FINAL STATEMENT OF REASONS
SAFER CONSUMER PRODUCTS

Department Reference Number: R-2011-02
Office of Administrative Law Notice File Number: Z-2012-0717-04

TABLE OF CONTENTS

I. GENERAL INFORMATION 4

II. DETAILED STATEMENT OF THE SPECIFIC PURPOSE AND RATIONALE 6

III. ECONOMIC IMPACT ANALYSIS 8

IV. REPORTS RELIED ON 9

V. REASONABLE ALTERNATIVES CONSIDERED 14

VII. DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS 23

ARTICLE 1. GENERAL 28
§ 69501. Purpose and Applicability 28
§ 69501.1. Definitions 35
§ 69501.2. Duty to Comply and Consequences of Non-Compliance 99
§ 69501.3. Information Submission and Retention Requirements 110
§ 69501.4. Chemical and Product Information 112
§ 69501.5. Availability of Information on the Department's Website 117

ARTICLE 2. PROCESS FOR IDENTIFYING CANDIDATE CHEMICALS 121
§ 69502. General 126
§ 69502.1. Applicability 126
§ 69502.2. Candidate Chemicals Identification 127
§ 69502.3. Candidate Chemicals List 166

ARTICLE 3. PROCESS FOR IDENTIFYING AND PRIORITIZING PRODUCT-CHEMICAL COMBINATIONS 169
§ 69503.1. Applicability 170
§ 69503.2. Product-Chemical Identification and Prioritization Factors 170
§ 69503.3. Adverse Impact and Exposure Factors 179
§ 69503.4 Priority Product Work Plan 189
§ 69503.5. Priority Products List 190
§ 69503.6. Initial Priority Products List 195
§ 69503.7. Priority Product Notifications 197

ARTICLE 4. PETITION PROCESS FOR IDENTIFICATION AND PRIORITIZATION OF CHEMICALS AND PRODUCTS 200

§69504. Applicability and Petition Contents 200
§69504.1. Merits Review of Petitions 203

ARTICLE 5. ALTERNATIVES ANALYSIS 206
§ 69505. Guidance Materials 209
§ 69505.1. Alternatives Analysis: General Provisions 210
§ 69505.2. Removal/Replacement Notifications in Lieu of Alternatives Analysis 216
§ 69505.3. Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis 231
§ 69505.4. Alternatives Analysis Process and Options 238
§ 69505.5. Alternatives Analysis: First Stage 249
§ 69505.6. Alternatives Analysis: Second Stage 258
§ 69505.7. Alternatives Analysis Reports 263
§ 69505.8. Public Comments on AA Reports 276
§ 69505.9. Department Review and Determinations for AA Reports and Work Plans 278

ARTICLE 6. REGULATORY RESPONSES 286
§ 69506. Regulatory Response Selection Principles 287
§ 69506.1. Applicability and Determination Process 292
§ 69506.3. Product Information for Consumers 299
§ 69506.4. Use Restrictions on Chemicals and Consumer Products 303
§ 69506.5. Product Sales Prohibition 305
§ 69506.6. Engineered Safety Measures or Administrative Controls 309
§ 69506.7. End-of-Life Management Requirements 310
§ 69506.8. Advancement of Green Chemistry and Green Engineering 318
§ 69506.9. Exemption from Regulatory Response Requirements 318
§ 69506.10. Regulatory Response Report and Notifications 322

ARTICLE 7. DISPUTE RESOLUTION PROCESSES 326
§ 69507. Dispute Resolution 326
§ 69507.1. Informal Dispute Resolution Procedures 327
§ 69507.2. Appeal to the Director 328
§ 69507.3. Formal Dispute Resolution Procedures 329
§ 69507.4. Time Lines for Requests for Review 329
§ 69507.5. Contents of Requests for Review 330
§ 69507.6. Department Procedures for Requests for Review 330

ARTICLE 8. AUDITS 333
§ 69508. Audits of Program Compliance 333

ARTICLE 9. TRADE SECRET PROTECTION 335
§ 69509. Assertion of a Claim of Trade Secret Protection 335
§ 69509.1. Department Review of Claims of Trade Secret Protection 341

ARTICLE 10. SEVERABILITY 344

TABLES

Table 1. Section 69502.2(a)(1) Chemicals Lists and Criteria 133
Table 2. Section 69502.2(a)(2) Chemicals Lists and Criteria 134
Table 3. Alternatives Analysis 208
Table 4. Removal / Replacement Notifications 217

FIGURES

Figure 1. Practical Quantitation Limit 81
Figure 2. Prioritization Concept 188

I. GENERAL INFORMATION

These regulations have been noticed three times for public review and comment:

45-Day Public Review and Comment Period:
This was for the originally proposed regulatory text offered for public review and comment on July 27, 2012. The public hearing on the proposed regulations was held on September 10, 2012. This public review and comment period, originally scheduled to conclude on September 11, 2012, was extended for thirty (30) days to October 11, 2012.

30-Day Notice of Post-Hearing Changes:
This was for changes made to the originally proposed regulatory text. This public review and comment period commenced on January 29, 2013 and concluded on February 28, 2013.

15-Day Notice of Additional Post-Hearing Changes:
This was for changes made to the revised proposed regulatory text public noticed on January 29, 2013. This public review and comment period commenced on April 10, 2013 and concluded on April 25, 2013.

In addition to the regulatory text first proposed in July 2012 and subsequently revised in January 2013 and April 2013, this Final Statement of Reasons reflects nonsubstantive changes made to the regulations following the April 2013 15-day public review and comment period. These nonsubstantive changes are summarized below in Section VIII. DETAILED STATEMENT OF REASONS: SUMMARY AND RATIONALE.

In addition to the three public review and comment periods noted above, a 30-day public review and comment period was held from December 21, 2012 to January 22, 2013 for revisions made to the Initial Statement of Reasons for the proposed regulations public noticed in July 2013. There were also three public review and comment periods provided for studies, reports, and/or similar documents added to the rulemaking file subsequent to publication of the July 2012 notice of the originally proposed regulations and supportive documents. For more information, refer below to Section IV. REPORTS RELIED ON.

Following consideration of the public comments received on the July 2012, January 2013, and April 2013 versions of the proposed regulations and on the various supporting documents made available for public review and comment, DTSC has prepared and included as part of the Final Statement of Reasons for these regulations the following response to comment documents:

Response to Public Comments Received during the 45-Day Public Review and Comment Period (July 2012)

Response to Public Comments Received during the 30-day public review of the External Scientific Peer Review (ESPR) Reports on the July 2012 version of the proposed regulations (November 2012)

Response to Public Comments Received during the 30-day public review of the Revised Initial Statement of Reasons (December 2012)

Response to Public Comments Received during the 15-day public review of the External Scientific Peer Review (ESPR) Reports on the revised proposed regulations (January 2013)

Response to Public Comments Received during the 30-Day Notice of Post-Hearing Changes (January 2013)

Response to Public Comments Received during the 15-day public review of the Resolution from the California Environmental Policy Council (March 2013)

Response to Public Comments Received during the 15-Day Notice of Additional Post-Hearing Changes (April 2013)

Response to Public Comments Received during the 15-Day public review of the Economic and Fiscal Impact Statement (Std. 399) (May 2013)

DTSC is still planning to file a Notice of Exemption (NOE) under the California Environmental Quality Act (CEQA). Based on the comments DTSC received, it has elected not to pursue the exemption in section 15061(b)(3), but maintains that the proposed regulations fall within the list of exempt categories or classes of projects that have been determined by the State Resources Agency not to have a significant effect on the environment and, therefore, further environmental review is not necessary. The draft revised NOE is included in the rulemaking package.

This Final Statement of Reasons is a stand-alone document that, in effect, replaces the Initial Statement of Reasons prepared for this rulemaking. As such, this document provides a description of, and a statement of necessity for, each provision of the final regulatory text. Each section of the Final Statement of Reasons takes one of (or a combination of) the following approaches:

- Reiterates the corresponding section of the Initial Statement of Reasons.

- Presents a revised version of the corresponding section of the Initial Statement of Reasons in order to reflect and explain changes to the originally proposed regulations as reflected in the revised proposed regulations made available for review and comment during the January 2013 30-day and the April 2013 15-day public review and comment periods.
- Provides additional information in response to comments and questions received during the three public comment periods for these regulations.

This stand-alone approach to preparation of the Final Statement of Reasons was chosen to avoid the need for the reader to refer back and forth between the Initial Statement of Reasons and the Final Statement of Reasons in order to get a complete understanding of the final regulatory text.

II. DETAILED STATEMENT OF THE SPECIFIC PURPOSE AND RATIONALE

Health and Safety Code section 25252 requires the Department of Toxic Substances Control (DTSC) to adopt regulations to establish a process by which chemicals or chemical ingredients in consumer products may be identified and prioritized for consideration as being chemicals of concern. This process is required to include, at a minimum, consideration of:

(1) the volume of a chemical in commerce in California;
(2) the potential for exposure to a chemical in a consumer product; and
(3) potential effects on sensitive subpopulations, including infants and children.

Health and Safety Code section 25252 directs DTSC, in adopting these regulations, to develop criteria by which chemicals and their alternatives may be evaluated. These criteria must include, at a minimum, the hazard traits and environmental and toxicological endpoints that the Office of Environmental Health Hazard Assessment (OEHHA) is required to adopt under Health and Safety Code section 25256.1, for purposes of the Toxic Information Clearinghouse that DTSC is required to establish under Health and Safety Code section 25256.

Health and Safety Code section 25252 also directs DTSC, in adopting these regulations, to reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies. However, the statute states that DTSC is not required to reference and use only this information.

Health and Safety Code section 25253 requires DTSC to adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of

hazard posed by a chemical of concern. This section requires that these regulations establish a process that includes:

(i) An evaluation of the availability of potential alternatives and potential hazards posed by those alternatives;
(ii) An evaluation of critical exposure pathways; and
(iii) Life cycle assessment tools that, at a minimum, take into consideration:
    (A) product function or performance;
    (B) useful life;
    (C) materials and resource consumption;
    (D) water conservation;
    (E) water quality impacts;
    (F) air emissions;
    (G) production, in-use, and transportation energy inputs;
    (H) energy efficiency;
    (I) greenhouse gas emissions;
    (J) waste and end-of-life disposal;
    (K) public health impacts (including potential impacts to sensitive subpopulations, including infants and children);
    (L) environmental impacts; and
    (M) economic impacts.

Health and Safety Code section 25253 also requires that the regulations specify the range of regulatory responses that DTSC may take following the completion of an alternatives analysis, including, but not limited to, requiring:

(1) no regulatory response;
(2) additional information to be provided to DTSC;
(3) labeling or other types of product information;
(4) a restriction on, or prohibition of, the use of a chemical of concern in a consumer product;
(5) controlling access to or limiting exposure to the chemical of concern in a consumer product;
(6) managing the product at the end of its useful life;
(7) funding green chemistry challenge grants; and
(8) any other outcome DTSC determines accomplishes the requirements of this statutory scheme.

Accordingly, DTSC proposes to add a new Chapter 55, Safer Consumer Products, to division 4.5 of Title 22, California Code of Regulations. These regulations are necessary to satisfy the mandates of Health and Safety Code sections 25252 and 25253, which require DTSC to adopt regulations to establish a process to identify and evaluate chemicals of concern in consumer products and identify safer alternatives, and

to specify regulatory responses that may be imposed upon completion of the alternatives analysis process.

III. ECONOMIC IMPACT ANALYSIS

In accordance with Government Code section 11346.3(b), DTSC has made the following assessments regarding the proposed regulation:

The proposed regulations establish a process for identifying and prioritizing chemicals and product-chemical combinations and a process by which chemicals of concern in products and their potential alternatives are evaluated to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. These Safer Consumer Products regulations do not require the private sector to take any actions specific to any chemicals or products and these process regulations do not have any physical impacts to public health or the environment.

Under the regulations, the only impacts to the private sector are that DTSC may request businesses to provide existing information or generate new information necessary to implement the regulations. DTSC is required to maintain and post on its website a "Response Status List" that identifies businesses that have been requested to provide information to DTSC and whether those businesses have provided the information, failed to make the information available, or have demonstrated to DTSC's satisfaction that the information is unavailable or cannot be produced.

Creation or Elimination of Jobs within California

DTSC has determined that no jobs in California will be created or eliminated as a result of the processes described in the regulations. DTSC has determined that no jobs will be created or eliminated in California if DTSC requests a business to provide existing or generate new information. DTSC has determined that businesses would use existing personnel to provide information to DTSC.

Creation of New Businesses or Elimination of Existing Businesses within California

DTSC has determined that no California businesses will be created or eliminated as a result of these process regulations. DTSC has determined that no California businesses will be created as a result of DTSC seeking information from businesses as DTSC will only request information from existing businesses. DTSC has determined that no California businesses will be eliminated as a result of DTSC seeking information as businesses should only incur minimal expense to provide existing information and businesses would not choose to generate new data for DTSC if it were too costly.

Expansion of Current California Businesses

For the reasons stated above, DTSC has determined that no current California businesses will expand as the result of the adoption of these regulations.

Benefits of the Regulations

The regulations themselves only describe the processes for identifying and prioritizing Priority Products-Chemicals of Concern, conducting Alternatives Assessments for Priority Products, and imposing regulatory responses (as required by Health and Safety Code sections 25252 and 25253) – as such the immediate benefits of these regulations are minimal. The direct benefits of these regulations are the information that DTSC will collect to help implement the program, the description of the processes DTSC will use in implementing the Safer Consumer Products program, and the guidance DTSC is required to develop.

However, looking into the future, implementation of the processes established by these regulations – which will be triggered by the adoption of future regulations listing Priority Products – will create one of the first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals. As such, these regulations are viewed as a possible national model for chemical reform. These regulations, in effect, will set in motion a preemptive strategy that reduces the use of toxic substances in the design of products and industrial processes with the aim of creating safer and more sustainable products that do not threaten human health or persist in the environment. The use of fewer hazardous substances means healthier air quality, cleaner drinking water, and safer workplaces. Implementation of the processes set forth in these regulations will promote transparency by compelling chemical manufacturers to provide sufficient information for businesses, consumers, and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products.

IV. REPORTS RELIED ON

The Safer Consumer Products Regulations implement one of six policy recommendations in the California Green Chemistry Report issued by DTSC in December 2008 (“Final Report”). The regulations build upon current environmental protection laws to shift the focus from end-of-pipe cleanup or “cradle to grave” regulation to up-front design and prevention of harm, fostering innovation, and prompting market changes toward a sustainable economy. The six recommendations in the Final Report ensure a comprehensive and collaborative approach to increase accountability and effectiveness of environmental programs across state government for evaluating risk, reducing exposure, encouraging less-toxic industrial processes, and identifying safer alternatives.

In accordance with Government Code section 11346.2(b)(3), DTSC notes that it relied upon the following reports, studies, and/or similar documents, in proposing the adoption of these regulations:

- Assembly Bill 1879 (Feuer, Chapter 559, Stats. 2008) and Senate Bill 509 (Simitian, Chapter 560, Stats. 2008) were signed into law on September 29, 2008, laying the critical foundation for the Green Chemistry program. These bills provide the authority and mandate to adopt the proposed regulations.
- DTSC's Preliminary Economic and Fiscal Impact Statement (STD. 399)
- State of California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, Safe Drinking Water and Toxic Enforcement Act of 1986, Chemicals Known to the State to Cause Cancer or Reproductive Toxicity, June 22, 2012: http://oehha.ca.gov/prop65/prop65_list/Newlist.html
- European Commission 1272/2008 Annex V1, December 16, 2008: http://esis.jrc.ec.europa.eu/index.php?PGM=cla
- European Commission 1272/2008 Annex V1, Category 1A and 1B carcinogens, reproductive toxins, and mutagens, December 16, 2008: http://esis.jrc.ec.europa.eu/index.php?PGM=cla
- European Commission DG ENV, Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption, June 21, 2000: http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm
- United States Environmental Protection Agency's Integrated Risk Information System (IRIS), A-Z List of Substances, as printed on July 2, 2012: http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList
- United States Environmental Protection Agency's Integrated Risk Information System (IRIS), A-Z List of Substances, 1986 Guidelines on Category A, 1B and 2B Human carcinogens and 2005 Guidelines on "carcinogenic to humans", as printed on July 2, 2012: http://www.epa.gov/iris/search_human.htm
- United States Department of Health and Human Services, Public Health Service, National Toxicology Program, Report on Carcinogens, Twelfth Edition (2011), "Substances Listed in the Twelfth Report on Carcinogens", June 10, 2011: http://ntp.niehs.nih.gov/go/roc12

- European Union, High Production Volume Persistent Bioaccumulating Toxins, as printed on June 30, 2012: http://esis.jrc.ec.europa.eu/index.php?PGM=pbt
- Canadian Environmental Protection Act, Environmental Registry, Domestic Substances List: Persistent, Bioaccumulative, and Inherently Toxic to the environment, as printed on July 1, 2012: http://www.ec.gc.ca/lcpe-cepa/D031CB30-B31B-D54C-0E46-37E32D526A1F/PB_20060905_eng.pdf
- International Agency for Research on Cancer, Agents Classified by the IARC Monographs, Volumes 1–105, June 28, 2012: http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf
- Agency for Toxic Substances and Disease Registry's Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, Nervous System, as printed on July 1, 2012: http://www.atsdr.cdc.gov/substances/toxorganlisting.asp?sysid=18
- United States Environmental Protection Agency's National Waste Minimization Program, Persistent Bioaccumulative and Toxic Priority Chemicals, as printed on July 1, 2012: http://www.epa.gov/osw/hazard/wastemin/priority.htm
- National Toxicology Program, Office of Health Assessment and Translation, Reproductive or developmental toxicants identified in Monographs on the Potential Human Reproductive and Developmental Effects, as printed on July 2, 2012: http://ntp.niehs.nih.gov/?objectid=4980AA81-E919-4E85-60B789CA36E59FA5
- United States Environmental Protection Agency's Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals that are subject to reporting under the Emergency Planning and Community Right-to-Know Act section 313, as printed on July 2, 2012: http://www.epa.gov/tri/trichemicals/pbt%20chemicals/pbt_chem_list.htm
- Washington Department of Ecology's Persistent, Bioaccumulative, Toxic Chemicals identified in the Washington Administrative Code, title 173, chapter 173-333, January 13, 2006: https://fortress.wa.gov/ecy/publications/publications/wac173333.pdf)
- California Department of Public Health, Drinking Water Notification Levels and Response Levels: An Overview, December 14, 2010: http://www.cdph.ca.gov/certlic/drinkingwater/Documents/Notificationlevels/notificationlevels.pdf

- California State Water Resources Control Board, Maximum Contaminant Levels, as printed on July 2, 2012: http://www.swrcb.ca.gov/rwqcb4/board_decisions/adopted_orders/general_orders/r4-2008-0083/Attachment_A.pdf

- California Air Resources Board, Toxic Air Contaminants, as printed on July 2, 2012: http://www.arb.ca.gov/toxics/cattable.htm.

- Code of Federal Regulations, title 40, section 303(c) and section 131.38, Priority Toxic Pollutants, May 18, 2000: http://ci.santarosa.ca.us/doclib/Documents/ut_irwp_PEIR_Appendix_C_1_California_Toxics.pdf

- California Office of Environmental Health Hazard Assessment, Air Toxics Hot Spots Program Guidance Manual for Preparation of Health Risk Assessments, August 2003: http://oehha.ca.gov/air/hot_spots/pdf/HRAguidefinal.pdf

- California Office of Environmental Health Hazard Assessment, Environmental Contaminant Biomonitoring Program, July 2012: http://oehha.ca.gov/multimedia/biomon/pdf/PriorityChemsCurrent.pdf

- Centers for Disease and Prevention, Fourth National Report on Human Exposure to Environmental Chemicals and Updated Tables, February 2012: http://www.cdc.gov/exposurereport/pdf/NER_Chemical_List.pdf

- Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic, OSPAR List of Chemicals for Priority Action (reference number 2004-12), 2011: http://www.ospar.org/content/content.asp?menu=00940304440000_000000_000000

After publication of the notice of the proposed regulations, DTSC added technical studies, reports, and/or similar documents to the rulemaking file, and relied on these documents in proposing the final regulations. In accordance with Government Code section 11347.1(a), DTSC made these documents available for public review, including posting the documents on DTSCs website for on-line access. DTSC also mailed notices to persons as specified in Government Code section 11347.1(b) identifying the added documents and informing those persons of the availability of the documents for public review. These notices were also posted on DTSC's website.

The following list includes the list of studies, reports, and/or similar documents that were added to the rulemaking file and the dates of compliance as required by Government Code section 11347.1(e).

- **July 2012 External Scientific Peer Review**
  DTSC released the External Scientific Peer Review (ESPR) Reports on the July 2012 version of the proposed regulations for a 30-day public review and comment period from November 30, 2012 through January 4, 2013.

  Pursuant to Health and Safety Code section 57004, DTSC submitted the scientific portions of the proposed regulations for external scientific peer review. The ESPR reports contain each of ten external scientific peer reviewer's evaluation, findings, and comments concerning the "scientific basis" and/or "scientific portions" of the proposed regulations, which were released for public comment on July 27, 2012.

- **January 2013 External Scientific Peer Review**
  DTSC released the External Scientific Peer Review (ESPR) Reports on the revised proposed regulations (January 2013) for a 15-day public review and comment period from March 13, 2013 through March 28, 2013.

  Pursuant to Health and Safety Code section 57004, DTSC submitted the scientific portions of the revised proposed regulations for external scientific peer review. The ESPR reports contain each of nine external scientific peer reviewer's evaluation, findings, and comments concerning the "scientific basis" and/or "scientific portions" of the revised proposed regulations, which were released for public comment on January 29, 2013.

- **California Environmental Policy Council Resolution**
  DTSC released a Resolution from the California Environmental Policy Council (the Council) for a 15-day public review and comment period from March 13, 2013 through March 28, 2013.

  Health and Safety Code section 25252.5, subject to a specified exception, requires DTSC to prepare, and submit to the Council for review, a multimedia life cycle evaluation prior to adopting these regulations. However, the law provides an exception to this requirement if the Council conclusively determines that the regulations will not have any significant adverse impact on public health or the environment. On February 28, 2013, the Council met and accepted written and oral testimony on the need for DTSC to conduct a multimedia life cycle evaluation of the regulations. The Council unanimously made a conclusive determination that the adoption of these regulations would not have a significant

adverse impact on public health or the environment. Thus, DTSC is not required to prepare a multimedia life cycle evaluation for these regulations

- **Revised Economic and Fiscal Impact Statement (STD. 399)**
  DTSC released a revised Economic and Fiscal Impact Statement (Std. 399), with attachments, for a 15-Day public review and comment period from May 22, 2013 through June 6, 2013.

  The Economic and Fiscal Impact Statement (Std. 399), and its attachments, were revised to reflect the revised proposed regulations, which were released for public comment on April 10, 2013.

V. REASONABLE ALTERNATIVES CONSIDERED

Pursuant to section 11346.9(a)(4) of the Administrative Procedure Act, DTSC has determined that no alternative considered by DTSC would be more effective in carrying out the purpose for which this regulation is proposed or would be as effective and less burdensome to affected private persons than the adopted regulation. The bases, and supporting information, for this determination are discussed below.

Chosen Alternative: DTSC has determined that adding Chapter 55, Safer Consumer Products, to Division 4.5 of Title 22, California Code of Regulations is the most effective and least burdensome approach to meeting its mandate to adopt regulations. It also provides the required flexibility to carry out the provisions of Health and Safety Code sections 25252 and 25253. Because these regulations were developed in tandem with stakeholders to build a program that is workable without compromising the safety of public health and the environment, DTSC has chosen these regulations as the preferred alternative. In addition, the development of these regulations has had the benefit of advice and counsel on scientific matters, including various recommendations on scientific approaches to chemicals policy and differing suggestions for implementation strategies from the legislatively mandated Green Ribbon Science Panel, and thousands of comments from members of the regulated community and the public.

These regulations provide a workable regulatory infrastructure that will develop safer consumer products for the citizens and marketplace of California, while meeting the mandates of the authorizing legislation. The authorizing legislation (Health and Safety Code sections 25252 and 25253) directs DTSC to adopt regulations that:

(1) Establish a process for the identification and prioritization of chemicals in products;

(2) Establish a process for the evaluation of alternatives to those harmful chemicals in order to limit exposure and reduce the level of hazard posed by a chemical of concern; and
(3) Specify the range of regulatory responses that DTSC may impose following the completion of the second process — an Alternatives Analysis (AA).

This level of specificity in the direction from the Legislature on how to proceed means that there were far fewer alternatives to the current regulations that were eligible for consideration as complying with the authorizing legislation's mandates than would otherwise be the case.

Least burdensome

In response to public input, DTSC has undergone several rounds of revisions in an effort to create a regulatory program that is both effective and the least burdensome alternative. The following highlights some of major revisions aimed at creating the least burdensome program possible.

Article 1

The regulations 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." (§69501.1(a)(15)) This definition directly ties into the definition of "assembler" in 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 newly added 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 as a component to create a new product. The definition of "assemble" has been revised to include repair and maintenance activities. This amended definition of "assemble" now results in the term "assembler" including 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." (This is because the definition of "manufacture" excludes acts that meet the definition of "assemble," §69501.1(a)(43).) 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 and/or maintenance activities using a Priority Product as a component.

Retailers and assemblers may not be involved in developing products; so, 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 conducting the AA and submitting the AA Reports. DTSC expects that ordinarily 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.

Article 2

The term used to describe the initial list of chemicals to be considered when prioritizing product-chemical combinations, formerly called "Chemicals of Concern," is now "Candidate Chemicals." Only those Candidate Chemicals that are the basis for a product-chemical combination being listed as a Priority Product will be designated "Chemicals of Concern" for that product. This change in terminology from "Chemicals of Concern" to "Candidate Chemicals" is in response to commenters expressing concern that identifying a large list of chemicals as "Chemicals of Concern" would result in a de facto "black list" of chemicals, and could affect market behavior even absent identification as a Priority Product.

Article 3

- DTSC has revised the process for establishing the Priority Products list. The revisions in section 69503.5(a)(2) require that the Priority Products list that is established be adopted as a rulemaking under the Administrative Procedure Act (APA) process. As such, DTSC will prepare an Economic and Fiscal Impact Analysis, as required with each rulemaking and address economic impacts on the affected industry(ies). Inclusion of those factors in these proposed regulations is not necessary. This is because all of the myriad APA requirements will apply to DTSC's rulemaking to adopt a Priority Products list; and, thus, DTSC need not repeat some or all of those requirements in these regulations in order for them to apply. Further, the regulations clearly state that DTSC will hold one or more public workshops to provide an opportunity for comments on product-chemical combinations prior to issuing a proposed Priority Products list, with the exception of the initial Priority Products list.

- The standards in the regulations for establishing the AA Threshold (section 69503.5) were narrative and thus, were not predictable or specific enough to assure the regulated community. DTSC understands that the latitude given to DTSC in setting such levels would increase the uncertainty for businesses and

that developing specific AA Thresholds for Priority Products will be challenging and resource-intensive.

In response to comments regarding the difficulty of setting a case-by-case AA Threshold and the appropriateness of the factors listed to establish a concentration level that will be protective of public health and the environment, DTSC has revised the regulations. DTSC has eliminated the provision to make a case-by-case AA Threshold determination for every Priority Product. In the proposed regulations, the AA Threshold is the Practical Quantitation Limit (PQL) for any Chemical(s) of Concern that is/are present solely as contaminants in a Priority Product. If during the product prioritization process, DTSC determines that an AA Threshold is needed for a particular intentionally added chemical in a particular product, this can be addressed in the rulemaking for that Priority Product listing. DTSC has reserved the ability to establish specific AA Thresholds on a case-by-case basis for intentionally added chemicals and for setting the AA Threshold for contaminants greater than the PQL in a separate rulemaking from this rulemaking. That is, should DTSC decide to take either of the above actions, it will do so during the APA process for establishing or revising the Priority Products list.

The PQL as the AA Threshold for contaminant chemicals will be practical and implementable. This will provide the certainty that the regulated community needs to ensure compliance and the success of these regulations. This default AA Threshold will not require responsible entities to hire toxicologists to justify product-specific thresholds that are no longer part of determining the AA Threshold. Once the PQL is known for a product-chemical combination, this will allow for better communication throughout the supply chain.

Article 4

DTSC has expanded the petition process to allow any person to petition DTSC to remove, as well as add, chemicals or lists of chemicals from the Candidate Chemicals list.

Article 5

- The authorizing legislation directed DTSC to establish a process for evaluating chemicals that includes an evaluation of the availability of potential alternatives and potential hazards caused by those alternatives, as well as an evaluation of critical exposure pathways. The statute also included the life cycle assessment criteria that must be included in the regulations. (Health and Safety Code section 25253((a)(2)(A) – (M).) These criteria are included in Article 5. While the statute allowed DTSC to add additional criteria to this list, DTSC found that these criteria were sufficient and no additional factors were added. Additionally, based on

comments received, DTSC added language allowing a responsible entity to streamline their AA by reviewing the "(A) to (M)" factors to determine which factors, exposure pathways, and life cycle segments are relevant to the comparison of the Priority Product and its alternatives; thereby reducing the number of factors, exposure pathways, and life cycle segments for which the Priority Product and each alternative must be evaluated.

- The proposed regulations provide ample opportunities for responsible entities to condense and/or minimize the amount of work that must be undertaken to conduct an AA, all while meeting the criteria and intent of the authorizing legislation. Under the regulations, a responsible entity is allowed to submit a Chemical/Product Removal/Replacement Notification if it meets the specified requirements. In response to public comments, the instances under which such a Notification may be submitted have been expanded. 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 off the California market.

  The provision allows reformulations, redesigns, or replacements to occur without DTSC oversight when the reformulated product does not contain any Chemical(s) of Concern. A responsible entity, without conducting an AA, may substitute a Chemical of Concern with a replacement chemical that is not on the Candidate Chemicals list, or a Candidate Chemical that is already in use to manufacture the same product.

  If a responsible entity does not meet the requirements for submitting a Removal/ Replacement Notification, as discussed above, it is then afforded other options to choose from to satisfy the requirements of Article 5. A responsible entity may choose to conduct:

  1) A conventional AA - that is first and second stage AAs followed by the corresponding Preliminary and Final AA Reports;
  2) An Abridged AA;
  3) An Alternate Process AA; or
  4) Submit a report for a previously completed AA to comply with the requirements of Article 5.

  The Removal/Replacement Notifications, coupled with the four options for complying with Article 5, provide maximum flexibility and ample pathways for responsible entities. In addition, should a responsible entity choose to retain the Priority Product after conducting the AA, it may do so. However, regulatory responses may be required to mitigate any adverse impacts.

In addition, the responsible entity may screen potential new ingredients for severe hazard "show stoppers" as a preliminary step to narrow the field of potential alternative replacement chemicals to those that show promise for further assessment.

Article 6

The authorizing legislation provided a non-exhaustive list of regulatory responses available to the Department following the completion of the AA process. (Health and Safety Code section 25253(b).) DTSC has not added any responses beyond what was created by this legislation. Additionally, in response to comments, DTSC has eliminated or revised prior provisions giving DTSC an essentially unlimited scope of regulatory responses and unlimited time for revising regulatory responses. The proision allowing DTSC to require a revised AA Report as a regulatory response has also been eliminated.

Article 7

The dispute resolution process allows responsible entities to dispute decisions made by DTSC and receive prompt review of such disputes.

Article 8

- DTSC eliminated the certified assessor program, now allowing responsible entities to conduct Alternatives Analysis that require no third-party verification before DTSC's review. The added costs to both industry and DTSC, coupled with the potential that the provisions could have the unintended consequence of redirecting efforts and thus delaying the assessment of products without ensuring quality AAs, led DTSC to consider adopting the regulations without the accreditation and certification program. Although adopting these regulations without a certification process could potentially increase the amount of time required for DTSC's review of the work that is submitted, DTSC nonetheless believes that the preferred course at this time is to delete the provisions.

  Responsible entities may conduct and prepare an in-house AA and the associated reports without becoming or necessitating the use of a certified assessor. Public review of Final AA Reports and Abridged AA Reports has been included in the proposed regulations to make use of stakeholder input to improve AA content.

- Article 8 now includes the audit provisions, which clarify the authority for DTSC to examine the adequacy of information submitted to DTSC under the regulations.

Article 9

The trade secret provisions have been revised in response to stakeholder concerns about shielding chemical identity from public disclosure. DTSC has substantially revised the contours of the limited exception from chemical identity disclosure with respect to hazard trait submissions. The new exception, contained in section 69509(g), permits time-limited masking of precise chemical identity where a patent for the subject chemical is pending. In so doing, DTSC has recognized the need to incentivize manufacturers to invest in safer product chemistries by protecting their intellectual property in the time while a patent application is pending, whether or not any new chemical will be immediately contained in an alternative to a Priority Product that is brought to market in California. At the same time, DTSC has recognized the public interest in knowledge of the specific chemistries of products that may in future result in exposures to Californians and their environment, and therefore believes that chemical-identity protection should be limited to the time necessary to secure patent protection.

Considered and Rejected Alternatives:

1. *Do Nothing.* DTSC rejected this option because Health and Safety Code sections 25252 and 25253 require that DTSC adopt regulations to address chemicals of concern in consumer products. To do nothing would place Californians in jeopardy of continued exposure to chemicals of concern in consumer products when the average U.S. consumer already comes into contact with 100 chemicals per day.

   To do nothing would also reject the California Legislature's direction to develop a broader, more comprehensive approach to chemicals policy for the State of California following the Green Chemistry Initiative's policy recommendation:

   > "Accelerate the Quest for Safer Products, creating a systematic, science-based process to evaluate Chemicals of Concern and identify safer alternatives to ensure product safety."

   Therefore, DTSC has rejected this option.

2. *Product and Chemical Hazard Categories Prioritization Process to Develop Safer Consumer Products.* While this alternative (described below) has many conceptual merits that appear in the chosen alternative, DTSC has determined that this alternative, in its original form, is not viable.

   To further develop this particular alternative, many meetings with stakeholders were held and DTSC evaluated numerous written comments that were received in response to this alternative. This process was a continuous process between DTSC and stakeholders that, in the end, transformed this alternative into the chosen alternative.

This alternative would require DTSC to identify product categories and chemical hazard categories. If a manufacturer produces a consumer product in a listed product category, the manufacturer would be required to evaluate the chemicals in the consumer product according to the chemical hazard categories and prioritize the chemicals according to a scheme to be set out in regulations. Based on the chemical priority, the manufacturer would be required to make the chemical hazard characterization data available to its supply chain and/or conduct an alternatives analysis to develop a safer consumer product. A wide range of stakeholders objected to this approach because of its lack of specific DTSC oversight of various parts of the proposed process. Additionally, this approach arguably did not fully comport with the requirements of the authorizing statutes.

Basic concepts from this original approach that remain in the chosen alternative include:

- a chemical and product prioritization process that factors in the same public health and environmental considerations, albeit a different prioritization pathway;
- manufacturer responsibility to develop safer consumer products and the requirements that must be addressed in the Alternatives Analysis; and
- DTSC specified regulatory responses.

Some of the significant changes include:

- an open and transparent process that includes a public comment period prior to finalizing the lists of chemicals and products that must undergo an Alternatives Analysis to examine ways to develop a safer consumer product;
- requiring DTSC to post on its website implementation progress by making information available that is not considered trade secret as it is received or developed; and
- creating a petition process to allow interested parties to request inclusion or removal of a chemical or product as part of the prioritization process.

The concerns expressed by a wide range of stakeholders about the lack of specific DTSC oversight have been addressed. Because much of this alternative no longer resembles the chosen alternative, DTSC considers this a separate alternative that is rejected.

3. *Other Options Considered in Earlier Proposed Drafts of the Regulations*. In addition to the 2010 and earlier proposed regulations, DTSC has undergone multiple revisions to the current regulations. This considered alternative represents an umbrella term that captures numerous prior iterations and variations of these regulations. DTSC has been extremely solicitous in seeking input to shape these

regulations. For example, DTSC convened numerous meetings of the statutorily established Green Ribbon Science Panel (GRSP) to seek the GRSP's advice and recommendations about how to craft these regulations. The GRSP met several times over the course of 2009-2011. In addition, DTSC convened various subcommittees of the GRSP. Here too, the subcommittees met in open session numerous times to provide DTSC advice and recommendations about how to draft these regulations. In addition, DTSC convened various public workshops and held dozens of meeting with interested parties. All of this was done to consider these regulations and alternatives to them.

4. *Performance Standards.* Although the conditions specified in Government Code sections 11340.1(a) and 11346.2(b)(5) do not apply to these regulations (as explained below*), DTSC did consider whether performance standards would be viable for any portion of the regulations. DTSC concluded that performance standards per se would not fulfill the mandates of Health and Safety Code sections 25252 and 25253 to adopt regulations to establish processes for identifying and prioritizing chemicals of concern in consumer products and conducting alternatives analyses to identify safer products and to specify a range of regulatory responses. However, as is discussed above, in Article 5 of the regulations, DTSC has chosen to provide responsible entities with a broad range of options (as opposed to a single approach that must be used by all responsible entities) for complying with Article 5 and the intent of the authorizing legislation. In addition, there is no specified outcome or benchmark that any of the options under Article 5 must attain. Likewise, the regulatory responses listed in Article 6 prescribe specific actions DTSC may impose, but responsible entities will have latitude in determining exactly how to achieve actions for their particular product.
    * The regulations do not mandate the use of any specific technologies or equipment – rather, responsible entities will choose the technologies and/or equipment they wish to use in, for example, conducting alternatives analyses and performing laboratory analyses. The regulations do impose some specific actions and procedures on DTSC (e.g., the chemical and product identification and prioritization processes in Articles 2 and 3). However, with the exception of the provisions in Articles 5 and 6, procedures in the regulations applicable to responsible entities and other interested parties are not "mandates" per se as these procedures only come into play if the person *chooses* to initiate a course of action (e.g., file a petition under Article 4 or a dispute under Article 7). Article 5 (alternatives analyses) and Article 6 (regulatory responses) are the only portions of the regulations that will *require* responsible entities to take action when they have a product that is listed as a Priority Product under a future rulemaking process. However, as explained above both these articles give responsible entities broad latitude in choosing

the specific actions, procedures, technologies, and equipment they wish to employ to satisfy the requirements of Articles 5 and 6.

VI. EVIDENCE SUPPORTING A DETERMINATION THAT THE REGULATIONS WILL HAVE NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

DTSC has significantly revised the proposed regulations since they were first submitted for public review and comment in July 2012. The originally proposed regulations covered the entire Safer Consumer Products program from identifying chemicals and prioritizing product-chemical combinations to listing Priority Products. In the preliminary Economic and Fiscal Impact Statement (Std. 399) and its attachments, DTSC concluded that the regulations may have a significant statewide impact to businesses but was unable to provide dollar values for the estimated impacts to the private sector, as too many key factors were unknowable pending the actual listing of Priority Products.

However, as currently proposed for adoption, the regulations establish a process for identifying chemicals and prioritizing product-chemical combinations and a process by which chemicals of concern in products and their potential alternatives are evaluated to determine how best to limit exposure to or reduce the level of hazard posed by a chemical of concern. The proposed regulations do not require the private sector to take any actions specific to any chemicals or products and these process regulations do not have any physical impacts to public health or the environment. Under the proposed regulations, the only impacts to the private sector are that DTSC may request businesses to provide existing information or generate new information necessary to implement the regulations. Thus, DTSC has concluded that the regulations will have no significant adverse impact on businesses.

NOTE: These regulations, as currently proposed for adoption, now require DTSC to use the Administrative Procedure Act rulemaking process for the listing of Priority Products. It is anticipated that these future rulemakings may have a significant adverse impact on some businesses. While any such impacts cannot be predicted or quantified at this time (and are not applicable to this current rulemaking), these impacts will be identified and, to the extent possible, quantified as part of these future rulemaking proceedings through preparation of Economic and Fiscal Impact Statements (Std. 399).

VII. DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

The proposed regulations by DTSC do not duplicate or conflict with existing federal law. The principal federal law that is mentioned in relation to this program is the Toxic Substances Control Act of 1976 (“TSCA,” Title 15, United States Code, section 2601 et seq.) But the focus and scope of these two regulatory regimes are actually quite

distinct. That is, the federal TSCA program is aimed at *chemicals* management. This Safer Consumer Products program is aimed at *product* safety from the standpoint of public health and the environment. More specifically, these regulations address harmful chemicals in products. TSCA, on the other hand, does not concern itself with product safety. Thus, there is no duplication or conflict in the scope or workings of these two different regulatory schemes. If anything, they may be viewed as complementary.

In addition, the Green Chemistry Initiative was developed, to a certain extent, to address structural weaknesses in TSCA. TSCA places the cost of obtaining data about chemical safety on the United States Environmental Protection Agency (U.S. EPA) rather than requiring chemical companies to develop and submit such information. Consequently, information about the 80,000 chemicals in U.S. commerce is severely limited and there is little to no information on the public health or environmental effects of many of these chemicals.

In 1998, U.S. EPA launched the voluntary High Production Volume (HPV) Challenge Program. The goal of the program was to collect health and environmental effects data to provide the public with basic hazard information, thus allowing the public to actively participate in environmental decision-making. HPV chemicals are classified as those chemicals produced or imported in the United States in quantities of one million pounds or more per year. The HPV program has had varying levels of success – while some information has been collected on approximately 2,500 chemicals, information on the overwhelming majority of chemicals used at lesser quantities than one million pounds per year is still unknown.

California's Green Chemistry legislation and accompanying regulations are among the first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals *in consumer products* and are viewed as a potential national model for chemical reform. The regulations would compel chemical manufacturers to provide sufficient information for businesses, consumers, and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products.

VIII. DETAILED STATEMENT OF REASONS: SUMMARY AND RATIONALE

The following nonsubstantive changes were made to the regulations after the 15-day public comment period for the revised proposed regulations text that closed on April 25, 2013:

- The title for section 69502.2(b) has been revised from "Additions to the Candidate Chemicals List" to "Revisions to the Candidate Chemicals List". This revision was made for consistency with the title of a closely related section, 69502.3(b). This revision has no impact on the regulatory text itself or its effect.

- In section 69502.2(b)(1)(A)6., the term “Candidate Chemical(s)” has been changed to “chemical(s)”. Similarly, in section 69502.2(b)(1)((A)7., “Candidate Chemical or a chemical” has been changed to “chemical”. Section 69502.2(b)(1)(A) lists factors that DTSC may use to evaluate the potential for a chemical to contribute to or cause adverse impacts for purposes of determining whether or not to propose listing the chemical as a Candidate Chemical. Since this evaluation takes place *before* a chemical is listed as a Candidate Chemical (and the chemical being evaluated may ultimately not be listed as a Candidate Chemical), the use of the term “Candidate Chemical” in these two sections was illogical.

- In section 69505(b), “person or entity” has been changed to “person”. This change was made for clarity since “entity” is captured under the definition for “person”.

- In section 69505.2(b)(9)(F)2., “responsible entity” has been changed to “manufacturer” for clarity. In the context of this sentence, this term is being used to refer to the person that manufactures a product. Of the four categories of responsible entities (manufacturers, importers, assemblers, and retailers), by definition, only a manufacturer could manufacture a product. Therefore, the use of the more broadly defined term, responsible entity, in this provision did not make sense, and was confusing.

- Section 69505.5(b)(2) has been corrected to provide that alternatives being considered that do not involve the use of replacement chemicals or otherwise adding chemicals to the product do not require compliance with *subsection (d)* (rather than subsection (c)). Subsection (d) (which was subsection (c) in a prior iteration of the proposed regulations) requires responsible entities to compare alternative replacement chemicals with the Chemicals of Concern in the Priority Product. In the April 2013 revisions to the proposed regulations, former subsection (c) was renumbered as (d) (as a result of adding a new subsection (c) to section 69505.5); however, the cross-reference in section 69505.5(b)(2) was inadvertently overlooked, and, thus, was not corrected (in the April 2013 revisions) to conform with this renumbering. Given the context of subsection (d), as described above, it would be illogical not to correct this cross-reference.

- Former section 69505.9(a)(4) has been stricken for the regulations. Section 69505.4(a) specifies the factors for DTSC to consider when reviewing Alternatives Analysis Reports for compliance with the requirements of Article 5 of the regulations. The stricken text read – “Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA Report were

determined using reliable information." Section 69505.9(a)(3) reads – "Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable." Although there is a very minor difference in the wording of these two provisions, there is no difference in the meaning and effect of the provisions. Therefore, section 69505.9(a)(4) has been deleted to avoid unnecessary and confusing duplication.

- Section 69506.1(d) has been revised to strike "The proposed regulatory response determination notice shall include the Department's rationale for the proposed regulatory response(s)." This provision is unnecessary, and potentially confusing, as it is duplicative of section 69505.9(f)(2) in meaning and effect. Specifically, section 69505.9(f)(2) requires that all proposed and final regulatory response determination notices include the "rationale, information, and information sources supporting the Department's determination(s)."

- Sections 69506.5(a), (b)(1), (c), and (c)(1) have all been revised to clarify that that the reference in these sections to a "notice" means a "regulatory response determination notice" issued by DTSC under section 69506.1. The revised text is consistent with, and does not impact, the meaning and effect of these sections. (As noted below, some of these sections have additional clarifying grammatical and sentence structure changes that are also non-substantive in nature.)

- The title for section 69508 has been revised from "Audit of Materials Submitted to the Department and Regulatory Responses" to "Audits of Program Compliance". The revised title more accurately describes the content of section 69508. However, this revision has no impact on the regulatory text itself or its effect. This change is reflected in the Table of Contents for the regulations.

- Minor grammatical, sentence structure, section numbering, cross-reference corrections, and other non-substantive corrections and clarifications have been made to the following sections of the regulations, without impact to the effect of the regulations: 69501, 69501.1(a)(1)(58)(E)6., 69501.2(c)(4)(C), 69501.3(c), 69501.4(d)(1), 69503.2(b)(1)(C), 69503.6, 69504.1(c), 69505(a), 69505.1(d) and (e), 69505.2(b)(9)(F)1., 69505.4(a)(2) and (3), 69505.4(b)(3) and (4), 69505.4(f), 69505.6(a)(2) and (3), 69505.7(k)(1)(A), 69506(c)(1)(A) and (2)(A), 69506.5(a), 69506.5(b)(1) and (3), 69506.5(d)(1), 69506.7(c)(2)(H)2., 69506.9(f), 69507(d), 69509(a)(3), and 69509.1(b)(2).

CHAPTER 55. SAFER CONSUMER PRODUCTS

Chapter 55 and all of its articles and sections (specifically, articles 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and 11, and sections 69501, 69501.1, 69501.2, 69501.3, 69501.4, 69501.5,

69502, 69502.1, 69502.2, 69502.3, 69503, 69503.1, 69503.2, 69503.3, 69503.4, 69503.5, 69503.6, 69503.7, 69504, 69504.1, 69505, 69505.1, 69505.2, 69505.3, 69505.4, 69505.5, 69505.6, 69505.7, 69505.8, 69505.9, 69506, 69506.1, 69506.2, 69506.3, 69506.4, 69506.5, 69506.6, 69506.7, 69506.8, 69506.9, 69506.10, 69507, 69507.1, 69507.2, 69507.3, 69507.4, 69507.5, 69507.6, 69508, 69509, 69509.1, 69510, and 69511 through 69599) are added to division 4.5 of the California Code of Regulations, title 22. Chapter 55, in its entirety, is necessary to fulfill the mandates of Health and Safety Code sections 25252 and 25253. Furthermore, these regulations are necessary to implement, interpret, and make more specific the provisions of Health and Safety Code sections 25251, 25252, 25253, 25257, and 25257.1. Specific descriptions of, and statements of necessity for, each provision of these new regulations is set forth below in the remainder of the Detailed Statement of Reasons: Summary and Rationale.

ARTICLE 1. General

§ 69501. Purpose and Applicability

Section 69501, in its entirety, describes the scope and purpose of these regulations (Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations). This section also establishes the applicability of the regulations by specifying which products are and are not subject to its requirements. Each of the provisions within section 69501 is, therefore, necessary to establish which parties and products are subject to the regulations.

These regulations, in their entirety, implement and make specific Health and Safety Code sections 25252 and 25253, which mandate that the Department of Toxic Substances Control (DTSC) adopt regulations to do the following:

- Establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern. This process must include, but is not limited to, consideration of all of the following:
    - The volume of the chemical in commerce in California;
    - The potential for exposure to the chemical in a consumer product; and
    - Potential effects on sensitive subpopulations.
- Establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.
- Establish a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. This process must include life cycle assessment tools that take into consideration all of the following:
    - Product function or performance;
    - Useful life;
    - Materials and resource consumption;
    - Water conservation;
    - Water quality impacts;
    - Air emissions;
    - Production, in-use, and transportation energy inputs;
    - Energy efficiency;
    - Greenhouse gas emissions;
    - Waste and end-of-life disposal;

    - Public health impacts, including potential impacts to sensitive subpopulations, including infants and children;
    - Environmental impacts; and
    - Economic impacts.
- Specify the range of regulatory responses that DTSC may take following the completion of an alternatives analysis, including, but not limited to, any of the following:
    - Not requiring any action;
    - Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives;
    - Imposing requirements on consumer product information;
    - Imposing a restriction on the use of the chemical of concern in the consumer product;
    - Prohibiting the use of the chemical of concern in the consumer product;
    - Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product;
    - Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product;
    - Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists; and
    - Any other outcome DTSC determines accomplishes the requirements of the statute.

Section 69501(a) specifies the purpose of the Safer Consumer Products regulations dictated by the authorizing legislation (described above) as an introduction to the regulations by restating the statutory mandates using terminology defined in the regulations. This introduction makes clear that the regulations fulfill the statutory mandate to "establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern" by establishing a process for identifying and prioritizing "Priority Products" and their "Chemicals of Concern" (not just a process for identifying and prioritizing chemicals). This approach was taken for consistency with the statutory mandate that the identification and prioritization process consider both hazards posed by the chemical and the potential for exposure to the chemical in a product. Prioritization of chemicals – without consideration of the product that contains the chemical – can largely only consider the hazards associated the chemical. Evaluation of potential exposures requires the evaluation to focus on a product-chemical combination since the exposure potential will differ from one product to another for a variety of reasons. This provision also specifies that regulatory responses may be imposed by operation of Article 6 or required by DTSC following completion of an Alternatives Analysis under Article 5. This

provision is necessary in order for interested parties to understand the purpose and scope of the regulations.

Section 69501(b)(1) specifies that the regulations apply to all consumer products placed into the stream of commerce in California, except as otherwise provided in sections 69501(b)(2) and (3) which are described below.

The applicability of these regulations to all consumer products "placed into the stream of commerce in California" (as this term is defined in the regulations) takes into account current and anticipated methods of selling or offering for sale consumer products – through mail order catalogs and Internet sales as well as traditional "brick and mortar" entities. In addition, the term includes products that are offered as promotional items with a purchase and manufacturer "giveaways." DTSC has determined that the scope of the consumer products subject to the regulations is consistent with and is required by the reach of the statute – both as to what is included and what is excluded – and that exempting any consumer products other than those exempted by the statute would not be in line with the intent, purpose, or requirements of the authorizing legislation.

Health and Safety Code section 25251(e) defines "consumer product" very broadly as a "product or part of the product that is used, brought *(sic)*, or leased for use by a person for any purposes", but provides a list of specific exemptions discussed below under section 69501(b)(2). Any additional exemptions beyond those set out in statute would impermissibly shrink the scope of consumer products that are subject to the regulations. This provision is necessary to conform to the statute, and establish a fair and appropriate scope of products that are subject to these regulations. More specifically, it is necessary for DTSC to be able to address consumer products containing harmful chemicals regardless of the method by which they are made available for purchase in California.

Section 69501(b)(2) exempts from the regulations any product that is statutorily exempted from the definition of "consumer product." The statutory definition of "consumer product" and the exemptions from this definition are set out in Health and Safety Code section 25251(e). Exemptions to the requirements of these regulations are necessary in order for the scope of the regulations to be consistent with the authorizing legislation.

Health and Safety Code section 25251(e) specifies that the term "consumer product" does not include:

(1) A dangerous drug or device as defined in section 4022 of the Business and Professions Code[1];
(2) Dental restorative materials[2] as defined in section 1648.20(b) of the Business and Professions Code;
(3) A device[3] as defined in section 4023 of the Business and Professions Code;
(4) A food[4] as defined in section 109935(a) of the Health and Safety Code;
(5) The packaging associated with any of the items specified in paragraph (1), (2), or (3) above; or
(6) A pesticide[5] as defined in section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. Sec. 136 and following).

Section 69501(b)(3)(A) exempts consumer products that are regulated by other specified regulatory programs if certain conditions apply. Specifically, this section provides that the regulations do not apply to a product that DTSC determines is regulated by other regulatory programs, if those other programs individually or in combination meet both of the requirements described below under sections 69501(b)(3)(A)1. and 2. For purposes of this exemption, other regulatory programs include other California State regulatory programs and other federal regulatory programs, including those that stem from applicable treaties or international agreements with the force of domestic law This exemption, in effect, means that a product meeting the criteria for exemption would not be subject to being listed as a Priority Product or be subject to the consequent requirements pertaining to alternatives analysis and regulatory responses.

---

[1] A drug or device that by federal or state law can be lawfully dispensed only on prescription. (http://www.leginfo.ca.gov/calaw.html)

[2] "Dental restorative materials" means any structure or device placed into a patient's mouth with the intent that it remain there for an indefinite period beyond the completion of the dental procedure, including material used for filling cavities in, or rebuilding or repairing the organic structure of, a tooth or teeth, but excluding synthesized structures or devices intended to wholly replace an extracted tooth or teeth, such as implants. (http://www.leginfo.ca.gov/calaw.html)

[3] "Device" means any instrument, apparatus, machine, implant, in vitro reagent, or contrivance, including its components, parts, products, or the byproducts of a device, and accessories that are used or intended for either of the following: (a) Use in the diagnosis, cure, mitigation, treatment, or prevention of disease in a human or any other animal. (b) To affect the structure or any function of the body of a human or any other animal. For purposes of this chapter, "device" does not include contact lenses, or any prosthetic or orthopedic device that does not require a prescription. (http://www.leginfo.ca.gov/calaw.html)

[4] "Food" means either of the following:(a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal. (b) Any article used or intended for use as a component of any article designated in subdivision (a). (http://www.leginfo.ca.gov/calaw.html)

[5] . "Pesticide" includes any of the following: (a) Any spray adjuvant. (b) Any substance, or mixture of substances which is intended to be used for defoliating plants, regulating plant growth, or for preventing, destroying, repelling, or mitigating any pest, as defined in Section 12754.5, which may infest or be detrimental to vegetation, man, animals, or households, or be present in any **agricultural** or nonagricultural environment whatsoever. (http://www.leginfo.ca.gov/calaw.html)

This exemption will ensure that DTSC maximizes the effective use of its resources by focusing on those public health and environmental concerns that are not already being adequately addressed by another federal or California State regulatory program. In addition, this provision is necessary to implement Health and Safety Code section 25257.1(c); and to ensure that the scope of the regulations is consistent with the limitations set forth in this authorizing statute, which reads: "The department [DTSC] shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this Article [Article 14 of Chapter 6.5 of Division 20 of the Health and Safety Code]". The purposes of Article 14, which must be used to evaluate if another regulatory program is covered by this statutory exemption, are articulated as follows:

- Article 14, in its totality, establishes an identification, prioritization, and alternatives analysis process for chemicals in products based on the hazards and potential exposures posed throughout the entire life cycle of the product. The full life cycle of the product, and the chemical hazards and potential for exposure to the chemicals in the product, are established by the statute and these regulations as the basis for comparing the current product to possible alternatives.
- Health and Safety Code section 25253(a)(1) provides that the purpose of the alternatives analysis process that is required to be established by these regulations is "to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern."
- Health and Safety Code section 25255(a) state that the goal of Article 14 of the statute is "significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the state's society, be encouraging the redesign of consumer products, manufacturing processes, and approaches."

NOTE: Though the prohibition in Health and Safety Code section 25257.1(c) is against regulating "product categories" that are already regulated, there are no specific product categories that will be regulated under these regulations. Rather, these regulations are "process regulations." In order to create a process that achieves the goals of the authorizing legislation, DTSC has determined that the regulations must assess product-chemical combinations, rather than broad product categories. That is, consistent with the mandates in the authorizing legislation, the regulations establish a process for the identification and prioritization of chemicals and products containing them that must be analyzed to determine if they can be made in a manner that reduces the risks they posed. As a result, the exemption in section 69501(b)(3) addresses "consumer product[s]" that are already regulated, rather than product categories.

The regulation limits the other regulatory programs that may be evaluated by DTSC to determine if they are covered by this exemption to federal and other California State regulatory regimes. This is necessary because regulatory authority over a consumer product by a foreign country, another state, or a local agency would not qualify for the statutory exemption, since in these situations there is no jurisdictional or consistent authority either in or throughout California with respect to which these regulations or their implementation might create a duplication or conflict.

The conditions limiting this exemption (as discussed below under section 69501(b)(3)(A)1. and 2.) are necessary to implement and ensure consistency with the statutory language that limits the other regulatory provisions that may qualify for the exemption to those that regulate products in a manner consistent with the purposes of the statute, as described above.

To effectuate this exemption, section 69501(b)(3)(A) requires an evaluation and determination by DTSC as to whether or not a product qualifies for the exemption based on the other programs under which the product is regulated. This is necessary to ensure that any product exempted from the regulations, and, thus, from the intent and requirements of the authorizing legislation, truly meets the qualifying conditions. Typically, DTSC's determination would occur at the point when DTSC is evaluating a product for possible listing as a Priority Product. If DTSC determines the conditions for the exemption are met, the product would not be further considered for listing as a Priority Product, and thus not subject to any of the consequent requirements of the regulations. If the other programs under which a product is regulated only partially meet the conditions for the exemption, the product would not be exempt; however, the degree to which these conditions are met would be considered in the product prioritization process. (See the statement of reasons for section 69503.2(b)(2) for additional discussion concerning this situation.)

Sections 69501(b)(3)(A)1. and 2. specify that for a consumer product to qualify for an exemption under section 69501(b)(3)(A), the other regulatory programs to which the project is subject must individually or in combination meet both of the following requirements:

1. The other program(s) must address the same potential adverse impacts, potential exposure pathways, and potential adverse waste and end-of-life effects that would otherwise be the basis for the product being listed as a Priority Product; and
2. The other program(s) must provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product were listed as a Priority Product.

Since an exemption under section 69501(b)(3)(A) means that there will be no alternatives analysis or regulatory responses to evaluate and if needed address any adverse impacts associated with the exempted product, it is necessary to ensure that these other regulatory requirements address the same potential adverse impacts, potential exposure pathways, and potential adverse waste and end of life effects that would be evaluated and addressed if the product was listed as a Priority Product. This is necessary to satisfy the statutory exemption criteria concerning consistency with the purposes of the statute (as described above).

This provision is also necessary to inform responsible entities of the bases for DTSC determining whether a consumer product qualifies for an exemption.

Section 69501(b)(3)(B) allows DTSC to re-evaluate a previous exemption determination made under section 69501(b)(3)(A), and to rescind that determination if DTSC finds that the underlying facts or assumptions were not, or are no longer, valid. This provision is necessary because the enabling statute (Health and Safety Code section 25257.1(c)) allows the exemption to apply to products already regulated or subject to “pending regulation” under another regulatory program. If pending regulations or statutes are not adopted or are revised prior to adoption, this provision would require the exemption determination to be re-evaluated and potentially rescinded. This provision is also necessary in case: (i) the other regulations that were in existence at the time of, and formed the basis for, the exemption determination are later revised and no longer meet the conditions for the exemption; or (ii) DTSC discovers the information on which the exemption determination was based was inaccurate. Without this provision, there would be the potential for a product to be exempted from these regulations without meeting the statutory requirements that provide the mandate and authorization for the exemption. This would also prevent DTC from using the processes set forth in these regulations to address any adverse impacts associated with the product that are no longer addressed by the other regulatory programs.

Section 69501(c) specifies that nothing in these regulations authorize DTSC to supersede other federal or State regulatory programs. This provision is necessary for consistency with the purposes of Health and Safety Code section 25257.1(b) which reads, “This article [14] does not authorize the department [DTSC] to supersede the regulatory authority of any other department or agency.” Even though the statute arguably only restricted DTSC from superseding other California regulatory authorities, DTSC believes that it is prudent to also acknowledge that under a broader body of law, DTSC also cannot supersede federal law. This provision is necessary to implement

Health and Safety Code section 25257.1(b) and to eliminate any concern that DTSC will supersede any California State or federal regulatory programs.

§ 69501.1. Definitions

Section 69501.1(a) defines terms that are used throughout these regulations (Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations) in order to avoid confusion and future disputes over the applicability of terms. For many of these defined terms, additional relevant information can be found in the statement of reasons for the sections of the regulations in which each term is used.

Section 69501.1(a)(1) defines **"AA Reports"** to mean all of the various Alternatives Analysis (AA) reports required under Article 5 – Preliminary AA Reports, Final AA Reports, Abridged AA Reports, AA Reports submitted for previously completed AAs, and, as applicable, AA Report Addendums. This is necessary to inform responsible entities and other interested parties of the requirements that apply to these reports and to facilitate the discussion on all the reports that collectively are AA Reports. The regulations allow for various options to meet the AA requirements of Article 5, and the report required to be submitted to DTSC on each type of AA has a different name, such as the Preliminary AA Reports, Final AA Reports, Abridged AA Reports, AA Reports submitted for previously completed AAs, and the AA Report Addendum. Again, the defined term "AA Reports" encompasses all of these reports and is necessary to have consistent requirements later in the regulations (Article 5) that apply to all of them.

Section 69501.1(a)(2) defines **"adverse air quality impacts"** to mean the resultant impacts due to indoor or outdoor air emissions of any of the air contaminants listed below that have the potential to result in adverse public health, ecological, soil quality, or water quality impacts. Adverse impacts on air quality may indirectly contribute to or directly cause adverse impacts on public health and environmental and ecological systems. The definition of "adverse air quality impacts" ensures that DTSC and responsible entities, when evaluating adverse impacts under the requirements of these regulations, consider those adverse air quality impacts that are commonly recognized by the scientific community as being of concern.

This definition of adverse air quality impacts includes definitions found in:

- California Air Pollution Control laws and regulations (Toxic Air Contaminants);
- The federal Clean Air Act (nitrogen oxides, sulfur oxides, and particulate matter); and

- Article 4 of Chapter 54, air exposure potential hazard traits (chemical substances that exhibit the stratospheric ozone depletion potential hazard trait and tropospheric ozone-forming compounds).

The California Air Resources Board is authorized to regulate various categories of air emissions that pose potential adverse impacts to human health and the environment under both State and federal laws and regulations. In Chapter 54, the Office of Environmental Health Hazard Assessment (OEHHA) has identified the exposure potential hazard traits, such as ambient ozone formation, global warming potential, particle size or fiber dimension, and stratospheric ozone depletion potential, that DTSC is statutorily required to use to develop criteria for evaluating chemicals and their alternatives (Health and Safety Code sections 25256.1 and 25252). DTSC's definitions of these air quality impacts are aligned with the definitions in the OEHHA regulations. This is necessary to meet the statutory mandate in the sections cited above ant to allow for ease of use and common understanding of terms.

The term "adverse air quality impacts" also includes indoor air emissions that affect the air quality of homes, offices, transport vehicles, and public buildings. The many sources of indoor air pollution include:

- consumer products for household cleaning and maintenance, personal care, and hobbies;
- building materials and furnishings, such as carpeting and furniture made of certain pressed wood products or upholstery treated with flame retardants; and
- outdoor air pollution that enters indoor spaces.

Sections 69501.1(a)(2)(A) *Toxic Air Contaminants (TAC)* – TACs are defined as "an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health" (see Health and Safety Code section 39655). (For a list of TACs, see Title 17, California Code of Regulations, sections 93000-93001). Chemicals identified by the California Air Resources Board's Air Toxics Program are monitored and controlled as TACs**.** TACs that can be found indoors include formaldehyde, benzene, asbestos, and other chemicals.

Section 69501.1(a)(2)(B) *Greenhouse gases* – Gases that trap heat in the atmosphere are called greenhouse gases. These gaseous components of the atmosphere transmit the visible portion of solar radiation but absorb specific spectral bands of thermal radiation emitted by the Earth. The theory is that terrain absorbs radiation, heats up, and emits longer wavelength thermal radiation that is prevented from escaping into

space by the blanket of carbon dioxide and other greenhouse gases in the atmosphere. As a result, the climate warms.

“Greenhouse gases” are defined in section 38505 of the Health and Safety Code as including: carbon dioxide, hydrofluorocarbons, methane, nitrogen trifluoride, nitrous oxide, perfluorocarbons, and sulfur hexafluoride. These same seven chemicals are included in these regulations as chemicals that constitute “greenhouse gases.” These chemicals are grouped together because of their roles in global warming.

Many greenhouse gases occur naturally in the atmosphere, such as carbon dioxide, methane, and nitrous oxide, while others are synthetic. There are three main categories of man-made fluorinated gases -- hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride.

Fluorinated gases have no natural sources and human activities are responsible for the bulk of long-lived atmospheric halogen-containing gas concentrations. Before industrialization, there were only a few naturally occurring halogen-containing gases. The development of new techniques for chemical synthesis resulted in a proliferation of chemically manufactured halogen-containing gases. They are emitted through a variety of industrial processes such as aluminum and semiconductor manufacturing. Many fluorinated gases are very effective absorbers of infrared radiation and have very high global warming potentials relative to other greenhouse gases, so small atmospheric concentrations can have large effects on global temperatures. They can also have long atmospheric lifetimes -- in some cases, lasting thousands of years. Like other long-lived greenhouse gases, fluorinated gases are well-mixed in the atmosphere, spreading around the world after they are emitted. In general, fluorinated gases are the most potent and longest lasting type of greenhouse gases emitted by human activities. Fluorinated greenhouse gases also include chlorofluorocarbons and hydrochlorofluorocarbons, but these ozone-depleting substances are currently being phased out and otherwise regulated under the Montreal Protocol and Title VI of the Clean Air Act. See the statement of reasons for sections 69501.1(a)(2)(B)2., 69501.1(a)(2)(B)4., 69501.1(a)(2)(B)6., and 69501.1(a)(2)(B)7 for additional related information.

Sections 69501.1(a)(2)(B)1. through 8. identify the gases encompassed under the definition of “greenhouse gases”.

69501.1(a)(2)(B)1. *Carbon Dioxide (CO_2)* - The natural production and absorption of carbon dioxide is achieved through the terrestrial biosphere and the ocean. However, humankind has altered the natural carbon cycle by burning coal, oil, natural gas and

wood, and, since the industrial revolution began in the mid-1700s, each of these activities has increased in scale and distribution. Emissions of carbon dioxide from fossil fuel combustion, with contributions from cement manufacture, are responsible for more than seventy-five percent (75%) of the increase in atmospheric carbon dioxide concentrations since pre-industrial times. The remainder of the increase comes from land use changes dominated by deforestation (and associated biomass burning) with contributions from changing agricultural practices. All these increases are caused by human activity.

69501.1(a)(2)(B)2. *Hydrofluorocarbons (HFCs)* - Hydrofluorocarbons are used as refrigerants, aerosol propellants, solvents, and fire retardants. The major emissions source of these compounds is their use as refrigerants -- for example, in air conditioning systems in both vehicles and buildings. These chemicals were developed as a replacement for chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs) because they do not deplete the stratospheric ozone layer. CFCs and HCFCs are being phased out under an international agreement, called the Montreal Protocol. Unfortunately, HFCs are potent greenhouse gases with long atmospheric lifetimes and high global warming potentials, and they are released into the atmosphere through leaks, servicing, and disposal of equipment in which they are used.

69501.1(a)(2)(B)3. *Methane* - Methane sources to the atmosphere generated by human activities exceed methane sources from natural systems. Between 1960 and 1999, methane concentrations grew an average of at least six times faster than over any 40-year period of the two millennia before 1800. The human activities that produce methane include energy production from coal and natural gas, waste disposal in landfills, raising ruminant animals (e.g., cattle and sheep), rice agriculture, and biomass burning. The natural sources include wetlands, termites, oceans, vegetation, and methane hydrates. Once emitted, methane remains in the atmosphere for approximately 8.4 years before removal, mainly by chemical oxidation in the troposphere. Minor sinks for methane include uptake by soils and eventual destruction in the stratosphere.

69501.1(a)(2)(B)4. *Nitrogen trifluoride (NF_3)* - Nitrogen trifluoride is an inorganic nitrogen-fluorine compound that is used most frequently in the electronics industry during various processes including plasma etching, cleaning chambers in which silicon chips are made, and semi-conductor and LCD panel manufacture. Additionally, it has several important applications within the photovoltaic and chemical laser industries. Its 100-year global warming potential of 17,200 is second only to sulfur hexafluoride, meaning that it is highly effective at trapping atmospheric heat, and it has a lifetime of 740 years.

69501.1(a)(2)(B)5. *Nitrous oxide* - Nitrous oxide sources to the atmosphere from human activities are approximately equal to nitrous oxide sources from natural systems. Human activities that emit nitrous oxide include transformation of fertilizer nitrogen into nitrous oxide and its subsequent emission from agricultural soils, biomass burning, raising cattle, and some industrial activities, including nylon manufacture. Natural sources of nitrous oxide include oceans, chemical oxidation of ammonia in the atmosphere, and soils. Once emitted, nitrous oxide remains in the atmosphere for approximately 114 years before removal, mainly by destruction in the stratosphere.

69501.1(a)(2)(B)6. *Perfluorocarbons (PFCs)* - Perfluorocarbons are used in firefighting and to manufacture semiconductors and other electronics. Perfluorocarbons have sources predominantly in the Northern Hemisphere, atmospheric lifetimes longer than 1,000 years, and will contribute to global warming over the next several millennia.

69501.1(a)(2)(B)7. *Sulfur hexafluoride (SF_6)* - Perfluorocarbons are compounds produced as a by-product of various industrial processes associated with aluminum production and the manufacturing of semiconductors. Sulfur hexafluoride (SF_6) is used in a diverse array of applications, including electrical transmission and distribution equipment (as an electrical insulator and arc quencher), in magnesium casting operations (as a cover gas to prevent oxidation of molten metal), and as a tracer gas for leak detection.

69501.1(a)(2)(B)8. *Gases that exhibit the global warming potential hazard trait* – "Global warming potential" is defined in section 69405.4 as the propensity for a chemical substance to be a greenhouse gas, that is, to absorb infrared radiation in the atmosphere and, thereby, contribute to the general warming of the planet.

Section 69501.1(a)(2)(C) *Nitrogen oxides* are gases consisting of one molecule of nitrogen and varying numbers of oxygen molecules. Nitrogen oxides are produced in the emissions of vehicle exhausts and from power stations. In the atmosphere, nitrogen oxides can contribute to formation of photochemical ozone (smog), can impair visibility, and have health consequences; they are thus considered pollutants. Chemicals that cause air emissions that result in nitrogen oxides cause acid rain, which causes negative effects on the ecosystem and ozone, which contributes to the greenhouse gas effect.

Section 69501.1(a)(2)(D) *Particulate matter that exhibits the particle size or fiber dimension hazard trait* is defined as the existence of a chemical substance in the form of small particles or fibers or the propensity to form into such small-sized particles or

fibers with use or environmental release. The size dimension specified under section 69405.7 of the OEHHA regulations renders the particle respirable and capable of ending up in the lungs. Particulate matter may cause public health respiratory impacts and their small sizes may serve as building blocks to secondary organic aerosols, which may contribute to greenhouse gases.

Section 69501.1(a)(2)(E) *Chemical substances that exhibit the stratospheric ozone depletion potential hazard trait* contribute to the deterioration of the Earth's ozone layer. That layer serves to prevent harmful exposures to ultraviolet light (which penetrates the Earth's atmosphere in the absence of an adequate ozone layer). This results in a number of adverse public health, ecological, and other environmental impacts. DTSC has included the same definition of this term as used in section 69405.8 of the regulations adopted by OEHHA.

Section 69501.1(a)(2)(F) *Sulfur oxides* are compounds composed of one sulfur and two oxygen molecules. Sulfur dioxide emitted into the atmosphere through natural and anthropogenic processes is changed in a complex series of chemical reactions in the atmosphere to sulfate aerosols. Chemicals that cause air emissions that result in sulfur oxides cause acid rain, which causes negative effects on the ecosystem and ozone, which contributes to the greenhouse gas effect.

Section 69501.1(a)(2)(G) *Tropospheric ozone-forming compounds, including compounds that exhibit the ambient ozone formation hazard trait*. The ambient ozone formation hazard trait is defined as the capacity for chemical substances, such as volatile organic compounds, to react outdoors in the presence of ultraviolet light to generate ozone and other oxidants, or indoors in the presence of visible light to produce ozone. Evidence for the ambient ozone formation hazard trait includes, but is not limited to, measurements of reactivity of the chemical substance, such as the Maximal Reactivity Scale adopted by the California Air Resources Board pursuant to Health and Safety Code section 41712.

Tropospheric ozone is produced by photochemical reactions in the atmosphere involving forerunner chemicals such as carbon monoxide, methane, volatile organic compounds, and nitrogen oxides. These chemicals are emitted by natural biological processes and by human activities including land use changes and fuel combustion. Because tropospheric ozone is relatively short-lived, lasting for a few days to weeks in the atmosphere, its distributions are highly variable and tied to the abundance of its forerunner compounds, water vapor, and sunlight. Tropospheric ozone concentrations are significantly higher in urban air, downwind of urban areas, and in regions of biomass burning, and contribute to a number of adverse public health impacts, including

respiratory impairment, as well as other direct and indirect ecological and other environmental impacts.

The section 69501.1(a)(2) definition of “adverse air quality impacts” is necessary for DTSC to carry out the statutory mandate in Health and Safety Code section 25252(b)(2) that in adopting these regulations, DTSC “use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies….” It is also necessary for DTSC to implement the mandate in Health and Safety Code section 25252(b)(1), which requires the criteria for evaluating chemicals and their alternatives to include the “traits, characteristics, and endpoints that are included in the clearinghouse data pursuant to section 25256.1.” DTSC has included the hazard traits specified by OEHHA under its Chapter 54 regulations, which is the set of regulations implementing the mandate in Health and Safety Code section 25256.1. Finally, this definition is necessary to harmonize these regulations with existing definitions of the same and related terms.

Section 69501.1(a)(3) defines **“adverse ecological impacts”** to mean any of the direct or indirect effects on living organisms and/or their environments that are listed below under sections 69501.1(a)(3)((A) through (D). This definition is necessary to ensure that DTSC and a responsible entity conducting an AA consider those adverse ecological impacts that are commonly recognized by the scientific community as being of concern when evaluating chemicals and products. The proposed definition also makes use of, and is consistent with, related regulations in Chapter 54. The regulations adopted by OEHHA in Chapter 54 implement the mandate for OEHHA to adopt the hazard traits that go into the clearinghouse required by Health and Safety Code section 25256.1. Therefore, this definition is necessary for DTSC to implement the mandate in Health and Safety Code section 25252(b)(1), which requires the criteria for evaluating chemicals and their alternatives to include the “traits, characteristics, and endpoints that are included in the clearinghouse data pursuant to section 25256.1.” This, in turn, allows for ease of use and a common understanding of terms used. Thus, this definition is necessary to harmonize these regulations with existing definitions of the same and related terms.

Adverse ecological impacts are direct or indirect effects on living organisms and their environments. Adverse ecological impacts from environmental pollutants occur at all levels of biological organization, such as ecosystem, community, assemblage, population, species, or individual level of biological organization.

Sections 69501.1(a)(3)(A) through (D) identify the effects encompassed by the definition of "adverse ecological impacts."

Section 69501.1(a)(3)(A) *Adverse effects to aquatic, avian, or terrestrial animal or plant organisms or microbes* – There are different ecological assessment endpoints, the selection of which depends on the levels of biological organization in question (i.e., individual, population, community, and entire ecosystem). The basic level of ecological organization is with the individual animal, a single plant, insect, or bird. The next level of organization is the population. Populations are a collection of individuals of the same species within an area or region. The next, more complex, level of organization is the community. Communities are made up of different populations of interacting plants, animals, and microorganisms also within some defined geographic area. This provision clarifies the scope of effects to either the individual species of fish, wildlife, plants, or other organisms, or the population or community of a species.

Section 69501.1(a)(3)(A)*1*. *Acute or chronic toxicity* - Adverse effects to aquatic, avian, or terrestrial animal or plant organisms or microbes includes both acute and chronic toxicity to organisms in the environment. Acute toxicity describes the adverse effects of a chemical that result either from a single exposure or from multiple exposures in a short time span. Typically, the adverse effects of acute toxicity should occur within fourteen (14) days of the administration of the substance. Many regulatory agencies still require the submission of *in vivo* fish lethality test data for acute aquatic toxicity. These acute aquatic toxicity tests measure a short-term effect induced by exposure to a chemical. The tests are typically forty-eight (48) to ninety-six (96) hours in duration and the endpoint (effect) that is measured is typically death of the organism. The amount of effect observed during acute toxicity tests is reported as a lethal concentration.

Chronic toxicity is the adverse health effects from repeated exposures, at lower levels, to a chemical over a longer time period. Chronic toxicity is a property of a substance that has toxic effects on a living organism, when that organism is exposed to the substance continuously or repeatedly. For chronic aquatic toxicity tests, the effect or effects induced by a relatively long-term exposure to a chemical can be seven or more days in duration. The sub-lethal endpoints (effect) that are measured are growth or reproductive effects as well as death of the organism. This definition is necessary to identify chemical hazards to the environment and the effects of chemicals on individual species of fish, wildlife, plants, and other organisms.

Section 69501.1(a)(3)(A)*2*. *Changes in population size, reductions in biodiversity, or changes in ecological communities* – Adverse effects to aquatic, avian, or terrestrial animal or plant organisms or microbes includes changes in population size and biodiversity reduction and negative impacts to historical communities of organisms. Chemicals released into the environment may produce negative, direct or indirect,

effects that alter the flow of energy, the chemical and physical constitution of the environment and abundance of the species. Chemical contaminants reduce the fitness and behavior of populations. For example, biological contamination or changes in the biological system may be caused by an increase of life forms due to the presence of a chemical, such as an unwanted increase of organisms due to the presence of the chemical being used as food. A historic example is the use of phosphorus in cleaning products, resulting in algae using phosphorus as a food source resulting in algae blooms. As a result of algae blooms, less dissolved oxygen was available for fish to breathe and fish kills resulted.

Biological organisms may also be contaminated with a chemical through chemical absorption or uptake of the chemical into plants or animals – with or without direct consequences on the biological organism's survival. Absorption without direct consequences may result in bioaccumulation in the plant or animal and eventually adversely affect higher organisms, which results in the loss of biodiversity.

Section 69501.1(a)(3)(A)3*. The ability of an endangered or threatened species to survive or reproduce* – Adverse effects to aquatic, avian, or terrestrial animal or plant organisms or microbes includes impacts on survival of a species. There are chemicals that interfere with natural hormone functions and affect the reproduction, development, and growth of fish and wildlife. When these chemicals are introduced into waterways and habitats, their effects may imperil species.

Section 69501.1(a)(3)(B) *Adverse effects on aquatic and terrestrial ecosystems* – An ecosystem consists of different communities of organisms associated within a physically defined space. Terrestrial ecosystems can be grouped into units of similar nature, termed biomes (such as a "deciduous forest," "grassland," "coniferous forest," etc.), or into a geographic unit, termed landscapes, containing several different types of ecosystems. Aquatic ecosystems are commonly categorized on the basis of whether the water is moving (streams, river basins) or still (ponds, lakes, large lakes), and whether the water is fresh, salty (oceans), or brackish (estuaries).

Terrestrial ecosystems and aquatic ecosystems are subject to global threats of pollution (*e.g.*, acid deposition, stratospheric ozone depletion, air pollution, and the greenhouse effect) and human activities (*e.g.*, soil erosion and deforestation). Examples of adverse impacts include deterioration or loss of environmentally sensitive habitats, populations, and biodiversity of plants or animals.

Section 69501.1(a)(3)(B)1. *Deterioration or loss of environmentally sensitive habitats* – Habitat, or the place where species live, can be characterized and described by the

physical, chemical, biological, and geological components of the environment. Habitat science is the study of relationships among species and their environment. Habitat science is not synonymous with ecosystem science, but habitats form the structural matrix of ecosystems.

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

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

Section 69501.1(a)(3)(B)2. *Impacts that contribute to or cause vegetation contamination or damage* – Chemical contamination may cause direct vegetation contamination or damage (including phytotoxicity) and may also lead to the loss of biodiversity through acute toxicity of organisms in the soil. This may result in the loss of organic matter and other physical changes in the environment, such as erosion, soil compaction, or other soil structural changes, which impact vegetation survival and negatively affect environmentally sensitive habitats, especially in environments already designated as impaired.

Section 69501.1(a)(3)(B)3. *Adverse effects on environments that have been designated as impaired by a California State or federal regulatory agency* – Regulatory agencies may designate environments that are impaired and detail the specific pollutants that are the cause for the impairment. The California State Water Resources Control Board maintains a listing of impaired water bodies in the State if a beneficial use is compromised. The following are considered beneficial uses that are protected:

- Areas of Special Biological Significance;
- Cold Freshwater Habitat;
- Commercial and Sports Fishing;
- Estuarine Habitat;
- Marine Habitat;
- Fish Migration;
- Fish Spawning
- Warm Freshwater Habitat; and
- Wildlife Habitat.

Section 69501.1(a)(3)(C) *Biological or chemical contamination of soils* - Adverse effects on terrestrial ecosystems and contaminant runoff effects on aquatic ecosystems must be assessed to determine if ecosystem function is altered, especially if the adverse changes are irreversible and endanger the long-term maintenance of the population of a species at that location. Soil quality is vital to maintain plant and animal health within an ecosystem.

Section 69501.1(a)(3)(D) *Any other adverse effect, as defined in section 69401.2(a), for environmental hazard traits and endpoints specified in Article 4 of Chapter 54* - Additional adverse ecological effects include domesticated animal toxicity, eutrophication, impairment of waste management organisms, loss of genetic diversity (including biodiversity), phytotoxicity, and wildlife development, growth, reproductive, and survival impairment.

Section 69501.1(a)(4) defines **"adverse environmental impacts",** which is useful as a naming convenience, to collectively refer to all adverse impacts other than adverse public health impacts. Many chemicals have enforceable regulatory standards related to their presence in air, soil, and water. To provide a measurable threshold to determine when an "adverse" impact has occurred, section 69501.1(a)(4)(E) clarifies that when a chemical exceeds an enforceable standard associated with the protection of the environment, an adverse impact has occurred. Including environmental compliance as a determinate of adverse environmental impacts ensures that specific impacts that are sufficiently important so as to be regulated under local, State, or federal environmental laws and regulation are considered. This provision is necessary to have a simple means of referring to adverse impacts other than those related to public health, and for that term to have a meaning in keeping with its general usage in the scientific community.

Section 69501.1(a)(4)(A) *Adverse air quality impacts* - This provision incorporates section 69501.1(a)(2) into the definition of "adverse environmental impacts."

Section 69501.1(a)(4)(B) *Adverse ecological impacts* - This provision incorporates section 69501.1(a)(3) into the definition of "adverse environmental impacts."

Section 69501.1(a)(4)(C) *Adverse soil quality impacts* - This provision incorporates section 69501.1(a)(7) into the definition of "adverse environmental impacts."

Section 69501.1(a)(4)(D) *Adverse water quality impacts* - This provision incorporates section 69501.1(a)(9) into the definition of "adverse environmental impacts."

Section 69501.1(a)(4)(E) *Exceedance of an enforceable California or federal regulatory standard relating to the protection of the environment* - Many chemicals have enforceable regulatory standards related to their presence in air, soil, and water. To provide a measurable threshold to determine when an "adverse" impact has occurred, section 69501.1(a)(4)(E) clarifies that when a chemical exceeds an enforceable standard associated with the protection of the environment, an adverse impact has occurred. Including environmental compliance as a determinate of adverse environmental impacts ensures consideration of specific impacts that are sufficiently important so as to be regulated under local, State, or federal environmental laws and regulations.

Section 69501.1(a)(5) defines **"adverse impacts"** as a naming convenience to include all "adverse public health" and/or "environmental impacts" relevant under these regulations, and to facilitate discussion. The term "adverse impact" is used about forty times throughout the text; so, it is necessary to simplify references to all of the adverse impacts included within this umbrella term.

Section 69501.1(a)(6) defines **"adverse public health impacts"** to mean any of those toxicological effects on public health specified in Articles 2 and 3 of Chapter 54. Again, this aligns with the related regulations in Chapter 54 of OEHHA's regulations. Thus, it is necessary to provide consistency of usage and to promote a common understanding of terms. These effects are as follows and are described in further detail in Chapter 54: carcinogenicity, developmental toxicity, reproductive toxicity, cardiovascular toxicity, dermatotoxicity, endocrine toxicity, epigenetic toxicity, genotoxicity, hemototoxcity, hepatotoxicity and digestive system toxicity, immunotoxicity, musculoskeletal toxicity, nephrotoxicity and other toxicity to the urinary system, neurodevelopmental toxicity, neurotoxicity, ocular toxicity, ototoxicity, reactivity in biological systems, and respiratory toxicity.

"Adverse public health impacts" is also defined to mean “exceedance of an enforceable California or federal regulatory standard relating to the protection of public health.” This provision is necessary to make it clear that when a chemical exceeds an enforceable regulatory standard, an adverse public health impact has occurred. Regulatory standards relating to public health may be set to protect against long-term exposures to low levels of contaminants or high doses from a single or short-term exposure. For example, exceedance of a regulatory standard that will be considered an adverse public health impact can be an exceedance of an air quality standard for respiratory toxicity, or an exceedance of a drinking water standard for a carcinogen.

Section 69501.1(a)(6) also specifies that public health includes occupational health. Workers who may be exposed to numerous chemicals daily are sometimes the first group to manifest the effects of high exposure to industrial chemicals. Occupational health is included in this definition to address workplace exposures that may be considered the cause of illness and disease. This part of the definition of public health is necessary to have the definition be in harmony with its use in the public health community.

Section 69501.1(a)(7) defines **“adverse soil quality impacts”** to mean any of the effects on soil function or properties listed below under sections 69501.1(a)(7)(A) through (D). This is necessary to ensure that DTSC and a responsible entity conducting an AA consider those adverse soil quality impacts that are commonly recognized by the scientific community as being of concern when evaluating chemicals and products, or any impacts on attributes, such as “materials and resource consumption.” As such, this definition is necessary to conform the language in the regulations to existing definitions of these same terms.

- **(A)** *Compaction and other soil structural changes* are forms of physical degradation resulting in distortion of the soil where biological activity, porosity, and permeability are reduced, strength is increased, and soil structure partly destroyed. Compaction can reduce water infiltration capacity and increase erosion risk by accelerating run-off.
- **(B)** *Soil erosion* is the removal of topsoil faster than soil forming processes can replace it. Soil erosion is normally a natural process occurring over geological timescales. But where (and when) the natural rate has been significantly increased by human activity, accelerated soil erosion becomes a process of degradation and, thus, an identifiable threat to soil that can result in land infertility, devastating flooding, and other adverse soil quality impacts.
- **(C)** *Loss of organic matter* may be due to a chemical’s direct effect (*e.g.*, poisoning or killing organic matter) or indirect “trickle down” effects on one organism leading to loss of other organisms. The loss of biodiversity and organic matter

may lead to soil compaction or other soil structural changes, erosion, and soil sealing.

(D) *Soil sealing* is the covering of surface soil with a layer of impervious material or changing the nature of the soil so that it behaves as an impermeable medium. Sealed areas are lost to uses such as agriculture or forestry, while the ecological soil functions are severely impaired or even prevented (*e.g.*, soil working as a buffer and filter system or as a carbon sink). In addition, surrounding soils may be influenced by change in water flow patterns or the fragmentation of habitats.

Section 69501.1(a)(8) defines **"adverse waste and end-of-life effects"** to mean the waste materials and byproducts generated during the life cycle of a product, and the associated adverse effects due to the factors listed below under sections 69501.1(a)(8)(A) through (E). This is necessary to ensure that a responsible entity considers the waste and end-of-life effects during a product's life cycle, when evaluating the Priority Product, its Chemical of Concern, and possible replacement chemicals during the AA. This definition is also necessary to enable DTSC to consider these effects when evaluating product-chemical combinations for possible listing as Priority Products. While each effect may be a factor in and of itself in determining an adverse impact, it may be that a combination of factors determines the adverse impact. Additionally, this definition is necessary to comply with the statutory mandate that the evaluation of chemicals of concern in products and their alternatives include at a minimum "waste and end-of-life disposal." Sections 69501.1(a)(8)(A) through (E), described below, are necessary to clarify, interpret, and make more specific the provisions of Health and Safety Code section 25253(a)(2)(J).

Section 69501.1(a)(8)(A) includes volume or mass generated as one factor that may lead to adverse waste and end-of-life effects. This is necessary to consider because chemicals in products can affect increases in volume or mass of waste materials or byproducts generated during the life cycle of a product. Chemicals may affect the volume of biosolids that are generated by wastewater treatment plants. The Clean Water Act and the Ocean Dumping Ban Act of 1988 eliminated all but land-based options for the "beneficial use" or disposal of sewage sludge. When the wastewater effluent cannot meet discharge requirements due to unacceptable levels of contaminants, there is a need for secondary treatment, which doubles the amount of biosolids produced at wastewater treatment plants. Biosolids are normally produced in great volumes on a daily basis. Due to storage capacity limitations, wastewater treatment plants may need to dispose of biosolids once or twice per day.

The contaminants removed from wastewaters are concentrated in the biosolids produced. If the biosolids cannot be marketed as a soil amendment (*i.e.*, by-product) due to the contaminants, then disposal as waste material is required. The primary requirement for sludge disposal at a sanitary landfill is that the biosolids cannot contain hazardous substances in excess of predetermined limits. When biosolids exceed these concentrations and meet the definition of hazardous waste, biosolids cannot be disposed at sanitary landfills.

Section 69501.1(a)(8)(B) specifies that special handling needed to mitigate adverse impacts is also a consideration for determining adverse waste and end-of-life effects. This is necessary because chemicals in products may require special handling to mitigate adverse impacts. If, for example, a product is a hazardous waste at the end-of-life for the product it must be disposed of at a hazardous waste landfill. As a hazardous waste, additional special handling requirements are necessary for proper handling, storage, transportation, and disposal to mitigate exposures to waste handling workers and to prevent releases to the environment.

Section 69501.1(a)(8)(C) provides that effects on solid waste and wastewater disposal and treatment are to be considered in determining whether there are adverse waste and end-of-life effects. This includes effects on operation of solid waste and wastewater handling and treatment facilities, and the ability to reuse or recycle materials resulting from the treatment of solid waste and wastewater. Contaminants due to chemicals in products in waste streams can make treatment and recycling difficult, and reduce the value of recycled material making it economically infeasible to reuse. Furthermore, use of these contaminated recycled materials could potentially pose a risk to public health. It has been reported that fifty percent (50%) to eighty percent (80%) of the electronic waste collected for recycling in industrialized countries ends up in recycling centers in Asia. However, the recycling industries in these countries, which include China, India, Pakistan, Vietnam, and the Philippines, are often crude and do not have the appropriate facilities to safeguard the environment and human health. Operations for the recovery of copper wires through the burning of polyvinyl chloride and flame retardant-protected cables and the open burning of computer casings and circuit boards stripped of metal parts can produce toxic fumes and ashes. This provision is necessary to account for any effects on solid waste and wastewater treatment and disposal, and the ability to reuse or recycle materials.

Section 69501.1(a)(8)(D) specifies that discharges or disposals to storm drains or sewers that adversely affect operation of wastewater or storm water treatment facilities is a type of adverse waste and end-of-life effect. This is necessary to address any impacts due to discharges or disposal to storm drains or sewers that affect the

operation of water treatment facilities. Wastewater treatment facilities are designed to treat biodegradable waste, but they are not designed to capture synthetic chemicals used to manufacture consumer products. Chemicals that leach out of products can pass through the municipal sewage plants virtually untreated and may be detrimental to the microbial activity necessary to digest biodegradable materials.

Section 69501.1(a)(8)(E) provides that releases into the environment as a result of solid waste handling, treatment, or disposal activities, or the discharge or disposal to storm drains or sewers, of chemicals contained in a product is a type of adverse waste and end-of-life effect. This provision is necessary to address releases to the environment due to waste handling, treatment, and disposal activities. Many municipal waste landfills are unlined and their leachate (water that drains through) and air emissions may be hazardous. Even lined landfills will eventually fail and leak leachate into ground and surface water.

Section 69501.1(a)(9) defines **"adverse water quality impacts"** to mean any of the adverse effects, listed below under sections 69501.1(a)(9)(A) through (E), on the beneficial uses of the waters of the State, including groundwater, fresh water, brackish water, marsh lands, wetlands, or coastal bodies or systems. This is necessary to ensure that, when evaluating chemicals and products, DTSC and a responsible entity conducting an AA consider those adverse water quality impacts affecting the water's beneficial use that are commonly recognized by the scientific community as being of concern. As such, this definition is necessary to conform the regulations to the existing definitions and usage of these terms. It is also necessary to have an appropriate scope of impacts that are captured as adverse water quality impacts.

(A) *Increase in Biological Oxygen Demand* is one of the most common measures of polluting organic material in water. Biological oxygen demand indicates the amount of putrescible organic matter present in water. Therefore, a low biological oxygen demand is an indicator of good quality water, while a high biological oxygen demand indicates polluted water.

(B) *Increase in Chemical Oxygen Demand* (COD) is a measure of the capacity of water to consume oxygen during the decomposition of organic matter and the oxidation of inorganic chemicals such as ammonia and nitrite. COD is expressed as the amount of oxygen consumed in mg/l. Chemical oxygen demand measurements are commonly made on samples of wastewaters or natural waters contaminated by domestic or industrial wastes and may provide information for water treatment activities. COD results do not necessarily correlate to the biological oxygen demand because the chemical oxidant may react with substances that bacteria do not stabilize. Biological oxygen demand

measures the amount of oxygen consumed by microbial oxidation and is most relevant to waters rich in organic matter.

(C) *Increase in Temperature.* Thermal pollution may cause degradation to the beneficial use of water. Thermal pollution is heat discharge into waters that adversely affect or kill aquatic life and disrupt an ecosystem.

(D) *Total Dissolved Solids (TDS)* tests measure the amount of all dissolved solids in water. These solids are primarily minerals and salts, but can also include organic matter. TDS concerns usually apply to freshwater systems, as salinity compromises some of the ions measuring total dissolved solids. The principal application of TDS is in the study of water quality for streams, rivers, and lakes. Although TDS is not generally considered a primary pollutant, (*e.g.* it is not deemed to be associated with health effects) it is used as an indication of aesthetic characteristics of drinking water and as an aggregate indicator of the presence of a broad array of chemical contaminants. Water is essential to the survival of all living organisms. Because it is important to protect this natural resource, there are a number of regulatory standards to prevent water pollution. This is to ensure that California will continue to provide quality drinking water and have healthy aquatic ecosystems.

(E) This subsection describes the various programs overseeing the waters of California and provides that introduction of, or increase in, the chemicals and pollutants listed by the specified regulatory programs are considered an adverse water quality impact.

1. *California priority pollutants identified under section 303(c) of the federal Clean Water Act* which requires states to develop water quality standards and review and update those standards every three years. Water quality standards must include designated uses of water bodies, water quality criteria that are necessary to protect those uses (expressed in either numeric or narrative form), and anti-degradation components. Water quality criteria promulgated by the U.S. EPA under section 303(c) are enforceable components of water quality standards. The regulation found in Code of Federal Regulations section 131.38 is known as the "California Toxics Rule."

2. *Pollutants listed by California or the U.S. Environmental Protection Agency for water bodies in California under section 303(d) of the federal Clean Water Act,* which requires states, territories, and authorized tribes to develop lists of impaired waters. The State Water Resources Control Board and Regional Water Quality Control Boards assess water quality monitoring data for California's surface waters every two years to determine if they contain pollutants at levels that exceed protective water quality standards.

3. *Chemicals for which primary Maximum Contaminant Levels have been established.* Maximum Contaminant Levels (MCLs) are established by the California Department of Public Health (CDPH) for specific chemicals in drinking water. MCLs are health protective drinking water standards to be met by public water systems. MCLs take into account not only a chemical's health risks, but also factors such as their detectability and treatability, as well as costs of treatment. Health and Safety Code section 116365(a) requires CDPH to establish in regulations a contaminant's MCL at a level as close to its Public Health Goal (PHG) as is technically and economically feasible, placing primary emphasis on the protection of public health. MCLs have been established under title 22, California Code of Regulations, sections 64431 and 64444.
4. *Chemicals for which Notification Levels have been specified.* Notification Levels (NLs) are health-based advisory levels established by CDPH for chemicals in drinking water that lack MCLs. When chemicals are found at concentrations greater than the notification levels, certain requirements apply. State law (Health and Safety Code section 116455(a)(2)) requires timely notification of the local agency (*i.e.*, city council, county board of supervisors, or both) by drinking water systems whenever a notification level is exceeded in drinking water that is provided to consumers by a retail water system. Other notification requirements apply depending on whether or not the water system is a wholesale water system and whether or not it is regulated by the Public Utilities Commission.
5. *Chemicals for which public health goals for drinking water have been published under the California Safe Drinking Water Act.* Public Health Goals (PHGs) are established by OEHHA. They are concentrations of drinking water contaminants that pose no significant health risk if consumed for a lifetime, based on current risk assessment principles, practices, and methods. OEHHA establishes PHGs (pursuant to Health and Safety Code section 116365(c)) for contaminants with MCLs, and for those chemicals for which CDPH will be adopting MCLs.

Section 69501.1(a)(10) defines **"alternative"** to identify the range of different approaches (described below under sections 69501.1(a)(10)(A) through (D)) that a responsible entity may choose to address the presence of a Chemical of Concern in a Priority Product during the AA process. This definition is necessary to have an appropriate range of choices and criteria that a responsible entity may consider in examining the Chemical of Concern in its Priority Product for possible alternatives. More specifically, this provision is necessary to allow a responsible entity to make the

most appropriate alternative selection decision to best limit exposures to or reduce the level of hazard posed by a Chemical of Concern in a Priority Product (as required under Health and Safety Code section 25253(a)(1)).

(A) Allows a responsible entity to use an alternate process or alternative that eliminates the use of a Chemical of Concern in the Priority Product with or without the use of one or more replacement chemicals.

(B) Allows a responsible entity to change the formulation or design of the product and/or the manufacturing process to eliminate or reduce the use of the Chemical of Concern in the Priority Product.

(C) Allows a responsible entity to redesign a product and/or its manufacturing process to reduce or restrict exposures to Chemicals of Concern in the product.

(D) Provides responsible entities the latitude to select from a broad range of alternatives to reduce the adverse impacts and/or exposures associated with the Chemicals of Concern in the product, and/or to reduce the adverse waste and end-of-life effects associated with the product.

Section 69501.1(a)(11) defines **"Alternatives Analysis"** or **"AA"** to mean an evaluation and comparison under Article 5 of a Priority Product with or more alternatives to the product. This term in particular, and Article 5 in general, is necessary to effectuate the requirements contained in the authorizing legislation. More specifically, Health and Safety Code section 25253(a) requires that an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways be conducted when a product contains a chemical of concern. This process must include life cycle assessment tools that take into consideration, but are not limited to, all of the following:

(A) Product function or performance;
(B) Useful life;
(C) Materials and resource consumption;
(D) Water conservation;
(E) Water quality impacts;
(F) Air emissions;
(G) Production, in-use, and transportation energy inputs;
(H) Energy efficiency;
(I) Greenhouse gas emissions;
(J) Waste and end-of-life disposal;
(K) Public health impacts, including potential impacts to sensitive subpopulations, including infants and children;
(L) Environmental impacts; and
(M) Economic impacts.

Article 5 requires an AA to be conducted in two stages. These two AA stages, collectively, address the above-mentioned impacts. (The AA is discussed in greater detail below in the statement of reasons for Article 5.)

Section 69501.1(a)(12) defines **"Alternatives Analysis Threshold"** to mean the Practical Quantitation Limit (PQL) for a Chemical of Concern that is a contaminant in a Priority Product, or the concentration (if any) specified by DTSC on a product/chemical-specific basis during the Priority Product listing process (under section 69503.5(c)) for either a contaminant or an intentionally added Chemical of Concern. The public review and comment period for each proposed Priority Product listing will give interested parties the opportunity to present information to DTSC to support: (i) an AA Threshold proposed by DTSC in the proposed Priority Product listing; (ii) a request that DTSC revise or eliminate the AA Threshold proposed by DTSC; or (iii) a request that DTSC specify an AA Threshold in the Priority Product listing in the event that DTSC has not proposed an AA Threshold.

This definition, in its entirety, is necessary to provide an appropriate threshold concentration below which a responsible entity is not required to complete an AA. The AA Threshold will be a default value equal to the PQL if the chemical is a contaminant, or will be established through rulemaking under the Administrative Procedure Act if DTSC chooses to set an AA Threshold for a particular Priority Product-Chemical of Concern. This is necessary to allow DTSC the flexibility to set an AA Threshold for an intentionally added chemical when appropriate to do so, and to set the AA Threshold higher than the PQL for contaminants when it is appropriate to do so. Additional information concerning the AA Threshold and the AA Threshold exemption, and their necessity, is provided in the statement of reasons for sections 69501.1(a)(1)(13), (26), and (52) and section 69505.3.

Section 69501.1(a)(12)(A) specifies the AA Threshold to be the PQL for a Chemical of Concern that is present in a Priority Product solely as a contaminant. This is a default AA Threshold, and section 69503.5(c) gives DTSC the latitude to establish an AAT higher than the PQL on a case-by-case basis if determined appropriate and necessary.

Section 69501.1(a)(12)(B), in conjunction with section 69503.5(c), provides that DTSC may specify in the proposed and/or final Priority Product listing an AA Threshold for a Chemical of Concern that is an intentionally added ingredient, or DTSC may specify an AA Threshold concentration that is greater than the default threshold (*i.e.*, the PQL) for a contaminant. This provision is necessary because there may be scientific information that indicates that the AA Threshold for a Priority Product-Chemical of Concern should be set on a case-by-case basis. This provision allows DTSC during the rulemaking

process for listing Priority Products to consider issues that may need to be addressed differently than is provided by the default value for the AA Threshold (*i.e.*, the PQL for contaminants or zero for intentionally added ingredients). Rulemaking will give stakeholders an opportunity to present information to DTSC demonstrating how the AA Threshold should be evaluated and set for each Chemical of Concern in each proposed Priority Product.

Section 69501.1(a)(13) defines **"Alternatives Analysis Threshold Notification"** to mean a notification submitted under section 69505.3. This is necessary to ensure that this AA Threshold Notification is clearly defined. It is necessary for DTSC to receive these notifications so that DTSC, other responsible entities for the Priority Product, and interested parties are made aware that the Priority Product qualifies for an AA Threshold exemption, and thus know not to expect an AA Report for the Priority Product. This AA Threshold Notification is a requirement under section 69505.3, which provides further details as to the contents of the notification and the necessity for the notification and its contents.

Section 69501.1(a)(14) defines **"aqueous hydrolysis half-life"** to mean the time required for the concentration of a chemical to be reduced by one-half after being introduced into water. This definition is consistent with the definitions for hydrolysis and half-life found in section 796.3500 of Title 40 of the Code of Federal Regulations – the half-life of a chemical is defined as the time required for the concentration of the chemical substance being tested to be reduced to one-half its initial value, and hydrolysis is defined as the reaction of an organic chemical with water.

Hydrolysis is a chemical transformation process in which a chemical reacts with water. Certain classes of chemicals, upon contact with water, can undergo hydrolysis, which is one of the most common reactions controlling chemical stability and is, therefore, one of the main chemical degradation paths of these substances in the environment. Some of these reactions can occur so rapidly that there may be greater concern about the products of the transformation than about the parent compounds. In other cases, a substance will be resistant to hydrolysis under typical environmental conditions, while, in still other instances, the substance may have an intermediate stability that can result in the necessity for an assessment of both the original compound and its transformation products.

Hydrolysis rates are generally described in half-lives, and indicate how long a chemical will persist in an aqueous environment. If the chemical resists hydrolysis then it may degrade via some other pathway. Aqueous hydrolysis half-life is one of the factors listed under environmental fate in section 69501.1(a)(29).

Section 69501.1(a)(15) defines **"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 is necessary to make clear that the term "assemble" includes commonly understood functions to assemble a product (*i.e.*, put together a multi-component product), but also means to repair, refurbish, maintain, or make non-material alterations to a product.

NOTE: In a previous version of the proposed regulations, the term "assemble" was included in the definition of "manufacture." However, DTSC found it necessary to define this term separately so as to make a distinction between the act of manufacturing and the act of assembling. This was done in order to provide regulatory relief to entities that do not manufacture the Priority Product itself, but simply use a Priority Product component to create a multi-component product (which could be a finished product or a product that is itself used as a component in a larger product). This definition directly ties into the definition of "assembler" in section 69501.1(a)(16). Together, these provisions effectively allocate a secondary burden of compliance on any person who performs an activity covered under the definition of "assemble." That is, an assembler, unlike a manufacturer or importer, may opt out of conducting an AA under Article 5 under section 69501.2(b). This is parallel to the opt-out provisions available for retailers.

Section 69501.1(a)(16) defines **"assembler"** to mean any person who assembles a product containing a component that is a product subject to the requirements of these regulations. This term is necessary to provide an appropriate gradation of responsibilities with regard to fulfillment of the various requirements of the regulations. The term "assembler" is encompassed by the term "responsible entity", and assemblers are subject to requirements and options similar to those of a retailer. This definition is necessary to clarify and confirm that product assemblers do not have a duty to comply with these regulations as a "manufacturer."

Section 69501.1(a)(17) defines **"atmospheric oxidation rate"** to mean the rate of change or degradation of a chemical through the interaction with oxygen in the atmosphere.

This environmental fate property, listed under section 69501.1(a)(32)(C), is typically described in half-lives. An atmospheric oxidation rate indicates stability in the atmosphere and the potential for long-range transport. Although experimental data are preferred, very little experimental data are available for atmospheric oxidation rates on many compounds. The Estimation Programs Interface (EPI) Suite is a Windows based

suite of physical/chemical property and environmental fate estimation models developed by the U.S. EPA's Office of Pollution Prevention Toxics and Syracuse Research Corporation. The EPI suite and other software programs can be used to estimate the atmospheric oxidation rate when experimental data is not available. If the substance has a very short atmospheric half-life, it will only occur in the lower troposphere. However, long-lived substances may also occur in the stratosphere or be transported to parts of the globe far removed from the original source. This definition is necessary so that the regulations conform to the usage and definition of these terms in other settings and programs.

Section 69501.1(a)(18) defines **"bioaccumulation"** to mean the same as OEHHA's definition found in section 69405.2. "Bioaccumulation" is used in this regulation as both a hazard trait and an environmental fate property. Defining bioaccumulation in this manner is necessary to be consistent with the OEHHA hazard traits.

Bioaccumulation occurs when chemicals accumulate in living things any time they are taken up and stored faster than they are broken down (metabolized) or excreted. Consideration of bioaccumulation is very important in protecting human beings and other organisms from the adverse effects of chemical exposure. Examples of chemicals that bioaccumulate are heavy metals (such as lead and mercury), dioxins, and polychlorinated biphenyls (PCBs).

Bioaccumulation, as an environmental fate property, is the ability of a substance to accumulate in living tissues to levels higher than those in the surrounding environment. It is usually quantified by a chemical's bioaccumulation factor (BAF) or bioconcentration factor (BCF), and different numerical values of BAF or BCF have been developed for the criteria by a number of organizations.

Several chemical-specific metrics can be used to evaluate the potential for a chemical to bioaccumulate in plants and animals and biomagnify in food webs. These values may be measured in laboratory tests or estimated with computer models based on chemical structure. Due to the many variations of the definition for "bioaccumulation," this term reflects both OEHHA's definition and a modified version of the definition used by the U.S. EPA. This definition is necessary to make clear the criteria for bioaccumulation and the usage of this hazard trait in this regulation and to ensure the term is consistent with the related Chapter 54 regulations.

Section 69501.1(a)(19) defines **"Candidate Chemical"** to mean a chemical that is a candidate for designation as a Chemical of Concern, and that is identified as a Candidate Chemicals under Article 2. This definition is necessary to bring clarity to

which chemicals are captured by use of the term, and to have a simple term for use throughout these regulations to refer to these chemicals. DTSC has determined that it is necessary to the effectiveness and efficiency of the safer consumer products program to have a broad pool of Candidate Chemicals that are "candidates" for possible consideration under Article 3, which sets out the criteria and process for evaluating product-Candidate Chemical combinations for possible listing as Priority Products subject to the AA and regulatory response requirements of the regulations. A Candidate Chemical that is the basis for a Priority Product listing is defined, and referred to throughout the regulations, as a "Chemical of Concern" with respect to that particular Priority Product and its alternatives (see sections 69501.1(a)(21) and 69503.5(a)(2)(B)). Article 2 lays out the framework for identifying and listing chemicals as Candidate Chemicals for the purposes of these regulations.

Section 69501.1(a)(20)(A) defines **"chemical"** to mean either of the following:

1. 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; or

2. A chemical ingredient, which means a substance comprised of one or more substances.

This definition is necessary to capture the different forms a chemical may take. The regulations need to be able to address all these various forms in order to deal with where and when public health and environmental harm may be occurring. "Chemical ingredient" is included in this definition to facilitate the readability of the regulations.

Section 69501.1(a)(20)(B) defines **"molecular identity"** to clarify its usage in the context of the definition of "chemical" in section 69501.1(a)(20)(A). Molecular identity in this definition includes fourteen properties, though most are usually represented by a definite structural diagram and discrete molecular formulas. This definition is necessary in order for the regulations to conform to the usage and definition of this term in other regulatory programs.

This provision is necessary because there may be different substances with the same chemical composition, but with significant differences in their properties (*i.e.*, nanomaterials and short chain, medium chain, and long chain chlorinated paraffins). Although there are no provisions in the regulations referring specifically to nanoscale

chemicals, this definition of molecular identity is necessary to capture all chemicals regardless of size, shape, or physical state. In order to correlate the properties of nanoscale chemicals to toxicity potential it is essential to characterize them in order to ensure that results are reproducible. The following properties can be used to describe a chemical's molecular identity, although not all the properties may be applicable to a specific chemical.

Section 69501.1(a)(20)(B)1. *Agglomeration state* – It is important to know whether the particles are in an agglomerated (weak bond between primary particles) or aggregated (hard bonds between primary particles) state, because their corresponding biological fate and effects will be different. The agglomeration state provides information on the likely size distribution of inhalable particles as well as on their relative ease of dispersion.

Section 69501.1(a)(20)(B)2. *Bulk density* - Bulk density provides a quick indication of how much dust a nanoscale chemical may generate when being handled in its powder form. Low bulk density materials often have a higher degree of dusting than high bulk-density materials of the same chemical composition.

Section 69501.1(a)(20)(B)3. *Chemical composition, including surface coating* - The chemical composition includes the concentrations of elemental chemicals or chemical compounds — particularly those known to be harmful. Accompanying substances should not be overlooked; surface treatments and lattice doping are often used in nanoscale chemicals and should be considered, as they may affect toxicity and exposure. Note also that chemical composition may change as nanoscale chemicals are incorporated into products or are broken down during use or after disposal or recycling. Impurities in the material, and the extent of contamination, should be identified as well.

Section 69501.1(a)(20)(B)4. *Crystal structure* – The crystal structure of an element or molecule can influence its potential toxicity.

Section 69501.1(a)(20)(B)5. *Dispersability* - This property is "the ease with which an insoluble solid or liquid material may be dispersed uniformly in a liquid." The dispersability of a nanomaterial, particularly in water, has implications for exposure and fate throughout the product's life cycle. It will influence the partitioning of the nanoscale chemical should it enter an aquatic environment.

Section 69501.1(a)(20)(B)6. *Molecular structure* – The understanding of phase and molecular structure can lead to better understanding of potential structure-property relationships.

Section 69501.1(a)(20)(B)7. *Particle density* – The density for nanoparticles requires a definition of the volume of the nanoparticle. Nanoparticle volume can be calculated by using the method of overlapping van der Waal spheres.

Section 69501.1(a)(20)(B)8. *Particle size, size distribution, and surface area* – Particle size is used to refer to the diameter or volume of a particle with a fixed number of atoms. Considering that multiple particle size groups are often present in the solution, a size distribution is necessary to describe the dispersion.

Section 69501.1(a)(20)(B)9. *Physical form and shape, at room temperature and pressure* - Physical form and shape influence how materials flow and interact with other particles (to agglomerate), how easily they disperse when entering various media or the environment, and how they interact with plants and animals.

Section 69501.1(a)(20)(B)10. *Physicochemical properties* - This is any physical or chemical property of a chemical (*e.g.*, properties that influence absorption and distribution affect). These properties also allow for the use of predictive models to be used to model the fate and transport of a chemical.

Section 69501.1(a)(20)(B)11. *Porosity* - This measure is an indication of the fraction of the particle that is devoid of material. The porosity and pore-size distribution of a material has implications for its interaction with substances in its surroundings.

Section 69501.1(a)(20)(B)12. *Solubility in water and biologically relevant fluids* - Whether the material is soluble in acids, bases, organic solvents, or biological media may be important at various stages in its life cycle as it interacts with other product components, materials, organisms, or the environment. Solubility plays a role not only in determining how the material behaves during its useful life but also in affecting its potential persistence in the environment thereafter.

Section 69501.1(a)(20)(B)13. *Surface charge* - The electric potential of a nanomaterial also suggests its likelihood of interacting with other materials. In solution, the surface charge — often determined by measuring the zeta potential 50 — has implications for the stability and aggregation of particles.

Section 69501.1(a)(20)(B)14. *Surface reactivity* - This measure provides an indication of the likelihood and nature of a nanoscale chemical's interaction with other materials. Specific assays may need to be tailored to specific nanoscale chemicals.

Section 69501.1(a)(21) defines **"Chemical of Concern"** to mean a Candidate Chemical that has been identified as the basis for listing a product-chemical combination as a Priority Product under Article 3. Chemical of Concern is a key term that is necessary to implement and make specific the intent of the enabling legislation. Health and Safety Code sections 25252 and 25253 require DTSC to establish in regulations processes to identify and prioritize chemicals [or chemical ingredients] of concern in consumer products and evaluate those chemicals and their alternatives. This definition is necessary because it makes specific that the Chemical of Concern has been identified and prioritized as the chemical in the Priority Product that is subject to the requirement to undergo an AA and other substantive requirements specific to Chemicals of Concern in Priority Products. DTSC has determined that it is necessary to have a two-step process for identification and prioritization of chemicals consisting first of the identification and listing of Candidate Chemicals; and to then have a subset of these chemicals further prioritized as Chemicals of Concern as part of a Priority Product-Chemical of Concern combination. This approach is necessary for a more precise description of the chemicals subject to the requirement to undergo an AA and to create a more efficient and effective program.

Section 69501.1(a)(22) defines **"Chemical Removal Intent Notification"** and **"Chemical Removal Confirmation Notification"** to mean the notifications submitted to DTSC under section 69505.2(a)(1)(A)1. This definition is necessary to indicate what this term means and where this provision is found in the regulations. These notifications include two sequential steps – the first notification certifies the intent to remove the Chemical of Concern from the Priority Product followed by a second notification that certifies that the Chemical of Concern has been removed. This option is restricted to the manufacturer only because the manufacturer controls the manufacturing process and is in the best position to remove chemicals from the product, unlike an importer, assembler, or retailer. Additionally, this provision enables DTSC to effectively implement these regulations and the authorizing legislation, as well as to provide a level playing field for those manufacturers who do expend the time and resources to comply with these requirements. See section 69505.2 for further explanation of these notifications and discussion of the necessity for them.

Section 69501.1(a)(23)(A) defines **"component"** to mean a uniquely identifiable homogeneous material, part, piece, assembly, or subassembly that is a necessary or intended element of a consumer product. This definition is necessary in order to allow

DTSC to name an identifiable part of a consumer product as a Priority Product (for purposes of the AA and regulatory response requirements), as opposed to naming the entire product.

The concept of “component” is used as a way to target materials within a product that are cause for concern, and, as such, must undergo an AA. In this manner, a Priority Product may be identified by DTSC as specifically as necessary to get at the adverse public health and/or environmental impacts. It ensures that the weight of the Chemical of Concern in the product will not be diluted to include the entire product; which is critical because it allows DTSC to narrow the applicability of the AA Threshold concentration calculation to a component when it is a chemical in the component that is the basis for public health or environmental concern. For example, DTSC could identify the insulation material (because of the flame retardant chemicals it contains) on a cable as the component that must undergo an AA. In such a case, an entire electronic product, such as a copier would not be subject to an AA. Rather, only the identified component — the insulation material on the cable — would be subject to the AA requirement.

Section 69501.1(a)(23)(B) defines **“homogeneous material”** to mean either of the types of materials described below under sections 69501.1(a)(23)(B)1. and 2. This is necessary to clarify the meaning of this term in the context of the definition of "component".

The concept of homogeneous material was introduced as a way of restricting substances within electronics through the European Union Restriction on the Use of Certain Hazardous Substances (RoHS). The RoHS definition has been incorporated into this definition of “homogeneous.” This will allow DTSC to name a uniquely identifiable homogenous material as a component that is a Priority Product subject to the AA and regulatory response requirements.

Section 69501.1(a)(23)(B)1. specifies that a material that is a single material of uniform composition throughout is a "homogeneous material." This provision is a way of designating chemical restrictions as specifically as is necessary to isolate and identify homogenous materials (defined as a component) within an assembled product. A component can then be any material, part, piece, assembly, or subassembly of a product that is finished or semi-finished. This material can be a single component, such as a water bottle or a protective phone cover.

Section 69501.1(a)(23)(B)2. specifies that a homogenous material can consist of a combination of various materials that cannot be readily disjointed or separated into

different materials by mechanical actions such as unscrewing, cutting, crushing, grinding, or abrasive processes.

Section 69501.1(a)(24)(A) defines **“consumer product”** or **"product"** differently from the common usage of this term. This definition is broader than what is found in the United States Consumer Product Safety Act enacted in 1972 (codified at title 15 United States Code §§ 2051– 2084), and has fewer exemptions than federal law does. This definition is necessary in order for the regulations to conform to the usage of this same term in the authorizing legislation.

Section 69501.1(a)(24)(A)1. specifies that a "consumer product" or "product" means either a "consumer product" as defined in Health and Safety Code section 25251, or, when applicable, a component of an assembled "consumer product." This definition is necessary for consistency with the enabling legislation and clarifies which consumer products will not be subject to the requirements of these regulations by virtue of being exempted under the statute. Health and Safety Code section 25251 defines “consumer product” to mean a product or part of the product that is used, brought (sic), or leased for use by a person for any purpose. “Consumer product”, as defined in the statute, does not include prescription drugs and medical devices, dental restorative materials, diagnostic or treatment instruments, packaging (for prescription drugs and devices, dental restorative materials, and medical instruments), food, and pesticides.

Section 69501.1(a)(24)(A)2. makes clear that DTSC could name as a Priority Product a part of a consumer product. This provides DTSC necessary flexibility to name any identifiable component in an assembled “consumer product.” This provision is necessary to be consistent with the enabling statute that provides that "consumer product” means "a product *or part of the product* that is used, brought (sic), or leased for use by a person for any purposes.” (Emphasis added) This definition is necessary to make clear that, depending on context, references to "consumer product" and "product" in the regulations includes components not just completely finished products.

This provision is also necessary because the regulations make a distinction between assemblers and manufacturers. The regulations need to allow DTSC to name a Priority Product that is a component, which an assembler uses but does not manufacture. For example, a motor vehicle may be made of thousands of parts, but the Chemical of Concern may be used in only one component of this product. By defining component, DTSC may name a uniquely identifiable component, such as a steering wheel, or could name only the outer cover of a steering wheel as the Priority Product subject to the regulations.

Section 69501.1(a)(24)(B) provides that "consumer product" or "product" does not mean a product that ceased to be manufactured prior to the date of a Priority Product listing that would otherwise encompass such a product. This is necessary to establish the time frame for applicability of the regulations. Those Priority Products manufactured after the listing of the Priority Product are subject to these regulations. On the other hand, Priority Products that are no longer manufactured as of the date of the Priority Product listing are not subject to these regulations. This provision is necessary to clarify that those products that ceased being manufactured before the Priority Product listing are outside the scope of these regulations. This regulation is forward looking and its goal is to accelerate the quest for safer consumer products.

Section 69501.2(a)(24)(C) specifies that “consumer product” or “product” does not mean a product previously owned or leased by someone other than the manufacturer, importer, distributor, assembler, or retailer of the product. This is necessary to clarify that someone who sells, imports, or distributes a used or second-hand product (or assembles a product using a used component) — that was previously owned by another person — will not be subject to the requirement to conduct an AA for that product. The seller, etc. of second-hand products would not be expected to have the expertise, resources, or capacity to be able to complete an AA. Even with the increased sales of second-hand products due to online auction and sales sites, no single second-hand product would represent a high sales volume of consumer products in California. This definition is necessary to appropriately establish products outside the scope of these regulations.

Section 69501.1(a)(25) defines **“contact information”** to specify the information (i.e., mailing and electronic addresses, headquarters location, phone numbers, titles, and website address) that is required to be provided to DTSC to allow DTSC to make contact, if necessary, with the party submitting (and/or parties whose products are covered by) a notification, document, and other information. This definition is necessary to establish a common sense and common usage for what is captured by this term and to authorize DTSC to require the submittal of this important information.

Section 69501.1(a)(26)(A) defines **“contaminant”** to mean a chemical that is not an intentionally added ingredient in a product, if the source(s) of the contaminant is/are a naturally occurring raw material, air, water, recycled material, or a processing agent (as further described below). This definition is necessary to implement the AA Threshold exemption, which makes a distinction between contaminants and intentionally added ingredients. This distinction, in turn, is necessary because manufacturers do not have complete control over the entire upstream supply chain and cannot always know what chemicals may be present as contaminants in materials purchased from suppliers and

used to manufacture a Priority Product. Thus, it is appropriate to have a measureable level of a contaminant, below which the manufacturer and other responsible entities for a qualified Priority Product need not conduct an AA. In the regulations, the default AA Threshold for an exemption from the AA requirements is defined as the Practical Quantitation Limit (PQL), but only if the Chemical of Concern is present in the Priority Product solely as a contaminant. The regulations, however, do allow for case-by-case determinations by DTSC to set an AA Threshold for intentionally added chemicals or an AA Threshold higher than the PQL for contaminants. Any case-by-case AA Thresholds that DTSC determines necessary and appropriate would be established during the rulemaking process for listing a Priority Product (under section 69503.5(c)).

Section 69501.1(a)(26)(A)1. specifies that the source of the Chemical of Concern may be a naturally occurring contaminant commonly found in raw materials that are frequently used to manufacture the product. Although impurities may be considered unavoidable, it may be technically feasible to reduce the content of these residues in the final product. Examples of naturally occurring Chemicals of Concern are heavy metals such as mercury, cadmium, lead, and arsenic.

Section 69501.1(a)(26)(A)2. specifies that the source of the Chemical of Concern may be air or water frequently used as a processing agent or an ingredient to manufacture the product. Water and air are both critical resources for manufacturing. Both have the potential to transmit chemical hazards to products during any process that involves direct contact with air or water, such as processing, heating, cooling, cleaning, etc. For example, chlorine, nitrates, pesticides, and lead are just a few of the contaminants that can be found in some water supplies, and treatment technologies may be limited depending on the source of the water.

Section 69501.1(a)(26)(A)3. specifies that the source of the Chemical of Concern may be a contaminant commonly found in recycled materials that are frequently used to manufacture the product. If the feedstock used is a recycled material, there may be great variability in the quality, or there may be concerns that contaminants from post-consumer materials may appear in the recycled material. Recovered material may contain some impurities that are unintended, have no function for the recycled material, and do not change the chemical identity of the selected material. Recycling can never reach 100% purity, and it is unavoidable that some small fractions of unintended contaminants are still present in the recycled material.

Section 69501.1(a)(26)(A)4. specifies that the source of the Chemical of Concern may be a processing agent, reactant, by-product, or intermediate frequently used to promote certain chemical or physical changes during manufacturing, and the incidental retention

of a residue is not desired or intended. This allows for the possibility that minor amounts of the catalyst are lost in the reaction and may be a source of the Chemical of Concern in the Priority Product.

Section 69501.1(a)(26)(B) defines **"intentionally added ingredient"** to mean a chemical that is deliberately used in the manufacture of a product where the continued presence is desired in the final product to provide a specific characteristic, appearance, or quality. This provision is necessary to make clear the applicability/inapplicability of the AA Threshold. That is, as discussed immediately above, the default AA Threshold (set at the PQL) is applicable to contaminants only – not to intentionally added ingredients. DTSC has determined it is not appropriate or necessary to have a default AA Threshold for intentionally added ingredients. By definition, the manufacturer knows that these chemicals are in the product because the manufacturer intentionally put them there. Accordingly, the manufacturer in these circumstances does not need to test to detect the measurable presence of the chemical. Additional information concerning the AA Threshold and the AA Threshold exemption, and their necessity, is provided in the statement of reasons for sections 69501.1(a)(1)(12), (13), and (52) and section 69505.3.

Section 69501.1(a)(26)(C) defines **"processing agent"** to mean a chemical used in a product manufacturing process to promote chemical or physical changes. This term is used in the definition of contaminant to account for the introduction of unintended contaminants into a manufacturing process. This provision is necessary to acknowledge processing agents as a source of contamination for purposes of determining whether a Priority Product qualifies for an AA Threshold exemption under section 69505.3.

Section 69501.1(a)(26)(D) defines **"recycled material"** to mean a material that has been separated from a waste stream for the purpose of recycling the material as feedstock. This definition is similar to the Federal Trade Commission's definition of "recycled content." Again, this provision is necessary to acknowledge recycled materials as a common source of contamination, and to make clear that "recycled" as is used in the definition of a "contaminant" means materials that are segregated for subsequent reuse. This definition is also necessary to acknowledge recycled materials as a source of contamination for purposes of determining whether a Priority Product qualifies for an AA Threshold exemption under section 69505.3.

Section 69501.1(a)(27) defines **"day"** to make clear that when time is specified in the regulations, a day will mean a calendar day, not a workday. The specified time periods are calculated by excluding the first day and including the last. The definition allows for

additional time when the last day is a Saturday, Sunday, or a California holiday specified in Government Code section 6700. This definition is necessary in order for the definition of the term in these regulations to conform to usage of the term in other California statutes and regulations. The holidays in this State, as of the writing of these regulations, are:

- January 1;
- The third Monday in January, known as "Dr. Martin Luther King, Jr. Day";
- The third Monday in February;
- March 31 known as "Cesar Chavez Day";
- The last Monday in May;
- July 4;
- The first Monday in September;
- The second Monday in October, known as "Columbus Day";
- November 11, known as "Veterans Day";
- The fourth Thursday in November, known as “Thanksgiving Day”;
- The fourth Friday in November; and
- December 25.

Section 69501.1(a)(28) defines **“Department”** to mean the Department of Toxic Substances Control. This definition is necessary to provide for clarity and ease of use.

Section 69501.1(a)(29) defines **“economically feasible”** to mean that an alternative product or replacement chemical does not significantly reduce the product manufacturer's operating margin. This is necessary to make specific the use of the term “economic impacts” in the enabling legislation in Health and Safety Code section 25253(a)(2)(M). The term “economically feasible” is used in Articles 3, 5, and 6. This criterion includes the economic viability of the alternative that would allow the product to be profitable for the manufacturer. The responsible entity must consider the effect on the operating margin of the manufacturer. This factor reflects marketplace realities and business realities in determining whether there is an economically viable alternative to a Priority Product. Thus, this term is necessary to make clear that one of the considerations during the AA is whether the use of an alternative will significantly reduce the operating margin of a manufacturer. The purpose of this program is not to put companies out of business, but to ensure a fair and reasonable search for safer alternatives that may actually be used.

Section 69501.1(a)(30) defines **“end-of-life”** to mean the point when the product is discarded by the consumer or the end of the useful life of the product, whichever occurs first. This definition clarifies what the two alternate triggers are for consideration of impacts after the use of the product. These two points in time delineate when the “use

phase" ends and the "end-of-life phase" begins in the continuum of a product's life cycle.

The first trigger is when a consumer no longer has use for a consumer product and discards a product regardless of whether or not the product has reached the end of its useful life. The second trigger occurs when a product has reached the end of the useful life due to failure or wear-out. Whichever occurs first will differentiate what is considered an end-of-life activity, which may include disposal, repair, maintenance, product reuse, component reuse, or recycling. This definition is necessary to have the use of the undefined statutory term "end-of-life" made clear and have its usage conform to common usage in other regulatory programs.

Section 69501.1(a)(31) defines **"environment"** to include land, air, water, soil, minerals, flora (plants), and fauna (animals). This definition sets the baseline scope for what must be considered at various places in the regulations when the term "environment" is used. This definition is necessary to give the term its commonly understood meaning and to shape a program with appropriate scope.

Section 69501.1(a)(32) defines **"environmental fate"** to mean all of the following:

- **(A)** Aerobic and anaerobic half-lives;
- **(B)** Aqueous hydrolysis half-life;
- **(C)** Atmospheric oxidation rate;
- **(D)** Bioaccumulation;
- **(E)** Biodegradation;
- **(F)** Mobility in environmental media, as specified in section 69405.6 of OEHHA's regulations;
- **(G)** Persistence; and
- **(H)** Photodegradation.

Environmental fate factors affect how a chemical moves in the environment, transforms (physically, chemically, or biologically), or accumulates in media or species. The environmental fate depends on the chemical's affinity to one of four environmental compartments: air, water, soil, and living organisms.

When chemicals are released into the environment, there is the potential for them to disperse and enter some or all of the adjacent compartments. Chemical properties, release rates, and degradation rates affect the distribution and concentration of a chemical in the environment, and its ultimate fate. For example, if a chemical is biodegradable, it may be broken down before it can become dangerous. If a chemical is not mobile, it will stay in one place and is less likely to be taken up by organisms in

comparison with chemicals that are mobile. If the chemical is persistent, it remains unchanged for a long time and may have a high potential for exposure to organisms. Thus, these factors are included to reflect the different risks to the environment based on the environmental fate of a chemical. The factors included are necessary for the term to be in keeping with mainstream scientific thinking in this field.

These properties include all of the following:

1) *Aerobic and anaerobic half-lives* refer to the rate chemicals transform in soil or sediment in the presence or exclusion of oxygen, respectively. These metabolism rates are used to predict the likelihood of the chemicals persisting in the environment, and also whether degradates of concern are likely to be produced and to persist. Soil metabolism rates assess aerobic and anaerobic formation and decline of transformation products of organic chemicals in soil. Aquatic sediment metabolism rates assess aerobic and anaerobic transformation of organic chemicals in aquatic sediment systems.
2) *Aqueous hydrolysis half-life* (see section 69501.1(a)(14)).
3) *Atmospheric oxidation rate* (see section 69501.1(a)(17)).
4) *Bioaccumulation* (see section 69501.1(a)(18).
5) *Biodegradation* of chemicals is a metabolic process by which organic substances are decomposed by micro-organisms (mainly aerobic bacteria) into simpler substances. A biodegradation rate is used to characterize the effect of biodegradation on contaminant migration. In general, if biodegradation of chemicals is confirmed in the laboratory, it will also occur in the wider environment. However, many of the dynamics of such processes are unknown, and biodegradation rate constants determined in the laboratory are not always applicable in the field. The rate is typically expressed in terms of a rate constant and/or half-life.
6) *Mobility of a chemical* is the tendency for a chemical to move in the environment. When a chemical is released into the environment, it is distributed to the air, soil, and water. The concentration in any of these environmental compartments will be a function of both the physicochemical characteristics of a chemical and the composition of the environmental media. Many factors will affect how a chemical is transported in the atmosphere, in aquatic environments, and how interactions with soil, groundwater, and biological alterations affect movement. Any substance may move between environmental compartments (air, water, soil/sediment, and biota) and be subject to environmental partitioning. Substances will move from their point of entry to the environmental compartment for which they have the most affinity. From this,

substances may be transferred again to other compartments. Substances can undergo chemical transformations in every environmental compartment.

7) *Persistence* (see section 69501.1(a)(46)).
8) *Photodegradation* is an important process for determining the residence time and fate of many chemicals in air, water, and soils. Photodegradation is the degradation of a chemical by means of light energy. Many chemical reactions in the environment are initiated by the photodissociation of chemicals. Solar radiation is converted into chemical energy to activate and dissociate chemical species. Photodegradation is categorized into direct and indirect reactions. Direct photodegradation occurs when chemicals absorb sunlight directly, and react in the resulting excited states. Indirect photodegradation occurs when chemicals react with unstable compounds, such as hydroxyl radicals, which have themselves been produced by the energy of sunlight. In the troposphere, indirect photodegradation is the most important reaction. In water, direct photodegradation is most important.

Section 69501.1(a)(33) defines **"environmental or toxicological endpoint"** to mean any environmental or toxicological endpoint specified in Chapter 54 of OEHHA's regulations. Chapter 54 defines the terms "environmental endpoint" and "toxicological endpoint" and provides specific endpoints for all toxicological and environmental hazard traits. This definition is necessary to allow for ease of use and understanding and to conform this term to its general usage. This definition is also necessary to align this term to have the same meaning as set out in Chapter 54, and, thus, promote a common understanding of what is meant by the use of this term and to harmonize this program with the work done by OEHHA in establishing hazard traits and environmental and toxicological endpoints for the toxics information clearinghouse specified in Health and Safety Code section 25256.1. This definition, and its use in these regulations, is also necessary to conform to the requirements of Health and Safety Code section 25252(b)(1) which requires that the criteria used to evaluate chemicals and their alternatives include the endpoints established by OEHHA under Health and Safety Code section 25256.1.

Section 69501.1(a)(34) defines **"Failure to Comply List"** to mean the list prepared by DTSC pursuant to subsection 69501.2(c). This definition and the implementation of the list is necessary in order for DTSC to keep interested parties and members of the general public apprised about the status of the program, including parties and products that are out of compliance with these regulations. DTSC will maintain this list on its website and regularly update it. Information will be removed once DTSC determines that the requirements that led to the inclusion on the list have been met. This provision clarifies what is meant by the use of this term in these regulations. A complete

description and explanation of the Failure to Comply List is provided in the statement of reasons for section 69501.2(c).

Section 69501.1(a)(35) defines **"functionally acceptable"** to mean that an alternative product will meet applicable legal requirements, and perform the functions of the original Priority Product to a degree and in a manner that consumers can be reasonably anticipated to accept. This definition is necessary to clarify the standards that an alternative product must meet in order to be considered "functionally acceptable" within the context of various provisions of these regulations.

Section 69501.1(a)(35)(A) specifies that a functionally acceptable alternative product must comply with all applicable legal requirements. An alternative that replaces a Priority Product must meet all specifications, performance standards, labeling requirements, etc. mandated under federal or California law. These requirements may include physical or chemical safety requirements or chemical restrictions, to name a few.

Section 69501.1(a)(35)(B) specifies that a functionally acceptable alternative product (in addition to meeting all legal requirements) must perform the functions of the Priority Product sufficiently well so that consumers can be reasonably anticipated to accept the product in the marketplace. In effect, this provision means that an alternative is not required to meet all of the original product's attributes to be a suitable alternative and can instead meet attributes that render the alternative suitable to be used in lieu of the original product. The alternative, however, must perform the essential functions of the original product. As a historic example, lead-free house paint is not functionally identical to lead-containing house paint, and in some respects may be functionally inferior – for example, it may not adhere to walls as strongly and, therefore, reapplication is required at more frequent intervals. However, lead-free house paint does last for many years, is suitable for the same applications formerly filled by lead-containing house paint, and has been widely accepted in the consumer marketplace. This definition is necessary to appropriately specify the attributes an alternative must have in order to be "functionally acceptable."

Section 69501.1(a)(36) defines **"hazard trait"** to mean any hazard trait specified or defined in Chapter 54 of OEHHA's regulations.

The hazard traits are intrinsic properties of chemicals that fall into broad categories of toxicological, environmental, exposure potential, and physical hazards, that may contribute to adverse effects in exposed humans, domesticated animals, wildlife, or in ecological communities, populations, or ecosystems. This definition is necessary to

allow for ease of use and understanding and to conform this term to its general usage. This definition is also necessary to align this term to have the same meaning as set out in Chapter 54, and, thus, promote a common understanding of what is meant by the use of this term and to harmonize this program with the work done by OEHHA in establishing hazard traits and environmental and toxicological endpoints for the toxics information clearinghouse specified in Health and Safety Code section 25256.1. This definition, and its use in these regulations, is also necessary to conform to the requirements of Health and Safety Code section 25252(b)(1) which requires that the criteria used to evaluate chemicals and their alternatives include the hazard traits established by OEHHA under Health and Safety Code section 25256.1.

Section 69501.1(a)(37) defines **"hazard trait submission"** to mean any health, safety, or environmental study of, or health, safety, or environmental information regarding, a chemical submitted to DTSC under these regulations or the authorizing statute. Precise chemical identity is part of any hazard trait submission, except as otherwise provided in section 69509(g). This definition is necessary to implement and make more specific Health and Safety Code section 25257(f), which precludes hazard trait submissions for chemicals, including chemical ingredients, from being protected as trade secrets. This concept comes into play in Article 9, and is discussed in more detail in the statement of reasons for that Article. Generally, though, "hazard trait submission" includes: health, safety, or environmental information as well as chemical identity information. The definition DTSC has chosen is necessary to give the term a fair and appropriate scope to achieve the purposes of the authorizing statute and these regulations.

Section 69501.1(a)(38) defines **"import"** to mean to bring, or arrange to bring, a product into the United States for purposes of placing the product into the stream of commerce in California. This definition is necessary to conform to common and ordinary usage of the term in commerce and regulatory arenas. "Import" is defined to include reimporting a consumer product manufactured or processed, in whole or in part, in the United States, but not to include ordering a product manufactured outside of the United States if the product is ordered from a person located in the United States. The last sentence in the provision allows a person, such as an assembler, to order components (that are consumer products) manufactured out-of-country to create a finished product without being designated as an "importer" under these regulations – as long as that person places the order with someone located in the U.S.. This was necessary to reasonably exclude assemblers (especially assemblers of complex durable products) who meet the conditions articulated in the definition from the requirements imposed on importers under these regulations.

Re-importation occurs when products are first placed into circulation in one market, and then (re-) imported into a second market without the authorization of the original owner. Myriad products are re-imported, including automobiles, clothing, perfume, and other consumer products. Re-imports also include products imported into the same state from which the products were previously exported.

Section 69501.1(a)(39) defines **"importer"** to mean a person who imports into the U.S. a consumer product subject to the requirements of these regulations. This definition is necessary for the regulations to be consistent with the general usage of the term in the world of commerce. It also allows DTSC to have another entity to carry out the duties of a "responsible entity" if the manufacturer is unable or unwilling to do so.

"Importer", as defined, does not include a person that imports a product solely for use in that person's workplace if that product is not sold or distributed by that person to others. This provision is necessary to make clear that if a product is not placed into the stream of commerce then it is outside the scope of these regulations.

Section 69501.1(a)(40) defines **"information"** to mean data, documentation, records, graphs, reports, or any other depiction of specific pieces of knowledge. This definition of an "umbrella term" is necessary to avoid duplicative drafting and gives a common sense meaning to a term used throughout the regulations.

Section 69501.1(a)(41) defines **"legal requirements"** to mean specifications, performance standards, and/or labeling requirements that a chemical, product, or product packaging is required to meet under federal or California law. This provision is necessary to ensure that these regulations do not conflict with other legal requirements that products must meet, and to include these requirements as a consideration in determining the functional requirements of a Priority Product and its alternatives.

Legal requirements are criteria for the definition of "functionally acceptable." An alternative should meet any applicable legal requirements for a product in order to be retained for further consideration as part of the AA.

Legal requirements are criteria in the first stage and the second stage of the AA. In the first stage AA, any legal requirements need to be identified for the Priority Product and its Chemical(s) of Concern, or any replacement chemicals that are being considered as part of the AA. In the second stage AA, legal requirements are a criterion for the identification of relevant factors for comparison of alternatives. This definition is necessary so that responsible entities do not waste time and resources pursuing

possible alternatives to the Priority Product if, ultimately, the potential alternative would not comply with other binding requirements applicable to the product.

Section 69501.1(a)(42) defines **"life cycle"** to mean the sum of all activities in the course of a consumer product's entire life span. This includes raw materials extraction, resource inputs and other resource consumption, intermediate materials processes, manufacture, packaging, transportation, distribution, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal. The enabling legislation requires that the evaluation of potential alternatives include life cycle assessment tools. This definition is intended to flesh out the various aspects of a product's life cycle that must be considered as part of the AA. It covers all of the key stages of a product's life. This definition and usage are necessary for the term to be used consistent with usage by practitioners in the field of life cycle analysis and to comply with the authorizing legislation, which requires that the AA cover the entire life cycle of a product. (See Health and Safety Code section 25253(a)(2).)

Section 69501.1(a)(43) defines **"manufacture"** to mean to make or produce. The definition excludes acts that meet the definition of "assemble." This provision is necessary to specify and clarify the principal activities that subject a person to the substantive requirements of the regulations applicable to manufacturers versus other responsible entities.

Section 69501.1(a)(44) defines **"manufacturer"** to include the entity that manufactures a product that is subject to the requirements of these regulations, and any entity that controls the manufacturing process for, or specifies the use of chemicals in, a product. A retailer that only contracts out to a manufacturer the production of a product without specifying the use of chemicals to be included in a product would not be considered a manufacturer under this definition. Note that specifying what chemicals NOT to use in the manufacture of a product does not make a retailer a "manufacturer." A private label retailer may wish to have more control over production and dictate to the manufacturer specifications for raw materials, ingredients, or designs in a contract. If the contract specifies which chemicals must be included in the product, it is necessary and appropriate to include the private label retailer as a manufacturer, since it is the retailer in that case that controls use of a Chemical of Concern.

"Manufacturer" does not include a person who orders a consumer product from a manufacturer or importer where the product is configured to include optional components, accessories, or characteristics (color, size, material, etc.) that are generally offered by the manufacturer or importer. For example, this term would not

capture a retailer such as a car dealership when the retailer is only specifying available options, such as power windows, air conditioning, or automatic transmission.

Section 69501.1(a)(45)(A) defines **"materials and resource consumption"** to mean the consumption of renewable and nonrenewable resources that are used for a consumer product throughout its life cycle. This definition is necessary to make an important distinction between renewable and nonrenewable natural resources, which include various finite resources and materials being depleted at an unsustainable rate. The consumption of materials and resources needs to be evaluated during consideration of the product's life cycle as part of the AA. All of the following are measures for determining the amount of materials and resource consumption associated with a Priority Product and alternatives being considered. This definition is necessary to comply with the statutory mandate that the evaluation of chemicals of concern in products and their alternatives include at a minimum "materials and resource consumption," "water conservation," "production, in-use, and transportation energy inputs," and "energy efficiency." (See Health and Safety Code sections 25253(a)(2)(C), (D), (G), and (H).)

Materials and resource consumption. U.S. and global consumption of materials has been increasing rapidly. People have consumed more resources in the last fifty years than all previous history. Of all the materials consumed in the U.S. over the last 100 years, more than half were consumed in the last twenty-five years. This increasing consumption has come at a cost to the environment, including habitat destruction, biodiversity loss, overly stressed fisheries, and desertification. Materials management is also associated with an estimated forty-two percent (42%) of total U.S. greenhouse gas emissions. Failure to find more productive and sustainable ways to extract, use, and manage materials – and change the relationship between material consumption and growth – has grave implications for our economy and society.

By looking at a product's entire life cycle, we can find new opportunities to reduce environmental impacts, conserve resources, and reduce costs. For example, a product may be redesigned so it is manufactured using different, fewer, less toxic, and more durable materials. It may be designed so that at the end of its useful life it can be readily disassembled. A manufacturer may maintain a relationship with the customer to ensure best use of the product, its maintenance, and return at end-of-life. This helps the manufacturer in identifying changing needs of its customers, creating customer loyalty, and reducing material supply risk. Furthermore, the manufacturer has a similar relationship with its supply chain, which helps the manufacturer respond more quickly to changing demands, including reducing supply chain environmental impacts. This definition is necessary to comply with the statutory mandate that the evaluation of

chemicals of concern in products and their alternatives include at a minimum "materials and resource consumption." (See Health and Safety Code section 25253(a)(2)(C).)

Water Conservation. Freshwater is the most fundamental of resources; it has no substitutes for most uses, and is expensive to transport. However, freshwater sources are dwindling or becoming contaminated throughout the world. However, existing technologies offer great potential for improving on the efficiency of its use. This definition is necessary to comply with the statutory mandate that the evaluation of chemicals of concern in products and their alternatives include at a minimum "water conservation." (See Health and Safety Code section 25253(a)(2)(D).)

Energy consumption: production, in-use, and transportation energy inputs. Many industrial processes require large amounts of heat and mechanical power, and about eighty-five percent (85%) of all energy produced in the United States comes from burning fossil fuels. There are a number of environmental problems associated with fossil fuels, most of which stem from the by-products created when they are burned to create energy. These byproducts contribute to global warming, acid rain, and smog formation. Renewable energy resources include wind power, hydropower, solar energy, biomass, biofuel, and geothermal energy. This definition is necessary to comply with the statutory mandate that the evaluation of chemicals of concern in products and their alternatives include at a minimum "production, in-use, and transportation energy inputs." (See Health and Safety Code section 25253(a)(2)(G).)

***Energy efficiency*.** Energy efficiency reduces the use of nonrenewable fossil fuels and their air impacts. The additional environmental benefits of energy efficiency include a decrease in the environmental impacts associated with fossil fuel production and use, a reduction of depletion of energy resources, and improvements in energy sustainability. Although the focus of a sustainable energy policy addresses cleaner and renewable energy, the consideration of energy efficiency is key to attaining sustainability goals. Slowing the growth of energy demand slows down the rate at which conventional energy supplies are depleted, including domestic energy resources. Energy efficiency yields energy and demand savings that can displace electricity generation from coal, natural gas, nuclear power, wind power, and other resources. This definition is necessary to comply with the statutory mandate that the evaluation of chemicals of concern in products and their alternatives include at a minimum "energy efficiency." (See Health and Safety Code section 25253(a)(2)(H).)

Section 69501.1(a)(45)(B) specifies that a renewable resource is a resource that is capable of being replaced by natural processes at a rate that is at least equal to or faster than the rate at which it is consumed. These include solar and wind energy,

timber, agriculture, and water. This term is necessary to assess the impacts on the attributes listed above in the AA and to distinguish these resources from nonrenewable resources.

Section 69501.1(a)(45)(C) specifies that a nonrenewable resource can be an inherently finite resource or a renewable resource being consumed at a rate that will exhaust it. This is key to assessing the use of resources, both short-term and long-term during the AA, and to preserve their regenerative capacity to ensure sustainable development.

Section 69501.1(a)(45)(C)1. specifies that a nonrenewable resource includes an inherently finite resource that is formed over long periods of geologic time, including petroleum, coal, mined and recycled metals, minerals, and other finite resources. These are resources that cannot be renewed on a sustainable basis. Resources like petroleum could potentially be exhausted in the future; while resources like coal and minerals may require more expensive extraction methods as these are found in deeper deposits or in deposits that are less concentrated.

Green energy today relies on multiple advanced technologies like solar cells, hybrid gas-electric motors, compact fluorescent light bulbs, and giant wind turbines. However, these technologies rely on components constructed from a set of minerals known as the rare earth elements. So while the demand is growing for these minerals, the supply is limited by the quantity and the location of these ores.

Section 69501.1(a)(45)(C)2. specifies that a nonrenewable resource can include a renewable resource that is consumed at a rate that will result in exhaustion of the resource. This could potentially apply to forestry practices, fishing, or even water use, depending on proximity to these resources.

Section 69501.1(a)(46) defines **"persistence"** to mean the same thing as the definition of "environmental persistence" in section 69405.3 of OEHHA's regulations. In effect, this cross reference is necessary to ensure the term is consistent with the related Chapter 54 regulations regarding hazard traits.

Persistence is the ability of a chemical to remain in an environment in an unchanged form. Chemicals with long persistence times in media might have a high capacity for uptake by living organisms, and for transport in food chains and food webs, leading to increasing concerns related to the public health and environmental effects.

Data on persistence are very important for hazard assessment of chemicals, but are difficult to obtain, particularly in a form useful for practical purposes, due to the intrinsic

stability of the molecule and the variability of environmental conditions. A chemical's persistence is usually measured or estimated for air, water, soil, and sediment.

Section 69501.1(a)(47) defines **"person"** to mean the same as in Health and Safety Code section 25118. A "person" is an individual, trust, firm, joint stock company, business concern, partnership, limited liability company, association, and corporation, including, but not limited to, a government corporation. "Person" also includes any city, county, district, commission, the State or any department, agency, or political subdivision thereof, any interstate body, and the federal government or any department or agency thereof to the extent permitted by law.

It is important for responsible entities and interested parties to understand that a "person" is more broadly defined than is an individual. This definition is necessary in order for the regulations to have an appropriate scope and to be consistent with other uses in programs administered by DTSC.

Section 69501.1(a)(48) defines **"physical chemical hazards"** to mean physical hazard traits specified in Article 6 of Chapter 54 of OEHHA's regulations, which defines "physical hazard traits" to include combustion facilitation, explosivity, and flammability. By adopting this definition, DTSC has again aligned these regulations with the related regulations in Chapter 54. This definition is necessary to promote consistency and a common understanding of the use of regulatory terms.

Section 69501.1(a)(49) defines **"physicochemical properties"** to mean the physicochemical properties specified in section 69407.2 of OEHHA's regulations, defined to include the following:

- physical state;
- molecular weight;
- density;
- vapor pressure and saturated vapor pressure;
- melting point;
- boiling point;
- water solubility;
- lipid solubility;
- octanol-water partition coefficient, octanol-air partition coefficient, and organic carbon partition coefficient;
- diffusivity in air and water;
- Henry's Law constant;
- sorption coefficient for soil and sediment;
- redox potential;

- photolysis rates;
- hydrolysis rates;
- dissociation constants; and
- reactivity including electrophilicity.

Physiochemical properties are the physical and chemical properties for a chemical that can be observed or measured without changing its composition. The definition is necessary in order for the regulations to be consistent with the use of this term in the relevant scientific community. DTSC has again aligned these regulations with the related regulations in Chapter 54, promoting consistency and a common understanding of the use of regulatory terms.

Section 69501.1(a)(50)(A) defines **"placed into the stream of commerce in California"** to mean that a consumer product has been sold, offered for sale, distributed, supplied, or manufactured in or for use in California as a finished product or as a component in an assembled product. In effect, this term applies to a product when the responsible entity serves the market in the State, or otherwise takes actions consistent with this definition. Products that are leased, sublet, given away, or are otherwise allowed the use of are included as having been supplied. Once a Priority Product is found to be in the State, it will be subject to this regulation. This definition is necessary to maintain a level playing field between all products placed into the California marketplace – both those manufactured in California and those manufactured outside of California. Both are equally subject to these regulations.

Section 69501.1(a)(50)(B) defines **"sold or offered for sale"** to mean any transfer or offer to transfer for consideration of title or the right to use, by lease or sales contract – including transactions conducted and offers made through sales outlets, catalogs, the Internet, or other similar electronic means. This is necessary to advance the goals of the authorizing statute to reduce toxic chemicals in consumer products used by Californians, regardless of a product's point of origin. The definition also does not discriminate between sales at "brick and mortar" establishments and sales made via other mechanisms. This provision is necessary to maintain a level playing field and foster the purpose of the statute: to reduce public health and environmental harm from consumer products.

Section 69501.1(a)(51)(A) defines **"potential"** to mean that the phenomenon described is reasonably foreseeable based on reliable information. This is consistent with Health and Safety Code sections 25252(a)(2) and (3), which mandate that the identification and prioritization process established in the regulations include, at a

minimum, evaluation of the "potential" for exposure to a chemical in a consumer product and "potential" effects on sensitive subpopulations.

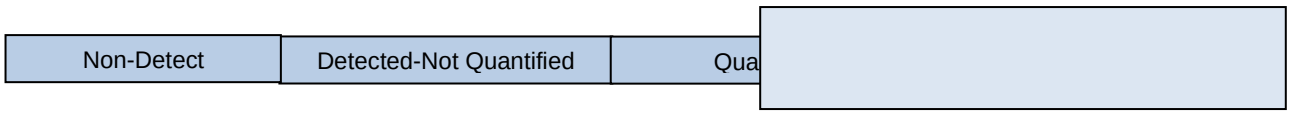
This definition requires that the phenomenon in question be "reasonably foreseeable." Reasonably foreseeable is a term of art in law that means that a reasonable person would be able to predict or expect the ultimately harmful results. This assures that adverse impacts are based on reasonable grounds and probable evidence. This will avoid unwarranted or hypothetical assumptions. Another criterion for this definition is that the determination of "potential" must be based on reliable information (which is defined in the regulations to mean scientific studies or scientific information). This provision is necessary to provide clarity and avoid the use of the term from being vague or unbounded.

In a prior version of the proposed regulations, the term "ability" was used in lieu of "potential." 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. In toxicology, adverse effects are "the empirical manifestation of experienced harm." The term "potential" is a critical definition because the regulations incorporate not only experienced harm but also address a chemical's "potential" to contribute to or cause harm.

Section 69501.1(a)(51)(B) is necessary to clarify that the definition of "potential" does not apply to the use of the term "potential" in the definition of "adverse air quality impacts" (see section 69501.1(a)(2)) or in the title of the document entitled "Reproductive or developmental toxicants identified in Monographs on the Potential Human Reproductive and Developmental Effects, National Toxicology Program, Office of Health Assessment and Translation" (see section 69502.2(a)(1)(M)). In these two instances, the term "potential" needs to be interpreted consistently with its use in the regulatory programs referenced in these two sections of the regulations.

Section 69501.1(a)(52) defines **"Practical Quantitation Limit"** or **"PQL"** to mean the lowest concentration of a chemical that can be reliably measured with statistical rigor (*i.e.*, within specified limits of precision and accuracy) using routine laboratory procedures. This provision is necessary because the default AA Threshold for contaminants is defined as the PQL. If a Priority Product contains the Chemical of Concern as a contaminant below this concentration, an AA is not required. Additional information concerning the AA Threshold and the AA Threshold exemption, and their necessity, is provided in the statement of reasons for sections 69501.1(a)(1)(12), (13), and (26) and section 69505.3.

Figure 1. Practical Quantitation Limit



Section 69501.1(a)(53) defines **"Priority Product"** to mean a product-chemical combination identified and listed as a Priority Product by DTSC under section 69503.5. A Priority Product is the combination of a Candidate Chemical and a product that has been prioritized as a high concern based on potential adverse impacts and exposures. This definition is necessary to distinguish Priority Products from all other products, with respect to the various requirements of these regulations, and to capture the notion that it is the product-chemical combination that constitutes a Priority Product. The application of this term and related concepts are explained in greater detail under Article 3.

"Priority Product" is a key term that is necessary to make specific the intent of the enabling legislation. Health and Safety Code sections 25252 and 25253 require DTSC to establish in regulation processes to identify and prioritize chemicals of concern in consumer products and evaluate those chemicals and their alternatives. This definition is necessary because it makes clear that the "chemical of concern in a consumer product" has been identified and prioritized as the Priority Product subject to the requirement to undergo an AA or other means of complying with Article 5.

Section 69501.1(a)(54) defines **"Product-Chemical Replacement Intent Notification"** and **"Product-Chemical Replacement Confirmation Notification"** to mean the notifications submitted to DTSC under section 69505.2(a)(1)(A)3. This definition is necessary to clarify what is meant by the use of those terms and to indicate where this provision is found in the regulations. These notifications include two

sequential steps – one certifies the intent to replace the Priority Product with another product-chemical combination in the California marketplace followed by a second notification that certifies that the Priority Product has been replaced. This option is restricted to only the manufacturer because manufacturers control the manufacturing process. Additionally, this provision enables DTSC to effectively implement these regulations and the authorizing legislation, as well as to provide a level playing field for those manufacturers who do expend the time and resources to comply with these requirements. See section 69505.2 for further explanation of this provision and discussion of the necessity for these notifications.

Section 69501.1(a)(55) defines **"Product Removal Intent Notification"** and **"Product Removal Confirmation Notification"** to mean the notifications submitted to DTSC under section 69505.2(a)(1)(A)2. This definition is necessary to clarify what is meant by the use of these two terms and to indicate where this provision is found in the regulations. These notifications include two sequential steps – one certifies the intent to remove the Priority Product from the California marketplace followed by a second notification that certifies that the Priority Product has been removed. This option is restricted to only the manufacturer. Additionally, this provision enables DTSC to effectively implement these regulations and the authorizing statutes, as well as to provide a level playing field for those manufacturers who do expend the time and resources to comply with these requirements. See section 69505.2 for further explanation of this provision and discussion of the necessity for these notifications.

Section 69501.1(a)(56) defines **"release"** to mean an intentional or unintentional liberation, emission, or discharge of a chemical into the environment. This definition is necessary to clarify the meaning of the term used in these Chapter 55 regulations, because this term is already defined in section 66260.10, which provides the generic definitions for all of Division 4.5 of Title 22 of the California Code of Regulations.

The existing definition of release in section 66260.10 is any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment, but does not include any release which results in exposure to persons solely within a workplace, with respect to a claim such exposed persons may assert against their employer and other exclusions. This new definition is necessary in order to have a more appropriate definition when evaluating releases of chemicals from consumer products and the potential exposures to the released chemicals.

Section 69501.1(a)(57) defines **"reliable information"** to mean a scientific study or other scientific information that meets the criteria in sections 69501.1(a)(57)(A) and (B).

"Reliable information" is used to define "potential," which is used extensively in the regulations. It is used elsewhere throughout the regulations as well. Reliable information is restricted to scientific studies or scientific information. The term is also used in the regulations to define the types of scientific information that can be used to add or remove chemicals or chemical lists from the Candidate Chemicals list, prioritize product-chemical combinations as Priority Products, verify the conclusions of an AA Report, and impose engineered safety measures or administrative controls as a regulatory response. This definition is necessary to ensure that the decisions that are made are science-based, wherever applicable. The regulations require the use of non-science information as well (*e.g.*, information such as product market volumes and use of products will be used in the product-chemical prioritization process).

The concept of "other scientific information" is necessary because there are scientific methods that are not studies, such as analytical chemistry methods, assays, and quantitative structure-activity relationships (QSARs) that are important to support the identification of Candidate Chemicals and prioritization of product-chemical combinations as Priority Products. This will be especially important because the trend in toxicology is to move from a system based on whole-animal testing to one founded primarily on in vitro methods that evaluate changes in biologic processes.

Analytical chemistry methods identify and/or quantify chemical components of natural and artificial substances. For example, laboratory analytical testing needed for documenting the AA Threshold includes the use of laboratory instruments to measure the physical quantities of the analyte, such as an inductively coupled plasma mass spectrometer. An assay is an investigative (analytic) procedure in laboratory medicine, pharmacology, environmental biology, and molecular biology for qualitatively assessing or quantitatively measuring the presence or amount or the functional activity of a target entity (the analyte). In other words, assays measure something and can be as simple as something is present, or they can be quantitative to determine exactly how much is present.

QSAR is an approach designed to find relationships between chemical structure (or structural-related properties) and biological activity (or target property) of studied compounds. As such, it is the concept of linking chemical structure to a chemical property (*e.g.*, water solubility) or biological activity including toxicity (*e.g.*, fish acute mortality). Qualitative quantitative relationships are derived for continuous data (*e.g.*, toxic potency data). QSARs correlate measurable or calculable physical or molecular properties to some specific biological activity in terms of an equation. Once a valid QSAR has been determined, it should be possible to predict the biological activity of a related chemical before biological testing is done.

Section 69501.1(a)(57)(A) specifies the types of scientific studies and other types of scientific information that will be considered to be "reliable information" for purposes of these regulations. This provision is necessary to ensure that DTSC uses information that is generally considered reliable in the scientific community for the purpose of implementing these regulations. The sources of the scientific studies must meet both of the criteria described in sections 69501.1(a)(57)(A) and (B). Reliable information may include, for example, mechanistic data, environmental monitoring data and animal or human scientific studies; but must also meet one or more of the criteria in sections 69501.1(a)(57)(A)1. through 4. DTSC will evaluate "reliable information" obtained from the sources listed in sections 69501.1(a)(57)(A)1. through 4. for suitable use in meeting the purposes of these regulations.

As an example, the Information Quality Act (Section 515 of Public Law 106-554 (Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153-154 (2000))) defines scientific information and scientific assessments. The term "scientific information" means factual inputs, data, models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms.

The Information Quality Act also defines "scientific assessment" to mean an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to: state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.

It is important to clarify that there may be valid scientific studies or other scientific information that may not initially meet the "reliable information" definition, but would be relevant and important to consider for these regulations. For instance, a manufacturer or other interested party 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 3. In this situation, a manufacturer may submit this information in response to an information request from DTSC under section 69501.4, or the manufacturer may submit the information to DTSC on its own initiative. In so doing, the scientific study or information will meet the first condition of

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.

DTSC will evaluate reliable information gathered or received, using the information quality criteria specified in section 69503.2(b)(1)(C), to substantiate the existence or absence of potential adverse impacts or exposures when considering the listing of Candidate Chemicals and Priority Products. In evaluating reliable information obtained for this purpose, an aspect of scientific study acceptability in the scientific community is the ability to have another researcher conduct the same study, using the same conditions, and achieve the same or similar results. In this manner, the original study's results and conclusions are validated. The more the study is repeated with the same or similar results, the more the scientific community will accept the study's results/conclusions. The study may be repeated with slight variations in the study parameters to determine when changes in the results start occurring. This is done to examine the boundaries of the results/conclusion. These studies also contribute to the acceptability of the conclusions reached by the studies.

While repeating scientific studies to confirm their results is the ideal situation to validate results and advance public policy decisions, studies are very expensive and often take years to complete. 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 a scientific study for acceptance as reliable information, DTSC will consider: (i) the quality criteria specified in section 69503.2(b)(1)(C); and (ii) the definitional criteria in section 69501.1(a)(57)(B), which requires scientific studies considered as "reliable information" to be based on a study design that is appropriate to the hypothesis being tested and sufficient to support the propositions for which the study is presented to DTSC. This might include, for example, evaluation as to 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. Examples of guidance that DTSC might consider are the following:

- U.S. Food and Drug Administration Good Laboratory Practices (Part 58 of Title 21 of the Code of Federal Regulations);
- U.S. EPA's Office of Chemical Safety and Pollution Prevention Harmonized Test Guidelines;
- Toxic Substances Control Act (TSCA) (Chapter 1 of Title 40 of the Code of Federal Regulations);
- TSCA Testing Guidelines (Parts 798 and 799 of Title 40 of the Code of Federal Regulations);

- Organization for Economic Co-operation and Development (OECD) Guidelines for Testing of Chemicals;
- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring;
- OECD Manual for Investigation of High Production Volume Chemicals;
- Registration, Evaluation, Authorisation and Restriction of Chemicals/European Chemicals Agency Guidance on Information Requirements and Chemical Safety Assessment and Regulation (EC) No. 440/2008 of the European Parliament and the Council; and
- Canadian Environmental Protection Act Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers.

However, it is emphasized that studies conducted under the examples provided above are not the only methods to determine “acceptance” and, therefore, status as reliable information. There is vast and informative scientific literature produced by academic institutions, which may also be considered under these regulations. The purpose of academic institutions is to gain and expand on the existing body of knowledge through scientific research, not necessarily to conduct studies that meet specific guidelines for regulatory compliance. Additionally, established guidelines simply cannot keep up in real time with scientific knowledge and advances.

There are many new and valuable methods of assessing chemical toxicity, for which there are no official guidelines from OECD or other institutions. Because guideline methods such as OECD’s (recommended in some of the public comments on these regulations) 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 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. Caution must also be used when evaluating scientific studies that use guidelines of other authoritative organizations to consider the underlying principles and purposes of the guidelines and the study itself, since not all guidelines such as those examples listed above were prepared with protection of public health and the environment as the primary foundational purpose. For example, OECD, while giving consideration to environmental policy is primarily focused on economic vitality and growth. For these reasons, it is necessary for DTSC to evaluate scientific studies, on a case by case basis, using expert judgment to determine whether they are acceptable for purposes of these regulations.

Some other types of information, such as analytical protocols submitted to DTSC, may be evaluated for acceptability using similar methods to evaluate a scientific study. Other relevant information will be reviewed on a case-by-case basis to determine whether the information is acceptable as reliable information for the purpose of these regulations. Overall, this definition is necessary to distinguish the types of scientific information that is of sufficient rigor such that it is appropriate for consideration in this regulatory program from information that is not.

Section 69501.1(a)(57)(A)1. identifies as reliable information scientific studies and other scientific information published in a scientifically peer reviewed report or other literature. Peer review is an essential arbiter of scientific quality. The scientific community uses peer review to maintain standards of quality, improve performance, and provide credibility. Thus, this provision is meant to increase the quality and credibility of the scientific information used in the implementation of these regulations. The peer review process subjects scientific research papers to independent scrutiny by other qualified scientific experts (peers) before they are made public. The selection of participants in a peer review is based on expertise, with due consideration of independence and conflict of interest.

Section 69501.1(a)(57)(A)2. identifies as reliable information scientific studies and other scientific information published in a U.S. National Academies report. Congress has assigned the National Academies of Science a special role in advising the federal government on scientific and technical issues. The procedures of the National Academies of Science are generally quite rigorous, and thus agencies should presume that major findings, conclusions, and recommendations of National Academies of Science reports meet the quality standards of these regulations. For example, the U.S. EPA referred their report entitled “Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (2002 External Peer Review) Draft Report” to the National Academy of Sciences' (NAS) National Research Council (NRC) for review. This NAS committee was composed of fifteen leading physicians and scientists with a combined range of expertise to evaluate every scientific aspect of the perchlorate database and of the U.S. EPA’s assessment of that database.

Section 69501.1(a)(57)(A)3. identifies as reliable information scientific studies and other scientific information published in a report by an international, federal, state, or local agency that implements laws governing chemicals. Many other governmental agencies implement laws governing chemicals may have reports relevant to the regulations, such as the United Nations, European Union, Australia, Canada, Washington, Maine, and the U.S. EPA. Scientific information that these governmental agencies have published in reports, especially if the report will have substantial impact

on important public policies or private sector decisions, are typically subject to rigorous evaluations, peer review, and public comment. For example, the U.S. Office of Management and Budget has established government-wide Information Quality Guidelines to improve and ensure the quality of the scientific information upon which policy decisions are based. This provision, along with sections 69501.1(a)(57)2. and 4.,is consistent with the directive in the authorizing statute (Health and Safety Code section 25252(b)(2)) for DTSC to use, to the maximum extent feasible, available information from other authoritative bodies that have undertaken similar chemical prioritization processes, so as to minimize costs and maximize benefits for California's economy.

Section 69501.1(a)(57)(A)4. identifies as reliable information scientific studies and other scientific information conducted, developed, submitted, prepared for, or reviewed by an international, federal, state, or local agency (including DTSC) for compliance or other regulatory purposes. This provision will be critical for maximizing the amount of reliable information available to implement these regulations, because if scientific information is provided to DTSC that does not meet the criteria in sections 69501.1(a)(57)(A)1. through 3., -- if DTSC reviews and accepts the information, the information will then meet the definition of reliable information. This provision would include information developed or commissioned by industry, NGOs, and other interested parties, as long as DTSC or another regulatory agency reviews the information and accepts it.

Section 69501.1(a)(57)(B) requires that for a scientific study to be considered reliable information, the study design must be appropriate to the hypothesis being tested, and sufficient to support the proposition for which the study is presented to DTSC. Basic scientific methodology includes a hypotheses, and experimental studies to test these hypotheses via predictions that can be derived from them. These steps must be repeatable, to guard against mistake. This provision is necessary to ensure that the study is adequately designed to support the results and answer the regulatory question.

Section 69501.1(a)(58) defines **"reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical"** to mean any of the types of information described below under sections 69501.1(a)(58)(A) through (E) that meet the definition of reliable information specified in section 69501.1(a)(57). This definition is necessary to clarify the types of information that qualify as evidence of an occurrence or potential occurrence of exposure and to have that definition conform to existing general scientific approaches and concepts.

"Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" (Reliable Information Demonstrating Exposures) is a subset of "reliable information," and is necessary to expressly define the types of reliable information that could demonstrate the occurrence or potential occurrence of exposures. The definition of "Reliable Information Demonstrating Exposures" provides DTSC and responsible entities methods to assess exposures to the chemical of interest. It is important to note that these methods demonstrating exposure must satisfy the definition of "reliable information." Each of the particular means of satisfying this definition and the necessity for them is discussed below.

Section 69501.1(a)(58)(A) describes exposure demonstrated through various monitoring information. Any chemical presence in an indoor setting may be considered reliable information showing exposure. In addition, data showing chemical accumulation or persistence in the environment or accumulation in flora or fauna are also considered indications of exposure. While mere presence may not be caused by a chemical in a product, the chemical presence is indicative of releases from a source, including the chemical in a product making it a potential source of exposure.

Section 69501.1(a)(58)(A)1. specifies that monitoring data showing a chemical to be present in household dust, indoor air, drinking water, or on interior surfaces should be considered in evaluating the occurrence or potential occurrence of exposures to a chemical. This is necessary to protect sensitive subpopulations such as infants, children, pregnant women, and elderly individuals. A residential setting would pose the highest probability of exposure due to time and proximity.

Section 69501.1(a)(58)(A)2. specifies that monitoring data showing a chemical to be present in, or released from products used in or present in, homes, schools, or places of employment would be considered a potential occurrence of exposures to a chemical. These are locations where sensitive subpopulations spend most of their time during the day and throughout the year.

Sections 69501.1(a)(58)(A)3. and 4. address monitoring data the show chemicals accumulating or persisting in the environment or in aquatic, avian, animal, or plant species. Generally, persistent accumulators are chemical substances that partition to water, sediment, or soil and are not removed at rates adequate to prevent their accumulation in aquatic, terrestrial, or plant species. Some of these chemicals have been identified by authoritative bodies as priority pollutants and potential risks to humans and ecosystems. The classic accumulative and persistence problems have been associated with food chain contamination, such as Polychlorinated biphenyl (PCBs), and Dichloro diphenyl trichloroethane (DDT). Monitoring for these chemicals is

important because, in general, measured values of accumulation and persistence, provided the data are of acceptable quality, are preferred over those that are predicted or estimated via a model or computer program.

Section 69501.1(a)(58)(B) specifies that a chemical identified as present in human organs, tissues, or fluids can be considered the occurrence or the potential occurrence of exposure to the chemical, and identifies sources of biomonitoring information in humans. While chemical presence in humans may not be directly caused by a chemical in a product, the biomonitoring information shows that exposure is occurring.

We come into contact with many chemicals each day that are used in industry and agriculture. These chemicals can be found in common products, such as cosmetics, toys, and plastics. Some of these chemicals get into our air, water, soil, dust, and food. As a result, all of us have chemicals in our bodies.

Biomonitoring is the measurement of chemicals (or their metabolites) in a person's body fluids or tissues, such as blood or urine. It tells us the amount of the chemical that actually gets into people from all sources (*e.g.*, from air, soil, water, dust, and food) combined. Because of this, biomonitoring can provide useful information on how much exposure to toxic chemicals a person has had and helps us determine how these chemicals affect our health.

Section 69501.1(a)(58)(B)1. specifies that data collected by the California Environmental Contaminant Biomonitoring Program can be used to demonstrate the occurrence or the potential occurrence of exposure. The California program includes sampling for halogenated organic compounds, volatile organic compounds, pesticides, metals, phthalates, and polychlorinated biphenyls, to name a few. These designated chemicals are the pool of chemicals from which the highest priority chemicals are selected for biomonitoring. Designated chemicals consist of those chemicals that are included in the Centers for Disease Control and Prevention's national biomonitoring program, as well as additional chemicals meeting certain criteria.

Section 69501.1(a)(58)(B)2. specifies that the data collected by the U.S. Centers for Disease Control and Prevention can be used to demonstrate the occurrence or the potential occurrence of exposure. The Centers for Disease Control obtains and releases health-related data for over 200 chemicals from a nationally representative sample in two-year cycles. The biomonitoring is a series of ongoing assessments of the U.S. population's exposure by measuring chemicals in people's blood and urine. The biomonitoring reports provide unique exposure information to scientists, physicians, and

health officials to help prevent effects that may result from exposure to environmental chemicals. Specific public health uses of the exposure information are to:

- determine which chemicals get into Americans' bodies and at what concentrations;
- determine what proportion of the population has levels above those associated with adverse health effects for chemicals with a known toxicity level;
- establish reference values that can be used by physicians and scientists to determine whether a person or group has an unusually high exposure;
- assess the effectiveness of public health efforts to reduce exposure of Americans to track levels over time;
- determine whether exposure levels are higher among minorities, children, women of childbearing age, or other special groups; and
- direct priorities for research on human health effects from exposure.

Section 69501.1(a)(58)(C) relies on information that is predictive of exposure based on calculations that are described in Article 5 of Chapter 54 as evidence for the hazard traits bioaccumulation, persistence, and lactational or transplacental transfer.

Section 69501.1(a)(58)(C)1. specifies that bioaccumulation is considered the occurrence or the potential occurrence of exposure. Bioaccumulation is defined in section 69405.2 as the "accumulation of a chemical substance in the tissue of organisms through any route, including respiration, ingestion, or dermal, including direct contact with contaminated water, sediment, and pore water in the sediment, or through transfer up the food chain." Evidence of this hazard trait may include thresholds or results from bioaccumulation models indicating potential for bioaccumulation; or if a chemical has structural similarity to other bioaccumulative chemicals. Animals and people accumulate these chemicals in their bodies. As these chemicals move up the food chain, they increase in concentration, and linger for generations in people and the environment.

Section 69501.1(a)(58)(C)2. specifies that persistence is considered the occurrence or the potential occurrence of exposure. Persistence is defined in section 69405.3 as "the propensity for a chemical substance to remain in the environment for a long time period subsequent to its release by resisting chemical and biological degradation." Evidence of this hazard trait may include thresholds or if a chemical has structural similarity to other persistent chemicals. These chemicals remain in the environment for a long time without breaking down. Persistent chemicals resist environmental degradation and can accumulate in soil and aquatic environments. Humans and animals are more likely to

be exposed to a chemical if the chemical does not easily degrade, or is dispersed widely in the environment.

Section 69501.1(a)(58)(C)3. specifies that lactational or transplacental transfer is considered an occurrence or the potential occurrence of exposure. Lactational or transplacental transfer is defined in section 69405.5 as "the ability of a chemical substance to transfer from the mother's tissues into breast milk or across the placenta." Evidence of this hazard trait may include biomonitoring data or pharmacokinetic properties that may lead to transfer of a chemical to breast milk or a fetus. This provision is necessary to protect sensitive subpopulations, such as fetuses and infants.

Section 69501.1(a)(58)(D) specifies that exposure or environmental modeling may be used to determine exposures or potential exposures to a chemical of interest. This type of modeling can be used to assess the release of a chemical, through transport (fate and transport), to its effect in a biological system. Exposure modeling may be used to measure how much of a chemical can be absorbed by an exposed target organism, in what form, at what rate, and how much of the absorbed amount is actually available to produce a biological effect.

Section 69501.1(a)(58)(D)1. specifies that an exposure point concentration associated with an adverse impact may indicate exposure or potential exposure. An exposure point concentration is an estimate of the true arithmetic mean concentration of a chemical in a medium at an exposure point. The concept of exposure point concentrations is used to quantify the amount of exposure from a contaminant that is likely to occur for each type of population that is potentially exposed. Thus, this provision would allow modeling using the exposure point concentration to compare against known thresholds for adverse impacts.

Section 69501.1(a)(58)(D)2. specifies that the environmental accumulation of a chemical may indicate exposure or potential exposure. Accumulation may also be modeled to estimate the environmental accumulation of a chemical in the environment. There are various models that could meet these criteria, such as equilibrium partitioning models, fugacity models, or food web models. Predictive modeling can also be used to estimate the extent and/or pattern of bioaccumulation of specific substances under specified exposure conditions and can be used when it is not practical to directly measure chemical concentrations.

This provision is necessary because the interpretation of exposure data is complicated by numerous factors, including variability in chemical bioavailability due to seasonal and physicochemical conditions. Modeling that indicates exposure point concentrations

associated with adverse impacts or the environmental accumulation of a chemical can be used when direct measurements are not possible.

Section 69501.1(a)(58)(E) is specific to monitoring data related to solid waste, wastewater, biosolids, or storm water streams collected and managed by the State or local agencies. Specific aspects of collection and treatment systems pose an exposure to the public and environment because without proper wastewater or storm water treatment or removal of the chemical of interest, exposure to the public, flora, and fauna will occur via the waters of California. This provision is necessary as evidence for adverse waste and end-of-life effects, which is critical for any impacts during a product's end-of-life phase.

Section 69501.1(a)(58)(E)1. specifies that monitoring data that indicates a chemical or its degradation product are found in concentrations or volumes that potentially contribute to or cause adverse impacts would qualify as reliable information demonstrating the occurrence or potential occurrence of exposure. This provision is necessary to document when a chemical has created an adverse impact during the end-of-life phase.

Section 69501.1(a)(58)(E)2. specifies that expenditure of public funds to mitigate potential adverse impacts associated with the chemical or its degradation products demonstrates occurrence or potential occurrence of exposure. While the expenditure of funds to treat the chemical of interest is not directly related to exposure, it is an important consideration in that until funds are available to treat or remove the chemical of interest, exposures may occur. Along the same line of thought, lack of funds to remove or treat the chemical of interest in order to recycle or reuse wastewater sludge will potentially result in exposures to flora and fauna if used as a soil amendment.

Section 69501.1(a)(58)(E)3. specifies that increased costs for reusing or recycling materials containing the chemical or its degradation products may demonstrate potential exposures to a chemical. When the costs of reusing or recycling a solid waste is increased, there may not be enough economic incentives to recycle these waste streams, thus depleting resources and increasing the generation of solid waste requiring disposal. A waste stream that is recycled or reused to make another product without eliminating the chemical contaminants will reintroduce the chemical into commerce and create another potential exposure to the chemical.

Section 69501.1(a)(58)(E)4. specifies that interference with the proper operation of solid waste, wastewater, or storm water treatment systems – that results in the discharge of the chemical or its degradation products to the environment –

demonstrates occurrence or potential occurrence of exposure. Wastewater and storm water collection and treatment systems operate under a permit to protect public health and the environment. Prior to discharge into waterways, these treatment systems must meet certain discharge requirements. If the treatment system is not operating correctly as shown by either violations of their permit or exceedances of regulatory thresholds for chemicals being monitored, the result is an increased likelihood of exposures via the waters to the public and the environment.

Biosolids are sewage sludge that has been treated and tested and shown to be capable of being beneficially and legally used as a soil amendment as specified under Title 40, Code of Federal Regulations Part 503. In August 2000, the State Water Resources Control Board adopted the General Order for General Waste Discharge Requirements for the Discharge of Biosolids to Land for Use in Agricultural, Silvicultural, Horticultural, and Land Reclamation Activities in California. The general order establishes a notification and permit review process applicable to all persons and public entities intending to apply biosolids to land for the purposes stated above. Chemicals that pass through water treatment plants and impact the quality of these biosolids can potentially disqualify the beneficial use of these biosolids and require the biosolids to be disposed of as hazardous waste.

Section 69501.1(a)(58)(E)5. specifies that exceeding regulatory thresholds for chemicals or their degradation products demonstrates the occurrence or potential occurrence of exposure to a chemical when this occurs in a volume or concentration that impacts the environment. This may lead to impaired water bodies, which compromises the beneficial uses of the waters of California. Many of these beneficial uses protect habitat, aquatic species, endangered species, or fisheries.

Section 69501.1(a)(58)(E)6. specifies that violating permits issued to facilities that manage solid waste, wastewater, biosolids, or storm water is considered a potential exposure. Facilities that exceed their discharge permits, improperly manage their storm water runoff, or otherwise release chemicals into the environment are creating the potential for exposures to these mismanaged chemicals.

Overall, section 69501.1(a)(58) is necessary to provide the criteria for the type of information that qualifies as evidence of an occurrence or potential occurrence of exposures to chemicals and ensure conformance to existing general scientific approaches and concepts. The provision allows actual monitoring data, evidence of potential exposure hazard traits, and modeling to demonstrate this exposure potential, provided the scientific information meets the definition of “reliable information.”

Section 69501.1(a)(59) defines **"replacement Candidate Chemical"** or **"replacement chemical"** to mean 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 meets one of the criteria specified in sections 69501.1(a)(59)(A) and (B). These two provisions are described more fully immediately below.

Section 69501.1(a)(59)(A) specifies the most commonly understood scenario for a replacement chemical, which is a chemical that is not present in the Priority Product. For example, Chemical A, not previously in the Priority Product replaces the Chemical of Concern that led to the listing of the product as a Priority Product. More importantly, the provision makes it clear that a Chemical of Concern can be replaced by a Candidate Chemical as an alternative to the Priority Product.

Section 69501.1(a)(59)(B) makes it clear that a chemical that is present in the Priority Product can qualify as a replacement chemical in an alternative. However, there is a condition – the replacement chemical must exist at a higher concentration in the alternative than it currently exists in the Priority Product relative to any other chemicals in the Priority Product, other than the Chemical(s) of Concern. For example, solder is a metal alloy that can be composed of tin, lead, bismuth, and other metals. If the Priority Product were identified as lead in solder, then tin if it already exists in solder could be considered a replacement chemical if the concentration of lead can be reduced by raising the concentration of tin. This replacement chemical provision may not apply to all situations. First, there may not be a chemical in the Priority Product that can replace the Chemical of Concern in the Priority Product. Secondly, this provision may be more applicable to formulations or homogenous materials. This provision is necessary to allow the use of an existing chemical in a Priority Product to be considered a replacement chemical.

Section 69501.1(a)(60) defines **"responsible entity"** to establish the persons who are required to comply with these regulations. All four of the entities listed below are encompassed in the definition of "responsible entity":

Section 69501.1(a)(60)1. *Manufacturer* - incorporates section 69501.1(a)(44) into the definition of "responsible entity."

Section 69501.1(a)(60)2. *Importer* - incorporates section 69501.1(a)(39) into the definition of "responsible entity."

Section 69501.1(a)(60)3. *Assembler* - incorporates section 69501.1(a)(16) into the definition of "responsible entity."

Section 69501.1(a)(60)4. *Retailer* - incorporates section 69501.1(a)(61) into the definition of "responsible entity."

The definition of "responsible entity" is a naming convenience to collectively refer to all of the above four definitions. This provision is necessary to have a simple means of referring to responsible entities.

There are some provisions in the regulations that are specific to retailers and assemblers due to their status that is distinct from manufacturers and importers. However, including retailers and assemblers as responsible entities is necessary to ensure that there is at least one entity in the product supply/sales chain that has responsibility for carrying out various duties under these regulations and that is under the jurisdiction of DTSC. That is, both the manufacturer and importer may be headquartered outside of California, making it legally and practically difficult for DTSC to compel compliance by manufacturers and importers with the regulatory requirement; however, DTSC does have mechanisms (see section 69501.2) to compel compliance from California retailers and assemblers (if the assembler is located in California). As explained under section 69501.2, retailers and assemblers can opt to cease ordering a non-compliant product rather than taking on the burden of complying with the AA and regulatory response requirements themselves. Overall, this definition is necessary to establish an appropriate scope of who must comply with these regulations.

This definition is not limited solely to the manufacturer, importer, assembler, and retailer of a Priority Product. This is because the responsible entity is also required to comply with regulatory responses, if any, imposed by DTSC; and the regulatory response may pertain to an alternative that is not the Priority Product. Therefore, the term "responsible entity" is not restricted to the term "Priority Product." Rather, the term responsible entity applies in reference to any product subject to these regulations.

Section 69501.1(a)(61) defines **"retailer"** to mean a person to whom a consumer product (that is subject to the requirements of these regulations) is delivered or sold for purposes of sale or distribution by that person to a consumer. This does not include wholesalers or suppliers that normally sell their products to another business. This definition is necessary in order for the term to be consistent with typical usage of this term in the world of commerce and to make it clear as to which entities are subject to the provisions of the regulations applicable to retailers.

Section 69501.1(a)(62) defines **"safer alternative"** to mean an alternative that, in comparison with another product or product manufacturing process, has reduced potential adverse impacts and/or exposures associated with Candidate Chemicals, Chemicals of Concern, and/or replacement chemicals, whichever are applicable. "Alternative" is already defined in Section 69501.1(a)(10). The term "safer alternative" is necessary to advance the purpose and intent of the enabling legislation to develop consumer products that are incremental improvements over time, thus, moving toward "safer" products. The term does not necessarily mean that the alternative is safe, especially if it is not technologically or economically feasible to implement.

Section 69501.1(a)(63) defines **"sales outlet"** to mean any place at which consumer products are sold, supplied, or offered for sale directly to consumers in California. Disclosure of sales outlets is required to be provided in AA Reports and in various notifications in the regulations, including the Priority Product Removal Notification, Priority Product Replacement Notification, and Priority Product Cease Ordering Notification. This information is necessary as relevant and helpful to DTSC in its efforts to determine sales volume in California of a consumer product, as is required by the authorizing legislation when identifying and prioritizing chemicals and products. (See Health and Safety Code section 25252(a)(1).) This information is also needed by DTSC for compliance and enforcement purposes.

Section 69501.1(a)(64) defines **"sensitive subpopulations"** to identify subgroups that comprise a meaningful portion of the general population that are identifiable as being at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait. This provision defines sensitive subpopulations to include, but not be limited to, infants, children, pregnant women, and elderly individuals. This definition is necessary to implement the statutory mandate that the regulations establish a prioritization process that includes consideration of the potential effects on sensitive subpopulations, including infants and children. (Health and Safety Code section 25252(a)(3).) This provision is also necessary to make specific the reference specified in the enabling legislation, at Health and Safety Code section 25253(a)(2)(K). The term "sensitive population" is defined more broadly than the statutory language (infants and children), as is allowed by Health and Safety Code section 25252(a).

"Sensitive subpopulations" can be thought of as groups of individuals who respond biologically at lower levels of exposure to a contaminant or who have more serious health consequences than the general population. The definition that DTSC has adopted addresses important factors to be considered including life stages, gender, genetic traits, health status, and exposure. As there is no universally accepted definition of the term "sensitive subpopulation," the definition used is intended for the

purposes of this regulation and furthers the purposes of the authorizing statute to protect “sensitive subpopulations.” It is also consistent with a broad, health-protective approach to protect the most vulnerable members of society as DTSC adopts and implements these regulations.

This definition also includes those individuals who have a greater risk of adverse health effects when exposed to chemicals because of a history of serious illness, greater exposures to chemicals, or with greater exposures to chemicals due to the nature of their occupation. Exposures to chemicals may exacerbate existing serious or chronic illness or disease, thereby increasing an individual’s susceptibility to adverse health impacts. For example, individuals with asthma, bronchitis, emphysema, or other upper respiratory illnesses are often more susceptible to adverse health effects caused by poor air quality. Some workers experience chemical exposures at higher levels and/or longer duration than the general public. Individuals living next to manufacturing sites can be exposed as products are manufactured in, stored in, or transported through their communities.

In evaluating chemicals for possible additions to the Candidate Chemicals lists, DTSC may give special consideration under Article 2 to a chemical if it contributes to or causes adverse impacts to sensitive subpopulations. Sensitive subpopulations are also given special consideration when products are prioritized under Article 3.

Section 69501.1(a)(65) defines "**technically feasible”** to mean that the technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement an alternative product or replacement chemical. This provision is necessary to ensure that there is a technical ability to develop and produce an alternative, and is referred to in Article 3, Article 5, and Article 6. As part of a determination of whether there is a readily available alternative, an alternative needs to meet the criteria for “functionally acceptable”, “technically feasible”, and “economically feasible” (see sections 69503.2(b)(3), 69505.4(b), 69505.6(a)(2)(C), 69506(a), 69506.5(b), and 69506.8).

The term “technically feasibility” establishes the criteria to determine if there are resources available to achieve implementation of the alternative. This evaluation may, for example, consider the generation of knowledge about the product’s or process's design, performance, production requirements, preliminary production costs, and level of resources needed and available.

The provisions of the regulations related to “technically feasible” ensure that an alternative is readily available.

Section 69501.1(a)(66) defines **"trade secret"** to mean the same as the definition in Civil Code section 3426.1(d). "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (1) derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

This definition in the California Civil Code is a codification of the Uniform Trade Secrets Act, which has been enacted into law by many states. DTSC has chosen to adopt this frequently used definition into these regulations for several reasons. This definition is necessary so that the usage is consistent with other uses in California regulatory regimes, is flexible enough to be suitable for these regulations, and has a substantial body of law and guidance developed regarding its application.

[Note: The California Public Records Act requires State agencies to provide public records to any member of the public. These "public records" include any writing containing information relating to the conduct of the public's business prepared, owned, used, or retained by any State or local agency regardless of physical form or characteristics. However, trade secrets are not considered public records that must be produced under these regulations.]

Section 69501.1(a)(67) defines **"useful life"** to mean the period of time during which a product can be used as intended. It may be expressed in terms of single use, number or applications, or days, months, or years of use. This definition is necessary to make specific the provisions in Health and Safety Code section 25253(a)(2)(B) and Article 5 of these regulations requiring a responsible entity to take into account and evaluate the useful life of the Priority Product in comparison to any alternative that is considered.

§ 69501.2. Duty to Comply and Consequences of Non-Compliance

Section 69501.2, in its entirety, sets out the responsibilities for compliance with the requirements of these regulations, and provides certain compliance options for responsible entities. This section also specifies the consequences of non-compliance, which include the placement of the responsible entity's name along with the name of the affected product on DTSC's Failure to Comply List.

A "responsible entity" means a manufacturer, importer, assembler, or retailer of the consumer product (see section 69501.1(a)(60)). 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. In fact, most of the consumer products in California's stream of commerce are manufactured by persons that have no presence in California and in many cases no presence in the United States. Due to these circumstances, DTSC determined that the option of placing the duty to comply with these regulations solely on the product's manufacturer was not viable or desirable for the following reasons:

(i) DTSC's ability to implement the directives of Health and Safety Code sections 25252 and 25253 requires that DTSC be able to compel and enforce compliance with the requirements of these regulations. In the case of the many product manufacturers that have no presence in California, DTSC has no practical, and in most cases no legal, ability to compel such manufacturers to comply with these requirements.

(ii) In light of the practical and legal limitations identified above, placing the duty to comply solely on product manufacturers would create a significantly uneven playing field for California product manufacturers.

Consequently, it is necessary that the duty to comply with the requirements of the regulations (*e.g.*, notifications, Alternatives Analysis (AA), and regulatory responses) fall to all responsible entities (as defined in these regulations) for a product subject to those requirements. However, as long as one of the responsible entities fulfills an applicable requirement, all of the responsible entities for the product are deemed to be in compliance with that requirement. This is similar to the duty to comply approach embodied in other California statutes and regulations that impose requirements on products that are sold in California, but manufactured both in-state and out-of-state (for example, California's Toxics in Packaging Prevention Act, article 10.4 of chapter 6.5 of division 20 of the Health and Safety Code). As another example, the Fair Packaging and Labeling Act only requires a single entity to be identified on the packaging. The manufacturer, the packer, or the distributor may comply with this labeling requirement. Similarly, these regulations allow for various responsible entities to comply with the regulatory requirements applicable to their mutual Priority Product. These regulations set up an appropriate hierarchy regarding which of the responsible entities has the primary and secondary duty to comply. That hierarchy is discussed in greater detail below.

Section 69501.2(a) provides criteria for when a responsible entity is required to comply with the regulations. The substantive requirements of the regulations include section 69503.7 (Priority Product Notification), Article 5 (AAs and AA Reports), and Article 6 (Regulatory Responses). While any one of the responsible entities for a Priority Product can comply with substantive requirements (with some limited exceptions as specified in

sections 69501.2(a)(1)(B) and (C)), there are various regulatory options available to each type of responsible entity. It is necessary to assign responsibilities based on the entity's control of the manufacturing process and the entity's control of the placement of the product into the stream of commerce in California.

Section 69501.2(a)(1)(A) specifies that the product manufacturer has the principal duty to comply with all of the regulatory requirements applicable to responsible entities for that product. If the manufacturer fails to comply, the compliance responsibility then falls on the importer. This duty is triggered once DTSC has provided a notice to the importer under section 69501.2(c)(1) of the manufacturer's failure to comply.

The secondary duty to comply falls on retailers and assemblers (if applicable), if the manufacturer and importer have both failed to comply. Retailers and assemblers will be notified via web posting on the Failure to Comply List under section 69501.2(c) if the manufacturer and the importer have failed to comply. Each retailer or assembler can then determine if it will cease ordering the product or take on the responsibility for complying with the requirement(s) that the manufacturer and importer have not complied with (e.g., AAs, required notifications and document submittals, and any imposed regulatory responses).

Logically and practically, a product's manufacturer should be the entity that conducts an AA and implements regulatory responses for the product. However, as explained above under section 69501.2 and below under section 69501.2(b), there are significant practical and legal limitations on DTSC's ability to compel an unwilling out-of-state or out-of-country manufacturer to comply with these regulatory requirements. The same may be true with respect to the importer who typically is most responsible for bringing the product into the U.S. and perhaps also California. Thus, the need for the tiered duty to comply approach set out in section 69501.2. After the manufacturer and importer, the next major point in the supply chain with responsibilities relating to a Priority Product is the assembler in those cases where the Priority Product is a component used in a larger multi-component product. Like manufacturers and importers, assemblers often will not be domiciled in California. This will typically leave the retailer who sells the product in California as the only entity in the supply chain that DTSC can compel to comply with the requirements of these regulations. It is anticipated, however, that most retailers and assemblers will not have the desire and/or ability to, for example, conduct AAs and implement regulatory responses. Therefore, the regulations provide the option for retailers and assemblers to cease ordering the product for sale in California (or for use as a component in product that will be sold in California) in lieu of conducting AAs, implementing regulatory responses, and complying with other regulatory requirements. This tiered approach to duty to comply is necessary to place primary responsibility for

conducting AAs and implementing regulatory responses where it most logically and practically belongs – with the manufacturer; and to provide a mechanism for DTSC to compel compliance with the requirements of these regulations or alternatively compel removal of the product from the California marketplace, which in many cases can only be done through retailers of the product. Both outcomes – compliance with the AA and regulatory response requirements or removal of the product from the California marketplace – will achieve the fundamental goals of the regulations and the enabling legislation by eliminating the exposure of California's citizens and environment to adverse impacts posed by the Chemicals of Concern in the Priority Product.

Section 69501.2(a)(1)(B) provides that only the manufacturer can fulfill the requirements to prepare and submit certain notifications. More specifically, the notifications under section 69505.2 (Removal/Replacement Notifications) and/or 69505.3 (Alternatives Analysis Threshold Notifications) may be submitted by the manufacturer only. This provision is necessary because these notifications require a level of knowledge and control over the manufacturing process that importers, assemblers, and retailers will typically not possess. For example, a retailer may wish to do a chemical analysis on a Chemical of Concern to qualify for the AA Threshold exemption (under section 69505.3), but the retailer would not have knowledge of any manufacturing process or feedstock changes that could potentially make the exemption unnecessary or invalid. Similarly, only the product manufacturer has the ability to take the actions necessary to meet the conditions for the exemption provided through the Removal/Replacement Notifications under section 69505.2

Section 69501.2(a)(1)(C) provides that DTSC cannot require any responsible entity other than the manufacturer to fulfill the requirements for certain regulatory responses. More specifically, the regulatory responses set out in sections 69506.6 (engineered and administrative controls), 69506.7 (end-of-life management requirements), and 69506.8 (research and development projects and challenge grants) may be imposed on the manufacturer only and not on any other responsible entity. This is necessary because from a practical standpoint it would be difficult if not impossible for an importer, assembler, or retailer to successfully implement these regulatory responses. Additionally, the authorizing statute specifies that the end-of-life management regulatory response applies only to product manufacturers.

If the manufacturer fails to comply with any of the regulatory responses discussed above, the importer is required to cease placing the product into the stream of commences in California. Furthermore, the retailers and assemblers must cease ordering the product. This is necessary to have a pragmatic means to compel and

enforce compliance with the requirements and to have appropriate consequences for a failure to comply.

Section 69501.2(a)(2) creates an additional option for manufacturers, importers, retailers, or assemblers to have a consortium, trade association, public partnership, or any other entity act on their behalf or in their stead in fulfilling the requirements of the regulations. This provision is necessary to grant flexibility to responsible entities regarding how they can best carry out their duties as responsible entities, and to allow for a more efficient use of resources in complying with these regulations. This provision does not apply to the provisions relating to Priority Product Notifications (section 69503.7), Removal/Replacement Notifications (section 69505.2), and Alternatives Analysis Threshold Notifications (section 69505.3). As explained above, the manufacturer is in the best and most appropriate position to prepare and submit a Removal/Replacement Notification or an Alternatives Analysis Threshold Notification. The Priority Product Notification can be submitted by any of the responsible entities for a Priority Product. However, it does not seem appropriate for this notification requirement to be fulfilled by a consortium, etc.

Section 69501.2(b), in its entirety, specifies the options that are available to the product retailer and assembler when DTSC provides notice (under section 69501.2(a)(1)(A)) on the Failure to Comply List that the product manufacturer and importer have failed to comply with the regulatory requirements applicable to their Priority Product. Retailers and assemblers may choose to comply with the substantive requirements of the regulations (e.g. conduct an Alternatives Analysis and comply with imposed regulatory responses) – or they may cease ordering the Priority Product. This provision is necessary because DTSC only has the authority to impose these regulations on responsible entities that reside in California, but retailers and assemblers probably do not have the sufficient knowledge regarding or control over the manufacturing process of any given Priority Product. Thus, DTSC has tailored the options for compliance by retailers and assemblers to the unique role that retailers and assemblers play in product manufacture, distribution, and sale. That is, unlike manufacturers and importers, retailers merely provide the consumer products for sale to the ultimate consumer/purchaser, and assemblers merely install the Priority Product in a multi-component product that will ultimately be sold as a finished product. Nonetheless, due to the fact that the manufacturer and importer may be beyond DTSC's jurisdictional reach, DTSC felt it necessary to include retailers and assemblers as responsible entities, while giving them more flexible means of complying with these regulations. The options specified as part of this section are all necessary to give retailers and assemblers the flexibility to comply with these regulations or take appropriate actions to remove themselves from being further subject to the regulations.

Section 69501.2(b)(1) provides the retailer and/or assembler the option of an additional ninety (90) days after the notice is posted in the Failure to Comply List to continue checking DTSC's website to verify whether the manufacturer or importer has rectified the non-compliance by fulfilling the requirement that is the basis for the failure to comply determination or, if applicable, has submitted a notification (under section 69505.2 or section 69505.3) in lieu of the specified requirement. This provision is necessary to enable retailers and assemblers to avoid prematurely stopping orders for the product in the event the manufacturer or importer belatedly comes into compliance. If neither the manufacturer nor the importer remedies the non-compliance within ninety (90) days after the non-compliance is posted on the Failure to Comply List (which occurs forty-five (45) to ninety (90) days after the notice of non-compliance is sent to the manufacturer and importer), it becomes increasingly less likely that the non-compliance will be remedied. Thus, this provision provides a reasonable period of time to accommodate the possibility of the manufacturer or importer coming into compliance before requiring retailers and assemblers to either fulfill the regulatory requirements or cease ordering the manufacturer's Priority Product.

Section 69501.2(b)(2) provides that, if the manufacturer or importer does not remedy a non-compliance and the retailer or assembler does not wish to take on responsibility for remedying the non-compliance, the retailer or assembler may instead cease ordering the product and submit a notification to DTSC within ninety (90) days after DTSC has provided notice on the Failure to Comply List that the manufacturer and importer have failed to comply with a specific requirement. Again, DTSC has tailored this option to coincide with the role played by retailers and assemblers, and to provide a reasonable period of time for a retailer or assembler to decide whether to fulfill the regulatory requirements themselves or cease ordering the product and take appropriate actions based on this decision.

Section 69501.2(b)(2)(A) specifies the first step of this option – the retailer or assembler must cease ordering the product. This is necessary to ensure that if an AA is not being prepared and/or regulatory responses are not being implemented, the goals of the regulations and the statute (i.e., protecting California's citizens and environment from the adverse impacts posed by the Priority Product and its Chemical(s) of Concern) are instead achieved by removing the product from the California marketplace. Because the manufacturer and importer may not be domiciled in California, this approach is necessary to compel removal of the product from the California marketplace when the adverse impacts associated with the product will not be addressed through an AA and regulatory responses.

Section 69501.2(b)(2)(B) specifies the second step of this option – within ninety (90) days after the non-compliance is noticed on the Failure to Comply List, the retailer or assembler must submit a Product Cease Ordering Notification. This notification is necessary to ensure that DTSC has a confirmation that the retailer or assembler has complied with the regulations by ceasing to order the Priority Product.

Each Product Cease Ordering Notification must include all of the following information:

1. The retailer's or assembler's name and contact information;
2. The manufacturer's and importer's name and contact information;
3. Identification and location of the retailer's sales outlets where the product is sold, supplied, or offered for sale in California;
4. The name of, and contact information for, the person immediately upstream from the retailer or assembler in the supply chain for the product;
5. Information describing the product, including the brand name(s) and product name(s) under which the retailer's or assembler's product is placed into the stream of commerce in California, and if the product is a component of one or more assembled products a description of the known product(s) in which the component is used;
6. Estimated length of time needed to exhaust remaining inventories of the Priority Product; and
7. A statement certifying that the retailer or assembler will not re-initiate ordering the product unless and until information posted on DTSC's website indicates that the non-compliance has been remedied.

This information is necessary to enable DTSC to: (i) contact persons in the product's supply chain if there are questions concerning the notification or to verify that the retailer or assembler has ceased ordering the product; (ii) take other actions necessary to verify that the retailer or assembler has ceased ordering the product; (iii) know exactly which products are covered by the notification; and (iv) hold the retailer or assembler accountable for not re-initiating ordering of the product unless the non-compliance is cured. This provision is also necessary to make it clear that retailers and assemblers may resume ordering the product if/when DTSC's website indicates that the non-compliance has been remedied. All of this is aimed at and is necessary for the tracking of products, and ensuring compliance with the requirements of these regulations.

Section 69501.2(c) specifies the criteria and process for DTSC to: (i) issue notices of non-compliance; and (ii) establish and maintain a Failure to Comply List. In addition to the Failure to Comply List, DTSC has the authority under article 8 of chapter 6.5 of division 20 of the Health and Safety Code to enforce any of the provisions of these regulations. This includes the issuance of orders imposing administrative penalties, the

referral of violations to prosecutors for civil or criminal prosecution, the settlement of cases, and the adoption of enforcement policies and standards related to those matters. DTSC is convinced that it cannot ensure compliance with these regulations unless it makes known to interested parties the names of responsible parties that are out of compliance, and may pursue various types of enforcement for violation of these regulations. Thus, this provision is necessary to meet that important objective. The Failure to Comply List is also necessary to put retailers and assemblers on notice that the manufacturer and importer have failed to comply with regulatory requirements applicable to their Priority Product, and is a necessary precursor to requiring retailers and assemblers to either comply with the requirements themselves or cease ordering the product. This, in turn, is necessary to achieve the fundamental goals of these regulations and the underlying statute by addressing the adverse impacts associated with the Priority Product through either an AA and regulatory responses or removal of the product from the California marketplace. The Failure to Comply List will also provide information to consumers to assist them in making informed purchasing decisions. The provisions of section 69501.2(c) are necessary, in their entirety, for these reasons.

Section 69501.2(c)(1)(A) requires DTSC to issue a notice of non-compliance to the manufacturer and the importer for a Priority Product when DTSC determines that one or more requirements of the regulations have not been fulfilled. This notice is to alert the manufacturer and importer of the non-compliance status of their product. The notice is necessary to allow these entities an appropriate amount of time to come into compliance (or dispute DTSC's non-compliance determination under Article 7) before the non-compliance determination and related information is posted to the Failure to Comply List on DTSC's website.

Section 69501.2(c)(1)(B) specifies that a notice of non-compliance issued under section 69501.2(c)(1)(A) must include: (i) a description of the nature of the non-compliance; (ii) the steps the manufacturer or importer must take to achieve compliance; and (iii) the fact that DTSC intends to place information about the non-compliance determination on the Failure to Comply List maintained on DTSC's website. This provision is necessary to ensure that there is consistency in the content of the notices of non-compliance, and that the recipient is aware of the provisions with which DTSC has determined the recipient is out of compliance and what steps are needed to achieve compliance so as to provide clear direction to enable the manufacturer or importer to come into compliance. This provision is also necessary to provide the recipient fair warning as to the consequences if they continue to be non-compliant.

Section 69501.2(c)(2) specifies that no sooner than forty-five (45) days and no later than ninety (90) days after DTSC issues a notice of non-compliance, if the non-compliance has not been remedied and there is no pending dispute under Article 7, then DTSC will post information about the non-compliance on the Failure to Comply List maintained on its website. This provision is necessary as an appropriate check and balance on the timing for posting information about manufacturers and importers being out of compliance with the regulations.

This provision is also necessary because it allows manufacturers and importers sufficient time (forty-five (45) to ninety (90) days) to remedy the non-compliance before it is posted on the Failure to Comply List on DTSC's website, triggering the 90-day clock for retailers and assemblers to either comply with the substantive requirements of the regulations or cease ordering the Priority Product. The need to post this information on the Failure to Comply List is explained above under section 69501.2(c).

Section 69501.2(c)(3) provides a responsible entity temporary relief from being named on the Failure to Comply List if the responsible entity has requested a dispute resolution for a notice of non-compliance. This provision is necessary because, without such a provision, dispute resolution could be a moot avenue of relief.

Section 69501.2(c)(4) requires DTSC to maintain a Failure to Comply List on DTSC's website that provides the information described below under sections 69501.2(c)(4)(A) through (H) for each Priority Product covered by a notice of non-compliance issued under section 69501.2(c)(1). This provision gives interested parties and the general public important information about which responsible entities are not in compliance with these regulations and identifies the affected Priority Products. It also specifies the information required to be posted. This provision is necessary to keep responsible entities, including especially retailers and assemblers, informed about the compliance status of the products for which they are responsible. This provision also gives important information to consumers allowing them to make informed decisions regarding consumer products. It also helps to maintain a "level playing field" for responsible entities that are in compliance with these regulations. Additional discussion of the need for the Failure to Comply List is provided above under section 69501.2(c).

Section 69501.2(c)(4)(A) requires the Failure to Comply List to include information identifying and describing the product, and the brand name(s) and product name(s) under which it is placed into the stream of commerce in California, and if the product is a component of one or more assembled products a description of the known product(s) in which the component is used. This information is necessary to specify and adequately describe (for retailers, assemblers, others in the supply chain, consumers,

and other interested parties) which consumer products are covered by the non-compliance notice leading to the Failure to Comply listing.

Section 69501.2(c)(4)(B) requires the Failure to Comply List to specify the regulatory requirement(s) and the applicable due date that are the basis for the notice of non-compliance. This provision is necessary to make clear and detail the specific requirement(s) that has/have not been met and the corresponding due date(s) for the submittal(s). This information is necessary to give retailers, assemblers, others in the supply chain, consumers, and other interested parties a clear understanding of the specific requirements of the regulations and compliance dates that were not complied with, and thus lead to a notice of non-compliance.

Section 69501.2(c)(4)(C) requires the Failure to Comply List to include a statement placing retailers and assemblers of the affected product on notice under subsection (a)(1)(A) of the failure to comply by the manufacturer and importer(s). The statement must include the identification of the requirement with which the retailers, and, if applicable, assemblers must comply and the timeframe for compliance. DTSC must allow retailers and assemblers at least ninety (90) days from the date the non-compliance is noticed on the Failure to Comply List to remedy the non-compliance. Alternatively, retailers and assemblers may cease ordering the affected product within this 90-day period under section 69501.2(b)(2).

This provision accomplishes two things. The notice makes it clear to the retailer and assembler that the manufacturer and the importer have not complied with the regulations. At this point, the retailer and assembler need to decide whether they wish to proceed with actions to fulfill the requirement that is the basis for the non-compliance (e.g., conduct an AA, submit an AA Report, implement regulatory responses) or submit a Product Cease Ordering Notification. The second objective of this provision, in concert with section 69501.2(b)(2), is that it allows the retailer and the assembler ninety (90) days to make the decision regarding how they chose to comply with the regulations.

This notice to retailers and assemblers will only be posted on the Failure to Comply List on DTSC's website. However, under section 69501.5(a), DTSC will establish an electronic mailing list that will be used to provide information concerning implementation of the regulations (including updates to the Failure to Comply List) to persons on the electronic mailing list. Retailers and assemblers wishing to receive electronic mail notices whenever new or revised information is posted to the Failure to Comply List may subscribe to the electronic mailing list.

This notice is necessary because it alerts retailers and assemblers that the manufacturer and the importer have not complied with the regulations. It also starts the compliance clock for retailers and assemblers.

Section 69501.2(c)(4)(D) requires the Failure to Comply List to include the Chemical(s) of Concern and any other Candidate Chemical(s) known to DTSC to be present in the product. This is necessary to inform the public regarding the identity of the Chemical(s) of Concern and Candidate Chemical(s) present in a product that is the subject of a non-compliance determination – as these chemicals pose public health and/or environmental concerns. This, in turn, is necessary to allow the public to take this information into consideration as part of purchasing decisions.

Section 69501.2(c)(4)(E) requires the Failure to Comply List to include the name of and, if known, the contact information for any person(s) listed on the product label as the manufacturer, importer, or distributor. This information is necessary to assist retailers, assemblers, and consumers to identify exactly which products are covered by the Failure to Comply listing. This information is especially important for retailers and assemblers who will need to cease ordering non-compliant products under section 69501.2(b)(2).

Section 69501.2(c)(4)(F) requires the Failure to Comply List to include the name of, and contact information for, any manufacturer or importer that has been noticed by DTSC under section 69501.2(c)(1). This information is necessary for the same reasons as the information required under section 69501.2(c)(4)(E).

Section 69501.2(c)(4)(G) requires the Failure to Comply List to include the name of, and the contact information for, retailers and, if applicable, assemblers known to DTSC who have not fully complied with section 69501.2(b). This information is necessary to identify for consumers and other interested parties retailers and assemblers who are still selling or using products that are not in compliance with these regulations; and, thus, contrary to the intent and goal of these regulations and the statute, these products continue to pose adverse impacts for California's citizens and environment as long as they remain in the California marketplace.

Section 69501.2(c)(4)(H) requires the Failure to Comply List to include the date the product is first listed on the Failure to Comply List. This is necessary to provide a record of the date that retailers and assemblers must use to track the time period for complying with section 69501.2(b).

DTSC has determined that the information requirements of sections 69501.2(c)(4)(A) through (H) will provide the appropriate amount and type of information needed to keep interested parties and the general public apprised as to the nature of the non-compliance relating to Priority Products posted on the Failure to Comply List.

Section 69501.2(c)(5) specifies that DTSC must remove a product and its related information from the Failure to Comply List if DTSC determines that the condition of non-compliance has been fully remedied. This provision is necessary to ensure information on DTSC's website is current and accurate as to the compliance status of responsible entities and their products subject to the regulations, and to provide a fair and level playing field for those responsible entities who take the necessary steps to remedy a non-compliance determination. This provision is also necessary so that all responsible entities (manufacturers, importers, assemblers, and retailers) for a particular Priority Product know when the regulatory requirement that was the basis for the non-compliance determination has been fulfilled so that they know they are now relieved of the responsibility to fulfill the requirement themselves. It also lets retailers and assemblers who ceased ordering the product under section 69501.2(b)(2) know that they can now resume ordering the product since the non-compliance has been remedied.

Section 69501.2(c)(6) requires DTSC to remove information regarding a retailer or assembler from the Failure to Comply List upon a determination by DTSC that the retailer or assembler has complied with subsection 69501.2(b). This is necessary as a common sense provision to keep the Failure to Comply List current, and to provide a fair and level playing field for retailers and assemblers who have taken the necessary steps to comply with section 69501.2(b)(2).

§ 69501.3. Information Submission and Retention Requirements

Section 69501.3, in its entirety, specifies the requirements for submitting information to DTSC, and establishes information and documentation requirements. All of the required elements below are necessary so that the information DTSC receives is credible, reliable, and useful to DTSC.

Section 69501.3(a) provides that all information that is required to be submitted to DTSC under these regulations must be signed by: (i) the responsible individual in charge of preparing or overseeing the preparation of the information; and (ii) the owner or an officer of the company, or their authorized representative. This requirement is necessary to improve the credibility and reliability of the documents submitted to DTSC, and to hold key individuals in the company accountable for the completeness and

accuracy of the information. It is consistent with other regulatory regimes that have limited governmental oversight or auditing capabilities.

Section 69501.3(b) specifies that all information submitted to DTSC must be in English, and generated and submitted in a manner and in an electronic format specified by DTSC. This provision is necessary to ensure information submitted to DTSC can be easily accessed, understood, compiled, processed, and incorporated into electronic data bases by DTSC employees. The requirement that all information must be submitted in English safeguards DTSC from receiving voluminous information that must be translated into English before being reviewed for completeness and compliance with the applicable requirements. In addition, this provision lowers the costs to DTSC in implementing the provisions of these regulations.

Section 69501.3(c) sets out a certification statement that must be included and signed for all documents submitted to DTSC under the regulations. Specifically, the following certification statement is required:

> "I certify that this document and all attachments were prepared or compiled under my direction or supervision to assure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person(s) directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that submitting false information or statements is a violation of law."

This certification statement is necessary in order to ensure all submittals are accurate and to apprise parties signing the statements of the applicable standards related to the documents' preparation. The signature requirement by an owner or officer with specific responsibilities related to these notifications, in addition to a signature by the responsible individual in charge of the preparation of the information, helps ensure the integrity and accuracy of, and accountability for, these submittals.

Section 69501.3(d) specifies that documents that are required to be submitted to DTSC within a specified time period must be postmarked or submitted electronically by the end date of that time period. This requirement is necessary to provide a consistent timeliness standard, and to enable DTSC to validate that a submittal is or is not in compliance with the applicable regulatory due date.

Section 69501.3(e) sets out a three-year document retention provision. Specifically, this section requires information that is required to be obtained or prepared under these regulations to be retained until whichever of the following first occurs: (i) the information

is submitted to DTSC; or (ii) three (3) years has passed since the date the information was required to be obtained or prepared.

This is necessary to ensure DTSC has continued access for a reasonable period of time to information that may be needed to support fulfillment of DTSC's responsibilities under these regulations, even when such information has not yet been required to be submitted to DTSC or requested by DTSC. A 3-year retention requirement is consistent with the regulatory/statutory records retention periods under other programs administered by DTSC.

§ 69501.4. Chemical and Product Information

Section 69501.4, in its entirety, specifies the process for DTSC to obtain and review information on chemicals and products. Health and Safety Code section 25252 requires DTSC to adopt regulations that establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be a chemical of concern. DTSC has concluded that it will need to engage in information-gathering activities to support and inform the chemical and product identification and prioritization processes. DTSC itself does not have the necessary information to administer this program without gathering information from various sources.

Section 69501.4 merely authorizes DTSC to obtain/review information in the public domain and to *request* information from chemical and product manufacturers and others in the supply chain. There is no regulatory requirement for a responsible entity or any other person to submit any information to DTSC before one's product is identified through a subsequent rulemaking process as a Priority Product. The status of parties' responses to information *requests* will be posted on the Response Status List on DTSC's website, but there are no compliance requirements or consequences.

The regulations lay out four different approaches for the collection of information in sections 69501.4(a)(1)(A) through (D) of the regulations. Information will be collected from the public domain that is readily available at no charge, and by subscription to the extent DTSC has the resources to pay for such information. DTSC may also *request* access to existing data from product and chemical manufacturers, importers, assemblers, and retailers, and DTSC may *request* the generation of new data necessary to implement these regulations.

The authorizing legislation did not specifically give DTSC authority for data call-ins prior to the completion of an AA. However, existing authority for DTSC to request data is found in Health and Safety Code sections 57018 through 57020 (also known as AB

289). Under this law, DTSC may request information regarding analytical test methods, fate and transport in the environment, and other relevant information about specified chemicals. The AB 289 provisions apply to individuals and companies who produce a chemical in California and to those who import a chemical into the State for sale in California. DTSC has determined that it is reasonably necessary to have information call-in provisions in these regulations prior to the regulatory response stage – the point in the process when DTSC is authorized to *require* the submittal of information. Thus, DTSC has included the information call-in provisions in Article 1, but has not made them compulsory. This information-gathering tool is necessary to allow DTSC to have a systematic means of requesting information that will be important to the implementation of the regulations.

Section 69501.4(a)(1) requires DTSC to use one or more of four specified approaches (described below under sections 69501.4(a)(1)(A) through (D)) to obtain and/or review information that it determines is necessary to implement these regulations. This information will enable DTSC to have sound and robust processes for identifying Candidate Chemicals, prioritizing consumer products that contain these chemicals as Priority Products, evaluating Alternatives Analyses, and determining needed regulatory responses. This information is useful to help ensure that decisions made by DTSC in carrying out its responsibilities under these regulations and the underlying statute are fully informed and based on sound science and other relevant information. This approach will minimize the unnecessary expenditure and use of resources by DTSC and responsible entities. This provision is necessary to allow for the most effective and efficient approach to seeking necessary information.

Section 69501.4(a)(1)(A) specifies that DTSC may obtain and/or review information in the public domain that is readily available in a usable format, without a subscription or other charge. This is necessary to establish a very simple and inexpensive method of seeking information and to inform the public that this will be one of the approaches to acquire data for implementing these regulations.

Section 69501.4(a)(1)(B) specifies that DTSC may obtain and/or review information in the public domain that is readily available in a usable format, with a subscription or other charge, to the extent resources are available to pay the required costs. This provision is necessary to establish this very useful information-gathering method and to make clear that DTSC may or may not have resources available to purchase information in the public domain that is not available free of charge.

Section 69501.4(a)(1)(C) specifies that DTSC may request a product or chemical manufacturer, importer, assembler, or retailer to make existing information available to

DTSC in accordance with a schedule specified by DTSC. This provision is necessary to establish this important information-gathering tool to assist DTSC in accessing information critical to implementation of these regulations in a time frame that enables DTSC to fulfill its regulatory responsibilities without undue delays due to lack of information. This provision is also necessary to put the affected parties on notice that DTSC may be making these types of information-gathering requests to help implement an effective regulatory program. Note that persons receiving such a request may satisfy the request by either sending the information to DTSC or giving DTSC access to view the information.

Section 69501.4(a)(1)(D) specifies that DTSC may request a product or chemical manufacturer, importer, assembler, or retailer to generate new information and provide it to DTSC in accordance with a schedule specified by DTSC. This provision is necessary to allow DTSC to request information that is important for its decision-making but that does not yet exist, and to put affected parties on notice that DTSC may be making these types of information-gathering requests to accelerate the chemical/product identification and prioritization, Alternatives Analysis, and regulatory response processes. This provision is necessary to establish this important information-gathering tool to assist DTSC in accessing information critical to implementation of these regulations in a time frame that enables DTSC to fulfill its regulatory responsibilities without undue delays due to lack of information.

Section 69501.4(a)(2) specifies that the use of the terms “manufacturer”, “importer”, “assembler”, and “retailer” in section 69501.4 are not restricted solely to manufacturers, importers, assemblers, and retailers of products or chemicals subject to the regulations. Rather, the provisions of sections 69501.4(a)(1)(C) and (D) allowing DTSC to request information extend to manufacturers, importers, assemblers, and retailers of *any* product or chemical – except those products that are exempted from the definition of “consumer product” specified in Health and Safety Code section 25251(e) of the enabling legislation. This provision is necessary to make clear the intended scope of DTSC’s authority to request information under section 69501.4. Because there is no regulatory requirement to submit any of the requested information, DTSC finds it necessary to extend the scope of the authority for information requests to all non-exempt products, not just those specifically covered by these regulations. This greatly enhances the likelihood that DTSC will receive important information for implementing these regulations, in particular the chemical and product identification and prioritization processes.

Section 69501.4(b) specifies the means by which DTSC may request that information be made available under section 69501.4(a). This provision is necessary to establish

the means for DTSC to request information, and to inform persons receiving these requests as to how they may be contacted or otherwise made aware of a request for information.

Section 69501.4(b)(1) makes clear that DTSC may request information by correspondence sent via U.S. mail or electronically to an individual. This provision is necessary to specify that DTSC may use common business communication methods to request information under this regulatory program.

Section 69501.4(b)(2) makes it clear that DTSC may use information call-ins to request information under section 69501.4(a); and that a call-in, unless specified otherwise, applies to all manufacturers, importers, assemblers, and retailers, as applicable, of a specific chemical or product or group of chemicals or product. This provision requires DTSC to post information call-ins on its website and provide notice to persons on electronic mailing lists established by DTSC related to these regulations. These methods are reasonably calculated to be efficient and effective methods of seeking relevant information. This provision is necessary to specify the appropriate and allowable means by which DTSC may request information under this regulatory program.

Section 69501.4(c)(1) requires DTSC to maintain a Response Status List on its website. Under section 69501.4(a) and (b), DTSC may request, from product and chemical manufacturers, importers, assemblers, and retailers, information that DTSC determines is necessary to implement these regulations. The Response Status List will give interested parties and the general public the status of various requests and provide additional information as to whether the recipient of an information request has: (i) submitted the requested information in a timely manner; (ii) failed to provide the requested information within the time specified; or (iii) demonstrated that the information is not available or cannot be produced. DTSC has determined that the Response Status List is a necessary and efficient means to inform interested parties and the general public as to the status of the information requests. This, in turn, will promote program effectiveness and efficiencies. This information will also provide positive recognition for those persons who assist DTSC in its implementation of these regulations by providing critical information requested by DTSC. Sections 69501.4(c)(1)(A) through (C) specify the information request status categories to be included on the Response Status List.

Section 69501.4(c)(1)(A) specifies that DTSC will include a category on the Response Status List that includes those persons who respond to a request for information and

submit the requested information to DTSC within the time specified. This provision is self-explanatory and necessary to keep the Response Status List accurate and useful.

Section 69501.4(c)(1)(B) specifies that DTSC will include a category on the Response Status List that includes those persons who do not submit the information requested within the time specified. Again, this provision is self-explanatory and necessary to have current information provided to the general public and interested parties.

Section 69501.4(c)(1)(C) specifies that DTSC will include a category on the Response Status List that includes those persons who demonstrate to DTSC's satisfaction that they do not possess and cannot produce the requested information. DTSC has determined it is necessary to distinguish parties that were unable, as opposed to unwilling, to provide requested information. This allows interested parties and the general public to be apprised of this distinction as well.

Section 69501.4(c)(2) specifies that the information required to be posted on the Response Status List must include the identification of the person from whom the information was requested and the chemical or product that is the subject of the request. This provision is necessary to provide interested parties and the general public the necessary level of specificity to understand which chemicals and/or products are covered by the information request, and who has and has not responded to DTSC's request.

Section 69501.4(c)(3) requires DTSC to update its website upon determining that the product or chemical manufacturer, importer, or other person has taken some action that results in a status change under section 69501.4. This requirement is necessary to ensure that DTSC's website is up-to-date and conveys accurate information about the program to interested parties and the general public, and gives due credit to persons who take the necessary actions to provide information to DTSC or to inform DTSC that the information is not available.

Section 69501.4(d) allows DTSC to provide recognition for parties that voluntarily provide information to DTSC that advances the quest for safer consumer products. This information will be maintained on a Safer Consumer Products Partner Recognition List posted on DTSC's website. This provision is necessary to reward persons that voluntarily expend their resources to assist DTSC in obtaining information helpful in fulfilling its regulatory responsibilities. It is also necessary to provide a cost effective mechanism to motivate other entities to make similar voluntary information contributions in the future.

Section 69501.4(d)(1) provides that persons that have voluntarily completed an alternatives analysis on a product that has not been listed as a Priority Product will be placed on the Safer Consumer Products Partner Recognition List. This provision is necessary to encourage parties to complete alternatives analyses without being compelled to do so. This provision is also necessary so that this information is made available to interested parties and the general public.

Section 69501.4(d)(2) specifies that persons that have voluntarily provided information that is helpful to DTSC in fulfilling its regulatory requirements will be placed on the Safer Consumer Products Partner Recognition List. As with the above section, this provision is necessary to encourage voluntary participation in this program and make the information available to interested parties and the general public.

§ 69501.5. Availability of Information on the Department's Website

Section 69501.5, in its entirety specifies the types of information 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. This section clearly specifies the information that DTSC will post to assist responsible entities (i.e., manufacturers, importers, assemblers, and retailers) in complying with the requirements of these regulations. This information will also assist the public and consumers to make informed choices regarding consumer products. Each of the required postings is necessary so that responsible entities, interested parties, and the general public be provided accurate, current, and important information regarding the operation of these regulations. This information is necessary to motivate compliance, engender confidence and facilitate participation in the program, and reward early and voluntary action. This section does not impose any requirements on responsible entities – it is simply a listing of the documents required to be submitted to, or prepared by, DTSC under these regulations. For additional discussion relating to the necessity of each of the documents listed under sections 69501.5(a) and (b) below, refer to the corresponding provision(s) in this statement of reasons.

Section 69501.5(a) specifies the information required to be posted on DTSC's website, *and* for which DTSC will be required to send a notice to persons on its electronic mailing list(s) regarding the posting. It requires that DTSC post on its website and update as needed all of the information set out below. The availability of the documents and information listed below, and updates thereto, will be sent to persons on any electronic mailing lists established by DTSC for purposes of implementing these regulations. All documents will be posted on DTSC's website and subscribers to the electronic mailing list(s) will receive an email indicating the availability of new documents or updates.

(1) The Failure to Comply List (see section 69501.2(c)).
(2) Requests for information (see section 69501.4).
(3) **(A)** Exemption determinations and supporting rationale; and **(B)** determinations rescinding exemptions and supporting rationale (see section 69501(b)(3)).
(4) Priority Product Work Plans (see section 69503.4), proposed and final Candidate Chemicals and Priority Products lists and revisions to the lists, supporting rationale and documentation, written comments received during public comment periods, and any written responses DTSC provides to the comments (see sections 69502.3 and 69503.5).
(5) Petitions (for additions to or deletions from the Candidate Chemicals and Priority Products lists) that DTSC designates as complete; and notices of decision and statements of basis prepared by DTSC in response to complete petitions (see Article 4).
(6) A list of due date extension requests approved for AA Reports (see Article 5).
(7) AA Report notices of public review periods, and notices of compliance, deficiency, disapproval, and ongoing review (see sections 69505.8 and 69505.9).
(8) Proposed and final regulatory response determination notices issued by the DTSC, written comments received during the public comment period, and any written responses DTSC provides to the comments (see section 69506.1).
(9) A list of regulatory response exemption requests submitted to DTSC, and copies of all notices issued by DTSC granting, denying, or rescinding a regulatory response exemption (see section 69506.9).
(10) Disputes and Requests for Review filed with DTSC, and DTSC decisions and notices of ongoing review issued in response to disputes and Requests for Review (see Article 7).

Section 69501.5(b) specifies additional items that DTSC must post on its website and update as appropriate, but for which a notice to persons on DTSC's electronic mailing list(s) is not required:

(1) The Response Status List (see section 69501.4(c)).
(2) The Safer Consumer Products Partner Recognition List (see section 69501.4(d)).
(3) The following information, as it becomes available and is updated, for each Priority Product for as long as the product continues to be placed into the stream of commerce in California:
  (A) Brand name(s) and product name(s) for the product, and if the product is a component a description of the known product(s) in which the component is used;

(B) Product manufacturer(s) and importers (unless a Removal or Replacement Notification has been submitted under section 69505.2);

(C) Other responsible entities for the product (except for responsible entities who have complied with section 69501.2(b));

(D) The identity of the person who will fulfill the requirements of Article 5, as specified in the Priority Product Notification;

(E) The due dates for, and dates of receipt of, each applicable AA Report and each Alternate Process AA Work Plan; and

(F) Lists and copies of all of the following, including the date of receipt by DTSC:

1. Priority Product Notifications (see section 69503.7);

2. Alternatives Analysis Threshold Notifications and related notices (see section 69505.3);

3. Chemical Removal Intent and Confirmation Notifications (see section 69505.2);

4. Product Removal Intent and Confirmation Notifications (see section 69505.2);

5. Product-Chemical Replacement Intent and Confirmation Notifications (see section 69505.2); and

6. Product Cease Ordering Notifications (see section 69501.2(b)).

(4) AA guidance documents (see section 69505(a)).

(5) AAs made available by DTSC (see section 69505(b)).

(6) A list of all AA Reports, Alternate Process AA Work Plans, and AA progress reports submitted to DTSC, the executive summary for each document, the date of receipt, and a full or redacted copy of each document, including both the originally submitted document and the document approved by DTSC (see Article 5).

(7) Written comments submitted to DTSC on AA Reports, and identification of those issues that DTSC determines must be addressed in an AA Report Addendum (see section 69505.8).

(8) A list and copies of all notices issued by DTSC and all documents submitted to DTSC concerning regulatory responses imposing product sales prohibitions (see section 69506.5).

(9) Copies of, or links to, product stewardship plans, substitute end-of-life management programs, exemptions from end-of-life management program requirements, and annual end-of-life management program reports (see section 69506.7).

(10) Regulatory response notifications submitted to DTSC, and the Regulatory Response Summary prepared by DTSC (see section 69506.10).

(11) Findings of audits conducted by DTSC (see section 69508).

Section 69501.5(c) requires that all information posted on DTSC's website under these regulations must include the date the item is posted and the date(s) of any revised postings. This is necessary to keep the information current and reliable for use by interested parties and the general public. In addition, compliance with the requirements of the regulations is in some cases triggered by the date certain information is posted on DTSC's website.

ARTICLE 2. Process for Identifying Candidate Chemicals

Article 2, in its entirety, is necessary to implement, clarify, and specify the process for Candidate Chemicals identification and listing. Identification of Candidate Chemicals is Step 1 in the continuous, science-based, and iterative process that identifies safer consumer product alternatives. Step 2 is set forth in Article 3, Process for Identifying and Prioritizing Product-Chemical Combinations. These first two steps of the process culminate in the identification of Priority Products for which manufacturers are required to identify safer alternatives through the Alternatives Analysis (AA) process in Article 5 (Step 3 of the process).

Statutory Requirements and Intent
The discussion here, which provides background information on the processes for the identification of chemicals and the identification and prioritization of product-chemical combinations, applies to both Articles 2 and 3. The processes established in Articles 2 and 3 of these regulations are necessary provisions drafted in response to the directives in Health and Safety Code sections 25252 and 25253 and the overarching legislative intent of the "Green Chemistry" statutes embodied in Health and Safety Code section 25255(a).

Health and Safety Code section 25252 requires the Department of Toxic Substances Control (DTSC) to "establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as a chemical of concern". Health and Safety Code section 25252 also requires DTSC to:

(1) Establish an identification and prioritization process that includes, but is not limited to, consideration of the following:
   a. Volume of the chemical in commerce in California;
   b. Potential for exposure to the chemical in the consumer product; and
   c. Potential effects on sensitive subpopulations, including infants and children.

(2) Evaluate chemicals and their alternatives by developing criteria that include, but are not limited to, traits, characteristics, and endpoints (collectively referred to as "hazard traits" for purposes of this Statement of Reasons) developed by the Office of Environmental Health Hazard Assessment (OEHHA) for the Toxics Information Clearinghouse established under Health and Safety Code section 25256.1.

(3) Use, to the extent feasible, "available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes". (Note: DTSC is not limited to the use of such information only.)

Health and Safety Code section 25253(a), in pertinent part, requires DTSC to "establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a Chemical of Concern."

Health and Safety Code section 25255(a) states that the goal of the statute is "significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches."

The provisions in Articles 2 and 3 are necessary to interpret, clarify, and make specific the Health and Safety Code sections cited above, consistent with the overarching legislative intent. In developing these regulations, DTSC consulted with the Green Ribbon Science Panel (GRSP), established pursuant to Health and Safety Code section 25254, and reviewed all of the stakeholder comments on an informal draft of the regulations as well as all comments received during three separate public comment periods (July 2012, January 2013, and April 2013). The regulations in Articles 2 and 3 reflect DTSC's consideration of the GRSP and stakeholder comments in meeting the authorizing legislation's requirement to establish the identification and prioritization processes.

(1) Article 2 establishes: (i) an initial Candidate Chemicals list based on specified criteria; and (ii) a process and criteria for revising the Candidate Chemicals list to add or remove chemicals. Only chemicals that exhibit a hazard trait and/or an environmental or toxicological endpoint, as defined and described in Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data, Chapter 54, Title 22, California Code of Regulations (Chapter 54) may be considered for listing as a Candidate Chemical.

(2) Article 3 establishes a process for evaluating and prioritizing product-chemical combinations for listing of consumer products with Candidate Chemicals as Priority Products. Prioritization of product-chemical combinations for listing as Priority Products includes evaluating the potential for exposures to a Candidate Chemical in a product, and the potential for the Candidate Chemical to contribute to, or cause, significant or widespread adverse impacts due to

exposure to that Candidate Chemical in the consumer product. A Candidate Chemical that is the basis for a product-chemical combination being listed by DTSC as a Priority Product is designated as a Chemical of Concern for that product.

Identification and Prioritization Process Development

In developing the identification and prioritization processes set out in Articles 2 and 3, DTSC consulted the GRSP to advise DTSC regarding the adoption of these regulations and related matters. DTSC provided various topics, including chemical and product identification and prioritization processes, and their associated underlying scientific principles, to the GRSP for discussion. The objective in consulting with the GRSP was not to reach a consensus among GRSP members on the various topics, but to obtain scientific insights based on each GRSP member's area of expertise for DTSC to consider during the development of these regulations.

Various options and expert opinions were provided by the GRSP for identifying and prioritizing chemicals and products – from a methodical, stepwise process to combining certain steps. One option discussed by the GRSP identified and prioritized chemicals as Chemicals of Concern in two steps: (1) an identification process that would produce a larger list of Chemicals under Consideration, and (2) a prioritization process that would yield a smaller number of Chemicals of Concern. Similarly, consumer products would undergo a two-step identification and prioritization process: (1) identification of products that contain Chemicals of Concern, and (2) a prioritization process to list a smaller number of products as Priority Products. Responsible entities for these Priority Products would then be subject to the requirement to conduct an AA.

The GRSP also discussed a variation of the consumer product prioritization process that combined the identification and prioritization processes together, which would be more efficient than a discrete two-step process. Furthermore, the GRSP considered an option that combined the chemical and product identification and prioritization processes, which provides for additional efficiencies. Efficiencies would be gained since the information needed to identify and prioritize products containing Chemicals of Concern would most likely be from the same information source, i.e., the manufacturer or in the public domain.

As DTSC examined these various options discussed by the GRSP, it became apparent that prioritizing chemicals is very much dependent on information about both chemicals and products. Information about a chemical informs the identification and prioritization of the product and information about the product informs the chemical prioritization process.

For example, consider the three factors in the authorizing legislation that DTSC, at a minimum, must take into account to "establish a process to identify and prioritize" Chemicals of Concern in consumer products: (1) volume of the chemical in commerce in California; (2) potential for exposure to the chemical in the product; and (3) potential effects on sensitive subpopulations.

Chemical information is needed to inform the factors regarding volume and potential effects on sensitive subpopulations. However, *consumer product information* is needed to evaluate the potential for exposure to the chemical in the consumer product. Consumer product use, and physical form, concentration, and function of the chemical in a consumer product all influence the potential for exposure to the chemical in the consumer product, as well as the potential effects on sensitive subpopulations. Additionally, information regarding chemical volumes in commerce available through the federal Toxic Substances Control Act (TSCA) may not be as accurate for DTSC's prioritization purposes as the volume of the Chemical of Concern in consumer products in California.

Prioritization and evaluation of Candidate Chemicals in consumer products, as well as the alternatives being considered, to determine how best to limit exposures and/or adverse impacts, which is required by Health and Safety Code section 25253, cannot be done practically without simultaneously considering both the chemical and the consumer product that contains the chemical.

The provisions in Articles 2 and 3 necessary to meet the authorizing legislation's requirements were developed by considering GRSP advice as well as stakeholders' input. DTSC then made policy decisions that incorporate science, practicality, efficiency, and transparency. The resulting processes are set out in Article 2 to identify Candidate Chemicals, and in Article 3 to identify and prioritize product-chemical combinations to list consumer products with Candidate Chemicals as Priority Products.

Narrative versus Prescriptive Processes

As discussed above, it became apparent that DTSC could not prioritize Candidate Chemicals and consumer products that contain Candidate Chemicals separately from each other; rather, it was necessary to consider them together. Evaluating and balancing information on both chemicals and products based on available information allows for flexible decision-making to propose Priority Products for listing. Along that same line of thought, the identification of Candidate Chemicals based on their hazard traits also could not be done without relevant toxicity profile information and an evaluation of exposures, where consumer products-related information may be extremely helpful. Thus, the interplay of chemical hazard trait information and other chemical-related information with information about product use and exposure

scenarios in Articles 2 and 3 is necessary to have a sensible and meaningful approach to identifying chemicals and products that come under further scrutiny under this program.

A prescriptive process for identifying and prioritizing chemicals and products, with rigid criteria for DTSC to evaluate and make decisions, may provide a greater level of predictability and certainty to manufacturers for chemicals and products not yet listed as Candidate Chemicals or Priority Products. DTSC appreciates the fact that some manufacturers may wish to take proactive steps to examine alternatives to a consumer product before the consumer product is subject to these regulations.

DTSC recognizes that there may be some value in the greater certainty and predictability provided by a prescriptive process with defined thresholds, versus a narrative approach. However, after considering extensive GRSP and stakeholder input on this issue, DTSC determined that any such benefits would be outweighed by the negative consequences. More specifically, by definition, a prescriptive process for decision-making entails a rigid adherence to a set of steps and/or specific weighting of various factors or criteria. This, in turn, would greatly limit DTSC from bringing its particular expertise and judgment to bear on an identification / prioritization decision. A prescriptive process would only reflect decisions based on current science and understanding and creates the very real probability that the current process in place ignores new science and understanding for future decisions. While the regulations may be amended to reflect new science, by the time the regulations are amended the regulations may need further amendment because the science has progressed again. Under a prescriptive approach, DTSC would constantly be behind new science and understanding, would constantly be amending the regulations, and would be strapped into making regulatory decisions knowing that the regulatory process will not allow consideration of new scientific understanding of chemicals and products.

In addition, there is a lack of knowledge and experience with a regulatory program of this scope and breadth, since this regulatory program is the first of its kind in the world. The GRSP and DTSC recognized that the processes in the regulations need a measure of predictability and certainty. Nevertheless, these regulations also need to remain relevant and appropriate as the Safer Consumer Products program grows and matures with the need to timely incorporate advances in science, knowledge, and experience. Regulatory decisions need to be informed by the best scientific information and approaches available. For all these reasons, DTSC is not specifying a prescriptive process with a numerical weighting or ranking system for identifying and prioritizing chemicals and products, but is instead using a narrative approach that allows DTSC to use best available scientific information and practices to identify Candidate Chemicals (Article 2) and prioritize product-chemical combinations (Article 3). Rather, it is

necessary that DTSC employ a narrative approach to decision-making to effectuate the statutory provisions in a timely and meaningful way.

DTSC has designed the regulations in Articles 2 and 3 to be pertinent, transparent, and flexible to: (1) accommodate the availability and type of chemical and product information being considered and evaluated; and (2) stand the test of time by allowing DTSC to consider chemical and product information based on advances in science and technology. The provisions in Articles 2 and 3 are necessary to meet these objectives, as well as addressing the other principles set out above.

The Statement of Reasons for Article 2 describes, and outlines the rationale for, the identification process for Candidate Chemicals.

§ 69502. General

Section 69502 specifies the purpose of Article 2 – identification of Candidate Chemicals that DTSC may consider under Article 3 for designation as Chemicals of Concern, and the process that DTSC may use to identify additional Candidate Chemicals. This provision is necessary to inform responsible entities and other interested parties of: (1) the purpose of this article; and (2) the potential implications of a chemical being identified as a Candidate Chemical – designation as a Chemical of Concern when paired with a product and listed as a Priority Product. Note that while section 69502.2 only mentions adding chemicals to the Candidate Chemicals list, the more specific and controlling provisions found in section 69502.3(b) allow DTSC to make additions to, <u>or deletions from</u>, the Candidate Chemicals list.

This section also specifies that, as part of the Candidate Chemicals identification process, DTSC may evaluate information from manufacturers and other sources. DTSC may rely on information about chemicals obtained under section 69501.4, but is not limited to solely using information obtained under section 69501.4, in performing its duties under Article 2. This provides DTSC with maximum latitude and flexibility to seek out and utilize a broad range of scientific data and other information that is necessary to ensure that the chemical identification process and the resulting Candidate Chemicals list are based on sound science.

§ 69502.1. Applicability

Section 69502.1 specifies the scope of chemicals that could be considered in the identification process for listing as Candidate Chemicals. This provision is necessary to make it clear, in advance, to all interested parties the scope of chemicals that could be

considered for identification as Candidate Chemicals using the criteria and process specified in Article 2.

The conditions under which a chemical could be considered in the identification process are as follows: (1) the chemical exhibits a hazard trait or an environmental or toxicological endpoint; and (2) the chemical is in consumer products that are placed into the stream of commerce in California. The terms “hazard trait” and “environmental or toxicological endpoint” have been defined in Article 1 of these regulations as those specified in Title 22, California Code of Regulations, Divisions 4.5, Chapter 54 (Chapter 54).

According to Chapter 54, “hazard traits” are properties of chemicals that fall into broad categories of toxicological, environmental, exposure potential, and physical hazards that may contribute to adverse effects in exposed humans, domesticated animals, wildlife, or in ecological communities, populations, or ecosystems. In addition, a hazard trait must be supported by evidence that the chemical exhibits an adverse environmental or toxicological endpoint, shown by “well-conducted studies,” as defined in Chapter 54. In some instances, a chemical may not exhibit a hazard trait even though research and well-conducted studies, as defined in Chapter 54, section 69401.2(i), have been conducted, because the studies are inconclusive. In other cases, the chemical’s mechanism to cause an adverse toxicological or environmental endpoint may not be known and, as such, a hazard trait cannot be assigned to the chemical. Also, as defined in Chapter 54:

> An "environmental endpoint" for a specific hazard trait is a measured or otherwise observed adverse environmental effect in ecological systems, or in components of ecological systems, or in non-human organisms within ecological systems that indicates the presence of the hazard trait.”
>
> A “toxicological endpoint” for a specific hazard trait is a measured or otherwise observed adverse effect in a biological system that indicates the presence of the hazard trait.”

As part of the supporting documentation for additions to the Candidate Chemicals list required under section 69502.3(c), DTSC will identify the Chapter 54 hazard trait(s) and/or environmental or toxicological endpoint(s) known to be associated with each Candidate Chemical when the chemical is added to the Candidate Chemicals list.

§ 69502.2. Candidate Chemicals Identification

Section 69502.2, in its entirety, is necessary to clarify and make specific the criteria for: (1) identifying the chemicals included on the initial Candidate Chemicals list; and (2) adding additional chemicals to the Candidate Chemicals list.

Section 69502.2(a) specifies the criteria that serve to identify the chemicals that are included on the initial Candidate Chemicals list. A chemical is a Candidate Chemical if it exhibits a hazard trait and/or an environmental or toxicological endpoint, and is listed on one or more of the authoritative organizations' lists identified in section 69502.2(a).

As of the effective date of the regulations, this section establishes a robust Candidate Chemicals list based on work already done by authoritative organizations. The initial Candidate Chemicals list is a list of approximately 1,200 chemicals. This represents a compilation of the chemicals listed on the authoritative organizations' lists identified in section 69502.2(a), with the exception of: (1) chemicals exempted under Health and Safety Code section 25251 (e.g., pesticides and prescription drugs); (2) non-chemicals (e.g., nutrients); (3) duplicate chemicals that appear on more than one list; and (4) chemicals that are not known to exhibit a Chapter 54 hazard trait or environmental or toxicological endpoint.

Chemicals known to fall into one of the four (4) categories listed above will not be included in the informational list of Candidate Chemicals posted on DTSC's website under section 69502.3(a). Having a robust Candidate Chemicals list as of the effective date of these regulations is necessary to enable DTSC to immediately focus on the identification and prioritization of product-chemical combinations for listing as Priority Products for which manufacturers will be required to perform alternatives analyses to identify safer products. This robust Candidate Chemicals list will also enable: (1) consumers to be more informed about the Candidate Chemicals that may be present in the products they purchase; and (2) manufacturers, importers, assemblers, and retailers (also referred to as responsible entities) to take early voluntary actions regarding the Candidate Chemicals in their quest for safer consumer products.

For example, some companies, such as Wal-Mart and Staples, are using lists of chemicals for disclosure purposes or to restrict the sale of products containing certain chemicals at their retail stores. Manufacturers, such as the automotive industry through their use of the Global Automotive Declarable Substance List (GADSL), use chemicals lists to implement their quest for safer consumer products. Manufacturers who wish to begin proactive efforts and voluntarily redesign of their products may use this initial Candidate Chemicals list as part of their process to make decisions regarding potential chemical alternatives or substitutions to consider. This, in turn, may also reduce the possibility of regrettable substitutions.

Health and Safety Code section 25252(b)(2) requires DTSC to use, to the maximum extent feasible, available information from other authoritative bodies, i.e., "organizations", that have undertaken similar chemical prioritization processes. It is important to note that DTSC relies on this foundational requirement to support the first step in the prioritization process, that is, the identification of Candidate Chemicals. By utilizing other authoritative organizations' scientific work and work products that support protecting public health or the environment to identify the initial list of Candidate Chemicals, DTSC is able to maximize resources, while minimizing time and costs to California. The Safer Consumer Products program is "jumpstarted" by starting with a robust initial Candidate Chemicals list. DTSC can immediately start evaluating product-chemical combinations to prioritize consumer products containing Candidate Chemicals to create the first Priority Products list. For all these reasons, it is necessary to have an immediate list of Candidate Chemicals that are subject to this regulatory program.

DTSC considered the GRSP's advice, public comments, and input from other State agencies, including the California Department of Public Health, California Air Resources Board, State Water Resources Control Board, and OEHHA in establishing this list of sources for identifying Candidate Chemicals. Use of each of the chemicals lists identified in Article 2 is necessary to have a robust, scientifically rigorous, and significant suite of chemicals identified as Candidate Chemicals for purposes of implementing the provisions of Article 3 (identification and prioritization of product-chemical combinations as Priority Products), Article 5 (AAs for Priority Products), and Article 6 (regulatory responses to limit exposures to or adverse impacts posed by Priority Products or selected alternative products). DTSC employed the criteria described below in selecting authoritative organization lists to be used to establish the initial Candidate Chemicals list. These were not applied in a rigid or weighted fashion for all the reasons set out in the above section entitled *Identification and Prioritization Process Development.*

In identifying the chemicals with hazard traits for the initial Candidate Chemicals list, a type of "prioritization" occurred. That is, Chapter 54 identifies many hazard traits, but only a few were selected for identifying the chemicals included in the initial Candidate Chemicals list established in these regulations. The criteria DTSC considered in selecting the source lists for purposes of identifying chemicals with hazard traits for the initial Candidate Chemicals list are described below (in no particular order):

- The chemicals list is supported, sponsored, and/or developed by an authoritative organization, such as, a state, federal, or international agency, to protect public health and/or the environment. Many authoritative organizations are charged with protecting public health and the environment, and have identified chemicals with regulatory or risk management consequences. DTSC sought to use the evaluative

work these authoritative organizations have done in identifying chemicals with hazard traits for these regulations, rather than "reinventing the wheel." For example, DTSC sought chemicals or a given chemicals list that:

- was adopted as part of a regulatory scheme with an enforcement component;
- exhibits a hazard trait based on the authoritative organization's determination; or
- is used to support or make policy or risk management decisions to protect public health and the environment.

- The chemicals list was developed to prevent or limit exposures to public health and/or the environment, i.e., has the same purpose as these regulations. For example, the chemicals list was developed to drive action plans to prevent pollution in the environment;

- The chemicals on the list meet the "strong evidence" criteria for toxicological hazard traits or the "evidence" criteria for the exposure potential hazard traits, as specified in Chapter 54, to ensure that each chemical exhibits the highest level of evidence for its hazard trait;

- The chemicals list is reviewed and updated periodically to ensure that the chemicals list is not a one-time static effort; and

- Harmonization with chemicals lists and hazard traits identified by the States of Washington, Maine, and Minnesota that have chemical programs similar to the statutory authority provided to DTSC.

DTSC endeavored to start the Safer Consumer Products program implementation with chemicals lists and hazard traits that were generally in agreement with the recommendations of the GRSP and stakeholders. This would allow all parties to learn, gain experience, build a knowledge base, and make informed decisions before full-scale implementation of these regulations. The criteria specified above were determined to be necessary and appropriate based on GRSP and stakeholder input. These criteria ensure transparency, are reasonable criteria, and provide for a sound scientific and practical approach for identifying chemicals lists to be used as sources for establishing the initial Candidate Chemicals list.

In developing and applying the criteria for the chemicals lists and hazard traits, a balance was struck. That is, in some cases, the chemical hazard trait became the driver to identify a chemicals list and the criteria naturally paired the hazard trait with the chemicals list. In other cases, the principal purpose or function of the chemicals list

became the driver to identify the chemicals list. For example, for chemicals that are carcinogens, reproductive toxins, or developmental toxins, the California Proposition 65 list naturally comes to mind as an authoritative organization. In all cases, the chemicals on the lists meet criteria as strong evidence for toxicological hazard traits or as evidence for the exposure potential hazard traits in Chapter 54 and each of the chemicals lists is reviewed and updated periodically. However, a chemicals list did not have to meet *all* of the above-mentioned criteria for the list to be included in section 69502.2(a) for purposes of identifying the chemicals included in the initial Candidate Chemicals list.

Other factors influencing the identification of chemical hazard traits or chemicals lists, also necessary for effective and meaningful program implementation, are as follows:

- DTSC sought to have a “manageable” number of Candidate Chemicals on the initial list that would provide DTSC with a robust list of chemicals without having to add Candidate Chemicals in the early implementation years. This robust list also provides an adequate market signal to industry about chemicals that are cause for concern in consumer products and provides DTSC with a pool of chemicals from which Priority Products may be listed, and allows all parties to learn, gain experience, build a knowledge base, and make informed decisions before full-scale program implementation;

- DTSC considered the availability of State resources to implement the Safer Consumer Products program in determining a “manageable” number of Candidate Chemicals;

- DTSC looked for chemicals lists that add value to the initial Candidate Chemicals list. That is, DTSC looked to see that the given chemicals list does not excessively duplicate chemicals that are already named by other chemicals lists; and

- DTSC sought to harmonize the lists. That is, DTSC desired to include chemical hazard traits that may yield partnerships with other California, state, and national chemicals programs to leverage resources and achieve results benefiting common goals – preventing exposures to harmful chemicals in consumer products.

Using the criteria for identifying chemicals lists and chemical hazard traits, DTSC identified and essentially “prioritized” the following chemical hazard traits for the initial Candidate Chemicals list. It is important to note that some chemicals may be listed for more than one hazard trait or a hazard trait that is not listed below; however, for

purposes of the initial list of Candidate Chemicals, the hazard traits listed below were selected.

Hazard traits identified for the initial Candidate Chemicals list consist of the following:

- Carcinogenicity
- Developmental toxicity
- Reproductive toxicity
- Genotoxicity (mutagenicity)
- Endocrine Toxicity
- Neurotoxicity
- Respiratory Toxicity
- Bioaccumulation
- Environmental Persistence

These hazard traits were prioritized over other hazard traits due to the toxicity these hazard traits pose in small amounts; and the ability of chemicals with these hazard traits to stay in an organism, which may lead to toxic effects (bioaccumulation), or persist in the environment and act as a continued source of exposure. The sources of chemicals listed in this section and their applicable listing criteria are summarized in Tables 1 and 2.

The lists identified in Table 1 are hazard trait based lists; i.e., all chemicals on a list were determined by the authoritative organization that developed the list to exhibit the hazard trait(s) that is/are the focus of the list. Each list in Table 2 was developed to prevent or limit potential public or environmental exposures to the chemicals on the list.

Table 1. Section 69502.2(a)(1) Chemicals Lists and Criteria

Section 69502.2	Criteria #	1: Authoritative organization				3	4	5
	Chemicals List	Hazard Trait Basis for Listing by Auth Org	Regulatory Basis	Enforcement Consequences	Supports Policy / Risk Management Decisions	Harmonize	Strong Evidence/ Evidence	Updated
(a)(1)	The chemical exhibits a Chapter 54 hazard trait and/or an environmental or toxicological endpoint, and is on one or more of the following lists:							
(A)	**California (CA) Proposition 65**	Carcinogenicity Developmental Reproductive	X	X	X	X	X	X
(B)	**European Commission (EC) carcinogens, mutagens, and reproductive toxicants**	Carcinogenicity Mutagenicity Reproductive	X	X	X	X	X	X
(C)	**EC Category 1 endocrine disruptors**	Endocrine Toxicity			X	X	X	X
(D)	**United States Environmental Protection Agency (U.S. EPA) Integrated Risk Information System (IRIS) neurotoxicity**	Neurotoxicity			X	X	X	X
(E)	**U.S. EPA IRIS carcinogens**	Carcinogenicity			X	X	X	X
(F)	**U.S. National Toxicology Program (NTP) 12th Report on Carcinogens**	Carcinogenicity			X	X	X	X
(G)	**EC Persistent, Bioaccumulative and Toxic (PBT) & Very Persistent and Very Bioaccumulative chemicals**	Persistence Bioaccumulation	X	X	X	X	X	X
(H)	**Canadian Environmental Protection Agency Persistent, Bioaccumulative, and Inherently Toxic chemicals**	Persistence Bioaccumulation	X	X	X	X	X	X
(I)	**EC Category 1 respiratory sensitizers**	Respiratory Toxicity	X					
(J)	**International Agency for Research on Cancer Groups 1, 2A and 2B carcinogens**	Carcinogenicity			X	X	X	X
(K)	**Agency for Toxic Substances and Disease Registry neurotoxicants**	Neurotoxicity			X	X	X	X
(L)	**U.S. EPA National Waste Minimization Program PBTs**	Persistence Bioaccumulation			X	X	X	X
(M)	**NTP Office of Health Assessment and Translation reproductive and developmental toxicants**	Reproductive Developmental			X	X	X	X
(N)	**Toxics Release Inventory PBTs**	Persistence Bioaccumulation	X	X		X	X	X
(O)	**Washington State PBTs**	Persistence Bioaccumulation	X		X	X	X	X

Table 2. Section 69502.2(a)(2) Chemicals Lists and Criteria

Section 69502.2	Criteria #	1: Authoritative organization				2	3	5
	Chemicals List	**Hazard Trait**	**Regulatory Basis**	**Enforcement Consequences**	**Supports Policy / Risk Management Decisions**	**Media/ Receptor**	**Harmonize**	**Updated**
(a)(2)	The chemical exhibits a Chapter 54 hazard trait and/or an environmental or toxicological endpoint, and is one or more of the following types of chemicals:							
(A)	**CA Department of Public Health Notification Levels**	Various	X	X		Water/ Human		X
(B)	**CA Maximum Contaminant Levels**	Various	X	X		Water/ Human		X
(C)	**CA Toxic Air Contaminants**	Various		X		Air/Human	X	X
(D)	**Federal Clean Water Act 303(c) and 303(d) pollutants**	Various	X	X		Water/ Environment		X
(E)	**OEHHA inhalation and oral Reference Exposure Levels**	Various	X		X	Air/Human		X
(F)	**California Biomonitoring Program Priority Chemicals**	Various	X		X	Unknown/ Human		X
(G)	**Centers for Disease Control and Prevention's Fourth National Report on Human Exposure to Environmental Chemicals**	Various			X	Unknown/ Human	X	X
(H)	**Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic Chemicals for Priority Action Part A**	Persistence, Bioaccumulation			X	Water/ Environment	X	X

Criteria #	Chemicals List Criteria
1	The chemicals list was supported, sponsored, and/or developed by an authoritative organization, such as, a state, federal, or international agency, to protect public health or the environment. For example, the chemicals/chemicals list: • is adopted as part of a regulatory scheme and may have enforcement consequences • exhibit a hazard trait based on the authoritative organization's determination • is used to support or make policy or risk management decisions to protect public health and/or the environment
2	The chemicals list was developed to prevent or limit potential public and/or environmental exposures
3	Harmonization with chemicals lists and hazard traits identified by the States of Washington, Maine, and Minnesota with similar chemicals programs
4	The chemicals on the list meet the "strong evidence" criteria for toxicological hazard traits or the "evidence" criteria for the exposure potential hazard traits, as specified in Chapter 54
5	The chemicals list is reviewed and updated periodically; not meant to be a static list

Section 69502.2(a)(1) enumerates the hazard trait based lists of chemicals developed by authoritative organizations used as sources to identify the chemicals included on the initial Candidate Chemicals list. A chemical that exhibits a Chapter 54 hazard trait and/or an environmental or toxicological endpoint, ***and*** is listed on one or more of the chemicals lists specified in this section is a Candidate Chemical, except for chemicals exempted under Health and Safety Code section 25251 (e.g., pesticides and prescription drugs).

Table 2.1 summarizes the subsection (a)(1) chemicals source lists, the hazard trait(s) that are the basis for each authoritative organization placing chemicals on the lists, and the criteria that each chemicals list meets. The principal criterion that placed these chemicals lists together in subsection (a)(1) is the chemical's hazard trait identification by each authoritative organization that is responsible for the source chemicals list. The chemicals on these chemicals lists exhibit strong evidence for toxicological hazard traits and evidence for the exposure potential hazard traits according to Chapter 54. DTSC evaluated and analyzed each of these chemicals lists for conformance with the important scientific and policy principles and criteria set out above. Use of each of these lists is necessary to effectuate the statutory mandate to advance the search for safer chemicals in consumer products, using available information from other authoritative organizations that have undertaken chemical prioritization processes so as to minimize costs and maximize benefits to California's economy.

The chemicals lists identified as source lists for the initial Candidate Chemicals list in subsection (a)(1) list chemicals on the basis of: (1) the toxicological hazard traits of carcinogenicity, developmental toxicity, reproductive toxicity, genotoxicity (mutagenicity), neurotoxicity, respiratory toxicity, or endocrine toxicity; or (2) exposure potential hazard traits of environmental persistence and bioaccumulation.

The following subsections briefly describe each chemicals source list and briefly explain how they meet the chemicals listing criteria summarized in Table 2.1. The listing criteria in Table 2.1 are all necessary in order to have a meaningful, robust, and scientifically rigorous set of chemicals subject to further scrutiny under this program. It is noted that "evidence" is used in some of the authoritative organization's descriptions to identify the hazard traits. However, "evidence" is used as a general term unless specifically noted or defined as meeting the definitions for a hazard trait in Chapter 54. Since DTSC has determined that each of the lists below meet the important listing criteria described above, and included in Table 2.1, the necessity for the use of each list is not repeated below.

Note that in the descriptions of the provisions found in sections 69502.2(a)(1)(A) through (a)(1)(O), wherever it is stated that chemicals meeting the specified authoritative organization's listing criteria "are Candidate Chemicals" these statements do not apply to chemicals that: (1) are products exempted under Health and Safety Code section 25251; and/or (2) are not known to exhibit a Chapter 54 hazard trait or environmental or toxicological endpoint.

Section 69502.2(a)(1)(A) specifies that chemicals listed as carcinogens, developmental toxins, and/or reproductive toxins on the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) list are Candidate Chemicals. Under Proposition 65, "reproductive toxicity" includes male and female reproductive harm and developmental toxicity. Proposition 65 was enacted as a California ballot initiative in November 1986 and was intended by its authors to protect California citizens and the State's drinking water sources from chemicals known to cause cancer and/or reproductive toxicity, and to inform citizens about exposures to such chemicals.

Proposition 65 is an enforceable regulatory program implemented by OEHHA, an authoritative organization, as the lead agency appointed by the Governor. The Proposition 65 list of chemicals is regularly maintained by OEHHA. Proposition 65 protects the public from carcinogens and reproductive toxins by requiring businesses to notify Californians about exposures to chemicals above specified risk levels. This "clear and reasonable warning requirement" applies to exposures from chemicals in products they purchase, chemicals in their homes or workplaces, or that are released into the environment. By providing this information, Proposition 65 enables Californians to make informed decisions about protecting themselves from exposure to these chemicals. Proposition 65 also prohibits California businesses from knowingly discharging significant amounts of listed chemicals into sources of drinking water and serves to inform other agencies on chemical policy to protect public health.

At least once each year OEHHA publishes an updated list of chemicals that are considered “Proposition 65 chemicals.” Since 1987, the list has grown to over 900 chemical listings. (Note: “chemical listings” is not synonymous with “chemicals”. Many chemicals have multiple entries for distinct endpoints. For instance, lead is listed as causing: cancer, male reproductive harm, female reproductive harm, and developmental toxicity.) The listings are for chemicals that are known to be carcinogens and/or reproductive toxins. There are four principal ways for a chemical to be added to the Proposition 65 list:

- A chemical is listed if either of two independent committees of scientists and health professionals finds that the chemical has been clearly shown to cause cancer and/or reproductive toxicity. These two committees, the Carcinogen Identification

Committee (CIC) and the Developmental and Reproductive Toxicant (DART) Identification Committee, comprise OEHHA's Science Advisory Board. They are also at times referred to as “the State’s Qualified Experts.” OEHHA staff scientists evaluate all currently available scientific information on substances considered for placement on the Proposition 65 list and compile the relevant scientific evidence for the pertinent committee(s) to review. The committees also consider public comments before making their decisions whether or not to add a chemical to the Proposition 65 list of chemicals.

- A chemical is listed if an organization designated as an "authoritative body" by the CIC or DART Identification Committee has formally identified the chemical as causing cancer and/or reproductive toxicity. The following organizations have been designated as authoritative bodies: the U.S. Environmental Protection Agency, U.S. Food and Drug Administration (U.S. FDA), National Institute for Occupational Safety and Health, National Toxicology Program, and International Agency for Research on Cancer. It should be noted that OEHHA has adopted implementing regulations that set out technical and administrative requirements applicable to this listing mechanism.

- A chemical is listed if an agency of the State or federal government formally requires that the chemical be labeled or identified as causing cancer and/or reproductive toxicity. Most chemicals listed in this manner are prescription drugs that are required by the U.S. FDA to contain warnings relating to cancer and/or reproductive toxicity. Here, too, OEHHA has adopted implementing regulations that prescribe the listing criteria and process.

- A chemical is listed if the chemical meets certain scientific criteria and is identified in the California Labor Code as causing cancer and/or reproductive toxicity. This method was used to establish the initial chemicals list following voter approval of Proposition 65 in 1986 and continues to be used as a basis for listing, as appropriate.

Section 69502.2(a)(1)(B) specifies that 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 are Candidate Chemicals.

Annex VI is maintained by the European Chemicals Agency (ECHA), an international authoritative organization working with the European Commission and the European Union member states for the safety of human health and the environment by identifying the needs for regulatory risk management at the European Union wide level. Annex VI

to Regulation European Commission (EC) 1272/2008 includes harmonized classification and labeling requirements for certain substances or groups of substances that are legally binding within the European Union. The classification and labeling system is the basis for a number of regulatory programs within the European Union, making Annex VI an enforceable regulatory list. Annex VI is updated on a regular basis and serves as an important tool for hazard communication and risk management to inform the European Union programs and regulatory actions required for certain chemicals to protect public health. Currently, Annex VI has about 1,200 chemicals harmonized as Category 1A and 1B carcinogens, Category 1A and 1B reproductive toxins, and Category 1A and 1B mutagens (which are considered to exhibit the genotoxicity hazard trait under Chapter 54).

The classification of a chemical's hazard trait is harmonized through a transparent, public process to ensure that the classification of the chemical is agreed upon and to ensure adequate risk management throughout the European Union. This could happen in three situations:

- When chemical suppliers provide multiple or contradictory classifications for the same chemical, which may be carcinogenic, mutagenic, toxic for reproduction, or a respiratory sensitizer;
- When the substance is an active substance in biocidal or plant protection products; or
- When member states, manufacturers, importers, and downstream users justify that a classification at the European Union level is needed.

A report is prepared for the chemical classification harmonization efforts and must contain sufficient information to make an independent assessment of various physical, toxicological, and ecotoxicological hazards based on the information presented. A 45-day public comment period is held. After the comment period, all comments received are forwarded to the member state or those companies who had submitted the report for the purpose of viewing and responding to the public comments.

The proposal, the comments, and the response to comments are forwarded to the ECHA's Risk Assessment Committee. The Risk Assessment Committee, comprising experts from the member states, issues a scientific opinion on the proposal, which is then forwarded to the European Commission. The European Commission, assisted by the Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) regulatory committee, consisting of representatives of the member states, then decides on the proposed classification and labeling of the substance concerned. Once a decision is made, the harmonized classification appears in Annex VI.

Section 69502.2(a)(1)(C) specifies that 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 are Candidate Chemicals.

Category 1 endocrine disruptors were identified by a group of experts in the Endocrine Disruption Report, one in a series of studies sponsored by the European Commission, to develop a coherent approach to establish a list of priority substances to further study the chemicals and their role in endocrine disruption. This list is not meant to be static, and the intent is to update the lists as scientific knowledge increases. Since the European Parliament adopted a Resolution calling upon the Commission to take action on the issue of endocrine disruptors in 1998, the Commission has published various staff working documents, which provide overviews of existing knowledge and of the challenges for risk assessment.

A working list of chemicals was compiled from various sources that listed suspected endocrine disrupters or described effects suggestive of endocrine disrupting activity for specific chemicals (564 chemicals). Then the information was reviewed to identify chemicals that might be either highly persistent in the environment (i.e., resistant to breakdown) or that are produced by industry at high volumes (i.e., more than 1,000 tons each year) as these would pose a greater likelihood for exposure to humans and animals. Subsequent studies also included Low Production Volume Chemicals, as well as chemicals that were found to be neither High Production Volume Chemicals nor Low Production Volume Chemicals. There were quite a few existing substances produced or imported in amounts of less than ten (10) tons per year.

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 based on 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:

- At least one (1) *in vivo* study providing clear evidence for endocrine disruption in an intact organism
- 194 substances categorized as Category 1 endocrine disruptors 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

Category 2:

- Potential for endocrine disruption
- *In vitro* data indicating potential for endocrine disruption in intact organisms
- Includes effects *in vivo* that may, or may not, be endocrine disruption-mediated
- 125 substances categorized as Category 2 endocrine disruptors

Category 3a:

- Endocrine disruption studies available, but no indication of endocrine disruption effects

Category 3b:

- Substances with no or insufficient data gathered
- 109 substances with insufficient data or no data at all

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 the Directorate-General for the Environment's Endocrine Disruptor Website.[6]

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

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

Long-term actions –
In accordance with Article 57 of the REACH Regulation, the following substances 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:

- 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 carcinogenic, mutagenic and/or reproductive toxicants, persistent bioaccumulative toxicants, or very persistent and very bioaccumulative substances; and

- Substances that have been identified on a case-by- case basis in accordance with the procedure set out in Article 59 of the Regulation.

Section 69502.2(a)(1)(D) specifies that chemicals for which a Reference Dose or Reference Concentration has been developed based on neurotoxicity in the U.S. EPA's Integrated Risk Information System (IRIS) are Candidate Chemicals.

The IRIS database contains information on human health effects that may result from exposure to various substances in the environment for more than 550 chemical substances. Approximately 20 chemicals have a Reference Dose or Reference Concentration based on neurotoxicity, a hazard trait that is not heavily included in the other source lists. U.S. EPA's IRIS database is a compilation of electronic reports on specific substances found in the environment and their potential to cause human health effects. IRIS was initially developed for U.S. EPA staff in response to a growing demand for consistent information on substances for use in risk assessments, decision-making, and regulatory activities. U.S. EPA develops a list of substances for IRIS assessment on an annual basis. Through the continuously improving IRIS Program, U.S. EPA provides the highest quality science-based human health assessments to support their regulatory activities.

The Guidelines for Neurotoxicity Risk Assessment, developed by a cross-agency Technical Panel organized by the Risk Assessment Forum, set forth principles and procedures to guide U.S. EPA scientists in evaluating environmental contaminants that may pose neurotoxic risks and to inform U.S. EPA decision makers and the public about these procedures. These Guidelines are the U.S. EPA's first statement on setting principles and procedures to guide U.S. EPA scientists in conducting neurotoxicity risk assessments.

A link between human exposure to some chemical substances and neurotoxicity has been firmly established. The Guidelines emphasize that risk assessments are conducted on a case-by-case basis. They stress that information is fully presented in U.S. EPA risk assessment documents and that U.S. EPA scientists identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment. The Guidelines bridge gaps in risk assessment methodology and data by identifying these gaps and the importance of the missing information to the risk assessment process, encouraging research and analysis that will lead to new risk assessment methods and data. The Guidelines specifically note the special vulnerability of the nervous system of infants and children to environmentally relevant chemicals and provide guidance for the interpretation of data from developmental and reproductive studies involving assessment of nervous system structure and function.

The Guidelines help develop a sound scientific basis for neurotoxicity risk assessment and promote consistency in the U.S. EPA's assessment of nervous system effects. As in the case of earlier risk assessment guidelines, the principles articulated in these Guidelines will be incorporated into program-specific guidance and procedures. Risk assessment guidelines are not regulations and do not impose legally binding requirements on U.S. EPA, states, or the regulated community.

Section 69502.2(a)(1)(E) specifies that chemicals that are identified as "carcinogenic to humans," "likely to be carcinogenic to humans," or Group A, B1, or B2 carcinogens in the U.S. EPA IRIS are Candidate Chemicals.

IRIS is a human health assessment program that evaluates information on health effects that may result from exposure to environmental contaminants. Through the IRIS Program, U.S. EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities.

The IRIS database contains information that can be used to support hazard identification and dose response evaluation as part of the risk assessment process. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

IRIS contains data on over 540 chemical substances, approximately 90 of these are carcinogens characterized as "carcinogenic to humans", "likely to be carcinogenic to humans," or as follows:

A = Human carcinogen
B1 = Probable human carcinogen (limited evidence in humans)
B2 = Probable human carcinogen (sufficient evidence in animals)
C = Possible human carcinogen
D = Not classifiable as carcinogenic to humans (inadequate information)
E = Evidence of non-carcinogenicity for humans

Section 69502.2(a)(1)(F) specifies that chemicals that are identified as "known to be" or "reasonably anticipated to be" a human carcinogen in the 12th Report on Carcinogens (RoC), U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program (dated June 10, 2011) are Candidate Chemicals.

The RoC is a congressionally mandated, science-based, public health document that is prepared by the National Toxicology Program (NTP), an interagency program within Health and Human Services (HHS), on behalf of the Secretary of HHS. The report identifies agents, substances, mixtures, and exposure circumstances that are "known" or "reasonably anticipated" to cause cancer in humans. The RoC is published biennially and each edition of the report is cumulative, consisting of substances newly reviewed in addition to those listed in previous editions. The 12th RoC, released in 2011, includes 240 listings, some of which are classes of related chemicals or agents. Regulatory agencies, as well as other entities, use the RoC for policy and decision-making.

For each listed substance, the RoC contains a substance profile, which provides information on:

- cancer studies that support the listing – including those on humans, animals, and possible mechanisms of action;
- potential sources of exposure to humans; and/or
- current federal regulations to limit exposure.

Conclusions regarding carcinogenicity as "known to be" or "reasonably anticipated to be" a human carcinogen are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub-populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent acts through mechanisms that do not

operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

Section 69502.2(a)(1)(G) specifies that 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 are Candidate Chemicals.

The European Commission initiated an interim strategy to identify and address persistent, bioaccumulative and toxic (PBT) chemicals. The criteria and steps to identify a chemical as a PBT are rigorous. From an initial list of 127 PBT chemicals, 28 chemicals met all of the criteria for being PBTs; 23 other chemicals are currently still under evaluation; 66 chemicals evaluated did not meet all of the PBT criteria; and ten (10) chemicals were deferred and not evaluated. Only those chemicals fulfilling the criteria as PBTs are included on the initial Candidate Chemicals list. Also, note that even though only one (1) hazard trait is required to be identified as a Candidate Chemical, for purposes of the initial Candidate Chemicals list, those 28 chemicals that were identified as PBTs, meet three (3) hazard traits for listing under the European Commission criteria for PBTs.

Potential PBTs were identified by evaluating high production volume chemicals (at least 1,000 tons produced or imported in the European Union by at least one (1) industry per year) that met certain screening criteria based on screening data and screening estimation techniques (quantitative structure-activity relationship (QSAR) models) for high production volume chemicals. This process identified 127 chemicals, which underwent additional testing to evaluate whether they met the PBT criteria, as defined below:

- Persistence – half-life greater than:
  - Sixty (60) days in marine water;
  - Forty (40) days in freshwater;
  - 180 days in marine sediment; or
  - 120 days in freshwater sediment.

- Bioaccumulative:
  - Bioconcentration factor (BCF) greater than 2,000 L/kg.

- Toxic:
  - Chronic No Observed Effect Concentration (NOEC) less than 0.01 mg/l;
  - Substance is classified as carcinogenic (Category 1 or 2);

- Substance is classified as mutagenic (Category 1 or 2);
- Substances is classified as toxic for reproduction (Category 1, 2 or 3); or
- There is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

Section 69502.2(a)(1)(H) specifies that chemicals that are identified as Persistent, Bioaccumulative, and inherently Toxic (PBiT) to the environment by the Canadian Environmental Protection Act (CEPA) Environmental Registry Domestic Substances List are Candidate Chemicals.

CEPA PBiT is a list of 397 substances that are persistent, bioaccumulative and inherently toxic to non-human organisms, according to the categorization criteria used. Industrialized countries that are undertaking a similar categorization process tend to focus only on chemicals that are used on a very large scale, such as the PBTs on the European Union's High Production Volume (HPV) PBT list described above, while the CEPA PBiT list does not. As in the above HPV PBT European Union list, even though only one hazard trait is required to be identified as a Chemical of Concern, these chemicals meet at least two of DTSC's/OEHHA's hazard traits – persistence and bioaccumulation, in addition to CEPA's criteria for inherent toxicity.

Using information from Canadian industry, academic research and other countries, Government of Canada scientists from the Existing Substances Program at Health Canada and Environment Canada worked with partners in applying a set of rigorous tools to each of the approximately 23,000 chemical substances on the Domestic Substances List. In September 2006, Canada completed this scientific evaluation and the information is being used to focus on those chemical substances of highest priority. The results of categorization indicated that 397 substances on the Domestic Substances List are PBiTs to non-human organisms, according to the categorization criteria.

The CEPA PBiT criteria used to identify suspected chemicals as either (1) persistent or bioaccumulative, and/or (2) inherently toxic to the environment, are described below:

- **Persistent**: Chemical substances that take a very long time to break down in the environment – sometimes many years – are defined to be "persistent". These substances can affect the environment for a long period of time. Because they last for so long, they can travel long distances and pollute a much wider area than those that break down quickly. Chemical substances are considered to be persistent if they have a half-life greater than or equal to:
    - Two (2) days in air;

- 182 days in water;
- One (1) year in sediment; or
- 182 days in soil.

- **Bioaccumulative:** Chemical substances that can be stored in the organs, fat cells or blood of living organisms and remain for a long time are defined to be "bioaccumulative." Over time, concentrations can build up and reach very high levels, and can also be transferred up the food chain:
  - Bioaccumulation Factor or Bioconcentration Factor greater than or equal to 5,000, or log-octanol water partition coefficient (log K_{ow}) greater than or equal to five (5).

- **Inherently Toxic to non-human organisms:** Chemical substances that are known or suspected through laboratory and other studies to have a harmful effect on wildlife, and the natural environment on which it depends, are defined to be "inherently toxic to non-human organisms." A substance is considered to exhibit acute toxicity to aquatic species (algae, invertebrates, fish) when the LC_{50} (EC_{50}) is less than or equal to 1 mg/L, and chronic toxicity when the NOEC is less than or equal to 0.1 mg/L.

Substances meeting these criteria proceed to a screening assessment, and are then subject to one of the following outcomes:

- No further action if the substance does not pose a risk to the environment or human health;
- Added to the CEPA Priority Substances List for a comprehensive risk evaluation; or
- Added to the List of Toxic Substances in Schedule 1 of CEPA, which can be considered for regulatory or other controls.

The proposed conclusion of the draft screening assessment was that there are 148 PBiT substances that are currently not entering, or not likely to enter, the environment as a result of commercial activity in Canada. However, given the hazardous PBiT properties of these substances, there is concern that new activities for these 148 substances that have not been identified or assessed under CEPA 1999 could lead to the substances meeting the criteria set out in section 64 of CEPA for toxicity. Therefore, it was recommended that the 148 PBiT substances be subject to the Significant New Activity (SNAc) provisions specified under subsection 81(3) of CEPA. The Significant New Activity provisions were to ensure that any new manufacture, import, or use of any of these substances in quantities greater than 100 kg/year is

notified and will undergo ecological and human health risk assessments prior to the substance being introduced into Canada.

Section 69502.2(a)(1)(I) specifies that chemicals classified by the European Commission as respiratory sensitizers Category 1 in Annex VI to Regulation (EC) 1272/2008 are Candidate Chemicals.

The European Union defines respiratory sensitizer as a substance that causes occupational asthma. The European Union identifies individual, well-substantiated cases of such substances having caused asthma and considers the prevalence of such instances, relative to the number of people exposed. The European Union criteria make it clear that, to be classified as a respiratory sensitizer, a substance must induce or initiate the state of airways hypersensitivity – not provoke an existing condition. Due to the uncertainty and inconclusive evidence about the mechanism(s) involved in the development of asthma, the European Union focuses on evidence that a substance has the ability to cause asthma, rather than on the existence of a specific underlying mechanism.

The proposed criteria for the Global Harmonized System (GHS) of hazardous substances classification acknowledge that the mechanisms by which substances induce symptoms of asthma are not yet fully known, and that immunological mechanisms do not have to be demonstrated.

Section 69502.2(a)(1)(J) specifies that chemicals that are Groups 1, 2A, and 2B carcinogens identified by the International Agency for Research on Cancer (IARC) are Candidate Chemicals. IARC is part of the World Health Organization. IARC's mission is to coordinate and conduct research on the causes of human cancer and the mechanisms of carcinogenesis, and to develop scientific strategies for cancer prevention and control. Public health agencies use this information as scientific support for their actions to prevent exposure to carcinogens and agents that may be carcinogens.

Interdisciplinary working groups of expert scientists review the published studies and evaluate the weight of the evidence that an agent can increase the risk of cancer. The principles, procedures, and scientific criteria that guide the evaluations are described in the Preamble to the *IARC Monographs*. A summary of the groupings and evaluations is provided below. Note that, while the term “evidence” is used in IARC evaluations, that term is used in a different manner than its use in Chapter 54.

Group 1: The agent is carcinogenic to humans.
This category is used when there is sufficient evidence of carcinogenicity in humans. An agent may be placed in this category when evidence of carcinogenicity in humans is less than sufficient but there is sufficient evidence of carcinogenicity in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.

Group 2: The agent is probably or possibly carcinogenic to humans.
This category includes agents for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost sufficient, as well as those for which, at the other extreme, there are no human data but for which there is evidence of carcinogenicity in experimental animals. Agents are assigned to either Group 2A (probably carcinogenic to humans) or Group 2B (possibly carcinogenic to humans) based on epidemiological and experimental evidence of carcinogenicity and mechanistic and other relevant data. The terms probably carcinogenic and possibly carcinogenic have no quantitative significance and are used simply as descriptors of different levels of evidence of human carcinogenicity, with probably carcinogenic signifying a higher level of evidence than possibly carcinogenic.

Group 3: The agent is not classifiable as to its carcinogenicity to humans.
This category is used most commonly for agents for which the evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals. Group 3 placement is not a determination of non-carcinogenicity or overall safety. It often means that further research is needed, especially when exposures are widespread or the cancer data are consistent with differing interpretations.

Group 4: The agent is probably not carcinogenic to humans.
This category is used for agents for which there is evidence suggesting lack of carcinogenicity in humans and in experimental animals.

Since 1971, more than 900 agents have been evaluated, of which more than 400 have been identified as Group 1 - Carcinogenic to humans, Group 2A - Probably carcinogenic to humans, and Group 2B - Possibly carcinogenic to humans. There are 111 Group 1 carcinogens, 65 Group 2A probable carcinogens, and 274 Group 2B possible carcinogens. There are 504 Group 3 chemicals that are not classifiable as to carcinogenicity to humans due to inadequate information available for review, and one (1) Group 4 chemical that is probably not carcinogenic to humans. As new information or studies are available on a chemical, the conclusion regarding its grouping may change. IARC is continually evaluating chemicals for carcinogenicity and reflecting updated evaluations through the monographs that are made available.

Section 69502.2(a)(1)(K) specifies that chemicals that are neurotoxicants identified in the Agency for Toxic Substances and Disease Registry's (ATSDR) Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, Nervous System are Candidate Chemicals.

ATSDR is a federal public health agency of the U.S. Department of Health and Human Services. ATSDR serves the public by using science, taking public health actions, and providing health information to prevent harmful exposures and diseases related to toxic substances. This list identifies approximately 60 neurotoxins, a hazard trait that is not heavily included in the other source lists identified in section 69502.2(a).

ATSDR is directed by congressional mandate to perform specific functions concerning the effect on public health of hazardous substances in the environment. These functions include: public health assessments of waste sites, health consultations concerning specific hazardous substances, health surveillance and registries, response to emergency releases of hazardous substances, applied research in support of public health assessments, information development and dissemination, and education and training concerning hazardous substances.

ATSDR produces "toxicological profiles" for hazardous substances found at National Priorities List (NPL) sites. These hazardous substances are ranked based on frequency of occurrence at NPL sites, toxicity, and potential for human exposure. Toxicological profiles are developed from a priority list of 275 substances. ATSDR also prepares toxicological profiles for the Department of Defense (DOD) and the Department of Energy (DOE) on substances related to federal sites. Toxicological profiles are developed in two stages:

- Drafts: The toxicological profiles are first produced as drafts. ATSDR announces in the Federal Register the release of these draft profiles for a 90-day public comment period.
- Finals: After the 90-day comment period, ATSDR considers incorporating all comments into the documents and finalizes the profiles; then the National Technical Information Service (NTIS) distributes them.

So far, 318 toxicological profiles have been published or are under development as "finals" or "drafts for public comment"; 291 profiles were published as finals; and 136 profiles have been updated. Currently, eleven (11) profiles are being revised based on public comments received and six (6) profiles are under development. These profiles cover more than 250 substances.

Section 69502.2(a)(1)(L) specifies that chemicals that are Persistent Bioaccumulative and Toxic Priority Chemicals identified by the U.S. EPA National Waste Minimization Program are Candidate Chemicals.

U.S. EPA established the National Waste Minimization (NWM) Program to support efforts to promote a more sustainable society, reduce the amounts of waste generated, and lower the toxicity and persistence of wastes that are generated. The NWM Program established a list of Priority Chemicals, which consists of 28 organic chemicals and chemical compounds and three (3) metals and metal compounds. Based on its review, U.S. EPA concluded that these chemicals are persistent, bioaccumulative, and toxic (PBTs). The metals are also a high priority in international waste minimization efforts to which the United States has made commitments. The NWM Program is voluntary in nature and U.S. EPA is focusing its waste minimization efforts on the 31 Priority Chemicals identified here. In addition, U.S. EPA remains receptive to any waste minimization efforts, including efforts to address chemicals other than, or in addition to, these Priority Chemicals.

If these Priority Chemicals cannot easily be eliminated or reduced at the source, then the focus is on recovering or recycling them. The NWM Priority Chemicals are currently being generated in industrial waste and are found in soil, sediment, ground water, surface water, air, and plant, animal, and human tissue as a result of past and present releases. The metals identified as NWM Priority Chemicals are: cadmium, lead, and mercury. These metals and their compounds are known to occur frequently in federal hazardous waste regulated industrial wastes and often meet Toxicity Characteristic criteria, meaning the waste streams they are found in must be managed under federal hazardous waste regulations.

Section 69502.2(a)(1)(M) specifies that chemicals that are reproductive or developmental toxicants identified in Monographs on the Potential Human Reproductive and Developmental Effects (2003 - 2008), National Toxicology Program, Office of Health Assessment and Translation (formerly the Center for the Evaluation of Risks to Human Reproduction) are Candidate Chemicals.

The National Toxicology Program (NTP) is an interagency program, managed by the U.S. Department of Health and Human Services, whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology.

The NTP and the National Institute of Environmental Health Sciences established the NTP Office of Health Assessment and Translation (OHAT) to serve as an environmental health resource to the public and to regulatory and health agencies for policy and risk

management decisions. This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. Assessments of potential adverse effects of environmental substances on reproduction or development carried out by the Center for the Evaluation of Risks to Human Reproduction from 1998 - 2010, are now carried out by OHAT. The OHAT assessments are published as NTP Monographs.

The NTP provides toxicological evaluation on substances of public health concern to provide a scientifically based, uniform assessment of the evidence for reproductive and developmental toxicity of man-made or naturally occurring chemicals or chemical mixtures. Nominations of chemicals to be evaluated come through solicitations from the public and scientific communities, including industry, federal, state, and local governments, academia, environmental groups, citizens, and workers.

Section 69502.2(a)(1)(N) specifies that chemicals that are identified on the U.S. EPA's Toxics Release Inventory (TRI) as Persistent, Bioaccumulative and Toxic (PBT) Chemicals that are subject to reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA) section 313 are Candidate Chemicals. Approximately 18 chemicals were identified as PBTs when U.S. EPA went through the process of identifying these chemicals. The criteria used by U.S. EPA for environmental persistence and bioaccumulation hazard traits are consistent with the definition of “evidence” in Chapter 54.

U.S. EPA implements EPCRA, which requires businesses and other organizations to report chemical releases to the environment. The reporting thresholds are 25,000 pounds for the manufacture or processing of a chemical and 10,000 pounds for other uses of the chemical. As part of this regulation, U.S. EPA maintains the Toxics Release Inventory (TRI) database, which summarizes releases reported to U.S. EPA under this regulation to provide communities with information about toxic chemical releases and waste management activities and to support informed decision-making by industry, government, non-governmental organizations, and the public. The chemicals list for TRI is changed through the federal regulatory process, which in turn may affect the listing of PBT chemicals.

U.S. EPA lowered the reporting thresholds for TRI chemicals that are persistent, bioaccumulative, and toxic to 100 pounds, if a chemical on the TRI list meets the criteria below:

- Persistent:
    - Half-life of two (2) days for air; or

    - Half-life of two (2) months for water, sediment, and soil.
- Bioaccumulative:
    - Bioaccumulation Factor or Bioconcentration Factor greater than or equal to 1,000.
- Toxic:
    - Moderately high to high chronic toxicity; or
    - High ecotoxicity.

This resulted in the identification of four (4) groups of chemicals as PBTs, including dioxins and dioxin-like compounds, mercury and lead compounds, Polycyclic Aromatic Hydrocarbons (PAHs), and 16 individual chemical species.

Section 69502.2(a)(1)(O) specifies that chemicals identified by the State of Washington's Department of Ecology as Persistent, Bioaccumulative, Toxic Chemicals in Chapter 173-333 of the Washington Administrative Code (WAC) are Candidate Chemicals.

Washington's goal in identifying PBTs in WAC Chapter 173 - 333 harmonizes with the objective of the Safer Consumer Products regulations. The goal of Washington's program is to reduce and phase-out PBT uses, releases, and exposures. The Safer Consumer Products regulations aim is to limit exposures or reduce the level of hazard posed by Chemicals of Concern in consumer products by requiring AAs. The AA may show that continued use of the Chemical of Concern is necessary – similarly, Washington recognizes that many factors will influence whether their reduction or phase-out goal for these PBTs can be attained and will vary depending on the PBT and the uses of the PBT.

The Washington PBT list contains 17 chemicals, eight (8) chemical groups, and two (2) metals that were identified using the categorization criteria described below. The State of Washington will use its PBT list to develop chemical action plans to reduce and/or phase out PBTs, conduct ambient monitoring or biomonitoring to inform decision-making, and encourage voluntary measures to reduce and/or phase out PBT uses. The Washington PBT list will be reviewed and updated periodically.

The Washington criteria for identifying a chemical as a PBT are as follows:

<u>Persistent:</u> The chemical or chemical group can persist in the environment based on credible scientific information that the half-life of the chemical in water, soil, and sediments is greater than or equal to sixty (60) days.

Bioaccumulative: The Bioconcentration Factor or Bioaccumulation Factor in aquatic species for the chemical is greater than 1,000 or, in the absence of such data, the log K_{ow} is greater than five (5).

Toxic: The chemical or chemical group:

- is a carcinogen, a developmental or reproductive toxicant, or a neurotoxicant;
- has a reference dose or equivalent toxicity measure that is less than 0.003 mg/kg/day;
- has a chronic No Observed Effect Concentration (NOEC) or equivalent toxicity measure that is less than 0.1 mg/L, or an acute NOEC or equivalent toxicity measure that is less than 1.0 mg/L; or
- is a metal and the Washington Department of Ecology determines that it is likely to be present in forms that are bioavailable.

Section 69502.2(a)(2) enumerates the chemical lists developed by authoritative organizations based on exposure potential concerns that are used as sources to identify chemicals that are included on the initial Candidate Chemicals list. A chemical that exhibits a Chapter 54 hazard trait and/or an environmental or toxicological endpoint, ***and*** is listed on one or more of the chemicals lists from authoritative organizations specified in this section is a Candidate Chemical, except for chemicals exempted under Health and Safety Code section 25251 (e.g., pesticides and prescription drugs). The chemicals identified in subsection (a)(2) are identified as Candidate Chemicals in order to address or prevent chemical contamination in environmental media, such as air and water, and to prevent exposures that may cause adverse impacts to public health or the environment. Other chemicals that are identified for biomonitoring in humans are included to identify whether chemical exposure is occurring in humans. All of these chemicals are identified to inform public health agency policy and risk management decisions. In effect, the purpose of these chemical identifications became the driver to include the chemicals here as Candidate Chemicals. Because these chemicals were identified for a specific purpose such as monitoring for exposure concerns or reducing contamination, DTSC is relying on the authoritative organization's determination regarding the chemical exhibiting a Chapter 54 hazard trait and/or environmental or toxicological endpoint. Table 2.2 provides a summary of the purpose (i.e., relevant media and receptor in criterion #2) as well as other listing criteria. The following subsections briefly describe each chemicals source list, and briefly explain how they meet the chemicals listing criteria summarized in Table 2.2. The listing criteria in Table 2.2 are all necessary in order to have a meaningful, robust, and scientifically rigorous set of chemicals subject to further scrutiny under this program. Since DTSC has determined that each of the lists below meet the important listing criteria described

above, and included in Table 2.2, the necessity for the use of each list is not repeated below.

Note that in the descriptions of the provisions found in sections 69502.2(a)(2)(A) through (a)(2)(H), wherever it is stated that chemicals meeting the specified authoritative organization's listing criteria "are Candidate Chemicals" these statements do not apply to chemicals that: (1) are products exempted under Health and Safety Code section 25251; and/or (2) are not known to exhibit a Chapter 54 hazard trait or environmental or toxicological endpoint.

Section 69502.2(a)(2)(A) specifies that chemicals for which Notification Levels, as defined in Health and Safety Code Section 116455, have been established by the California Department of Public Health (CDPH) are Candidate Chemicals.

Notification Levels (NLs) are health-based advisory levels established by CDPH for chemicals in drinking water that lack Maximum Contaminant Levels (MCLs). When chemicals are found at concentrations greater than their NLs, certain requirements apply. State law (Health and Safety Code section 116455) requires timely notification of the local governing bodies (e.g., city council, county board of supervisors, or both) by drinking water systems whenever an NL is exceeded in drinking water that is provided to consumers. The NLs serve to protect public health through notification requirements and, while not enforceable as drinking water standards, exceedance of a NL has enforcement consequences.

Section 69502.2(a)(2)(B) specifies that chemicals for which primary MCLs have been established and adopted in Title 22, California Code of Regulations, sections 64431 and 64444 are Candidate Chemicals.

There are approximately 100 chemicals that have primary MCLs for drinking water, which are adopted as regulations by CDPH. MCLs are health protective drinking water standards to be met by public water systems. MCLs must be reviewed every five (5) years and take into account not only a chemical’s health risks but also factors such as detectability and treatability, as well as costs of treatment. Health and Safety Code section 116365(a) requires CDPH to establish a contaminant's MCL at a level as close to its Public Health Goal (PHG) as is technically and economically feasible, placing primary emphasis on the protection of public health. The PHG is established by OEHHA through a human health risk assessment and is the contaminant’s maximum concentration in drinking water that does not pose any significant risk to health. MCLs are health protective, adopted in regulations, and enforceable.

Section 69502.2(a)(2)(C) specifies that chemicals identified as Toxic Air Contaminants (TACs) under Title 17, California Code of Regulations, sections 93000 and 93001, are Candidate Chemicals.

The California Air Resources Board (CARB) regulates TACs through its Air Toxics Program to protect the public health by reducing TAC emissions and public exposure to TACs. This requires two separate steps. The first step is risk assessment, when the CARB identifies the highest risk substances. The second step is risk management, when the CARB and local air pollution control districts investigate and adopt measures requiring air toxics sources to minimize risk to public health.

TAC means “an air pollutant which may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health. A substance that is listed as a hazardous air pollutant pursuant to subsection (b) of Section 112 of the federal act (42 U.S.C. §7412(b)) is a toxic air contaminant.” (Health and Safety Code §39655(a).) Based on this definition, a TAC exhibits a toxicological endpoint and may be listed as a Candidate Chemical. Currently, there are over 200 substances listed as TACs, including 189 federal hazardous air pollutants. TACs are updated periodically and in selecting substances for review, CARB considers criteria relating to "the risk of harm to public health, amount or potential amount of emissions, manner of, and exposure to, usage of the substance in California, persistence in the atmosphere, and ambient concentrations in the community." (Health and Safety Code §39660(f).)

During the first step (identification), CARB determines if a substance should be formally identified as a TAC in California. During this process, CARB drafts a report that serves as the basis for this determination. CARB staff assesses the potential for human exposure to a substance and OEHHA staff, upon request of CARB, evaluates the health effects of substances being evaluated. A thorough public process to allow for interested parties to participate and present information is conducted prior to finalizing the identification of a substance as a TAC. In the second step (risk management), CARB reviews the emission sources of an identified TAC to determine if any regulatory action is necessary to reduce the risk.

Section 69502.2(a)(2)(D) specifies that chemicals that are identified as priority pollutants in California Water Quality Control Plans (Basin Plans) under section 303(c) of the federal Clean Water Act and in section 131.38 of Title 40 of the Code of Federal Regulations are Candidate Chemicals. In addition, chemicals that are identified as pollutants by California or U.S. EPA for one or more water bodies in California under section 303(d) of the federal Clean Water Act and section 130.7 of Title 40 of the Code of Federal Regulations are Candidate Chemicals.

In order to preserve our water resources, and prevent and control pollution to California waters, California Water Quality Control Plans are adopted under section 303(c) of the federal Clean Water Act. Section 303(c) requires states to develop water quality standards, and review and update those standards every three (3) years. Water quality standards must include designated uses of water bodies, water quality criteria that are necessary to protect those uses, expressed in either numeric or narrative form, and anti-degradation components. Because the Basin Plans identify priority pollutants that may affect water quality and cause toxicological and environmental endpoints to be exhibited, the chemicals that are priority pollutants in the Basin Plans may be listed as Candidate Chemicals. There are approximately 120 chemicals on this list.

The 303(d) list essentially identifies water pollutants impairing the State's waters to the degree that they violate water quality standards as specified by the federal Clean Water Act and California's Porter Cologne Water Quality Control Act. The pollutants listed on the 303(d) list are managed by water quality agencies by monitoring what enters the waterways via treated wastewater or storm water runoff to improve the water quality, and helping public agencies comply with permits issued under the Clean Water Act and the California Water Code.

Section 69502.2(a)(2)(E) specifies that chemicals that are identified with non-cancer endpoints and listed with an inhalation or oral Reference Exposure Level by OEHHA under Health and Safety Code section 44360(b)(2) are Candidate Chemicals.

OEHHA is responsible for conducting health risk assessments of chemical contaminants found in air and develops Reference Exposure Levels (RELs) for a variety of non-cancer health impacts. These RELs are required to be used in risk assessments for stationary sources for airborne emissions (California's Air Toxics Hot Spots program) and are the basis for regulatory action. There are approximately 100 RELs developed to date.

Section 69502.2(a)(2)(F) specifies that Priority Chemicals that are identified under the California Environmental Contaminant Biomonitoring Program (CECBP) are Candidate Chemicals. The Priority Chemicals were selected for the CECBP because there is a concern that humans are being exposed to harmful chemicals causing a health risk or toxicological endpoint. There are approximately 200 chemicals on the CECBP list.

The selection of priority chemicals is a two-step process. The first step is to identify "designated chemicals" – those chemicals that should be considered for biomonitoring. The enabling legislation (Senate Bill 1379, Perata, Chapter 599, Stats. 2006) identified as the initial set of designated chemicals roughly 300 chemicals currently biomonitored

by the U.S. Centers for Disease Control and Prevention (CDC). Additional designated chemicals were recommended by the Scientific Guidance Panel for inclusion in the program as designated chemicals.

The second step is to identify “high priority” chemicals from the pool of “designated chemicals” to conduct biomonitoring in California. The Scientific Guidance Panel makes recommendations regarding which chemicals should be given priority from the pool of “designated chemicals” due to the limited CECBP resources. Limited resources include the staff and instrumentation to analyze all of the designated chemicals as well as developing analytical methods.

Section 69502.2(a)(2)(G) specifies that chemicals included in the *Fourth National Report on Human Exposure to Environmental Chemicals*, *and Updated Tables*, published by the Centers for Disease Control and Prevention (CDC) (National Exposure Report) are Candidate Chemicals.

The CDC is a part of the U.S. Department of Health and Human Services and is one of the primary federal agencies for conducting and supporting public health activities in the United States. The CDC is the principal federal agency that investigates threats to public health and the environment. The National Exposure Report is a series of ongoing assessments of the U.S. population's exposure to environmental chemicals. Scientists measure chemicals or their metabolites in blood and urine samples obtained from a random sample of participants in CDC's National Health and Nutrition Examination Survey (NHANES). Data are presented for the population as a whole and for subgroups characterized by age, sex, race, or ethnicity.

CDC's Environmental Health Laboratory develops analytical methods to measure synthetic and naturally occurring environmental chemicals in people. Currently, more than 300 environmental chemicals or their metabolites are measured in human samples (e.g., urine, blood, serum, breast milk, and meconium) and reported in the National Exposure Report.

The *Fourth National Report on Human Exposure to Environmental Chemicals, Centers for Disease Control and Prevention, February 2009* was revised to include new and updated tables in February 2012 *(Updated Tables).* The *Updated Tables, February 2012,* present data from the 2005-2006 and 2007-2008 survey periods and data for a few chemicals from the 2003-2004 survey period. The Updated Tables are cumulative and include data reported in earlier updates. Specific public health uses of the exposure information in the *Fourth Report* are to:

- determine which chemicals get into Americans’ bodies and at what concentrations;

- determine what proportion of the population has levels above those associated with adverse health effects for chemicals with a known toxicity level;
- establish reference values that can be used by physicians and scientists to determine whether a person or group has an unusually high exposure;
- assess the effectiveness of public health efforts to reduce exposure of Americans by tracking levels over time;
- determine whether exposure levels are higher among minorities, children, women of childbearing age, or other special groups; and
- direct priorities for research on human health effects from exposure.

The Environmental Health Laboratory, within CDC, has a biomonitoring program that identifies potential chemicals to monitor based on solicitations from the public and other governmental agencies. Chemicals are selected based on:

- scientific data that suggests exposure in the United States population;
- the seriousness of health effects known or thought to result from some levels of exposure;
- the need to assess the efficacy of public health actions to reduce exposure to a chemical;
- the availability of an analytical method that is accurate, precise, sensitive, specific, and rapid;
- the availability of adequate blood, urine, or other samples from the biomonitoring survey; and
- the analytical cost to perform the analysis.

The results of the biomonitoring program provide information to determine what proportion of the population has chemical levels above those associated with adverse health effects for chemicals with a known toxicity.

Section 69502.2(a)(2)(H) specifies that chemicals listed in Part A of the Oslo and Paris (OSPAR) Conventions for the Protection of the Marine Environment of the North-East Atlantic List of Chemicals for Priority Action (OSPAR List) Reference number 2004-12 are Candidate Chemicals.

There are approximately 30 chemicals listed in Part A of the OSPAR List. The OSPAR Convention is the current legal instrument guiding international cooperation on the protection of the marine environment of the North-East Atlantic. In 2002, the OSPAR Convention adopted the OSPAR List to protect the marine environment, indicating that the chemicals on the OSPAR List exhibit an environmental hazard trait. There are currently 42 substances or groups of substances on the OSPAR List, of which OSPAR action is focused on the 29 substances identified in Part A of the OSPAR List. For each

of these substances or groups of substances, a background document is prepared to assess the uses and risks for the substance and to conclude what actions OSPAR should take to move towards the cessation target. These documents are reviewed periodically when new information is available, resulting in review statements or revised background documents, which may affect the risk evaluation and the recommended actions. OSPAR has adopted monitoring strategies for the hazardous substances for which background documents have been prepared. These describe information to be collected in order to monitor progress towards the cessation target.

Section 69502.2(b) specifies the factors for DTSC to consider when adding a chemical that exhibits a Chapter 54 hazard trait and/or environmental or toxicological endpoint to the Candidate Chemicals list using the procedures specified in section 69502.3(b) through (d). A factor listed in section 69502.2(b) may only be considered for a chemical if there is reliable information (as defined in section 69501.1) for that factor with respect to that chemical. Note that section 69502.3(b) provides that the factors listed in section 69502.2(b) are also to be used when DTSC is considering removing a chemical from the Candidate Chemicals list. The provisions of this section list the potential adverse impact and potential exposure factors that may be considered by DTSC, and require DTSC to consider the extent and quality of available information pertaining to those for factors for each chemical being evaluated. These provisions are necessary to specify relevant science-based factors and considerations to be used to add chemicals to the Candidate Chemicals list. (Note that the initial Candidate Chemicals list established under section 69502.2(a) includes only a limited subset of the chemicals in commerce that may upon evaluation be determined to be necessary and appropriate for listing as Candidate Chemicals.) In accordance with section 69502.3, DTSC will make available the rationale and supporting information for proposed revisions to the Candidate Chemicals list. The information that is to be used is set out in greater detail and explained below in describing the various paragraphs within section 69502.2(b).

Section 69502.2(b)(1) specifies that *Adverse Impacts* is one category of factors that DTSC must consider in deciding whether to add a chemical to the Candidate Chemicals list. This criterion is necessary since potential adverse impacts along with potential exposures are the most important bases for further scrutinizing chemicals used in consumer products.

Section 69502.2(b)(1)(A) specifies the menu of factors of which DTSC is to consider one or more in evaluating the potential of a chemical to contribute to or cause adverse public health and/or environmental impacts using reliable information. The factors set out in subparagraphs 1 through 7, relate to the chemical's toxicity profile, physical properties, and its mobility in the environment. Each criterion discussed below, when

considered individually or in combination with other listed criteria, will ensure a scientifically rigorous and meaningful evaluation of a chemical to determine if it should be added to the Candidate Chemicals list. For each chemical being evaluated for possible listing as a Candidate Chemical, reliable information demonstrating the potential existence of any one of the listed adverse impact factors could be sufficient to warrant listing the chemical as a Candidate Chemical. This section is necessary to clearly identify the menu of potential adverse impact factors that may individually or in combination form the scientific basis for listing a Candidate Chemical. Accordingly, the necessity for each subparagraph is not repeated below; however, each is discussed and further explained below:

1. One of the factors to consider in evaluating potential adverse impacts is the chemical's hazard trait(s) and/or environmental or toxicological endpoint(s). This factor was included as a very basic factor in determining whether or not a chemical should be a Candidate Chemical. The number of hazard traits and/or environmental or toxicological endpoints exhibited by a chemical could also be a factor in evaluating a chemical for possible listing as a Candidate Chemical. This provision is also consistent with the statutory directive to take advantage of the work of other agencies in this field. In this case, it is the hazard traits and environmental and toxicological endpoints identified in Chapter 54.

2. The chemical's aggregate effects are a consideration in evaluating potential adverse impacts. Aggregate effects are the chemical's effects resulting from exposure to the same chemical from multiple sources. For example, exposure to DEHP, one of the more commonly used phthalate plasticizers, comes from a number of sources. All those exposure sources would be considered in assessing its potential to contribute to or cause adverse public health impacts. This method of determining adverse public health impacts is an acceptable method for evaluating exposure (e.g., it is used in developing public health goals for drinking water).

3. The chemical's cumulative effects with other chemicals with the same or similar hazard traits and/or environmental or toxicological endpoints are factors to consider in evaluating potential adverse impacts. "Cumulative" refers to a chemical, along with other chemicals, causing the same effects (i.e., hazard trait) in the organism. This factor is appropriate to consider in identifying a Candidate Chemical because some chemicals may not cause a toxic effect through exposure by itself, but combined with other chemical exposures will cause a toxic effect.

For example, DEHP is only one of several phthalates in widespread use. Several phthalates exhibit reproductive and developmental toxicity, such as testosterone effects. In evaluating the public health impacts, widespread exposure to the other phthalates that produce the same toxic effect on testosterone would also be considered to determine the cumulative effects. And, to take it a step further, the cumulative effects of phthalates and other reproductive and developmental toxicants that act in the same way may be considered to evaluate the potential for the chemical to contribute to or cause adverse impacts.

4. The chemical's physicochemical properties are a consideration in evaluating potential adverse impacts. The chemical's physicochemical properties provide DTSC basic information on a chemical and its behavior in manufacture and use. Physicochemical properties may also be used, to some extent, as predictive indicators of behavior in humans, wildlife, ecosystems, and the environment and may be used to evaluate a chemical and its potential adverse public health and environmental impacts.

5. The chemical's environmental fate is a consideration in evaluating potential adverse impacts. The chemical's environmental fate identifies a chemical's behavior and its exposure potential hazard trait, as defined in Chapter 54. Examples of the types of information that may be used to evaluate the chemical's environmental fate include field and laboratory scientific information, as well as predictive chemical behavior using models to provide information on the chemical being considered, as well as the chemical's degradation products and fate and transport data in environmental compartments.

The following is a non-exhaustive list of examples of tools or approaches that may be used to determine the potential for the chemical to contribute to or cause an adverse impact on the environment:

- Fugacity modeling, a chemical fate and transport multimedia model;
- Field studies in the environment;
- Observations and measurements conducted in the field; and
- Microcosm studies, which include simulating an ecosystem in a laboratory setting.

In addition, environmental or biological presence may also be estimated using a point source or market-wide source term calculation, modeling or measurement, or a combination of these options.

6. The chemical's potential to contribute to or cause adverse impacts on human populations and/or aquatic, avian, or terrestrial animal or plant organisms is a consideration in the evaluation of potential adverse impacts. This criterion is an appropriate indicator of a chemical's potential to cause harm to various human and animal organisms. This evaluation may include the chemical's impact to the receptors specifically identified resulting from a single, intermittent, or chronic use or contact with the chemical through dermal, oral, and inhalation routes of exposure.

The hazard traits and toxicological endpoints in Chapter 54 are considered in conjunction with other chemical behaviors specified in subsections (b)(1)(A)(1) through (5) of section 69502.2 to ultimately determine the consequences to humans, and aquatic, avian, and terrestrial animal and plant organisms. For instance, mercury's bioaccumulation and toxicity is well documented and fish health advisories were issued by OEHHA due to potential mercury exposure from contaminated fish. This was one reason why regulatory actions were taken in the mid-2000s to ban and control the collection of mercury-containing consumer devices, such as fluorescent lamps and mercury-containing switches and thermostats.

7. The chemical's potential to degrade, form reaction products, or metabolize into another Candidate Chemical or a chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints is a consideration in the evaluation of potential adverse impacts. This factor is important since not only may chemicals themselves be harmful, but their metabolites, degradation products, and reaction products may be as well. The original Candidate Chemical may not be detected any longer, but the potential adverse impact(s) continues due to this factor. Types of data or information that may be considered include:

- Data that shows other chemical species that exhibit a hazard trait are formed during:
  - breakdown of the chemical;
  - chemical transformation in an environmental setting; or
  - combination with other chemicals;
- Computational modeling for structural activity relations to predict chemical behavior;
- Short term in-vitro bioassays to predict chemical behavior;
- Computational modeling data that provides information for this factor; and
- Information or data from public health and environmental agencies that are experiencing impacts to their responsibilities due to a chemical's potential to

degrade, metabolize, form reaction products, or transform into chemicals that are adversely affecting public health and the environment.

Section 69502.2(b)(1)(B) specifies that DTSC will give special consideration to the potential for a chemical to contribute to or cause adverse impacts to specific receptors and environmental conditions that may be especially sensitive to effects caused by a chemical, using reliable information. These criteria are necessary to effectuate the statutory mandate to give special attention to certain risk factors, exposure endpoints, and kinds of harm to public health and the environment.

1. *Sensitive subpopulations*
   Health and Safety Code section 25252 requires DTSC to consider sensitive subpopulations as part of this program. The definition of "sensitive subpopulations" in these regulations provides examples of subgroups that may be at greater risk of adverse health impacts due to exposures to chemicals, but is not limited to those named in the definition. The definition includes those that may be of "greater risk of adverse health effects when exposed to chemicals because they are either individuals with a history of serious illness or greater exposures to chemicals, or workers with greater exposures to chemicals due to their occupation."

2. *Environmentally sensitive habitats*
   Environmentally sensitive habitats are an important and necessary factor to consider when identifying a Candidate Chemical. Ecology is intertwined with human survival -- adverse impacts to the ecological system will affect public health as well as the organisms living in the habitat. For example, chemicals that affect plants or animals may affect public health through ingestion of the chemical. Also, chemicals that affect plant survival may adversely affect the delicate balance of nature that may ultimately affect the balance of carbon dioxide and oxygen in the air. Areas in California, such as wetlands, may be identified as an environmentally sensitive habitat through environmental impact reports, the California Regional Water Quality Control Boards, California Department of Fish and Wildlife, and other similar agencies or organizations.

3. *Endangered and threatened plant and animal species listed by the California Department of Fish and Wildlife*
   The fact that a chemical's toxicity or behavior has a potential adverse impact on endangered and threatened species is an important and necessary consideration when identifying a Candidate Chemical, in order to preserve these species.

4. *Environments in California that have been designated as impaired by a California State or federal regulatory agency*
   A chemical may be identified as a Candidate Chemical based on its potential adverse impact on impaired environments. For example, the California Regional Water Quality Control Boards may identify the environment around a water body, as well as the water body itself, as impaired due to chemicals found in the water and sediments. In these cases, the chemicals found to cause impairment to these environments may be given consideration in identifying a Candidate Chemical. Other federal or State agencies may also determine that environments that they protect and preserve are impacted by chemicals and deemed impaired. Those chemicals will be given special consideration based on the impaired environment. This special consideration is necessary so that particularly important types of harm done to vulnerable and threatened environments are addressed when considering possible additions to the Candidate Chemicals list.

Section 69502.2(b)(1)(C) specifies that DTSC will give special consideration to the potential for the chemical to contribute to or cause widespread adverse public health and/or environmental impacts. Impacts of this magnitude could cause severe pollution or public health impacts, and it is necessary to control the chemical before widespread impact has occurred rather than after the chemical has done its damage. By allowing special consideration of the chemical's potential to contribute to or cause these widespread adverse public health and environmental impacts such impacts may be prevented. Some examples of the types of information that might indicate potential widespread impacts include:

- data that indicates that the chemical or its degradation products are present in the California solid waste, waste water, or storm water streams that pose potential public health or environmental threats;
- chemical clean up or corrective action information from facilities that require permits to operate and handle chemicals;
- significant public funds are required to clean up or mitigate chemical threats to public health and/or the environment;
- chemical presence in consumer products that increases the cost of reusing or recycling the consumer product’s materials; and
- widespread usage of chemicals or consumer products containing the chemical.

Section 69502.2(b)(1)(D) specifies that DTSC may also evaluate and consider, based on reliable information, structurally or mechanistically similar chemicals for which there is a known toxicity profile. This provision is necessary because a chemical with a slightly altered molecule is technically a different chemical from a closely related

chemical, but in practice performs the same function and exhibits similar public health and environmental impacts. These technically new chemicals may not have the body of data as their sister chemicals but the absence of data does not equate to absence of harm.

Section 69502.2(b)(2) specifies that potential exposures to a chemical is a factor to be considered in identifying a Candidate Chemical. This criterion is necessary for all the reasons set out above discussing the need to consider both a chemical's potential adverse public health and environmental impacts and the potential for receptors to be exposed to the chemical as the basis for identifying additional chemicals as Candidate Chemicals – that is, without exposure, adverse impacts would not occur. DTSC's evaluation of potential exposures is to be based on: **(A)** reliable information regarding potential public or environmental exposures to the chemical; and **(B)** reliable information demonstrating the occurrence, or potential occurrence, of exposures to the chemical. Both terms are defined in section 69501.1.

Evidence of potential chemical exposure may be shown, for example, by human biomonitoring, such as the Report on Human Exposure to Environmental Chemicals conducted by CDC or data that indicates the presence in the indoor environment, air, food, or drinking water. Anecdotal evidence in and of itself of the chemical’s presence in biomonitoring data, an indoor environment, or drinking water is not sufficient evidence for identification as a Candidate Chemical, unless the anecdotal evidence is, or is verified as, reliable information. For a complete list of the types of information that could be evaluated as evidence of potential exposure to a chemical refer to the definitions of "reliable information" and " reliable information demonstrating the occurrence, or potential occurrence, of exposures to the chemical", which are discussed under Article 1 of this Statement of Reasons.

Authoritative organizations are also using the volume of a chemical in commerce as a surrogate regarding exposure concerns. For instance, if only ten (10) pounds of a chemical are manufactured each year, there is much less chance of widespread exposure than if chemical manufacturers are producing ten (10) million pounds each year.

Section 69502.2(b)(3) specifies that DTSC shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts and potential exposures in evaluating chemicals for identification as Candidate Chemicals. In evaluating the quality of available information, DTSC will consider, as applicable, the factors specified in section 69503.2(b)(1)(C).

This provision is necessary to ensure that DTSC gives consideration to the amount and quality of information available to support a decision to list or delist a Candidate Chemical to ensure that such decisions are well-informed and based on sound science. This provision is also necessary to clearly identify the factors that DTSC will consider in evaluating information quality. It is true that new chemicals, and existing chemicals that have not been studied sufficiently, will frequently lack robust data sets. However, there are provisions for DTSC to consider structurally or mechanistically similar chemicals for which there is a known toxicity profile. See the discussion below regarding section 69503.2(b)(1)(C) for additional information concerning the factors DTSC will use to evaluate the quality of information.

§ 69502.3. Candidate Chemicals List

Section 69502.3(a) specifies that DTSC will make available on its website an informational list of the initial Candidate Chemicals within thirty (30) days after the effective date of these regulations. This provision is necessary to ensure that all of the stakeholders – including responsible entities and other interested parties – are informed as to the chemicals identified as Candidate Chemicals under section 69502.2(a) as of the effective date of the regulations.

This section also requires DTSC to periodically update the Candidate Chemicals list to reflect changes to the underlying lists and sources using the procedures specified in subsections (c) and (d). This provision is necessary to ensure that the list of Candidate Chemicals is kept current.

Section 69502.3(b) specifies that DTSC may make additions to, or deletions from, the Candidate Chemicals list using the factors specified in section 69502.2(b) and the procedures in subsections (c) and (d) of this section. This section is necessary to make it clear that DTSC may revise the Candidate Chemicals list to either add or remove chemicals, and to establish the criteria and processes that DTSC will follow for revising the list.

Section 69502.3(c) specifies the process by which DTSC will provide for public review and comment on proposed revisions to the Candidate Chemicals list. Specifically, this section requires DTSC to:

- Make proposed revisions to the Candidate Chemicals list, along with supporting documentation (including DTSC's rationale and a bibliography of the supporting information and information sources), available on its website for public review and comment prior to finalizing the proposed revisions;
- Hold one or more public workshop(s) to provide an opportunity for comment on the proposed revisions; and

- Send to persons on its electronic mailing list, and post on its website, a notice regarding the availability of the proposed revisions and supporting documentation.

DTSC recognizes that before Candidate Chemical listing decisions are finalized, stakeholders need to examine and have the opportunity to comment on the rationale, data, and information sources that led DTSC to those decisions. The comment period is necessary to provide interested parties an opportunity to present information and data not previously considered to have a chemical added to or removed from the Candidate Chemicals list prior to finalization of the list. These provisions are necessary to provide transparency with respect to DTSC's decision-making, and to obtain public input and perhaps additional relevant information to better inform the final decision. These provisions are also necessary to inform interested parties as to the process for providing comments on proposed changes to the Candidate Chemicals list.

Section 69502.3(c)(1) through (3) specify that the following information must be included in the notice regarding the availability of proposed revisions to the Candidate Chemicals list for public review and comment:

(1) The last day for the public to submit written comments on the proposed revisions to the Candidate Chemicals list;
(2) The method(s) for submitting comments to DTSC; and
(3) The date, time, and location of the public workshop(s).

This provision is necessary to ensure that the public notice provides the information needed by interested parties to enable them to review and comment on proposed changes to the Candidate Chemicals list. Section 69502.3**(c)(1)** also provides that the public comment period shall be *at least* forty-five (45) days from the date the notice is posted on DTSC's website or is sent to persons on the electronic mailing list, whichever date is later. This provision is needed to ensure that interested parties are afforded adequate time to consider and comment on proposed revisions to the Candidate Chemicals list. Forty-five (45) days was selected as the minimum time allowed for public comment, as this is consistent with many other regulatory processes that embody a public comment period. However, in order to provide additional time when DTSC determines it is necessary, this section enables DTSC to establish a public comment period of more than forty-five (45) days.

Section 69502.3(d) specifies that after DTSC considers public comments, DTSC will finalize and post on its website the finalized revisions to the Candidate Chemicals list. This provision is necessary to ensure that DTSC does not finalize its decision-making until after it gives consideration to information provided during the public comment

period for the proposed revisions to the Candidate Chemicals list. This section also provides that DTSC may, at its own discretion, respond to some or all of the public comments received during the comment period. This provision is necessary to maximize the effective use of DTSC's limited resources.

ARTICLE 3. Process for Identifying and Prioritizing Product-Chemical Combinations

Article 3, in its entirety, is necessary to implement, clarify, and specify the process for identifying and prioritizing product-chemical combinations for listing as Priority Products. Article 2 describes the first step in the process to develop safer consumer products – establishing a process to identify chemicals as Candidate Chemicals. Article 3 describes the second step – establishing a process to identify and prioritize product-Candidate Chemical combinations for proposed listing as Priority Products. These first two steps of the process culminate in the identification of Priority Products for which manufacturers are required to identify safer alternatives through the Alternatives Analysis (AA) process in Article 5.

As described in the introduction for Article 2 in this Statement of Reasons, the authorizing legislation requires the Department of Toxic Substances Control (DTSC) to identify and prioritize chemicals or chemical ingredients in consumer products. For the reasons discussed in the introduction for Article 2, DTSC has established a process to identify Candidate Chemicals in Article 2, and a process to identify and prioritize consumer products containing Candidate Chemical(s) as Priority Products in Article 3. Article 3, in its entirety, is necessary to clarify and make specific the provisions of Health and Safety Code sections 25252 and 25253 by establishing the process to identify and prioritize consumer products containing Candidate Chemical(s) as Priority Products.

For additional background information pertinent to Article 3, refer to the introductory discussion for Article 2 in this Statement of Reasons. The remainder of the Statement of Reasons for Article 3 describes, and outlines the rationale for, the identification and prioritization process for Priority Products.

§ 69503. General

Section 69503 introduces the purpose of Article 3 – to specify the process by which DTSC will identify and prioritize product-Candidate Chemical combinations under this article. This provision is necessary to inform responsible entities and other interested parties of the purpose of this article.

This section also specifies that, as part of the Priority Product identification and prioritization process, DTSC may evaluate information from manufacturers and other sources. DTSC may rely on information about products obtained under section 69501.4, but is not limited to solely using information obtained under section 69501.4, in

performing its duties under Article 3. This provides DTSC with maximum latitude and flexibility to seek out and utilize a broad range of scientific data and other information that is necessary to ensure that the Priority Product identification and prioritization process and the resulting Priority Products list are based on sound science.

§ 69503.1. Applicability

Section 69503.1 specifies that Article 3 applies to all products that contain one or more Candidate Chemicals and that are placed into the stream of commerce in California, with the exception of those products that are exempted under section 69501(b). (See the Statement of Reasons for section 69501 for information concerning the exemption provisions of section 69501(b).) This provision is necessary to make it clear to all interested parties the scope of products that may be considered in the product-chemical combination prioritization process and potentially listed as Priority Products. The scope specified in this section is consistent with, and is necessary to implement, the broad scope of the authorizing legislation.

The first point of entry into the Article 3 prioritization process is that the product contains one or more Candidate Chemical(s). The second criterion that must be met is that a product containing a Candidate Chemical is placed into the stream of commerce in California. (See the Statement of Reasons for section 69501.1 for information concerning what it means for a product to be "placed into the stream of commerce in California.") This provision is necessary to ensure that the process is focused on those products that are of concern to the citizens and the environment of California and to maintain consistency in scope with the authorizing legislation.

§ 69503.2. Product-Chemical Identification and Prioritization Factors

Section 69503.2 specifies the factors DTSC will/may use to identify and prioritize product-chemical combinations as Priority Products. The factors considered emphasize characteristics of product-chemical combinations that would contribute to or cause potential adverse impacts, such as: a Candidate Chemical's toxicity profile; the physical attributes exhibited by a Candidate Chemical in a consumer product; potential exposures to a Candidate Chemical contained in a product; and potential adverse waste and end-of-life effects. DTSC is also required to consider the extent and quality of information available to identify and prioritize product-chemical combinations, and the scope of other regulatory programs under which products and/or their Candidate Chemical(s) are regulated. DTSC may also consider whether there are readily available safer alternatives.

This section is necessary to specify for DTSC and to inform interested parties regarding relevant science-based factors and other considerations for use in identifying and prioritizing product-chemical combinations as Priority Products.

Section 69503.2(a) specifies the key prioritization principles for the listing of Priority Products. Specifically, any product-chemical combination listed as a Priority Product must meet both key prioritization criteria:

(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.

This provision is necessary to ensure that the limited resources of DTSC, responsible entities, and other interested parties are focused on product-Candidate Chemical combinations that are of high priority because there are both potential exposures to the Candidate Chemical(s) and there is the potential for those exposures to lead to significant or widespread adverse impacts.

The public and/or aquatic, avian, or terrestrial animal or plant organisms' exposure to the Candidate Chemical(s) in the product will be evaluated considering routes of exposure to the product and the Candidate Chemical(s) in the product throughout the product's life cycle. This evaluation will take into account reasonably available information regarding one or more exposure scenarios and an evaluation of the extent and quality of the relevant available information. This evaluation will include consideration of one or more of the exposure potential factors listed in section 69503.3(b).

The second key prioritization principle requires DTSC to evaluate whether one or more exposures to a Candidate Chemical in the product have a potential to contribute to or cause significant or widespread adverse public health and/or environmental impacts. Evaluating the potential for significant adverse impacts might include, for example, consideration of the Candidate Chemical's toxicity profile and/or its adverse impacts on sensitive subpopulations and/or sensitive environmental receptors. Similarly, the evaluation of the potential for widespread adverse impacts could include, for example, consideration of the Candidate Chemical's mobility in different types of environmental media and/or how widely the product is sold or used.

In some instances, the nature of the Candidate Chemical in the product may drive the listing as a Priority Product even though the exposure may be relatively small. As an example, if the toxicity of the Candidate Chemical is high and the product sources of the

Candidate Chemical are numerous, the resulting aggregate exposures and adverse impacts may drive the Priority Product listing. In other cases, the exposure will drive the listing of the product even though the Candidate Chemical exhibits only moderate toxicity if, for example, its market presence and concentration in the product is relatively high.

Section 69503.2(b) specifies the process to evaluate a product-chemical combination for possible identification and prioritization as a Priority Product. This section provides that:

- DTSC may identify and list as a Priority Product one or more product-chemical combinations that is/are determined to be of high priority;
- DTSC's decision to list a Priority Product must be based on an evaluation of the product-chemical combination's potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects – by considering the factors described in sections 69503.2(b)(1) (adverse impacts and exposures) and (b)(2) (other regulatory programs) for which information is reasonably available; and
- DTSC may also, in its discretion, consider section 69503.2(b)(3) (existence of safer alternatives).

This section is necessary to make it clear to DTSC, as well as responsible entities and other interested parties, that only product-chemical combinations determined to be of high concern based on potential adverse impacts and potential exposures may be listed as Priority Products. This section also serves to make it clear that DTSC is not required to list <u>all</u> product-chemical combinations of high concern. This is necessary since listing all product-chemical combinations of high concern would not be doable given DTSC's limited resources. This section is also necessary to provide to the public, responsible entities, and other interested parties an overview of the range of factors that DTSC is <u>required</u> to consider and those that it <u>may</u> consider in its discretion.

Section 69503.2(b)(1)(A) specifies that DTSC's evaluation of product-chemical combinations will begin with consideration of the potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures during the life cycle of the product.

This section provides that DTSC's *evaluation* of potential adverse impacts and potential exposures must include consideration of one or more potential adverse impact factors listed in section 69503.3(a) and one or more potential exposure factors listed in section 69503.3(b). Finally, this section requires that the *listing* of Priority Products be based on one or more potential adverse impact factors listed in section 69503.3(a) and one or

more potential exposure factors listed in section 69503.3(b), in addition to the other factors specified in section 69503.2 (adverse waste and end-of-life effects, extent and quality of available information, other pertinent regulatory programs, and availability of safer alternatives).

This section, in concert with section 69503.3, is necessary to specify for DTSC and other interested parties the menu of potential adverse impact / exposure factors that DTSC may use in evaluating a product-chemical combination for possible listing as a Priority Product. This section is also necessary to make it clear that DTSC is not required to evaluate all listed adverse impact / exposure factors, but must consider at least one potential adverse impact factor and at least one exposure potential factor. Further, this section is necessary to require and make it clear that a decision to list a Priority Product mist be based on at least one potential adverse impact factor <u>and</u> at least one exposure potential factor, as well as the other factors specified in section 69503.2 (some of which are mandated for consideration, while others may be considered at DTSC's discretion). DTSC's limited resources make it impossible for DTSC to consider every single factor relating to potential adverse impacts / exposures; and a single potential adverse impact coupled with a single potential exposure can be sufficient to make a product-Candidate Chemical combination of high concern and, thus, warrant its listing as a Priority Product.

Section 69503.2(b)(1)(B) specifies that DTSC <u>may</u> also consider product uses, discharges, or disposals in a manner that have the potential contribute to or cause adverse waste and end-of-life effects associated with the Candidate Chemical(s) in the product. (See the Statement of Reasons for section 69501.1 for a description of adverse waste and end-of life effects.) This provision is necessary to allow DTSC to consider an important potential environmental, as well as taxpayer cost, consequence as part of its product-chemical combination identification and prioritization process.

For example, if a discharge or disposal is into the sewer, the Publicly Owned Treatment Works (POTW) may not be able to remove or treat the Candidate Chemical(s) before it is discharged into California waters or it may be costly to do so. All life depends on water and, consequently, there may be exposure to and resulting adverse impacts from the discharged Candidate Chemical(s). An indirect method that may be used to measure or quantify exposure is the POTW's cost to treat or remove the Candidate Chemical(s) or its metabolites before the treated water is discharged into California waters. If treatment or removal is not conducted, the consequence is an increase in the likelihood of public and environmental exposures to the discharged Candidate Chemical(s).

Section 69503.2(b)(1)(C) specifies that DTSC will consider the extent and quality of available information to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. This section is necessary to ensure that the proposed and final listing of Priority Products is based on sound scientific and other information, to the extent available.

Section 69503.2(b)(1)(C) also specifies the following criteria that DTSC will use in evaluating the quality of available information, as applicable:

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, as well as 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 DTSC.

Specifying these factors for evaluating information quality in the regulations is necessary to give DTSC clear direction as to the criteria to be used to evaluate the relative quality of the various pieces of information obtained or submitted relative to the identification of chemicals and the identification and prioritization of product-chemical combinations. This also provides responsible entities and other interested parties who submit information to DTSC with advance guidance as to how their information may be viewed by DTSC in terms of its quality.

While the regulations specify the criteria that DTSC will use to evaluate the quality of information (and, thus, the “weight of evidence”), DTSC has chosen not to include a specific strictly defined weight-of-evidence process or rules for applying these criteria in its decision-making. Rather, DTSC will apply these criteria on a case-by-case basis using expert judgment. This is necessary as it would not be rationale to include a single strictly defined process in the regulations that would be expected to adequately anticipate the potential diversity of information, variable processes and approaches, and expertise needed for research, evaluation, and analysis – and at the same time dictate rigid rules of logic and decision-making.

Health and Safety Code section 25252 requires DTSC to establish an identification and prioritization process that includes, but is not limited to, all of the following considerations:

1) The volume of the chemical in commerce in California;
2) The potential for exposure to the chemical in consumer products; and
3) Potential effects on sensitive subpopulations, including infants and children.

Unfortunately, the information about chemicals and consumer products containing chemicals (e.g., product concentrations, toxicity, exposure, and fate and transport) that is available in the open market or literature ranges from no information to a very substantial amount of information. A full complement of quantitative adverse impact and exposure information has rarely accompanied any chemical or product into the marketplace. In anticipation of the variability of available information, especially information on adverse impacts and exposures for chemicals and Candidate Chemicals in products, these regulations do not specify a rigid and explicit process that demands the absolute existence and consideration of quantitative information prior to DTSC making a prioritization decision.

For these regulations and the program they establish to be practical and meaningful, DTSC cannot be constrained in making public health and environmental protection decisions because of the lack of precise quantitative information. DTSC will consider relevant readily available scientific and/or other evidence of potential and actual adverse impacts and potential and actual exposures in the prioritization process. The extent to which non-published information from industry or other sources meets the criteria relative to rigor and independent review by disinterested parties will be considered in evaluating the quality of those studies and other information.

DTSC recognizes that the available scientific information has to be viewed in the overall context of the available information on a specific chemical in evaluating product-chemical combinations for listing on the proposed Priority Products list. In addition, DTSC recognizes that the available information regarding market presence, product type and concentration, toxicity, exposure, and fate and transport may become available from various sources such as scientific peer reviewed literature, other governments or authoritative sources, and from private research holdings, which can range from non-existent to very substantial.

The criteria specified in section 69503.2(b)(1)(C) provide a practical and valid approach to evaluation of information quality in the prioritization process. For example, the issue of conflicts of interest that may be germane to the findings in any given report or study

that is conducted and/or published can be addressed if the report or study is reviewed by a qualified disinterested reviewer with suitable education and experience.

The information supporting DTSC's prioritization approach and decisions will be available to the public for review and comment prior to finalizing the Priority Products list. All stakeholders may provide scientific and other information for the purpose of rebutting, clarifying, or supporting DTSC's approach and decisions during the product-chemical prioritization process for the listing of Priority Products and the identification process for listing Candidate Chemicals.

> NOTE: The process to prioritize products containing Candidate Chemicals as Priority Products will need to be based on consideration of both scientific information and other information that is not generally considered to be scientific in nature (e.g., market data and product uses). Numerous public comments have urged DTSC to specify and limit the types of scientific information that it will use in the chemical identification and product-chemical prioritization processes because of the wide variability in the quantity, quality, and reliability of relevant available scientific studies and other scientific information. In response to these comments, DTSC defined the term "reliable information" (in section 69501.1(a)(57)) to list the types of scientific information (*e.g.*, scientifically peer-reviewed information and reports by government agencies) that it will consider in identifying Candidate Chemicals and Priority Products.
>
> The public comments also urged DTSC to specify in the regulations how DTSC will evaluate "weight-of-evidence" in its decision-making for identification of Candidate Chemicals and Priority Products – in other words, how DTSC will evaluate each scientific information source with respect to its quality, validity, and reliability – on a stand-alone basis, in comparison with other scientific information sources that may draw different conclusions, and/or as serving to bolster the validity of other scientific information sources that draw the same conclusions. In response to these comments, DTSC articulated in the regulations (section 69503.2(b)(1)(C)1. through 5.) the criteria that DTSC will use for the purposes of evaluating information quality. (For purposes of evaluating information quality for the identification of Candidate Chemicals, there is a cross-reference in section 69502.2(b)(3) to the criteria specified in section 69503.2(b)(1)(C).) While most of the comments on this issue focused on the evaluation of scientific information, DTSC determined it appropriate and necessary to apply these criteria to the quality evaluation of all types of information used to identify Candidate Chemicals and Priority Products.

An earlier version of the proposed regulations placed the information quality evaluation criteria within the definition of "reliable information" in the definitions section of the regulations (section 69501.1(a)). However, DTSC determined that the criteria should more appropriately be specified in section 69503.2(b)(1)(C) (which requires DTSC to consider the extent and quality of information available to substantiate the existence or absence of potential adverse impacts and exposures), for several reasons, including: (i) these criteria (unlike the listing of the types of information that are defined as "reliable information") are not definitional in nature, and, therefore, do not appropriately belong in the definitions section of the regulations; (ii) the criteria need to be placed in the regulations in a location that would readily make them applicable to both scientific and other types of information; and (iii) the intended purpose of embodying these criteria in the regulations (in response to public comments) is to guide DTSC's decision-making in the evaluation of chemicals and products under Articles 2 and 3.

Section 69503.2(b)(2) specifies that DTSC is to consider the scope of other regulatory programs and the extent to which they address and provide adequate protection against the same potential adverse public health and environmental impacts, exposure pathways, and adverse waste and end-of-life effects being considered as a basis for listing a Priority Product. Other regulatory programs include: other California State regulatory programs and other federal regulatory programs, including those that stem from applicable treaties or international agreements with the force of domestic law. This section further provides that if a product is regulated by another entity, with respect to the same potential adverse impacts, exposure pathways, and adverse waste and end-of-life effects, DTSC may list that product as a Priority Product only if DTSC determines that the listing would meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts, exposure pathways, and/or adverse waste and end-of-life effects that are the basis for listing the product as a Priority Product. These provisions are necessary to ensure that DTSC maximizes the effective use of its resources by focusing on those public health and environmental concerns that are not already being adequately addressed by another federal or California State regulatory program.

This provision is also necessary to implement and ensure consistency with Health and Safety Code section 25257.1(c), which provides that "DTSC shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article [14]." Federal and California regulatory agencies, and regulatory regimes created by legally binding treaty obligations, will be evaluated to determine if they fall under this statutory provision.

Regulatory authority over a consumer product by a foreign country, another state, or a local agency would not qualify for this statutory exemption (and this implementing regulation) since in these situations there is no jurisdictional or consistent authority either in or throughout California.

DTSC will assess each regulatory program to determine to what extent public health and the environment are protected from threats posed in comparison to the protection that would be achieved under these regulations. The more co-extensive the degree of protection under the collective application of other programs is with the protections afforded under this program, the greater the likelihood that DTSC will not prioritize a product-chemical combination for further consideration under this program. Note that this “sliding scale” prioritization criteria in section 59503.2(b)(2) is in addition to the complete exemption provided in section 69501(b)(3). Therefore, DTSC may determine that a product that does not meet the exemption criteria in section 69501(b)(3) is nonetheless not a good candidate for identification and prioritization as a Priority Product given the nature and extent of existing regulatory program(s) that apply to the product.

For example, Chemical A in one product is adequately regulated from its production through consumer use, but the disposal causes an adverse environmental impact that is not regulated. Chemical B in another product may result in consumer exposure during use and its disposal also causes an adverse environmental impact. Setting aside all other prioritization factors, DTSC might conclude that the product containing chemical B is largely “unregulated” and is a higher priority than the product containing Chemical A. All other things being equal, the product containing chemical B might be proposed as a Priority Product based on this difference.

By way of further example, a product that might qualify for low prioritization under these regulations is a fuel additive that has undergone a multimedia evaluation as required by Health and Safety Code section 43830.8. Before adopting new specifications for chemical fuel additives, the California Air Resources Board (CARB) is required to prepare a multimedia evaluation to examine the relative risks posed by any newly proposed fuel additive to the State’s resources, human health, and the environment. Health and Safety Code section 43830.8 requires that a multimedia evaluation must identify and evaluate any significant adverse impact on public health and the environment, including air, water, or soil that may result from the production, use, or disposal of a motor vehicle fuel that may be used to meet CARB motor vehicle fuel specifications. The evaluation not only includes engine performance and emission requirements, but also includes considerations of health and environmental criteria involving air emissions, cross environmental media transfer and associated health risks,

ozone formation potential, hazardous waste generation and management, and surface and groundwater contamination resulting from production, distribution, and use. This is a rigorous multimedia risk assessment that also incorporates life cycle concepts to provide policy makers with reliable information to make policy decisions regarding public health and environmental protection. A consumer product that is subject to this type of multimedia evaluation under another federal or California State regulatory program might be determined by DTSC to be of low priority under Article 3.

Section 69503.2(b)(3) specifies that when deciding whether to list a product-chemical combination as a Priority Product DTSC may consider whether there is a readily available safer alternative that is functional acceptable, technically feasible, and economically feasible. This section is necessary to provide DTSC the discretion to consider whether such a safer alternative exists in making a decision to list a product-chemical combination as a Priority Product. More specifically, the existence of a known safer alternative could make the listing as a Priority Product more likely than if this were not the case. This provision allows DTSC to consider giving priority to a product based on publicly available information on safer alternatives. This in turn fosters the ability of the manufacturer to consider and to expeditiously complete the Alternatives Analysis process for the Priority Product to hasten the introduction of a safer product into the marketplace.

§ 69503.3. Adverse Impact and Exposure Factors

Section 69503.3(a) specifies the menu of adverse public health and environmental impact and exposure factors DTSC may use to evaluate and prioritize product-chemical combinations for possible listing as Priority Products. The list of factors that may be considered emphasize the product's Candidate Chemical's toxicity profile and physical attributes and the potential exposures to the Candidate Chemical(s) in the product that have the potential to contribute to or cause potential adverse impacts.

This section along with section 69503.2(b)(1(A) explain that the first step in evaluating a product-chemical combination is a two-fold evaluation. The two broad criteria are potential adverse impacts and potential exposures. These may also be thought of as:

1) the Candidate Chemical's behavior in terms of its toxicity and physical profile in the product; and
2) potential exposures to the Candidate Chemical in the product that may contribute to or cause potential adverse impacts.

This section, in its entirety, is necessary to clearly identify for DTSC and interested parties the menu of potential adverse impact and potential exposure factors that may,

individually or in combination, form a basis for listing a Priority Product. As discussed in the Statement of Reasons for section 69503.2, both potential adverse impacts and potential exposures are critical factors in the identification and prioritization of product-chemical combinations for possible listing as Priority Products.

Section 69503.3(a) specifies that the *Adverse Impacts* associated with the Candidate Chemical(s) in a product is one category of factors that DTSC must consider in deciding whether to list a product-chemical combination as a Priority Product. This criterion is necessary since potential adverse impacts along with potential exposures are the most important bases for determining whether to require Alternatives Analyses for a product-chemical combination by listing is as a Priority Product.

Section 69503.3(a)(1) specifies the menu of factors of which DTSC is required to consider one or more in evaluating the potential of a Candidate Chemical in the product to contribute to or cause adverse public health and/or environmental impacts using reasonably available information. The factors set out in subparagraphs (A) through (G) relate to the chemical's toxicity profile, physical properties, and its mobility in the environment. Each criterion identified below, when considered individually or in combination with other listed criteria, will ensure a scientifically rigorous and meaningful evaluation of a product's Candidate Chemical to determine if the product-chemical combination should be listed as a Priority Product:

- **(A)** The Candidate Chemical's hazard trait(s) and/or environmental or toxicological endpoint(s);
- **(B)** The Candidate Chemical's aggregate effects;
- **(C)** The Candidate Chemical's cumulative effects with other chemicals;
- **(D)** The Candidate Chemical's physicochemical properties;
- **(E)** The Candidate Chemical's environmental fate;
- **(F)** The human populations, and/or aquatic, avian, or terrestrial animal or plant organisms for which the Candidate Chemical has the potential to contribute to or cause adverse impacts; and/or
- **(G)** The potential for the Candidate Chemical to degrade, form reaction products, or metabolize into another chemical.

Section 69503.3(a)(2) specifies that DTSC will give special consideration to the potential for a Candidate Chemical in the product to contribute to or cause adverse impacts to specific receptors and environmental conditions that may be especially sensitive to effects caused by the Candidate Chemical. Specifically, DTSC is required to give special consideration to all of the following:

(A) Sensitive subpopulations;
(B) Environmentally sensitive habitats;
(C) Endangered and threatened species; and
(D) Environments in California that have been designated as impaired.

Section 69503.3(a)(3) specifies that DTSC may also evaluate and consider, based on reliable information, adverse impacts associated with structurally or mechanistically similar chemicals for which there is a known toxicity profile.

The factors to be considered in section 69503.3(a) are the same as those listed in Article 2, sections 69502.2(b)(1)(A), (B), and (D) for Candidate Chemicals identification, except that the evaluation in this section emphasizes the adverse impacts of Candidate Chemicals *in consumer products*. Accordingly, the necessity for each of these factors is not repeated here. Please see Article 2, sections 69502.2(b)(1)(A), (B), and (D) of this Statement of Reasons for further description of these factors and the necessity for each of them.

Section 69503.3(b) specifies that, in evaluating product-chemical combinations for possible listing as Priority Products, DTSC is required to evaluate the potential for public and/or aquatic, avian, or terrestrial animal or plant organism *Exposures* to the Candidate Chemical(s) in the product. A factor listed in section 69503.3(b) may only be considered for a product-chemical combination if there is reasonably available information for that factor with respect to that product-chemical combination.

This section also specifies the menu of factors of which DTSC is required to consider one or more in evaluating the potential exposure pathways for a Candidate Chemical in a product. The factors set out in paragraphs (1) through (4) relate to market presence of the product, occurrences or potential occurrences of exposures, household and workplace presence of the product, and potential exposures during the product's life cycle. Each criterion discussed below, when considered individually or in combination with other listed criteria, will ensure a scientifically rigorous and meaningful evaluation of a product-chemical combination to determine if it should be listed as a Priority Product. This section is necessary to clearly identify the menu of potential exposure factors that may individually or in combination form a scientific basis for listing a product as a Priority Product. Accordingly, the necessity for each paragraph is not repeated below; however, each is discussed and further explained below:

Section 69503.3(b)(1)(A) through (C) specifies that market presence information for the product may be used as a surrogate to assess potential exposures to the Candidate Chemical(s) in the product. In addition, this section calls out specific subsets of market presence information that may be considered by DTSC as part of the prioritization

process because the specified information is a further valuable surrogate for measures of potential exposure for which there is little data. The specific types of market presence information called out in this section are:

(A) Statewide sales by volume;
(B) Statewide sales by number of units; and/or
(C) Intended product uses, and types and age groups of targeted customer base(s).

Note that DTSC is not precluded from considering other types of market presence information that is relevant and for which information is reasonably available. The factors listed in this provision are consistent with the statutory mandate (Health and Safety Code section 25252(a)(1)) that DTSC consider the volume of a chemical in commerce as part of the identification and prioritization process.

Section 69503.3(b)(2) specifies that DTSC may consider the occurrence, or potential occurrence, of exposures to the Candidate Chemical(s) in a product as part of the product-chemical combination identification and prioritization process. Examples of the types of information that DTSC might consider in evaluating this factor for a product-chemical combination include:

- monitoring data that indicates that the Candidate Chemical or its degradation products are present in the California solid waste, waste water or storm water streams;
- environmental media data that indicates the presence of the Candidate Chemical or its degradation products; and
- biomonitoring or environmental monitoring data showing the presence of the Candidate Chemical or its degradation products in humans or other biological organisms.

Section 69503.3(b)(3) specifies that in evaluating product-chemical combinations for listing as a Priority Product, DTSC may also consider the household and workplace presence of the product and other products containing the same Candidate Chemical(s) that is/are the basis for considering identifying the product-chemical combination as a Priority Product. Examples of information that DTSC might consider in evaluating household or workplace presence include: the number of products with the same Candidate Chemical(s) that are present in the household or workplace; how common their household or workplace presence is; the frequency of use; and the concentration of the Candidate Chemical(s) in those products.

Information concerning the household and/or workplace presence of the product is important with respect to public health exposures to the Candidate Chemical(s) in the product. This information can be used to assess aggregate exposure – the total exposure to the same Candidate Chemical(s) from various sources of products that contain the Candidate Chemical(s) that may contribute to or cause adverse impacts to individuals using products within a household or workplace.

DTSC acknowledges that in many cases this information will be difficult to obtain. As determined necessary, this type of information may be sought by using the data gathering mechanisms set out in section 69501.4. DTSC may also consider using survey techniques to obtain this information.

Section 69503.3(b)(4) specifies that in evaluating a product-chemical combination for possible listing as a Priority Product, DTSC may consider potential exposures to the Candidate Chemical(s) in the product during the product's life cycle. This could include public and/or aquatic, avian, or terrestrial animal or plant organism exposures. Sections 69503.3(b)(4)(A) through (H) identify the types of information that can be used and the types of situations that can be considered when evaluating potential life cycle exposures. This information, in turn, is valuable in evaluating and assessing the potential of the Candidate Chemical(s) to contribute to or cause adverse impacts as a result of exposures to the product during each life cycle stage. This includes assessing the types of individuals and environmental receptors that may be exposed to the Candidate Chemical(s) in the product and the types of conditions surrounding uses that have the potential to lead to exposures. All of the factors listed in section 69503.3(b)(4) are consistent with the statutory mandate (Health and Safety Code section 25252(a)(2)) to consider the potential for exposures to a chemical in a product as part of the identification and prioritization process.

Section 69503.3(b)(4)(A) specifies that manufacturing, use, storage, transportation, waste, and end-of-life management practices and locations applicable to the product-chemical combination may be assessed to evaluate if potential exposures have the potential to contribute to or cause adverse impacts to public health and/or the environment. Releases of chemicals from products during each life cycle stage and circumstance can, and do, occur with varying degrees of frequency.

Information that DTSC might consider in evaluating potential exposures to Candidate Chemical(s) in products under this factor includes, but is not limited to:

- How well the Candidate Chemical is physically contained or chemically bound in the product, including the long-term integrity of the containment method;

- How a product containing the Candidate Chemical(s) is managed to control exposure to the public and/or the environment;
- Whether there are any regulatory restrictions imposed by the federal government or the State of California to reduce or prevent chemical exposure;
- Whether there are warnings or other precautions regarding the use of the product; and
- How often and how long the public or the environment is exposed to the Candidate Chemical in the product for each scenario involving product use.

Section 69503.3(b)(4)(B) allows DTSC, when evaluating potential exposures for a product-chemical combination, to consider whether the product is manufactured or stored in, or transported through, California solely for use outside of California. There is a potential for exposures (e.g., workplace exposures and community exposures along transportation corridors) if a consumer product is manufactured or stored in, or transported through, California, even if that consumer product is not actually placed into the stream of commerce in California. However, the relatively limited number of life cycle segments and scenarios during which potential exposures could occur for these products could mean that such a product would not be as high a priority as products that are sold and used in California. The potential adverse impacts resulting from any potential exposures would also have to be factored in when making this prioritization evaluation.

Section 69503.3(b)(4)(C) allows DTSC, when evaluating potential exposures for a product-chemical combination, to consider whether the product is placed into the stream of commerce in California solely for the manufacture of one or more products statutorily exempt from this program under Health and Safety Code section 25251 (e.g., pesticides or prescription drugs). There may be potential exposures to such products during the manufacturing and pre-manufacturing life cycle segments. However, the relatively limited number of life cycle segments and scenarios during which potential exposures could occur for these products could mean that such a product would not be as high a priority as products that are sold and used in California. The potential adverse impacts resulting from any potential exposures would also have to be factored in when making this prioritization evaluation.

Section 69503.3(b)(4)(D) specifies that DTSC may consider the following use scenarios for products that contain Candidate Chemical(s) when evaluating potential exposures that may contribute to or cause adverse public health impacts:

1. Household and recreational use. This might include, for example, household consumers using the product as well as do-it-yourselfers and hobbyists.

2. Sensitive subpopulations' potential use of the product and potential exposures to the product and the Candidate Chemical(s) in the product. Sensitive subpopulations are often susceptible to adverse impacts at smaller exposures than the general population. Thus, product use or exposure at locations frequented by members of sensitive subpopulations, including, for instance, service workers who may be using "household" products at a greater than normal rate due to the service being provided, is an exposure factor to consider. For example, household cleaning services workers or nail salon workers may use the same products used by the general population in their households, but at a much greater frequency and length of duration. Other sensitive subpopulations may be found at locations such as health care facilities, recreational facilities, and day care facilities.

3. Workers, customers, clients, and members of the general public who use, or otherwise come in contact with, the product or releases from the product in homes, schools, workplaces, or other locations. Individuals who frequent these locations may include members of sensitive subpopulations. However, potential exposure considerations under this factor apply to all populations, not just sensitive populations as in the previous factor. This factor allows DTSC to consider the full range of locations where potential exposures could occur for a broad array of individuals.

The factors listed in this provision are consistent with the statutory mandate (Health and Safety Code section 25252(a)) to take into account in the identification and prioritization process: the volume of the chemical in commerce in California; the potential exposures to the Candidate Chemical(s) in the product; and potential effects on sensitive subpopulations.

Section 69503.3(b)(4)(E) describes aspects of exposure which relate to subsections 69503.3(b)(4)(A) through (b)(4)(D) discussed above. Specifically, frequency, extent, level, and duration of potential exposure for each use scenario and end-of-life scenario are all factors that may be assessed when evaluating potential exposures for product-chemical combinations:

- Frequency (how often) – repeated uses of a product containing a Candidate Chemical may vary and is considered in determining the aggregate exposure;
- Extent (number of routes of exposure);
- Level (concentration of the Candidate Chemical); and
- Duration (how long).

Section 69503.3(b)(4)(F) allows DTSC to consider, when evaluating product-chemical combinations, how and to what degree the Candidate Chemical is contained within the product. How the Candidate Chemical is contained or bound during the use of the product and the degree to which the containment is sustainable at end-of-life (e.g., recycling or disposal) determine, in part, the potential for and amount of exposure that may occur. For instance, the Candidate Chemical may be a component inside a product and may not be accessible to the user, in which case there is little to no exposure resulting from use of the product. However, there could still be exposures to the Candidate Chemical during other aspects of the life cycle of the product.

Section 69503.3(b)(4)(G) allows DTSC to consider, as part of the product-chemical combination prioritization process, engineering and administrative controls that reduce exposure concerns associated with the product. Some consumer products that contain Candidate Chemical(s) come with recommended precautionary measures and/or have warning labels intended to reduce the potential for exposures during use and/or end-of-life – this is an example of an administrative control. An example of an engineering control would be the use of specialized ventilation equipment in the area where the product is being used.

Section 69503.3(b)(4)(H) provides that DTSC may, in identifying and prioritizing product-chemical combinations, consider the potential for the Candidate Chemical(s) or its/their degradation products to:

- be released into, migrate from, or distribute across environmental media; and/or
- accumulate and persist in biological and/or environmental compartments or systems.

A Candidate Chemical's potential to persist, bioaccumulate, and move into different environmental compartments are exposure pathways that may contribute to or cause adverse impacts to the public and environment. Evaluation of this exposure potential factor would include consideration of the chemical's environmental fate properties. Estimates of persistence, bioaccumulation, and fate and transport of the Candidate Chemical or its degradation products may be used as a consideration for identifying and prioritizing product-chemical combinations and may be based on one or more of the following, for example:

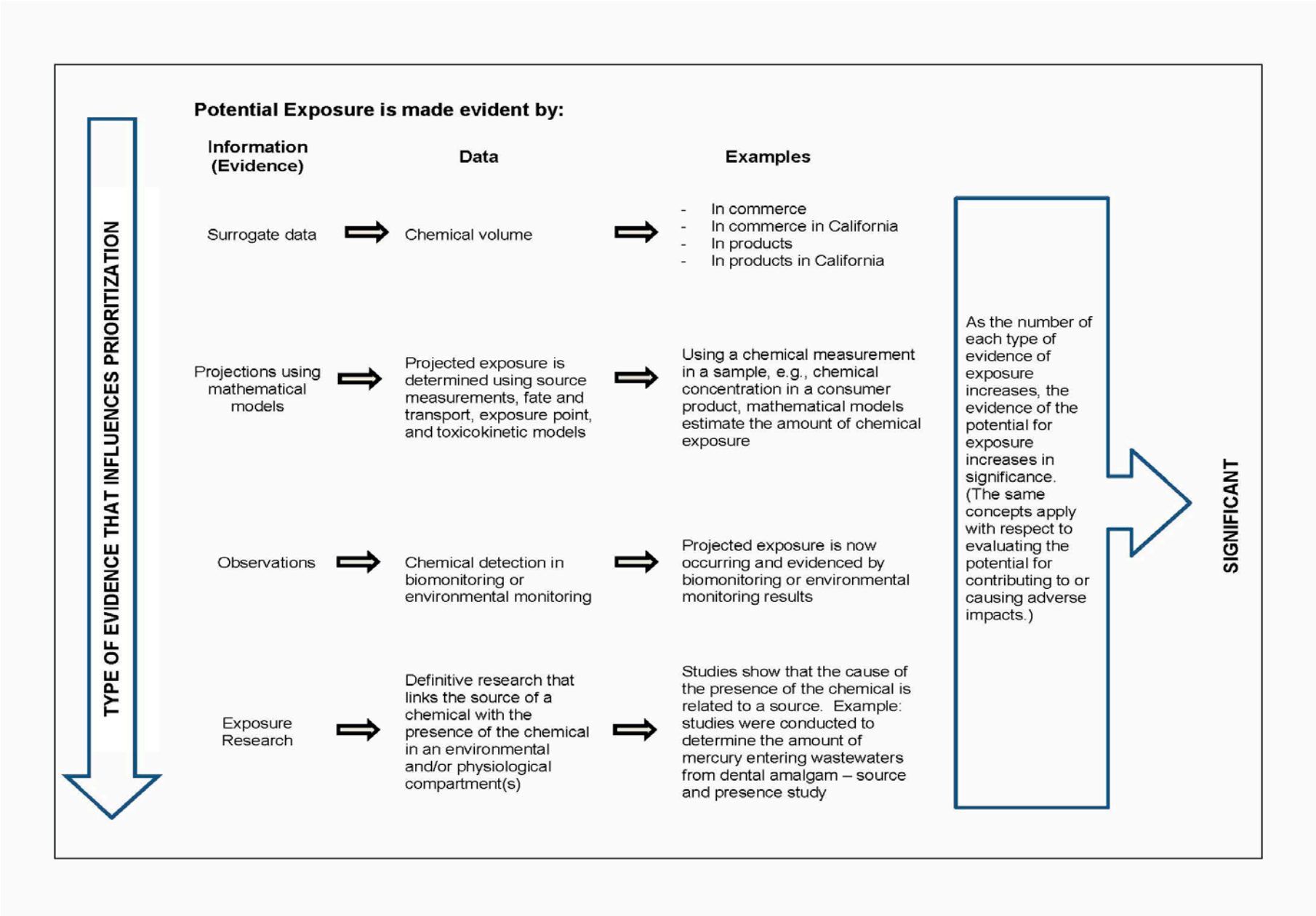
- fugacity modeling, a chemical fate and transport multimedia model;
- field studies in the environment;
- observations and measurements conducted in the field;

- microcosm studies, which include simulating an ecosystem in a laboratory setting;
- use of computational modeling for structural activity relations to predict chemical behavior;
- short term in-vitro bioassays to predict chemical behavior; and
- computational modeling data.

Environmental or biological presence may also be estimated using a point source or market-wide source term calculation, modeling or measurement, or a combination of these options.

Figure 2, Prioritization Concept, provides a graphic representation of how some of the exposure factors specified in section 69503.3(b)(2) might be used to prioritize products and how the significance of available information might be evaluated. It is important to note that this diagram does not capture all of the prioritization factors or types of information that might be considered. This diagram is included only to conceptually depict how available information might be evaluated and used to inform the product-chemical combination prioritization process. As each product-chemical combination is proposed for Priority Product listing, DTSC will provide stakeholders the rationale used to evaluate the information used in the prioritization process.

Figure 2. Prioritization Concept



§ 69503.4 Priority Product Work Plan

Section 69503.4(a) specifies that within one (1) year after the effective date of these regulations, DTSC must issue a Priority Product Work Plan for purposes of identifying and describing the product categories that will be evaluated during the next three (3) years following issuance of the work plan. (Note that, under section 69503.6, the initial Priority Products list is not subject to the work plan requirements of this section.) The scope of products covered by an identified product category will vary. Examples of possible product category scopes include a product Family (i.e., Cleaning Products) or product Class (i.e., Laundry Products) hierarchy level used in the Global Product Classification (GPC) Standards[7]. The work plan must include a general explanation of the product category selection decision. The work plan will plot a course for DTSC's product prioritization efforts for the next three (3) years following its issuance.

This provision is necessary to provide a level of predictability to responsible entities and other stakeholders regarding the types of products that could be considered for evaluation of product-chemical combinations to be added to the Priority Products list during the next 3-year period.

Section 69503.4(b) specifies that subsequent Priority Product Work Plans must be issued by DTSC no later than one (1) year before the 3-year expiration date of the current work plan. The revised work plan becomes effective upon expiration of the current work plan. This provides stakeholders a minimum of one (1) year's notice prior to DTSC releasing a proposed Priority Products list under the newest work plan.

This is necessary to ensure responsible entities have adequate time to review their products, formulations, and supply chain prior to entering the public comment period for a proposed Priority Products list under section 69503.5. This, in turn, is necessary to provide more predictability to responsible entities about possible actions by DTSC involving products made by those responsible entities.

Section 69503.4(c) allows DTSC to revise an already adopted Priority Product Work Plan prior to its expiration to add one or more additional product categories as a result of either of the following conditions:

(1) DTSC is legally required to take action on a particular chemical or product, or both, prior to the expiration of the current work plan; and/or

[7] http://www.gs1.org/gdsn/gpc

(2) DTSC grants a petition under Article 4 of these regulations.

This section is necessary to give DTSC the necessary latitude to adjust a work plan when doing so is required to comply with a legal mandate such as a new law or a Governor's Executive Order. This provision is also necessary to enable DTSC to adjust the work plan to take into consideration important public health and/or environmental protection issues implicated by granting a petition under Article 4.

Section 69503.4(d) requires DTSC to hold at least one workshop to allow for public comment before issuing each work plan. This is necessary in order to provide stakeholders an opportunity to participate in the prioritization planning process and provide input. This, in turn, is necessary to allow DTSC to gather a robust amount of information in a relatively easy fashion and to be able to consider the information gathered to make sound prioritization planning decisions.

Section 69503.4(e) requires DTSC to post on its website and send to persons on the electronic mailing list a notice of availability for each work plan and revised work plan. This is necessary in order to provide responsible entities and other stakeholders notice of DTSC's upcoming actions. This makes the opportunity for comment more feasible. Again, this is necessary to ensure interested parties are aware of DTSC's work plans and revised work plans and have an opportunity to comment prior to DTSC finalizing each work plan.

§ 69503.5. Priority Products List

Section 69503.5(a)(1) specifies that DTSC must follow the procedures specified in the remainder of section 69503.5 and the criteria and process specified in sections 69503.2 and 69503.3 to identify and list product-chemical combinations as Priority Products. This section is necessary to indicate to interested parties and the public, in general, how DTSC will go about listing Priority Products. This is especially important because the listing of a Priority Product triggers the next step in the quest for safer products – the requirement for responsible entities to conduct Alternatives Analyses for their Priority Products or otherwise comply with Article 5.

Section 69503.5(a)(2) specifies that DTSC must establish and update the Priority Products list through rulemaking under the Administrative Procedure Act (APA) process specified in the Government Code, commencing with section 11340. This will include complying with all applicable requirements of the APA including, for example, the APA provisions pertaining to economic and fiscal impact analysis. This section also requires DTSC to hold one or more public workshop(s) to provide an opportunity for comment on

the candidate product-chemical combinations prior to issuing a proposed Priority Products list. While the APA process also includes a workshop requirement, there are some exceptions to that requirement. The effect and purpose of the workshop requirement in section 69503.5(a)(2) is to ensure that a workshop will be held in all cases prior to issuing a proposed Priority Products list, even if there were to be circumstances that did not require a workshop under the APA.

The provisions of this section requiring compliance with the APA process are necessary in order to provide assurances to stakeholders that DTSC will comply with its obligations under that regime. In addition, compliance with the APA and holding at least one public workshop (even when not required under the APA) is necessary in order to engage all of the responsible entities and stakeholders in prioritizing product-chemical combination(s) for possible designation as Priority Product(s), and to allow for the submittal of useful information to DTSC prior to issuing a final Priority Products list.

DTSC recognizes that before Priority Product listing decisions are finalized stakeholders need to examine and have the opportunity to comment on the rationale, data, and information sources that led DTSC to those decisions. Workshops and the APA public comment period are necessary to provide interested parties an opportunity to present information and data that may not have been previously considered to have a product added to or removed from the Priority Products list prior to finalization of the list. These provisions are necessary to provide transparency with respect to DTSC's decision-making, and to obtain public input and hopefully a broad array of additional relevant information to better inform the final Priority Products listing decision(s). These provisions are also necessary to inform interested parties as to the process for providing comments on proposed Priority Products.

Section 69503.5(b) specifies the information that DTSC must provide in the proposed and finalized Priority Products list for each listed product-chemical combination. All of this information, collectively, is necessary to provide the responsible entities with sufficient information to determine: **(1)** if their products are being proposed or finalized as Priority Products; **(2)** which chemical(s) in their product is/are the Chemical(s) of Concern for that product for purposes of complying with Articles 5 and 6; and **(3)** when they must submit a Preliminary AA Report for their Priority Products. Therefore, DTSC is not including a separate statement of necessity for each paragraph described below.

Section 69503.5(b)(1)(A) requires DTSC to provide a description of the product-chemical combination that is sufficient for a responsible entity to determine whether one or more of its products is a Priority Product and, thus, subject to the requirement to undergo an AA, or otherwise comply with Article 5 of these regulations.

Section 69503.5(b)(1)(B) specifies that if the Priority Product is a component of one or more assembled products DTSC must provide a description of the known assembled product(s) in which the component is used. (Note that this provision does not preclude DTSC from naming an entire multi-component product as a Priority Product.) This information will serve to inform assemblers, retailers, and consumers of those assembled products that contain a Priority Product as a component.

Section 69503.5(b)(2)(A) specifies that DTSC must identify in the Priority Products list the Candidate Chemical(s) that is/are the basis for the product being listed as a Priority Product, and the hazard traits and/or environmental or toxicological endpoints known to be associated with the Candidate Chemical(s).

Section 69503.5(b)(2)(B) specifies that a Candidate Chemical, that is a basis for a product-chemical combination being listed as a Priority Product, is designated as a Chemical of Concern <u>for that product and for any alternative product considered or selected as a replacement for the Priority Product</u>. For a Candidate Chemical to be designated as a Chemical of Concern the Candidate Chemical must be in the product-chemical combination listed as a Priority Product <u>and</u> the Candidate Chemical must be a basis for listing of the product-chemical combination as a Priority Product. This provision is necessary to provide clear and specific terminology to distinguish between Candidate Chemicals and Chemicals of Concern for purposes of the provisions of Articles 5 and 6. Note that a Candidate Chemical is <u>not</u> a Chemical of Concern with respect to any product other than the product(s) for which the Candidate Chemical is a basis for the Priority Product listing as identified under section 69503.5(b)(2)(A) (and any alternatives considered or selected to replace such Priority Product(s)).

Section 69503.5(b)(3) specifies that DTSC is required to specify in the Priority Products list the due date for submission of the Preliminary AA Report required under Article 5. The default due date for the Preliminary AA Report is 180 days from the date a product-chemical combination is listed as a Priority Product on the final Priority Products list. However, based on each Priority Product's uniqueness, or availability of resources, DTSC may specify a due date that is shorter or longer than the default for the Preliminary AA Report due date. This provision is necessary in order to provide certainty to responsible entities as to when the Preliminary AA Reports are due to DTSC. In addition, this provision acknowledges DTSC's resource constraints, and the fact that there may be circumstances unique to a particular Priority Product that warrant a due date for the Preliminary AA Report other than 180 days, and, thus, provides the necessary flexibility in determining when the Preliminary AA Reports are due to DTSC.

Section 69503.5(c) allows DTSC to specify in the proposed and/or final Priority Products listing for a product-chemical combination: (1) an Alternatives Analysis Threshold (AA Threshold) for a Chemical of Concern that is an intentionally added ingredient; or (2) an AA Threshold greater than the Practical Quantitation Limit (PQL) for a Chemical of Concern that is a contaminant. Under section 69505.3, the default AA Threshold for any Chemical of Concern that is a contaminant is the PQL. However, there is no default AA Threshold for any Chemical of Concern that is an intentionally added ingredient. Refer to the statement of reasons for sections 69501.1(a)(12), (26), and (52) and 69505.3 for further information and discussion regarding AA Thresholds and their necessity.

This provision is necessary to provide DTSC with the flexibility when warranted to establish on a case-by-case basis during the rulemaking process for the Priority Products list: (i) an AA Threshold for Chemicals of Concern that are intentionally added ingredients; or (ii) an AA Threshold above the PQL for contaminants. If an AA Threshold is specified in the Priority Products list, this will be based on the most current and appropriate scientific information and the rulemaking documents for the list will include the information sources and rationale supporting DTSC's proposed or final AA Threshold determination.

Sections 69503.5(d)(1) through (3) specify the factors DTSC must consider when listing components of complex durable products as Priority Products. These provisions are described and explained in detail immediately below.

Section 69503.5(d)(1) specifies that DTSC may not list more than ten (10) components contained in a single complex durable product as Priority Products within a 3-year period. Limiting the number of components for a complex durable product that may be listed as Priority Product and subject to an AA assists responsible entities in addressing the design complexities of such a product, which are typically increased as a result of the number of components that must be simultaneously evaluated for re-design. This is necessary to give certainty to manufacturers of complex durable products, that have longer product development time frames, as to the maximum number of components for which AAs could be required within a specified time frame, and to enable them to focus on a manageable number of components during a design and AA cycle.

Section 69503.5(d)(2) defines "complex durable product" as a product that meets the following criteria:

(A) The product has 100 or more manufactured components;

(B) Manufacturers of the product routinely prepare information for consumers that indicates that the product has a useful life, or average useful life, of five (5) or more years; and
(C) The product is not consumed, destroyed, or discarded after a single use.

Examples of complex durable products include automobiles, consumer electronics, and home appliances. This definition, which is consistent with generally understood concepts of "complex" and "durable", is necessary to make it clear as to which products are covered by the provisions of section 69503.5(d)(1).

Section 69503.5(d)(3) specifies that the limitation in section 69503.5(d)(1) on the number of components that may be listed as Priority Products during a 3-year period for complex durable products does not apply to either of the following:

(A) Products designed or intended primarily for children twelve (12) years of age or younger, as determined by information made available to consumers or as determined by whether the product is commonly recognized by consumers as being primarily intended for use by children twelve (12) years of age or younger; or
(B) Products intended to be worn or placed on the human body.

These exceptions are necessary to account for the unique risks attendant to the specified products, so as to enable DTSC to adequately, fully, and timely address potential adverse impacts and exposures associated with children's products and products that come in direct contact with the human body.

Section 69503.5(e) specifies that DTSC must review and revise, as appropriate, the Priority Products list at regular intervals of at least once every three (3) years. This section is necessary to ensure that the Priority Products list is reviewed for progress, and does not remain stagnant. DTSC may choose to review the Priority Products list more frequently, and it is possible that the review may indicate the Priority Products list is adequate and no revisions are needed. The review must also incorporate any petitions granted under Article 4 to either add or remove a Priority Product.

Section 69503.5(f) specifies that the responsible entity for a product-chemical combination listed on the Priority Products list must provide a Priority Product Notification to DTSC within sixty (60) days after the product-chemical combination is listed as a Priority Product. If a product-chemical combination is introduced into California after it has been listed as a Priority Product, the responsible entity must submit a Priority Product Notification to DTSC within sixty (60) days of the product's

introduction into the stream of commerce in California. DTSC may specify a later due date for the Priority Product Notification in the Priority Products list. (It is important to note that when a Priority Product is introduced into commerce in California after the date of the applicable Priority Product listing, the due dates for complying with the requirements of Article 5 are triggered by the date the product is first placed into the stream of commerce in California. See section 69505.1(b)(2)(C).)

This notification requirement is necessary as it informs DTSC regarding which products and responsible entities are subject to the next process step – the AA process. This provision is also necessary to put responsible entities on notice as to the applicable due date for submitting a Priority Product Notification to DTSC.

If applicable, the responsible entity may concurrently submit any of the other notifications as specified in sections 69505.2 and 69505.3, which are listed below; or, the responsible entity may choose to submit any of these notifications at a later date as provided in sections 69505.2 and 69505.3.

- Chemical Removal Intent Notification
- Chemical Removal Confirmation Notification
- Product Removal Intent Notification
- Product Removal Confirmation Notification
- Product-Chemical Replacement Intent Notification
- Product-Chemical Replacement Confirmation Notification
- AA Threshold Notification

Responsible entities that submit any of these notifications (in conformance with the applicable requirements of section 69505.2 or 69505.3) for any of the product-chemical combinations listed as Priority Products are not subject to the AA requirements for those products.

The above listed notifications, along with the Priority Product Notification, are necessary to provide the public and other interested parties information regarding the status of listed Priority Products that are on the market and their status in terms of being subject to the requirement to conduct an AA. They also allow DTSC to assess the resources needed to implement DTSC's responsibilities for reviewing AA Reports, determining regulatory responses, and conducting audits with respect to Priority Products.

§ 69503.6. Initial Priority Products List

Sections 69503.6(a) through (d) specify that the provisions described below apply only to the initial list of Priority Products.

Section 69503.6(a) narrows the scope of Candidate Chemicals that DTSC may identify on the initial list of Priority Products as the basis for listing Priority Products. This limitation also applies to any revisions to the Priority Products List adopted prior to January 1, 2016.
For the initial Priority Products list, DTSC may list a product-chemical combination as a Priority Product only if the Candidate Chemical(s) that is/are the basis for listing the product meet both of the following criteria:

1) The Candidate Chemical is on one or more of the lists specified in section 69502.2(a)(1); **and**
2) The Candidate Chemical is on one or more of the lists specified in section 69502.2(a)(2).

Thus, only those Candidate Chemicals listed on one or more of the authoritative organizations' hazard trait based chemical lists specified in 69502.2(a)(1), ***and*** that also appear on a chemicals list developed based on exposure potential concerns and specified in 69502.2(a)(2), may serve as the basis for a product being identified as a Priority Product on the initial Priority Products list. This provision will ensure that during early stages of implementation DTSC will focus on those Candidate Chemicals that have already been identified by other authoritative organizations for both adverse impacts and exposure concerns. This is necessary to send more predictable signals to responsible entities and other interested parties as to which Candidate Chemicals may be identified as Chemicals of Concern in Priority Products during the early years of program implementation.

Section 69503.6(b) specifies that the initial Priority Products list will consist of no more than five (5) Priority Products. This section is necessary to make it clear to all interested parties what the initial size of the program will be. Starting with a small number of Priority Products allows for the program to be implemented in a measured fashion during its initial implementation phase. This section also serves to make it clear that DTSC may identify more than one Chemical of Concern (i.e., a Candidate Chemical that is the basis for the Priority Product listing) for each Priority Product.

This section also assures responsible entities that during the initial stages of implementation DTSC will be taking action on a relatively small number of Priority Products in order to gain experience and knowledge to refine implementation of these regulations, if needed. It is important to note that the initial number of Priority Products will also be based on available DTSC resources to implement these regulations. DTSC

will make the most efficient use of resources, which might include considering strategies such as staggering the dates when notifications and AA Reports are due to DTSC.

Section 69503.6(c) specifies that the first list of proposed Priority Products is to be made available within 180 days after the effective date of these regulations for public review and comment.

This provision is necessary to provide certainty to responsible entities and other interested parties regarding when to expect the initial proposed Priority Products list, and to establish a reasonable time frame for DTSC to publish the initial proposed list.

Section 69503.6(d) specifies the following procedural exemptions for the initial Priority Products list:

(1) Provides that the first Priority Product Work Plan to be developed by DTSC under section 69503.4 will not pertain to the initial list of up to five (5) Priority Products that DTSC is required to propose within 180 days after the effective date of these regulations.

(2) Provides that the public workshop requirements of section 69503.5(a)(2) do not apply to the initial list of up to five (5) Priority Products. Note that this section does not negate any APA workshop-related requirements that may apply to the rulemaking process for the initial (and subsequent) Priority Products listings.

These provisions are necessary in order to allow DTSC to expeditiously begin working on identifying and prioritizing product-chemical combinations as soon as the regulations become effective. This section is also necessary to make it clear that the Priority Products Work Plan requirements are not relevant to the initial Priority Products list, since the initial proposed Priority Products list is required to be released by DTSC six (6) months prior to the release date for the first Priority Product Work Plan.

§ 69503.7. Priority Product Notifications

Section 69503.7(a) specifies that the responsible entity for a product-chemical combination listed on the Priority Products list must provide a Priority Product Notification to DTSC within sixty (60) days after the product-chemical combination is listed as a Priority Product. If a product-chemical combination is introduced into California after it has been listed as a Priority Product, the responsible entity must submit a Priority Product Notification to DTSC within sixty (60) days of the product's introduction into the stream of commerce in California. DTSC may specify a later due date for the Priority Product Notification in the Priority Products list. (It is important to note that when a Priority Product is introduced into commerce in California after the

date of the applicable Priority Product listing, the due dates for complying with the requirements of Article 5 are triggered by the date the product is first placed into the stream of commerce in California. See section 69505.1(b)(2)(C).)

(Also, see the Statement of Reasons for section 69503.5(f) for a discussion of other optional notifications that may, if applicable, be submitted simultaneously with the Priority Product Notification under section 69505.2 or section 69505.3.)

This notification requirement is necessary as it informs DTSC regarding which products and responsible entities are subject to the next process step – the AA process. This provision is also necessary to put responsible entities on notice as to the applicable due date for submitting a Priority Product Notification to DTSC.

Sections 69503.7(a)(1) through (4) specify the information to be included in the Priority Product Notification, as described below:

- **(1)** The responsible entity's name and contact information, and a statement indicating whether the responsible entity is the product manufacturer, importer, assembler, or retailer;
- **(2)** The type, brand name(s), and product name(s) of the Priority Product, and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used;
- **(3)** If applicable, the name of, and contact information for, the person that will be complying with the requirements of Article 5 on behalf of or in lieu of the responsible entity; and
- **(4)** If applicable, an indication that a notification is being submitted under section 69505.2 or section 69505.3 concurrently with the Priority Product Notification, or will be submitted later as provided in section 69505.2 or section 69505.3.

These notification content requirements are necessary to provide information to DTSC regarding the products and responsible entities that are subject to the next process step – the AA process. This information is needed to enable DTSC to better assess the resources needed in implementation of Article 5, Article 6, and Article 8, as well as to focus compliance and enforcement efforts on products known to be Priority Products but for which the required notification and/or AA Reports are not received.

Overall, this section is necessary to specify the contents of the notification and related time frames for submitting the specified notifications to DTSC.

Section 69503.7(b) specifies that a responsible entity is not in compliance if a timely and fully completed Priority Product notification has not been submitted to DTSC by the

responsible entity after its product-chemical combination has been listed as a Priority Product.

This provision is necessary to inform responsible entities and the public about the compliance status of responsible entities, which informs responsible entities of the consequences of failing to submit a Priority Product Notification and may influence consumer purchasing decisions.

Refer to section 69501.2 for information concerning: (1) the compliance responsibility hierarchy for manufacturers, importers, assemblers, and retailers; (2) options for assemblers and retailers; and (3) consequences of non-compliance.

ARTICLE 4. Petition Process for Identification and Prioritization of Chemicals and Products

Article 4, in its entirety, is necessary to specify the process for petitioning the Department of Toxic Substances Control (DTSC) to add a chemical or list of chemicals to the Candidate Chemicals list, add a product-chemical combination to the Priority Products list, or to delist a chemical, list of chemicals, or product-chemical combination. The provisions in Article 4 are necessary to enable interested parties, including individuals, industry, organizations, educational institutions, and government agencies, to present DTSC with information that demonstrates a chemical, list of chemicals, or product-chemical combination poses a threat, and should be evaluated for its potential listing as a Candidate Chemical or Priority Product. Conversely, Article 4 is necessary to provide a mechanism to remove a chemical, list of chemicals, or product-chemical combination from the Candidate Chemicals list or Priority Products list to reflect increased knowledge about, or a change in market circumstances with respect to, the chemical(s) or product that was initially listed. The flexibility for DTSC to respond to stakeholder input, in crafting and maintaining its Candidate Chemicals and Priority Products lists, is especially important given that knowledge of the attributes of particular chemicals will increase over time. Similarly, safer chemical or engineering substitutes for known-hazardous chemicals will be developed over time; the consumer product marketplace will continue to evolve; and information about all of these factors will be widely dispersed. Article 4 provides that all chemicals and products that petitioners propose for listing or delisting must be evaluated via the Article 2 and/or Article 3 identification and prioritization processes before a final decision is made on the merits of the petition.

§69504. Applicability and Petition Contents

Section 69504, in its entirety, is necessary to specify the process by which to petition DTSC to:

- add chemicals or lists of chemicals to the Candidate Chemicals list;
- add product-chemical combinations to the list of Priority Products; or
- remove a chemical or list of chemicals from the Candidate Chemicals list or a product-chemical combination from the Priority Products list.

Section 69504(a), subject to the limitations in subsection (b), allows a person ("petitioner") to petition DTSC to evaluate a chemical or a product-chemical combination or list of chemicals using the chemical identification or product prioritization processes specified in Articles 2 and/or 3. The petition must include the information specified in sections 69504(a)(1) through (a)(6). The information specified in sections 69504(a)(1)

through (a)(6), summarized below, is necessary for DTSC to make an informed decision regarding the petition, and to contact the appropriate person should additional information be necessary.

Section 69504(a)(1) requires that the name and contact information be provided to DTSC for both:

- **(A)** The petitioner; and
- **(B)** The person responsible for the petition contents, if different from the petitioner, along with this person's affiliation with the petitioner.

This information is necessary so that DTSC can notify the petitioner of its determination relative to the petition, and in the event DTSC needs to contact either party to obtain additional information about the petition.

Section 69504(a)(2) requires that the petition include a description of the chemical or product-chemical combination, or both, which is/are the subject of the petition. This information is necessary to define the scope of the petition, and to assess the relevance of the information submitted.

Section 69504(a)(3) requires that the petition include the use(s) of the chemical or product-chemical combination, or both, which is/are the subject of the petition. This information is necessary to assess the relevance and completeness of the information submitted.

Section 69504(a)(4) requires that the petition include the basis for the petition, which must include the basis for the existence or absence of potential adverse impacts, potential exposures, and/or potential adverse waste and end-of-life effects associated with the chemical or product-chemical combination. This requirement is necessary to ensure that DTSC gets quality petitions with some substantial basis for being filed, and to assist DTSC in making informed assessments of the merits of the petitions.

Section 69504(a)(5) requires that the petition include information supporting the petition. This requirement is necessary to deter petitions based on limited and/or weak supporting information, and to assist DTSC in making informed assessments of the merits of the petitions.

Section 69504(a)(6) requires that the petition include the identity of any known manufacturers and importers of the chemical or product-chemical combination. Identification of known manufacturers and importers in the petition is necessary to reduce costs to DTSC by eliminating the need for DTSC to determine these

manufacturers and importers, and to facilitate DTSC's request of specific information from these manufacturers and importers to assist in filling data gaps for any chemical or product included in the petition.

Section 69504(b) describes the limitations on petitions that will be accepted by DTSC under Article 4. The limitations are necessary to prevent a wasteful use of limited resources when trying to implement a complex regulatory program.

Section 69504(b)(1) specifies a limitation on the ability of a person to petition DTSC to remove a chemical from the list of Candidate Chemicals: a person may not petition DTSC seeking the removal of a Candidate Chemical identified as such in section 69502.2(a) unless the chemical is no longer listed on any of the lists specified in section 69502.2(a). This provision is necessary to preclude a wasteful expenditure of scarce DTSC resources on reviewing petitions for removal of chemicals that have been well-established as possessing one or more hazard traits and exposure potential indicators and that are appropriately captured as Candidate Chemicals.

Section 69504(b)(2) specifies a limitation on the ability of a person to petition DTSC to remove an entire chemicals list from the lists specified in section 69502.2(a) until three (3) years after the effective date of the regulations. This provision is necessary to ensure that DTSC is not flooded with petitions in the early stages of regulation implementation. This provision is also necessary to preclude a wasteful expenditure of limited DTSC resources on reviewing petitions for removal of chemicals lists that have been well established as capturing one or more hazard traits and exposure potential indicators and that are appropriately included in the list of Candidate Chemicals. Careful consideration, extensive external input, and numerous resources went into choosing the lists of chemicals for the initial Candidate Chemicals list, and DTSC does not feel that immediately considering petitions to remove these lists would be a wise use of limited resources when trying to implement a complex new regulatory program.

Section 69504(b)(3) specifies a limitation on the ability of a person to petition DTSC to remove a product-chemical combination from the Priority Products list until three (3) years after the date the product-chemical combination was placed on the Priority Products list. This provision is necessary to ensure that DTSC is not flooded with petitions in the early stages of regulation implementation. This provision is also necessary to preclude a wasteful expenditure of DTSC resources on petitions for immediate removal of product-chemical combinations that have been carefully considered by DTSC and appropriately listed as Priority Products.

Section 69504(c) requires DTSC to respond within sixty (60) days of receiving a petition, and to designate the petition complete if it contains the items specified in

section 69504(a)(1) through (6). If DTSC determines that the petition is complete, the petitioner will be notified, and the petition will undergo a substantive review to determine whether to grant or deny the petition on its merits. If DTSC determines the petition to be incomplete, it will notify the petitioner and provide the basis for this determination. These provisions are necessary to provide certainty to petitioners as to when their petition will be acted upon for purposes of determining completeness, and to ensure that DTSC provides necessary feedback to petitioners in response to their petitions.

§69504.1. Merits Review of Petitions

Section 69504.1(a) requires DTSC to make decisions on whether to grant or deny a petition no later than the next regular update of the Candidate Chemicals list or Priority Products List, whichever is applicable. In addition, it provides that DTSC will give high priority to petitions from federal or other California State agencies that relate to the petitioning agency's programs or authorities. This approach is consistent with the instructions within Health and Safety Code section 25252(b)(2) for DTSC to use information from other government bodies to the maximum extent feasible "to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy,". It will also assist federal and other California State regulatory programs in fulfilling their statutory and regulatory responsibilities. Both parts of this provision are necessary to provide DTSC with sufficient time to conduct a merits review of petitions, and to set petition-review priorities, in light of resource constraints. Although DTSC will conduct an initial completeness review of all incoming petitions, only those deemed complete will undergo a merits review. For all these reasons, this provision is necessary to specify appropriate bases for DTSC to conduct its merits review of petitions.

Section 69504.1(b) requires DTSC to conduct a merits review of petitions based on the criteria specified in sections 69504.1(b)(1) through (b)(5). This provision is necessary to ensure that DTSC's determination on each petition is a scientifically based decision, and that petitioners and the general public know what criteria DTSC uses to evaluate petitions.

Section 69504.1(b)(1) requires DTSC to evaluate the comprehensiveness of the information supporting the petition that pertains to the prioritization factors specified in sections 69502.3 and/or 69503.3, and **section 69504.1(b)(2)** requires DTSC to evaluate the quality of information submitted to support the petition. These requirements are necessary to make effective use of DTSC resources, by ensuring that the petitioner provides a significant body of high-quality information wherever possible,

to facilitate DTSC's scientific review of the chemical or product that is the subject of the petition.

Section 69504.1(b)(3)(A) and (B) specify that DTSC will evaluate the availability of information, other than the information submitted with the petition, that supports the petitioner's claim that the chemical does or does not exhibit hazard traits , and that an evaluation of the chemical or product based on the factors specified in sections 69502.3 and/or 69503.3 does or does not indicate potential adverse impacts, potential exposures, and adverse waste and end-of-life effects. These provisions enable DTSC to consider in its determination to grant or deny a petition whether there is adequate information available to evaluate the petitioner's claim(s) with respect to the chemical or product under the Article 2 and Article 3 identification and prioritization factors and processes. Again, these provisions are necessary to ensure that DTSC has a robust and balanced body of scientific information on which to base its decision, rather than relying exclusively on information provided by the petitioner.

Section 69504.1(b)(4) requires DTSC to evaluate whether a chemical has changed status on any source list(s) that led to its inclusion on the Candidate Chemicals list when considering a petition to remove a chemical from the Candidate Chemicals list. This provision is necessary to preclude a wasteful expenditure of limited DTSC resources on petitions for removal of chemicals that have been well-established as possessing one or more hazard traits or exposure potential indicators and are appropriately captured as Candidate Chemicals.

Section 69504.1(b)(5) requires DTSC, when considering a petition to remove an entire existing chemicals list from the lists specified in section 69502.2(a), to evaluate whether the entity responsible for the underlying 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. This provision is necessary to preclude a wasteful expenditure of limited DTSC resources on further review of petitions for removal of lists of chemicals that have been well established as capturing one or more hazard traits or exposure potential indicators and that are appropriately included on the list of Candidate Chemicals. DTSC has established that the lists in section 69502.2(a) represent a robust group of chemicals that have certain hazard traits and/or exposure potential indicators. DTSC considered the advice of the Green Ribbon Science Panel, public comments, and input from other State agencies when compiling the initial group of chemical lists in section 69502.2(a). These lists have been compiled by authoritative bodies and address issues of carcinogenicity, developmental toxicity, reproductive toxicity, mutagenicity, endocrine toxicity, neurotoxicity, respiratory sensitivity, bioaccumulation, environmental

persistence, and exposure potential concerns. In selecting the lists specified in section 69502.2(a), DTSC also considered the manner and rigor of the scientific assessment process used by the authoritative body in compiling each list. In general, DTSC does not feel that granting a petition to remove one of these carefully selected lists would be a wise use of limited resources when trying to implement a complex new regulatory program. However, granting such a petition might be warranted if the authoritative body that compiled the list no longer conducts its scientific assessments in the same manner or with the same rigor as was the case at the time of the adoption of these regulations.

Section 69504.1(c) specifies that DTSC may request that the petitioner provide additional information to assist with the merits review. The petitioner must provide the information, to the extent available, within the time frame specified by DTSC. This provision is necessary to provide DTSC the ability and flexibility to request additional information that is needed to complete the merits review.

Section 69504.1(d) specifies that after completing the merits review, DTSC will approve or deny the petition, provide a notice to the petitioner of its decision that includes a statement of basis explaining the rationale for the decision. This section is necessary to inform the petitioner of the decision rendered on the petition and the basis for DTSC's decision.

ARTICLE 5. Alternatives Analysis

Article 5, in its entirety, is necessary to clarify, interpret, and make specific the provisions of Health and Safety Code section 25253. More specifically, this article is necessary to specify the requirements applicable to conducting a comprehensive Alternatives Analysis (AA) for consumer products that are listed as Priority Products under Article 3. As described in Article 3, consumer products that are listed as Priority Products are of concern due to the presence of one or more Chemicals of Concern in the consumer product. Article 5 is also key to achieving the overarching goal of the authorizing legislation set forth in Health and Safety Code section 25255(a) – "significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches."

Health and Safety Code section 25253(a)(1) requires the Department of Toxic Substances Control (DTSC) to adopt regulations to establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.

Additionally, Health and Safety Code section 25253(a)(2) requires the regulations to establish a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. The process must include life cycle assessment tools that take into consideration, but are not limited to, all of the following:

(A) Product function or performance;
(B) Useful life;
(C) Materials and resource consumption;
(D) Water conservation;
(E) Water quality impacts;
(F) Air emissions;
(G) Production, in-use, and transportation energy inputs;
(H) Energy efficiency;
(I) Greenhouse gas emissions;
(J) Waste and end-of-life disposal;
(K) Public health impacts, including potential impacts to sensitive subpopulations, including infants and children;
(L) Environmental impacts; and
(M) Economic impacts.

In accordance with Health and Safety Code section 25253(a)(1), the regulations establish a process for evaluating Chemicals of Concern in Priority Products, and potential alternative product-chemical combinations, to determine how best to limit exposure or to reduce the level of hazard posed by the Chemical(s) of Concern in a product. The thirteen, (A) through (M), criteria listed in Health and Safety Code section 25253(a)(2) are embodied in the regulations and collectively address the life cycle impacts (*i.e.*, from raw materials extraction through materials processing, manufacture, distribution, use, repair and maintenance, and end-of-life disposal or recycling) associated with the Priority Product or any alternative(s) considered.

The thirteen criteria listed in Health and Safety Code section 25253(a)(2) comprise the contents of an AA – a systematic process for evaluating the life cycle impacts of a Priority Product and any alternatives considered. The concept of an AA is not new, and parallels other popular life cycle assessment tools for evaluating and/or taking inventory of the impacts of products or services, and are commonly known as *Life Cycle Assessment, Life Cycle Impacts, Life Cycle Inventory, Decision Analysis, Life Cycle Management, or Environmental Impact Assessment.* For consistency with the authorizing legislation, DTSC has retained the use of the term “alternatives analysis” used in Health and Safety Code section 25253.

For simplicity and harmonization with commonly used life cycle assessment tools, the thirteen criteria have been grouped, where appropriate, to better align with criteria commonly taken into account by manufacturers who are faced with balancing choices and making tradeoffs when re-designing and re-manufacturing a product to address a consumer or market need or demand. The AA process in the regulations is divided into two stages, is consistent with commonly used life cycle assessment tools, and requires:

- the goal and scope be identified;
- the relevant factors for comparison be identified;
- evaluation/comparison of the Priority Product and alternatives; and
- interpretation and summation of basis for conclusions and decisions.

The first and second stage AAs, and the corresponding Preliminary and Final AA Reports, respectively, comprise the process for identification and evaluation of potential alternatives and address the impacts through a multimedia lifecycle evaluation. During the first stage, the goal, scope, range of alternatives, and relevant factors 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(s)

to the Priority Product, if any, and lay the foundation for imposition of the appropriate regulatory response(s) under Article 6.

The first stage AA involves six steps and the second stage AA contains five steps that typically should be performed to the extent practical in a sequential order but may be carried out iteratively, as determined necessary. The first stage AA and the Preliminary AA Report are intended to identify and report existing or potential alternatives, including a comparative evaluation of the adverse public health and environmental impacts of the product's Chemical(s) of Concern and potential alternative replacement chemicals; whereas, the second stage AA and the Final AA Report are intended to compare potential alternatives based on additional life cycle assessment factors and to report the alternative selection decision – which can be a decision to retain the Priority Product. The Preliminary AA Report must include an implementation schedule for the second stage AA; and the Final AA Report must include an implementation schedule for implementing the selected alternative and any recommended regulatory responses.

Table 3. Alternatives Analysis

Two Stage AA		Abridged AA
First Stage	**Second Stage**	
Step 1: Identification of Product Requirements & Function of Chemicals of Concern.	**Step 1:** Identification of Factors Relevant for Comparison of Alternatives.	**Step 1:** Identification of Product Requirements & Function of Chemicals of Concern.
Step 2: Identification of Alternatives.	**Step 2:** Comparison of the Priority Product & Alternatives.	**Step 2:** Identification of Alternatives.
Step 3: Identification of Factors Relevant for Comparison of Alternatives.	**Step 3:** Consideration of Additional Information.	**Step 3:** Identification of Factors Relevant for Comparison of Alternatives.
Step 4: Initial Evaluation and Screening of Alternative Replacement Chemicals.	**Step 4:** Alternative Selection Decision.	**Step 4:** Initial Evaluation and Screening of Alternative Replacement Chemicals.
Step 5: Consideration of Additional Information.	**Step 5:** Final AA Report Preparation.	**Step 5:** Consideration of Additional Information.
Step 6: Preliminary AA Report Preparation.		**Step 6:** Abridged AA Report Preparation.

The regulations do not require that a specific alternative be selected, but instead embody the goals of the authorizing statute, Health and Safety Code section 25255(a). That provision states that the goals of the statute include "significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the

overall costs of those impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches." The responsible entity – not DTSC – makes the alternative selection decision at the conclusion of the AA process (which may be a decision to retain the Priority Product). However, there may be consequences resulting from the alternative selection decision in the form of regulatory responses, which are determined by DTSC under Article 6 when needed to address adverse impacts posed by the Priority Product or the selected alternative product.

Some alternatives may lend themselves to being quickly adopted as a result of concurrent development of the alternative, and addressing market requirements, such as consumer acceptance and costs. Unfortunately, some alternatives will not. It is expected that upon the completion of the Final AA Report, some responsible entities will only require six (6) to twelve (12) months for making the alternative available in the marketplace, while others may require twelve (12) months, twenty-four (24) months, thirty-six (36) months, or longer. As such, the regulations do not specify a deadline by which the selected alternative must be ready for market distribution, but require that the implementation plan include the anticipated period for making the alternative available in the market place, if an alternative is selected.

In addition, given that a functionally acceptable and technically feasible alternative may not be readily available, the regulations provide an Abridged AA process, which truncates some of the AA steps to instead dedicate a responsible entity's resources to further research and development following submission of an Abridged AA Report. The Abridged AA Report must be submitted by the due date for the pertinent Preliminary AA Report. Upon receipt and review of an Abridged AA Report, DTSC will issue a regulatory response determination notice for the Priority Product, which at a minimum will require the responsible entity to: (i) provide product information for consumers (section 69506.3); and (ii) conduct a research and development project or fund a challenge grant to seek and make available a safer product to replace the Priority Product (section 69506.8). The two-stage AA and Abridged AA processes are summarized above in Table 1, and discussed in much greater detail below.

§ 69505. Guidance Materials

Section 69505(a) requires DTSC, prior to finalizing the initial list of Priority Products under Article 3, to make available on its website guidance materials to assist persons in performing AAs under Article 5. DTSC must periodically revise and update the AA guidance materials. This provision is necessary to require DTSC to provide technical guidance to parties that will be conducting AAs and preparing AA Reports. Without this

provision, entities that become subject to the requirement to conduct an AA and submit the related reports may have insufficient knowledge and ability to do so in a timely and compliant manner. Since this is a new endeavor for many responsible entities, DTSC's guidance is essential to ensuring that AAs are performed and reported in a manner that is timely and in compliance with the regulations.

Section 69505(b) requires that DTSC post on its website example AAs that are available in the public domain at no cost. The posting must indicate the name of the person that prepared the AA. This provision is necessary to require DTSC to make available easily accessible AAs for consumer products that responsible entities may wish to consider as they undertake their own AAs.

Both sections 69505(a) and (b) are necessary to allow for thoughtful, comprehensive, and appropriate AAs to be performed and reported to DTSC in a timely manner.

§ 69505.1. Alternatives Analysis: General Provisions

Section 69505.1, in its entirety, establishes the general provisions applicable to responsible entities that are subject to the AA requirements, and the persons who execute or manage the execution of the AA and the preparation of the corresponding reports, including, for example, due dates for AA Reports, provisions for due date extensions, and exceptions to AA requirements. The specific provisions of section 69505.1 are discussed below.

Section 69505.1(a) specifies that this article does not apply to a product for which the notification requirements of section 69505.2 or section 69505.3 have been fully and timely met. Under section 69505.2, a responsible entity may provide a Chemical/Product Removal/Replacement Notification meeting the applicable content and timeline requirements of section 69505.2 in lieu of conducting an AA and submitting an AA Report. Likewise, under section 69505.3, a responsible entity may submit an AA Threshold Notification meeting the content and timeline requirements of section 69505.3 in lieu of conducting an AA and submitting an AA Report. This section is a companion provision to sections 69505.2 and 69505.3, and is necessary to make clear the interaction between section 69505.1 and the latter two sections. The necessity of these notification options is explained in the statement of reasons for sections 69505.2 and 69505.3.

Section 69505.1(b)(1) specifies that, except as provided in section 69505.1(a) and sections 69505.4(b), (c), and (d), a responsible entity for a Priority Product must

conduct an AA for the Priority Product, and must comply with all applicable requirements of Article 5.

Section 69505.1(a) and sections 69505.4 (b), (c), and (d) identify the options a responsible entity has to comply with the requirements of Article 5 by means other than conducting an AA and submitting the Preliminary and Final AA Reports. That is, a responsible entity may submit a Removal/Replacement Notification (under section 69505.2) or an AA Threshold Notification (under section 69505.3) in lieu of conducting an AA and submitting an AA Report. In addition, a responsible entity may submit an Abridged AA Report (under section 69505.4(b)), use an alternate AA process (under section 69505.4(c)), or submit a report for a previously completed AA (under section 69505.4(d)) in lieu of following the two-stage AA process set forth in Article 5 and submitting both a Preliminary AA Report and a Final AA Report.

Section 69505.1(b)(1) is necessary to clearly set forth who must perform an AA and submit the AA Reports – responsible entities; and for which products an AA must be performed – Priority Products. The performance of AAs is arguably the most important step in the quest for safer products; and is the fundamental purpose and objective of these regulations. The performance of AAs for Priority Products (*i.e.*, products that present the potential public health and environmental exposures to Chemicals of Concern) is fundamentally necessary to implement the statutory mandates of Health and Safety Code section 25253 and to achieve the goals articulated in Health and Safety Code sections 25253(a)(1) and 25255(a).

This is also needed to provide clarity as to when a responsible entity for a Priority Product is not required to perform an AA. The reasons for providing these options and exceptions are explained in the statement of reasons for sections 69505.2, 69505.3, and 69505.4.

Section 69505.1(b)(2) requires a responsible entity subject to the requirement to perform an AA under section 69505.1(b)(1) to prepare, sign, and submit to DTSC a Preliminary AA Report and a Final AA Report. These reports must be submitted within the time periods specified in sections 69505.1(b)(2)(A), (B), or (C). Requiring responsible entities to submit AA Reports to DTSC is necessary for two critical reasons: (i) receipt and review of the AA Report is essential for DTSC to be able to ensure compliance with the AA requirements of Article 5 (the necessity of which is explained above under section 69505.1(b)(1)); and (ii) the information in the AA Reports is also essential for DTSC to determine what, if any, regulatory responses are required under Article 6 (the necessity of which is detailed in the statement of reasons for Article 6).

The need for the AA Report signature requirement is explained in the statement of reasons for section 69501.3.

Section 69505.1(b)(2)(A) requires the Preliminary AA Report to be submitted no later than 180 days following the date that the applicable final Priority Products listing is posted on DTSC's website, unless DTSC specifies a different due date for the product in the Priority Products list. Specifying a due date for the Preliminary AA Report is necessary to ensure that: (i) responsible entities know how long they have to submit the Preliminary AA Report; (ii) the AA process proceeds on a timely basis; and (iii) to put all responsible entities on a level playing field. Based on the activities required to be conducted during the first stage AA and the information required to be included in the Preliminary AA Report, 180 days should, in most cases, provide a sufficient amount of time for preparation of the Preliminary AA Report.

The statement of reasons for section 69503.5(b)(3) explains the need for DTSC to be able to set a due date other than 180 days when listing a Priority Product. An extension process is provided in section 69505.1(c)(1) to address those situations for which 180 days (or such other time period as may be specified by DTSC in the Priority Products list) may not be adequate. Further, as a result of the public comment process during the development and issuance of the proposed and final Priority Products list, responsible entities will get advance signals of whether their product is being considered for listing as a Priority Product and thus subject to the AA requirements of Article 5. Additionally, the public comment process will provide responsible entities the opportunity to present information to DTSC in support of allowing a longer period of time for completing the first stage AA and submitting the Preliminary AA Report.

Section 69505.1(b)(2)(B) requires the Final AA report to be submitted no later than twelve (12) months after the date DTSC issues a notice of compliance for the Preliminary AA Report, unless DTSC approves an extended due date under section 69505.9(b)(4). Specifying a reasonable due date for the Final AA Report is necessary to ensure that: (i) responsible entities know the time period for submitting the Final AA Report; (ii) responsible entities are kept on a level playing field; and (iii) the AA process is completed on a timely basis.

However, the provision also provides the necessary latitude for DTSC to approve a longer period of time for submitting the Final AA Report, when warranted. This provision establishes a set time period for submitting the Final AA Report, but also provides flexibility for accommodating more complex Priority Products or more complex types/range of alternatives being considered that require additional time to conduct the second stage AA and prepare the Final AA Report. Because responsible entities are

not required to fill the information gaps associated with alternatives under consideration as part of the AA, for less complex AAs, twelve (12) months should be adequate time to compile and evaluate existing information, make an alternative selection decision, and prepare the Final AA Report.

Section 69505.1(b)(2)(C) specifies that for a Priority Product that is first placed into the stream of commerce in California after the date the product is listed as a Priority Product, the Preliminary AA Report must be submitted within 180 days after the product is placed into the stream of commerce, unless a different due date is specified by DTSC in the Priority Products list. This provision is necessary to capture Priority Products that were not subject to the Priority Products list at the time it was issued because the products were not in the California stream of commerce at the time the list was published, and to provide a reasonable time period for completion of the first stage AA and preparation of the Preliminary AA Report for these products. This provision is also necessary to provide a level playing field. It requires all responsible entities for a Priority Product to comply with the requirements of Article 5 – regardless of when they first introduce a Priority Product into the stream of commerce in California – and sets forth comparable compliance due dates.

Section 69505.1(b)(3) specifies that the requirements of this article applicable to a responsible entity may be fulfilled entirely or in part by the responsible entity, and/or entirely or in part by a person acting on behalf of or in the stead of the responsible entity. However, the requirements of section 69505.2 (Removal/Replacement Notifications) and section 69505.3 (AA Threshold Notifications) must be fulfilled by the product manufacturer itself.

Section 69505.1(b)(3) allows responsible entities to elect to conduct the AA and prepare the AA Reports (in part or in whole) entirely in-house, through contract, and/or by some collaborative effort with other parties (*e.g.*, a consortium of manufacturers). This is necessary to provide responsible entities the flexibility to obtain the necessary resources, expertise, and partnerships to fulfill their AA obligations in the most effective and cost efficient manner as they see fit. It also provides the option to keep some work in-house to protect trade secrets, while collaborating on other aspects that will not jeopardize trade secrets.

Restricting preparation and submittal of the Removal/Replacement Notifications and AA Threshold Notifications to the product manufacturer is necessary because the technical and informational requirements for the completion of these notifications will often only be known by the manufacturer of the Priority Product, and the manufacturer is in the

best position to make the required certifications and ensure continued conformance to the conditions certified to in the notifications.

Section 69505.1(c)(1) allows DTSC to grant a one-time 90-day extension to the deadline for the AA Report or Alternate Process AA Work Plan in response to a request for extension. The extension request must be based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. Any extension request must be received by DTSC no later than sixty (60) days before the applicable due date for the AA Report or Alternate Process AA Work Plan. This provision is necessary to provide the appropriate latitude to DTSC to accommodate reasonable and justified requests for time extensions for completing these documents. The requirement to submit the request no later than sixty (60) days before the due date is necessary to provide DTSC with enough time to meaningfully evaluate and reply to the request. In some cases, the circumstances necessitating an extension might not arise or be known until this late in the process. However, the request needs to be submitted far enough in advance of the due date so that if DTSC denies the request there is still a reasonable amount of time for the responsible entity to meet the due date. The provision limiting the extension to no more than ninety (90) days is necessary to ensure the AA process is not unduly delayed, and to prevent extension requests from being used as a mechanism to indefinitely delay the AA process.

Sections 69505.1(c)(2)(A) through (G) specify that an extension request must include:

- **(A)** The name of, and contact information for, the person filing the extension request;
- **(B)** The name of, and contact information for, the responsible entity(ies) on whose behalf the Preliminary and Final AA Reports will be submitted;
- **(C)** The name of, and contact information for, the manufacturers and the importers, if applicable, of the product, if different from the persons identified under subparagraphs (A) and (B);
- **(D)** Information identifying and describing the responsible entity's Priority Product, and the brand name(s) and product name(s) under which the Priority Product is placed into the stream of commerce in California, and if the Priority Product is a component of one or more assembled products a description of the known product(s) in which the component is used;
- **(E)** The due date for the AA Report;
- **(F)** The amount of additional time requested, not to exceed ninety (90) days; and
- **(G)** The reason the extension is needed, including an explanation as to why the circumstances necessitating the extension could not reasonably be anticipated or controlled by the responsible entity.

The provisions in sections 69505.1(c)(2)(A) through (G) ensure each extension request includes all of the information necessary for DTSC to:

- get in contact with the requesting entity, the manufacturer, importer, or other responsible entities, if necessary;
- know which responsible entities and Priority Products are covered under the extension request for tracking and compliance purposes;
- appropriately consider the request; and
- evaluate whether a time extension is warranted.

Section 69505.1(c)(3) requires DTSC to approve or deny, in whole or in part, an extension request within thirty (30) days of receipt, and to notify the person submitting the extension request of its decision. Failure by DTSC to issue a decision within thirty (30) days does not constitute an approval of the extension request. This provision confers appropriate latitude for DTSC to grant or deny the extension request to the extent warranted. It is also necessary to ensure that the request is responded to in a timely manner, while providing a sufficient amount of time for DTSC to review the contents and basis for the extension request and make a determination. Finally, this provision is necessary to prevent inadvertent errors or delays by DTSC resulting in an unwarranted extension request being granted.

Section 69505.1(d) requires any person performing an AA to consider all relevant information made available on DTSC's website and any additional information or technical assistance DTSC may provide regarding alternatives analysis. These efforts must be summarized in the Final AA Report or Abridged AA Report, whichever is applicable. This provision is necessary to ensure that a responsible entity does not, knowingly or unknowingly, fail to utilize and take into consideration existing information that may be relevant to conducting an AA for a Priority Product; and to compel responsible entities to take into account the current state of knowledge when evaluating alternatives to their Priority Product.

Section 69505.1(e) specifies that DTSC's failure to make a compliance determination for an AA Report or Alternate Process AA Work Plan within the applicable timeframe specified under 69505.9, or failure of the DTSC Director to respond to an appeal or Request for Review under Article 7 within sixty (60) days, does not result in the AA Report or Alternate Process AA Work Plan being deemed in compliance with Article 5. This is necessary to prevent the de facto, and potentially harmful, approval of an AA Report or Alternate Process AA Work Plan that does not comply with the applicable requirements of Article 5, in the event DTSC is unable to act within the specified time period due to resource limitations or other reasons.

§ 69505.2. Removal/Replacement Notifications in Lieu of Alternatives Analysis

Section 69505.2, in its entirety, is intended to 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 off the California market. This provision also provides an incentive (*i.e.*, an exemption from the AA requirements of Article 5) for manufacturers to take early action to remove the Chemical(s) of Concern from the Priority Product or remove the Priority Product from the marketplace. The incentive provided by this section will serve to accelerate the quest for safer products.

This provision allows reformulations, redesigns, or replacements to occur without conducting an AA, if a prescribed notification is submitted to DTSC prior to the due date for an AA Report for the Priority Product and the reformulated product does not contain any Chemical(s) of Concern. As discussed below, a manufacturer may, without conducting an AA, substitute a Chemical of Concern with a replacement chemical that is not on the Candidate Chemicals list or that is a Candidate Chemical that is already in use to manufacture the same product.

The overarching goal of the regulations and the statute 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. As such, the notifications allowed under this section create an incentive for manufacturers to begin considering reformulations to create safer products, while avoiding the time and expense of undergoing a full Article 5 AA. A manufacturer that takes the initiative to remove the Chemical(s) of Concern from its product is afforded opportunities to minimize the amount of DTSC oversight and avoid the requirement to conduct an AA under Article 5. Table 4 (below) graphically depicts the various options available to manufacturers to take expeditious action without the requirement to conduct an AA, and indicates the notifications that must be sent to DTSC to qualify for the exemption afforded by this section.

Table 4. Removal / Replacement Notifications

Manufacturers who...	May submit a:
Will remove or have removed the Chemical(s) of Concern from the Priority Product without the use of any replacement chemical(s)	Chemical Removal Intent and/or Confirmation Notification
Will cease or have ceased fulfilling orders for the product from persons selling or distributing the Priority Product in California	Product Removal Intent and/or Confirmation Notification
Will remove or have removed the Chemicals of Concern from the Priority Product, and any replacement chemical is not a Candidate Chemical or if it is a Candidate Chemical it is already in use (in lieu of the Chemical of Concern) to manufacture the same product	Product-Chemical Replacement Intent and/or Confirmation Notification

Given the timelines for submittal of a Removal/Replacement Notification, this option may be more attainable for manufacturers with a known alternative that can be confirmed as workable within nine (9) months (to avoid both the first and second stage AAs and the Preliminary and Final AA Reports) or eighteen (18) months (to avoid the second stage AA and the Final AA Report) after the product is listed as a Priority Product. The proposed regulations do not allow for extensions in submitting Removal/Replacement Notifications.

Section 69505.2 creates a practical means of allowing manufacturers to expedite the selection of safer alternatives without DTSC oversight. Section 69505.2(b)(9)(D) requires that the manufacturer identify the known hazard traits and/or environmental or toxicological endpoints of the replacement chemical(s) – whether a “Candidate Chemical” or not. In selecting a replacement chemical, it seems likely that the manufacturer would only consider replacement chemicals that exhibit fewer hazard traits and endpoints than those of the chemical being replaced. The information contained in the notifications is necessary to enable DTSC to conduct audits, ensure compliance, and take enforcement action if necessary. The hazard trait information included in the notification is necessary to enable DTSC to evaluate whether a selected replacement chemical should be added to the Candidate Chemicals list and/or the replacement product-chemical combination should be added to the Priority Products list.

Removal/Replacement Notifications are necessary to provide to DTSC information regarding: (i) manufacturers that elect the exemption option provided under section 69505.2, and the other responsible entities for the product; (ii) Priority Products removed from the marketplace; and (iii) replacement product-chemical combinations.

Without a notification, DTSC would have no means to identify the Priority Products that have been reformulated, making compliance confirmation and enforcement unworkable. The notification provides a means to identify the responsible entities and the Priority Products to ensure that those products may be tested and determined to be free of the Chemical(s) of Concern that is/are the basis for the product being listed as a Priority Product.

The notification requirements require that manufacturers include the content requirements specified in section 69505.2(b). The name of the replacement chemical(s), the concentration of each replacement chemical in their reformulated product, and the hazard traits and/or environmental or toxicological endpoints associated with the replacement chemical(s) must be included in the notification. This information is necessary so that DTSC can evaluate whether a selected replacement chemical should be added to the Candidate Chemicals list and/or the replacement product-chemical combination should be added to the Priority Products list. In addition, the information submitted to DTSC related to Intent and Confirmation Notifications will be posted on DTSC's website, thereby providing consumers the information they seek to make informed purchasing decisions.

The Product-Chemical Replacement 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 adverse public health and/or environmental impacts. However, to the extent that replacement chemicals exhibit hazard traits, those chemicals may be addressed through a subsequent Candidate Chemical and/or Priority Product listing process. In addition to the prioritization processes afforded through the regulations, consumers may provide the necessary feedback in the marketplace through their buying preferences.

The Intent and Confirmation Notifications will provide DTSC and interested parties, including consumers, information regarding the Priority Product, the reformulated product, and the replacement chemicals used in the reformulated product. The Removal/Replacement Notifications provide a necessary and logical exemption to the requirements of Article 5 if the manufacturer elects to: (i) remove the Chemical of Concern from the product; (ii) no longer make the Priority Product available in the California marketplace; or (iii) reformulate the product with a replacement chemical meeting specified criteria.

Section 69505.2(a)(1)(A) provides that the requirements to perform an AA and submit AA Reports under Article 5 do not apply to a responsible entity's Priority Product if the

manufacturer of the Priority Product submits one of the following notifications to DTSC no later than the due date for submitting the Preliminary AA Report:

1. A Chemical Removal Intent and/or Confirmation Notification that complies with sections 69505.2(b) and (c);
2. A Product Removal Intent and/or Confirmation Notification that complies with sections 69505.2(b) and (d); or
3. A Product-Chemical Replacement Intent and/or Confirmation Notification that complies with sections 69505.2(b) and (e).

This provision provides manufacturers the option to take one of the following actions in lieu of conducting an AA and submitting AA Reports:

- Remove Chemical(s) of Concern that are not necessary for the product performance or function without using replacement chemicals;
- Cease placing the Priority Product into the stream of commerce in California; or
- Reformulate the Priority Product to use replacement chemicals meeting specified criteria in lieu of the Chemical of Concern(s).

The Intent and Confirmation Notifications are necessary to inform DTSC and interested parties, including consumers, as to which Priority Products the Chemical of Concern will be or has been removed from; which Priority Products will be or have been removed from the California marketplace; and which Priority Products will be or have been replaced by products containing replacement chemicals in lieu of the Chemical of Concern. This information is necessary to DTSC for purposes of ensuring compliance with the requirements of Article 5. These notifications are also necessary to provide to DTSC and interested parties information regarding replacement chemicals used in the products that replace a Priority Product. This will assist consumers in making informed purchasing decisions, and will provide DTSC with information needed to evaluate the replacement chemical and the new product-chemical combination to determine if an addition to the Candidate Chemicals list and/or the Priority Products list is warranted.

The notification needs to be submitted to DTSC by the due date for the Preliminary AA Report, otherwise the manufacturer and the Priority Product will be deemed non-compliant with Article 5 and DTSC will add this information to the Failure to Comply List (under section 69501.2) and pursue appropriate enforcement action.

Giving manufacturers the option to first submit an Intent Notification followed by a Confirmation Notification is necessary to give a manufacturer who makes the decision to take one of the actions allowing for an exemption under section 69505.2 additional time to implement the actions upon which the exemption is conditioned.

Section 69505.2(a)(1)(B) specifies that if only an Intent Notification for a chemical removal, product removal, or product-chemical replacement is submitted to DTSC by the due date for the Preliminary AA Report, within ninety (90) days after the Intent Notification is submitted, or by the due date for the Preliminary AA Report, whichever is later, the manufacturer must submit one of the following to DTSC:

1. A removal or replacement Confirmation Notification; or
2. A Preliminary AA Report, Abridged AA Report, or Alternate Process AA Work Plan.

This section is necessary for DTSC to have a means of ensuring that appropriate action follows the Intent Notifications, and that manufacturers do not avoid compliance by simply filing Intent Notifications without taking the next substantive step(s). Given that the exemption allowed under section 69505.2 provides a significant cost-saving off-ramp for manufacturers wishing to avoid AAs, it is necessary that they follow through promptly on their stated *intent* and do not use this exemption process to significantly delay complying with the AA requirements of Article 5. This is the basis for requiring a Confirmation Notification within ninety (90) days after the Intent Notification is submitted. However, manufacturers who submit an Intent Notification well in advance of the due date for the Preliminary AA Report are given until the Preliminary AA Report due date or ninety (90) days (whichever is later) to submit the Confirmation Notification. Some manufacturers, after submitting an Intent Notification, may later determine that they need or wish to go through the AA process rather than pursuing one of the expedited options afforded under section 69505.2 that preclude the need to undertake an AA. Therefore, it is necessary that this section allow such manufacturers to submit a Preliminary AA Report, Abridged AA Report, or Alternate Process AA Work Plan in lieu of a Confirmation Notification.

Section 69505.2(a)(2)(A) specifies that if a Preliminary AA Report or Alternate Process AA Work Plan has already been submitted to DTSC, the requirements of Article 5 pertaining to performing the second stage AA and submission of a Final AA Report do not apply if an Intent or Confirmation Notification is submitted to DTSC prior to the due date for submitting the Final AA Report.

This provision provides a manufacturer a logical opportunity to reconsider its initial decision to conduct an AA. After submitting a Preliminary AA Report or an Alternate Process AA Work Plan, a manufacturer may decide that it can and wants to proceed with an expedited Chemical of Concern removal and/or replacement or Priority Product removal rather than completing the AA process and submitting a Final AA Report. This section is necessary to accommodate this option, which is consistent with the objective of accelerating the quest for safer products. In these situations, the Intent or

Confirmation Notification must be submitted by the due date for the Final AA Report. Otherwise, the manufacturer and the Priority Product will be deemed non-compliant with Article 5 and DTSC will add this information to the Failure to Comply List (under section 69501.2) and pursue appropriate enforcement action

Section 69505.2(a)(2)(B) requires that, if only an Intent Notification for a chemical removal, product removal, or product-chemical replacement is submitted to DTSC by the due date for the Final AA Report, the manufacturer must submit a removal or replacement Confirmation Notification or a Final AA Report by the later of the following dates:

1. Ninety (90) days after the Intent Notification is submitted; or
2. The due date for the Final AA Report.

The necessity bases discussed above for section 69505.2(a)(1)(B) apply equally to section 69505.2(a)(2)(B).

Section 69505.2(a)(3) specifies that a manufacturer is not in compliance with section 69505.1(b), if the manufacturer submits a notification under section 69505.2, in lieu of submitting the otherwise required AA Report(s), and the notification is not submitted by the applicable due date or does not fully meet the applicable content requirements specified in sections 69505.2(b) through (e). Section 69505.1(b) specifies the general provisions applicable to AAs and the time periods by when AA Reports must be submitted, if a notification is not submitted pursuant to section 69505.2 or 69505.3. A determination of non-compliance with the requirements of section 69505.1(b) triggers the non-compliance notice and Failure to Comply listing provisions of section 69501.2. This, in turn, will ultimately require California retailers to cease ordering the product, unless someone else (*e.g.,* the importer or a retailer) performs the required AA and submits the AA Reports in lieu of the manufacturer. Section 69505.2(a)(3) is necessary to make it clear what the consequences are of not submitting a timely and/or adequate Intent and/or Confirmation Notification under section 69505.2.

Section 69505.2(b) specifies the content requirements for Chemical Removal, Product Removal, and Product-Chemical Replacement Intent and Confirmation Notifications. These content requirements are necessary to ensure that each Intent and Confirmation Notification includes all of the information necessary for DTSC to:

- get in contact with the manufacturer and/or any other responsible entities, if necessary;
- know which Priority Products are covered by the notification and which responsible entities are relieved (as a result of the notification) of the requirement to conduct an AA and submit AA Reports;

- verify that the manufacturer has followed through on the actions certified to in the notification;
- ensure the manufacturer has an effective plan to implement the actions certified to in the notification (including laboratory confirmation testing and outreach to retailers and distributors);
- ensure compliance and/or pursue appropriate actions in the event of non-compliance;
- evaluate the reformulated product (including product uses and users, hazard traits, laboratory methodologies for detection and concentration measurements, and other factors considered in the reformulation decision) to determine if it represents a safer viable alternative to the Priority Product for purposes of Article 6, or to determine if a reformulated product containing replacement chemicals raises adverse impact and exposure concerns that might warrant an addition to the Candidate Chemicals list and/or the Priority Products list; and
- ensure that any replacement chemical is not a Candidate Chemical that DTSC did not identify as a Chemical of Concern for the Priority Product solely because the chemical was not used to manufacture the product at the time of the Priority Product listing.

Each Chemical Removal, Product Removal, and Product-Chemical Replacement Intent and Confirmation Notification must contain all of the following:

(1) The name of, and contact information for, the person submitting the notification. This information is needed should it become necessary to contact this person with questions regarding the notification.

(2) The name of, and contact information for, any known responsible entity(ies). This information is needed should contacting the responsible entities become necessary to verify compliance, as well as to help identify the specific product that is the subject of the notification.

(3) The name of, and contact information for, the manufacturer(s) and the importer(s) of the product, if different from paragraphs (1) and (2). This information is needed should it become necessary to contact these persons with questions regarding the notification or to confirm implementation of the actions certified to in the notification.

(4) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer directly sold the Priority Product within the prior twelve (12) months. This information is necessary for

DTSC to understand the product's supply chain and to assist DTSC in monitoring implementation of the chemical removal, product removal, or product-chemical replacement.

(5) Identification and location of the manufacturer's retail sales outlets where the manufacturer sold, supplied, or offered for sale the Priority Product in California, if applicable. This information is necessary for DTSC to understand the product's supply chain and to assist DTSC in monitoring implementation of the chemical removal, product removal, or product-chemical replacement.

(6) Information identifying and describing the Priority Product and the reformulated product, if applicable, and the brand name(s) and labeling information under which the Priority Product and the reformulated product, if applicable, are/were placed into the stream of commerce in California. In addition, if the product is a component of one or more assembled products a description of the known product(s) in which the component is used must be included. This information is necessary to assist DTSC in monitoring implementation of the chemical removal, product removal, or product-chemical replacement.

(7) The intended uses, and targeted customer base(s), for the Priority Product and the reformulated product, if applicable. This information is necessary to understand to whom the product is sold and where it may be found, so as to assist DTSC in monitoring implementation of the chemical removal, product removal, or product-chemical replacement. With respect to a reformulated product, this information is also necessary to DTSC's evaluation of potential exposure pathways and adverse impacts associated with the product and the replacement chemicals used in the product to determine if an addition to the Candidate Chemicals list and/or Priority Products list is warranted.

(8) The measures the manufacturer will take or has taken to:

- **(A)** If applicable, provide information regarding the reformulated product to persons selling or distributing the Priority Product in California; and
- **(B)** Cease fulfilling orders for the Priority Product from person selling or distributing the Priority Product in California.

This information is necessary to ensure the manufacturer has an effective plan for removing the Priority Product from the California marketplace and making sure that California retailers and distributors are aware of the availability of the reformulated product that replaces the Priority Product. This provision is also

necessary to assist DTSC in monitoring implementation of the chemical removal, product removal, or product-chemical replacement.

(9) For Chemical Removal Notifications and/or Product-Chemical Replacement Notifications, the Chemical(s) of Concern that will be, or have been, removed from the product, and, as applicable, the information listed in sections 69505.2(b)(9)(A) through (F). The requirement to identify in the notification the Chemical(s) of Concern removed or to be removed from the product is necessary to be sure that all Chemicals of Concern are removed – otherwise, the manufacturer and other responsible entities and the Priority Product are not eligible for the exemption provided under section 69505.2.

(A) Information explaining the rationale and the factors considered in deciding to reformulate the product. This information is necessary to assist DTSC in evaluating: (i) whether the reformulated product may be a safer viable alternative to the Priority Product for purposes of Article 6; or (ii) conversely, whether the replacement product-chemical combination presents exposure and adverse impact concerns that may warrant an addition to the Candidate Chemicals list and/or Priority Products list.

(B) The laboratory analytical testing methodology and quality control and assurance protocols used or that will be used to confirm that the Chemical(s) of Concern has/have been removed from the product, and identification of the testing laboratory. This information is necessary to enable DTSC to evaluate the scientific appropriateness of the methodologies used, and, thus to evaluate the validity of the manufacturer's certification that the Chemicals of Concern have been removed.

(C) Information demonstrating that the Chemical(s) of Concern has/have been removed from the product that was a Priority Product. This information is necessary to enable DTSC to validate the manufacturer's certification that the Chemicals of Concern have been removed, and thus ensure that adverse impacts are no longer of concern.

(D) The name of the replacement chemical(s), the concentration of each replacement chemical in the reformulated product, and the hazard traits and/or environmental or toxicological endpoints known to be associated with the replacement chemical(s). This information is necessary to assist DTSC in evaluating: (i) whether the reformulated product may be a safer

viable alternative to the Priority Product for purposes of Article 6; or (ii) conversely, whether the replacement product-chemical combination presents exposure and adverse impact concerns that may warrant an addition to the Candidate Chemicals list and/or Priority Products list.

(E) The laboratory analytical testing methodology and quality control and assurance protocols used or that will be used to measure the concentration of the replacement chemical(s) in the product, and identification of the testing laboratory. This information is necessary to enable DTSC to evaluate the scientific appropriateness of the methodologies used, and, thus, the validity of the chemical concentration information provided in the notification.

(F) Information demonstrating that each replacement chemical meets one of the following criteria:

1. The replacement chemical is not on the list of Candidate Chemicals; or
2. The replacement chemical is Candidate Chemical that is already in use to manufacture the same product, in lieu of the Chemical of Concern, by the same or a different manufacturer. For purposes of this subsection, “same product” means a product that has the same or similar product description as the Priority Product; has the same intended use(s) and targeted customer base(s) as the Priority Product; and fulfills the functional, performance, and legal requirements of the Priority Product.

Section 69505.2(b)(9)(F), in effect, limits the chemicals that may be used as replacement chemicals to those chemicals that DTSC has not identified as Candidate Chemicals, or Candidate Chemicals used in the product but that DTSC has not identified as Chemicals of Concern for the Priority Product. The fact that DTSC did not list a Candidate Chemical used to manufacture the product as a Chemical of Concern for the Priority Product means that DTSC has already determined *that* Candidate Chemical in *that* product does not pose adverse impacts that warrant requiring an AA.

This provision is necessary to preclude a reformulation (without the benefit of an AA) that uses as a replacement chemical a Candidate Chemical that DTSC did not identify as a basis for listing the Priority Product (*i.e.*, a Chemical of Concern) merely because the Candidate

Chemical was not previously used to manufacture that product. Although not identified as a Chemical of Concern, such a Candidate Chemical could pose potential adverse impact and exposure concerns not previously evaluated by DTSC if used as a replacement chemical for the Chemical of Concern.

(10) The certification statement required under section 69505.2(c), (d), or (e), as applicable. This requirement and its necessity are discussed below.

Section 69505.2(c) specifies that Chemical Removal Intent and Confirmation Notifications must include a certification statement as specified in sections 69505.2(c)(1) or (2), whichever is applicable. Section 69505.2(c)(1) specifies the certification requirements for Chemical Removal *Intent* Notifications, and section 69505.2(c)(2) specifies the certification requirements for Chemical Removal *Confirmation* Notifications. The necessity for these certification requirements is discussed immediately below.

Section 69505.2(c)(1) requires that Chemical Removal *Intent* Notifications include a statement certifying that the manufacturer intends to do all of the following within ninety (90) days of the date the notification is submitted to DTSC:

(A) Remove the Chemical(s) of Concern from the Priority Product without the use of one or more replacement chemicals or otherwise adding other chemicals to the product – this is necessary to ensure that the product will no longer present the adverse impact concerns that led to the product being listed as a Priority Product.

(B) Provide information regarding the reformulated product to persons selling or distributing the Priority Product in California – this is necessary so that retailers and distributors are aware that a safer product is available in the California marketplace.

(C) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California – this is necessary to expeditiously facilitate replacement of the Priority Product with the safer reformulated product in the California marketplace.

(D) Submit a Chemical Removal Confirmation Notification to DTSC for the Priority Product – this is necessary so that DTSC and other interested parties will know that the manufacturer has followed through on the actions certified to under section 69505.2(c)(1)(A) through (C) within the required time period.

This provision is necessary to require that manufacturers acknowledge that the substantive requirements of the Chemical Removal Intent Notification must be complied

with within ninety (90) days of submitting the Intent Notification. This provision provides a logical requirement that the Confirmation Notification be submitted within the specified time period for assurance that the intended action is taken and to allow for a means of determining compliance.

This provision is also necessary to ensure that manufacturers understand, and formally commit to fulfilling, the conditions for the exemption afforded under section 69505.2. This provision is necessary to ensure that the substantive and administrative requirements of the exemption will be met. This, in turn, ensures that adverse public health and environmental impacts associated with the Priority Product will be addressed and an effective enforcement program can be implemented, if needed.

Section 69505.2(c)(2) specifies that Chemical Removal *Confirmation* Notifications must include a statement certifying that:

- **(A)** The Chemical(s) of Concern has/have been removed from the product that was a Priority Product without the use of one or more replacement chemicals or otherwise adding other chemicals to the product – this is necessary to ensure that the product no longer presents the adverse impact concerns that lead to the product being listed as a Priority Product.
- **(B)** Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California – this is necessary so that retailers and distributors are aware that a safer product is available in the California marketplace.
- **(C)** The manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California – this is necessary to expeditiously facilitate replacement of the Priority Product with the safer reformulated product in the California marketplace.

The Chemical Removal Confirmation Notification is necessary to confirm for DTSC and other interested parties that the manufacturer has followed through on the requirements for the exemption provided under section 69505.2, as committed to in the Intent Notification. This provision is necessary to ensure that the substantive and administrative requirements of the exemption are met. This, in turn, ensures that adverse public health and environmental impacts associated with the Priority Product have been addressed and an effective enforcement program can be implemented, if needed.

Section 69505.2(d) requires that <u>Product Removal</u> Intent and Confirmation Notifications include a certification statement as specified in sections 69505.2(d)(1) or (2), whichever

is applicable. Section 69505.2(d)(1) specifies the certification requirements for Product Removal *Intent* Notifications, and section 69505.2(d)(2) specifies the certification requirements for Product Removal *Confirmation* Notifications. The necessity for these certification statements is discussed immediately below.

Section 69505.2(d)(1) specifies that Product Removal *Intent* Notifications must include a statement certifying that the manufacturer intends to do both of the following within ninety (90) days of the date the notification is submitted to DTSC:

- **(A)** Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California – this is necessary to expeditiously facilitate removal of the Priority Product from the California marketplace.
- **(B)** Submit a Product Removal Confirmation Notification to DTSC for the Priority Product – this is necessary so that DTSC and other interested parties will know that the manufacturer has followed through on the action certified to under section 69505.2(d)(1)(A) within the required time period.

This provision is necessary to require that manufacturers acknowledge that the substantive requirements of the Product Removal Intent Notification must be complied with within ninety (90) days of submitting the Intent notification. This provision provides a logical requirement that the Confirmation Notification be submitted within the specified time period for assurance that the intended action is taken and to allow for a means of determining compliance.

This provision is also necessary to ensure that manufacturers understand, and formally commit to fulfilling, the conditions for the exemption afforded under section 69505.2. This provision is necessary to ensure that the substantive and administrative requirements of the exemption will be met. This, in turn, ensures that adverse public health and environmental impacts associated with the Priority Product will be addressed and an effective enforcement program can be implemented, if needed.

Section 69505.2(d)(2) specifies that Product Removal *Confirmation* Notifications must include a statement certifying that the manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California – this is necessary to expeditiously facilitate removal of the Priority Product from the California marketplace.

The Product Removal Confirmation Notification is necessary to confirm for DTSC and other interested parties that the manufacturer has followed through on the requirements for the exemption provided under section 69505.2, as committed to in the Intent Notification. This provision is necessary to ensure that the substantive and

administrative requirements of the exemption are met. This, in turn, ensures that adverse public health and environmental impacts associated with the Priority Product have been addressed and an effective enforcement program can be implemented, if needed.

Section 69505.2(e) specifies that Product-Chemical Replacement Intent and Confirmation Notifications must include a certification statement as specified in sections 69505.2(e)(1) or (2), whichever is applicable. Section 69505.2(e)(1) specifies the certification requirements for Product-Chemical Replacement *Intent* Notifications, and section 69505.2(e)(2) specifies the certification requirements for Product-Chemical Replacement *Confirmation* Notifications. The necessity for these certification statements is discussed immediately below.

Section 69505.2(e)(1) specifies that Product-Chemical Replacement *Intent* Notifications must include a statement certifying that the manufacturer intends to do all of the following within ninety (90) days of the date the notification is submitted to DTSC:

- **(A)** Remove the Chemical(s) of Concern from the Priority Product – this is necessary to ensure that the product will no longer present the adverse impact concerns associated with the Chemical(s) of Concern that led to the product being listed as a Priority Product.
- **(B)** Provide information regarding the reformulated product to persons selling or distributing the Priority Product in California – this is necessary so that retailers and distributors are aware that a reformulated product that does not contain the Chemical(s) of Concern is available in the California marketplace.
- **(C)** Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California – this is necessary to expeditiously facilitate replacement of the Priority Product with the reformulated product in the California marketplace.
- **(D)** Submit a Product-Chemical Replacement Confirmation Notification to DTSC for the Priority Product – this is necessary so that DTSC and other interested parties will know that the manufacturer has followed through on the actions certified to under section 69505.2(e)(1)(A) through (C) within the required time period.

This provision is necessary to require that manufacturers acknowledge that the substantive requirements of the Product-Chemical Replacement Intent Notification must be complied with within ninety (90) days of submitting the Intent Notification. This provision provides a logical requirement that the Confirmation Notification be submitted within the specified time period for assurance that the intended action is taken and to allow for a means of determining compliance.

This provision is also necessary to ensure that manufacturers understand, and formally commit to fulfilling, the conditions for the exemption afforded under section 69505.2. This provision is necessary to ensure that the substantive and administrative requirements of the exemption will be met. This, in turn, ensures that adverse public health and environmental impacts associated with the Priority Product are being addressed and an effective enforcement program can be implemented, if needed.

Section 69505.2(e)(2) provides that Product-Chemical Replacement *Confirmation* Notifications must include a statement certifying that:

- **(A)** The Chemical(s) of Concern has/have been removed from the product that was a Priority Product – this is necessary to ensure that the product no longer presents the adverse impact concerns associated with the Chemical(s) of Concern that lead to the product being listed as a Priority Product.
- **(B)** The replacement chemical(s) meet the criteria specified in section 69505.2 (b)(9)(F)1. or 2. – this is necessary to ensure that any replacement chemical is not a Candidate Chemical that DTSC did not consider for identification as a possible Chemical of Concern for the Priority Product solely because the chemical was not used to manufacture the product at the time of the Priority Product listing (and thus DTSC did not evaluate the potential, if any, exposure and adverse impact concerns for the Candidate Chemical in the product).
- **(C)** Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California – this is necessary so that retailers and distributors are aware that a reformulated product that does not contain the Chemical(s) of Concern is available in the California marketplace.
- **(D)** The manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California – this is necessary to expeditiously facilitate replacement of the Priority Product with the reformulated product in the California marketplace.

The Product-Chemical Replacement Confirmation Notification is necessary to confirm for DTSC and other interested parties that the manufacturer has followed through on the requirements for the exemption provided under section 69505.2, as committed to in the Intent Notification. This provision is necessary to ensure that the substantive and administrative requirements of the exemption are met. This, in turn, ensures that adverse public health and environmental impacts associated with the Chemical(s) of Concern in the Priority Product have been addressed and an effective enforcement program can be implemented, if needed.

§ 69505.3. Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis

The processes in Articles 2 and 3 are designed to identify chemicals (as Candidate Chemicals) that have adverse impacts on public health and/or the environment if exposures to the chemicals occur; and identify and prioritize product-chemical combinations for which there is the potential for exposures to the Candidate Chemicals in the product potentially resulting in adverse impacts. In Article 3, consumer products containing chemicals listed as Candidate Chemicals under Article 2 will be prioritized based on potential adverse public health and environmental impacts, potential exposures, and relevant factors. The Candidate Chemical(s) that is/are the basis for listing a product as a Priority Product become the Chemical(s) of Concern for that product. An AA under Article 5 must be performed for each product that is a Priority Product by one of the responsible entities for the product. A Priority Product is exempted from Article 5 AA requirements if the concentrations of the Chemical(s) of Concern in the Priority Product do not exceed the applicable AA Threshold(s) (if AA Thresholds have been set for the Priority Product-Chemical of Concern) and the manufacturer of the product submits an AA Threshold Notification to DTSC.

Section 69501.1(a)(12) defines the AA Threshold as either: (i) the Practical Quantitation Limit (PQL) for a Chemical of Concern present in the Priority Product solely as a contaminant; or (ii) the applicable concentration, if any, specified by DTSC during the Priority Product listing process under section 69503.5(c). Given the Chemicals of Concern's adverse public health and environmental impacts, it would not be prudent for DTSC to establish a threshold above the PQL absent information demonstrating that a higher level is appropriate. Establishing the AA Threshold at the PQL for Chemicals of Concern present in Priority Products solely as contaminants – and having no default AA Threshold for intentionally added Chemical(s) of Concern – in effect, requires that manufacturers ask whether the Chemical(s) of Concern in the products that they manufacture is/are necessary – both for chemicals knowingly used to manufacturer a product and other chemicals present in a product that can be reasonably and reliably detected and measured.

If information demonstrates that an AA threshold is necessary and appropriate for an intentionally added Chemical of Concern in a particular product or that an AA Threshold above the PQL is necessary and appropriate for a contaminant, such an AA Threshold could be established at the time of the Priority Product listing. Section 69503.5(c) specifies that DTSC may for one or more product-chemical combinations specify in the proposed or final Priority Products list an AA Threshold concentration for any Chemical of Concern that is an intentionally added ingredient. It further provides that DTSC may

specify an AA threshold concentration greater than the default AA Threshold (*i.e.*, the PQL) for any Chemical of Concern that is a contaminant.

In most cases, DTSC will list products as Priority Products because of Chemicals of Concern that are intentionally used to manufacture the product. Most of the products covered by any given Priority Product listing will have the Chemicals of Concern as intentionally added ingredients. DTSC has determined that it is not appropriate or necessary to establish an across-the-board default AA Threshold for intentionally added ingredients in Priority Products because: (i) the manufacturer knows the Chemical of Concern is present in their product without the need for laboratory testing; and (ii) as part of the product prioritization process, DTSC has determined that the Chemical of Concern is typically present in products covered by the Priority Product listing in concentrations that pose potential exposures and potential adverse impacts and so an AA followed by regulatory responses is needed to address those adverse impacts.

It is possible, however, that some products covered by a Priority Product listing will have the Chemical of Concern present either: (i) as an intentionally added ingredient but at much lower concentrations than most other products covered by the same Priority Product listing; or (ii) solely as contaminants. If DTSC becomes aware (either prior to issuing the proposed Priority Product listing or upon receipt of public comments) of the existence of products containing the Chemical of Concern at relatively small concentrations compared to most other products covered by the same Priority Product listing, the regulations (at section 69503.5(c)) give DTSC the latitude to establish an AA Threshold for that particular Priority Product listing that would allow such products (with lower concentration Chemicals of Concern) to be exempted under section 69505.3 from the AA requirements – the AA requirements would still apply to the other products covered by the same Priority Product listing that contain the Chemical of Concern at higher concentration levels.

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 threshold. 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 DTSC decides to list a product as a Priority Product on the basis of a contaminant Chemical of Concern, this will likely be because the contaminant is frequently found in products covered by the Priority Product listing in concentrations that present potential adverse impacts and potential exposures – in some cases this could be at the PQL and in other cases it could be at a much higher concentration level. If DTSC determines an AAT above the PQL is warranted for such a Priority Product, the regulations again provide the latitude for DTSC to set a higher AA Threshold.

If DTSC determines an AA Threshold for an intentionally added Chemical of Concern, or an AA Threshold above the PQL for a contaminant Chemical of Concern, is warranted for a particular Priority Product-Chemical of Concern, DTSC may propose the AA Threshold as part of the proposed Priority Product listing. In some cases, such a determination may be made subsequent to issuance of the proposed Priority Product listing based on information received during the public comment period – in this instance, DTSC would revise the proposed Priority Product listing to reflect the proposed AA Threshold and reissue the proposed listing for public comment on the proposed AA Threshold prior to issuing a final Priority Product listing. (The same process would be followed if DTSC decided to revise or eliminate a previously proposed AA Threshold in response to public comments.)

The provisions of the regulations pertaining to 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%).

For purposes of the default AA Threshold for a contaminant, the regulations (at section 69505.1(a)(25)) define the Practical Quantitation Limit (PQL) to mean “the lowest concentration of a chemical that can be ***reliably*** measured within specified limits of precision and accuracy using routine laboratory operating procedures.” (Emphasis added.)

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 a higher default level 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, the MDL is used to extrapolate the PQL through the application of statistically and scientifically acceptable methods. 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) to 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 PQLs that were originally 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 laboratory methods and limits of detection 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 PQLs on an as-needed basis.

Section 69505.3, in its entirety, is necessary to provide an exemption from the requirement to conduct an AA under Article 5, if the Chemical of Concern in a product that is listed as a Priority Product does not exceed the applicable AA Threshold (if one is established in the regulations or subsequently by DTSC). To effectuate the exemption the manufacturer of the product must submit an AA Threshold Notification to DTSC so that DTSC, other responsible entities for the product, and interested parties are made aware that the manufacturer's product is exempt and know not to expect an AA for the product.

As explained above, a default AA Threshold is available for a Priority Product only if the Chemical of Concern is present in the product solely as a contaminant, and the concentration of the Chemical of Concern does not exceed the PQL for the chemical. If during the product prioritization process, DTSC determines that an AA Threshold is needed for a particular intentionally added chemical in a particular product or that the AA Threshold for a contaminant should be set higher than the PQL – this can be addressed in the rulemaking for that Priority Product listing. That is, DTSC has the authority to establish specific AA Thresholds on a case-by-case basis for intentionally added chemicals and contaminants.

Section 69505.3 specifies the information that must be included in an AA Threshold Notification. 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.

Section 69505.3(a) provides that the Article 5 AA Requirements 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. Each AA Threshold Notification is required to include all of the following information:

- **(1)** The name of, and contact information for, the person submitting the notification;
- **(2)** The name of, and contact information for, any known responsible entities;
- **(3)** The name of, and contact information for, the manufacturer(s) and importer(s) of the Priority Product, if different from paragraphs (1) and (2);
- **(4)** One of the following certification statements, as applicable:
  - **(A)** A statement certifying that the Chemical(s) of Concern is/are present in the manufacturer's Priority Product only as contaminants and the concentration of each Chemical of Concern does not exceed the PQL for that chemical; or
  - **(B)** A statement certifying that the Chemical(s) of Concern does/do not exceed the AA Threshold(s) specified by DTSC during the Priority Product listing process.
- **(5)** If applicable, identification of the PQL for each Chemical of Concern in the Priority Product, and the information and method used to determine the PQL;
- **(6)** The source of the Chemical(s) of Concern in the Priority Product;
- **(7)** Information identifying and describing the Priority Product, the brand name(s) and labeling information under which the Priority Product is placed into the stream of commerce in California, and if the Priority Product is a component of one or more assembled products a description of the known product(s) in which the component is used;
- **(8)** Laboratory analytical testing methodology and quality control and assurance protocols used to measure each Chemical of Concern in the Priority Product, and identification of the testing laboratory; and
- **(9)** A demonstration and certification that the manufacturer meets and will continue to meet the criteria and conditions that are the basis for the exemption provided under section 69505.3.

The content requirements are necessary to ensure that each AA Threshold Notification includes all of the information necessary for DTSC to:

- get in contact with the manufacturer and/or any other responsible entities with questions concerning the notification, to ensure the conditions for the exemption

are satisfied, and to notify affected responsible entities in the event the exemption is no longer valid and an AA is required;

- know which Priority Products are covered by the notification and which responsible entities are relieved (as a result of the notification) of the AA requirements;
- understand the specific facts that qualify the manufacturer's Priority Product for an AA Threshold exemption;
- evaluate the appropriateness of the laboratory testing methodologies used, and, thus, evaluate the validity of the manufacturer's certification that the Priority Product meets the conditions for an AA Threshold exemption;
- hold the manufacturer accountable for meeting the conditions on which the exemption is based; and
- conduct audit and compliance activities to ensure a Priority Product covered by a notification actually meets the conditions for an AA Threshold exemption, and pursue appropriate enforcement actions if those conditions are not met.

These provisions allow the AA Threshold Notification to be submitted with the Priority Product Notification required under section 69503.7(a). However, the manufacturer has until the time the Preliminary AA Report is due to submit either an AA Threshold Notification or a Preliminary AA Report. The AA Threshold Notification is necessary so that DTSC, other responsible entities for the product, and interested parties are made aware that the manufacturer's product is exempt and know not to expect an AA for the product. The AA Threshold Notification and its contents are also necessary for DTSC to be in a position to conduct an audit and/or other compliance actions, if appropriate. The notification provides a means to identify the manufacturers and other responsible entities and the Priority Products to ensure that those products may be tested to verify that the concentrations of the Chemical(s) of Concern do not exceed the applicable AA Threshold.

Section 69505.3(b) specifies that the manufacturer bears the burden of proof to demonstrate that the concentration of the Chemical(s) of Concern in its Priority Product do not exceed the applicable AA Threshold. This provision clarifies that it is the manufacturer, and not DTSC, that has the burden of proof to show the product's compliance with all the requirements of this exemption for as long as the exemption is claimed. It is necessary to place the burden of proof on the manufacturer since it is in the best position to evaluate the product that it manufactures. In addition, this approach is necessary to prevent placing this burden on DTSC's limited resources.

Section 69505.3(c) requires the manufacturer to submit to DTSC a revised AA Threshold Notification if any of the information provided in a previously submitted AA

Threshold Notification significantly changes. A revised AA Threshold Notification must be submitted to DTSC within thirty (30) days of a significant change. This is necessary so that the information on which the manufacturer makes its determination is current and available to DTSC for confirmation or audit.

Section 69505.3(d) requires the manufacturer to notify DTSC, within thirty (30) days, if the product no longer meets the criteria for an AA Threshold exemption. In addition, the manufacturer is required to submit a Preliminary AA Report or an applicable Intent and/or Confirmation Notification under section 69505.2 to DTSC within 180 days of the change in status. Notification of a change in a product's exemption status is necessary so that manufacturers and DTSC are both basing decisions on current information. This provision is necessary to inform DTSC, other responsible entities for the product, and interested parties that the affected Priority Product is now subject to the AA requirements, and so that DTSC knows when the Preliminary AA Report is due – so that compliance actions can be taken if the AA Report is not received by the due date. It is also necessary to prevent a manufacturer from relying on an exemption for which it no longer qualifies. The 180-day time period allowed for submitting a Preliminary AA Report or an Intent and/or Confirmation Notification is consistent with comparable due dates in the regulations and ensures that the AA process is not unduly delayed.

Section 69505.3(e) disallows the AA Threshold exemption if DTSC notifies the person who submitted the AA Threshold Notification that the information or findings contained in the notification are inaccurate or inadequate to support an AA Threshold exemption. Although DTSC is not required to approve the AA Threshold Notification, if DTSC determines that the information or findings submitted with the AA Threshold Notification are not adequately substantiated, the exemption may be invalidated by DTSC. This provision is necessary to put manufacturers on notice that the AA Threshold Notification must include information that substantiates their findings and if necessary DTSC may reject the AA Threshold exemption if the findings are not substantiated. This provision is also necessary to ensure that Priority Products that do not actually qualify for an exemption proceed into the AA process.

§ 69505.4. Alternatives Analysis Process and Options

Section 69505.4, in its entirety, specifies the general process a responsible entity must follow to comply with the requirements for conducting an AA in accordance with Article 5, and the optional courses of action available to the responsible entity. Section 69505.4 affords responsible entities four options for complying with the AA requirements. A responsible entity may choose to comply with the AA requirements by following any of the options listed below:

- A two-stage AA;
- An Abridged AA;
- An Alternate Process AA; or
- A Previously Completed AA.

A responsible entity that elects to conduct a two-stage AA must follow the processes set out in sections 69505.5 and 69505.6 for a first and second stage AA, respectively. The first stage AA is followed by the preparation of a Preliminary AA Report, and the second stage AA is followed by the preparation of a Final AA Report. Section 69505.7 specifies the requirements for AA Reports. If, after completion of the first stage AA, a responsible entity determines a functionally acceptable and technically feasible alternative is not available, the responsible entity may prepare and submit an Abridged AA Report as prescribed in sections 69505.4(b) and 69505.7. An Abridged AA is followed by implementation of regulatory responses to limit or reduce potential adverse impacts associated with the Priority Product until a safer alternative can be researched and developed.

A responsible entity may elect to employ an Alternate Process AA that uses a process that differs from, but that meets the substantive requirements of, the two-stage AA as specified in sections 69505.5 and 69505.6. A responsible entity wishing to use an Alternate Process AA must submit an Alternate Process AA Work Plan to DTSC for review and approval that demonstrates that the necessary requirements will be meet.

Finally, a responsible entity may submit a report for a previously completed AA if the report is substantially equivalent to the Final AA Report requirements of section 69505.7. The previously completed AA may be an AA conducted by the responsible entity or a publicly available AA.

If after completion of the Final AA Report, and prior to introducing the selected alternative into the market place, a responsible entity selects a different alternative, the responsible entity must notify DTSC and submit a revised Final AA Report that identifies the differences between the two alternatives and the rationale for the new selection.

Section 69505.4(a)(1) requires that an AA be conducted in two stages, as specified in section 69505.5 for the first stage and section 69505.6 for the second stage. This provision is necessary to require that responsible entities adequately assess and scope the breadth of the assessment that they plan to undertake, and submit it to DTSC for review before undertaking the second and final stage. The Preliminary AA Report, including its work plan, is necessary to ensure that the second stage AA and the Final AA Report will provide sufficient detail to explain and support the selection of an

alternative – or explain and support a decision to retain the existing Priority Product in lieu of an alternative; and to provide sufficient information for DTSC to determine which, if any, regulatory response(s) are needed to address any adverse impacts posed by the selected alternative or the retained Priority Product. This provision requires that the AA be conducted in two stages to enable DTSC to review the first stage and provide any necessary guidance in meeting the objectives of the AA prior to commencing the second stage AA. The second stage AA work plan and implementation schedule required to be included in the Preliminary AA Report are necessary to enable DTSC to determine if an extended period of time is necessary for completion of the second stage AA and preparation of the Final AA Report. This also serves to inform interested parties as to when the Final AA Report can be expected to be available for public review and comment under section 69505.8.

Section 69505.4(a)(2) requires the responsible entity to complete the first stage of the AA, and submit a Preliminary AA Report within 180 days from the date the Priority Product was listed unless a different time is specified in the Priority Product listing. The Preliminary AA Report must include the contents specified in section 69505.7 so as to ensure that the AA for the Priority Product has been adequately scoped prior to beginning the second stage of the AA. The need for the AA to be conducted in two stages – and the Preliminary AA Report submitted to DTSC prior to initiation of the second stage AA – is explained above.

The time period provided in this section is necessary to allow responsible entities to collect the appropriate information to conduct the first stage AA and to include in a Preliminary AA Report. DTSC believes this will generally be ample time to collect and compile the information being requested given that responsible entities are not required to fill data gaps at this stage. However, there will be circumstances warranting additional time, as discussed above for section 69505.1(b)(2)(A). Further, as a result of the public comment process during the development and issuance of the proposed and final Priority Products list, responsible entities will get advance signals of whether their product is being considered for listing as a Priority Product and thus subject to the AA requirements of Article 5. Additionally, the public comment process will provide responsible entities the opportunity to present information to DTSC in support of allowing a longer period of time for completing the first stage AA and submitting the Preliminary AA Report.

Section 69505.4(a)(3) requires the responsible entity to next complete the second stage of the AA, and submit a Final AA Report within twelve (12) months from the date DTSC issues a notice of compliance for the Preliminary AA Report unless DTSC has granted an extended period of time for conducting the second stage AA and preparation

of the Final AA Report (as discussed above under section 69505.1(b)(2)(B)). The Final AA Report must include the contents specified in section 69505.7. The activities required to be conducted during the second stage of the AA, and the content requirements of the Final AA Report, are necessary to ensure the Priority Product and its alternatives have been adequately evaluated. The Final AA Report must document the activities of the second stage AA and contain sufficient information for DTSC to review the Final AA Report and determine whether the AA complies with Article 5 and to be able to select any regulatory responses determined necessary under Article 6.

Section 69505.4(b) specifies that after completion of the first five (5) steps of the first stage of the AA, under sections 69505.5(a) through (e), a responsible entity that determines a functionally acceptable and technically feasible alternative is not available may prepare and submit an Abridged AA Report, in lieu of the Preliminary and Final AA Reports. The Abridged AA Report must comply with sections 69505.4(b)(1) through (4), which are set out below. This section provides the necessary and appropriate latitude to the responsible entity conducting the AA and preparing the AA Reports. It is anticipated that some responsible entities will determine during the first stage of the AA that an acceptable alternative is not readily available. This provision allows responsible entities in this instance to expedite the process toward research and development of safer alternatives. The provision is necessary to allow for a more efficient and effective use of the responsible entities' and DTSC's limited resources by providing for a more streamlined process to proceed to the determination and implementation of regulatory responses when performing a second stage AA would not be productive since there are no acceptable available alternatives. Responsible entities who use the Abridged AA approach will be subject to the regulatory responses requiring product information for consumers (section 69506.3) and research and development to identify and market a safer alternative (section 69506.8), and perhaps other regulatory responses if determined necessary to address the adverse impacts posed by the Priority Product.

Section 69505.4(b)(1) requires the responsible entity to summarize in the Abridged AA Report the first stage AA findings as required under section 69505.7. The first stage AA findings are critical in establishing the breadth and scope of the second stage AA. The first stage AA will establish the basis for either electing to submit an Abridged AA Report or conducting the second stage AA. The information upon which a responsible entity relied on to make its decision is necessary for DTSC to have an informed basis for evaluating the decision by the responsible entity and determine if regulatory responses (in addition to product information for consumers and research and develop) are necessary.

Section 69505.4(b)(2) requires the responsible entity to complete the first step of the second stage AA specified in section 69505.6(a) and summarize in the Abridged AA Report its findings in accordance with the applicable requirements in section 69505.7. More specifically, the responsible entity must identify the factors that are relevant for comparison of the Priority Product and any alternatives (*i.e.*, chemical adverse impacts, exposure pathways, life cycle segments, product function and performance, and economic impacts). This is necessary to conform to the requirements of Health and Safety Code section 25253(a)(2), which requires each AA to consider the factors listed in subparagraphs (A) through (M) of that section. This information will be useful in the conducting research and develop, under section 69506.8, to identify a safer alternative.

The provision in section 69505.4(b)(1), coupled with this provision, are necessary to document and explain the relevant findings that establish the basis for a determination that a functionally acceptable and technically feasible alternative is not currently available. DTSC will use the provided information to determine whether the responsible entity made an appropriate decision.

Section 69505.4(b)(3) requires the responsible entity to submit an Abridged AA Report to DTSC by the due date for the Preliminary AA Report, as specified in section 69505.1(b)(2)(A). Having the due date coincide with the due date of the Preliminary AA Report instills consistency in the process so that the responsible entity can readily be in compliance, regardless of the entity's chosen approach. Otherwise, the responsible entity would be deemed to be non-compliant with the requirements of Article 5, and DTSC would proceed with the non-compliance notification and Failure to Comply listing procedures under section 69501.2 as well as pursuing appropriate enforcement actions.

Section 69505.4(b)(4) specifies that the responsible entity must identify in the Abridged AA Report the milestones and dates for implementation of proposed regulatory responses, which, at a minimum, must include the regulatory responses required under section 69506.3 (Product Information for Consumers) and section 69506.8 (Advancement of Green Chemistry and Green Engineering). In addition to these two regulatory responses, a responsible entity may propose, or DTSC may require, other regulatory responses to be put in place to address the potential adverse impacts and/or exposures associated with the Chemicals of Concern in the Priority Product while safer alternatives are being pursued. This provision requires responsible entities to pursue safer alternatives to a Priority Product, while simultaneously addressing adverse public health and environmental impacts until the safer alternative is introduced into the market. The provision is necessary to compel responsible entities to invest in research and development in safer alternatives to the Priority Product, while immediately providing the necessary safeguards through other regulatory responses to minimize

adverse impacts from continued use of the Priority Product. The commitment of time and resources that this will entail is anticipated to deter responsible entities who might be inclined to claim, without adequate basis, that an acceptable alternative is not readily available just to avoid conducting the second stage AA. This is necessary to achieve the goals of the statute to significantly reduce adverse public health and environmental impacts from chemicals and reduce the overall costs of those impacts to California's society.

Section 69505.4(c)(1) allows a responsible entity to use an AA process that differs from the first and second stage AA process if the process and report contents substantially comply with the requirements in section 69505.5, 69505.6, and 69505.7. Allowing responsible entities to use an alternate AA process is necessary to provide flexibility to responsible entities in using their own existing assessment protocols, which may: (i) be more applicable to their product; (ii) be more quickly implemented; and (iii) reduce duplication of efforts and waste of resources.

Section 69505.4(c)(1)(A) specifies that the responsible entity's alternate process must generate the information needed to prepare a Final AA Report that substantially meets the requirements of section 69505.7. The information that must be scoped and evaluated during the first and second stage AAs must be scoped and evaluated under the alternate AA process used by the responsible entity. The information must then be summarized in a Final AA Report. This provision is necessary to ensure that the scope and rigor of the alternate process substantially complies with the requirements in Article 5 and that the requirements of Health and Safety Code section 25253(a) are satisfied.

Section 69505.4(c)(1)(B) requires the responsible entity's alternate AA process to compare the Priority Product and the alternatives using, at a minimum, the same relevant factors and, when applicable, associated exposure pathways and life cycle segments specified for the first and second stage AAs in sections 69505.5 and 69505.6. This provision is necessary to ensure that an alternate AA process used by a responsible entity: (i) is of the same scope and rigor as the two-stage AA process set forth in sections 69505.5 and 69505.6; (ii) substantially complies with the requirements in Article 5; and (iii) meets the requirements of Health and Safety Code section 25253(a).

Section 69505.4(c)(1)(C) requires the responsible entity to submit an Alternate Process AA Work Plan to DTSC with sufficient information to demonstrate that the alternate process will meet the requirements of sections 69505.4(c)(1)(A) and (B), above, and sufficient information for DTSC to specify an appropriate due date for submittal of the Final AA Report. This provision is necessary so that DTSC can ensure – prior to a

responsible entity pursing an alternate AA process – that the responsible entity has a work plan that will ensure that the scope and rigor of the alternate AA process will substantially comply with the requirements of Article 5 and Health and Safety Code section 25253(a). The work plan must also ensure that the alternate AA process is completed and a Final AA Report is submitted within an appropriate time frame that conforms to section 69505.4(c)(1)(E)2., which is necessary to provide a level playing field for those responsible entities who perform the two-stage AA specified in Article 5 and those responsible entities who use an alternate AA process.

Section 69505.4(c)(1)(C)1. requires that the Alternate Process AA Work Plan include the information specified in sections 69505.7(c), (d), and (e). That is, in addition to the information required under section 69505.4(c)(1)(A) and (B), the Alternate Process AA Work Plan must include "Preparer Information," "Responsible Entity and Supply Chain Information," and "Priority Product Information." The information required under this provision is the same as would be required if the responsible entity submitted a Preliminary AA Report rather than an Alternate Process AA Work Plan. The necessity for these requirements is explained in the statement of reasons for sections 69505.7(c), (d), and (e).

Section 69505.4(c)(1)(C)2. specifies that if the Alternate Process AA Work Plan includes information for which trade secret protection is claimed, the responsible entity must also submit a redacted copy of the work plan that excludes the information claimed to be trade secret. This provision is necessary to ensure that non-trade secret information submitted to DTSC for compliance with the requirements of Article 5 is readily available for public review and does not require DTSC to expend any additional resources in redacting information claimed as trade secret. It further prevents DTSC from inadvertently releasing information that the responsible entity may claim as protected from disclosure.

Section 69505.4(c)(1)(C)3. requires the Alternative Process AA Work Plan to be accompanied by an executive summary organized in conformance with the organization of the work plan conveying to the public a general understanding of the work plan. No trade secret information is to be included in the executive summary. It further provides that if DTSC subsequently rejects a trade secret claim, the responsible entity – at DTSC's request – must submit a revised executive summary within thirty (30) days of the request to add any information for which a trade secret claim is rejected and which DTSC specifies must be included in the executive summary. This provision is necessary to ensure that the information submitted to DTSC will be readily available for public review, summarized and written in lay terms, and does not require DTSC to expend any resources in clarifying the work plan for the public. This provision is also

necessary, in the event the responsible entity inappropriately claims some information to be a trade secret, to ensure that this information is expeditiously added to the executive summary and made available to interested parties. Given that this information is already available to the responsible entity, thirty (30) days is sufficient time for the responsible entity to revise the executive summary to include this information. This provision supports the objective of providing as much information as possible to the public and other interested parties regarding the AA process, without infringing upon legitimate claims for protection of trade secrets.

Section 69505.4(c)(1)(D) specifies that the Alternate Process AA Work Plan must be submitted to DTSC no later than the due date for the Priority Product Notification. Given that the Alternate Process AA option is geared toward responsible entities who may have already conducted an internal AA or who have a process in place that substantively meets the requirements of Article 5, preparing the work plan within the time period allowed should be reasonably doable. The period specified in this section is necessary to allow DTSC to timely review the work plan submitted and determine if it meets the substantive requirements to meet the goals and objectives of Article 5. In the event the work plan does not meet the substantive requirements, it could be augmented or the responsible entity could timely pursue complying with one of the other options afforded to responsible entities under Article 5. These provisions effectively provide a level playing field by eliminating incentives for delaying the process and simultaneously allowing responsible entities to consider other options.

Section 69505.4(c)(1)(E)1. requires the responsible entity to timely submit a Final AA Report to DTSC that substantially complies with section 69505.7. (Section 69505.4(c)(1)(E)2. below specifies what is considered “timely”.) This provision is necessary to ensure that the Final AA Report that is submitted after completing an Alternate Process AA Work Plan is of the same rigor as the AA Report requirements in section 69505.7, and contains the necessary information required in section 69505.7 for DTSC to evaluate and determine the most appropriate regulatory response for the selected alternative. The content and timeliness requirements of this section are necessary to ensure compliance with Health and Safety Code section 25253(a), avoid undue delays in completing the AA process and moving to regulatory responses, and provide a level playing field between those responsible entities who perform the two-stage AA specified in Article 5 and those responsible entities who use an alternate AA process

Section 69505.4(c)(1)(E)2. specifies that the due date for the Final AA Report for an alternate process AA is eighteen (18) months after the date DTSC issues a notice of compliance for the Alternate Process AA Work Plan *unless* DTSC grants an extension

pursuant to section 69505.7(k)(1)(B), or DTSC otherwise approves an extended due date under section 69505.9(b)(4)(A). If DTSC approves an extended due date, the responsible entity must provide a yearly progress report until the Final AA Report is submitted. Each progress report must provide all of the information specified in section 69505.7(k)(1)(A). This provision is necessary to ensure that the alternate AA process being used by a responsible entity conducting the AA is completed in an appropriate period commensurable to the time afforded to those entities conducting an AA under the two-stage AA, Abridged AA, and/or previously completed AA. Refer to the statement of reasons for sections 69505.7(k)(1) and 69505.9(b)(4)(A) for information concerning the necessity of the time extension and progress report requirements.

Section 69505.4(c)(2) specifies that if the Alternate Process AA Work Plan is disapproved by DTSC under section 69505.9(b)(3), the responsible entity must submit a Preliminary AA Report to DTSC within 180 days after DTSC issues the notice of disapproval. This provision is necessary to ensure that, if the proposed alternate AA process is determined by DTSC to not be viable for purposes of Article 5 and Health and Safety Code section 25253(a), the responsible entity moves expeditiously to begin the two-stage AA process set forth in sections 69505.5 and 69505.6. The 180-day deadline is commensurate with the time period afforded other responsible entities for submitting a Preliminary AA Report.

Section 69505.4(d) provides that a responsible entity, in lieu of performing a new AA and submitting Preliminary and Final AA Reports, may submit a report for a previously completed AA regarding the Priority Product. The previously completed AA may be either an AA conducted or obtained by the responsible entity or a publicly available AA. The report must be substantially equivalent to the Final AA Report set out in section 69505.7, and the report must contain sufficient information for DTSC to determine necessary regulatory responses under Article 6. This provision recognizes the body of work that already exists, and will exist, regarding safer alternatives for certain chemicals and/or products. This provision is necessary to provide latitude to responsible entities to use existing information to the extent suitable to expedite the quest for safer products. This will expedite the AA process and determination of regulatory responses for these Priority Products, and will avoid the unnecessary expenditure of resources on essentially duplicative work.

Section 69505.4(d)(1) requires a report that is based on a previously completed AA that is being submitted under section 69505.4(d) to be provided to DTSC no later than the due date for the Preliminary AA Report – 180 days following the date that the applicable final Priority Products list is posted on DTSC's website, unless DTSC specifies a different due date in the Priority Products list. This section further specifies

that a one-time extension may be requested under section 69505.1(c). This provision is necessary to keep responsible entities on a level playing field; and to ensure the AA process proceeds on a timely basis. Requiring the report for the previously completed AA to be submitted no later than the Preliminary AA Report would be due enables DTSC to expeditiously redirect the responsible entity's efforts to the performance of a new two-stage AA and submittal of Preliminary and Final AA Reports in the event DTSC finds that the report for the previously completed AA is not substantially equivalent to the Final AA Report set out in section 69505.7. Given that the report already exists, 180 days will provide a sufficient amount of time for submitting a report for a previously conducted AA, even if the report needs to be supplemented, as specified in section 69505.1(d)(2). An extension process is provided in section 69505.1(c) to address those unusual situations for which 180 days are inadequate.

Section 69505.4(d)(2) specifies that a responsible entity submitting an existing report may submit supplemental information to render the report substantially equivalent to the Final AA Report requirements of section 69505.7. This provision makes allowance for existing reports that may differ from the specific requirements of section 69505.7, but in a manner that such differences can be remedied with additional information. This provision along with section 69505.4(d) is necessary to provide an efficient and cost effective option for meeting the requirements and intent of Article 5.

Section 69505.4(e)(1) allows a responsible entity to select a different alternative to replace the Priority Product from the one identified in the Final AA Report submitted to DTSC. The responsible entity must submit a revised Final AA Report to DTSC at least sixty (60) days prior to placing the newly selected alternative product(s) into the stream of commerce in California. The revised Final AA Report must explain the differences from the original Final AA Report, identify the information used to support the revisions to the Final AA Report, and describe the rationale for selecting the different alternative(s). DTSC must review and make a compliance determination with respect to the revised Final AA Report in accordance with the procedures and criteria set forth in section 69505.9. This provision is necessary to take into account that changed facts or circumstances may cause some responsible entities to select a different alternative from the one identified in the Final AA Report. This provision allows responsible entities to adjust to facts and circumstances that warrant or justify a different analysis and/or conclusion from that reached by the responsible entity in the Final AA Report. This type of flexibility is necessary to allow for the most appropriate alternative(s) to be implemented by the responsible entity.

The requirement to submit a revised Final AA Report, and the information required to be included in the report, is necessary to enable DTSC to determine compliance with

Article 5 and determine necessary regulatory response under Article 6. This provision also ensures that the information used by the responsible entity to substantiate a change in the final decision is made available to the public. Requiring the revised Final AA Report to be submitted to DTSC sixty (60) days prior to the introduction into the California marketplace of the newly selected alternative is necessary to prevent responsible entities from circumventing the process by selecting one alternative in the Final AA report and knowingly instituting a different alternative, and to provide DTSC sufficient time to evaluate the revised Final AA Report for compliance with Article 5 and impose any necessary regulatory responses.

Section 69505.4(e)(2)(A) also requires a responsible entity to submit a revised AA Report and meet the requirements of section 69505.4(e)(1) if the selection decision in the original Final AA Report was to retain the Priority Product, and the responsible entity later decides to select an alternative to replace the Priority Product. This provision is necessary for the same reasons as section 69505.4(e)(1).

Section 69505.4(e)(2)(B) also requires a responsible entity to submit a revised AA Report and meet the requirements of section 69505.4(e)(1) if the responsible entity later decides to retain the Priority Product in lieu of a previously selected alternative product. This provision is necessary for the same reasons as section 69505.4(e)(1).

Section 69505.4(e)(3) provides that the requirements of section 69505.4(e) only apply for three (3) years after the date the original Final AA Report is approved by DTSC. This section essentially gives the responsible entity three (3) years after submitting the Final AA Report to determine if the alternative selected is valid and implementable. That period is sufficient for the responsible entity to identify challenges, barriers, or solutions to implement the recommended alternative. This provision is necessary to ensure that responsible entities are able to determine if facts and circumstances warrant or justify a different analysis and/or conclusion from that reached in the Final AA Report.

This provision is also necessary to provide an “end” to the AA process, and to make it clear that responsible entities are not required to conduct a new AA and submit a new AA Report every time they make product modifications in the future (beyond the three (3) year time period). Three (3) years was selected as the “end” of the AA process for a given product, as in most cases the redesign process for a product should be completed or close to completion within this time period.

Section 69505.4(f) specifies that except as provided in section 69505.2 (Removal / Replacement Notifications), if prior to submitting the Final AA Report for a Priority Product the responsible entity removes, or reduces the concentration of, the Chemicals

of Concern and uses one or more replacement Candidate Chemical(s), the evaluation and comparison must include consideration of both the Priority Product and the reformulated product. While reformulations are allowed and encouraged under sections 69505.5 and 69505.6 (and section 69505.7(j) requires that it be addressed in the Final AA Report), section 69505.4(f) explicitly requires that a comparison of Priority Product and the reformulated product be conducted. This provision is necessary to ensure that reformulations involving replacement Candidate Chemicals that do not meet the conditions for a Removal/Replacement Notification under section 69505.2 are evaluated under an Article 5 AA followed by a regulatory response determination. This is necessary to ensure that any adverse impacts associated with the reformulated product are adequately evaluated in the AA and addressed by necessary regulatory responses.

§ 69505.5. Alternatives Analysis: First Stage

Section 69505.5, in its entirety, specifies the process, scope, and suggested order for conducting a first stage AA. The principal goal of the first stage AA and corresponding Preliminary AA Report is to identify all potential alternatives to the Priority Product, and eliminate those alternatives that pose greater aggregate or cumulative public health and environmental impacts than the Chemical of Concern. The first stage AA involves the gathering, organizing, and evaluating of the scientific and technical information necessary to decide whether a particular alternative is likely to constitute a potential alternative. The relevant information about an alternative is assembled for subsequent thorough evaluation in the second stage AA and Final AA Report. Under section 69503.2, one of the key prioritization factors for listing a Priority Product is based on the Chemical of Concern's potential to contribute to or cause adverse public health and environmental impacts. As such, alternatives to Priority Products should be preferable to the Priority Product, and be evaluated first for their Chemical of Concern's potential adverse public health and environmental impacts. Therefore, other factors (*e.g.,* performance, consumer preference, and economic impacts) are not usually evaluated as part of the first stage AA. Those factors are included in the second stage AA when alternatives have been "short listed" for further consideration. However, a responsible entity, if they so choose, *may* consider performance, consumer preference, and economic impacts during the first stage AA.

The first stage of the AA includes the six steps specified in section 69505.5(a) through (f). This provision establishes a sequential process for conducting the first stage of an AA and guides those conducting AAs in an order and manner in which the AA may be procedurally performed. However, it is possible that some responsible entities may prefer a different process where the steps are not always conducted in the order presented or where one step is repeated to refine the information collected or multiple

steps are repeated iteratively. While the regulations do not limit, restrict, or require that the first stage AA steps be undertaken in the sequence presented in the regulations – all six steps must be conducted and the Preliminary AA Report that is submitted must address all applicable requirements specified in section 69505.7. This provision is necessary to ensure consistency in the information that is gathered, evaluated, and subsequently reported; all of which is necessary to conduct an AA for the Priority Product and its alternatives that meet the objectives and specific requirements of Health and Safety Code section 25253(a), and to enable DTSC to readily evaluate the AA and the Preliminary AA Report for compliance with Article 5 and to determine whether an extended due date for the Final AA Report is warranted.

Section 69505.5(a) requires the *Identification of Product Requirements and Function of the Chemical of Concern* as the first step in the AA. This provision makes specific the first criterion that a responsible entity must take into account in evaluating alternatives for the Priority Product and is consistent with and required by Health and Safety Code section 25253(a)(2)(A) of the authorizing legislation. Product requirements and the function or role that the Chemical of Concern plays in the Priority Product is fundamental to knowing the alternatives that may or may not be considered. In other words, if a Chemical of Concern plays a key role in the Priority Product's function such as, for example, a plasticizer in plastic products or surfactants in cleaning products, any alternative considered must either replace or compensate for that function. This provision is necessary to compel responsible entities to identify and later document the role of the Chemical of Concern in the Priority Product, so as to ensure that the AA is focused on alternatives that are viable with respect to meeting the requirements for the product.

Section 69505.5(a)(1) requires the responsible entity to identify the function, performance, and legal requirements associated with the Priority Product that must be met by the alternatives being considered. This provision is necessary to make specific that in identifying and evaluating alternatives to the Priority Product, the functional, performance, and legal requirements must be considered, evaluated, and reported. The product function, performance, and legal requirements are necessary as the starting point for identifying potential viable alternatives.

Section 69505.5(a)(2) requires the responsible entity to identify the role of the Chemical(s) of Concern in meeting the Priority Product's function, performance, and legal requirements. This provision is necessary to ensure that responsible entities will evaluate, and later summarize in the Preliminary AA Report, this crucial information about the relationship of the Chemical(s) of Concern to key aspects of the Priority Product. This information ensures an informed and appropriate comparison of product

function, performance, and legal criteria between the Chemical(s) of Concern and potential alternatives, and is a necessary precursor to section 69505.5(a)(3)(A) discussed below.

Section 69505.5(a)(3)(A) requires the responsible entity to determine if the Chemical(s) of Concern or replacement chemical(s) is/are necessary to meet the Priority Product's function, performance, and legal requirements. An evaluation of the role the Chemical of Concern plays in the Priority Product is critical in identifying alternative replacement chemicals that play the same role but with fewer adverse public health and environmental impacts. The determination of whether a Chemical of Concern is necessary is left up to the responsible entity; however, the rationale must be documented in the Preliminary and Final AA Reports. This provision is necessary to have the responsible entity evaluate whether a Chemical of Concern or alternative replacement chemical is even necessary in the Priority Product and later document that determination. This, in turn, is necessary to ensure that the AA is properly focused on the role of the chemical(s) in the product, and to require the responsible entity in the Final AA Report to justify using the Chemical of Concern or a replacement chemical if it is not needed. This is necessary to achieve the goals of the statute articulated in Health and Safety Code sections 25253(a) and 25255(a).

Section 69505.5(a)(3)(B) requires that if the responsible entity determines that neither the Chemical(s) of Concern nor replacement chemical(s) is/are necessary to meet the Priority Product's function, performance, and legal requirements, the responsible entity must evaluate as one of the alternatives to the Priority Product the removal of the Chemical(s) of Concern from the Priority Product without the addition of replacement chemical(s). Alternatively, the responsible entity may submit a Chemical Removal Intent and/or Confirmation Notification to DTSC in lieu of completing the AA and submitting the required AA Reports.

This provision is necessary to compel the responsible entity to consider removing the Chemical(s) of Concern without adding a replacement chemical if it is not necessary to meet the product's function, performance, or legal requirements. This is necessary to achieve the goals of the statute. This provision is also necessary to make it clear that the responsible entity does not have to conduct the required AA and prepare the required AA reports if it decides to remove the Chemical of Concern in its Priority Product and it submits Chemical Removal Intent and/or Confirmation Notifications to DTSC pursuant to section 69505.2. This approach removes the harmful chemical that led to listing of the Priority Product without the risk of regrettable substitutes. Thus, it is necessary in these circumstances to exempt the responsible entity from the need to conduct an unnecessary AA. Requiring the responsible entity to consider alternatives

that do not use a substitute chemical drives the market to pursue and consider alternatives that are inherently safer.

Section 69505.5(b) requires the *Identification of Alternatives* as the second step in the AA. This provision is necessary to ensure that after completing step 1, the responsible entity identifies alternatives that meet the product's function, performance, and legal requirements as the next logical step in the AA process. The alternatives (*e.g.*, reformulation or redesign) are then evaluated and compared with the Priority Product and with each other in the subsequent steps of the AA.

Section 69505.5(b)(1)(A) requires that in addition to the evaluation of an alternative identified under section 69505.5(a)(3)(B) (*i.e.*, removal of the Chemical of Concern without use of a replacement chemical), if applicable, the responsible entity must also identify other "alternatives," as defined in section 69501.1 that meet the product criteria identified under section 69505.5(a)(1) for the Priority Product. This provision is necessary to ensure that the AA will evaluate and consider all alternatives that remove or reduce the amount of Chemical(s) of Concern, reduce or restrict exposure to the Chemical of Concern, and/or reduce adverse public health and environmental impacts and/or adverse waste and end-of-life effects associated with the Priority Product, and still meet the Priority Product's function, performance, technical feasibility, and legal requirements.

Section 69505.5(b)(1)(B) requires the responsible entity to research and take into account available information that may identify existing viable alternatives for consideration in the AA, including information posted on DTSC's website. The responsible entity must take into consideration any identified alternative or explain in the Preliminary AA Report why such an alternative is not viable. This provision ensures that the AA evaluates all existing potentially viable alternatives that could be evaluated to remove or reduce the amount of and/or exposure to Chemical(s) of Concern in a Priority Product. This provision is necessary to compel responsible entities to take into account the current state of chemical and product knowledge when evaluating alternatives to their Priority Products, and not preclude due consideration of a potentially viable safer alternative. This is consistent with and necessary to achievement of the goals of the statute.

Section 69505.5(b)(2) specifies that alternatives that do not involve the addition of a substitute chemical do not require completion of step 4, *Initial Evaluation and Screening of Alternative Replacement Chemicals*. This provision is necessary to make specific that if a chemical substitute is not being considered, the screening of chemical substitutes is not necessary (or logical) as part of the AA for that particular alternative.

Alternatives that do not include chemical substitutions but are instead process modifications will require a more thorough evaluation during the second stage AA using the factors identified in sections 69505.5(c) and 69505.6(a).

Section 69505.5(c) requires the *Identification of Factors Relevant for Comparison of Alternatives* as the third step in the first stage of the AA. Relevant factors, as described in further detail below, are those factors that materially contribute to the adverse impacts associated with the Priority Product and/or one or more alternatives being considered, and with respect to which there are material differences in the factor's contribution to these adverse impacts between the Priority Product and one or more alternatives and/or between the alternatives. If, for example, the Priority Product and the alternatives being considered all have the same amount and type of environmental impact, those impacts need not be further evaluated. If, however, the Priority Product were prioritized, for example, for its adverse air impacts consisting of greenhouse gas emissions and the alternatives being considered would provide varying degrees of reduction in greenhouse gas emissions, those factors are relevant and must be further evaluated. This provision is necessary to compel the responsible entity to identify the factors that are relevant for comparison, compare them and include in the Preliminary AA Report the differential impacts for the Priority Product and the alternatives being considered. This step is also necessary to reduce the time and resources required to complete the AA by eliminating from consideration the factors that do not meet the relevancy criteria as such factors would not meaningfully contribute to the comparison of the Priority Product and the alternatives.

Section 69505.5(c)(1) specifies that a factor, in conjunction with an associated exposure pathway and life cycle segment, is relevant if it would meet the criteria specified in 69505.5(c)(1)(A) *and* (B). These factors are described in greater detail immediately below. This provision is necessary to have a consistent and appropriate understanding of the term "relevant factor" for purposes of the AA process required by these regulations.

Section 69505.5(c)(1)(A) provides that the first criterion for determining if a factor is relevant is if it makes a material contribution to the adverse public health / environmental impacts, adverse waste and end-of-life effects, and/or materials and resource consumption impacts associated with the Priority Product and/or one or more of the alternatives under consideration. This factor is necessary to ensure that responsible entities do not devote efforts to evaluating factors that will not result in any meaningful difference between the Priority Product and/or the alternatives being considered. By limiting the scope of what is evaluated and reported, costs to both

responsible entities and DTSC are reduced and resources are focused on evaluating factors that will render meaningful comparisons and improvements.

Section 69505.5(c)(1)(B) specifies that there must also be a material difference in the factor's contribution to the impacts between the Priority Product and one or more alternatives being considered, and/or between two or more alternatives, in order for the factor to be relevant. As with section 69505.5(c)(1)(A), this provision is necessary to ensure that only factors that are meaningful in comparing the Priority Product and its alternatives are required to be considered, so as to ensure that responsible entities do not devote efforts to evaluating factors that will not result in any meaningful comparison. This will ensure costs to responsible entities and DTSC are reduced, and resources are focused on evaluating factors that will render meaningful comparisons and improvements. By implication, the provision also establishes which factors are not relevant and, thus, need not be evaluated. This provision is necessary to set an appropriate scope for the AA (*i.e.*, one that focuses on meaningful factors).

Section 69505.5(c)(2) requires the responsible entity to collect and use available *quantitative* information and analytical tools, supplemented by available *qualitative* information and analytical tools, to identify the factors listed below that are relevant for comparison of the Priority Product and its alternatives. In addition, the associated exposure pathways and life cycle segments, if applicable, relevant for the comparison of the Priority Product and the alternatives must be identified. The responsible entity must collect information related to, a make a relevancy determination for, the following factors:

- **(A)** Adverse environmental impacts;
- **(B)** Adverse public health impacts;
- **(C)** Adverse waste and end-of-life effects;
- **(D)** Environmental fate;
- **(E)** Materials and resource consumption impacts;
- **(F)** Physical chemical hazards; and
- **(G)** Physicochemical properties.

This provision is necessary to ensure that a responsible entity collects the available quantitative data on the Priority Product and the alternatives being considered and takes into account the available qualitative information to supplement and fill gaps in available quantitative information. Requiring that a responsible entity use existing information and analytical tools is critical to quantifying the extent or magnitude of a potential problem. By requiring that the responsible entity supplement the existing quantitative information with qualitative information, the potential problem can be better addressed by taking into account situational circumstances or nuances related to the

problem at hand. Limiting the information gathering requirement to available information is necessary to place reasonable limits on the time and costs necessary to satisfy the AA requirements of Article 5. If responsible entities were required to fill all information gaps, in some cases, the cost could escalate significantly and AAs could take many years to complete which would likewise delay the identification and implementation of regulatory responses for many years. Responsible entities are required to identify any information gaps in the AA Report; and, as a regulatory response, under section 69506.2, DTSC can require the responsible entity to fill any information gaps that DTSC determines are necessary to adequately determine the need for regulatory responses.

The information collected and used under section 69505.5(c)(2)(A) through (G), effectively addresses those criteria specified in Health and Safety Code section 25253(a)(2)(A) through (M) that are relevant for the first stage AA comparison of the Chemical of Concern and possible alternative replacement chemicals. Section 69505.6(a)(2) coupled with the requirements of section 69505.5(c)(2)(A) through (G) address the thirteen (A) through (M) criteria, in their entirety. Thus, these provisions are necessary to ensure that the statutorily-required criteria are considered and evaluated as part of the AA and that they are considered at the appropriate stage of the evaluation.

Section 69505.5(c)(3) requires the responsible entity to identify the relevant exposure pathways for evaluating and comparing the Priority Product and its alternatives by considering chemical quantity information and the exposure potential factors available for identification of Priority Products under section 69503.3(b). This provision is necessary to ensure that the responsible entity identifies the relevant and non-relevant pathways for exposure to the Chemical of Concern in the Priority Product and for exposure to the Chemical of Concern and/or replacement chemicals in alternatives being considered. Sections 69505.5(c)(3)(A) and (B), discussed below, further elaborate on the types of information that must be identified to adequately assess the potential exposure pathways for the AA. Collectively, these requirements are necessary to ensure that the AA is of appropriate scope and focus, and that it meets the criteria required by statute – Health and Safety Code section 25253(a)(2) which requires evaluation of critical exposure pathways. This provision is also necessary to ensure that responsible entities do not devote efforts to evaluating exposure pathways that will not result in any meaningful comparison. This will ensure costs for responsible entities and DTSC are reduced, and resources are focused on evaluating factors that will render meaningful comparisons and improvements.

Section 69505.5(c)(3)(A) requires that in identifying the relevant exposure pathways, the responsible entity must consider chemical quantity information related to:

1. Quantities of the Chemical(s) of Concern or alternative replacement chemical(s) necessary to manufacture the Priority Product and each alternative being considered; and
2. Estimated volume and/or mass of the Chemical(s) of Concern or alternative replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product and each alternative being considered**.**

Chemical volume impacts that differ between the Priority Product and one or more alternatives and/or between multiple alternatives are considered in the AA as this type of information often serves as a surrogate for assessing exposure potential when actual exposure data is not available. This provision is also necessary to ensure that the AA addresses the quantities of a chemical being used or under consideration for use. This information is necessary to assess the short and long term ramifications of using a chemical, and to comply with the statutory mandate that the AA address the life cycle impacts of the Health and Safety Code section 25253(a)(2) (A) through (M) criteria.

Section 69505.5(c)(3)(B) requires that in identifying the relevant exposure pathways, the responsible entity consider the exposure factors specified in section 69503.3(b). Section 69503.3(b) lists the full array of factors that could influence the potential for public health and/or environmental exposures to Chemicals of Concern in a Priority Product or replacement chemicals in an alternative product. In order to properly scope each AA, and ensure resources are focused on factors that will identify meaningful differences between a Priority Product and its alternatives and between multiple alternatives, it is necessary to first examine each factor listed in section 69503.3(b) to determine which factors will contribute to a meaningful comparison.

Section 69505.5(d) requires the *Initial Evaluation and Screening of Alternative Replacement Chemicals* as the fourth step in the first stage AA for those alternatives being considered that involve replacing the Chemical(s) of Concern with other chemical(s). This provision is necessary to make specific that for the alternatives that include replacement of a Chemical of Concern with another chemical, the AA must include an assessment of the adverse public health and environmental impacts associated with each alternative replacement chemical being considered as compared to the Chemical of Concern and any other alternative replacement chemical being considered. This, in turn, is necessary so that regrettable substitutes can be avoided. Comparison of adverse impacts on public health and the environment is necessary in that it is the basis for the listing of the Chemical of Concern as part of the Priority

Product listing. Chemicals that are subsequently evaluated to replace a Chemical of Concern should have less of an adverse impact on public health and the environment than the Chemical of Concern.

Section 69505.5(d)(1) requires the responsible entity to use available *quantitative* information and analytical tools, supplemented by available *qualitative* information and analytical tools, to evaluate and compare each of the alternative replacement chemicals under consideration with the Chemical(s) of Concern in the Priority Product with respect to each of the following factors, to the extent relevant:

- **(A)** Adverse environmental impacts;
- **(B)** Adverse public health impacts;
- **(C)** Environmental fate;
- **(D)** Physical chemical hazards; and
- **(E)** Physicochemical properties.

This provision makes specific that for the alternatives that include replacement of Chemical(s) of Concern (in whole or in part) with another chemical, the AA must include a comparison of the alternative replacement chemicals and the Chemical(s) of Concern in the Priority Product using the criteria specified above in (A) through (E). Chemical alternatives exhibiting an improvement in one or more of the criteria should naturally rise to the top for further evaluation. This provision is necessary to ensure that the key adverse public health and environmental factors associated with the Chemical of Concern and possible alternative replacement chemicals are evaluated prior to screening alternatives for further consideration in the second stage AA. Alternatives that rise to the top due to their incremental improvements over the Chemical of Concern should be retained for evaluation in the second stage of the AA. The necessity for limiting the information collection requirement to <u>available</u> information is explained above with respect to section 69505.5(c)(2).

Section 69505.5(d)(2) allows a responsible entity to eliminate from further consideration in the AA any alternative replacement chemical(s) that the responsible entity determines has the potential to pose equal or greater adverse public health and/or environmental impacts than those posed by the Chemical(s) of Concern. A chemical alternative that may pose greater adverse public health and/or environmental impacts than the Chemical(s) of Concern should not be given further unnecessary consideration. However, a responsible entity may wish to retain for further consideration chemical(s) that demonstrate less aggregate or cumulative impacts relative to the Chemical(s) of Concern. This provision is necessary to encourage responsible entities to exclude from further consideration alternatives that are no better than the current Chemical(s) of Concern in the Priority Product. It is also necessary in order to provide responsible

entities latitude to further consider and evaluate alternatives that may represent an improvement with respect to one of the hazard traits in comparison to that of the Priority Product or Chemical(s) of Concern that they are seeking to replace.

Section 69505.5(e) allows the *Consideration of Additional Information* as step five of the first stage of the AA. More specifically, a responsible entity may consider in the first stage AA other pertinent factors and information not specifically required by sections 69505.5(a) through (d), which may include factors and information identified for consideration in the second stage of the AA. This section also provides that a responsible entity may eliminate an alternative from further consideration based on the additional factors and information as long as the reason for its elimination is explained in the Preliminary AA Report and there are alternatives remaining to be evaluated in the second stage AA. This provision is necessary to provide responsible entities latitude to take into account in the first stage AA other factors that they consider relevant and significant in identifying viable alternatives. This, in turn, is necessary so that the AA process is flexible enough to be workable for the innumerable types of chemicals and products that will be subject to the AA process. The provisions of this section are also necessary to prevent a responsible entity from using this latitude to screen out all alternatives in the first stage AA, and thus avoid the requirement to conduct a substantive and meaningful second stage AA and submit a Final AA Report.

Section 69505.5(f) requires the *Preliminary AA Report Preparation* as the sixth step of the first stage AA. The responsible entity must prepare and submit:

(1) A work plan and proposed implementation schedule for completion of the second stage AA and preparation and submittal of the Final AA Report; and
(2) A Preliminary AA Report that complies with section 69505.7.

The Preliminary AA Report and its required contents and their necessity are discussed above under section 69505.4(a)(1) and below under section 69505.7(k)(1) and other pertinent portions of section 69505.7.

§ 69505.6. Alternatives Analysis: Second Stage

Section 69505.6, in its entirety, specifies the process, scope, and suggested order for conducting the second stage of the AA after DTSC has approved the Preliminary AA Report or Alternate Process AA Work Plan. The principal goal of the second stage AA and corresponding Final AA Report is to further evaluate the alternatives to the Priority Product identified in the first stage AA and reach and explain an alternative selection decision. The second stage AA and companion Final AA Report requires the collection and use of available information and tools to identify the relevant factors and an

evaluation of those factors to quantify or qualify the impacts posed by the alternatives being evaluated. The second stage addresses the thirteen multimedia lifecycle (A) through (M) criteria set out in the statute (Health and Safety Code section 25253(a)(2)). This section makes specific to responsible entities the procedural requirements and expectations for completing a second stage AA, after having completed the first stage of the AA. It is also necessary to provide certainty to the responsible entities as to what is required and to keep the AA process moving.

Section 69506.6 requires the responsible entity in the second stage AA to compare the Priority Product with the alternatives still under consideration following completion of the first stage AA, and specifies the five steps to be included in the second stage AA.

The second stage of the AA includes the five steps specified in sections 69505.6(a) through (e). This provision establishes a sequential process for conducting the second stage of an AA and guides those conducting AAs in an order and manner in which the AA may be procedurally performed. However, it is possible that some responsible entities may prefer a different process where the steps are not always conducted in the order presented or where one step is repeated to refine the information collected or multiple steps are repeated iteratively. While the regulations do not limit, restrict, or require that the second stage AA steps to be undertaken in the sequence presented in the regulations – all five steps must be conducted and the Final AA Report that is submitted must address all applicable requirements specified in section 69505.7. This provision is necessary to ensure consistency in the information that is gathered, evaluated, and subsequently reported; all of which is necessary to conduct an AA for the Priority Product and its alternatives that meets the objectives and specific requirements of Health and Safety Code section 25253(a), and to enable DTSC to readily evaluate the AA and the Final AA Report for compliance with Article 5 and to determine what, if any, regulatory responses are needed under Article 6.

Section 69505.6(a) requires the *Identification of Factors Relevant for Comparison of Alternatives* as the first step in the second stage AA. The factors evaluated for relevancy under section 69505.5(c) coupled with the factors identified in section 69505.6(a)(2) and (3) address the thirteen (A) through (M) criteria specified in Health and Safety Code section 25253(a)(2), in their entirety. Thus, these provisions are necessary to ensure that the statutorily-required criteria are considered and evaluated as part of each AA.

Section 69505.6(a)(1) specifies that the responsible entity may use available *quantitative* information and analytical tools, supplemented by available *qualitative* information and analytical tools, to re-evaluate the factors, and associated exposure

pathways and life cycle segments, determined to be relevant under section 69505.5(c). In addition to the factors determined to be relevant under sections 69505.5(c) and 69505.6(a)(1), the responsible entity must consider the factors in sections 69505.6(a)(2) and (3) related to product function and performance and economic impacts as relevant for all comparisons of the Priority Product and its alternatives. The necessity for limiting the information collection requirement to available information is explained above with respect to section 69505.5(c)(2).

The evaluation for relevancy under section 69505.5(c) coupled with the requirements of sections 69505.6(a)(2) and (3) address the thirteen (A) through (M) criteria specified in Health and Safety Code section 25253(a)(2), in their entirety. Thus, these provisions are necessary to ensure that the statutorily-required criteria are considered and evaluated as part of the AA and that they are considered at the right stage of the AA process. This section is also necessary to give responsible entities the latitude to re-evaluate the factors determined to be relevant for comparing the Priority Product and its alternatives during the first stage AA. This could become necessary in light of new information, re-evaluation of prior information, or a change in the alternatives being considered. Finally, these provisions necessarily make it clear that product function/performance and economic impacts are relevant for all comparisons involving the Priority Product and the alternatives. This is because these factors are expected to make a meaningful difference in the comparison of the Priority Product and most alternatives under consideration.

Section 69505.6(a)(2) requires that the responsible entity identify the principal manufacturer-intended use(s) or application(s), functional and performance attributes, and legal requirements applicable to the Priority Product. This must include, at a minimum, identification and evaluation of the following:

- **(A)** The useful life of the Priority Product, and that of the alternatives being considered;
- **(B)** The function and performance for each alternative as compared to the Priority Product and each of the other alternatives being considered; and
- **(C)** Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.

This provision is necessary to ensure that each AA incorporates consideration of the factors identified in Health and Safety Code sections 25253(a)(2)(A) and (B).

Section 69505.6(a)(3) requires the responsible entity to include in the AA a comparative evaluation of economic impacts for the Priority Product and the alternatives being considered, as follows:

(A) The responsible entity must evaluate, monetize, and compare – for the relevant exposure pathways and life cycle segments – the impacts of the Priority Product and the alternatives on:

1. Public health and environmental costs; and
2. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.

(B) If the responsible entity's alternative selection decision is to retain the Priority Product based in whole or in part on internal cost impacts, this decision must be explained in the Final AA Report. The Final AA Report must include a quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs.

Collectively, the above provisions are necessary to address the mandate in Health and Safety Code section 25253(a)(2)(M), which requires each AA to include consideration of the economic impacts of the Priority Product and potential alternatives using life cycle assessment tools. The economic impacts must address the impacts across the life cycle (*i.e.,* from raw materials extraction through materials processing, manufacture, distribution, use, repair and maintenance, and disposal or recycling) associated with the Priority Product and the alternatives being considered. The requirements specified are consistent with commonly used principles in product assessment and reformulation. While externalized costs may have been traditionally passed on to the public, taxpayers and/or government, DTSC believes it was the intent of the Legislature to depart from this paradigm. This view is consistent with the statutory requirement that economic impacts be considered as part of the AA.

If the responsible entity chooses to retain the Priority Product, in lieu of a safer alternative product, based on internal cost impacts, this needs to be explained and quantified in detail in the Final AA Report so that DTSC can evaluate the validity of the rationale for this decision.

Section 69505.6(b) requires the *Comparison of the Priority Product and Alternatives* as step two in the second stage of the AA. The responsible entity must use available *quantitative* information and analytical tools, supplemented by available *qualitative* information and analytical tools, to evaluate and compare the Priority Product and each of the alternatives under consideration with respect to each relevant factor and, where applicable, associated exposure pathways and life cycle segments identified under

sections 69505.6(a) and 69505.5(c). The responsible entity must compare each alternative with the Priority Product and with each of the other alternatives being considered.

This provision, in its entirety, is necessary to ensure that a responsible entity takes into account the existing data and adequately compares the impacts of a Priority Product to those of the alternatives. The necessity for limiting the information collection requirement to available information is explained above with respect to section 69505.5(c)(2).

To provide balanced and comprehensive evaluation, the responsible entity must evaluate both the Priority Product and the alternatives considered using the same relevant factors, exposure pathways, and life cycle segments. If information for a relevant factor, exposure pathway, or life cycle segment is known for one alternative, but is missing for another alternative, the responsible entity must identify the missing information (*i.e.*, information gap) in the AA Report. This provision is necessary to address the wide range of variability in the information that is available and the products being assessed.

Section 69505.6(c) allows the *Consideration of Additional Information* as step three in the second stage of the AA. The responsible entity may consider information not already required under section 69505.6, including re-consideration of the factors and information specified in section 69505.5. This provision gives responsible entities latitude to consider information not specifically identified in section 69505.6 but that the responsible entity considers relevant to the AA. Given that the preparers of the AA must exercise professional judgment, it is necessary to provide latitude in including information as it becomes available to reassess and apply the appropriate level of judgment to make sound decisions.

Section 69505.6(d) requires the *Alternative Selection Decision* as step four in the second stage of the AA. This provision requires the responsible entity to select the alternative that will replace the Priority Product, unless the decision is to retain the existing Priority Product. Further, this section requires that the selection of an alternative, or the decision to retain the Priority Product, must be based on and supported by the comparative analysis conducted under section 69505.6(b) and (c). This provision makes clear that the selected alternative may be to retain the existing Priority Product. Whatever the alternative selection decision is, the responsible entity must base the decision on the findings of the AA and document the findings that support the responsible entity's decision. In general, this provision is necessary to ensure that the alternative selection decision is based on a finding that the alternative selected is

the safer alternative to any other "viable" (*e.g.*, functionally acceptable, technologically feasible, and economically feasible) alternative considered. This provision is necessary to specify that this is the appropriate and required time at which to make an alternative selection decision.

Section 69505.6(e) requires the *Final AA Report Preparation* as step five of the second stage of the AA. This section requires the responsible entity to prepare and submit a Final AA Report containing the information specified in section 69505.7. This provision is necessary to ensure that the responsible entity knows that the Final AA Report is required to be submitted after conducting the second stage of the AA process. The Final AA Report must contain the information specified in section 69505.7 to provide DTSC the necessary information to evaluate the AA and the Final AA Report for compliance with Article 5, and determine which, if any, regulatory responses are needed to address the adverse impacts associated with the Priority Product and/or the selected alternative(s).

§ 69505.7. Alternatives Analysis Reports

Section 69505.7, in its entirety, specifies the required contents of the Preliminary AA Report, Final AA Report, and Abridged AA Report (collectively referred to as "AA Report"), which are necessary to ensure that the AA has been thought through thoroughly and adequately documented. This, in turn, is necessary to ensure that the AA meets the requirements of Article 5 and the authorizing legislation. It is also necessary to provide DTSC with sufficient information to adequately consider and evaluate the results of the AA and to put DTSC in a position to make an informed decision about which regulatory response(s), if any, it needs to impose.

Section 69505.7(a)(1) requires that the Preliminary and Final AA Reports, and Abridged AA Reports include, as applicable, all of the information specified in sections 69505.7(b) through (k). This section is necessary to specify the required AA report contents. It is also necessary to ensure that all responsible entities know the required contents and to ensure that DTSC receives AA Reports that meet its needs. The content requirements for AA Reports are discussed in detail below.

Section 69505.7(a)(2)(A) requires the responsible entity to include in the AA Reports sufficient information for DTSC to determine compliance with the substantive and administrative requirements of Article 5. Since AA Reports will typically rely on existing data or previously prepared reports, the AA Reports will need to sufficiently summarize the data or information used and provide the appropriate reference to information sources to allow for meaningful review by DTSC. This provision is necessary to ensure

that each AA report submitted for DTSC review is complete, complies with Article 5, and is of the rigor necessary for DTSC to make an appropriate evaluation.

Section 69505.7(a)(2)(B) requires the responsible entity to include sufficient information in the Preliminary AA Report for DTSC to determine the appropriate due date for submission of the Final AA Report, and sufficient information in the Final AA Report for DTSC to determine the appropriate due date for any regulatory response(s) required under Article 6. This provision is necessary to compel responsible entities to fully describe in the Preliminary AA Report the work that will be undertaken in the second stage AA, and the planning that has occurred in preparation for carrying out the second stage AA, in order to allow DTSC to make an informed decision about the deadline for submittal of the Final AA Report. This section is also needed to ensure that the responsible entity includes in the Final AA Report any information that DTSC will need in order to set reasonable and workable deadlines for implementation of regulatory responses and to explain the basis for these deadlines in the proposed regulatory response determination notice.

Section 69505.7(a)(3) requires the responsible entity to identify and explain in the Final AA Report all differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report. The responsible entity must also identify in the Final AA Report the information sources used to support changes from the Preliminary AA Report to the Final AA Report. This provision is necessary to provide the responsible entity latitude to make necessary adjustments between the two reports based on what is learned during the second stage AA. It is necessary that such changes and supporting information be explained so that DTSC can make an informed evaluation of the two reports, and understand any differences between them.

Section 69505.7(a)(4) requires that the responsible entity maximize the scope of information in the AA Report that can be made available to the public, while maintaining protection of legitimate trade secrets. This provision, coupled with sections 69505.7(a)(4)(A) and (B), support the objective of providing as much information as possible to the public, without infringing upon legitimate claims for protection of trade secrets. To make a claim of trade secret, a responsible entity must comply with the provisions in Article 9 (Trade Secret Protection). Responsible entities wishing to protect trade secrets under Article 9, must submit redacted AA reports that will be made available to the public and posted on DTSC's website. This provision is necessary to maximize the amount of information contained in the AA reports that can be made available to the public so that the public is informed as to the comparative differences between the Priority Product and the alternatives, the basis for the alternative selection

decision, and other information that may assist consumers in making more informed purchasing decisions.

Section 69505.7(a)(4)(A) requires a responsible entity submitting an AA Report containing information claimed to be a trade secret to submit a separate publicly available AA Report that excludes the claimed trade secret information only to the extent necessary to protect its confidential nature. This provision is necessary to strike a balance between the legitimate need to protect trade secret information with the legitimate need of the public to see the basis for the AA Reports. It is also necessary so that if DTSC receives Public Records Act requests for AA Reports, DTSC can make the redacted copy readily available without the need for further review.

Section 69505.7(a)(4)(B) specifies that if DTSC subsequently rejects a trade secret claim and/or the nature and/or extent of redaction, the preparer of the AA report must, at DTSC's request, submit a revised publicly available AA Report. The revised report must be submitted within thirty (30) days of the request, containing any information for which a trade secret claim was rejected. This provision supports the objective of providing as much information as possible to the public and other interested parties regarding the AA, without infringing upon legitimate claims for protection of trade secrets. This provision is necessary to specify a reasonable period within which the redacted AA report must be resubmitted, including any information DTSC determine is not trade secret. Since the information to be added in the revised report is already available to the responsible entity, thirty (30) days is adequate time in which to submit the revised report.

Section 69505.7(b) specifies that AA Reports submitted to DTSC must be accompanied by a publicly available *Executive Summary*. The executive summary must contain sufficient information to convey to the public a general understanding of the scope and results of the AA and the basis for the alternative selection decision. Further, this section requires the publicly available executive summary to be organized in conformance with the format and organization of the AA Report, and to include for each section of the AA Report a detailed summary of the information presented in the AA Report. However, the publicly available executive summary must not include any information claimed as trade secret under Article 9. This provision is necessary to facilitate the objective of providing as much information as possible to the public and other interested parties, in a manner that is tailored to those who are not experts in the field, regarding the AA without infringing upon legitimate claims for protection of trade secrets. This provision limits the resources DTSC must devote to preparing documents for posting to DTSC's website since the reports must be submitted with trade secrets redacted, making them ready for posting.

Section 69505.7(c) specifies that the AA Report must include the following information regarding the person who prepared the report and other persons involved with the AA:

(1) The name of, and contact information for, the person submitting the AA Report;
(2) The name of, and contact information for, all responsible entities on whose behalf the AA Report is being submitted, if applicable; and
(3) The names of the parties that were involved in funding, directing, overseeing, preparing, and/or reviewing the AA.

The information required under this provision is necessary: (i) in the event it becomes necessary for DTSC to contact the person submitting the report; (ii) for DTSC to know which responsible entities have complied with the Article 5 AA requirements; and (iii) for DTSC to understand the financial and other interests of those involved with the AA in the event DTSC needs to contact any of these parties.

Section 69505.7(d) requires that the AA Report contain the following information regarding the responsible entity and the rest of the supply chain for the Priority Product:

(1) The name, contact information, and headquarters location of the manufacturer and importer, if applicable. If the AA Report is prepared on behalf of a consortium of manufacturers or other persons in the product's supply chain, a list of the participants must be provided as well as their corresponding contact information. This information is necessary should DTSC need to contact any of these entities, for DTSC to know and understand who was involved in the compilation of the reports, and for DTSC to know which responsible entities have complied with the Article 5 AA requirements.
(2) The name of, and contact information for, any persons identified on the Priority Product label as the manufacturer, importer, or distributor. This information is necessary should contacting any of these persons become necessary. It is necessary as well to help identify the specific product that is the subject of the AA as well as for DTSC to understand the supply chain for the Priority Product – this information can be useful when considering regulatory response feasibility and in compliance and enforcement activities.
(3) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months. This information is necessary for DTSC to understand the product's supply chain and to assist DTSC in monitoring implementation of the AA selection decision and implementation of the required regulatory responses.
(4) Identification and location of the manufacturer's and importer's retail sales outlets where the manufacturer and/or importer sold, supplied, or offered for

sale the Priority Product in California, if applicable. This information is necessary for DTSC to understand the product's supply chain and to assist DTSC in monitoring implementation of the AA selection decision and implementation of the required regulatory responses.

Section 69505.7(e) requires the AA Report to include the following information identifying and describing the Priority Product that is the subject of the AA Report:

(1) The brand name(s) and product name(s) under which the Priority Product is placed into the stream of commerce in California. This information is necessary for DTSC to understand which products are covered by the AA Reports, to distinguish the product that is the subject of the AA from other similar products, and to monitor implementation of alternative selection decisions and regulatory responses.

(2) If the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used. This information is necessary for DTSC to understand which products are covered by the AA Reports, to understand where those products may be found in the stream of commerce in California, and to monitor implementation of alternative selection decisions and regulatory responses.

(3) Identification of the Chemical(s) of Concern in the Priority Product. This information is necessary so that DTSC and interested parties are fully informed as to which Chemicals of Concern identified in the Priority Product listing are contained in the Priority Product that is the subject of the AA. When DTSC identifies multiple Chemicals of Concern for a Priority Product, it may be that some of the products captured by the Priority Product listing do not contain all of the listed Chemicals of Concern. This information is necessary for DTSC to have sufficient information to make an informed evaluation of the AA Reports.

(4) Any Material Safety Data Sheets and/or Safety Data Sheets related to the Priority Product. This information is necessary for DTSC to gather useful information regarding the Priority Product and for DTSC to make an informed decision regarding safe handling requirements related to the Priority Product and its alternatives.

(5) The information specified in sections 69505.5(a)(1) and (2), which includes the product criteria such as function, performance, and legal requirements for the product, and the role and function that the Chemicals of Concern play in meeting the requirements for the Priority Product. This information is necessary so that DTSC has pertinent information available to it in order to make an informed evaluation of the AA Reports, and may be useful for determining if there is a safer viable alternative to the Priority Product for purposes of Article 6.

Section 69505.7(f) requires that the AA report include information on the scope of relevant comparison factors used for the AA. Each AA Report must identify the factors, and associated exposure pathways and life cycle segments, that were determined to be relevant, under sections 69505.5(c) and 69505.6(a), for evaluation and comparison of the Priority Product and its alternatives. For each factor, exposure pathway, and life cycle segment determined not be relevant, the AA Report must explain the rationale, and identify and explain the pertinent findings of the supporting information for this determination. This provision is necessary for DTSC to ensure that the responsible entity has identified the appropriate and necessary factors, exposure pathways, and life cycle segments for the AA; and that the responsible entity has not disregarded factors, exposure pathways, or life cycle segments that warrant consideration because they meet the criteria of relevancy as specified in section 69505.5(c)(1). This information is also necessary for DTSC to ensure that the AA meets the requirements of Health and Safety Code section 25253(a)(2), and to make an informed evaluation of the AA Report.

Section 69505.7(g) requires the AA report to include information on the scope and comparison of alternatives. The AA report must identify and describe the alternatives chosen to be evaluated and compared with the Priority Product, and explain the rationale for selecting and screening out specific alternatives at each stage of the alternatives comparison. For any alternative that is screened out – because it is determined that its adverse impacts are equal to or greater than those of the Priority Product – the responsible entity must describe in the AA Report the method used to determine that the impacts were equal to or greater than those of the Priority Product. The AA Report must also include the method use to compare the multiple factors associated with the impacts and the rationale for any trade-offs made amongst the factors. This provision, along with sections 69505.7(g)(1) through (g)(3), are necessary to provide DTSC and other interested parties the necessary information to understand and evaluate the responsible entity's alternative section decision and the rationale and methodologies underlying that decision.

Section 69505.7(g)(1) requires each Preliminary AA Report and Abridged AA Report to include the information collected and the comparison conducted under section 69505.5 for the Chemical(s) of Concern and the alternative replacement chemical(s). This information must include a matrix, or other summary format, that provides a clear visual comparison that summarizes the information collected regarding relevant adverse impacts, and associated exposure pathways and life cycle segments, for the Chemical of Concern and each alternative replacement chemical, and the comparative results of evaluating this information. This provision is necessary to ensure that information used in the initial screening of the alternatives is appropriate and is presented in a format that

is readily understood to facilitate an expeditious review and audit by DTSC and review by other interested parties.

Section 69505.7(g)(2) requires the Final AA Report to include all of the information collected and the comparison conducted under sections 69505.5 and 69505.6 for the Priority Product and its alternatives. The Final AA Report must take into account the findings presented in the Preliminary AA Report and the findings of the second stage AA. This provision is necessary to ensure that information used in the initial screening and subsequent final screening meets the substantive requirements of Article 5, and is presented in a format that is readily understood to facilitate an expeditious review and audit by DTSC and review by other interested parties.

Section 69505.7(g)(2)(A) requires that the Final AA Report include a matrix, or other summary format, that provides the reviewer with an easily understood clear visual comparison that summarizes the information collected regarding the relevant comparison factors, and their associated relevant exposure pathways and life cycle segments, for the Priority Product and each alternative considered, and the comparative results of evaluating this information. This provision is necessary to ensure that information used in the screening of the alternatives is appropriate and is presented in a format that is readily understood to facilitate an expeditious review and audit by DTSC and review by other interested parties.

Section 69505.7(g)(2)(B) requires that the Final AA Report include a description of how any relevant safeguards provided by other federal and California State regulatory programs were considered in the AA, including identification of those programs and safeguards considered. This provision is necessary to ensure that other safeguards provided by federal and California state regulatory programs are taken into account to determine if those in place address the hazards posed by a selected alternative. This information is also necessary to allow DTSC to make an informed evaluation of the AA Report and to make an appropriate selection of regulatory response(s).

Section 69505.7(g)(3) requires the responsible entity to demonstrate in the Final AA Report that all of the requirements of section 69505.6 have been met. This provision is necessary to compel responsible entities to undertake a rigorous and thorough evaluation of the Priority Product and the alternatives considered in a manner that meets all of the enumerated criteria, and to enable DTSC to ensure compliance with the requirements of Article 5 and Health and Safety Code section 25253(a).

Section 69505.7(h) requires the AA report to include the methodology used in the AA. The AA Report must identify and describe the analytical tools, models, and software

used to conduct the AA, and discuss any of their limitations. The AA Report must also identify any published methodologies or guidelines used, and any deviations taken from the published methodologies and/or guidelines. The information required under this provision is necessary to ensure that the relevant background and contextual information is provided to DTSC and other interested parties so that an informed evaluation of the AA Report and its conclusion can be made.

Section 69505.7(i)(1) requires the AA Report to provide information on supporting information used for the AA. Specifically, all information used as supporting information in the performance of the AA and preparation of the AA Reports must be cited in the AA Reports and made available to DTSC, upon request. The AA Report must include a brief summary of the information reviewed and considered under section 69505.1(d), which requires the responsible entity to consider all relevant information available on DTSC's website and any additional information DTSC may provide regarding alternatives analysis. This information is necessary to ensure the AA is adequately supported and substantiated by scientifically sound information that can be reviewed by DTSC in the event DTSC or interested parties wish to obtain a better understanding of the information, data, assumptions, etc. that formed the basis of the AA and the responsible entity's alternative selection decision. This will ensure that the relevant background and contextual information is available to DTSC and other interested parties so that an informed evaluation of the AA Report and its conclusion can be made. This information is also necessary to assist DTSC in selecting necessary and appropriate regulatory response(s).

Section 69505.7(i)(2) requires the Final AA Report to include the identification of information that is currently not available but, if available, could be used to:

- **(A)** Validate information used for purposes of the evaluation and comparison required under sections 69505.5 and 69505.6; and/or
- **(B)** Address any uncertainties in the analyses conducted during the AA under sections 69505.5 and 69505.6.

While the regulations do not require information gaps be filled, there is the recognition that with additional information, whether readily available or not, better informed decisions can be made in scoping and subsequently addressing or validating uncertainties when comparing the Priority Product and any potential alternatives during the first and second stage AA. Although responsible entities are not required to fill information gaps as part of the AA, identification of the information gaps may be used to establish where additional scientific or technical work may be productive. More generally, this identification of information gaps is necessary to give DTSC a better basis for evaluating the AA Reports. If DTSC determines any of the information gaps

need to be filled to enable DTSC to determine which, if any, regulatory responses are needed, section 69506.2 allows DTSC to require information gaps to be filled as an initial regulatory response.

Limiting the information gathering requirement to available information, rather than requiring all information gaps to be filled during the AA, is necessary to place reasonable limits on the time and costs necessary to satisfy the AA requirements of Article 5. If responsible entities were required to fill all information gaps, in some cases, the cost could escalate significantly and AAs could take many years to complete which would likewise delay the identification and implementation of regulatory responses for many years. Section 69505.7(i)(2), in concert with section 69506.2, provides an effective and efficient process to focus responsible entity resources on filling only those information gaps that DTSC determines are necessary to proceed with the regulatory response determination process.

Section 69505.7(j) requires the AA Report to include information on the selected alternative(s). The AA Reports must identify and describe the alternatives chosen to be evaluated and compared, and explain the rationale for selecting and screening out specific alternatives at each stage of the alternatives comparison process. This provision is necessary to ensure the relevant background and contextual information is provided to DTSC and other interested parties. This information is also necessary to enable DTSC to make an informed evaluation of the AA Reports and the alternative selection decision and to assign appropriate and necessary regulatory responses.

Section 69505.7(j)(1) requires the Preliminary AA Report to identify and describe the alternatives selected for further evaluation in the second stage of the AA, and explain the rationale for the selection decision. The Preliminary AA Report identifies the viable alternatives that will be subsequently evaluated, and thus establishes the scope of the second stage AA. This provision is necessary to ensure the relevant background and contextual information is provided to DTSC and other interested parties so that the scope of the AA is properly understood, and so that DTSC may make an informed evaluation of the AA Reports and the alternatives selection decision.

Section 69505.7(j)(2) requires the Final AA Report to identify and describe the alternative(s), if any, selected to replace the Priority Product. This must include an analysis that evaluates and compares the selected alternative(s) against the Priority Product and a detailed list and explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable. The information required under this provision is necessary to provide DTSC and other interested parties with an in-depth explanation of

the rationale for the responsible entity's selection decision; and is necessary for DTSC to make an informed evaluation of the AA Report and the alternative selection decision. This information will then be used by DTSC to make an informed decision to determine the necessary regulatory responses.

Section 69505.7(j)(2)(A) requires the Final AA Report or Abridged AA Report, as applicable, to include the information specified in section 69505.6(a)(2) regarding product function and performance, for the selected alternative(s). If no alternative is selected, this information must be provided in the Final AA Report or Abridged AA Report, as applicable, for each alternative considered. The information required under this provision is necessary to provide DTSC and other interested parties the product function and performance information evaluated and taken into account by the responsible entity in selecting an alternative, and is necessary for DTSC to make an informed evaluation of the Final AA Report and the alternative selection decision and to determine necessary and workable regulatory responses.

Section 69505.7(j)(2)(B) specifies that the Final AA Report must explain the rationale for deciding to retain the Chemical of Concern or to use a replacement chemical, if section 69505.5(a)(3)(B) applies, and one or more selected alternative retains the Chemical(s) of Concern or uses a replacement chemical – if under section 69505.5(a)(3)(B) the responsible entity made a determination that neither the Chemical of Concern nor a replacement chemical is needed to meet the Priority Product's function, performance, or legal requirements. The information required under this provision is necessary to inform DTSC and other interested parties of the basis for a responsible entity choosing to retain Chemical(s) of Concern or use replacement chemicals when the responsible entity has determined that this is not necessary. This information will be taken into consideration by DTSC when determining the necessary regulatory responses for the selected alternative.

Section 69505.7(j)(2)(C) requires the Final AA Report to include a list of all chemical ingredients known, based on available information, to be in the selected alternative that: (i) are Chemicals of Concern; (ii) differ from the chemical(s) in the Priority Product; or (iii) are present in the selected alternative(s) at a higher concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern. All of the following information that is available must be provided for those chemicals:

1. Environmental fate;
2. Hazard trait and environmental and toxicological endpoint information for any of those chemicals for which such information has not already been provided to DTSC under these regulations;

3. Information on the purity of the chemicals and identification of known impurities and additives in the chemical;
4. Physicochemical properties; and
5. Substance identification information, including all of the following that are applicable:
    - **a.** Chemical abstract services number;
    - **b.** Structural formula;
    - **c.** Molecular weight;
    - **d.** Synonyms;
    - **e.** International Union of Pure and Applied Chemistry name;
    - **f.** European Commission number;
    - **g.** Registry of Toxic Effects of Chemical Substances number;
    - **h.** International Union of Biochemistry and Molecular Biology number;
    - **i.** Japan Ministry of International Trade and Industry number;
    - **j.** Number assigned by the United Nations Experts on the Transport of Dangerous Goods;
    - **k.** North America Department of Transportation number;
    - **l.** European Inventory of Existing Commercial Chemical Substances number;
    - **m.** European List of Notified Chemical Substances number;
    - **n.** European Commission Directive 67/548/EEC No Longer Polymers number; and
    - **o.** Other commonly recognized substance identification system numbers.

The information required under this provision is necessary for DTSC to adequately assess the potential adverse impacts associated with the selected alternative product as a result any Chemicals of Concern in the product; or any chemicals in the alternative product that differ from chemicals in the Priority Product or are present at higher concentrations in the alternative product than in the Priority Product. Chemicals present in the alternative product, but not in the Priority Product, would not have been assessed by DTSC during the chemical identification or product-chemical prioritization process. A chemical present in the Priority Product at a lower concentration than in the alternative product may not have risen to the level of concern for listing as a Chemical of Concern; however, at a higher concentration there could be increased concerns that would need to be addressed through regulatory responses. NOTE: Much of the substance identification information specified in sections 69505.7(j)(2)(C)5.a. through o. are naming conventions that are currently in use throughout the world. Although there are efforts underway to globally harmonize information related to chemicals, these regulations will go into effect before those efforts are complete. As such, the regulations require responsible entities to identify each chemical by all applicable

naming conventions to assist DTSC and others in identifying information relating to that chemical in scientific literature.

Section 69505.7(k)(1) requires that the Preliminary AA Report include the work plan and proposed implementation schedule for completion of the second AA stage. The work plan is necessary to identify: (i) the scope of the second stage AA; (ii) the work phases and tasks that must be performed to further evaluate alternatives (which could include collecting and analyzing additional information) and make an alternative selection decision; and (iii) the proposed implementation schedule for carrying out the work plan. For additional discussion relative to this requirement and its necessity, refer to the statement of reasons for section 69505.4(a)(1).

Section 69505.7(k)(1)(A) specifies that the work plan and implementation schedule for the second stage AA must specify the proposed submission date for the Final AA Report, and must ensure that the Final AA Report or progress report, if applicable, will be submitted to DTSC no later than twelve (12) months after DTSC issues a notice of compliance for the Preliminary AA Report. This section further provides that if DTSC approves an extended due date under section 69505.9(b)(4), the responsible entity must provide a yearly progress report until the Final AA Report is submitted. The first yearly progress report must be submitted no later than twelve (12) months after DTSC issues a notice of compliance for the Preliminary AA Report. Each progress report must include:

1. Preparer information specified in section 69505.7(c);
2. Priority Product information specified in section 69505.7(e);
3. A summary of achievements since the last progress report;
4. A summary and discussion of issues that have arisen and their resolutions;
5. A summary of work that is pending; and
6. An assessment of whether the milestones in the schedule set forth in the Preliminary AA Report or Alternate Process AA Work Plan are anticipated to be completed on time and any contingency plans to ensure timely completion.

This section is necessary to inform DTSC as to when the responsible entity proposes to submit the Final AA Report, which is necessary for DTSC to determine if an extended due date is necessary and appropriate for the second stage AA and preparation of the Final AA Report. This provision is also necessary to ensure that the responsible entity has a viable plan to ensure that the Final AA Report or annual progress report will be submitted timely. Finally, this section is necessary to ensure that DTSC is kept apprised annually of the progress being made on the second stage AA so that DTSC can evaluate whether the responsible entity is taking necessary and reasonable measures to meet applicable deadlines.

The information requirements of section 69505.5(k)(1)(A)1. through 6., specified for the progress reports, ensures progress is being monitored and includes all of the information necessary for DTSC to:

- Contact the person who is preparing the report or the responsible entities for the product should there be questions or the need to follow-up on the status of the AA (see section 69505.7(c) for additional information);
- Know which Priority Products are the subject of the progress report (see section 69505.7(e) for additional information);
- Evaluate the progress being made towards completing the second stage AA and preparing the Final AA Report, and whether the responsible entity is taking appropriate steps to meet applicable due dates; and
- Anticipate when the Final AA Report will be submitted for DTSC review and issuance for public review and comment.

Section 69505.7(k)(1)(B) allows the responsible entity to request an extended due date for submittal of the Final AA Report, not to exceed twenty-four (24) months from the date DTSC issues a notice of compliance for the Preliminary AA Report, unless additional time is needed to conduct regulatory safety and/or performance testing on multiple alternatives prior to making an AA selection decision – in which case the requested extension must not exceed thirty-six (36) months. The extended due date request must include a detailed explanation of why additional time is needed. This provision provides necessary latitude to responsible entities when the complexity and/or scope of the AA or other circumstances are encountered that impact the submittal of the Final AA Report; including, in part, when the extent of regulatory safety and/or performance testing makes an extended due date necessary. The information required to accompany an extension request is necessary to enable DTSC to evaluate the validity of the need for an extension.

Section 69505.7(k)(2) requires that the Final AA Report include a detailed plan for implementing any selected alternative(s). An implementation plan that details the list of activities and critical pathways to achieve the endpoint of final deployment of the selected alternative is necessary for DTSC and other stakeholders to fully assess if the alternative is being deployed in a timely manner and to anticipate when the alternative will be available in the marketplace. This information is also necessary to alert DTSC as to when it should start monitoring regulatory response compliance for the alternative, if applicable.

Section 69505.7(k)(2)(A) requires the implementation plan to include key milestones and dates for implementing the selected alternative(s), if applicable. The

implementation plan must include any steps necessary to ensure compliance with applicable federal, state, or local laws. This provision is necessary to enable DTSC to monitor implementation of the selected alternative and ensure it is done within a specific period, and that measureable progress is occurring. This is necessary for DTSC to be able to monitor and enforce compliance with the Final AA Report and the requirements and intent of the authorizing legislation. This section is also necessary to ensure that the implementation plan and milestone dates take into account the steps and time required to comply with any applicable federal, state, or local laws.

Section 69505.7(k)(2)(B) allows the responsible entity, if they so choose, to propose in the Final AA Report regulatory responses that the responsible entity believes would best limit the exposure to or reduce the level of adverse impacts posed by a Chemical of Concern or replacement Candidate Chemical that will be contained in the selected alternative or that is contained in the Priority Product. In the event the responsible entity chooses to propose regulatory responses, the Final AA Report must include an implementation plan for the proposed regulatory responses. This provision is necessary to allow a responsible entity, at their option, to provide DTSC with suggestions to consider in determining what regulatory response(s) may be appropriate. DTSC may take into account the regulatory responses proposed by the responsible entity.

§ 69505.8. Public Comments on AA Reports

Section 69505.8 provides an opportunity for interested persons to review and provide comments to DTSC on Final AA Reports and Abridged AA Reports, and enables DTSC to get feedback from the person who prepared the report on those comments that DTSC determines need to be addressed through preparation of an AA Report Addendum. This section also allows responsible entities to make revisions to their Final AA Report or Abridged AA Report if they determine this is necessary to address any issues raised in the public comments. This section, in its entirety, is necessary to provide a workable mechanism, that will not significantly delay completion of the AA process, to allow interested parties including members of the public to participate in the AA process and potentially affect changes to the AA Reports before DTSC completes its final review of the reports for purposes of determining what, if any, regulatory responses are needed under Article 6.

Section 69505.8(a) specifies that upon receipt of a Final AA Report or an Abridged AA Report DTSC must post on its website, and send to persons on its electronic mailing list, a notice regarding the availability of the AA Report for public review and comment. The notice must include the last day for the public to submit written comments to DTSC,

the method for submitting comments, and a link to the location on DTSC's website where a copy of the AA Report may be viewed. The last day for submission of public comments must be no sooner than forty-five (45) days from the date the notice of the availability of the AA Report is posted on the DTSC's website or the date the notice is sent to persons on the electronic mailing list, whichever is later.

This section is necessary to increase public confidence in the AA process through public participation, receive additional information before regulatory responses are imposed, and to strike an appropriate balance between keeping stakeholders informed and involved and ensuring progress is made towards completing the AA process and assigning needed regulatory responses. Forty-five (45) days was selected as the minimum time allowed for public comment, as this is consistent with many other regulatory processes that embody a public comment period. Forty-five (45) days generally will allow adequate time for opportunity for involvement, without unduly delaying completion of the AA process. However, in order to provide additional time when DTSC determines it is necessary, this section enables DTSC to establish a public comment period of more than forty-five (45) days. DTSC will take into account the complexity of the Final AA Report or Abridged AA Report in establishing public review periods longer than forty-five (45) days. This provision is necessary to provide an adequate amount of time for public review and comment, while not unduly delaying completion of the AA process and initiation of the regulatory response determination process.

Section 69505.8(b) specifies that no later than thirty (30) days after the close of the public comment period established under section 69505.8(a), DTSC must review the public comments received 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. The notice must include the due date for submitting the AA Report Addendum to DTSC under section 69505.8(c). In determining the due date for the AA Report Addendum, DSTC must take into consideration the scope and complexity of the issues DTSC is requiring be addressed in the AA Report Addendum. In defining which issues must be addressed, DTSC will review the merits of the comments, and use professional judgment in identifying the issues that need to be addressed in the AA Report Addendum. That is, DTSC will evaluate whether the public comment has validity and points out areas in need of further evaluation. This provision is necessary to provide an adequate amount of time for DTSC to review and consider the comments and to compile the issues that must be addressed in the AA Report Addendum for inclusion in the Final AA Report, while not unduly delaying the AA Process. This provision is also necessary to provide an adequate amount of time for the responsible entity to take into account and address the issues identified for further consideration

following the public comment period. Due to the potentially wide variety of issues and corresponding complexities, it is necessary for DTSC to be able to tailor the time period allowed for completion of the AA Report Addendum to the nature of the work that this will require.

Section 69505.8(c) specifies that a person that receives a notice under section 69505.8(b) must prepare, and submit to DTSC by the due date specified under section 69505.8(b), an AA Report Addendum that addresses the issues identified by DTSC as requiring further attention. The AA Report Addendum must include any revisions to the Final AA Report or Abridged AA Report determined to be necessary based on consideration of the issues DTSC identifies. This section is necessary to require the responsible entity to address any public comments that DTSC determines need to be addressed before DTSC completes its review of the AA Report. This, in turn, is necessary so that DTSC can consider this additional information in determining compliance with Article 5 and in assigning regulatory responses. This section is also necessary to give the responsible entity the opportunity to make revisions to their AA Report if they determine this appropriate in light of the public comments.

§ 69505.9. Department Review and Determinations for AA Reports and Work Plans

Section 69505.9, in its entirety, specifies the review and determination process that DTSC will use for Preliminary and Final AA Reports and Abridged AA Reports (collectively referred to as “AA Reports”) and Alternate Process AA Work Plans. These provisions are necessary to clarify and make specific to responsible entities and other interested parties how DTSC will conduct its review of these documents and the time periods that apply to various actions to be taken by DTSC. It is also necessary to keep the AA process moving towards completion and into the determination of regulatory responses.

Section 69505.9(a) specifies that when reviewing AA Reports and Alternate Process AA Work Plans for compliance with the substantive and administrative requirements of this article, DTSC must consider:

(1) Whether the AA Report or Alternate Process AA Work Plan was submitted timely;

(2) Whether, and to what extent, the responsible entity considered and addressed all applicable provisions of this article pertaining to the preparation and submittal of an AA Report or Alternate Process AA Work Plan, whichever is applicable; and

(3) Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable.

Section 69505.9(a)(1) is necessary to make it clear that AA Reports or Alternate Process AA Work Plans that are not submitted by the applicable due date specified in the regulations will be deemed out of compliance with Article 5.

Section 69505.9(a)(2) requires that in its evaluation DTSC consider whether and to what extent the responsible entity complied with all the requirements of Article 5. This is necessary to ensure compliance with both Article 5 and Health and Safety Code section 25253(a)(2). In its evaluation, DTSC will evaluate how thoroughly the relevant provisions required for the AA Report or Alternate Process AA Work Plan were addressed, including, for example, the following, as applicable:

- The sufficiency of the information provided that is necessary for DTSC to determine that appropriate due date for the Final AA Report or to identify needed regulatory responses and their due dates, whichever is applicable.
- How well the executive summary provides the public with a lay person understanding of the AA scope and results and the rationale for the alternative selection decision.
- The adequacy and completeness of the information provided pertaining to: the parties involved in or covered by the AA; the supply chain for the product; and the Priority Product.
- The identification of relevant factors, exposure pathways, and life cycle segments, and the rationale for any that are determined not to be relevant;
- The methodologies, guidelines, and available information used to conduct the AA.
- The description of and rationale for the alternative selection decision.
- The clarity and sufficiency of the work plan for the second stage AA or implementation of the alternative selection decision, as applicable.

AA Reports and Alternate Process AA Work Plans that do not meet the substantive content requirements of Article 5 will be deemed out of compliance, unless the responsible entity resubmits the AA Report and/or Alternate Process AA Work Plan within the applicable time period specified section 69505.9(b). These provisions are necessary to make it clear to all concerned that AA Reports and Alternate Process AA Work Plans must meet <u>all</u> applicable Article 5 requirements to be deemed compliant, and that DTSC's compliance review of these documents will cover all such requirements.

Section 69505.9(a)(3) requires DTSC to evaluate whether, and to what extent, the AA Report demonstrates that the conclusions of the AA are based on reliable information, when applicable. This information is necessary to assist DTSC in evaluating the analyses and conclusions of the AA and the rationale for the alternative selection decision. It will also assist DTSC in determining if additional information is needed to determine which, if any, regulatory responses are needed to address adverse impacts posed by the Priority Product and/or the alternative product, including whether or not to require the responsible entity to fill one or more information gaps as an initial regulatory response.

Section 69505.9(b)(1) specifies that within sixty (60) days of receiving a Preliminary AA Report or Alternate Process AA Work Plan, DTSC must review the report or work plan for compliance with Article 5, and issue a notice of compliance, notice of deficiency, notice of disapproval, or notice of ongoing review. The time period specified is consistent with the time need for reviews conducted by DTSC to evaluate similar documents for completeness and scope. This provision allows DTSC sixty (60) days to make a determination or notify the responsible entity that the material submitted is still under review. This provision is necessary to give DTSC an appropriate amount of time to conduct its review and to provide responsible entities certainty to plan for, and expect, a response from DTSC informing them of DTSC's decision on their Preliminary AA Reports or Alternate Process AA Work Plan.

Section 69505.9(b)(2)(A) requires that DTSC specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date for submitting the necessary information which may not exceed sixty (60) days from the date the notice of deficiency is issued. In response to a notice of deficiency, the responsible entity must submit a revised report or work plan within the time period specified and address the areas of deficiency. These provisions are necessary to give the responsible entity an opportunity to correct any deficiencies in their report or work plan prior to DTSC proceeding to a notice of disapproval and consequent action (*i.e.*, initiation of the notice of non-compliance and Failure to Comply listing process and pursuit of appropriate enforcement actions). The areas of deficiency noted by DTSC are necessary to inform the responsible entity of the contents requiring resolution to deem the Preliminary AA Report or Alternate Process AA Work Plan in compliance with Article 5. In addition, the time period specified for correcting the deficiencies and submitting a revised compliant document is necessary to provide responsible entities a reasonable amount of time for remedying deficiencies before being deemed out of compliance. This provision is necessary to ensure clear guidance is provided by DTSC on areas determined to be deficient, ensure AA Reports are remedied on a timely basis, and the AA process is not unduly delayed.

Section 69505.9(b)(2)(B) requires DTSC, within thirty (30) days of receipt of the additional information requested in the notice of deficiency, to issue a notice of compliance, notice of disapproval, or notice of ongoing review for the report and work plan. A disapproved Preliminary AA Report or Alternate Process AA Work Plan is not in compliance with the requirements of section 69505.1(b), and the name of the responsible entity will be posted on the Failure to Comply List on DTSC's website pursuant to section 69501.2. Retailers for a Priority Product for which a Preliminary AA Report or Alternate Process AA Work Plan has been disapproved must cease ordering the Priority Product for purposes of selling the product in California (unless the retailer opts to fulfill the requirements of Article 5 for the product). This section obligates DTSC to respond in a timely manner to submittals of additional information so as to limit delays in proceeding to the next step in the AA process or in proceeding to consequences for non-compliance if the responsible entity is unable or unwilling to fully comply with the requirements of Article 5.

Section 69505.9(b)(3) specifies that if the revised Preliminary AA Report or Alternate Process AA Work Plan does not fully address the identified areas of deficiency, DTSC must issue a notice of disapproval. DTSC must also issue a notice of disapproval if a revised Preliminary AA Report or Alternate Process AA Work Plan is not submitted by the due date specified by DTSC in the notice of deficiency under section 69505.9(b)(2)(A). If the report or work plan is disapproved, DTSC must explain the basis for the disapproval. A disapproved report or work plan is not in compliance with section 69505.1(b). This section makes clear that a disapproved AA Report or Alternate Process Work plan constitutes non-compliance with the requirements of the regulations, which triggers various requirements on the manufacture, importers, retailers, and/or assemblers, as specified in section 69501.2. The provisions of this section are necessary to make it clear that responsible entities will only be granted one opportunity to address deficiencies in their report or work plan – and what the consequences are for failing to address deficiencies. Requiring DTSC to explain the basis for disapproval is necessary for transparency, to provide guidance for other responsible entities as to what will lead to a notice of disapproval, and to provide the responsible entity that is the subject of the notice of disapproval with information that will be needed if the responsible entity wishes to pursue dispute resolution concerning the notice of disapproval under Article 4.

Section 69505.9(b)(4) requires that DTSC specify in a notice of compliance for a Preliminary AA Report or Alternate Process AA Work Plan the due date for submitting the Final AA Report. DTSC must specify a due date twelve (12) months from the date DTSC issues the notice of compliance, except that DTSC may specify an extended due

date for submission of the Final AA Report if it determines based on information in the Preliminary AA Report or Alternate Process AA Work Plan that more time is needed. DTSC may also specify an extended due date for submission of the Final Report if the responsible entity submits a request under section 69505.7(k)(1)(B). Section 69505.9(b)(4) provides a necessary default time frame as well as necessary flexibility for the date by which a Final AA Report must be submitted. For less complex Priority Products and smaller scope AAs, twelve (12) months should generally be sufficient time to complete the second stage AA and prepare the Final AA Report. However, a responsible entity may request a due date for the Final AA Report up to twenty-four (24) months from the date DTSC issues a notice of compliance for the Preliminary AA Report as allowed for under section 69505.7(k)(1)(B). A responsible entity may also request a 90-day extension for submitting the Final AA Report under section 69505.1(c)(1). If a responsible entity requires additional time to conduct safety and/or performance testing prior to making a final AA alternative selection decision, the responsible entity may request up to thirty-six (36) months pursuant to section 69505.7(k)(1)(B). This provision is necessary to provide the necessary latitude in extending the due date for the Final AA Report if available information demonstrates that twelve (12) months will not be sufficient to complete the Final AA Report, and the additional time is necessary to accommodate the time the pertinent tasks may take.

Section 69505.9(c)(1) requires that within sixty (60) days of receiving an AA Report Addendum under section 69505.8, DTSC must review the Final AA Report or Abridged Report, including the AA Report Addendum, for compliance with Article 5, and issue a notice of compliance**,** notice of deficiency, notice of disapproval, or notice of ongoing review. If an AA Report Addendum is not required under section 69505.8, DTSC must complete its review of the Final AA Report or Abridged AA Report within sixty (60) days of whichever of the following dates is applicable:

- **(A)** The close of the public comment period, if no public comments are received; or
- **(B)** Thirty (30) days after the close of the public comment period, if DTSC determines after reviewing the public comments that there are no issues that need to be addressed in an AA Report Addendum.

The time period specified is consistent with the time required for reviews conducted by DTSC to evaluate similar documents for completeness and scope. This provision allows DTSC sixty (60) to make a determination or notify the responsible entity that the information submitted is still under review. This provision is necessary to give DTSC an appropriate amount of time to conduct its review and to provide responsible entities certainty to plan for, and expect, a response from DTSC informing them of DTSC's decision on their AA Reports. This provision is also necessary to adjust the start and end dates for DTSC's review based on whether public comments are received and

whether DTSC determines any of the comments need to be addressed in an AA Report Addendum, so as to provide sufficient time for DTSC to evaluate the AA Report Addendum (in addition to the AA Report), if applicable.

Section 69505.9(c)(2)(A) requires that DTSC specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date – not to exceed sixty (60) days from the date the notice of deficiency is issued – for submitting the revised Final AA Report or Abridged AA Report. In response to a notice of deficiency, the responsible entity must submit a revised AA Report within the time period specified and address all areas of deficiency. If requested by the responsible entity, DTSC may approve a one-time extension, of not more than ninety (90) days, for submission of the revised AA Report to correct the deficiencies. Because of the complexities anticipated for many second stage AAs and AA Reports, it may be necessary to provide more than sixty (60) days for the responsible entity to address the deficiencies and submit a revised report.

These provisions are necessary to give the responsible entity an opportunity to correct any deficiencies in their AA Report prior to DTSC proceeding to a notice of disapproval and consequent actions (*i.e.*, initiation of the notice of non-compliance and Failure to Comply listing process and pursuit of appropriate enforcement actions). The areas of deficiency noted by DTSC are necessary to inform the responsible entity of the contents requiring resolution to deem the AA Report in compliance with Article 5. In addition, the time period specified for correcting the deficiencies and submitting a revised compliant document is necessary to provide responsible entities a reasonable amount of time for remedying deficiencies before being deemed out of compliance. This provision is necessary to ensure clear guidance is provided by DTSC on areas determined to be deficient, ensure AA Reports are remedied on a timely basis, and the AA process is not unduly delayed.

Section 69505.9(c)(2)(B) requires DTSC to issue either a notice of compliance, a second notice of deficiency, or a notice of ongoing review within sixty (60) days of receipt of the requested additional information. This section is necessary to ensure a timely determination is made on the resubmittal of a Final AA Report or Abridged AA Report to ensure that the AA process and assignment of regulatory responses, if any, is not unduly delayed. The time period specified is consistent with the time required for reviews conducted by DTSC to evaluate similar documents for completeness and scope.

Section 69505.9(c)(2)(B)1. specifies that if DTSC issues a second notice of deficiency, the notice must grant no more than thirty (30) days for submission of the requested

information. This provision is necessary to provide responsible entities a final opportunity to rectify any deficiencies prior to being deemed out of compliance with the requirements of Article 5, and triggering other requirements under section 69501.2. Because of the complexities anticipated for many second stage AAs and AA Reports, DTSC determined it necessary and appropriate to provide responsible entities a second opportunity to remedy identified deficiencies and submit a compliant AA Report before proceeding to a notice of disapproval and consequent actions (*i.e.*, initiation of the notice of non-compliance and Failure to Comply listing process and pursuit of appropriate enforcement actions). Given that this is the second opportunity for addressing deficiencies, and given the amount of time provided for the first opportunity, thirty (30) days should be sufficient to enable willing and able responsible entities to bring their AA Reports into compliance. This time period will also avoid undue delays in completing the AA process and proceeding to regulatory responses.

Section 69505.9(c)(2)(B)2. specifies that within sixty (60) days of receipt of the requested additional information, DTSC must issue notice of compliance, notice of disapproval, or notice of ongoing review for the AA Report. A disapproved AA Report is not in compliance with the requirements of section 69505.1(b) and the name of the responsible entity will be posted on the Failure to Comply List on DTSC's website pursuant to section 69501.2. Retailers for a Priority Product for which an AA Report has been disapproved must cease ordering the Priority Product for purposes of selling the product in California (unless the retailer opts to fulfill the requirements of Article 5 for the product). This section is necessary to ensure a timely determination is made on the revised AA Report to ensure that the AA process and assignment of regulatory responses (or proceeding to consequences of non-compliance if the responsible entity is not willing and able to fully comply with Article 5) is not unduly delayed.

Section 69505.9(c)(3) specifies that if the Final AA Report or Abridged AA Report does not fully address the areas of deficiency identified in the second notice of deficiency, DTSC must issue a notice of disapproval. DTSC must also issue a notice of disapproval if a revised AA Report is not submitted by the applicable due date. If the Final AA Report or Abridged AA Report is disapproved, DTSC must explain the basis for the disapproval. A late submittal or failure to provide the information requested will result in a disapproved Final AA Report or Abridged AA Report and a determination of non-compliance with Article 5. A disapproved AA Report is not in compliance with section 69505.1(b). This section makes clear that a disapproved AA Report constitutes non-compliance with the requirements of the regulations, which triggers various requirements on the manufacture, importers, retailers, and/or assemblers, as specified in section 69501.2. The provisions of this section are necessary to make it clear that responsible entities will only be granted two opportunities to address deficiencies in their

AA Report -- what the consequences are for failing to address deficiencies. Requiring DTSC to explain the basis for disapproval is necessary for transparency, to provide guidance for other responsible entities as to what will lead to a notice of disapproval, and to provide the responsible entity that is the subject of the notice of disapproval with information that will be needed if the responsible entity wishes to pursue dispute resolution concerning the notice of disapproval under Article 4.

Section 69505.9(d) requires that DTSC specify in a notice of ongoing review the estimated date by which DTSC expects to issue a notice of compliance or a notice of deficiency. DTSC must take into account its available resources and the complexity of the document under review in estimating the date for issuance of a notice of compliance or notice of deficiency. This provision is necessary to provide responsible entities with an estimated date by when a determination on the information submitted on a document may be expected. This, in turn, is necessary so that responsible entities are not left in the dark about important next steps. This provision is also necessary to ensure DTSC has adequate time to thoroughly evaluate the document under review and identify and explain any deficiencies that need to be remedied so as to achieve compliance with Article 5 and the enable the responsible entity and DTSC to proceed to the next step in the process.

Section 69505.9(e) specifies that all notices issued by DTSC under section 69505.9 must be issued to the person who submitted the document, and a copy of the notice must be sent by DTSC to all responsible entities on whose behalf the document is being submitted and parties that were involved in funding, directing, overseeing, preparing, and/or reviewing the AA, as identified under sections 69505.7(c)(2) and (3). This section is necessary to ensure that all persons particularly affected are notified of DTSC's decisions concerning AA Reports and Alternate Process AA Work Plans.

ARTICLE 6. Regulatory Responses

Article 6, in its entirety, is necessary to implement, clarify, and make specific the provisions of Health and Safety Code section 25253(b). Specifically, the purpose of this article is to delineate the criteria for regulatory responses that may be imposed on a Priority Product, or an alternative product chosen to replace a Priority Product, following completion of an Alternatives Analysis (AA) under Article 5. Because of the vast array of consumer products potentially subject to regulatory responses, this article necessarily contains a broad menu of regulatory response options. The purpose of Article 6 is to identify the principles for regulatory response selection and the general sets of circumstances that will give rise to specific regulatory responses. Article 6 is also necessary to detail the process by which the Department of Toxic Substances Control (DTSC) will impose regulatory responses.

Health and Safety Code section 25253(b) requires these regulations to specify the range of regulatory responses that DTSC may impose following the completion of an AA, including, but not limited to, any of the following actions:

(1) Not requiring any action;
(2) Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives;
(3) Imposing requirements on the labeling or other type of consumer product information;
(4) Imposing a restriction on the use of the chemical of concern in the consumer product;
(5) Prohibiting the use of the chemical of concern in the consumer product;
(6) Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product;
(7) Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product;
(8) Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists; and
(9) Any other outcome DTSC determines accomplishes the requirements of the authorizing legislation.

All of the specific regulatory responses listed in the statute are included in Article 6 of these regulations. The regulations include a process for issuing a proposed regulatory response determination for public review and comment before DTSC makes its final determination on a regulatory response for a product (or a determination that no regulatory response is needed).

In specifying the criteria for, and the operation of, the regulatory responses, DTSC has sought to fulfill the legislative intent embodied in the following sections of the authorizing legislation:

- Health and Safety Code section 25253(a)(1) sets forth the purpose of the AA process, which is the step leading to the imposition of a regulatory response. Specifically, the purpose of the AA is "to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern."

- Health and Safety Code section 25255(a) states that the overall goal of the authorizing legislation is "significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches."

All of the regulatory responses specified in Article 6 are intended, and are necessary, to:

- limit exposure to chemicals of concern;
- reduce the level of hazard posed by chemicals of concern; and/or
- encourage the redesign of consumer products in a manner that reduces their adverse health and environmental impacts.

§ 69506. Regulatory Response Selection Principles

Health and Safety Code section 25253(b) confers broad discretion on DTSC to select from a large menu of regulatory responses to impose after completion of an AA. Except as provided in sections 69506.3 and 69506.7, regulatory response determinations will be made on a case-by-case product-specific basis. (See the statement of reasons for sections 69506.3 and 69506.7 for a description of the circumstances that will trigger these two regulatory responses in all cases when these circumstances are present.) Section 69506, in its entirety, is intended, and is necessary, to identify the overarching principles that will guide DTSC in selecting from among the broad array of permissible regulatory responses. This increases the predictability of the potential future imposition of such responses for all stakeholders, helps guide DTSC program implementation staff, and increases the consistency of regulatory decision-making.

Section 69506(a) requires DTSC, after a Priority Product has undergone an AA, to impose for the Priority Product and/or selected alternative product(s) one or more regulatory responses if DTSC determines the regulatory response(s) is/are necessary to protect public health and/or the environment. This provision also directs DTSC in

selecting regulatory responses to seek to maximize the use of those alternatives of least concern when such alternatives are functionally acceptable, technically feasible, and economically feasible. This statement of principle gives effect to the statement of goals in Health and Safety Code section 25255: "[T]he goals of this Article . . . [are] significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of these impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches." This provision is necessary to inform the general public and interested parties of the principles that DTSC will use when selecting regulatory responses. This gives more clarity and certainty to the general public and responsible entities about how regulatory responses will be selected by DTSC.

Section 69506(b) states that DTSC must, in selecting regulatory responses, give preference to those responses that provide the greatest level of "inherent protection" from adverse impacts, rather than relying on control systems to limit exposure to, or release of, chemicals. "Inherent protection" refers to avoidance or reduction of adverse impacts, exposures, and/or adverse waste and end-of-life effects that is achieved through the redesign of a product or process rather than through administrative or engineering controls designed to limit exposure to, or the release of, a Chemical of Concern or replacement Candidate Chemical in a product. This provision is likewise necessary to state DTSC's policy preference for, and duty under Health and Safety Code section 25255(a) of, "encouraging the redesign of consumer products" as a means of reducing adverse impacts, rather than merely encouraging the development of better control systems for existing products with known hazards. Without this provision, DTSC would not have the authority to favor one regulatory response over another based on inherent protection from the harmful chemical(s) being addressed under this program.

Section 69506(c) identifies three categories of criteria (discussed in detail below) that DTSC may consider in selecting a regulatory response:

(1) Public health and environmental protection;
(2) Private economic interests of responsible entities; and
(3) Government interest in efficiency and cost containment.

For each of these categories, the regulations specify three criteria that may be evaluated by DTSC in selecting the most appropriate regulatory response. The criteria are described and discussed below.

These criteria make clear that DTSC's selection of regulatory responses may, when appropriate, be guided by its determination of: (1) the overall benefits of the regulatory

response to protection of public health and the environment; (2) cost impacts on responsible entities who must implement regulatory responses; and (3) public agency costs associated with the Priority Product or alternative product at end-of-life. Further, DTSC's regulatory response selection may be based in part on pragmatic considerations relating to the ease and burdens of implementation and enforcement.

This section identifies criteria not elsewhere enumerated that may cause DTSC to favor one regulatory response among a range of seemingly facially reasonable responses. This section is necessary to enumerate the factors DTSC may take into account in selecting the appropriate regulatory response and is consistent with the authorizing legislation. All of the criteria in section 69506 are consistent with and necessary to implement and give effect to Health and Safety Code section 25253(a)(1) which states that the purpose of the AA (the step that leads to the selection of regulatory responses) is to determine how best to limit exposures to or reduce the level of hazards associated with chemicals of concern in products. These criteria are also all necessary to achieve the statutory goal (Health and Safety Code section 25255(a)) to significantly reduce adverse public health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the State's society, by encouraging product redesign.

Section 69506(c)(1) specifies that in selecting a regulatory response DTSC may consider public health and environmental protection factors. More specifically, DTSC may consider:

- **(A)** The degree to which, and speed with which, the regulatory response can address the adverse impacts and/or adverse waste and end-of-life effects of the Chemical(s) of Concern or replacement Candidate Chemical(s) in the selected alternative, or the Chemical(s) of Concern in the Priority Product;
- **(B)** The ability of end-users to understand and act upon any regulatory response involving provision of information and/or directions with respect to the Priority Product; and
- **(C)** Any adverse ecological impacts of the regulatory response on sensitive resources, or unique or additional burdens that the regulatory response would impose upon sensitive subpopulations.

Section 69506(c)(1)(A) specifies that DTSC may take into account the timeliness with which regulatory responses can be implemented and may simultaneously take into account the effectiveness of a regulatory response in addressing adverse impacts. This provision is necessary to enable DTSC to give preference to regulatory responses that will be most effective in addressing adverse public health and environmental impacts,

and/or can address the adverse impacts more quickly than other possible regulatory responses.

Section 69506(c)(1)(B) allows DTSC to take into account the ability of consumers to understand and act upon a regulatory response that involves dissemination of information and/or directions related to the Priority Product. This provision is necessary because regulatory responses that rely on consumer information to achieve the statutory goal of reducing adverse impacts and costs to society will be ineffective if consumers are not able to understand and/or act upon the information.

Section 69506(c)(1)(C) allows DTSC to take into account any adverse ecological impacts on sensitive resources, or unique or additional burdens upon sensitive subpopulations, that a regulatory response may impose. This provision is consistent with the concern for sensitive subpopulations and sensitive environmental receptors reflected throughout the regulations. This provision is necessary to enable DTSC to take into consideration when selecting regulatory responses the impacts on sensitive subpopulations and sensitive environmental receptors, both of which can be more susceptible to chemical adverse impacts than the general population or environment.

Section 69506(c)(2) specifies that in selecting a regulatory response DTSC may consider impacts on the private economic interests of responsible entities. More specifically, DTSC may consider:

- **(A)** Existing federal and/or California State regulatory requirements applicable to the Chemical(s) of Concern or replacement Candidate Chemical(s) in the product;
- **(B)** The cost to the responsible entity of the regulatory response(s) relative to the cost of other possible responses; and
- **(C)** The practical capacity of responsible entities to comply with regulatory response(s).

Section 69506(c)(2)(A) specifies that in selecting a regulatory response DTSC may consider existing federal and/or State of California regulatory requirements applicable to the Chemical(s) of Concern or replacement Candidate Chemical(s) in the product. Inclusion of this provision allows DTSC to consider if additional regulatory responses would meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts and/or exposure pathways that were the basis for the Priority Product listing.

This provision is necessary to enable DTSC to maximize the effective use of its resources by focusing on those public health and environmental concerns that are not already being adequately addressed by another federal or California State regulatory program. This provision is also necessary to implement and ensure consistency with Health and Safety Code section 25257.1(c), which provides that "DTSC shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article." Federal and California regulatory agencies, and regulatory regimes created by legally binding treaty and international agreement obligations, will be evaluated to determine if they fall under this statutory provision.

Section 69506(c)(2)(B) allows DTSC, when selecting a regulatory response, to consider the implementation costs for the responsible entity relative to the implementation costs of other possible regulatory responses. This provision is necessary to allow DTSC to consider the cost effectiveness of the various possible appropriate regulatory responses, which can in some cases effect the economic feasibility of a selected alternative product when the costs of the new product are considered together with the costs of any regulatory responses.

Section 69506(c)(2)(C) allows DTSC, when selecting a regulatory response to consider the practical capacity of the responsible entity to comply with the regulatory response. This provision is necessary because a regulatory response that cannot practically be implemented would not be effective in achieving the underlying statutory goals.

Section 69506(c)(3) specifies that in selecting a regulatory response, DTSC may consider government agency interests in efficiencies and cost containment. More specifically, DTSC may consider the following:

- **(A)** The management and clean-up costs imposed on public agencies by the ongoing sale of the Priority Product or a selected alternative;
- **(B)** DTSC's administrative burden in overseeing implementation of the regulatory response; and
- **(C)** The ease of enforcing the regulatory response.

Section 69506(c)(3)(A) allows DTSC to take into account the costs to public agencies as a result of the ongoing sale of a Priority Product or a selected alternative. This section in effect allows DTSC to take into account the financial burdens placed on public agencies associated with end-of-life management and/or environmental contamination cleanup activities involving Priority Products or selected alternative products. These activities are necessary to prevent and remediate adverse public health and

environmental impacts stemming from discharges or disposals of a product at the end of its useful life. These criteria are necessary to achieve the statutory goals articulated in Health and Safety Code section 25255(a).

Sections 69506(c)(3)(B) and (C) allow DTSC to take into account the burden on DTSC of overseeing and/or enforcing the implementation of a regulatory response. This provision is necessary because a regulatory response that would place a sizable burden on DTSC's limited resources so as to ensure its implementation is likely not going to be very effective, in contrast to other possible regulatory responses, in achieving the statutory goals described above.

§ 69506.1. Applicability and Determination Process

Section 69506.1 specifies which products Article 6 applies to, and the process by which DTSC will provide an opportunity for affected responsible entities, and other interested parties, to review and comment on proposed regulatory response determinations before DTSC issues a final determination that must then be implemented by the responsible entity (or a determination that no regulatory response is needed). This section is necessary to inform responsible entities and other interested parties as to which products may be subject to regulatory responses following completion of an AA.

These provisions are also necessary to inform interested parties as to the process by which they may review and comment on proposed regulatory response determinations. DTSC recognizes that before regulatory response determination decisions are finalized, stakeholders need to examine and have the opportunity to comment on the rationale, information, and information sources that led DTSC to those decisions. The comment period is necessary to provide interested parties an opportunity to present information not previously considered that is relevant to the regulatory response determination. These provisions are necessary to provide transparency with respect to DTSC's decision-making, and to obtain public input and perhaps additional relevant information to better inform the final decision.

Section 69506.1(a) specifies that, in general, the requirements of Article 6 apply to:

- **(1)** A Priority Product if an alternative is not selected,
- **(2)** An alternative product selected under section 69505.6(d),
- **(3)** A Priority Product, if it will remain in commerce in California pending development and distribution of a selected alternative, and
- **(4)** A Priority Product for which the Final AA Report or Abridged AA Report is disapproved by DTSC.

This section is necessary to establish, and inform responsible entities and other interested parties as to, the scope of products and circumstances for which DTSC may exercise its authority to impose a regulatory response.

Section 69506.1(b) specifies that Article 6 does not apply to a Priority Product if the manufacturer submits to DTSC a Removal or Replacement Confirmation Notification that fully meets the applicable content requirements specified in section 69505.2(b) through (e). To qualify for this exception, the notification must be submitted prior to the due date for implementing any regulatory response that would otherwise apply to the product. This provision is necessary to provide a logical exception to the regulatory response requirements if a responsible entity: (i) removes the Chemical(s) of Concern from the Priority Product; (ii) replaces the Chemical(s) of Concern with a chemical meeting the criteria in section 69505.2(b)(9)(F); and/or (iii) removes the Priority Product from the stream of commerce in California. In each of these situations, the potential adverse impacts and exposures that led to the listing of the product as a Priority Product will have been addressed. Thus, there would be no purpose in imposing a regulatory response in these circumstances.

Section 69506.1(c) specifies that, after issuing a notice of compliance or a notice of disapproval for a Final AA Report or an Abridged AA Report, DTSC must issue a notice of DTSC's proposed determination that one or more of the regulatory responses specified in Article 6 is/are required or that no regulatory response is required. The notice must be issued no later than ninety (90) days after DTSC issues the notice of compliance or a notice of disapproval for the AA Report. This provision is necessary to put responsible entities and other interested parties on notice as to when to expect a proposed determination by DTSC of the applicable regulatory response(s), if any. The period afforded to DTSC is commensurable with other programs implemented by DTSC, and should be sufficient for DTSC to review the information in a Final AA Report or an Abridged AA Report to identify, summarize, and make public the proposed regulatory response(s). This provision is integral to the public review and comment process provided under section 69506.1(d) and (e), the necessity of which is discussed below.

Section 69506.1(d) specifies that a notice issued under section 69506.1(c) must be sent to all known responsible entities for the product and made available on DTSC's website for public review and comment. DTSC must hold one or more public workshop(s) to provide an opportunity for comment on the proposed regulatory response determination. DTSC must send to all persons on its electronic mailing list for the regulations, and post on its website, a notice regarding the availability of the proposed regulatory response determination, including all of the following:

(1) The period during which the public may submit written comments, which must be a minimum of forty-five (45) days from the date the notice is posted on DTSC's website or the date the notice is sent to persons on the electronic mailing list(s), whichever is later;
(2) The method(s) for submitting comments to DTSC; and
(3) The date, time, and location of the public workshop(s).

This provision is necessary to ensure that a public notice is provided that includes the information needed by interested parties to enable them to review and comment on proposed regulatory response determinations. This provision is also needed to ensure that interested parties are afforded adequate time to consider and comment on proposed determinations. Forty-five (45) days was selected as the minimum time allowed for public comment, as this is consistent with many other regulatory processes that embody a public comment period. Forty-five (45) days generally will allow adequate time for opportunity for involvement, without unduly delaying finalization of the regulatory response determination. However, in order to provide additional time when DTSC determines it is necessary, this section enables DTSC to establish a public comment period of more than forty-five (45) days.

Section 69506.1(e) specifies that, after review and consideration of public comments, DTSC must post on its website and send to known responsible entities the final regulatory response determination notice. DTSC may respond to some or all public comments received. This provision requires DTSC to review and consider public comments prior to making a final decision on the regulatory response(s) selected or a final decision that not regulatory response is needed. This section is necessary to ensure that DTSC provides responsible entities with proper notice of the final regulatory response determination that it is required to implement, as well as to inform other interested parties as to what regulatory responses can/cannot be expected to be implemented for the product. It also ensures that DTSC considers all public comments received prior to finalizing its determination, while retaining the latitude to determine which comments warrant a response. This is necessary to maximize the effective use of DTSC's limited resources

Section 69506.1(f) specifies that all proposed and final regulatory response determination notices must include all of the following information:

(1) A description of the required regulatory response or a determination that no regulatory response is required. This information is necessary to ensure that responsible entities and interested parties are informed of the nature of the

applicable regulatory response, or DTSC's determination that there is no regulatory response required.

(2) The rationale, information, and information sources supporting DTSC's determination. This information is necessary to ensure that the basis for DTSC's regulatory response determination is made available to responsible entities and other interested parties. Inclusion of this information in the *proposed* regulatory response determination notice is necessary to better equip interested parties to consider and comment on the proposed determination. Including this information in the *final* regulatory response determination notice is necessary to provide an understanding of any changes to the basis for the determination that occur after DTSC receives and considers public comments. Additionally, a responsible entity wishing to dispute a regulatory response determination decision under Article 7 will need this information since a dispute must include a supporting statement of reasons and a showing that DTSC's decision is based on: (i) erroneous facts, assumptions, approaches, or conclusions of law; and/or (ii) a policy judgment that DTSC should reconsider.

(3) The implementation due date for any regulatory response imposed. This provision establishes the compliance date for the responsible entity to implement the regulatory response, and informs other interested parties (i.e., retailers and consumers) as to when they can expect to see the regulatory response implemented. This is necessary so that all affected and interested parties are aware of the compliance date for the selected regulatory response, and can plan their actions accordingly.

(4) DTSC's determination as to whether or not the regulatory response applies to either or both of the following:

(A) Priority Products ordered by a retailer prior to the effective date of the Priority Product listing, and still for sale by the retailer as of the date of the final regulatory response determination notice; and/or

(B) Priority Products manufactured after the effective date of the Priority Product listing, but before the date of the final regulatory response determination notice.

Section 69506.1(f)(4)(A) and (B) effectively allow DTSC, at the time the regulatory response is imposed, to consider whether or not it should be required for products already distributed in retail stores. While it is difficult to

predict the frequency with which such products would be subject to regulatory responses, it would not be prudent to categorically exclude them. This provision is necessary to allow DTSC to take into account the adverse impacts of Priority Products on public health and/or the environment, even if they are already in retail stores, and to inform interested parties that DTSC may extend the applicability of a regulatory response to these situations.

Section 69506.1(g) specifies that in assigning a due date for completing a regulatory response, DTSC must consider the complexity of implementing the response. This provision is necessary to provide flexibility in establishing due dates for implementation of a regulatory response. This is necessary because of the broad range of consumer products that are within DTSC's regulatory purview and the variability in the complexity of the menu of regulatory responses – which taken together mean that there will be a wide variability in the lead time reasonably needed to implement a specific regulatory response for a specific product.

Section 69506.1(h) specifies that once a final regulatory response determination notice has been issued, DTSC may not augment or revise the regulatory responses for the affected product, except as provided otherwise in section 69506.2 and Article 7.

Section 69506.2(b) authorizes DTSC when imposing a regulatory response to include a requirement for the responsible entity to provide information to fill information gaps identified in the AA Report, if DTSC determines the information is needed to re-evaluate the initial regulatory response(s). Following receipt of the additional information, DTSC may revise the initial regulatory response determination. Section 69506.2(c) also authorizes DTSC to revise a prior regulatory response determination if the responsible entity revises its initial alternative product selection decision. *Article 7* specifies the provisions for disputing a DTSC determination. In effect, the processes set out in Article 7 may be used to "petition" DTSC to revise or amend a final regulatory response determination.

Section 69506.1(h) is necessary to provide certainty and finality to the regulatory response selection process, with the appropriate exceptions so that responsible entities and other interested parties can plan accordingly. These exceptions: (i) allow DTSC to take new information into account in modifying a regulatory response when DTSC has determined that the AA Report did not provide sufficient information upon which to base a final regulatory response determination; and (ii) to provide responsible entities an opportunity to request DTSC to modify its determination through the Article 7 dispute resolution procedures.

§ 69506.2. Supplemental Information and Regulatory Response Revisions

Section 69506.2 is necessary to implement and make specific the regulatory response identified in Health and Safety Code section 25253(b)(2), which states that after completion of an AA DTSC may take the action of "[i]mposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives." Specifically, this section allows DTSC to delay a regulatory response determination until additional requested information is received, or to adjust a prior regulatory response determination based on such information. This section also allows regulatory response determinations to be revised if the responsible entity changes their alternative product selection decision. These provisions provide DTSC the necessary latitude to require more information from a responsible entity in certain specified circumstances, and the ability to take this information into account in selecting the regulatory responses that will best achieve the goals of the statute and the principles set forth in section 69506.

Section 69506.2(a) specifies that prior to imposing any regulatory response for a product, DTSC may require the responsible entity to obtain or develop and provide to DTSC any information supplementary to the AA Report that DTSC determines is necessary to select and ensure implementation of one or more regulatory responses under Article 6. The responsible entity must provide the requested information within the time period specified by DTSC. Given that responsible entities are not required to fill information gaps during the AA, it is likely that the Final AA Report may contain information gaps that, if known, would better inform the selection of the most appropriate regulatory response(s). This provision is necessary to accommodate AA Reports that are substantially complete, but that require critical information to allow for an informed regulatory response determination, without necessitating rejection of an AA Report in its entirety. Giving DTSC the flexibility to specify how quickly the additional information must be provided is necessary to ensure that DTSC can take into consideration pertinent factors (e.g., the complexity of the producing the additional information, and the impacts of the delay in issuing a final regulatory response determination) in setting the due date, while also ensuring against undue delays in the identification and implementation of needed regulatory responses.

Sections 69506.2(b)(1) and (2) specify that DTSC may when imposing regulatory responses include a requirement that the responsible entity provide information to DTSC to fill one or more information gaps identified in the AA Report, if DTSC determines that further information is necessary to re-evaluate one or more of the regulatory response(s) initially imposed. Based on this new information, DTSC may revise the initial regulatory response(s) imposed for the product under the procedures

set out in section 69506.1. Any revisions to the initial regulatory responses must be noticed for public review and comment no later than ninety (90) days after receiving the information required to be provided under section 69506.2(b)(1).

This provision is necessary to allow DTSC to make an initial regulatory response determination to address adverse impacts while at the same time seeking from the responsible entity additional information needed to further evaluate the Priority Product or selected alternative product to make a final regulatory response determination. This is necessary to avoid delays, as needed, in addressing adverse impacts while providing a mechanism to obtain additional needed information and adjust the regulatory responses based on this information. The amount of time that the responsible entity will be granted to provide the additional information will be determined on a case-by-case basis as part of the regulatory response determination process for the initial regulatory responses. This is necessary because of the variability in the complexity of developing, and the urgency of obtaining, the additional information. This section is also necessary to ensure that an opportunity for public review and comment is provided for any revisions for the same reasons that this is necessary for the initial regulatory response determination.

Requiring DTSC to issue the revised regulatory response determination within ninety (90) days of receiving the additional information should provide a reasonable amount of time for DTSC to evaluate the new information, and is necessary to ensure that there are not undue delays in selection and implementation of any revised regulatory responses. This is also necessary to limit the amount of time during which there is uncertainty as to the ultimate regulatory responses so that the responsible entity can proceed with its business plans necessary for product development and marketing and implementation of the final regulatory responses.

Section 69506.2(c) provides that DTSC may revise the initial regulatory response(s) imposed for a product when the responsible entity alters their alternative selection decision within three (3) years after DTSC approves the Final AA Report. When this occurs, the responsible entity is required to submit a revised Final AA Report under section 69505.4(e). If DTSC determines that the regulatory responses need to be revised based on the revised alternative selection decision, DTSC must issue a proposed revised regulatory response determination notice within ninety (90) days after issuing the notice of compliance or notice of disapproval for the revised Final AA Report. This provision is necessary to allow DTSC to take appropriate action in response to a revised alternative selection decision that may render a previously imposed regulatory response as no longer appropriate. The prior regulatory response determination may not be necessary for the new alternative selection decision, and/or a

different or additional regulatory response may be necessary to adequately address the adverse impacts associated with the new alternative selection decision.

§ 69506.3. Product Information for Consumers

Section 69506.3, in its entirety, is necessary to implement and make specific Health and Safety Code section 25253(b)(3), which provides that permissible regulatory responses include "[i]mposing requirements on the labeling or other type of consumer product information." Additionally, this section achieves the requirements and purpose of the statute, and in particular the provisions of Health and Safety Code sections 25253(a)(1) and 25255(a) discussed above. More specifically, this section clearly delineates those circumstances that will give rise to the regulatory requirement that a responsible entity make product information available to consumers, and identifies the form and contents of the required consumer information.

This section is necessary to ensure that product information is provided to consumers for a Priority Product or its alternative that contains a Chemical of Concern or replacement Candidate Chemical. This information is necessary to make consumers aware of the presence of the chemicals, their known hazard traits, and required or recommended handling procedures so that consumers can consider this information when making their purchasing decisions and take appropriate actions following purchase.

Section 69506.3(a) specifies that the requirement to provide product information for consumers applies to all of the following products:

(1) Priority Products for which an alternative is not selected by the responsible entity at the conclusion of the AA;
(2) Priority Products that continue to be introduced into commerce in California pending development and distribution of an alternative product for longer than twelve (12) months after DTSC issues a notice of compliance or a notice of disapproval for the AA Report; and
(3) Selected alternative products that retain the Chemical(s) of Concern (i.e., the chemical(s) that is/are the basis for the product being listed as a Priority Product), and/or contain any replacement Candidate Chemical(s) (as defined in section 69501.1(a)(59)).

A product-chemical combination that is listed as a Priority Product has been determined by DTSC under Article 3 to pose potential exposures to the Chemical(s) of Concern in the product that can lead to potential adverse impacts. Therefore, if such a product will

continue to be in the California marketplace indefinitely (as in the case of products described in section 69506.3 (a)(1) above) or for an extended period of time (as described in section 69506.3 (a)(2) above), it is necessary as provided in this section to make available to consumers who purchase or are considering purchase of these products information as described below for section 69506.3(b) so that they may consider this information in making their product selection decisions and/or take appropriate and necessary precautions when using the product or discarding the product at the end of its useful life. Likewise, for these same reasons, this type of product information needs to be provided when a Priority Product is replaced by an alternative product that contains a Chemical of Concern or replacement Candidate Chemical. Requiring product information for consumers for the three categories of products identified in section 69506.3(a) is necessary to achieve the goals and objectives of the statute as articulated in Health and Safety Code sections 25253(a)(1) and 25255(a).

Section 69506.3(b) requires that the information specified in sections 69506.3(b)(1) through (b)(7), detailed below, must be made available to consumers by the date specified by DTSC in the final regulatory response determination for the product or when the product is first placed into the stream of commerce in California, whichever is later. The information must be provided for as long thereafter as the product continues to be placed into the stream of commerce in California, and must be provided in such a way that it is available to consumers prior to product purchase (see the options set forth in section 69506.3(c)). The information specified is necessary to ensure that consumers have basic information about the product, the harmful chemicals it contains, and product use safety measures when making purchasing decisions. It also informs consumers about any required special handling or disposition requirements at the end of the useful life of the product. The timing provisions in this section are necessary to ensure that information that is key to protecting both consumers and the environment from adverse impacts posed by a product is made available within a reasonable but relatively short period of time following completion of the AA (for Priority Products) or concurrent with introduction into the marketplace of the alternative selection decision, whichever is applicable.

Section 69506.3(b)(1) requires the product information to include identification of the manufacturer's name and importer's name, and/or any other entity listed on the product label. This information is necessary to allow DTSC to perform audits to determine compliance with this requirement. It is also necessary to assist consumers in readily connecting the product information (which may or may not be directly attached to the product) with the product to which the information applies.

Section 69506.3(b)(2) requires the product information to include the brand name(s), product name(s), and a description of the product. This provision is also necessary to ensure that consumers know which product the information pertains to, and enables consumers to look up additional information about the product on the manufacturer's website. Without this information, consumers may not be able to distinguish one product from another because many products are seemingly similar, but may pose vastly different hazards.

Section 69506.3(b)(3) requires the product information to include a list of and common names for any Chemical(s) of Concern that remain in the product and/or any replacement Candidate Chemical(s) and known hazards traits and/or environmental or toxicological endpoints for those chemicals. In many cases, it may be that the only hazard traits known to the responsible entity providing the product information are those hazard traits identified by DTSC on the Priority Product listing for the product. Including this information with the product information makes it readily accessible to the consumer prior to product purchase and/or use.

This information is necessary to provide retailers and consumers with key information that will enable them to make informed purchasing and use decisions for products that contain harmful chemicals. Without this information, consumers may not be informed of the presence of these harmful chemicals and the hazards posed by those chemicals.

Section 69506.3(b)(4) requires the product information to include a statement informing consumers that a product must be disposed of or otherwise managed as a hazardous waste at the end of its useful life, if applicable. This provision is necessary to provide information to consumers to enable them to make informed purchasing decisions and allow them to take into account and comply with any special requirements for products that must be managed as a hazardous waste at the end of their useful lives. Informing consumers of hazardous waste management requirements is a critical piece of information on which consumers may act. Without this information, consumers may not know of the existence of the hazardous waste management requirements, and may not discard of their products in a manner that complies with hazardous waste laws and that is protective of public health and the environment.

Section 69506.3(b)(5) requires the product information to include identification of safe handling and storage procedures needed to protect public health or the environment during the useful life of the consumer product, including precautions that consumers may take to prevent or limit exposure to the Chemical(s) of Concern or replacement Candidate Chemical(s), and first aid and accidental release procedures. Consistent with the statutory goals, this provision is necessary to prevent/minimize mishandling by

consumers of products containing harmful chemicals in a manner that may lead to adverse public health and/or environmental impacts.

Section 69506.3(b)(6) requires the product information to include identification of any end-of-life management requirements specified by law and any existing end-of-life management programs for the product. This provision is necessary to enable consumers considering purchase of the product to be made aware of any available options and restrictions for the product at the end of its useful life and to make consumers aware of existing end-of-life management requirements and programs to assist them in ensuring the product is safely and properly managed at end-of-life. Section 69506.3(b)(4) and section 69506.3(b)(6) work together to ensure the product is properly disposed of at the end of its useful life. This provision is necessary to ensure that consumers are aware of end-of-life programs, thus making compliance far easier and more likely. Consistent with the statutory goals, this provision is necessary to prevent/minimize mishandling by consumers of products containing harmful chemicals at the end-of-life in a manner that may lead to adverse public health and/or environmental impacts, and/or increased costs to society to avoid or address these adverse impacts.

Section 69506.3(b)(7) requires the product information to include identification of the manufacturer's website address and importer's website address where the consumer can obtain additional information about the product, the adverse public health and environmental impacts associated with the product, and proper end-of-life disposal or management for the product. This provision is necessary to allow consumers to know where they can obtain additional information about the safety issues and handling of the product that are not made available with the product at the point of purchase. This provision is necessary to further advance the objective of enabling informed consumer purchasing decisions and safe and appropriate handling by consumers of products containing harmful chemicals so as to protect public health and the environment.

Section 69506.3(c) requires the responsible entity to provide the product information required under section 69506.3(b) by making the information available to consumers in an easily understood, seen, and legible format, by both: **(1)** posting the information in a prominent place on the manufacturer's website and the importer's website; and **(2)** using one or both of the following means to provide the information to consumers at the point of sale:

(A) Providing the required information on the product packaging or in accompanying written material that is accessible without breaking the product seal; and/or

(B) Posting the information in a prominent place at the point of retail display – for products offered for sale online, the point of retail display is/are the web page(s) on which the product is offered for sale.

This section is necessary to ensure that, in all cases, the information is easily seen, legible, and understandable to the consumer. Product information that does not meet these standards is unlikely to achieve the objective of this regulatory response as explained above. This provision ensures that the required information is useful to the consumer and is made readily available and visible to the consumer prior to purchase, while at the same time providing flexibility in how this is achieved so as to accommodate the wide variability (e.g., shape, size, structure and packaging) among the range of product types that may be subject to this regulatory response. This provision also reflects the reality that, with respect to certain product types, on-product label requirements may be preempted by federal law, necessitating other means of providing the required information to consumers prior to purchase. This section is necessary to provide a reasonable mechanism for making the information available to consumers prior to product purchase so that consumers can make an informed purchasing decision taking into account the information listing in section 69506.3(b).

§ 69506.4. Use Restrictions on Chemicals and Consumer Products

Section 69506.4 is necessary, in its entirety, to implement Health and Safety Code section 25253(b)(4), which provides that permissible regulatory responses include "[i]mposing a restriction on the use of the chemical of concern in the consumer product." Specifically, this section provides that DTSC may impose restrictions on: (i) Chemicals of Concern or replacement Candidate Chemicals in a selected alternative; (ii) Chemicals of Concern in a Priority Product for which an alternative is not selected; or (iii) the use of the product itself. DTSC must base a restriction on its determination that the restriction is necessary to reduce the potential for the product to contribute to or cause adverse impacts and/or waste and end-of-life effects. Sections 69506.4(a) through (f) described immediately below are all types of use restrictions that DTSC may impose.

Section 69506.4(a) specifies that DTSC may impose a use restriction that would limit the amount or concentration of the Chemical of Concern or replacement Candidate Chemical permitted in a product. These use restrictions may be necessary and appropriate in instances in which some amount of the chemical appears to be functionally necessary, but a reduced concentration would reduce or eliminate adverse impacts and still meet functionality requirements. This provision provides a necessary flexibility to allow for the use of Chemicals of Concern or replacement Candidate

Chemicals at a reduced concentration without adversely impacting public health and the environment.

Section 69506.4(b) specifies that DTSC may impose a restriction on the settings in which a product may be sold or used. As an example, restricting use of a product to industrial or commercial settings may be appropriate when engineering controls – such as specialized ventilation equipment – are necessary to limit exposure to the Chemical(s) of Concern or replacement Candidate Chemical(s) in the product. Such controls would not be feasible in a residential setting, and thus retail sale of the product for home use might be restricted or prohibited. This provision provides a necessary flexibility to allow for the use of Chemicals of Concern in specific settings that have the appropriate engineering or other controls to limit exposure and/or environmental impacts.

Section 69506.4(c) specifies that DTSC may impose a use restriction on the form in which a product is sold. A restriction on sale of one or more product forms might consist of, for example, a restriction on the sale of a product in concentrated form or aerosol form, since these forms might present greater exposure or toxicity concerns. This provision provides a necessary flexibility that allows for DTSC to impose use restrictions on a case-by-case basis based on the adverse impacts and/or exposure concerns that may vary depending on the form in which a product may be sold and used.

Section 69506.4(d) specifies that DTSC may impose a restriction on the persons who may purchase and/or use a product. Such a restriction might include, for example, a requirement that the product is sold to adults only, or that it is sold only to licensed professional users. This provides DTSC the necessary flexibility to determine on a case-by-case basis when a use restriction based on the risks to particular types of end users is appropriate.

Section 69506.4(e) specifies that DTSC may impose a restriction that requires training of product purchasers and/or users. This provides the necessary flexibility to allow DTSC to determine that a product may be appropriately used by a sector of the population if the users are properly trained in safe use and/or handling procedures.

Section 69506.4(f) specifies that DTSC may impose any other use restriction that reduces the amount of any Chemical(s) of Concern or replacement Candidate Chemical(s) in the product, or reduces the potential for the product to contribute to or cause exposures to these chemicals. This provision is necessary to give DTSC the latitude to evaluate products on a case-by-case basis to determine if restrictions other

than those enumerated in sections 69506.4(a) through (e) are needed to provide necessary public health and environmental safeguards with respect to a product.

§ 69506.5. Product Sales Prohibition

Section 69506.5, in its entirety, is necessary to implement and make specific Health and Safety Code section 25253(b)(5), which provides that regulatory responses may include "[p]rohibiting the use of the chemical of concern in the consumer product." Section 69506.5 specifies the conditions and requirements for a product sales ban – which DTSC has determined is the most effective regulatory mechanism to effectively prohibit the use of a chemical in a consumer product, as called for by Health and Safety Code section 25253(b)(5). This includes clearly identifying those circumstances that trigger a product sales ban. This section also provides an option for responsible entities that would otherwise be required to implement such a ban to instead submit a revised Final AA Report. This section also helps DTSC to effectuate other requirements and purposes of the statute, in particular the provisions of Health and Safety Code section 25255(a) discussed above. Specifically, this section applies to products containing replacement Candidate Chemicals, not just Chemicals of Concern, so that DTSC may use this regulatory response to address adverse impacts and exposures associated with replacement Candidate Chemicals in alternative products when the conditions specified in this section apply.

Section 69506.5(a) specifies that unless section 69506.5(c) applies, DTSC may require a responsible entity to stop placing into the stream of commerce in California either of the following: (i) a selected alternative product containing one or more Chemical(s) of Concern or replacement Candidate Chemical(s); or (ii) a Priority Product for which an alternative is not selected. In order to impose this regulatory response DTSC must provide a regulatory response determination notice under section 69506.1 that includes a determination that a functionally acceptable, technically feasible, and economically feasible safer alternative exists that does not contain the Chemical(s) of Concern or replacement Candidate Chemical(s). In addition, DTSC must consider the potential adverse impacts and potential exposure pathways associated with the pertinent product. This provision is necessary in order for DTSC to be able to impose a product sales ban when a known safer viable alternative exists, but the responsible entity chooses not to use this safer alternative. The purpose of this entire program would be thwarted if DTSC could not impose a product sales prohibition in those circumstances.

Section 69506.5(b)(1) provides that even if there is no existing safer alternative that is functionally acceptable, technically feasible, and economically feasible, DTSC may issue a regulatory response determination notice imposing a product sales prohibition,

unless section 69506.5(c) applies. The criteria for DTSC to impose a product sales prohibition, notwithstanding the fact that there is no safer viable alternative, are addressed in section 69506.5(b)(2)(A) and (B). That is, DTSC may impose this regulatory response based on its determination that the overall beneficial public health and/or environmental impacts and/or social utility of the product do not significantly outweigh the overall adverse impacts of the product; and that administrative and/or engineering restrictions on the nature and/or use of the product will not adequately protect public health and the environment. This provision is necessary to provide DTSC with an effective mechanism to protect public health and the environment with respect to a product that has overall adverse impacts (that cannot adequately be mitigated) that outweigh its overall benefits.

Section 69506.5(b)(2) specifies that prior to issuing a regulatory response determination notice under section 69506.5(b)(1) prohibiting the sale in California of a product for which there is no safer viable alternative, DTSC must request that the responsible entity provide information within sixty (60) days that demonstrates to DTSC's satisfaction both of the following:

(A) **T**he overall beneficial public health and/or environmental impacts of the product significantly outweigh its overall adverse public health and environmental impacts; and
(B) Administrative and/or engineering restrictions on the nature and/or use of the product will adequately protect public health and the environment.

These provisions reflect the reality that not all products are of equal social utility, and the level of chemical exposure risk that may be acceptable in, for example, a lifesaving medical device or a safety-critical machine part may reasonably be higher than the level of chemical exposure risk acceptable in, for example, a children's novelty item. This regulatory provision merely makes explicit what is generally implicit in product regulatory programs; namely, that the nature of regulation must be tailored in part to reflect the degree of societal necessity of maintaining a given product in the consumer marketplace. The 60-day period specified is sufficient time for a responsible entity to provide information that would already be in existence on the overall benefit of a product and the existing administrative or engineering controls that would adequately mitigate adverse public health and environmental impacts. This provision is necessary to provide DTSC the authority to impose a product sales ban in circumstances that warrant this regulatory response. It is also necessary to allow responsible entities the opportunity to demonstrate to DTSC, prior to DTSC making such a sales ban determination, that the product benefits outweigh its adverse impacts and that the adverse impacts can be can be adequately mitigated through restrictions.

Section 69506.5(b)(3) specifies that DTSC may issue a notice under section 69506.5(b)(1) prohibiting the sale of a product in California, if the responsible entity does not provide the requested information within sixty (60) days or if the information submitted does not demonstrate to DTSC's satisfaction that the criteria under sections 69506.5(b)(2)(A) and (B) have been met. This provision, in combination with the provisions of section 69506.5(b)(1) and (2), make explicit the requirements that a responsible entity must meet to avoid a sales ban for a product for which there is no safer viable alternative if it is notified by DTSC that the product may become subject to a product sales ban. If the responsible entity does not provide the requested information by the deadline or fails to make the required demonstration, DTSC may issue a regulatory response determination notice imposing a product sales ban. This provision is a companion provision to sections 69506.5(b)(1) and (2) and is necessary for the same reasons as those provisions.

Section 69506.5(c) specifies that a responsible entity for a product that is the subject of a regulatory response determination notice under section 69506.5(a) or (b) is not subject to the requirements of section 69506.5(a) or (b) if all of the conditions in section 69506.5(c)(1) through (c)(3) are met. This provision is necessary to give a responsible entity that wishes to avoid a product ban, the opportunity to do so by investing the time and resources to provide a revised Final AA Report. This option is necessary to foster the goal of introducing safer products into the California marketplace.

Section 69506.5(c)(1) specifies that, within sixty (60) days after a regulatory response determination notice is issued under section 69506.5(a) or (b), a responsible entity wishing to avoid a product ban must notify DTSC of its intent to submit a revised Final AA Report that selects an alternative that does not contain the Chemical(s) of Concern or the replacement Candidate Chemical(s). This provision allows DTSC to be informed of the responsible entity's decision to submit a revised Final AA Report in lieu of implementing a product sales ban. This is necessary so that DTSC is alerted to monitor the responsible entity's compliance with the revised Final AA Report requirement rather than the product sales ban requirement.

Section 69506.5(c)(2) specifies that a responsible entity wishing to avoid a product ban must submit a revised Final AA Report to DTSC by the date specified by DTSC in the final regulatory response determination notice issued under section 69506.1. The revised Final AA Report must select an alternative that does not contain the Chemical(s) of Concern or the replacement Candidate Chemical(s), and that fully meets the requirements of section 69505.7. A responsible entity could satisfy this requirement by revising pertinent sections of the previously completed and submitted Final AA

Report. This provision ensures that if the product sales ban is essentially waived, the responsible entity does in fact take the steps necessary to place a safer product into the California marketplace that eliminates the chemicals whose presence lead to the DTSC determination giving rise to the products sales ban. This provision also works to ensure that responsible entities given this second chance do not use it to unduly delay fulfillment of the condition tied to this second chance – submission of a revised Final AA Report.

Section 69506.5(c)(3) specifies that a responsible entity wishing to avoid a product sales ban must no longer place the product containing the Chemical(s) of Concern or the replacement Candidate Chemical(s) into commerce in California, whether directly or indirectly, by the date specified by DTSC in the final regulatory response determination notice issued under section 69506.1. This provision is necessary to ensure that the responsible entity for a product containing the Chemical(s) of Concern or the replacement Candidate Chemical(s) that warrant a product sales ban takes timely action to remove the product from the marketplace if the responsible entity is seeking to avoid a product sales ban under the provisions of section 69506.5(c). The exception provided in section 69506.5(c) is a logical exception to the product sales prohibition. If a responsible entity complies with sections 69506.5(c)(1) through (c)(3) and the product containing the Chemical(s) of Concern and/or the replacement Candidate Chemical(s) is no longer placed into the stream of commerce in California, then the concerns that led to it being listed as a Priority Product or that arose from the replacement Candidate Chemical(s) are no longer present.

Section 69506.5(d)(1) specifies that a responsible entity may request an extension to the due date for the revised Final AA Report to be submitted under section 69506.6(c), using the procedures specified in section 69505.1(c) or section 69505.7(k)(1)(B). This provision provides the necessary flexibility to accommodate unexpected delays that warrant an extension.

Section 69506.5(d)(2) specifies that if DTSC grants an extension, the responsible entity must satisfy one of the following requirements by the due date specified in the extension approval:

- **(A)** Submit a revised Final AA Report meeting the requirements of subsection 69506.5(c)(2); or
- **(B)** Cease placing the product into the stream of commerce in California.

This provision is necessary to ensure that if the product sales ban is essentially waived, the responsible entity does in fact take the steps necessary to place a safer product into

the California marketplace and to fulfill the conditions that are the basis for the waiver. This provision is also necessary to ensure that responsible entities given this second chance do not use it to unduly delay fulfillment of the condition tied to this second chance – submission of a revised Final AA Report.

§ 69506.6. Engineered Safety Measures or Administrative Controls

Section 69506.6(a*)* specifies that DTSC may require a manufacturer to use engineered safety measures that integrally contain or control access to, and/or implement administrative controls that limit exposure to, the Chemical(s) of Concern or replacement Candidate Chemical(s), so as to reduce potential adverse public health and/or environmental impacts.

Controlling and/or eliminating hazards through engineered safety measures could include permanent workplace modifications or redesign of the product to limit public and/or environmental exposures that could lead to adverse impacts. Engineered measures may be coupled with administrative controls that could include training or information dissemination for maximum effectiveness. For example, a Priority Product might be required to be placed behind a store counter for sale, or dispensed only by an informed intermediary who can explain relevant risks to purchasers (forms of administrative control). As another example, a product might be required to have a childproof cap or other packaging designed to deter improper use. This provision is necessary to implement and make specific the provisions of Health and Safety Code section 25253(b)(6), which provides that regulatory responses may include "[i]mposing requirements that control access to or limit exposure to the chemical of concern in the consumer product."

Section 69506.6(b) specifies that DTSC may impose engineered or administrative controls if any of the conditions in sections 69506.6(b)(1) through (b)(3), detailed below, apply. This provision is necessary to identify the appropriate set of circumstances under which engineered safety measures and/or administrative controls may be imposed. Those circumstances include: (i) the presence of a Chemical of Concern or a replacement Candidate Chemical in a particular subpopulation; (ii) information demonstrating the occurrence of a Chemical of Concern or replacement Candidate Chemical in an indoor building or other enclosed environment; and/or (iii) the improper handling of the product increases the potential for release of the chemicals or exposure to the chemicals. These are described in greater detail immediately below.

Section 69506.6(b)(1) specifies that if reliable information indicates the presence of a Chemical of Concern or replacement Candidate Chemical, or its degradate, metabolite,

or reaction product, in a particular subpopulation that has one or more routes of exposure to the chemical, DTSC may mandate an engineered or administrative control to prevent or reduce exposures to the chemical(s). This provision is necessary to allow DTSC to use this regulatory response to protect sensitive subpopulations, and to identify the information necessary to a determination by DTSC that engineered and/or administrative controls are required to protect sensitive subpopulations. This is consistent with the protection of sensitive subpopulations throughout the regulations and the authorizing legislation.

Section 69506.6(b)(2) specifies that if reliable information indicates an elevated level of the Chemical(s) of Concern or replacement Candidate Chemical(s) in an indoor building or other enclosed environment, DTSC may mandate an engineered or administrative control to prevent or reduce exposures to the chemicals. Exposures in these settings may be especially deleterious to public health. Examples of enclosed environments that are not buildings include the ordinarily inhabited spaces of a motor vehicle, train, ship, or airplane. This provision is necessary to allow DTSC to use this regulatory response to address adverse public health impacts arising from exposures to a Chemical of Concern or replacement Candidate Chemical in enclosed environments, and to identify the information necessary to a determination by DTSC that engineered and/or administrative controls are required for this purpose.

Section 69506.6(b)(3) specifies that if improper handling of a product would increase the potential for release of, or exposure to, a Chemical of Concern or replacement Candidate Chemical, DTSC may require engineered and/or administrative controls. This provision is necessary to provide DTSC with the ability to use this regulatory response to ensure that a product is appropriately managed throughout its life cycle so as to protect public health and the environment.

§ 69506.7. End-of-Life Management Requirements

Section 69506.7, in its entirety, is necessary to implement and make specific Health and Safety Code section 25253(b)(7), which provides that regulatory responses may include “[i]mposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product.” Additionally, this section allows DTSC to satisfy the requirements and purposes of the authorizing statute, in particular Health and Safety Code sections 25253(a)(1) and 25255(a), as discussed above in the introductory statement for Article 6. More specifically, this section clearly demarcates those circumstances that trigger the regulatory response requiring a manufacturer to provide an end-of-life management

program for a product, and identifies the required elements of the end-of-life management program.

The requirements of this section apply to products that are sold to consumers as finished products and that are required to be managed as hazardous waste at the end of the product's useful life. The requirements of this section are necessary to build on, but do not duplicate or conflict with, existing regulatory requirements for products that must be handled as hazardous wastes at the end of their useful lives. For many of these products, there are no end-of-life management programs in place, whether mandatory or voluntary – this places a logistical burden and financial hardship on local and State agencies, and ultimately taxpayers, to provide for management of these products at the end of their useful lives.

Additionally, the lack of an adequate end-of-life management program often leads to illegal end-of-life disposal practices that result in adverse public health and environmental impacts. (As an example, only a small fraction of Californians disposes of their mercury-containing Compact Fluorescent Light (CFL) bulbs at a hazardous waste collection facility, as is required by law.) This regulatory provision is necessary to describe the situations in which comprehensive product stewardship programs are required and to specify the elements that must be included in a DTSC-mandated product stewardship program. These provisions are based in part on guidance provided by the Association of State and Territorial Solid Waste Officials, the California Department of Resources Recycling and Recovery, and the California Product Stewardship Council. These provisions are meant to address both the environmental impact of products, and the fiscal impacts of waste management on local and State governments and taxpayers. These provisions provide a comprehensive yet flexible method for managing products that may have significant adverse impacts on public health and the environment if not properly managed at end-of-life.

Section 69506.7(a) requires a manufacturer of a selected alternative, or a Priority Product for which the responsible entity does not select an alternative, that is sold to consumers as a finished product and is required to be managed as a hazardous waste at the end of its useful life, to comply with the requirements of subsection (c), except as provided under subsections (d) and (e). Thus, this provision is necessary to establish the entity that is responsible for the duties that follow in this section – the manufacturer; and to establish the scope of activities that trigger the enumerated duties – a finished product that must be managed as a hazardous waste at the end of its useful life. Without this provision, these products would continue to place a financial hardship on local and State governments, and ultimately taxpayers, to provide for management of these products at the end of their useful lives.

Section 69506.7(b) specifies that a manufacturer may individually fulfill these end-of-life management requirements, or may join with other manufacturers to form a non-profit third-party product stewardship organization, funded by participating manufacturers, to fulfill these requirements on behalf of the participating manufacturers. This provision is necessary to provide the necessary flexibility for manufacturers to collaborate with other manufacturers to implement an end-of-life management program. The flexibility and critical mass that may result from collaboration are intended to incentivize the creation of more effective end-of-life programs than may occur if a manufacturer were required to act independently. While manufacturers are encouraged to participate in and/or form a consortium, collaborative, and/or similar partnership to offset costs – particularly if the manufacturer is a small to medium enterprise – it is not required. The option provided by this section is limited to non-profit third-party product stewardship organizations. This was determined necessary based on the experience of existing programs, which showed the programs operated by these types of organizations to be the most effective and sustainable.

Section 69506.7(c) requires a manufacturer, no later than the date specified by DTSC in the final regulatory response determination notice for the product, or no later than the date the product is first placed into the stream of commerce in California, whichever is later, to establish and maintain an end-of-life management program for the product in compliance with sections 69506.7(c)(1) through 69506.7(c)(5). In an effort to accommodate the broad range of products subject to these requirements, the regulations do not stipulate a specific amount of time for establishing and funding an end-of-life management program, but instead allow DTSC to issue a due date on a case-by-case basis. This section is necessary to implement and make specific Health and Safety Code section 25253(b)(7), which requires these regulations to include a regulatory response requiring manufacturers to manage their products at end-of-life. The provisions set out in sections 69506.7(c)(1) through (c)(5) are necessary to inform manufacturers of the required elements to establish an effective end-of-life management program as required under this section, and are discussed in greater detail below.

Section 69506.7(c)(1) requires the manufacturer to develop and submit to DTSC for approval a comprehensive product stewardship plan, and to maintain the plan after it is approved by DTSC. If DTSC disapproves the plan, DTSC will notify the manufacturer in writing, identifying what is necessary to correct deficiencies in the plan, and specifying a due date for submission of a revised plan. If the plan is not resubmitted by the due date or does not address all of the deficiencies, the plan will be considered to be non-compliant. Product-specific stewardship plans are necessary to provide retailers,

consumers, collection facilities, and local government with the information required for a successful end-of-life collection plan. It is also necessary that there be a plan approval process to ensure that the product stewardship program set forth in the plan complies with this section and is appropriate and workable. There must also be consequences for failure to comply with this requirement.

Section 69506.7(c)(2) specifies the elements that a product stewardship plan must include. These elements are collectively necessary to ensure that the manufacturer has an effective product stewardship plan. Product stewardship plans must include all of the information specified in sections 69506.7(c)(2)(A) through (M) described immediately below:

(A) A list of, and contact information for, participating manufacturers, importers, and other participating persons. This provision is necessary to identify the persons responsible for the product stewardship plan, and so that DTSC knows which manufacturer(s) is/are meeting their section 69506.7 obligations under each plan. This information will also be useful to DTSC should it decide to convene various manufacturers and interested parties to develop programs for similar products, thus saving resources for participating parties.

(B) The scope of products and brands to be covered by the plan. This provision is necessary to ensure that the range of products covered by the plan are appropriate and well-defined for the benefit of all affected parties, including DTSC, manufacturers, retailers, consumers, and other interested parties. This information is necessary so that DTSC knows which products subject to the requirements of section 69506.7 are covered by the plan and thus are in compliance with the regulations.

(C) The roles and responsibilities for manufacturers, importers, assemblers, retailers, consumers, and government throughout the life cycle of the product; and identification of the retailers and/or assemblers that have agreed to participate in the end-of-life management program. Defining roles that manufacturers and other entities will play and knowing who these participants are is essential to hold the various parties accountable and ensure the success of the product stewardship program. This will help to ensure that all necessary roles and responsibilities are clearly assigned, and will inform all participants as to which parties they need to work with in implementing each aspect of the plan. While government can assist in bringing the parties together, it is ultimately the responsibility of the manufacturers to ensure that the plan is effective in reaching its stated goals.

(D) Identification and description of the collection systems that will be used. This provision is necessary to identify potential opportunities for government and other entities to assist multiple responsible parties in meeting their mutual collection needs. It is also necessary for DTSC to monitor the effectiveness of the various collection systems that are used.

(E) End-of-life management information that addresses any adverse multimedia impacts, and that identifies what steps will be taken to ensure compliance with all applicable federal and California State and local laws. This provision is necessary to: (i) assess the assumptions underlying the plan; and (ii) ensure the plan has assessed and addressed applicable regulatory requirements, and any potential multimedia adverse environmental impacts.

(F) Identification of anticipated resources needed to implement and sustain the plan – which must ensure that the end-of-life management program is maintained for sufficient time to be available at the end-of-life for the last covered product, and all previously covered products, that the manufacturer places into the stream of commerce in California. The manufacturer must provide an estimate of the annual and total long-term program costs along with the information, assumptions, calculations, and any models used to develop the cost estimate. This provision is necessary to ensure that end-of-life programs are properly and fully funded and to enable DTSC to monitor compliance with the plan requirements, including proper funding.

(G) The funding mechanism to cover the costs identified in section 69506.7(c)(2)(F) which shall be satisfied by whichever of the following means is applicable:

1. If the end-of-life management program will be administered by a non-profit third-party product stewardship organization, the plan must identify and describe how the organization will collect operating revenues in an amount necessary to cover the costs, including the method and calculations for determining how much each participant will contribute. This section builds on section 69506.7(b), which provides that multiple manufacturers may form a third-party product stewardship organization, funded by participating manufacturers, to provide the collection, recycling, and other services necessary to appropriately manage covered products and ensure compliance with section 69506.7. This provision is necessary to enable DTSC to assess the financial assumptions under which the plan is being developed, and to ensure that responsibility for financing the product stewardship program is appropriately assigned to participating

manufacturers. This, in turn, is necessary to ensure that the program is appropriately and fully funded.

2. If an individual manufacturer is administering and funding its own end-of-life management program, the manufacturer must provide a financial guarantee that will ensure that adequate funding is available to cover the costs identified in section 69506.7(c)(2)(F). This provision is necessary to ensure that products for which an end-of-life management program is required will be handled properly, and in compliance with section 69506.7, regardless of the financial health or ongoing business status of the responsible manufacturer.

(H) Program performance goals, which shall be quantitative to the extent feasible, for:

1. Increasing the capture rate of products at the end-of-life; and

2. Increasing recyclability (e.g., reuse of the product at end-of-life for feedstock to manufacture new products) and recycling rate.

This provision is necessary to hold parties involved accountable for the success of the program, and to identify areas for improvement.

(I) A description of how each program goal will be achieved. This provision is necessary to ensure that the program is capable of meeting stated performance goals.

(J) Public education, outreach, and communications plans. This provision is necessary to ensure that the product stewardship plan takes into account and promotes consumer awareness, a critical component of the success of any end-of-life management program.

(K) A description of public and stakeholder consultation activities during preparation of the plan. The plan, at minimum, must be made available for thirty (30) days for public comment on the manufacturer's website and the comments received on the plan must be submitted to DTSC with the plan. This provision is necessary to ensure consultation with key stakeholders is held and taken into account in developing the plan that is submitted to DTSC for review and approval. Consultation and coordination with interested parties is essential to developing a successful product stewardship program.

(L) A description of public and stakeholder consultation activities for review and updating of the plan, which must occur no less frequently than annually. This

provision is necessary to ensure consultation with key stakeholders is held at a minimum annually and taken into account in ensuring the plan is being implemented, and revised as needed, so as to ensure the success of the program. Consultation and coordination with interested parties is essential to developing and maintaining a successful product stewardship program.

(M) Reporting and evaluation procedures. This provision is necessary to ensure that the program includes features essential to continual program evaluation and improvement.

Section 69506.7(c)(3) requires the product stewardship program and plan for collecting and, if applicable, recycling the product to be developed in consultation with California retailers and other owners/operators of potential collection sites. The establishment of effective and robust collection infrastructure is an essential element of an end-of-life management program. Accordingly, this provision is necessary to ensure the success of the end-of-life management program. For many products, this will require establishing collection sites that are operated by businesses other than the manufacturer. This provision provides manufacturers that are located out of state the flexibility to establish a program to be implemented by entities located in California who are willing to implement aspects of the program on behalf a manufacturer.

Section 69506.7(c)(4) requires the manufacturer to provide its product stewardship plan to DTSC for review and approval, post a copy of the product stewardship plan on its website, and provide a link to DTSC for posting on DTSC's website. Consumers increasingly consult web sites as information sources of first resort. It is, therefore, important and necessary to program success that consumers have access to basic information about the end-of-life program through the internet on both the manufacturer's website and DTSC's website. DTSC review and approval of the plan is necessary to ensure that the product stewardship program set forth in the plan complies with this section and is appropriate and workable.

Section 69506.7(c)(5) requires the manufacturer for a product subject to end-of-life management requirements to provide a report to DTSC annually. The annual report is due one (1) year from the date the end-of-life management program is required to be implemented, and annually thereafter. The report must include by total tonnage:

(A) The quantity of products placed into the California stream of commerce in the previous one-year period; and
(B) The quantity of products recovered in that one-year period.

This reporting requirement is necessary to provide DTSC with information necessary to conduct program performance evaluations to ensure attainment of performance goals for the end-of-life management program, and to evaluate the effectiveness of the regulatory response as a means of mitigating public health and environmental impacts.

Section 69506.7(d) specifies that a manufacturer subject to the end-of-life management program requirements may request DTSC's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent possible, the same results as the program required by section 69506.7. If the manufacturer's end-of-life management program will rely on other persons to implement the program, the manufacturer must provide written substantiation (e.g., a contract) of their agreement to participate in the end-of-life management program at a level necessary to ensure successful implementation of the plan. A manufacturer may not implement an alternative plan in lieu of a plan as specified in section 69506.7 unless it receives advance written approval from DTSC. This provision is necessary to provide manufacturers the flexibility to use innovative and/or customized approaches to address the end-of-life management concerns associated with their products. Without this provision, manufacturers would be required to follow the same end-of-life management program that may or may not suit their individual needs. This section is also necessary to ensure that if the alternative end-of-life management program relies on the participation of other parties that those parties are committed to fulfilling their roles and responsibilities as set forth in the alternative plan. This is necessary to ensure the viability and success of alternative program. Additionally, the provisions of this section ensure that a manufacturer does not assume that their alternative plan will be approved by DTSC, and thus wastes resources beginning implementation of a program that is ultimately disapproved by DTSC.

Section 69506.7(e)(1) specifies that a manufacturer subject to the requirements of section 69506.7 may request an exemption by demonstrating to DTSC's satisfaction in the AA Report that an end-of-life management program cannot feasibly be implemented for its product. This provision is necessary because there may be products that would otherwise be subject to the requirements of section 69506.7 for which an end-of-life management program cannot feasibly be implemented because of some unique characteristic of, or circumstance associated with, the product that was not brought to DTSC's attention prior to the issuance of the final regulatory response determination notice for the product. This provision provides a logical exemption to the end-of-life management program requirements of section 69506.7 in the event unforeseen circumstances are encountered.

Section 69506.7(e)(2) specifies that a manufacturer who has requested an exemption from end-of-life management program requirements is not exempt from these requirements until it receives written concurrence from DTSC that such a program cannot be feasibly implemented for its product. This provision is necessary to ensure that a manufacturer who submits an exemption request does not make business decisions and plans based on a potentially faulty assumption that DTSC will approve the exemption request. Unless and until the manufacturer receives an exemption approval from DTSC, the manufacturer needs to be prepared to comply with the requirements of section 69506.7.

§ 69506.8. Advancement of Green Chemistry and Green Engineering

Section 69506.8 specifies that when a manufacturer concludes that no safer alternative to its Priority Product is functionally acceptable, technically feasible, and economically feasible, or a manufacturer selects an alternative that reduces but does not eliminate the use of Candidate Chemicals in the product, DTSC may require a manufacturer to initiate a research and development project or fund a challenge grant pertinent to the Priority Product. A project or grant required under this provision would be required to use green chemistry and/or green engineering principles to achieve one or more of the objectives identified in sections 69506.8(a) through (d):

- **(a)** Designing a safer alternative to a Priority Product – for example, a product without Chemicals of Concern;
- **(b)** Improving the performance of a safer alternative to the Priority Product – for example, by improving its function or extending its useful life;
- **(c)** Decreasing the cost of a safer alternative to the Priority Product – for example, by optimizing production methods or increasing the scale of production; and/or
- **(d)** Increasing market penetration of a safer alternative to the Priority Product.

This provision is necessary to implement and make specific Health and Safety Code section 25253(b)(8), which provides that DTSC's regulatory responses may include "[i]mposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists." It is also necessary to provide clarity to the regulated community as to the possible objectives of these challenge grants or research and development projects.

§ 69506.9. Exemption from Regulatory Response Requirements

Section 69506.9, in its entirety, specifies the conditions for and the process by which a responsible entity may obtain an exemption from the requirements of Article 6. This

section provides a process for a responsible entity to request an exemption from otherwise applicable regulatory responses. There are two separate bases for obtaining an exemption. The first basis is that the request must demonstrate that the regulatory response would conflict with a requirement of another California or federal regulatory program or a treaty or international trade agreement such that the responsible entity could not reasonably be expected to comply with both requirements. The other basis for obtaining an exemption is a demonstration that the required regulatory response substantially duplicates a requirement of another regulatory program and does not provide additional public health or environmental protection. In the first instance, DTSC may require implementation of a modified regulatory response to resolve the conflict. This provision is necessary to effectuate the non-conflict/non-duplication prohibition in the authorizing statute (Health and Safety Code section 25257.1(c)). It is also necessary to establish a workable program that does not: (i) place responsible entities in the untenable position of having to simultaneously implement two conflicting regulatory requirements; or (ii) waste government or private resources implementing unnecessary duplicative regulatory requirements.

Section 69506.9(a) specifies that a product is exempt from the requirements of sections 69506.3 through 69506.8 if the responsible entity requests, and DTSC grants, an exemption. The exemption request must be submitted to DTSC no later than sixty (60) days after DTSC issues a final regulatory response determination notice for the product.

After completing review of the Final AA report, DTSC must make a determination of compliance with Article 5 requirements and notify the responsible entity of any proposed regulatory response(s) to mitigate any adverse impacts. Pursuant to section 69506.1, DTSC must send a notice of its proposed determination that one or more regulatory responses is required, or that no regulatory response is required. After receiving and considering public comments, DTSC will issue a final regulatory response determination notice. A responsible entity seeking an exemption from a regulatory response, must file its exemption request within sixty (60) days of DTSC's sending the notice for the final regulatory response determination. The period specified is sufficient for a responsible entity to request an exemption, and ensures that the exemption request and regulatory response processes are completed in a timely manner. This is necessary so as not to significantly delay implementation of a regulatory response if DTSC denies the requested exemption. This provision is necessary to have a reasonable and known period of time in which a responsible entity may request an exemption. Note that while an exemption request must be submitted no later than sixty (60) days after a final regulatory response determination notice is issued a responsible entity is not precluded from seeking an exemption prior to DTSC issuing its final regulatory response determination.

Section 69506.9(b) specifies that a request for an exemption from a required regulatory response must include all of the information listed in sections 69506.9(b)(1) through (b)(6), which are described below. The information required by section 69507.9(b) is necessary in total for DTSC to make a factually and legally informed decision whether to grant an exemption request.

(1) The name of, and contact information for, the person filing the request. This information is necessary should DTSC need to contact the filer.

(2) The name of, and contact information for, the person(s) on whose behalf the exemption request is being submitted. This information is necessary should DTSC need to contact the responsible entity on whose behalf the exemption is sought, and so that DTSC and interested parties know which responsible entity's product is the subject of the exemption request.

(3) The name of, and contact information for, the manufacturer and importer of the product (if different from the persons identified in (1) and (2)). This information is necessary should DTSC need to contact the manufacturer or importer of the product, and so that DTSC and interested parties know which manufacturer's and importer's product is the subject of the exemption request.

(4) The name of, and contact information for, any other responsible entity for the product, to the extent known to the person submitting the exemption request. This information is necessary should DTSC need to notify other responsible entities, and so that DTSC and interested parties know which responsible entities' products are the subject of the exemption request.

(5) Information identifying and describing the product, including the brand name(s) and product name(s) under which the product is placed into the California stream of commerce, and, if the product is a component of one or more assembled products, a description of the known products in which it used. This information is necessary to distinguish the product or component that is the subject of the exemption request from other similar products/components and for DTSC to understand the background, implications, and consequences of granting or denying the exemption request.

(6) Information that demonstrates to DTSC's satisfaction that one or both of the following conditions applies:

(A) The required or proposed regulatory response would conflict with a requirement of another California or federal regulatory program, or a treaty or international trade agreement with the force of domestic law, in such a way that the responsible entity could not reasonably be expected to comply with both requirements; and/or

(B) The required or proposed regulatory response substantially duplicates a requirement of another California or federal regulatory program, or a treaty or international trade agreement with the force of domestic law, without conferring additional public health or environmental protection benefits.

Section 69506.9(b)(6) is necessary to clearly inform responsible entities and other interested parties as to the qualifying conditions for an exemption, and to implement Health and Safety Code section 25257.1(c) which provides that DTSC shall not adopt regulations that duplicate or conflict with existing regulations. Whether or not any DTSC regulatory response that would partially or wholly duplicate a substantive requirement imposed by another sovereign would confer "additional public health or environmental protection benefits" under section 69506.9(b)(6) will be determined by examining the scope and stringency of the other existing requirements.

Section 69506.9(c) specifies that within sixty (60) days of receiving an exemption request, DTSC must issue a notice to the person who submitted the request granting or denying it. A copy of the notice must also be sent to any responsible entity known to DTSC. This provision should provide a reasonable time period for DTSC to review and act on an exemption request, and is necessary to ensure that a determination is made on the exemption request in a timely manner so as not to significantly delay implementation of the applicable regulatory response in the event that DTSC denies the requested exemption. This provision is also necessary to ensure that DTSC provides adequate notice to affected responsible entities regarding regulatory response exemption determinations.

Section 69506.9(d) specifies that if the exemption request or DTSC's granting of an exemption is based solely on the criteria specified in section 69506.9(b)(6)(A), DTSC may require implementation of a modified regulatory response that resolves the identified conflict. This provision is necessary to provide DTSC the flexibility to impose regulatory responses to address adverse impacts, while at the same time resolving any potential conflict with another regulatory requirement unknown to, or insufficiently considered by, DTSC at the time of the initial regulatory response determination.

Section 69506.9(e) specifies that an exemption granted pursuant this section will be revoked if DTSC determines that the facts and/or assumptions that DTSC relied upon in granting the exemption were not, or are no longer, valid. If DTSC rescinds an exemption, DTSC must notify the person who submitted the exemption request and any affected responsible entity known to DTSC. This provision is necessary to make it clear that exemptions are not always permanent, and to ensure that responsible entities and

other interested parties are aware of the circumstances that could lead to revocation of an exemption. Specifically, revocation may become necessary if the information submitted in the exemption request is subsequently determined to be erroneous, or if the facts upon which the exemption was based change so as to no longer support an exemption.

Section 69506.9(f) specifies that all notices issued under this section granting, denying, or revoking an exemption must include a statement of the basis for DTSC's decision, and a new date for compliance with the regulatory response determination, if applicable. This provision is necessary to ensure that DTSC provides adequate notice to affected responsible entities and other interested parties of the bases for DTSC's determinations in response to regulatory response exemption requests. A responsible entity wishing to file a request for review (i.e., a dispute) under Article 7 concerning a DTSC exemption decision will need this information since a request for review must include a supporting statement of reasons and a showing that DTSC's decision is based on: (i) erroneous facts, assumptions, approaches, or conclusions of law; and/or (ii) a policy judgment that DTSC should reconsider.

§ 69506.10. Regulatory Response Report and Notifications

Section 69506.10, in its entirety, is necessary to: (i) hold responsible entities accountable for timely implementation of required regulatory responses and, if applicable, their selected alternative products; (ii) ensure that retailers are made aware of regulatory responses that affect the products they sell; and (iii) ensure that DTSC is kept apprised of the implementation status of required regulatory responses and, if applicable, selected alternative products. In total, the provisions of this section are a necessary component of the implementation of regulatory responses to address adverse impacts and achieve the goals of the statute.

Section 69506.10(a) requires a responsible entity for a product subject to a regulatory response to send a notice, informing notice recipients of the regulatory response(s) for the product, to: (i) persons in California, other than the final purchaser, to whom the responsible entity directly sells the product; and (ii) any other person, other than the final purchaser, to whom the responsible entity directly sells the product if it is reasonably foreseeable that the product will be placed into the stream of commerce in California. A copy of the notice must be sent to DTSC. The responsible entity must send the notice no later than thirty (30) days after receiving a final regulatory response determination notice.

This notification requirement does not apply for a regulatory response under section 69506.2 (supplemental information requirements) or section 69506.8 (research and development projects and challenge grants). This is because these two regulatory responses will not impact retailers and distributors, whereas the other regulatory responses have the likelihood or at least a possibility of having a direct or indirect impact on retailers and distributors.

The provisions of this section are necessary to:

- Inform California retailers and other parties who place products into the stream of commerce in California of the regulatory responses applicable the products they handle so that they can assess whether there are any actions they need or wish to take in light of the regulatory responses.
- Place a reasonable limit on the universe of persons who must be notified so as to avoid requiring unnecessary notices.
- Provide a reasonably adequate amount of time for responsible entities to issue their notices, and yet avoid undue delay in providing necessary information to retailers and other potentially affected parties.
- Provide DTSC with information needed for DTSC to conduct compliance reviews and take other actions to ensure compliance with regulatory response decisions.

Section 69506.10(b) specifies that the notice required under section 69506.10(a) must include all of the following information:

(1) Name of, and contact information for, the person providing the notification;
(2) Name of, and contact information for, the responsible entity(ies) on whose behalf the notification is being provided;
(3) Name of, and contact information for, the manufacturer and the importer of the product, if different from (1) and (2);
(4) Information identifying and describing the original Priority Product and the selected alternative, including the brand name(s) and product name(s) under which the product is sold or otherwise placed into the stream of commerce in California, and the name(s) of any persons identified as the manufacturer, importer, and/or distributor on the product label; and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used; and
(5) A description of the required regulatory response and the due date for implementation.

Collectively, the information required to be included in the notice is necessary to ensure that California retailers (and others who place products into the California marketplace) and DTSC are able to easily identify which specific products are affected by a regulatory response, so that retailers can make decisions with respect to actions they may wish to take in light of the regulatory response and DTSC can take steps to ensure compliance. This information is also necessary so that retailers and DTSC know whom to contact in the event of questions regarding a notice or implementation of a regulatory response. This is also necessary so that retailers know when they can expect to see the effects of regulatory responses impacting their products – again, so that they can plan according.

Section 69506.10(c) requires the responsible entity to notify DTSC upon completing implementation of the required regulatory response(s) and, if applicable, upon completing development and introduction of the selected alternative into the stream of commerce in California. The notification must include information describing how the regulatory response(s) was/were implemented. If requested by DTSC, the responsible entity must provide periodic implementation status reports regarding the selected regulatory response(s) and/or the development and introduction into the California marketplace of the selected alternatives. The information provided to DTSC under this subsection must also be posted on the responsible entity's website. This provision is necessary to keep DTSC, retailers, and other interested parties informed regarding the implementation status of required regulatory response(s), and the availability of alternative products in the marketplace. This information is also necessary to facilitate DTSC's compliance tracking, and its enforcement in the event that the responsible entity does not implement the regulatory response(s) by the specified due date.

Section 69506.10(d)(1) requires DTSC to prepare and post on its website, and update at least annually, a Regulatory Response Summary that identifies the regulatory response(s) for each selected alternative for a Priority Product, or for the Priority Product itself, whichever is applicable. The following information must be included in the Regulatory Response Summary:

- **(A)** Name of, and contact information for, the manufacturer(s) and importer(s);
- **(B)** Names of, and contact information for, any other responsible entities known to DTSC;
- **(C)** Information identifying and describing the original Priority Product and the selected alternative, if any, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California; the name(s) of any persons identified as the manufacturer, importer, and/or distributor on the product label; and, if the product is a component of one or

more assembled products, a description of the known product(s) in which the component is used;

(D) The due date and actual date for completing development and introduction into the California marketplace of the selected alternative(s), if any;

(E) The regulatory response(s), if any;

(F) The applicable section in Article 6 specifying the regulatory responses;

(G) The implementation due date(s), and the actual implementation date(s), for the regulatory response(s); and

(H) Any other information provided to DTSC under sections 69506.10(a) through (c).

This information is necessary to ensure that retailers and other persons in the product supply chain, and consumers, are kept fully informed as to:

- the requirements that apply to specific products, and how to identify those products;
- the implementation status for regulatory response(s), and any selected alternative products; and
- who to contact with questions.

Section 69506.10(d)(2) specifies that DTSC must also include in the Regulatory Response Summary the information specified in sections 69506.10 (d)(1)(A) through (D) for each exemption granted by DTSC under section 69506.9. This is necessary to inform retailers, others in the product supply chain, consumers, and other interested parties of products for which a regulatory response exemption has been granted so that these parties know not to expect implementation of a regulatory response determination for these products – and, thus, can plan accordingly.

ARTICLE 7. Dispute Resolution Processes

Article 7, in its entirety, describes the processes available to responsible entities who wish to dispute any of the enumerated actions of the Department of Toxic Substances Control (DTSC) that are subject to the administrative dispute resolution procedures set out in the article. Article 7 is necessary to allow responsible entities to bring further information to the attention of DTSC that may persuade DTSC to make a different decision from the one being disputed. Article 7 provides for a transparent and efficient process for seeking review of important DTSC decisions and actions under this chapter. By providing for both informal and formal dispute resolution processes, the article tailors the manner of review to the nature of the decision being disputed.

§ 69507. Dispute Resolution

Section 69507(a) specifies that the dispute resolution procedures set forth in this article are available for responsible entities that are subject to decisions made by DTSC under these regulations, except as provided in section 69507(c). This provision is necessary to specify who is eligible for dispute resolution and to limit dispute resolution to only those parties directly affected by DTSC's decisions—the responsible entities. Otherwise, implementation of the regulations would be inappropriately subject to unnecessary delay.

Section 69507(b) specifies that a responsible entity's failure to avail itself of the procedures in Article 7 constitutes a waiver of its right to further review of the disputed issue, either administratively or judicially, because the responsible entity has failed to exhaust its administrative remedies. This provision is necessary in order to put affected parties on notice of what constitutes exhaustion of administrative remedies, and what the implications are of failing to avail oneself of these procedures.

Section 69507(c) identifies the following DTSC actions as categories of action for which administrative dispute resolution procedures are *not* available – any decision of DTSC made under Article 2, 4, or 9. Decisions made under these articles are not appropriate for administrative dispute resolution. More specifically, Article 2 addresses the identification and listing of Candidate Chemicals. The entire program hinges on this basic determination of what is and is not a Candidate Chemical. If a responsible entity could challenge this determination, it could bring the whole program to a halt. In addition, no burdens are imposed on responsible entities by virtue of having a chemical identified as a Candidate Chemical. Article 4 establishes a petition process. DTSC could become overwhelmed and unable to administer the program if one could enter

into dispute resolution regarding an adverse decision on a petition. Additionally, no burdens are imposed on responsible entities as a direct result of a decision granting or denying a petition. Finally, Article 9 sets out trade secret procedures and time frames. In effect, it has a stand-alone process for pursuing relief. And DTSC could not properly carry out its duties under the Public Records Act if it could not release records that were caught up in dispute resolution. Any party wishing to challenge such determinations must do so in trial court. For all the reasons set out above, it is necessary that decisions made under Articles 2, 4, and 9 not be subject to dispute resolution under this article.

Section 69507(d) specifies that any disputed requirement imposed by DTSC under this chapter, and any posting concerning the requirement on the Failure to Comply list, is stayed while the administrative dispute is pending, thus allowing the party disputing the DTSC action to postpone compliance until the administrative dispute resolution process is complete. This is necessary to avoid prejudice to the responsible entity's interests while the matter is under review, and prevents the waste of resources that would occur were a responsible entity to initiate changes that might be rendered unnecessary by any change in a departmental requirement as a result of review.

§ 69507.1. Informal Dispute Resolution Procedures

Section 69507.1(a) specifies which issues being disputed, under this Chapter, are subject to informal dispute resolution, as opposed to the formal dispute resolution procedures set out in section 69507.3. Disputes regarding regulatory response decisions made by DTSC under Article 6 are not eligible for informal dispute resolution. This distinction is necessary in order to tailor the type of dispute resolution procedures available to the nature of the decision being disputed. This section also provides that informal dispute processes must be initiated within thirty (30) days following the mailing of the notice, or the posting on DTSC's website of the decision that is the basis of the dispute, whichever is later.

Failure to request informal dispute resolution within thirty (30) days renders DTSC's decision final and ineligible for any administrative dispute resolution under this article. This provision is necessary so that responsible entities are on notice of the deadline for requesting an informal dispute resolution, and of the consequences of failing to initiate the informal dispute resolution process by the deadline. This provision is also necessary to ensure that disputes are expeditiously resolved, and to avoid unnecessary protracted delays in compliance by responsible entities with DTSC decisions that are upheld at the conclusion of the dispute resolution process. Finally, this section provides

that DTSC must provide an opportunity for the responsible entity filing the dispute to have the matter resolved informally within thirty (30) days of receiving the dispute. This provision is necessary to ensure that disputes are expeditiously resolved, and to give responsible entities certainty as to how quickly they will know whether the relief sought will be granted or denied through the informal dispute resolution process.

Section 69507.1(b) provides that if a responsible entity disagrees with DTSC's decision following the informal dispute resolution process, the responsible entity may appeal to DTSC's Director under section 69507.2. This provision is necessary to inform responsible entities of the opportunity to elevate the disputed decision to the Director in the event the responsible entity disagrees with the informal dispute resolution decision.

§ 69507.2. Appeal to the Director

Section 69507.2(a) specifies the information the responsible entity must supply to DTSC if the responsible entity appeals an informal dispute resolution decision to the Director of DTSC. The required information includes: the reason for seeking additional review; and why the disputed decision does not comply with the regulations or is unreasonable. This section also specifies additional supporting information required for review by DTSC's Director, which includes:

(1) the original statement of dispute;
(2) supporting information; and
(3) copies of DTSC's responses to the dispute.

This provision is necessary to put all parties on notice of what information is required for DTSC's Director to review an unresolved dispute, and to provide the DTSC Director with the information needed to make an informed decision.

Section 69507.2(b) sets the time frame for appealing a dispute to the DTSC Director. An appeal must be made within thirty (30) days after the issuance of the informal dispute resolution decision. This provision is necessary so that parties are on notice of the applicable deadlines for appealing an issue to the Director, and so that disputes may be resolved expeditiously so as to avoid unnecessary protracted delays in compliance by responsible entities with DTSC decisions that are upheld at the conclusion of the dispute resolution process.

Section 69507.2(c) specifies that either DTSC's Director or the Director's designee will make a decision on a dispute appeal on behalf of DTSC. In either case, that decision is to be issued within sixty (60) days of receipt of the appeal, or DTSC may issue a notice

of ongoing review if a decision has not been made. This section also confers authority for the Director or designee to grant or deny relief in whole or in part. If the relief sought is denied, DTSC must:

(1) give a short explanation of the basis for its decision; and
(2) specify the date by which compliance is required for the requirements of the regulations that were in dispute.

This provision is necessary in order to: have timely and efficient resolution of appealed issues; put all parties on notice of the applicable time frames for decision-making; have decisions clearly communicated; and compliance dates clearly established.

Section 69507.2(d) specifies that a decision made under subsection (c) is DTSC's final decision; and, thus, is the last step in the administrative dispute resolution process and is not subject to further administrative dispute resolution procedures. This provision is necessary to ensure that all parties understand that an appeal decision under subsection (c) constitutes the end of the administrative dispute resolution process.

Section 69507.2(e) provides that DTSC must indicate in a notice of ongoing review the date by which it expects to make a decision under subsection (c). That estimation must take into account the complexity of the issue(s) raised and the availability of DTSC resources. This provision is necessary to keep the dispute appeal process efficient, keep the parties informed of status and anticipated resolution dates, and ensure that estimated decision dates are realistic and are based on consideration of pertinent factors.

§ 69507.3. Formal Dispute Resolution Procedures

Section 69507.3 specifies which DTSC decisions are subject to the formal dispute resolution procedures set out in sections 69507.4 through 69507.6 — namely, those decisions made under Article 6. Under Article 6, DTSC may require a responsible entity to take one or more specific action(s) (referred to as regulatory responses) following completion of an Alternatives Analysis. With respect to decisions made under Article 6, this section provides that these procedures operate in lieu of informal dispute resolution procedures. This section is necessary to inform affected parties of which procedures apply to which disputes.

§ 69507.4. Time Lines for Requests for Review

Section 69507.4 specifies that a responsible entity receiving a final regulatory response determination notice under Article 6 has thirty (30) days from receipt of that decision to submit a Request for Review to DTSC. If a Request for Review is not filed within the 30-day period, then DTSC's decision is final and not subject to further administrative dispute resolution procedures. This section is necessary so that responsible entities know the time lines for a responsible entity to initiate a formal dispute resolution process. This section is also necessary to ensure that formal disputes are expeditiously resolved and to avoid unnecessary protracted delays in compliance by responsible entities with DTSC regulatory response decisions that are upheld at the conclusion of the formal dispute resolution process.

§ 69507.5. Contents of Requests for Review

Section 69507.5 specifies that a Request for Review must include a statement of the reasons why the dispute is being filed. The request must include a showing that the DTSC decision is based on:

- **(a)** erroneous facts, assumptions, approaches, or conclusions of law; and/or
- **(b)** a policy judgment that makes DTSC's review an appropriate exercise of discretion.

This provision is necessary so that responsible entities know what information is required in their Requests for Review, and DTSC understands the nature of the requestor's grievance.

§ 69507.6. Department Procedures for Requests for Review

Provisions (a) through (d) of this section identify time frames for DTSC response to Requests for Review, and explain the effect of, and procedures associated with, a grant or denial of review. Collectively, these provisions are necessary to ensure efficient handling of matters under review and to keep parties informed of the status and progress made regarding these matters.

Section 69507.6(a) specifies that DTSC has sixty (60) days from receipt of a Request for Review filed under section 69507.4 to issue an order granting or denying the request, or a notice of ongoing review. This provision is necessary in order to have timely and efficient resolution of matters under review, and to put all parties on notice of the applicable time frames for decision-making.

Section 69507.6(b) specifies that an order denying review is DTSC's final decision, and, thus, is the last step in the administrative dispute resolution process and is not subject to further administrative dispute resolution procedures. The decision is effective on the date the order is issued. This provision is necessary to ensure that all parties understand that a decision denying a Request for Review under subsection (a) constitutes the end of the administrative dispute resolution process, and to provide clarity as to the effective date of the decision.

Section 69507.6(b)(1) requires that an order denying review must specify the date by which the responsible entity must come into compliance with the regulatory response requirements that were the subject of the Request for Review. This provision is necessary so that responsible entities are put on notice of the applicable compliance date for the requirements that were the subject of the denied Request for Review.

Section 69507.6(b)(2) requires that DTSC include a short and plain description for its decision to deny a Request for Review. This is necessary so that responsible entities understand the basis for DTSC's decision.

Section 69507.6(c) provides that an order granting review must specify when the briefs are due from the responsible entity and DTSC. This provision is necessary so that parties are on notice of when briefs are due and so that the process moves along efficiently.

Section 69507.6(d) specifies that DTSC has 180 days from the decision granting review to make a decision on the merits of the Request for Review or to issue a notice of ongoing review. This provision is necessary to ensure timely and efficient resolution of matters under review, and to put all parties on notice of the applicable time frames for decision-making.

Section 69507.6(d)(1) specifies that if the final order issued under subsection (d) denies the Request for Review the order is DTSC's final decision, and, thus, is the last step in the administrative dispute resolution process and is not subject to further administrative dispute resolution procedures. The final order must inform the responsible entity of the date by which compliance with the disputed regulatory response decision(s) is required. This provision is necessary to ensure that all parties understand that a denial order under subsection (d) constitutes the end of the administrative dispute resolution process, and to clearly establish the compliance date for the requirements that were the subject of the denied Request for Review.

Section 69507.6(d)(2) specifies that if the final order grants relief, in whole or in part, to the responsible entity the matter is to be returned to DTSC staff involved with the substantive issue(s) for re-evaluation. The order must specify a deadline for completion of the re-evaluation by DTSC staff that is no more than ninety (90) days from the date of the order. The order may, but need not, provide additional guidance or criteria for the re-evaluation. This provision is necessary so that appropriate DTSC staff members are involved in a technical scientific re-evaluation of the decision, and that the re-evaluation is concluded within a reasonable amount of time.

Section 69507.6(e) provides that DTSC must indicate in a notice of ongoing review the date by which it expects to make a decision and issue an order under subsection (a) or (d). That estimation must take into account the complexity of the issue(s) raised and the availability of DTSC resources. This provision is necessary to keep the formal dispute resolution process efficient, keep the parties informed of status and anticipated resolution dates, and ensure that estimated decision dates are realistic and are based on consideration of pertinent factors.

Section 69507.6(f) provides that no DTSC staff who participated in making or reviewing the disputed regulatory response decision may participate in the decision-making or review of decisions made with respect to the Request for Review under this section. This provision is necessary to ensure that DTSC's review is fair and objective.

Section 69507.6(g) establishes a communications firewall between DTSC staff involved in the decision-making and review of decisions under this section and those staff that originally participated in the disputed regulatory response decision, unless the issue(s) under discussion are simultaneously discussed with the responsible entity or its representative. This provision is necessary to ensure that there is no ex parte communication regarding matters under review, which would be inappropriate.

ARTICLE 8. Audits

Article 8, in its entirety, is necessary to implement, clarify, and make specific the provisions of Article 14 of Chapter 6.5 of Division 20 of the Health and Safety Code. More specifically, this Article establishes an audit program that the Department of Toxic Substances Control (DTSC) may administer to ensure the accuracy and integrity of actions performed under these regulations and of documents submitted to DTSC under these regulations. While various documents are called out specifically, they are not the only actions or documents subject to DTSC's auditing. Rather, the items enumerated are a non-exhaustive list of some of the critical activities and documents that are subject to DTSC's audit to ensure the integrity of DTSC's Safer Consumer Products program.

§ 69508. Audits of Program Compliance

Section 69508 establishes the existence of DTSC's audit program. This is necessary so that responsible entities and other interested parties are aware that such a program exists and are put on notice as to its scope.

Section 69508(a) sets out a non-exhaustive list of actions taken by or on behalf of responsible entities that may be subject to audit by DTSC. This is necessary so that responsible entities are put on notice of the existence and scope of this audit function. The non-exhaustive list establishes some of the important items that are subject to audit and to inform parties that these are not the only actions and documents subject to DTSC's audit.

Section 69508(b) specifies the non-exhaustive permissible scope of audits undertaken by DTSC under this article. This provision is necessary to put interested parties on notice of the types of information and focus of audits that may be undertaken by DTSC. Paragraphs **(b)(1) through (b)(4)** specify some of the key regulatory compliance information and actions that may be subject to audit under this program. These provisions are necessary to point out some of the important documents and regulatory compliance actions that may be subject to audit by DTSC.

Section 69508(c) sets out the actions that DTSC is required to take after completing an audit. More specifically, DTSC must inform the responsible entity(ies) of:

- the audit findings; and
- the process for disputing the audit findings.

This provision is necessary to ensure that responsible entities are informed of DTSC's findings concerning the documents and/or actions reviewed during the audit so that they

know which documents and/or actions are determined to be, or not to be, in compliance with the regulations. This provision is also to ensure that the responsible entity(ies) are informed of their recourse should they disagree with any audit findings.

ARTICLE 9. Trade Secret Protection

Article 9, in its entirety, is necessary to detail requirements for the submission and handling of information submitted to the Department of Toxic Substances Control (DTSC) under Chapter 55 that is claimed by the submitter to be protected from disclosure as trade secret material.

Health and Safety Code section 25257(a) authorizes persons submitting information to DTSC to "identify a portion" thereof as trade secret; section 25257(b) requires DTSC employees to "maintain the confidentiality of that trade secret"; and section 25257(c) provides that all information that is not identified as trade secret shall, to the extent consistent with other laws, "be available to the public," including, "[t]he fact that information is claimed to be a trade secret." Subsection (a) further provides that submitters must comply with any written request from DTSC for "support for the claim that . . . information is trade secret." Article 9 implements these requirements by establishing mechanisms for insuring that trade secret claims are meritorious; insuring that genuinely trade secret material is well protected from inadvertent disclosure; and delineating clearly which information submitted under Chapter 55 may be publicly released, and in what time frame. The provisions of Article 9 also reduce administrative burdens on DTSC by outlining a clear process for the designation, handling, and evaluation of trade secrecy claims.

Consistent with Health and Safety Code section 25257(a), these regulations – in Article 1, section 69501.1 ("Definitions"), subsection (a)(66), incorporate by reference the definition of "trade secret" in the California Uniform Trade Secrets Act (CUTSA). (See Civ. Code § 3426.1, subd. (d).) This two-pronged definition requires that a person asserting a trade secrecy claim demonstrate both that the information sought to be protected has economic (*i.e.,* "trade") value, and that reasonable efforts have been made to maintain its confidentiality (*i.e.,* keep it "secret"). This definition is consistent with the trade secrecy definition in the California Public Records Act, Government Code section 6254.7, which is also referenced in Health and Safety Code section 25257(a). It is also consistent with the broader definition of trade secrecy contained in the Restatement (Third) of Unfair Competition (Section 39), which is an authoritative treatise on the Model Uniform Trade Secrecy Act that has been adopted in California.

§ 69509. Assertion of a Claim of Trade Secret Protection

Section 69509(a) specifies that a person who asserts a claim of trade secret protection with respect to information submitted to DTSC under Chapter 55 will receive a written

request from DTSC to furnish DTSC with all of the substantiating information specified in paragraphs (1) through (10) of subdivision (a). This provision implements Health and Safety Code section 25257(a), which authorizes DTSC to make a written request for "support for the claim that . . . information is trade secret." This provision also reflects DTSC's determination that for reasons of both fairness to trade-secrecy claimants and administrative efficiency, DTSC will in writing request substantive support for all trade secrecy claims concurrent with submission of any claim. It is necessary for this support to address multiple factors, both because "[i]t is not possible to state precise criteria for determining the existence of a trade secret" (Restatement (Third) of Unfair Competition, § 39),and because analysis of a trade secrecy claim necessarily involves evaluating multiple relevant factors, no single one of which is determinative.

Section 69509(a)(1) requires identification of the person asserting a trade secrecy claim, which is necessary to identify a point of contact for any issues that arise with respect to processing trade secret documents, safeguarding trade secret information, and any challenge to the trade secrecy claim.

Section 69509(a)(2) requires a brief description of the nature of the information that is the subject of the claim. This provision is necessary to demarcate the non-trade secret and trade secret portions of an information submittal, consistent with the instruction in Health and Safety Code section 25257(c) to make public "[t]he fact that information is claimed to be a trade secret."

Section 69509(a)(3) requires an explanation of the extent to which the information is known by employees or others involved *within* the facility or business of the person, and whether or not those individuals are bound by nondisclosure agreements.

Section 69509(a)(4) requires an explanation of the extent to which the information is known *outside of* the facility or business of the person asserting the claim, and whether or not individuals with such knowledge are bound by nondisclosure agreements.

Section 69509(a)(5) requires an explanation of the measures taken to restrict access to and safeguard the information, and whether or not the trade-secrecy claimant plans to continue to use these measures.

All three of the provisions in subsections (a)(3) through (a)(5) are necessary for DTSC to assess whether, consistent with Civil Code section 3426.1(d), the claimant has made "efforts that are reasonable under the circumstances" to maintain the secrecy of the information at issue. As noted in the Restatement (Third) of Unfair Competition, section 39, many forms of precaution may be taken to preserve secrecy, including, but not

limited to, use of physical security measures, need-to-know policies, nondisclosure agreements, signs, and restrictive legends that communicate the confidential nature of the underlying information.

Section 69509(a)(6) requires an explanation of the estimated value of the information to the claimant and the claimant's competitors.

Section 69509(a)(7) requires an explanation of the estimated amount of effort and/or money expended by the claimant to develop the information.

Provisions (a)(6) and (a)(7) are necessary for DTSC to assess whether, consistent with Civil Code section 3426.1(d), the information at issue has "independent economic value, actual or potential, from not being generally known" to the public or others who can benefit from it. Where precise value is difficult to ascribe to a trade secret, expenditures to develop that information provide a useful proxy. See Restatement (Third) of Unfair Competition, Comment (e) ("Although a trade secret may consist of information discovered fortuitously, a significant expenditure of time, money, or effort in the production of the information is evidence of value.")

Section 69509(a)(8) requires an explanation of the estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including, with respect to any chemical identity for which trade secrecy is claimed, an explanation of why the chemical identity is not readily discoverable through reverse engineering. This provision is necessary because determining whether information is "readily ascertainable through proper means" is fundamental to the trade secrecy inquiry. (See Restatement (Third) of Unfair Competition, Comment (f).) In the case of chemical formulations, the ease or difficulty of determining a chemical's identity through laboratory deformulation (also known as "reverse engineering") is central to whether that identity is trade secret. (*See, e.g.,* Cal. Civ. Code § 3426.1, subd. (a) [stating that reverse engineering is not alone a misappropriation of a trade secret]; Emergency Planning and Community Right to Know Act, 43 U.S.C. § 11042, subd. (b)(4) [stating that a person claiming trade secrecy for a chemical identity must show that "[t]he chemical identity is not readily discoverable through reverse engineering"]; and *Worthington Compressors, Inc. v. Costle,* 662 F.2d 45, 52 (D.C. Cir. 1981) [stating that "the cost of reverse engineering" is material to evaluating whether there will be "competitive harm resulting from disclosure"].)

Section 69509(a)(9) requires that the submitter of claimed trade secret information provide DTSC with copies of, or references to, any pertinent trade secret or other confidentiality determinations previously made by DTSC or other government agencies.

This provision is necessary to ensure consistent treatment of information within and among government agencies, and to streamline DTSC's evaluation of a trade secrecy claim where other agencies have already made a confidentiality determination with respect to the same information.

Section 69509(a)(10) requires an explanation of the nature and extent of harm that would be caused if the claimed trade secret information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed. Because trade secret designation disserves both the public interest in access to information and the marketplace interest in promoting competition, this provision is necessary to ensure that claims for trade secrecy are not frivolously asserted with respect to information that has minimal value to the submitter.

The substantiation requirements in subsections (a)(1) through (a)(10) of section 69509 are also consistent with the suite of factors used to examine trade secrecy claims under the Restatement (Second) of Torts (see id., § 757, comment (b)); California case law (*see, e.g.*, *Futurecraft Corp. v. Clary Corp.* (1962) 205 Cal.App.2d 279, 289); other California regulations (see, *e.g.,* Cal. Code Regs., tit. 8, § 5194, App. D); and formal Departmental policy regarding Public Records Act requests for trade secret information. (DTSC Public Records Act Policy, dated October 8, 2003, Administrative Directive DO 1-03-10.) Submitters are not precluded from providing to DTSC any other information they deem relevant to the justification of their trade secrecy claim.

Section 69509(a)(11) requires the signature of the submitter's general counsel or other executive with knowledge of the preparation of the substantiating information to certify, based upon knowledge and belief, that:

- **(A)** the substantiating information is true, accurate, and complete;
- **(B)** the information for which trade secret protection is sought is not otherwise available to the public; and
- **(C)** there is a reasonable basis for trade secrecy protection for the information subject to the claim.

These three requirements are necessary to insure the submitter's careful internal review of and accountability for trade-secret claim justifications, and are expected to prevent the submission of frivolous, erroneous, or unsubstantiated claims of trade secrecy.

Section 69509(a)(12) requires the contact information for the individual to be contacted if any of the information claimed as trade secret is the subject of a California Public Records Act request. DTSC needs this information so that it may contact the submitting

party if DTSC has any questions about the claim of trade secret protection, and/or to carry out its duties under section 69509.1.

Section 69509(b) specifies that while substantiating information required under subsections (a)(1) through (a)(10) must be provided for each trade secret claim, information that is identical between or among claims may be incorporated by reference. This section also specifies that the requirements of subsections (a)(11) and (a)(12) may be met once for all trade secret claims submitted together. These provisions are necessary to reduce the regulatory compliance burden for persons submitting multiple claims to DTSC under a claim of trade secret protection, and to reduce the administrative burden on DTSC in reviewing redundant information.

Section 69509(c) requires that a person who submits a claim of trade secret protection must also at the time of submission provide DTSC with:

(1) a complete copy of the documentation being submitted, including the information claimed as trade secret, except where prohibited by federal law or by a nondisclosure agreement whose text is provided to DTSC; and
(2) a redacted copy of the documentation being submitted, excluding the information claimed as trade secret.

This section is necessary to place the burden for redacting submitted information on the party making the trade secret claim(s) as this is the best means of reducing errors and the possibility of DTSC's inadvertent release of trade secret information. Redacted copies of documents will be available to the public as specified in section 69501.5(b)(6). This section is also necessary to avoid potential legal conflicts with federal laws or legally binding agreements prohibiting the release of specified information with other parties including DTSC.

Section 69509(d) requires the submitter, at the time of submission, to conspicuously mark each page containing claimed trade secret information with the words "Trade Secret." The requirement for conspicuous marking makes clear to DTSC staff the claimed trade-secret status of each individual page, which will inform proper document handling and reduce the chance of inadvertent disclosure. This section also specifies that if no claim of trade secret protection is made at the time of submission, DTSC may make the submitted information available in full to the public without further notice. This provision is also necessary to make clear to the submitter the consequences of not making a claim of trade secrecy at the time of submission, *i.e.,* potential public disclosure as specified in Health and Safety Code section 25257(c).

Section 69509(e) provides that if the documentation supporting a claim of trade secret protection contains information that itself is subject to a claim of trade secret protection, the supporting documentation must be separately supplied for each claim and provided in both complete and redacted form, as specified in section 69510(c), but shall not itself require further supporting documentation. This provision is necessary to ensure proper treatment of substantiation information, and to minimize DTSC's administrative burden. It is also necessary to avoid an infinite substantiation loop with respect to justificatory documents. Any redacted substantiation document submitted to DTSC becomes a public record subject to request under the Public Records Act (PRA).

Section 69509(f) provides that, except as specified in section 69510(g), trade secret protection may not be claimed for any hazard trait submission, or any chemical identity information associated with a hazard trait submission. This provision is necessary to effectuate the intent of Health and Safety Code section 25257(f), which provides that trade secret protection may not attach to "hazardous [stet] trait submissions for chemicals and chemical ingredients under this Article [14]." (In Article 1 ("Definitions"), DTSC has assumed that the word "hazardous" is a typographical error, and that the Legislature intended to use the phrase "hazard trait submissions," which is consistent with the terminology used in companion green chemistry legislation, Senate Bill 509 (Health & Saf. Code §§ 25251-25257.1 (2008)). The regulatory requirement to allow public access to data regarding the hazards of specific chemicals and chemical ingredients is central to fulfilling the purpose of Health and Safety Code 25257, by informing the public about toxic risks associated with consumer product constituents, and incentivizing manufacturers to reduce or eliminate those risks.

Nonetheless, DTSC has acknowledged and accommodated the need for possible protection for chemical identity or chemical ingredient identity in very specific, time-limited circumstances. Those circumstances are set out in section 69509(g).

Section 69509(g)(1) provides a very limited exception to section 69509(f), by describing circumstances in which a submitter may temporarily mask the precise identity of a chemical or chemical ingredient. Specifically, section 69509(g)(1) provides that when a chemical is an alternative considered or proposed in an Alternatives Analysis, and a patent application is pending for that chemical or its contemplated use in a product, the submitter may mask the chemical's precise identity until such time as this identity is made public through any means.

This provision is necessary to reconcile two themes embodied in the green chemistry legislation (Article 14 of Chapter 6.5 of Division 20 of the Health and Safety Code). On the one hand, the Legislature instructed DTSC to increase public disclosure of

information about a product's chemical constituents, by categorically instructing DTSC to deny trade secret status to "hazard[] trait submissions for chemicals and chemical ingredients." (See Health & Saf. Code § 25257 (f).) This is consistent with the statute's stated goal of "significantly reducing adverse health and environmental impacts of chemicals used in commerce." (Id. at § 25255(a).) Therefore, DTSC has by regulation established that precise chemical identity is an essential component of a "hazard trait submission." (See Article 1, § 69501.1(a)(33).)

On the other hand, the green chemistry legislation (Article 14 of Chapter 6.5 of Division 20 of the Health and Safety Code) also has among its stated goals "encouraging the redesign of consumer products, manufacturing processes, and approaches. " (Health & Saf. Code § 25255(a).) This goal may be advanced by providing intellectual property protection that incentivizes private investment in development of safer product chemistries.

Section 69509(g)(1) balances these two goals by allowing temporary protection of chemical identity information under specified circumstances, but providing for ultimate public disclosure of all chemical identities. Notwithstanding may commenters' request that DTSC additionally extend chemical identity protection to those chemicals whose nature is held as a trade secret, DTSC believes the unlimited nature of a trade secret claim too greatly undermines the public disclosure aspects of the green chemistry legislation (Article 14 of Chapter 6.5 of Division 20 of the Health and Safety Code) described above.

Section 69509(g)(2) builds on the requirements of section 69509(g)(1). More specifically, any person temporarily masking a chemical identity under section 69509(g)(1) must, to the fullest extent consistent with a trade secret protection claim, provide DTSC with a non-confidential description of the nature of the chemical or chemical ingredient. This provision is necessary in order for DTSC to engage with members of the public in a general way about the substitute chemical or chemical ingredient, without undermining the potential intellectual property protection of the proposed chemical alternative to the Chemical of Concern.

§ 69509.1. Department Review of Claims of Trade Secret Protection

Section 69509.1(a) provides that DTSC may review a trade secret claim upon receipt of the information claimed to be protected, or at any later time. This provision allows DTSC to be effective and efficient. This puts DTSC in a position of settling some potential disputes about what is and is not trade secret information before such information is even subject to a Public Records Act request. As such, this provision is

necessary to allow for efficient implementation of the regulations and prompt compliance with obligations under the Public Records Act.

Section 69509.1(b)(1) provides that if DTSC determines the information provided in support of a request for trade secret protection is incomplete or insufficiently responsive to allow DTSC to determine if the trade secret claim is valid, DTSC shall:

- **(A)** notify the submitter of DTSC's finding of insufficiency, and the reason(s) therefor;
- **(B)** identify the specific areas that are deficient and for which additional information is needed; and
- **(C)** indicate the date by which the submitter must provide the requested information.

This provision is necessary to inform submitters of the status of their trade secret claims and to provide them a time-limited opportunity to cure defects with their submittals.

Section 69509.1(b)(2) provides that if the submitting party fails to provide the information requested under subsection (b)(1) within the time specified, DTSC must, by certified mail, notify the submitter that it is out of compliance with Article 9, and that the information claimed to be trade secret is subject to disclosure by DTSC thirty (30) days after the mailing of the notice. During the 30-day period, the submitter may seek judicial relief in specified forms that would preclude DTSC from releasing the claimed trade secret information. During the 30-day period, DTSC may not release the information claimed as trade secret. This provision is necessary to ensure that DTSC has adequate information upon which to base its trade secrecy determination, and establishes an orderly process for resolving claims related to sufficiently justifying trade secrecy claims.

Section 69509.1(c) provides that if DTSC determines the information claimed as trade secret does not meet the substantive criteria for trade secret protection, DTSC will notify the submitting party of its determination by certified mail. As with section 69509.1(b), DTSC will inform the submitting party that thirty (30) days from the date of the notice of DTSC's decision, the information will be regarded as a public record subject to disclosure. During that 30-day period, the submitting party may seek judicial intervention by bringing an action for a preliminary injunction and/or declaratory relief to prevent disclosure of the information claimed as trade secret. During this 30-day period, DTSC may not publicly release information subject to a claim of trade secrecy. This provision implements Health and Safety Code section 25257(c)(3), which requires DTSC to give thirty (30) days notice to the submitter of trade secret claimed information before releasing any such information, authorizes submitters to seek judicial intervention to prevent information release, and specifies judicial remedies that may be

sought. This provision is necessary to establish a time frame and procedure for resolving disputed trade secrecy claims, and to allow time for a claimant that receives an adverse decision from DTSC to seek judicial review of the DTSC decision.

Section 69509.1(d) provides that if a party claiming trade secret protection for information initiates an action under sections 69509(b)(2) or (c), then DTSC is precluded from publicly releasing the information that is the subject of the trade secret claim until the judicial action, including any appeal, is resolved. This provision is necessary to preserve the asserted trade secret protection of information submitted to DTSC, and thereby prevents any economic harm to the submitter, while a court case is pending.

ARTICLE 10. Severability

Article 10 and **section 69510**, which comprises the entirety of Article 10, specify that if any provision of Chapter 55, or its application to any person or circumstances, is held invalid by the courts such invalidity will not affect other provisions or applications that can separately be given effect without the invalidated provision or application. This provision is necessary to make clear DTSC's intention that if one or more provisions of these regulations is invalidated, either facially or as applied in a specific context, the remaining provisions shall continue in full force and effect to the extent possible without the severed provision(s). Although courts generally presume that statutes and regulations are severable – particularly where the scheme involved is long and complex – the severability statement is here intended to resolve any doubt as to the drafters' intent in this regard.