTSC determines must be addressed in an AA Report Addendum. In summary, the following point was made:

- It is not clear how DTSC will determine which public comments merit additional input from the preparer of the Final AA Report or Abridged AA Report.

Response:
Section 69505.8(b) requires that DTSC review the public comments within thirty (30) days after the close of the public comment period and notify the person that submitted the Final AA Report or Abridged AA Report of those issues that DTSC determines must be addressed in an AA Report Addendum.

In determining which issues must be addressed, DTSC will review the comments on the merits, and use professional judgment in identifying the issues that must be addressed by the responsible entity. That is, DTSC will evaluate whether the public comment has validity and points out areas in need of further evaluation. In establishing a due date for an AA Report Addendum, the scope and complexity of the comments/issues that must be addressed will be taken into account by DTSC.

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ARTICLE 6. REGULATORY RESPONSES

Support for the Amendments in Article 6

Comments: 8-8, 25-13, 36-14,41-2,
Comments Summary:
The above comments expressed support for the amended provisions in Article 6. The provisions in Article 6 clarify, implement 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. Support was expressed for the following sections:

- Section 69506.7 which provides a manufacturer with flexibility when a regulatory response calls for an end of life management program;
- Section 69506.7, which is only required for products that must be managed as a hazardous waste at the end of its useful life;
- Section 69506.7, which was modified to remove the requirement that a collection program must include the collection mechanism and compensation requirements to retailers and other entities that agree to participate in an end of-life collection program.

Comments Out of Scope

Comments: 6-4, 11-9, 12-4, 13-2, 13-3, 21-1, 22-23, 30-11, 30-12, 30-13, 35-3

Comments Summary:

The above comments expressed concerns with the following provisions in the revised proposed regulations dated April 2013:

- Section 69506, which specifies the regulatory response selection principles;
- Section 69506.1(d)(1), which specifies that the “last day for submission of public comments shall be no sooner than forty-five (45) days from the date the notice of the availability of the proposed regulatory response determination notice is posted on the DTSC’s website;
- Section 69506.3, which specifies the product information for consumers;
- Section 69506.3(b)(7), which specifies the required information for consumers;

- Section 69506.7(c)(1)(F), which specifies that the end-of life Program must anticipate the resources needed to implement and sustain the plan; and
- Section 69506.7(c)(5), which specifies that an annual report must be submitted containing the specified information.

Response:
The regulatory text to which these comments are directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Article 6 portion of the Response to Comments for the July 2012 version of the regulations.

§ 69506.1. Applicability and Determination Process

§ 69506.1(a) Applicability

Comments: 12-4

Comment Summary:

The above comments expressed concern with section 69506.1(a), which specifies when regulatory responses will be applied. In summary, the comment expressed the view that the proposed regulations should be drafted to clarify that a product is explicitly exempted if the Chemical(s) of Concern in a Priority Product meets the Alternatives Analysis (AA) Threshold provision. The current regulatory responses are unclear.

Response:

The provisions contained in section 69506.1(a) did not substantively change from the January 2013 to the April 2013 version of the proposed regulations. While the text "Except as specified otherwise," "Final," and "or Abridged AA" was added and other minor conforming changes were made, the function of the provisions in the section remains the same.

Regulatory response(s) 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;

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. To the extent that end-of-life impacts are the cause for listing of the Priority Product, end-of-life requirements as a regulatory response may be imposed while an alternative are selected—"pending development and distribution." It is not necessary to add the suggested language as it is already included.

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.

In addition, a responsible entity is 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. 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 and Article 5 of the July 2012 Response to Comments document 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 and different 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.

DTSC made no changes to the regulations in response to this comment.

§ 69506.7 End-of-Life Management Requirements

§ 69506.7(c)(3) Product Stewardship Program and Plan

Comment: 13-1

Comment Summary:

The above comments expressed concern with section 69506.7(c)(3), which requires that a manufacturer develop a product stewardship program and plan for collecting and, if applicable, the recycling of the product in consultation with California retailers and other owners/operators of prospective collection sites. The plan must include a description of public and stakeholder consultation activities for reviewing and updating of the plan which must occur annually. In summary, the following concerns were expressed:

- To ensure the end-of-life management programs have meaningful and reasonable performance goals, DTSC should establish the performance goals, in consultation with the manufacturers or stewardship organizations and affected stakeholders; and
- The performance goals should be established by the state, and the manufacturers/stewardship organizations identify how to attain the performance goals in their stewardship plans, and report on their progress annually.

Response:
The stakeholders concerned or impacted through a Priority Product will likely be identified during the public comment period of the Final AA and the regulatory response(s) that are required. In consultation with all affected stakeholders, DTSC will take into account any other performance goals specified by other state and/or local agencies and work with the manufacturer to developing feasible performance goals. It is not necessary to include this in the proposed regulations; however, the manufacturer must describe in the end-of-life plan that is submitted the coordination efforts that were undertaken. DTSC is not making any changes to the regulations in response to this comment.

ARTICLE 9. TRADE SECRET PROTECTION

§ 69509 General: Confidential Business Information

Comments: 20-7, 20-49, 30-14, 37-5, 41-12, 41-16

Comments Summary:
The definition of trade secret should include the concept of confidential business information (CBI); trade secrets encompass more than engineering and "know-how." The regulations pertaining to trade secrets do not provide the necessary clarity and certainty that proprietary manufacturing information that is considered a trade secret will remain confidential.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Article 10 portion of the Response to Comments for the July 2012 version of the regulations. (Note: the trade secret provisions were in Article 10 of the July 2012 version of the regulations. The trade secret provisions were moved into Article 9 of the January 2013 version of the regulations, where they remain.) Viewed together, that Response to Comments document and the present regulatory text make clear that trade secret "manufacturing information" that is neither part of a hazard trait submission, nor a chemical identity associated therewith, is protectable as confidential business information.

The Department of Toxic Substances Control (DTSC) is not making any changes to the regulations in response to these comments.

§ 69509(a) Substantiation Requirements

Comments: [Burdensomeness]: 3-7, 20-51, 20-63, 20-64, 20-65, 41-11, 41-13

Comments Summary:
DTSC is requiring manufacturers to provide significant substantiation information to support a claim of trade secrecy, and some of the information is difficult to quantify. This is burdensome and goes beyond what is required by state or federal law. DTSC should model its substantiation requirements on the federal Chemical Data Reporting rule. DTSC should also defer requiring substantiation information until the agency

receives a request for disclosure, rather than requiring it when a trade secrecy claim is first made in a submission.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Article 10 portion of the Response to Comments for the July 2012 version of the regulations.

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

§ 69509(f) Hazard Trait Submissions

Comments: [Chemical identity disclosure]: 20-66, 20-69, 26-8, 38-7, 41-14, 41-16

Comments Summary:
The requirement to disclose precise chemical identity is misguided, exceeds DTSC's legal authority, and fails to acknowledge that chemical identity is legitimate intellectual property worthy of trade secret protection. Chemical identity should always be claimable as a trade secret, particularly where the claim will be related to the identification and development of alternatives for a Priority Product. Generic chemical names provided in connection with hazard information are completely adequate for public use. DTSC should remove section 69509(f) and allow responsible entities to file a claim for trade secret protection of chemical identities. This would be consistent with U.S. EPA's Chemical Data Reporting Rule at 40 CFR Part 2 and 40 CFR § 711.30.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Article 10 portion of the Response to Comments for the July 2012 version of the regulations.

DTSC notes two additional points. First, commenters' criticisms of DTSC's approach ignore the extremely limited circumstances in which innovators must immediately disclose the precise identities of safer chemicals that they may formulate: where a chemical is the subject of a "hazard trait submission," and that chemical is not an alternative considered or proposed in an Alternatives Analysis (AA) for which a patent application is pending. In *all other circumstances*—including the myriad circumstances

in which industries are anticipated to reformulate their products so that they may avert potential designation as “Priority Products”—industries investing in and discovering safer chemicals and chemical uses may protect chemical identities as their trade secrets. Thus, when viewed in proper regulatory context, section 69509(f) cannot reasonably be said to have the broad anti-innovative effects its critics claim.

Second, to the extent that industry indicates its willingness to share precise chemical identity with DTSC, but not with the broader public, DTSC regards this as inadequate to fulfill AB 1879’s potential. In light of its own resource and expertise constraints, DTSC views it as broadly desirable to enable university researchers, private parties, and others to learn from, disseminate, and innovate based on the totality of information contained in hazard trait submissions, including information about precise chemical identities.

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

§ 69509(g) Chemical Identity Masking When a Patent is Pending

Comments: [Patents versus Trade Secrets]: 3-5, 3-6, 4-9, 4-10, 9-9, 15-2, 15-3, 20-52, 20-53, 20-54, 20-55, 20-56, 20-57, 20-58, 20-59, 20-60, 20-61, 20-70, 20-71, 20-72, 20-73, 20-74, 20-75, 20-76, 20-77, 20-78, 20-79, 22-21, 24-10, 24-11, 24-12, 25-2, 25-17, 25-18, 25-19, 26-7, 26-8, 28-4, 31-8, 36-10, 36-11, 36-12, 36-13, 38-4, 38-5, 38-6, 38-7

Comments Summary:
The proposed regulation improperly limits trade secret protection to those ingredients and products where patent protection is being sought, and only for the time period until the patent is issued or denied. This appears to evidence an ongoing DTSC misunderstanding of the nature of trade secret protection and the patent process.

DTSC’s regulation fails to provide adequate protection to confidential chemical identity, because a trade-secret chemical may not qualify for a patent. It also denies an often used mechanism to protect CBI used by many industries to provide an effective probability of securing return on research and development investment. As an example, Procter & Gamble protects several types of technology from competition through trade secret designation, such as novel mixed polymer systems and low levels of unique catalysts that are extremely difficult to reverse-engineer.

Further, even if a chemical or its presence in a formula for a mixture is covered by a patent, improvements to the chemical structure or formula through additional research

and development may qualify as trade secrets. In this way, patents freeze technology, while trade secrets build on it. Trade secrecy has gained in importance in recent decades because in many fields, technology is changing so rapidly that it is outstripping the existing laws intended to encourage and protect inventions and innovations. Thus, the applicability and validity of other forms of legal protection for intellectual property in many emerging technologies have been fraught with uncertainty.

DTSC should give the same level of protection to trade secrets, including confidential business information, that it affords to information contained in a patent application. Industry has no problem with sharing the full range of confidential information with the State's regulatory authorities to enable them to exercise their responsibilities under the Safer Consumer Products regulations, but to require systematic sharing with the public—thereby, the global marketplace—is unnecessary, and threatens damage to California's economy. There is no public policy or legal basis for DTSC's requirement that trade secret information in a hazard trait submission, including chemical identity, may be protected only if patent protection is sought.

DTSC has no legal basis to require entities to waive their property rights in their trade secrets. DTSC's approach also violates the statute, which requires all trade secrets, not just patents, to be protected. DTSC's approach, of requiring filing of a patent application to protect certain trade-secret information, is also inconsistent with federal and state law.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Article 9 portion of the Response to Comments for the January 2013 version of the regulations.

In response to various legal objections to this section raised by commenters, DTSC makes two additional points. First, DTSC does have legal authority to determine the extent of private parties' trade-secret rights with respect to chemical identities, insofar as the Legislature left to DTSC the definition of "hazard[] trait submission," and DTSC has defined that phrase in a manner both consistent with the statute, and objectively reasonable. (See *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842–843 (1984) (holding that where a statute is silent or ambiguous, a court must defer to an agency's reasonable construction.)

In a related vein, contrary to the commenter's assertion, AB 1879 does not require all trade secrets to be protected in all circumstances; this is manifest in the express trade-secrecy carve-out in Health and Safety Code section 25257(f).

Second, commenters err in asserting that DTSC's approach, of requiring filing of a patent application to protect certain trade-secret information, is inconsistent with federal and state law. DTSC's approach cannot be inconsistent with *federal* law, insofar as trade secrecy is the exclusive province of state law, and a state is not obligated to confer any legal protections on trade secrets (much less, the particular protections urged by commenters). As the U.S. Supreme Court explained in *Kewanee Oil Co. v. Bicron Corp.,* 416 U.S. 470, 479-480(1974): "States may hold diverse viewpoints in protecting intellectual property to invention [. . .] and patent law does not explicitly endorse or forbid the operation of trade secret law." (See also Comment 4-9 (American Chemistry Council), noting that "State law generally governs trade secrets.") DTSC's approach also cannot violate *state* trade secrecy law, insofar as DTSC's approach is consistent with AB 1879, and that statute both post-dates the California Uniform Trade Secret Act (CUTSA) and is more specific, and therefore, in the event of any hypothetical conflict, supersedes it.

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

Unconstitutional "Taking"

Comment: 20-78

Comment Summary:
DTSC's requirement for entities to waive certain intellectual property rights unless a patent application is filed may be an unconstitutional "taking" of property.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 9 portion of the Response to Comments for the January 2013 version of the regulations.

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

Patent Enforcement

Comments: 4-10, 36-12

Comments Summary:
Patents may be difficult to enforce. It is incumbent upon the inventor to defend the innovation by patent litigation. This may not be economically reasonable or meaningful, as in the case of foreign imitators not easily constrained by judicial decision. This is one reason that companies may prefer to protect even a patentable innovation by instead protecting it as a trade secret. The patent system's critical role in protecting intellectual property works only where the interests of the innovator coincide with making the innovation systematically available to the market.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 9 portion of the Response to Comments for the January 2013 version of the regulations.

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

Intellectual Property Safeguards

Comment: 38-8

Comment Summary:
Protection of many types of sensitive information will be required to insure that submitters retain their competitiveness. Manufacturers' AA Reports will contain detailed technical information regarding the function of particular chemicals to achieve desired results, and CBI such as information about operating margin and retail sales outlets, which may provide key information to a competitor about a manufacturer's financial strength and marketing strategy. DTSC will need to protect that information from public review during program implementation.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent

that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Article 10 portion of the Response to Comments for the July 2012 version of the regulations. DTSC agrees with the thrust of the commenters' concerns, and further agrees that this is a future implementation issue rather than present regulatory issue.

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

Competitive Concerns

Comments: 4-10, 4-11, 20-67, 20-68, 20-69, 20-79

Comments Summary:
It is problematic that only a nondisclosure agreement or federal legal prohibition on disclosure can shield certain confidential information from disclosure to potential competitors. Furthermore, a patent may not protect against foreign competitors, because it is only good in the country for which it is granted. A U.S. patent would not prevent foreign competitors from using patented information to their own advantage. Federal and state pesticide laws provide a useful model for how to prevent disclosure of health and safety studies to competitors.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 10 portion of the Response to Comments for the July 2012 version of the regulations, and further responded to in the Article 9 portion of the Response to Comments for the January 2013 version of the regulations.

DTSC further notes that the problem of intellectual property disclosure to domestic or foreign competitors inheres in holding trade secrets, just as in holding patented inventions. As the U.S. Supreme Court long ago explained: "The holder of a trade secret also takes a substantial risk that the secret will be passed on to his competitors, by theft or by breach of a confidential relationship, in a manner not easily susceptible of discovery or proof." *Kewanee Oil Co. v. Bicron Corp.,* 416 U.S. at 490.

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

§ 69509(g)(1) Temporary Masking of Precise Identity

Comment: 5-13 [requirement to notify DTSC of publication]

Comment Summary:
The requirement that DTSC be notified when the identity of a chemical that is considered as an alternative in an AA is no longer trade secret seems like added bureaucracy that provides little value to the public and may add burdens to innovators of safer products and chemicals.

Response:
DTSC believes that the possessor of intellectual property for which a patent application has been filed is in the best position to know when that information is no longer secret, and that requiring the party to inform DTSC of that fact will facilitate DTSC response to public inquiries about chemical identities through the Public Records Act or otherwise. DTSC believes that this regulatory section imposes minimal burden, allocates that burden correctly, and will confer public benefit.

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

§ 69509.1 Department Review of Claims of Trade Secret Protection
§ 69509.1(a) Review of Support for Trade Secret Designation

Comment: 41-15

Comment Summary:
The 30-day time period for a company to correct the deficiency of a claim for trade secret protection or seek judicial relief from this obligation is too short, and should be extended to sixty (60) days.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 10 portion of the Response to Comments for the July 2012 version of the regulations.

Inadvertent Disclosure

Comments: 20-50, 20-62

Comments summary:
The commenter is not aware that DTSC has any protocols in place for the protection of information claimed as trade secret under this regulatory program. The White House has recently acknowledged the escalation of industrial espionage and the risk of cyber intrusions. DTSC should provide written assurances that it has, or will have, protocols in place to protect trade secret information against unauthorized disclosure.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Article 10 portion of the Response to Comments for the July 2012 version of the regulations. DTSC has repeatedly noted that the agency protocols for protecting confidential information—which are a matter of DTSC's internal operations, rather than a set of rules for regulated parties—are a matter of implementation, rather than regulatory text.

As one commenter notes, "[t]he Obama Administration has called on private businesses to share information regarding best practices to protect trade secrets, including practices related to information security policies." (Comment 20-62) DTSC invites private businesses to share with DTSC information regarding best information security practices and policies with respect to the types of documents and confidential information anticipated to be submitted pursuant to these regulations.

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PROCEDURAL, LEGAL, AND OVERARCHING ISSUES

Environmental Policy Council

Comment: 20-41

Comment Summary:
The Department of Toxic Substances Control (DTSC) has shifted responsibility from the Environmental Policy Council (EPC) to responsible entities to conduct a multimedia life cycle evaluation in the process of identifying product-chemical combinations.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issue with respect to the prior text of the proposed regulations, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations.

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

Interstate Commerce

Comment: 26-26

Comment Summary:

- The regulations would impose on businesses that import their products into California significant burdens, which vastly outweigh any purported benefit. California lacks the legal authority to set the rules of the game governing interstate and international markets for consumer goods sold in California in a manner designed solely to benefit California economic interests.

Response:

The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent

that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations.

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

Preemption

Comments: 1-5, 1-7

Comments Summary:

- In the context of aviation, if those performing repair and maintenance in California were not able to continue purchasing needed parts and supplies, aircraft operators would be unable to comply with the Federal Aviation Act (FAA) requirement to have repair stations along the routes of service. As written, the "assembler" definition provided in the revised regulation would have the effect of forcing aircraft operators to obtain an injunction based on federal preemption, blocking enforcement of the Safer Consumer Products regulations as applied to repair and maintenance activities, as well as resulting in lost maintenance and repair jobs out of California; and
- DTSC is preempted from regulating aviation because the FAA was granted exclusive authority to specify the requirements under which U.S. aircraft and aircraft components are approved, aircraft maintenance is performed, and aircraft are operated.

Response:

Preliminarily, DTSC notes that although the comment refers to an amended definition of "assembler," the definition of "assembler" was unchanged from the January 2013 to April 2013 version of the proposed regulations. But the closely related definition of "assemble" was changed from the January 2013 to April 2013 version of the proposed regulations. So, the rest of this response will address that change. DTSC respectfully disagrees that the effect of this changed definition of "assemble" will be to force aircraft operators to obtain an injunction to block enforcement of these regulations or to force maintenance and repair jobs out of California. Quite simply, the revised definition of "assemble" was written to ensure that repair, refurbishment, maintenance, and non-material alterations to assembled products still fit within the definition of "assemble."

This change was made in response to comments on the January 2013 version of the regulations. This definition comes into play in Article 5.

More specifically, an assembler, unlike a manufacturer or importer, has the option to perform an Alternatives Analysis (AA) for a component of its finished product that is identified as a Priority Product or simply ceasing to order the component that is the Priority Product. So, the effect of the amended definition of "assemble" is to give the airline industry, as well as all other assemblers, a broader range of circumstances in which it may opt out of conducting an AA. So, the change made in the April 2013 version of the proposed regulations does not increase any responsibilities or requirements on assemblers. On the contrary, it gives more flexibility to those entities that meet this revised definition of "assemble," and by extension, the new meaning of "assembler." Given that, and the fact that there is no basis at this time for concluding that any aircraft component will inevitably be identified as a Priority Product, there is also no basis for presuming that the aircraft industry will need to seek injunctions or will suffer repair and maintenance job losses in California.

The regulatory text to which the other comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations.

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

Duplication/Conflict

Comments: 8-23, 8-24, 8-25, 8-28, 9-1, 15-1, 20-6, 20-11, 20-24, 20-25, 24-8, 25-1, 25-15, 25-16, 26-24, 26-25, 37-4

Comments Summary:

- As currently proposed in section 69501(b), DTSC has given itself wide latitude in determining whether or not a Priority Product is adequately regulated under another California or federal statute:
    - Including end-of-life effects in the scope of consideration for this exemption, DTSC has essentially ensured that it will be narrowly applied; and

  - This language leaves the regulated community uncertain as to whether they will be subject to multiple state and federal regulatory requirements at any stage of a product's life cycle. DTSC should revise the exemption and create a clear "out" for consumer products that are already regulated by one or more federal and/or California State regulatory program(s).
- DTSC has not provided an up-front exemption for products that are manufactured or stored in California solely for use outside of California or where the product is used only to manufacture a product exempted from the regulations. While DTSC considers these factors in section 69503.3(b)(3), there should be language that expressly exempts these products from the regulations;
- Home appliances are well-regulated by other entities at the federal level, and should thus be given a very low priority or excluded entirely from the regulatory program. For example, member manufacturers must conform to the Consumer Product Safety Act, the Consumer Product Safety Improvement Act, the Refrigerator Safety Act, and the Toxic Substances Control Act, among other requirements;
- The narrow standard being imposed to justify deference to other regulatory programs is seriously flawed and effectively could allow DSTC's interpretation to ride roughshod over whole programs administered by other agencies. DTSC must consider that the regulations cannot limit or supersede the authority of any other agency in addition to the requirement not to duplicate or adopt conflicting regulations;
- A comment notes continued concern with exemption and regulatory overlap;
- Section 69501(c) improves the regulation, but an additional clause should be added to say that the regulation may not be interpreted or implemented in a way that duplicates requirements imposed by other State or federal agencies;
- There is concern about regulatory overlap in which the presence of the product/releases now includes homes, schools, workplace, and other locations, calling into question how this aligns with authorities of other regulatory agencies (*i.e.*, Cal/OSHA);
- There is concern that a responsible entity could be in full compliance with existing regulatory authority and DTSC could exercise its discretion and imbue additional burdens;
- Food contact materials are already fully and effectively regulated by the U.S. Food and Drug Administration and California governmental agencies, and any regulation by DTSC would be duplicative and in direct conflict with these existing regulatory schemes; and

- The regulations do not contain the necessary clarity and certainty that they will not apply to consumer products that are adequately regulated by other state or federal agencies.

Response:

The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations.

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

Requests for Exemption

Comments: 8-18, 8-21, 8-22, 9-1, 9-2, 9-10, 10-3, 10-8, 17-7, 17-8, 17-9, 21-3, 24-1, 24-9, 36-3

Comments Summary:

- DTSC should reconsider earlier requests to exempt the automotive sector from these regulations;
- DTSC should provide an up-front exemption for businesses that "repair, refurbish, maintain or make non-materials alterations" to a consumer product, and those activities in general. To achieve this, revisions should be made to the definition of "manufacture," "assemble," and "consumer product";
- Home appliances are well-regulated by other entities, and should thus be given a very low priority or excluded entirely from the regulatory program;
- The appliance industry is already taking significant voluntary steps to achieve the goals of the proposed regulations. These regulations would, therefore, not have any significant impact in protecting human or environmental health;
- The regulations will place unnecessary burdens on manufacturers of home appliances and they should be granted an exemption from the program;
- Regulatory hurdles will discourage individuals from taking advantage of direct selling opportunities in California and reduce state revenue. Direct sellers should be exempted from the program;

- Food contact materials and substances used as components of food contact materials should be excluded from the regulations;
- The inclusion of food contact materials would not further the goals of the regulations and could impede the development of new materials; and
- Over-the-counter drugs need to be exempted from the scope of the regulations in order to avoid the inevitable conflicts with mandatory federal drug requirements.

Response:

The only comment that is directed to a provision in the regulations that was changed from the January 2013 version of the regulations to the April 2013 version is the comment requesting an up-front exemption for businesses that "repair, refurbish, maintain or make non-materials alterations" to a consumer product, and those activities in general. To achieve this, the comment urges revisions to the definition of "manufacture," "assemble," and "consumer product." As noted above, the revised definition of "assemble" was written to ensure that repair, refurbishment, maintenance, and non-material alterations to assembled products still fit within the definition of "assemble." This change was made in response to comments on the January 2013 version of the regulations. This definition comes into play in Article 5.

More specifically, an assembler, unlike a manufacturer or importer, has the option to perform an AA for a component of its finished product that is identified as a Priority Product or simply ceasing to order the component that is the Priority Product. So, the effect of the amended definition of "assemble" made in the April 2013 version is to give the airline industry, as well as all other assemblers, a broader range of circumstances in which it may opt out of conducting an AA. So, it does not increase any responsibilities or requirements on assemblers. On the contrary, it gives more flexibility to those entities that meet this revised definition of "assemble," and by extension, the new meaning of "assembler."

In addition, DTSC notes that there has been some confusion about the regulatory status of "replacement parts" throughout the development of the proposed regulations. At no time did DTSC ever draft the proposed regulations to create an exemption from this program for repair and/or replacement parts. While some commenters have urged DTSC to do so, DTSC has declined to do so. The reasons for this decision are set out in detail in Article 1 of DTSC's Response to Comments for the July 2012, January 2013, and April 2013 versions of the proposed regulations.

The regulatory text to which the remainder of these comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations.

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

Exceeds Authority/Conflicts with Statute

Comments: 4-4, 8-21, 17-6, 20-14, 20-22, 20-23, 26-27

Comments Summary:

- It is questionable whether DTSC has authority under Health and Safety Code sections 25252 through 25255 and 25257 to require manufacturers, importers, assemblers, and retailers of "any product" to provide information regardless of whether these chemicals or products are subject to the regulation [referring to section 69501.4(a)(2)];
- It is an inappropriate expansion of authority for DTSC to include businesses that "repair, refurbish, maintain or make non-materials alterations" to a consumer product in the hierarchy of entities with a duty to comply;
- It is unclear that DTSC has authority to regulate persons who provide repair, refurbishment, and maintenance services under AB 1879, as these people sell services, not consumer products;
- DTSC has given itself authority to regulate a product that is already regulated where DTSC claims enhanced protection under the regulations, in excess of the authority granted under Health and Safety Code section 25257.1(a) through (c);
- The regulations exceed DTSC's authority by regulating products that are manufactured transported through, or stored in California solely for use outside of California; and
- The timelines and requirements of the AA process are unworkable and exceed DTSC's authority under the statute.

Response:

In response to numerous comments that demonstrated a misunderstanding of the scope of section 69501.4(a)(2), DTSC revised section 69501.4(a)(2) in the April 2013

version of the proposed regulations. Section 69501.4(a)(2) now explicitly states that that the information-gathering provisions in section 69501.4 do not apply to products exempted from the definition of "consumer product" specified in Health and Safety Code section 25251.

In addition, under the comments and responses addressing Preemption and Requests for Exemption above in this Response to Comments, DTSC has already addressed the revised definition of "assemble." See those topics above for a detailed discussion of the nature of the revision that was made to this definition and the effect of this change.

All of the other comments are directed to regulatory text that is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations.

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

Other Legal Issues

Comments: 2-7, 8-1, 8-2, 8-3, 8-11, 8-44, 8-45, 10-1, 17-19, 22-1, 22-24, 43-2

Comments Summary:

- If DTSC moves forward with its current intent to include components of motor vehicles and other complex durable goods in these regulations, there is a compelling need to provide the maximum degree of clarity, as well as concise definitions, exemptions and regulatory requirements. This will ensure that DTSC creates meaningful, practical and legally defensible regulations;
- The regulations, as currently written, build so much uncertainty into the regulatory process that it will be impossible to predict the outcome of any DTSC regulatory response. Predictability is a key aspect of regulation for manufacturers, importers and/or assemblers of complex durable goods. The lead time needed to develop new components for those that DTSC will regulate requires years, not months;
- As written, the regulations create an unworkable system for manufacturers, importers and assemblers of complex durable goods;
- The current proposal may create a system that is workable for less complex, simple and/or formulated consumer products, such as personal hygiene

products, cleaning products and similar consumer goods that can be modified in short periods of time and that have a very narrow shelf life as compared to complex durable goods that are manufactured to provide service for decades;

- Proposed section 69505.8 fails to establish any criteria by which DTSC will filter what public comments warrant a response. DTSC must identify objective, science-based criteria for reviewing and responding to public comments on Final and Abridged AA Reports. Currently, this provision falls short of the statutory mandate in Health and Safety Code section 25253(c) that the tools for evaluating chemicals of concern be "in a form that allows… transparency of application"; and
- Sierra Club California reserves the right to exhaust all administrative remedies if DTSC does not go forward with the adoption of the regulations.

Response:

The only comment directed at a change made from the January 2013 to April 2013 version of the propose regulations is the comment directed to the public comment process in section 69505.8. That comment is responded to immediately below. All of the other comments are directed to regulatory text that is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations.

In determining which issues must be addressed, DTSC will review the comments on the merits, and use professional judgment in identifying the issues that must be addressed by the responsible entity. That is, DTSC will evaluate whether the public comment has validity and points out areas in need of further evaluation. DTSC is unclear how the review of the AA Reports is purportedly in conflict with Health and Safety Code section 25253(c) requiring that tools for evaluating chemicals of concern be in a form that "allows ease of use and transparency of application."

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

Compliance with the Administrative Procedure Act's Standards for Review

Comments: 7-4, 8-11, 8-42, 41-3

Comments Summary:

Comments on the revised Initial Statement of Reasons (ISOR):

- DTSC should have provided a revised ISOR with the April 2013 proposed rule. For stakeholders to be informed, and therefore able to give valuable feedback to DTSC, the proposed regulations should be accompanied by a corresponding ISOR; and
- One comment recognizes that a revised ISOR is not required to accompany all drafts of proposed regulations under the Administrative Procedure Act (APA), but still maintains that such a document would be useful.

Response:

The commenter(s) have a mistaken understanding of the function and requirements under the APA regarding the ISOR. More specifically, the principal purpose of the ISOR is to give interested parties an understanding of the purpose and rationale for the provisions of the adopting agency's initial regulatory proposal. (Government Code section 11346.2(b)(1)) The APA does not require that every revised iteration of proposed regulations be accompanied by an additional or revised ISOR. Rather, the APA requires that the adopting agency make the revised proposed regulations available for comment, and then respond to the comments submitted, as DTSC is doing here. (Government Code section 11346.9(a)(3))

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

Comments: 1-3, 17-20

Comments Summary:
The following comments expressed the belief that the comment period for the April 2013 revisions to the proposed regulations needed to be longer than 15 days:

- The changes in the April 2013 revisions, including changes to the definition of "assemble" are not "sufficiently related changes" as defined in Government Code section 11346.8 and Title 1, California Code of Regulations, section 42. Accordingly, these changes require a public comment period of more than 15 days;
- Proposed section 69505.8 fails to establish any criteria by which DTSC will filter which public comments warrant a response. DTSC must identify objective, science-based criteria for reviewing and responding to public comments on Final

and Abridged AA Reports and allow the public another chance to provide input on those criteria via another round of public comments; and

- Due to the extensive potential impact the change to the public comment process in section 69505.8 has on the AA process, DTSC should have allowed more than a 15 day public comment period on this change to the proposed regulations.

Response:
DTSC respectfully disagrees that the change made to the definition of "assemble" and the change made to the public comment process for AA were such that they needed to undergo a 45-day public comment period, rather than a 15-day public comment period. DTSC is firmly of the opinion that these changes are "sufficiently related" changes as defined in Government Code section 11346.8 and Title 1, California Code of Regulations, section 42. More specifically, section 42 provides: "Changes to the original text of a regulation shall be deemed to be "sufficiently related," as that term is used in Government Code Section 11346.8, if a reasonable member of the directly affected public could have determined from the notice that these changes to the regulation could have resulted."

Again, DTSC believes that a reasonable member of the directly affected public could have determined from the notice for these regulations that there could be changes related to the definition of "responsible entity," "manufacturer," "importer," "component," "assemble," "assembler," "retailer," numerous other definitions that have the effect of specifying who must conduct an AA. In this case, one following these regulations could easily have anticipated that there could be changes, in response to numerous comments and for other reasons, as to who must conduct an AA and under what circumstances. This lynchpin requirement of conducting an AA remains in the regulations, but with some modest related changes—as with the definition of "assemble" and the related change to the meaning of "assembler."

Along these same lines, a reasonable member of the directly affected public could have anticipated changes to the provisions aimed at ensuring the quality and integrity of the AA process. Initially, DTSC proposed a full-blown accreditation and certified assessor program to accomplish the goal of ensuring AA of high quality and integrity. Due to an overwhelming number of comments that objected to these provisions from virtually all broad stakeholder groups, DTSC decided to abandon that approach. But in doing so, it established a limited public comment process for the AA. This modification from an institutionalized structure to ensure quality and integrity to a much more limited public comment process to allow the public at large and interested parties to provide a check-

and-balance on the AA conducted by responsible entities themselves is well within the definition of a “sufficiently related” change.

In determining which issues must be addressed, DTSC will review the comments on the merits, and use professional judgment in identifying the issues that must be addressed by the responsible entity. That is, DTSC will evaluate whether the public comment has validity and points out areas in need of further evaluation.

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

Comments: 8-11, 8-43, 17-18, 17-25, 20-3, 20-8, 20-9

Comments Summary:
Additional comments on the APA:

- A comment notes that DTSC intends to develop the Initial Priority Products list through a notice and comment rulemaking process, and intends to do an economic analysis at that time along with the Initial Priority Products list. Commenter requests that this be expressly noted in the regulatory text;
- There is no precedent for a California public comment process in which a regulated private entity, rather than the regulatory agency, directly responds to public comments in a regulatory proceeding like the one being proposed. This procedure is not lawful under the APA and is contrary to Health and Safety Code section 25253(c) (requiring that tools for evaluating chemicals of concern be “in a form that allows ease of use and transparency of application”). DTSC must revise section 69505.8 so that DTSC is the entity responding to public comments;
- Comment expresses disappointment at the piecemeal approach of the entire regulatory process, which made it difficult for members of the public and the regulated community to provide meaningful input;
- Comment requests that DTSC explicitly indicate its intention to comply with CEQA Analysis, Economic Analysis, and multimedia analysis when creating the Initial Priority Products List under APA rulemaking procedures; and
- Comment notes that the APA process undertaken by DTSC has been piecemeal and will have a chilling effect on judicial review of agency decisions.

Response:

The comment directed to the public comment process in section 69505.8 of the proposed regulations is the only comment directed at a change made from the January 2013 version to the April 2013 version of the proposed regulations. All of the other comments are directed to regulatory text that is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations.

DTSC does note, however, that by virtue of the requirement in section 69503(a) (2) that DTSC adopt the Priority Products lists by a rulemaking under the APA, DTSC will be subject to the APA requirement to conduct an economic analysis in conjunction with the adoption of the list. Since this is already a requirement in the APA, there is no need to repeat that requirement, or any other selected requirement of the APA, in these regulations.

The public comment process in proposed section 69505.8 is not subject to or governed by the APA. So, by definition, it cannot be in violation of the APA. As explained briefly above, this provision was first placed in the January 2013 version of the regulations to serve very loosely as a type of substitute for the accreditation and certified assessor programs that were eliminated from the proposed regulations. That is, it was and is a provision aimed at getting more and better information to DTSC about the quality and integrity of the AA than DTSC would otherwise have without this process. The change made from the January 2013 to April 2013 versions merely streamlined the proposal first included in the January 2013 version. More specifically, the public comments are now directed to the Final AA Report-- not the Preliminary AA Report—and the comments are made to DTSC—not the responsible entity that prepared the Final AA Report. DTSC then informs the responsible entity if, based on consideration of the public comments, DTSC determines that one or more issues needs to be addressed further in an AA Report Addendum.

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

Economic Analysis

Comments: 8-43, 20-8, 20-43, 37-3

Comments Summary:

- A comment notes that DTSC intends to develop the Initial Priority Products list through a notice and comment rulemaking process, and intends to do an economic analysis at that time along with the Initial Priority Products list. Commenter requests that this be expressly noted in the regulatory text;
- A comment requests that DTSC explicitly indicate its intention to comply with CEQA Analysis, Economic Analysis, and multimedia analysis when creating the Initial Priority Products List; and
- DTSC should have the responsibility of evaluating the economic impacts to the State and improperly shifts this burden to regulated entities in section 69505.6(a)(2)(C)(1).

Response:

The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text of the proposed regulations, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations.

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

CEQA

Comment: 20-8

Comment Summary:

- The comment requests that DTSC explicitly indicate its intention to comply with CEQA Analysis, Economic Analysis, and multimedia analysis when creating the Initial Priority Products List.

Response:
The regulatory text to which this comment is directed is unchanged, or has not changed in relevant part, since the prior iteration of these proposed regulations. To the extent that commenters timely raised the present issues with respect to the prior text, these issues are responded to in the Procedural, Legal, and Overarching Issues portion of the Response to Comments for the July 2012 and January 2013 version of the regulations

as well as in Article 3 of the Response to Comments for the July 2012 and January 2013 Response to Comments.

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

MISCELLANEOUS

Comments: 2-1, 2-3, 2-8, 2-9, 2-10, 2-11, 4-1, 14-1, 14-2, 14-3, 17-1, 20-2, 22-22, 24-2, 25-20, 26-1, 26-22, 28-1, 36-1, 36-2, 36-15, 37-1, 41-19, 46-1, 48-1, 48-2, 48-3

Comments Summary:
The above listed comments either summarize the comments that have been included in a comment letter, incorporate the comments of another entity's comment letter by reference, or incorporate previously submitted comment letters by reference.

Response:
Because all of the substantive comments that these comments are summarizing or incorporating have been responded to separately in this document and the Response to Comments documents for the July 2012 and January 2013 versions of the regulations, 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: 2-2, 23-1

Comments Summary:
The above listed comments expressed general support for the regulations.

Response:
DTSC appreciates these comments. DTSC is not making any changes to the regulations in response to these comments.

Comment: 43-1

Comment Summary:
The above listed comment urged DTSC to implement the regulations immediately and robustly to retain public support and protect the environment and public health.

Response:

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

Comment: 22-3

Comment Summary:
DTSC should review the regulations nine months after their effective date to determine if the rules are likely to achieve their intended benefits at a cost commensurate to those benefits.

Response:
While DTSC appreciates the value of reviewing its programs, it is unlikely that a review nine months after the effective date would allow for a meaningful evaluation of the program in its entirety. DTSC is not making any changes to the regulations in response to this comment.

Comment: 42-6

Comment Summary:
This comment suggests that DTSC should leverage existing information management efforts such as the California Environmental Data Exchange Network (CEDEN) to create a chemical occurrence database to track studies that identify the presence or absence of Candidate Chemicals in the California environment.

Response:
It was unclear to DTSC how the commenter thought this suggestion should be integrated into the proposed regulatory program. DTSC is not making any changes to the regulations in response to this comment.

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