

1 **INITIAL STATEMENT OF REASONS**

2 **SAFER CONSUMER PRODUCTS**

3  
4 **Department Reference Number: R-2011-02**

5 **Office of Administrative Law Notice File Number: Z-2012-0717-04**

6  
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1 **I. DETAILED STATEMENT OF THE SPECIFIC PURPOSE AND RATIONALE**

2  
3 Health and Safety Code section 25252 requires the Department of Toxic Substances Control  
4 (DTSC) to adopt regulations to establish a process by which chemicals or chemical ingredients  
5 in consumer products may be identified and prioritized for consideration as being Chemicals of  
6 Concern. This process is required to include, at a minimum, consideration of:

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

10  
11 Health and Safety Code section 25252 directs DTSC, in adopting these regulations, to develop  
12 criteria by which chemicals and their alternatives may be evaluated. These criteria must  
13 include, at a minimum, the hazard traits and environmental and toxicological endpoints that the  
14 Office of Environmental Health Hazard Assessment (OEHHA) is required to adopt under  
15 Health and Safety Code section 25256.1, for purposes of the Toxic Information Clearinghouse  
16 that DTSC is required to establish under Health and Safety Code section 25256.

17  
18 Health and Safety Code section 25252 also directs DTSC, in adopting these regulations, to  
19 reference and use, to the maximum extent feasible, available information from other nations,  
20 governments, and authoritative bodies. However, the statute states that DTSC is not required  
21 to reference and use only this information.

22  
23 Health and Safety Code section 25253 requires DTSC to adopt regulations that establish a  
24 process for evaluating Chemicals of Concern in consumer products, and their potential  
25 alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by  
26 a Chemical of Concern. This section requires that these regulations establish a process that  
27 includes:

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

1  
2 Health and Safety Code section 25253 also requires that the regulations specify the range of  
3 regulatory responses that DTSC may take following the completion of an alternatives analysis,  
4 including, but not limited to, requiring:

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

16  
17 Accordingly, DTSC proposes to add a new Chapter 55, Safer Consumer Products, to division  
18 4.5 of Title 22, California Code of Regulations. These regulations are necessary to satisfy the  
19 mandates of Health and Safety Code sections 25252 and 25253, which require DTSC to adopt  
20 regulations to establish a process to identify and evaluate Chemicals of Concern in consumer  
21 products and identify safer alternatives, and to specify regulatory responses that may be  
22 imposed upon completion of the alternatives analysis process.

## 23 24 **II. ECONOMIC IMPACT ANALYSIS**

25  
26 In accordance with Government Code sec. 11346.3(b), DTSC has made the following  
27 assessments regarding the proposed regulation:

### 28 29 **Creation or Elimination of Jobs within California**

30 DTSC has determined that until the initial list of Priority Products is released that it cannot  
31 quantify the number of jobs that may be created or eliminated; however, DTSC has identified  
32 factors that would contribute to the creation or elimination of jobs in California.

### 33 34 **Creation of New Businesses or Elimination of Existing Businesses within California**

35 DTSC has determined that the regulation may result in the creation of new businesses as new  
36 materials and processes are created. Furthermore, current firms have time to adapt prioritized  
37 consumer products to meet regulatory requirements. The regulations apply equally to  
38 manufacturing businesses in California and outside of California.

### 39 40 **Expansion of Current California Businesses**

41 DTSC has determined that the regulation provides opportunities for growth as California  
42 businesses have access to wider range of safer consumer products and can provide services  
43 and products for an expanding number of consumers demanding safer and greener products.

1 **Benefits of the Regulation**

2  
3 The proposed regulations are among the first comprehensive, state-level efforts to find safer  
4 alternatives to hazardous chemicals and are viewed as a possible national model for chemical  
5 reform. The rulemaking is, in effect, a preemptive strategy that reduces the use of toxic  
6 substances in the design of products and industrial processes with the aim of creating safer  
7 and sustainable products that do not threaten human health or persist in the environment. The  
8 use of fewer hazardous substances means healthier air quality, cleaner drinking water and a  
9 safer workplace. The rulemaking also promotes transparency by compelling chemical  
10 manufacturers to provide sufficient information for businesses, consumers and public agencies  
11 to choose viable safer alternatives to hazardous chemicals used in consumer products.  
12

13 **III. REPORTS RELIED ON**

14  
15 The Safer Consumer Products Regulations implement one of six policy recommendations in  
16 the Final California Green Chemistry Report issued by DTSC in December 2008. The  
17 regulations build upon current environmental protection laws to shift the focus from end-of-pipe  
18 cleanup or “cradle to grave” regulation to up-front design and prevention of harm, foster  
19 innovation, and prompt market changes toward a sustainable economy. The six  
20 recommendations in the Final Report ensure a comprehensive and collaborative approach to  
21 increase accountability and effectiveness of environmental programs across state government  
22 for evaluating risk, reducing exposure, encouraging less-toxic industrial processes, and  
23 identifying safer alternatives.  
24

25 Assembly Bill 1879 (Feuer, Chapter 559, Stats. 2008) and Senate Bill 509 (Simitian, Chapter  
26 560, Stats 2008) were signed into law on September 29, 2008, laying the critical foundation for  
27 the Green Chemistry program. These bills provide the authority and mandate to adopt the  
28 proposed regulations.  
29

30 DTSC has relied upon the Economic and Fiscal Impact Statement (STD. 399) and the  
31 following documents in this rulemaking:

32 State of California Environmental Protection Agency, Office of Environmental Health Hazard  
33 Assessment, Safe Drinking Water and Toxic Enforcement Act of 1986, Chemicals Known to  
34 the State to Cause Cancer or Reproductive Toxicity:  
35 [http://oehha.ca.gov/prop65/prop65\\_list/Newlist.html](http://oehha.ca.gov/prop65/prop65_list/Newlist.html), June 22, 2012.

36 European Commission 1272/2008 Annex V1, December 16, 2008.

37 European Commission 1272/2008 Annex V1, Category 1A and 1B carcinogens, reproductive  
38 toxins, and mutagens, December 16, 2008.

39 European Commission DG ENV, Towards the establishment of a priority list of substances for  
40 further evaluation of their role in endocrine disruption:  
41 [http://ec.europa.eu/environmental/docum/pdf/bkh\\_main.pdf](http://ec.europa.eu/environmental/docum/pdf/bkh_main.pdf), June 21, 2000.

1 United States Environmental Protection Agency's Integrated Risk Information System (IRIS),  
2 A-Z List of Substances:  
3 <http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList> as printed on July  
4 2, 2012.

5 United States Environmental Protection Agency's Integrated Risk Information System (IRIS),  
6 A-Z List of Substances, 1986 Guidelines on Category A, 1B and 2B Human carcinogens and  
7 2005 Guidelines on "carcinogenic to humans": [http://www.epa.gov/iris/search\\_human.htm](http://www.epa.gov/iris/search_human.htm) as  
8 printed on July 2, 2012.

9 United States Department of Health and Human Services, Public Health Service, National  
10 Toxicology Program, Report on Carcinogens, Twelfth Edition (2011), "Substances Listed in the  
11 Twelfth Report on Carcinogens": <http://ntp.niehs.nih.gov/go/roc12>, June 10, 2011.

12 European Union, High Production Volume Persistent Bioaccumulating Toxins:  
13 <http://esis.jrc.ec.europa.eu/index.php?PGM=pbt> as printed on June 30, 2012.

14 Canadian Environmental Protection Act, Environmental Registry, Domestic Substances List:  
15 Persistent, Bioaccumulative, and Inherently Toxic to the environment:  
16 [http://www.ec.gc.ca/lcpe-cepa/D031CB30-B31B-D54C-0E46-  
17 37E32D526A1F/PB\\_20060905\\_eng.pdf](http://www.ec.gc.ca/lcpe-cepa/D031CB30-B31B-D54C-0E46-37E32D526A1F/PB_20060905_eng.pdf) as printed on July 1, 2012.

18 International Agency for Research on Cancer, Agents Classified by the IARC Monographs,  
19 Volumes 1–105, <http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf>,  
20 June 28, 2012.

21 Agency for Toxic Substances and Disease Registry's Toxic Substances Portal, Health Effects  
22 of Toxic Substances and Carcinogens, Nervous System:  
23 <http://www.atsdr.cdc.gov/substances/toxorganlisting.asp?sysid=18> as printed on July 1, 2012.

24 United States Environmental Protection Agency's National Waste Minimization Program,  
25 Persistent Bioaccumulative and Toxic Priority Chemicals:  
26 <http://www.epa.gov/osw/hazard/wastemin/priority.htm> as printed on July 1, 2012.

27 National Toxicology Program, Office of Health Assessment and Translation, Reproductive or  
28 developmental toxicants identified in Monographs on the Potential Human Reproductive and  
29 Developmental Effects: [http://ntp.niehs.nih.gov/?objectid=4980AA81E9194E85  
30 60B789CA36E59FA5](http://ntp.niehs.nih.gov/?objectid=4980AA81E9194E8560B789CA36E59FA5) as printed on July 2, 2012.

31 United States Environmental Protection Agency's Toxics Release Inventory Persistent,  
32 Bioaccumulative and Toxic Chemicals that are subject to reporting under the Emergency  
33 Planning and Community Right-to-Know Act section 313:  
34 [http://www.epa.gov/tri/trichemicals/pbt%20chemicals/pbt\\_chem\\_list.htm](http://www.epa.gov/tri/trichemicals/pbt%20chemicals/pbt_chem_list.htm) as printed on July 2,  
35 2012.

1 Washington Department of Ecology's Persistent, Bioaccumulative, Toxic Chemicals identified  
2 in the Washington Administrative Code, title 173, chapter 173-333:  
3 <https://fortress.wa.gov/ecy/publications/publications/wac173333.pdf>), January 13, 2006.

4 California Department of Public Health, Drinking Water Notification Levels and Response  
5 Levels: An Overview:  
6 <http://www.cdph.ca.gov/certlic/drinkingwater/Documents/Notificationlevels/notificationlevels.pdf>,  
7 December 14, 2010.

8 California State Water Resources Control Board, Maximum Contaminant Levels:  
9 [http://www.swrcb.ca.gov/rwqcb4/board\\_decisions/adopted\\_orders/general\\_orders/r4-2008-  
10 0083/Attachment\\_A.pdf](http://www.swrcb.ca.gov/rwqcb4/board_decisions/adopted_orders/general_orders/r4-2008-0083/Attachment_A.pdf) as printed on July 2, 2012.

11 California Air Resources Board, Toxic Air Contaminants:  
12 <http://www.arb.ca.gov/toxics/catable.htm> as printed on July 2, 2012.

13 Code of Federal Regulations, title 40, section 303(c) and section 131.38, Priority Toxic  
14 Pollutants: [http://ci.santa-  
15 rosa.ca.us/doclib/Documents/ut\\_irwp\\_PEIR\\_Appendix\\_C\\_1\\_California\\_Toxics.pdf](http://ci.santa-rosa.ca.us/doclib/Documents/ut_irwp_PEIR_Appendix_C_1_California_Toxics.pdf), May 18,  
16 2000.

17 California Office of Environmental Health Hazard Assessment, Air Toxics Hot Spots Program  
18 Guidance Manual for Preparation of Health Risk Assessments:  
19 [http://oehha.ca.gov/air/hot\\_spots/pdf/HRAguidefinal.pdf](http://oehha.ca.gov/air/hot_spots/pdf/HRAguidefinal.pdf), August 2003.

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

23 Centers for Disease and Prevention, Fourth National Report on Human Exposure to  
24 Environmental Chemicals and Updated Tables:  
25 [http://www.cdc.gov/exposurereport/pdf/NER\\_Chemical\\_List.pdf](http://www.cdc.gov/exposurereport/pdf/NER_Chemical_List.pdf), February 2012.

26 Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East  
27 Atlantic, OSPAR List of Chemicals for Priority Action (reference number 2004-12):  
28 [http://www.ospar.org/content/content.asp?menu=00940304440000\\_000000\\_000000](http://www.ospar.org/content/content.asp?menu=00940304440000_000000_000000), 2011.

#### 29 **IV. REASONABLE ALTERNATIVES CONSIDERED**

30

31 *Available alternatives included the following:*

32

33 **Chosen Alternative:** DTSC has determined that adding Chapter 55, Safer Consumer  
34 Products, to Division 4.5 of Title 22, California Code of Regulations is the most effective and  
35 least burdensome approach to meeting its mandate to adopt regulations. It also provides the  
36 required flexibility to carry out the provisions of Health and Safety Code sections 25252 and  
37 25253. Because these regulations were developed in tandem with stakeholders to build a  
38 workable program, but without compromising the safety of public health and the environment,

1 DTSC has chosen these regulations as the preferred alternative. In addition, the development  
2 of these regulations has had the benefit of advice and counsel on scientific matters, and  
3 various recommendations on scientific approaches to chemical policy and differing  
4 suggestions for implementation strategies, from the legislatively mandated Green Ribbon  
5 Science Panel.

6  
7 This regulatory development process included active and virtually continuous public and  
8 stakeholder involvement that embraced transparency. This process began in 2009 with a  
9 series of meetings with stakeholders to identify regulatory concepts. Numerous meetings and  
10 public workshops played a critical role in collecting additional concepts. After considering input  
11 received during this phase, DTSC released a draft conceptual flowchart in the February 2010.  
12 This conceptual flowchart became the genesis of the chosen alternative.

13  
14 DTSC continued stakeholder discussions regarding a proposed regulatory framework  
15 throughout much of 2010. The conceptual flowchart was soon followed by the release of a  
16 detailed outline for the draft regulations. After receiving feedback from a wide variety of  
17 stakeholders (via email and website submissions, letters, and stakeholder meetings) and the  
18 Green Ribbon Science Panel on the detailed outline, DTSC released the informal, draft  
19 regulations for Safer Consumer Products on June 23, 2010. DTSC held two half-day  
20 workshops to receive comments on these regulations on July 7 and 8, 2010. Based on  
21 numerous stakeholder letters, comments, and meetings following the workshops, the  
22 regulations were developed for adoption. All formal stakeholder submissions were posted on  
23 the DTSC public website. DTSC filed an Initial Notice of Rulemaking in September 2010,  
24 followed by a revised set of proposed regulations in November, 2010. DTSC ultimately  
25 withdrew the proposed regulations on August 1, 2011.

26  
27 DTSC, with the substantial public and stakeholder input, has developed these regulations.  
28 These regulations provide a workable regulatory infrastructure that will develop safer  
29 consumer products for the citizens and marketplace of California. DTSC has determined that  
30 these regulations are the chosen alternative.

### 31 32 **Rejected Alternatives:**

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

38  
39 To do nothing would also reject the California Legislature's direction to develop a broader,  
40 more comprehensive approach to chemicals policy for the State of California following the  
41 Green Chemistry Initiative's policy recommendation:

42 "Accelerate the Quest for Safer Products, creating a systematic, science-based  
43 process to evaluate Chemicals of Concern and identify safer alternatives to ensure  
44 product safety."  
45

1 Therefore, DTSC has rejected this option.

2

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

7

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

12

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

23

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

- 25 • a chemical and product prioritization process that factors in the same public health  
26 and environmental considerations, albeit a different prioritization pathway;
- 27 • manufacturer responsibility to develop safer consumer products and the  
28 requirements that must be addressed in the alternatives assessment; and
- 29 • DTSC specified regulatory responses.

30

31 Some of the significant changes include:

- 32 • an open and transparent process that includes a public comment period prior to  
33 finalizing the lists of chemicals and products that must undergo an alternatives  
34 analysis to examine ways to develop a safer consumer product;
- 35 • requiring DTSC to post on its website implementation progress by making  
36 information available that is not considered trade secret as it is received or  
37 developed;
- 38 • phasing in a requirement that a certified assessor review a manufacturer's  
39 alternatives analysis, and;
- 40 • creating a petition process to allow interested parties to request inclusion or  
41 removal of a chemical or product as part of the prioritization process.

42

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

1  
2 **V. DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS**  
3

4 The proposed regulations by DTSC do not duplicate or conflict with existing federal law. The  
5 Green Chemistry Initiative was developed, to a great extent, to address structural weaknesses  
6 in the federal Toxic Substances Control Act of 1976 (“TSCA”, Title 15, United States Code,  
7 section 2601 et seq). TSCA places the cost of obtaining data about chemical safety on the  
8 United States Environmental Protection Agency (US EPA) rather than requiring the chemical  
9 companies to develop and submit such information. Consequently, information about the  
10 80,000 chemicals in U.S. commerce is severely limited and there is little to no information on  
11 the health or environmental effects of many of these chemicals.  
12

13 In 1998, US EPA launched the voluntary High Production Volume (HPV) Challenge Program.  
14 The goal of the program was to collect health and environmental effects data to provide the  
15 public with basic hazard information, thus allowing the public to actively participate in  
16 environmental decision-making. HPV chemicals are classified as those chemicals produced or  
17 imported in the United States in quantities of 1 million pounds or more per year. The HPV  
18 program has had varying levels of success – while some information has been collected on  
19 approximately 2,500 chemicals, information on the overwhelming majority of chemicals used at  
20 lesser quantities than 1 million pounds per year is still unknown.  
21

22 Pending legislation to overhaul TSCA, the Safe Chemicals Act of 2010 (S.3209), and a House  
23 Discussion Draft “Toxics Chemicals Safety Act of 2010” both incorporate Green Chemistry  
24 principles in sections titled “Safer Alternatives and Green Chemistry and Engineering.” Based  
25 on the timelines specified in the draft legislative documents, it is anticipated that a federal  
26 program similar or comparable to California’s Green Chemistry Program will be delayed at  
27 least five years.  
28

29 California’s Green Chemistry legislation and accompanying regulations are among the first  
30 comprehensive, state-level efforts to find safer alternatives to hazardous chemicals and are  
31 viewed as a potential national model for chemical reform. The regulations would compel  
32 chemical manufacturers to provide sufficient information for businesses, consumers and public  
33 agencies to choose viable safer alternatives to hazardous chemicals used in consumer  
34 products.  
35

36 **VI. DETAILED STATEMENT OF REASONS: SUMMARY AND RATIONALE**  
37

38 **Article 1. General**  
39

40 **§ 69501. Purpose and Applicability**  
41

42 **Section 69501**, in its entirety, is describes the scope and purpose of Chapter 55. This section  
43 also establishes the scope of the applicability of Chapter 55 by specifying which products are  
44 and are not subject to its requirements.  
45

1 **Section 69501(a)** specifies that Chapter 55 sets out the process for identifying Chemicals of  
2 Concern, the process for prioritizing consumer products containing Chemicals of Concern and  
3 identifying potential alternatives for Priority Products to determine how best to limit exposures  
4 or the level of adverse impacts posed by the Chemical of Concern in the product. This  
5 Chapter also specifies the regulatory responses that may be imposed by DTSC following  
6 completion of an alternatives analysis by a responsible entity.

7  
8 **Section 69501(b)(1)** specifies that Chapter 55 applies to all consumer products placed into the  
9 stream of commerce in California, except as otherwise provided in paragraphs (2) and (3) of  
10 this subsection, which are described below:

11  
12 Applicability to Consumer Products: The applicability of these regulations to all consumer  
13 products “placed into the stream of commerce in California,” takes into account current and  
14 anticipated methods of selling or offering for sale consumer products containing a Chemical of  
15 Concern, through mail order catalogs and Internet sales as well as traditional “brick and  
16 mortar” entities. In addition, the term includes products that are offered as promotional items  
17 with a purchase and manufacturer “giveaways.” DTSC has determined that the scope of the  
18 consumer products subject to the regulations is consistent with existing statutory reach — both  
19 as to what is included and what is excluded — and that exempting any other consumer  
20 products would not be in line with the intent and purpose of the authorizing legislation. Any  
21 additional exemptions beyond those set out in statute would impermissibly shrink the scope of  
22 consumer products that are subject to the regulations.

23  
24 DTSC notes that the public comment periods provided in the chemical and product  
25 identification and prioritization processes specified in Articles 2 and 3 provide ample  
26 opportunity for interested parties to provide evidence to DTSC that additional Chemicals of  
27 Concern or Priority Products should or should not be included on those lists.

28  
29 **Section 69501(b)(2)** exempts from the regulations any product that is statutorily exempted  
30 from the definition of “consumer product” and any product that is placed into the stream of  
31 commerce in this State solely for the manufacture of one or more statutorily exempt products.  
32 The statutory definition of “consumer product” and the exemptions from this definition are set  
33 out in Health and Safety Code section 25251. Exemptions to the requirements in this Chapter  
34 are necessary in order for the scope of the regulations to be consistent with the authorizing  
35 legislation.

36  
37 Health and Safety Code section 25251 defines “consumer product” as a “product or part of the  
38 product that is used, brought (*sic*), or leased for use by a person for any purposes.” In  
39 accordance with Health and Safety Code section 25251, a consumer product does not include:

- 40 (1) a dangerous drug or device as defined in Section 4022 of the Business of (*sic*)  
41 Professions Code;
- 42 (2) dental restorative materials as defined in subdivision (b) of Section 1648.20 of the  
43 Business and Professions Code;
- 44 (3) a device as defined in Section 4023 of the Business and Professions Code;
- 45 (4) a food as defined in subdivision (a) of Section 109935 of the Health and Safety Code;

1 (5) the packaging associated with any of the items specified in paragraph (1), (2), or (3); or  
2 (6) a pesticide as defined in Section 12753 of the Food and Agricultural Code or the  
3 Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. Sec. 136 and following).  
4

5 **Section 69501(b)(3)** specifies that the regulations do not apply to any consumer product that  
6 is manufactured or stored in, or transported through, California solely for use outside of  
7 California. This provision clarifies that Chapter 55, consistent with the intent of Health and  
8 Safety Code section 25251, does not apply to any consumer product manufactured or stored  
9 in, or transported through, California, but not actually placed into the stream of commerce in  
10 California. The purpose of the authorizing statutes and these regulations is to protect  
11 California consumers from harmful chemicals in products; that purpose is not furthered by  
12 regulating products that will not be made available to California consumers.  
13

#### 14 **§ 69501.1. Definitions**

15  
16 **Section 69501.1(a)** defines terms that are used throughout Chapter 55 in order to avoid  
17 confusion and future disputes over the applicability of terms. The following terms have been  
18 defined.  
19

20 **Section 69501.1(a)(1)** defines “**AA Reports**” to facilitate the discussion on Preliminary  
21 Alternative Analysis Reports and Final Alternatives Analysis Reports.  
22

23 **Section 69501.1(a)(2)** defines “**accreditation body**” to specify the standards for the  
24 organization that develops the curriculum and evaluation standards for the practioners of  
25 alternatives analyses. An accreditation body can focus on different standards with regional,  
26 national, or international scopes; so, it is necessary to define what type of accreditation body  
27 will be qualified to accord the formal status of certified assessors.  
28

29 The accreditation body will be delegated to make decisions on behalf of DTSC about the  
30 legitimacy or appropriateness of the certified assessors. An entity wishing to be designated as  
31 an accreditation body must possess the educational and technical experience in teaching, as  
32 specified in section 69508.1. The accreditation body concept helps to ensure that persons  
33 training individuals to perform alternatives analysis are entities with the capacity, experience  
34 and expertise. This in turn, promotes reliability, auditability, and consistency of AAs and AA  
35 Reports.  
36

37 **Section 69501.1(a)(3)** defines “**adverse air quality impacts**” to mean air emissions of any of  
38 the air contaminants listed. Adverse impacts on air quality may indirectly contribute to or  
39 directly cause adverse impacts on public health and other environmental and ecological  
40 systems. The proposed definition of “adverse air quality impacts” ensures that DTSC and a  
41 responsible entity consider those adverse air quality impacts during the Alternatives Analysis  
42 that are commonly recognized by the scientific community as being of concern when  
43 evaluating a Chemical of Concern, a Priority Product, or a chemical substitute for a Priority  
44 Product.  
45

- 1 This definition of adverse air quality impacts incorporates definitions found in:
- 2 • California Air Pollution Control laws and regulations (California Toxic Air Contaminants);
  - 3 • The federal Clean Air Act (nitrogen oxides, sulfur oxides, and particulate matter); and
  - 4 • Article 4 of Chapter 54, air exposure potential hazard traits (chemical substances that
  - 5 exhibit the stratospheric ozone depletion potential hazard trait, and tropospheric ozone-
  - 6 forming compounds).

7

8 The California Air Resource Board is authorized to regulate various categories of air emissions  
9 that pose potential adverse impacts to human health and the environment under both state  
10 and federal laws and regulations. Chapter 54 has identified the exposure potential hazard  
11 traits, such as ambient ozone formation, global warming potential, particle size or fiber  
12 dimension, and stratospheric ozone depletion potential, that DTSC will use to develop criteria  
13 by which chemicals and their alternative may be evaluated (Health and Safety Code sections  
14 25256.1 and 25252 respectively). DTSC’s definition is aligned with the definition in its  
15 regulations. This allows for ease of use and common understanding of terms.

16

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

- 20 • consumer products for household cleaning and maintenance, personal care, or hobbies;
- 21 • building materials and furnishings, such as carpeting and furniture made of certain
- 22 pressed wood products or upholstery treated with flame retardants; and
- 23 • outdoor air pollution<sup>1</sup>.

24

25 **(A)** *Toxic Air Contaminants (TAC)* have been defined as “an air pollutant which may cause or  
26 contribute to an increase in mortality or in serious illness, or which may pose a present or  
27 potential hazard to human health.” (Health and Safety Code Section 39655) (For a list of  
28 Toxic Air Contaminants, see Title 17, California Code of Regulations, sections 93000-  
29 93001). Chemicals identified by the California Air Resources Board’s Air Toxics Program  
30 are monitored and controlled as toxic air contaminants (TACs). Toxic Air Contaminants  
31 that can be found indoors include formaldehyde, benzene, asbestos, and others.

32 **(B)** *Greenhouse gases* are gaseous components of the atmosphere that transmit the visible  
33 portion of solar radiation but absorb specific spectral bands of thermal radiation emitted by  
34 the Earth. The theory is that terrain absorbs radiation, heats up, and emits longer  
35 wavelength thermal radiation that is prevented from escaping into space by the blanket of  
36 carbon dioxide and other greenhouse gases in the atmosphere. As a result, the climate  
37 warms.<sup>2</sup>

38 “Greenhouse gases” are defined in section 38505 of the Health and Safety Code as  
39 including:

- 40 1. carbon dioxide;

---

<sup>1</sup> An Introduction to Indoor Air Quality (IAQ), Environmental Protection Agency, <http://www.epa.gov/iaq/ia-intro.html>  
<sup>2</sup> [NASA's Earth Observatory library](http://earthobservatory.nasa.gov/Glossary/index.php), <http://earthobservatory.nasa.gov/Glossary/index.php>

- 1       2. hydrofluorocarbons;
- 2       3. methane;
- 3       4. nitrogen trifluoride;
- 4       5. nitrous oxide;
- 5       6. perfluorocarbons; and
- 6       7. sulfur hexafluoride.

7       These same seven chemicals are included in these regulations as chemicals that constitute  
8       “greenhouse gases.” These chemicals are grouped together because of their roles in  
9       global warming.

10       8. “Global warming potential” is defined in section 69405.4 of Chapter 54 as the propensity  
11       for a chemical substance to be a greenhouse gas, that is, to absorb infrared radiation in  
12       the atmosphere and, thereby, contribute to the general warming of the planet.

13       **(C)** *Nitrogen oxides* are gases consisting of one molecule of nitrogen and varying numbers of  
14       oxygen molecules. Nitrogen oxides are produced in the emissions of vehicle exhausts and  
15       from power stations. In the atmosphere, nitrogen oxides can contribute to formation of  
16       photochemical ozone (smog), can impair visibility, and have health consequences; they are  
17       thus considered pollutants<sup>3</sup>. Chemicals that cause air emissions that result in nitrogen  
18       oxides cause acid rain, which causes negative effects on the ecosystem and ozone, which  
19       contributes to the greenhouse gas effect.

20       **(D)** *Particulate matter that exhibit the particle size or fiber dimension hazard trait* is defined as  
21       the existence of a chemical substance in the form of small particles or fibers or the  
22       propensity to form into such small-sized particles or fibers with use or environmental  
23       release. The size dimension specified under section 69405.7 renders the particle  
24       respirable and capable of ending up in the lungs. Particulate matter may cause public  
25       health respiratory impacts and their small sizes may serve as building blocks to secondary  
26       organic aerosols, which may contribute to greenhouse gases.

27       **(E)** *Chemical substances that exhibit the stratospheric ozone depletion potential hazard trait*  
28       contribute to the deterioration of the Earth’s ozone layer. That layer serves to prevent  
29       harmful exposures to ultraviolet light (which penetrates the Earth’s atmosphere in the  
30       absence of an adequate ozone layer.) This results in a number of adverse public health,  
31       ecological and other environment impacts.

32       **(F)** *Sulfur oxides* are compounds composed of one sulfur and two oxygen molecules. Sulfur  
33       dioxide emitted into the atmosphere through natural and anthropogenic processes is  
34       changed in a complex series of chemical reactions in the atmosphere to sulfate aerosols.<sup>4</sup>  
35       Chemicals that cause air emissions that result in sulfur oxides cause acid rain, which  
36       causes negative effects on the ecosystem and ozone, which contributes to the greenhouse  
37       gas effect.

38       **(G)** *Tropospheric ozone-forming compounds, including compounds that exhibit the ambient*  
39       *ozone formation hazard trait* contribute to a number of adverse public health, including  
40       respiratory impairment, as well as other direct and indirect ecological and other  
41       environmental impacts.

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<sup>3</sup> [NASA's Earth Observatory library](http://earthobservatory.nasa.gov/Glossary/index.php), <http://earthobservatory.nasa.gov/Glossary/index.php>

<sup>4</sup> [NASA's Earth Observatory library](http://earthobservatory.nasa.gov/Glossary/index.php), <http://earthobservatory.nasa.gov/Glossary/index.php>

1  
2 **Section 69501.1(a)(4)** defines “**adverse ecological impacts**” to ensure that DTSC and a  
3 responsible entity conducting the Alternatives Analysis consider those adverse ecological  
4 impacts that are commonly recognized by the scientific community as being of concern when  
5 evaluating a Chemical of Concern, a Priority Product, or a chemical substitute for a Priority  
6 Product. The proposed definition also makes use of, and is consistent with, related regulations  
7 in Chapter 54. This, in turn, allows for ease of use and a common understanding of terms  
8 used.

9  
10 Adverse ecological impacts are direct or indirect effects on living organisms and their  
11 environments. Adverse ecological effects from environmental pollutants occur at all levels of  
12 biological organization, such as ecosystem, community, assemblage, population, species, or  
13 individual level of biological organization.

14  
15 Ecotoxicity as an adverse impact to the environment includes acute or chronic toxicity to  
16 organisms in the environment, as well as changes in population size and biodiversity reduction  
17 and negative impacts to historical communities of organisms. For example, biological  
18 contamination or changes in the biological system may be caused by an increase of life forms  
19 due to the presence of the chemical, such as an unwanted increase of organisms due to the  
20 presence of the chemical being used as food. A historic example is the use of phosphorus in  
21 cleaning products, resulting in algae using phosphorus as a food source resulting in algae  
22 blooms. As a result of algae blooms, less dissolved oxygen was available for fish to breathe  
23 and fish kills resulted.

24  
25 Biological organisms may also be contaminated with a chemical through chemical absorption  
26 or uptake of the chemical into plants or animals – with or without direct consequences of the  
27 biological organism’s survival. Absorption without direct consequences may result in  
28 bioaccumulation in the plant or animal and eventually adversely affect higher organisms, which  
29 results in the loss of biodiversity.

30  
31 Terrestrial ecosystems and aquatic ecosystems are subject to global threats of pollution (acid  
32 deposition, stratospheric ozone depletion, air pollution, the greenhouse effect) and human  
33 activities (soil erosion, deforestation). Examples of adverse impacts include deterioration or  
34 loss of environmentally sensitive habitats, loss of populations, or biodiversity of plants or  
35 animals.

36  
37 Chemical contamination may cause direct vegetation contamination or damage (including  
38 phytotoxicity) and may also lead to the loss of biodiversity through acute toxicity of organisms  
39 in the soil. This may result in the loss of organic matter and other physical changes in the  
40 environment, such as erosion, soil compaction or other soil structural changes, which impact  
41 vegetation survival and negatively affect environmentally sensitive habitats, especially in  
42 environments already designated as impaired.

43  
44 Additional adverse ecological effects are described in Article 4 of Chapter 54 and include  
45 domesticated animal toxicity, eutrophication, and impairment of waste management

1 organisms, loss of genetic diversity, including biodiversity, phytotoxicity, and wildlife  
2 development, growth, reproductive, and survival impairment.

3  
4 **Section 69501.1(a)(5)** defines “**adverse environmental impacts**”, which is useful as a  
5 naming convenience to collectively refer to all adverse impacts other than public health  
6 impacts. Many of the chemicals have enforceable regulatory standards related to their  
7 presence in air, soil, and water. To provide a measurable threshold to determine when an  
8 “adverse” impact has occurred, subsection (E) clarifies that when a chemical exceeds an  
9 enforceable standard associated with the protection of the environment, an adverse impact  
10 has occurred.

11  
12 **Section 69501.1(a)(6)** defines “**adverse public health impacts**” to clarify that “adverse  
13 public health impacts” include those toxicological effects in Articles 2 and 3 of Chapter 54.  
14 Again, this aligns with the related regulations in Chapter 54. Thus, it provides consistency of  
15 usage and promotes a common understanding of terms. They are as follows and are  
16 described in further detail in Chapter 54: carcinogenicity, developmental toxicity, reproductive  
17 toxicity, cardiovascular toxicity, dermatotoxicity, endocrine toxicity, epigenetic toxicity,  
18 genotoxicity, hemotoxicity, hepatotoxicity and digestive system toxicity, immunotoxicity,  
19 musculoskeletal toxicity, nephrotoxicity and other toxicity to the urinary system,  
20 neurodevelopmental toxicity, neurotoxicity, ocular toxicity, ototoxicity, reactivity in biological  
21 systems, and respiratory toxicity.

22  
23 The phrase “exceedance of an enforceable California or federal regulatory standard relating to  
24 the protection of public health” is added to clarify that when a chemical exceeds an  
25 enforceable regulatory standard, an adverse public health impact has occurred. For example,  
26 exceedance of a regulatory standard that will be considered an adverse public health impact  
27 can be an exceedance of an air quality standard for respiratory toxicity, or an exceedance of a  
28 drinking water standard for a carcinogen. Information about these exceedances will have to be  
29 evaluated to determine if a product is a major source of the Chemical of Concern. Workers  
30 who may be exposed to numerous chemicals daily are sometimes the first group to manifest  
31 the effects of high exposure to industrial chemicals. Occupational health is included in this  
32 definition to address the workplace exposures that may be considered the cause of illness and  
33 disease.

34  
35 **Section 69501.1(a)(7)** defines “**adverse public health and environmental impacts**” or  
36 “**adverse impacts**” as a naming convenience to include all adverse impacts relevant under  
37 these regulations, and to facilitate discussion.

38  
39 **Section 69501.1(a)(8)** defines “**adverse soil quality impacts**” to ensure that DTSC, and a  
40 responsible entity conducting the Alternatives Analysis, consider those adverse soil quality  
41 impacts that are commonly recognized by the scientific community as being of concern when  
42 evaluating a chemical and product as a Chemical of Concern, a Priority Product, or a chemical  
43 substitute for a Priority Product.

44 **(A) Soil compaction and other soil structural changes** are forms of physical degradation  
45 resulting in distortion of the soil where biological activity, porosity and permeability are

1 reduced, strength is increased and soil structure partly destroyed. Compaction can reduce  
2 water infiltration capacity and increase erosion risk by accelerating run-off.

3 **(B) Soil Erosion** is the removal of topsoil faster than the soil forming processes can replace it.  
4 Soil erosion is normally a natural process occurring over geological timescales. But where  
5 (and when) the natural rate has been significantly increased by human activity accelerated  
6 soil erosion becomes a process of degradation and, thus, an identifiable threat to soil that  
7 can result in land infertility, devastating flooding, and other adverse soil quality impacts.

8 **(C) Loss of organic matter** may be due to the chemical's direct (e.g., poisoning or killing  
9 organic matter) or indirect "trickle down" effects on one organism leading to loss of other  
10 organisms. The loss of biodiversity and organic matter may lead to soil compaction or  
11 other soil structural changes, erosion and soil sealing.

12 **(D) Soil sealing** is a change in the nature of the soil leading to impermeability (e.g. compaction  
13 by machinery). Sealed areas are lost to uses such as agriculture or forestry while the  
14 ecological soil functions are severely impaired or even prevented (e.g. soil working as a  
15 buffer and filter system or as a carbon sink). In addition, surrounding soils may be  
16 influenced by change in water flow patterns or the fragmentation of habitats.

17  
18 **Section 69501.1(a)(9)** defines "**adverse waste and end-of-life impacts**" to ensure that a  
19 responsible entity considers, when evaluating the Priority Product, its Chemical of Concern, or  
20 alternative chemical substitute during the Alternatives Analysis, the waste, and end of life  
21 impacts during its life cycle. While each may be a factor in itself to determine the adverse  
22 impact, it may also be a combination of more than one that determines the adverse impact.

23  
24 For instance, any impacts due to an increase in volume or mass are to be considered. The  
25 Clean Water Act and the Ocean Dumping Ban Act of 1988 eliminated all but land-based  
26 options for the "beneficial use" or disposal sewage sludge. When the wastewater effluent  
27 cannot meet discharge requirements due to unacceptable levels of contaminants, there is a  
28 need for secondary treatment, which doubles the amount of biosolids produced at wastewater  
29 treatment plants. Biosolids are normally produced in great volumes on a daily basis. Due to  
30 storage capacity, wastewater treatment plants may need to dispose of biosolids once or twice  
31 per day.

32  
33 The contaminants removed from the wastewaters are concentrated in the biosolids produced.  
34 If the biosolids cannot be marketed as a soil amendment (by-product) due to the contaminants,  
35 then disposal as waste material is required. The primary requirement for sludge disposal at a  
36 sanitary landfill is that the biosolids cannot contain hazardous substances in excess of  
37 predetermined limits. When biosolids exceed these concentrations and meet the definition of  
38 hazardous waste, biosolids cannot be disposed at sanitary landfills. As a hazardous waste,  
39 additional special handling requirements are necessary for proper handling, storage,  
40 transportation and disposal of biosolids to mitigate exposures to waste handling workers and to  
41 prevent releases to the environment.

42  
43 **Section 69501.1(a)(10)** defines "**adverse water quality impacts**" to clarify that DTSC and a  
44 responsible entity conducting the Alternatives Analysis consider those adverse water quality  
45 impacts affecting the water's beneficial use and that are commonly recognized by the scientific

1 community as being of concern when evaluating a chemical and product as a Chemical of  
2 Concern, a Priority Product, or a chemical substitute for a Priority Product.

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

7 **(B)** *Chemical Oxygen Demand (COD)* is a measure of the capacity of water to consume  
8 oxygen during the decomposition of organic matter and the oxidation of inorganic  
9 chemicals such as ammonia and nitrite. COD is expressed as the amount of oxygen  
10 consumed in mg/l. Chemical oxygen demand measurements are commonly made on  
11 samples of waste waters or of natural waters contaminated by domestic or industrial  
12 wastes and may provide information for water treatment activities. COD results do not  
13 necessarily correlate to the biochemical oxygen demand because the chemical oxidant  
14 may react with substances that bacteria do not stabilize. Biological oxygen demand  
15 measures the amount of oxygen consumed by microbial oxidation and is most relevant to  
16 waters rich in organic matter.

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

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

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

34 1. *Section 303(c) of the federal Clean Water Act* requires states to develop water quality  
35 standards and review and update those standards every three years. Water quality  
36 standards must include designated uses of water bodies, water quality criteria that are  
37 necessary to protect those uses, expressed in either numeric or narrative form, and  
38 antidegradation components.

39 2. *Section 303(d) of the federal Clean Water Act*, requires states, territories, and  
40 authorized tribes to develop lists of impaired waters. The State and Regional Water  
41 Quality Boards assess water quality monitoring data for California's surface waters  
42 every two years to determine if they contain pollutants at levels that exceed protective  
43 water quality standards.

44 3. *Maximum Contaminant Levels (MCLs)* are established by the California Department of  
45 Public Health (CDPH) or by the U.S. EPA for specific chemicals in drinking water.

1 MCLs are health protective drinking water standards to be met by public water systems.  
2 MCLs take into account not only a chemical's health risks, but also factors such as their  
3 detectability and treatability, as well as costs of treatment. Health & Safety Code  
4 §116365(a) requires CDPH to establish, in regulations, a contaminant's MCL at a level  
5 as close to its Public Health Goal (PHG) as is technically and economically feasible,  
6 placing primary emphasis on the protection of public health.

7 **4. Notification Levels (NLs)** are health-based advisory levels established by CDPH for  
8 chemicals in drinking water that lack Maximum Contaminant Levels (MCLs). When  
9 chemicals are found at concentrations greater than their notification levels, certain  
10 requirements and recommendations apply. State law (Health & Safety Code §116455)  
11 requires timely notification of the local governing bodies (e.g., city council, county board  
12 of supervisors, or both) by drinking water systems whenever a notification level is  
13 exceeded in drinking water that is provided to consumers.

14 **5. Public Health Goals (PHGs)** are established by OEHHA. They are concentrations of  
15 drinking water contaminants that pose no significant health risk if consumed for a  
16 lifetime, based on current risk assessment principles, practices, and methods. OEHHA  
17 establishes PHGs pursuant to Health & Safety Code §116365(c) for contaminants with  
18 MCLs, and for those chemicals for which CDPH will be adopting MCLs.

19  
20 **Section 69501.1(a)(11)** defines “**alternative**” to identify the range of different approaches that  
21 a responsible entity may choose to address the presence of a Chemical of Concern in a  
22 Priority Product during the Alternatives Analysis.

23 **(A)** Allows a responsible entity to use an alternate process or alternative that eliminates the  
24 use of a Chemical of Concern in the Priority Product if the responsible entity determines it  
25 is not necessary for the function of the product and the alternate substantially meets the  
26 function of the original product.

27 **(B)** Allows a responsible entity to change the formulation or design of the product to eliminate  
28 or reduce the use of the Chemical of Concern in the Priority Product.

29 **(C)** Provides the same latitude as is provided in section 69501.1(a)(11)(B), except that under  
30 this provision a responsible entity may elect to switch from manufacturing a Priority Product  
31 with one material to another material in order to reduce or eliminate the use of Chemicals of  
32 Concern in the final product.

33 **(D)** Provides responsible entities a broad range of activities that may be undertaken by the  
34 entity to reduce or eliminate the use of Chemical of Concerns.

35  
36 **Section 69501.1(a)(12)** defines “**alternatives analysis**” or “**AA**” to mean an evaluation and  
37 comparison of a Priority Product and one or more alternatives to the product, under Article 5.  
38 The term and Article 5 embody the requirements contained in the enabling statute, Health and  
39 Safety Code subsection 25253(a)(2), which requires that an evaluation of the availability of  
40 potential alternatives and potential hazards posed by those alternatives, as well as an  
41 evaluation of critical exposure pathways be conducted when a product contains a Chemical of  
42 Concern. This process must include life cycle assessment tools that take into consideration,  
43 but are not be limited to, all of the following:

- 44 (A) Product function or performance;
- 45 (B) Useful life;

- 1 (C) Materials and resource consumption;
- 2 (D) Water conservation;
- 3 (E) Water quality impacts;
- 4 (F) Air emissions;
- 5 (G) Production, in-use, and transportation energy inputs;
- 6 (H) Energy efficiency;
- 7 (I) Greenhouse gas emissions;
- 8 (J) Waste and end-of-life disposal;
- 9 (K) Public health impacts, including potential impacts to sensitive subpopulations,
- 10 including infants and children;
- 11 (L) Environmental impacts; and
- 12 (M) Economic impacts.

13  
14 The AA conducted during the first stage, coupled with the assessment carried out in the  
15 second stage, collectively, address the above- mentioned impacts. (The AA is discussed in  
16 greater detail below in Article 5.)

17  
18 **Section 69501.1(a)(13)** defines “**Alternatives Analysis Threshold**” to mean a concentration  
19 specified by DTSC under section 69503.5(c). DTSC has the ability to determine the AA  
20 Threshold for specific Priority Products (chemical-product combination) under the criteria in  
21 section 69503.5(c). A proposed Priority Product, will be subject to public workshops and a  
22 public notice before the AA Threshold for the Priority Product is listed. This will give  
23 stakeholders an opportunity to present reliable information to DTSC demonstrating how the AA  
24 Threshold should be evaluated and set for each proposed Priority Product. Ultimately, DTSC  
25 will set the AA Thresholds based on the criteria set out in the regulations, which include  
26 principles of sound science and reliable information.

27  
28 **Section 69501.1(a)(14)** defines “**Alternatives Analysis Threshold Exemption Notification**”  
29 to clarify that the requirements for this notification can be found in section 69503.6.

30  
31 **Section 69501.1(a)(15)** defines “**aqueous hydrolysis half-life**” to ensure consistency with  
32 the definitions for hydrolysis and half-life found in section 796.3500 of Title 40 of the Code of  
33 Federal Regulations (40 CFR). The half-life of a chemical is defined as the time required for  
34 the concentration of the chemical substance being tested to be reduced to one-half its initial  
35 value and hydrolysis is defined as the reaction of an organic chemical with water.

36  
37 Hydrolysis is a chemical transformation process in which a chemical reacts with water. Certain  
38 classes of chemicals, upon contact with water, can undergo hydrolysis, which is one of the  
39 most common reactions controlling chemical stability and is, therefore, one of the main  
40 chemical degradation paths of these substances in the environment. Some of these reactions  
41 can occur so rapidly that there may be greater concern about the products of the  
42 transformation than about the parent compounds. In other cases, a substance will be resistant  
43 to hydrolysis under typical environmental conditions, while, in still other instances, the  
44 substance may have an intermediate stability that can result in the necessity for an

1 assessment of both the original compound and its transformation products. [40 CFR  
2 796.3500]

3  
4 Hydrolysis rates are generally described in half-lives and indicate how long a chemical will  
5 persist in an aqueous environment. If the chemical resists hydrolysis then it may degrade via  
6 some other pathway. Aqueous hydrolysis half-life is one of the factors listed under  
7 environmental fate, paragraph 69501.1(a)(29).

8  
9 **Section 69501.1(a)(16)** defines “**atmospheric oxidation rate**” to mean the rate of change or  
10 degradation of a chemical through the interaction with oxygen in the atmosphere.

11  
12 This environmental fate property listed under section 69501.1(a)(29) is typically described in  
13 half-lives. An atmospheric oxidation rate indicates stability in the atmosphere and the potential  
14 for long-range transport. Although experimental data are preferred, very little experimental  
15 data are available for atmospheric oxidation rates on many compounds. The Estimation  
16 Programs Interface (EPI) Suite is a Windows based suite of physical/chemical property and  
17 environmental fate estimation models developed by the US EPA’s Office of Pollution  
18 Prevention Toxics and Syracuse Research Corporation. The EPI suite and other software  
19 programs can be used to estimate the atmospheric oxidation rate when experimental data is  
20 not available. If the substance has a very short atmospheric half-life, it will only occur in the  
21 lower troposphere. However, long-lived substances may also occur in the stratosphere or be  
22 transported to parts of the globe far removed from the original source.

23  
24 **Section 69501.1(a)(17)** defines “**bioaccumulation**” to be broader than the definition found in  
25 section 69405.2. The phrase “tissues of an organism or an individual biological component”  
26 has been added to clarify DTSC’s intent to account for accumulation of a chemical in the  
27 organism or an individual biological component. “Bioaccumulation” is used in this regulation as  
28 both a hazard trait and an environment fate property.

29  
30 Bioaccumulation occurs when chemicals accumulate in living things any time they are taken up  
31 and stored faster than they are broken down (metabolized) or excreted<sup>5</sup>. Consideration of  
32 bioaccumulation is very important in protecting human beings and other organisms from the  
33 adverse effects of chemical exposure. Examples of chemicals that bioaccumulate are heavy  
34 metals (such as lead and mercury), dioxins, and polychlorinated biphenyls (PCBs).

35  
36 Bioaccumulation, as an environmental fate property, is the ability of a substance to accumulate  
37 in living tissues to levels higher than those in the surrounding environment. It is usually  
38 quantified by a chemical's bioaccumulation factor (BAF) or bioconcentration factor (BCF), and  
39 different numerical values of BAF or BCF have been developed for the criteria by a number of  
40 organizations<sup>6</sup>.

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<sup>5</sup> U.S. EPA, Bioaccumulation Testing and Interpretation for the Purpose of Sediment Quality Assessment. Status and Needs. EPA-823-R-00-001. Office of Water, February 2000, pp. 53-55.

<sup>6</sup> <http://www.ec.gc.ca/inrp-npri/default.asp?lang=en&n=889870FD-1>

1  
2 Several chemical-specific metrics can be used to evaluate the potential for a chemical to  
3 bioaccumulate in plants and animals and biomagnify in food webs. These values may be  
4 measured in laboratory tests or estimated with computer models based on chemical structure.  
5 **Section 69501.1(a)(18)** defines “**certified assessor**” to provide clarity and gives the  
6 appropriate context for the later use of this term.

7  
8 **Section 69501.1(a)(19)(A)** defines “**chemical**” to mean either of the following: 1. a substance  
9 of a particular molecular identity; or 2. a chemical ingredient, as defined. For purposes of this  
10 regulation to facilitate discussion, the term is also used to include “chemical ingredient”.  
11 Consequently, “chemical” may include an element, ion or uncombined radical, and any  
12 degradate, metabolite, or reaction product of a substance, or compound substances or  
13 mixtures of substances.

14  
15 **Section 69501.1(a)(19)(B)** defines the term “Molecular identity” to clarify its usage here.  
16 Molecular identity is similar to TSCA Class 1 substances, which can be represented by a  
17 definite structural diagram and molecular formula. Examples include: acetone, lead, benzene  
18 and sodium chloride. These substances have discrete molecular formulas and fully-defined  
19 structural diagrams.

20  
21 **Section 69501.1(a)(20)** defines “**Chemical of Concern**” to identify the subset of chemicals  
22 that have been prioritized under Article 2 as Chemicals of Concern. Although there may be  
23 over a million chemicals that have been identified, the number of chemicals that are  
24 manufactured or processed vary by country. There are over 85,000 chemicals on the Toxic  
25 Substances Control Act (TSCA) inventory manufactured or processed in the United States; the  
26 European Union lists over 100,000 chemicals used in Europe. Article 2 lays out the framework  
27 for identifying and prioritizing chemicals for the purpose of these regulations.

28  
29 The initial list of chemicals will be chemicals that have been identified by authoritative  
30 organizations as exhibiting a hazard trait. At least every three years, DTSC must review, and  
31 revise, as appropriate, the Chemicals of Concern list. Additions to the list of Chemicals of  
32 Concern will be based on the chemical’s adverse impacts. All revisions will be subject to  
33 public notice. This process is explored in much greater detail in the discussion of Article 2.

34  
35 **Section 69501.1(a)(21)** defines “**component**” to allow the Department to name an identifiable  
36 part of a consumer product as a Priority Product, as opposed to naming the entire product.

37  
38 The concept of “component” is used as a way to target materials within a product that are  
39 cause for concern, and, as such, must undergo an Alternatives Analysis. In this manner, a  
40 Priority Product can be identified by DTSC as specifically as necessary to get at the public  
41 health and/or environmental threat, and the weight of the Chemical of Concern in the product  
42 will not be diluted to include the entire product. For example, DTSC could identify the catalytic  
43 converter in a vehicle as the component that must undergo an Alternatives Analysis due to the  
44 release of nitrous oxide, a potent greenhouse gas. In such a case, an entire vehicle would not

1 be subject to an Alternatives Analysis. Rather, only the identified component—the catalytic  
2 converter-- would be subject to the AA.

3  
4 **Section 69501.1(a)(22)(A)** defines “consumer product” differently from the common usage  
5 of this term. This California definition is broader than what is found in the United States  
6 Consumer Product Safety Act enacted in 1972 (codified at 15 U.S.C. § 2051–§ 2084), and has  
7 fewer exemptions than federal law does.

8  
9 **Section 69501.1(a)(22)(A)1.** is consistent with the enabling statute and clarifies which  
10 consumer products will not be subject to the requirements of this Chapter. Health and Safety  
11 Code section 25251 defines “consumer products” to mean a product or part of the product that  
12 is used, brought (sic), or leased for use by a person for any purpose. Consumer product does  
13 not include prescription drugs and medical devices, dental restorative materials, diagnostic or  
14 treatment instruments, packaging (for prescription drugs and devices, dental restorative  
15 materials, and medical instruments), food, and pesticides products. “Person” in Health and  
16 Safety Code section 25118 is defined to mean more than just an individual; person can also  
17 mean a company or governmental agency.

18  
19 **Section 69501.1(a)(22)(A)2. and 3.** The definition of “consumer product” will provide DTSC  
20 flexibility to name any identifiable constituent or part or a homogeneous layer of material in the  
21 finished product or that makes up the finished product as a Priority Product. For example, a  
22 motor vehicle may be made of thousands of parts, but the Chemical of Concern may be used  
23 in only one component of this product. By defining component, DTSC may name a uniquely  
24 identifiable component as being subject to the requirement for an alternatives analysis, such  
25 as a tire or DTSC could name only the outer homogeneous layer of a tire as the Priority  
26 Product. See definition of “homogeneous material” under section 69501.1(a)(35).

27  
28 **Section 69501.1(a)(22)(B)** clarifies that “historic products” will not be subject to the  
29 requirements of these regulations, including the requirement to conduct an Alternatives  
30 Analysis. This regulation is forward looking and its goal is to accelerate the quest for safer  
31 consumer products. On the other hand, historic products still exist, but ceased being produced  
32 prior to identification of them as Priority Products. This provision clarifies that those products  
33 are outside the scope of these regulations.

34  
35 **Section 69501.2(a)(22)(C)** clarifies that a private individual who sells a used product (second-  
36 hand) to another individual will not be subject to the requirement to conduct an Alternatives  
37 Analysis. The seller of second-hand products would not be expected to have the expertise,  
38 resources, or capacity to be able to complete an Alternatives Analysis. Even with the  
39 increased sales of second-hand products due to online auction and sale sites, no single  
40 second-hand product would represent a high sales volume of consumer products in California.

41  
42 **Section 69501.1(a)(23)** defines “contact information” to specify what information is required  
43 to be provided to DTSC to allow DTSC to make contact with the submitting party, if necessary.

1 **Section 69501.1(a)(24)** defines “**day**” to make clear that when time is specified in the  
2 regulations, a day will mean a calendar day, not a workday. The specified time periods are  
3 calculated by excluding the first day and including the last. The definition allows for additional  
4 time when the last day is a Saturday, Sunday, or a California holiday specified in Government  
5 Code section 6700. The holidays in this state, as of the writing of these regulations, are:

- 6 • January 1;
- 7 • The third Monday in January, known as "Dr. Martin Luther King, Jr. Day";
- 8 • The third Monday in February;
- 9 • March 31 known as "Cesar Chavez Day";
- 10 • The last Monday in May;
- 11 • July 4;
- 12 • The first Monday in September;
- 13 • The second Monday in October, known as "Columbus Day";
- 14 • November 11, known as "Veterans Day";
- 15 • The fourth Thursday in November, known as "Thanksgiving Day";
- 16 • The fourth Friday in November; and
- 17 • December 25.

18  
19 **Section 69501.1(a)(25)** defines “**Department**” to mean the Department of Toxic Substances  
20 Control. This definition is provided for clarity and ease of use.

21  
22 **Section 69501.1(a)(26)** defines “**end-of-life**” to mean the point when the product is discarded  
23 by the consumer or the end of the useful life of the product, whichever occurs first. This  
24 definition clarifies what the two alternate triggers are for consideration of impacts after the  
25 initial use of the product. These two points in time delineate when the “use phase” ends and  
26 the “end-of-life phase” begins in the continuum of a product’s lifecycle.

27  
28 The first trigger is when a consumer no longer has use for a consumer product and discards a  
29 product regardless of whether or not the product has reached the end of its useful life. The  
30 second trigger occurs when a product has reached the end of the useful life due to failure or  
31 wear-out. Whichever occurs first will differentiate what is considered an end-of-life activity,  
32 which may include disposal, repair, maintenance, product reuse, component reuse, or  
33 recycling.

34  
35 **Section 69501.1(a)(27)** defines “**environment**” to include land, air, water, soil, minerals, flora,  
36 and fauna. The environment that surrounds an organism or group of organisms includes land,  
37 air, water, soil, minerals, flora (plants), and fauna (animals). This definition does not include  
38 abiotic factors such as light and temperature. This definition sets the baseline for what must  
39 be considered later at various places in the regulations when the term “environment” is used.  
40 It is given its commonly understood meaning.

41  
42 **Section 69501.1(a)(28)** defines “**environmental fate**” to mean all of the following:

- 43 **(A)** aerobic and anaerobic half-lives;
- 44 **(B)** aqueous hydrolysis half-life;

- 1 (C) atmospheric oxidation rate;
- 2 (D) bioaccumulation;
- 3 (E) biodegradation;
- 4 (F) mobility in environmental media;
- 5 (G) persistence; and
- 6 (H) photodegradation

7  
8 Environmental fate factors affect how a chemical moves in the environment, transforms  
9 (physically, chemically, or biologically), or accumulates in media or species. The  
10 environmental fate depends on the chemical's affinity to one of four environmental  
11 compartments: air, water, soil, and living organisms.

12  
13 When chemicals are released into the environment, there is the potential for them to disperse  
14 and enter some or all of the adjacent compartments. Chemical properties, release rates, and  
15 degradation rates affect the distribution and concentration of a chemical in the environment,  
16 and its ultimate fate. For example, if a chemical is biodegradable, it may be broken down  
17 before it can become dangerous. If a chemical is not mobile, it will stay in one place and is  
18 unlikely to be taken up by organisms. If the chemical is persistent, it remains unchanged for a  
19 long time and may have a high potential for exposure to organisms. Thus, these factors are  
20 included to reflect the different risks to the environment based on the environmental fate of a  
21 chemical. The factors included are in keeping with mainstream scientific thinking in this field.

22  
23 These properties include all of the following:

- 24  
25 (A) *Aerobic and anaerobic half-lives* refer to the rate chemicals transform in soil or sediment in  
26 the presence or exclusion of oxygen. These metabolism rates are used to predict the  
27 likelihood of the chemicals persisting in the environment, and also whether degradation products, of  
28 concern, are likely to be produced and to persist. Soil metabolism rates assess aerobic  
29 and anaerobic formation and decline of transformation products of organic chemicals in  
30 soil. Aquatic sediment metabolism rates assess aerobic and anaerobic transformation of  
31 organic chemicals in aquatic sediment systems.
- 32 (B) *Aqueous hydrolysis half-life*, see paragraph 69501.1(a)(15).
- 33 (C) *Atmospheric oxidation rate*, see paragraph 69501.1(a)(16).
- 34 (D) *Bioaccumulation*, see paragraph 69501.1(a)(17).
- 35 (E) *Biodegradation* of chemicals is a metabolic process by which organic substances are  
36 decomposed by micro-organisms (mainly aerobic bacteria) into simpler substances. A  
37 biodegradation rate is used to characterize the effect of biodegradation on contaminant  
38 migration. In general, if biodegradation of chemicals is confirmed in the laboratory, it will  
39 also occur in the wider environment. However, many of the dynamics of such processes  
40 are unknown, and biodegradation rate constants determined in the laboratory are not  
41 always applicable in the field. The rate is typically expressed in terms of a rate constant  
42 and/or half-life.
- 43 (F) *Mobility of a chemical* is the tendency for a chemical to move in the environment. When a  
44 chemical is released into the environment, it is distributed to the air, soil, and water. The  
45 concentration in any of these environmental compartments will be a function of both the

1 physicochemical characteristics of a chemical and the composition of the environmental  
2 media. Many factors will affect how a chemical is transported in the atmosphere, in aquatic  
3 environments, and how interactions with soil, groundwater and biological alterations affect  
4 movement.<sup>7</sup> Any substance will move between environmental compartments (air, water,  
5 soil/sediment and biota) and be subject to environmental partitioning. Substances will  
6 move from their point of entry to the environmental compartment for which they have most  
7 affinity. From this, substances may be transferred again to other compartments.

8 Substances can undergo chemical transformations in every environmental compartment.

9 **(G) Persistence**, see paragraph 69501.1(a)(45).

10 **(H) Photodegradation** is an important process for determining the residence time and fate of  
11 many chemicals in air, water, and soils. Photodegradation is the degradation of a chemical  
12 by means of light energy. Many chemical reactions in the environment are initiated by the  
13 photodissociation of chemicals. Solar radiation is converted into chemical energy to  
14 activate and dissociate chemical species.

15  
16 Photodegradation is categorized into direct and indirect reactions. Direct photodegradation  
17 occurs when chemicals absorb sunlight directly, and react in the resulting excited states.  
18 Indirect photodegradation occurs when chemicals react with unstable compounds, such as  
19 hydroxyl radicals, which have themselves been produced by the energy of sunlight. In the  
20 troposphere, indirect photodegradation is the most important reaction. In water, direct  
21 photodegradation is important.<sup>8</sup>

22  
23 **Section 69501.1(a)(29)** defines “**environmental or toxicological endpoint**” to mean any  
24 environmental or toxicological endpoint specified in Chapter 54. Chapter 54 defines the terms  
25 “environmental endpoint” and “toxicological endpoint” and provides specific endpoints for all  
26 toxicological and environmental hazard traits. This definition aligns this term to have the same  
27 meaning set out in Chapter 54 and, thus, promotes a common understanding of what is meant  
28 by the use of this term.

29  
30 **Section 69501.1(a)(30)** defines “**Failure to Comply List**” to mean the list prepared by DTSC  
31 pursuant to subsection 69501.2(d). DTSC will maintain this list on its website and regularly  
32 update it. Information will be removed once DTSC determines that the requirements have  
33 been met. This provision clarifies what is meant by the use of this term later in this Article. A  
34 complete description and explanation of the Failure to Comply List is provided

35  
36 **Section 69501.1(a)(31)** defines “**functionally acceptable**” to mean the functions of the  
37 original product that consumers can be reasonably anticipated to accept while meeting all  
38 applicable legal requirements. DTSC drafted this definition to clarify the standards that an

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<sup>7</sup> Principles for evaluating chemicals in the environment: A report of the Committee for the Working Conference on Principles of Protocols for Evaluating Chemicals in the Environment, Environmental Studies Board, National Academy of Sciences-National Academy of Engineering, and Committee on Toxicology, National Research Council, 1975

<sup>8</sup> <http://www.env.go.jp/en/chemi/pops/Appendix/04-GuideLine/guidelines.pdf>

1 alternative product must meet in order to be considered “functionally acceptable” because  
2 there were different interpretations being urged by various commenters.

3  
4 An alternative is not required to meet all of the original product’s attributes to be a suitable  
5 alternative and can instead meet some of the attributes that render the alternative suitable to  
6 be used in lieu of the original product. The alternative, however, must perform the essential  
7 functions of the original product and meet any legal requirements, as defined. The definition  
8 appropriately specifies the attributes an alternative must have in order to be “functionally  
9 acceptable.”

10  
11 **Section 69501.1(a)(32)** defines “**hazard trait**” to mean any hazard trait specified or defined in  
12 Chapter 54, related regulations, and allows for ease of use and understanding of how the term  
13 is used.

14  
15 The hazard traits are intrinsic properties of chemicals that fall into broad categories of  
16 toxicological, environmental, exposure potential, and physical hazards, that may contribute to  
17 adverse effects in exposed humans, domesticated animals, wildlife, or in ecological  
18 communities, populations, or ecosystems. By using this definition, DTSC has aligned these  
19 regulations with the related regulations in Chapter 54. This allows for ease of use and  
20 understanding.

21  
22 **Section 69501.1(a)(33)** defines “**hazard trait submission**” to implement and make more  
23 specific Health and Safety Code section 25257(f), which precludes hazard trait submissions for  
24 chemicals, including chemical ingredients, from being protected as trade secret. This concept  
25 comes into play in Article 10 and is discussed in more detail under that Article. The definition  
26 DTSC has drafted gives the term a fair and appropriate scope to achieve the purposes of the  
27 authorizing statute and these regulations.

28  
29 **Section 69501.1(a)(34)** defines “**homogeneous material**” to allow DTSC to target materials  
30 with a Chemical of Concern within certain products. By naming only the homogenous material,  
31 the concentration of the Chemical of Concern will not be diluted with the weight of the entire  
32 assembly or subassembly. This is critical because it allows DTSC to narrow the applicability of  
33 the alternatives analysis threshold to a homogenous material when it is a chemical in the  
34 homogeneous material that is the basis for public health or environmental concern.

35  
36 The concept of homogeneous material was introduced as a way of restricting substances  
37 within electronics through the European Union Restriction on the Use of Certain Hazardous  
38 Substances (RoHS). The RoHS definition has been incorporated into this definition of  
39 “homogeneous”. This will allow DTSC to name a uniquely identifiable homogenous material as  
40 being subject to the requirement to conduct an Alternatives Analysis.

41  
42 **Section 69501.1(a)(35)** defines “**import**” to keep with common and ordinary usage of the  
43 term in commerce and regulatory arenas. “Import” includes reimporting a consumer product  
44 manufactured or processed, in whole or in part, in the United States.

1 Re-importation occurs when products are first placed into circulation on one market, and then  
2 (re-) imported into a second market without the authorization of the original owner of the  
3 intellectual property rights. Myriad products are re-imported, including automobiles, clothing,  
4 perfume and other consumer products. Re-imports also include products imported in the same  
5 state as previously exported.

6  
7 **Section 69501.1(a)(36)** defines “**importer**” to mean a person who imports a consumer  
8 product into the U.S. “Importer” does not include the distributor that purchases products from  
9 the manufacturer and resells them to retailers or to customers. This definition is consistent  
10 with the general usage of the term in the world of commerce. It also allows DTSC to have  
11 another responsible entity carry out the duties of a “responsible entity” if the manufacturer is  
12 unable or unwilling to do so.

13  
14 **Section 69501.1(a)(37)** defines “**information**” to mean data, documentation, records, graphs,  
15 reports or any other depiction of specific pieces of knowledge. This definition of an “umbrella  
16 term” avoids duplicative drafting and gives a common sense meaning to a term used  
17 throughout the regulations.

18  
19 **Section 69501.1(a)(38)** defines “**legal requirements**” to mean specifications and/or  
20 performance standards that a chemical, product, or product packaging is required to meet  
21 under federal or California law.

22  
23 Legal requirements are criteria for the definition for functionally acceptable”. An alternative  
24 must meet any applicable legal requirements for a product in order to be retained for further  
25 consideration as an alternative to the Priority Product.

26  
27 Legal requirements are also criteria in the First Stage and the Second Stage of the alternatives  
28 analysis. In the First Stage of the Alternatives Analysis, any legal requirements need to be  
29 identified for the Priority Product and the Chemical of Concern that is the basis of the listing for  
30 the Priority Product, or any chemical substitutions that are being considered as part of the  
31 alternatives analysis. In the Second Stage, legal requirements are a criterion for the  
32 identification of relevant factors for comparison of alternatives.

33  
34 **Section 69501.1(a)(39)** defines “**life cycle**” to mean the sum of all activities in the course of a  
35 consumer product’s entire life span. The enabling statute requires that the evaluation of  
36 potential alternatives include life cycle assessment tools. DTSC has crafted this definition to  
37 flesh out the various aspects of a product’s life cycle that must be considered as part of the  
38 Alternatives Analysis. It covers the key stages of a product’s life. Its definition and usage are  
39 consistent with usage by practitioners of the field of life cycle analysis.

40  
41 **Section 69501.1(a)(40)** defines “**manufacture**” to mean to make, produce, or assemble and  
42 excludes from the definition repair, refurbishment, replacement parts, and alterations. Existing  
43 products, especially durable goods, may need to have replacement parts available for service,  
44 repair, and maintenance. By allowing these three exclusions, repair and maintenance of  
45 existing products can continue without the involvement of this regulatory program.

1  
2 For example, if one owns a printer, ink cartridges need to be regularly purchased in order to  
3 continue using the printer. Replacing the ink cartridges with non-original parts may result in  
4 compatibility issues with the printing mechanism. Similarly, if one owned a furnace and  
5 needed to purchase a new flame sensor switch, a replacement part may not easily be found if  
6 the replacement part: contained a Chemical of Concern; was named a Priority Product;  
7 underwent an Alternatives Analysis; and was subject to certain Regulatory Responses. The  
8 consumer might have to purchase a brand new furnace. The goal of this regulation is forward  
9 looking and is intended to accelerate the quest for safer consumer products. These critical  
10 components of durable goods would not represent a high volume chemical in commerce.

11  
12 **Section 69501.1(a)(41)** defines “**manufacturer**” to not only include the entity that  
13 manufactures a product, but also any entity that controls the specifications, design of or the  
14 use of specific material, for example a private label retailer. A private retailer contracts out to a  
15 manufacturer the actual production of a product. The private label retailer may wish to have  
16 more control over production and may dictate to the manufacturer specification for raw  
17 materials, ingredients, or designs in a contract. As such, it is appropriate to include the private  
18 label retailer as a manufacturer, since it is the retailer in that case that controls product design.

19  
20 “Manufacturer” does not include a person who orders a consumer product from a manufacturer  
21 or importer where the product is configured to include optional components, accessories, or  
22 characteristics (color, size, material, etc.) that are generally offered by the manufacturer or  
23 importer. For example, this term would not capture a retailer such as a car dealership when  
24 the retailer is only specifying available options, such as power windows, air conditioning, or  
25 automatic transmission.

26  
27 **Section 69501.1(a)(42)(A)** defines “**materials and resource consumption**” to make a  
28 necessary distinction between renewable and nonrenewable natural resources, which include  
29 various finite resources and materials being depleted at an unsustainable rate. The  
30 consumption of materials and resources need to be evaluated during consideration of the  
31 product’s life cycle as part of the Alternatives Analysis. All of the following are measures for  
32 determining the amount of materials and resource consumption associated with a Priority  
33 Product and alternatives being considered.

34  
35 ***Materials and resource consumption.*** U.S. and global consumption of materials has been  
36 increasing rapidly. People have consumed more resources in the last 50 years than all  
37 previous history. And, of all the materials consumed in the U.S. over the last 100 years, more  
38 than half were consumed in the last 25 years. This increasing consumption has come at a  
39 cost to the environment, including habitat destruction, biodiversity loss, overly stressed  
40 fisheries and desertification. Materials management is also associated with an estimated 42 %  
41 of total U.S. greenhouse gas emissions. Failure to find more productive and sustainable ways  
42 to extract, use and manage materials, and change the relationship between material  
43 consumption and growth, has grave implications for our economy and society.

1 By looking at a product's entire lifecycle, we can find new opportunities to reduce  
2 environmental impacts, conserve resources, and reduce costs. For example, a product may  
3 be re-designed so it is manufactured using different, fewer, less toxic and more durable  
4 materials. It may be designed so that at the end of its useful life it can be readily  
5 disassembled. A manufacturer may maintain a relationship with the customer to ensure best  
6 use of the product, its maintenance and return at end-of-life. This helps the manufacturer  
7 identify changing needs of its customers, create customer loyalty, and reduce material supply  
8 risk. Further, the manufacturer has a similar relationship with its supply chain, which helps the  
9 manufacturer respond more quickly to changing demands, including reducing supply chain  
10 environmental impacts.<sup>9</sup>

11

12 **Water Conservation.** Freshwater is the most fundamental of resources; it has no substitutes  
13 for most uses and is expensive to transport. But freshwater sources are dwindling or  
14 becoming contaminated throughout the world. However, existing technologies offer great  
15 potential for improving on the efficiency of its use.

16

17 **Energy consumption: production, in-use, and transportation energy inputs.** Many  
18 industrial processes require large amounts of heat and mechanical power and about 85% of all  
19 energy produced in the United States comes from burning fossil fuels. There are a number of  
20 environmental problems associated with fossil fuels, most of which stem from the by-products  
21 created when they are burned to create energy. These byproducts contribute to global  
22 warming, acid rain, and form smog<sup>10</sup>. Renewable energy resources include wind power,  
23 hydropower, solar energy, biomass, biofuel, and geothermal energy.

24

25 **Energy efficiency.** Energy efficiency reduces the use of nonrenewable fossil fuels and their  
26 air impacts. The additional environmental benefits of energy efficiency include a decrease in  
27 the environmental impacts associated with fossil fuel production and use, a reduction of  
28 depletion of energy resources, and improvements in energy sustainability. Although the focus  
29 of a sustainable energy policy addresses cleaner and renewable energy, energy efficiency is  
30 key to attaining sustainability goals. Slowing the growth of energy demand slows down the  
31 rate at which conventional energy supplies are depleted, including domestic energy resources.  
32 Energy efficiency yields energy and demand savings that can displace electricity generation  
33 from coal, natural gas, nuclear power, wind power, and other resources.

34

35 **Section 69501.1(a)(43)** defines “**persistence**” to mean the same thing as “environmental  
36 persistence” defined in section 69405.3. In effect, this cross reference will ensure the term is  
37 consistent with the related Chapter 54, regarding hazard traits.

38

39 Persistence is the ability of a chemical to remain in an environment in an unchanged form.  
40 Chemicals with long persistence times in media might have a high capacity for uptake by living

---

<sup>9</sup> <http://www.epa.gov/osw/conserve/smm/basic.htm>

<sup>10</sup> [http://www.epa.gov/climatechange/emissions/downloads06/6\\_Complete\\_Report.pdf](http://www.epa.gov/climatechange/emissions/downloads06/6_Complete_Report.pdf)

1 organisms and transport in food chains and food webs, leading to increasing concerns related  
2 to the health and environmental effects.

3  
4 Data on persistence are very important for hazard assessment of chemicals, but are difficult to  
5 obtain, particularly in a form useful for practical purposes, due to the intrinsic stability of the  
6 molecule and the variability of environmental conditions. A chemical's persistence is usually  
7 measured or estimated for air, water, soil, and sediment.

8  
9 **Section 69501.1(a)(44)** defines “**person**” to mean the same as in Health and Safety Code  
10 section 25118. A person is an individual, trust, firm, joint stock company, business concern,  
11 partnership, limited liability company, association, and corporation, including, but not limited to,  
12 a government corporation. "Person" also includes any city, county, district, commission, the  
13 state or any department, agency, or political subdivision thereof, any interstate body, and the  
14 federal government or any department or agency thereof to the extent permitted by law.

15  
16 It is important for responsible entities and interested parties to understand that a “person” is  
17 more broadly defined than an individual is. This definition is consistent with other uses in  
18 programs administered by DTSC and allows for an appropriate scope for these regulations.

19  
20 **Section 69501.1(a)(45)** defines “**physical chemical hazards**” to mean physical hazard traits  
21 specified in Article 6 of Chapter 54, which defines physical hazard traits to include combustion  
22 facilitation, explosivity, and flammability. By adopting this definition, DTSC has again aligned  
23 these regulations with the related regulations in Chapter 54. This promotes consistency and a  
24 common understanding of the use of regulatory terms.

25  
26 **Section 69501.1(a)(46)** defines “**physicochemical properties**” to mean the physicochemical  
27 properties specified in section 69407.2, defined to include the following:

- 28 • physical state;
- 29 • molecular weight;
- 30 • density;
- 31 • vapor pressure and saturated vapor pressure;
- 32 • melting point;
- 33 • boiling point;
- 34 • water solubility;
- 35 • lipid solubility;
- 36 • octanol-water partition coefficient, octanol-air partition coefficient, organic carbon  
37 partition coefficient;
- 38 • diffusivity in air and water;
- 39 • Henry’s Law constant;
- 40 • sorption coefficient for soil and sediment;
- 41 • redox potential;
- 42 • photolysis rates;
- 43 • hydrolysis rates;
- 44 • dissociation constants; or

- 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 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)(47)** defines “**place into the stream of commerce in California**” to apply to products when a responsible entity, with or without an intent or purpose to serve the market in the State, takes actions consistent with the above definition. Regardless of a responsible entity’s awareness of placing the product into the California stream of commerce, once a Priority Product is found to be in the State, it will be subject to this regulation. This definition maintains a level playing field between products manufactured in California and those manufactured outside of California. Both are equally subject to these regulations. In addition, this definition advances the goals of the authorizing statute to reduce toxic chemicals in consumer products used by Californians, regardless of their point of origin. The definition also does not discriminate between sales at “brick and mortar” establishments and sales made via other mechanisms. This maintains a level playing field and fosters the purpose of the statute: to reduce public health and environmental harm from consumer products.

**Section 69501.1(a)(48)** defines “**Priority Product**” to mean a product identified and listed as Priority Product by DTSC under section 69503.4. A Priority Product is the combination of a Chemical of Concern and a product that has been prioritized as a high concern based on adverse impacts and exposures. The application of this term and related concepts are explained in greater detail in Article 3 where the term is used.

**Section 69501.1(a)(49)** defines “**processing agent**” to mean a chemical used in a product manufacturing process to promote chemical or physical changes. This term is used when describing the criteria for considering and specifying alternatives analysis threshold based on factors related to the manufacturing process. That process is discussed in greater detail in Article 3.

**Section 69501.1(a)(50)** defines “**recycled material**” to make clear that the term means materials that have been recovered or otherwise diverted from the solid waste stream, either during the manufacturing process, or after consumer use. This approach is similar to the Federal Trade Commission’s definition of recycled content.

“Recycled material” is used in two provisions of the regulations. The use of recycled material is one of criteria that can be evaluated to determine if an alternatives analysis threshold needs to be revised to a higher number in Article 3. The second provision is the proximity of feedstock, such as recycled material, to the manufacturer’s facility location. This information is required in the final alternatives analysis report to assess whether this distance directly or indirectly influences the type and amount of Chemical(s) of Concern in the Priority Product.

1 This definition makes it clear that “recycled” as is used in Article 5 means materials that are  
2 segregated for subsequent reuse.

3  
4 **Section 69501.1(a)(51)** defines “**release**” to mean an intentional or unintentional liberation,  
5 emission, or discharge of a chemical into the environment. This definition clarifies the meaning  
6 of the term used in this Chapter because this term is already defined in section 66260.10,  
7 which provides the definitions for all of Division 4.5 of Title 22.

8  
9 The existing definition of release is any spilling, leaking, pumping, pouring, emitting, emptying,  
10 discharging, injecting, escaping, leaching, dumping, or disposing into the environment, but  
11 does not include any release which results in exposure to persons solely within a workplace,  
12 with respect to a claim such exposed persons may assert against their employer and other  
13 exclusions. This new definition will allow for a more appropriate definition when evaluating  
14 releases of Chemicals of Concern in consumer product use and the potential exposures.

15  
16 **Section 69501.1(a)(52)** defines “**reliable information**” to mean a scientific study or other  
17 information that is one or more of the following:

18 **(A)** Published in a scientifically peer reviewed report or other literature;

19 **(B)** Published in a report of the United States National Academies;

20 **(C)** Published in a report by an international, federal, state, or local agency that implements  
21 laws governing chemicals; and/or

22 **(D)** Conducted, developed, submitted, or reviewed and accepted by an international, federal,  
23 state, or local agency for compliance or other regulatory purposes.

24  
25 The sources of scientific studies and information described in (A), (B), (C) and (D) are  
26 available to DTSC as reliable information for the purpose of these regulations and may include  
27 mechanistic data, environmental monitoring data and animal or human scientific studies, etc.  
28 While DTSC will use these sources for scientific studies and information, it is important to note  
29 that DTSC will also be evaluating the scientific studies and information obtained from these  
30 sources for purposes of these regulations.

31  
32 It is also important to clarify that there may be valid scientific studies or other information that  
33 may not meet the reliable information definition, but would be relevant and important to  
34 consider for these regulations. For instance, a manufacturer may have a scientific study or  
35 information on animals, humans, or mechanistic data relevant to a chemical that does not meet  
36 the criteria described in (A), (B), (C) or (D). In this situation, a manufacturer may choose to  
37 respond to section 69501.4, Chemical and Product Information requests. In so doing, the  
38 scientific study or information will meet the first condition of (D), that is, it is “conducted,  
39 developed or submitted” to DTSC. The second condition is dependent on DTSC’s acceptance  
40 of the scientific studies or information.

41  
42 One aspect of scientific study acceptability in the scientific community is the ability to have  
43 another researcher conduct the same study, using the same conditions, and achieve the same  
44 or similar results. In this manner, the original study’s results and conclusions are validated.  
45 The more the study is repeated with the same or similar results, the more the scientific

1 community will accept the study's results/conclusions. The study may be repeated with slight  
2 variations in the study parameters to determine when changes in the results start occurring.  
3 This is done to examine the boundaries of the results/conclusion. These studies also  
4 contribute to the acceptability of the conclusions reached by the studies.

5  
6 While repeating scientific studies to confirm their results is the ideal situation to validate results  
7 and advance public policy decisions, studies are very expensive and often take years to  
8 complete. The scientific community and public policy makers have taken steps to increase the  
9 confidence in study results by establishing quality control and quality assurance guidelines,  
10 which allow for informed decision-making. In reviewing the scientific study for acceptance,  
11 DTSC will evaluate whether the scientific study provided was conducted according to generally  
12 accepted principles, including testing protocols in which the test parameters documented are  
13 based on specific testing guidelines, or in which all parameters described are comparable to  
14 guideline methods, including, but not limited to:

- 15 • US Food and Drug Administration Good Laboratory Practices (Part 58 of Title 21 of the  
16 Code of Federal Regulations);
- 17 • US EPA's Office of Chemical Safety and Pollution Prevention Harmonized Test  
18 Guidelines;
- 19 • TSCA (Chapter 1 of Title 40 of the Code of Federal Regulations);
- 20 • TSCA Testing Guidelines (Parts 798 and 799 of Title 40 of the Code of Federal  
21 Regulations);
- 22 • OECD Guidelines for Testing of Chemicals;
- 23 • OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring;
- 24 • OECD Manual for Investigation of High Production Volume Chemicals;
- 25 • REACH/ECHA Guidance on Information Requirements and Chemical Safety  
26 Assessment and Regulation (EC) No. 440/2008 of the European Parliament and the  
27 Council; or
- 28 • CEPA Guidelines for the Notification and Testing of New Substances: Chemicals and  
29 Polymers.

30  
31 However, it is emphasized that studies conducted under the examples provided above are not  
32 the only methods to determine "acceptance." There is a vast and informative scientific  
33 literature, produced by academic institutions that would not be considered under these  
34 regulations because it did not conform to these examples of protocols above. The purpose of  
35 academic institutions is to gain and expand on the existing body of knowledge through  
36 scientific research, not necessarily to conduct studies that meet specific guidelines for  
37 regulatory compliance. Additionally, established guidelines simply cannot keep up in real time  
38 with scientific knowledge and advances.

39  
40 For example, there are many new and valuable methods of assessing chemical toxicity, for  
41 which there are no official guidelines from OECD or other institutions. Because the guideline  
42 methods such as OECD's are limited to specific tests, they do not include more recent  
43 scientific procedures or methodologies that have been accepted in the general scientific  
44 community, nor some important older procedures that are accepted in the scientific research  
45 community. While following established quality control and quality assurance guidelines is a

1 good step towards establishing confidence in a study, simply following guidelines does not  
2 ensure that the study objectives were met. DTSC will evaluate these types of scientific studies  
3 on a case by case basis to determine whether they are acceptable for purposes of these  
4 regulations.

5  
6 Some other types of information, such as analytical protocols, submitted to DTSC may be  
7 evaluated for acceptability using similar methods to evaluate a scientific study. Other relevant  
8 information will be reviewed on a case-by-case basis to determine whether the information is  
9 acceptable as reliable information for the purpose of these regulations.

10  
11 **Section 69501.1(a)(53)** defines “**Reliable information demonstrating the occurrence of**  
12 **exposures to a chemical**” to clarify the type of information that qualifies as evidence of an  
13 occurrence of exposure.

14  
15 “Reliable information demonstrating the occurrence of exposures to a chemical” (Reliable  
16 Information Demonstrating) is a subset of “reliable information,” and is necessary to expressly  
17 define the types of reliable information that could demonstrate the occurrence of exposures.  
18 The proposed definition of “Reliable Information Demonstrating” provides DTSC and  
19 responsible entities methods to assess exposures to the chemical of interest. It is important to  
20 note that these methods demonstrating exposure must satisfy the definition of “reliable  
21 information.”

22  
23 Subsection (A) describes exposure demonstrated through various monitoring information. Any  
24 chemical presence in an indoor setting may be considered reliable information showing  
25 exposure. In addition, data showing chemical accumulation or persistence in the environment  
26 or accumulation in flora, or fauna are also considered indications of exposure. While mere  
27 presence may not be caused by a chemical in a product, the chemical presence is indicative of  
28 releases from a source, including the chemical in a product making it a potential source of  
29 exposure. Subsection (A) also describes exposures from products containing a chemical that  
30 are present or used in the home or places of employment.

31  
32 Subsection (B) identifies sources of biomonitoring information in humans. And while again,  
33 chemical presence in humans may not be directly caused by a chemical in a product, the  
34 biomonitoring information shows that exposure is occurring. Subsection (C) relies on  
35 information that is predictive of exposure based on calculations that are described in Article 5  
36 of Chapter 54 as evidence for the hazard traits bioaccumulation, persistence, and lactational or  
37 transplacental transfer. Subsection (D) identifies exposure modeling that may be used to  
38 determine exposure to a chemical of interest.

39  
40 Subsection (E) is specific to monitoring data related to wastewater or storm water collection  
41 and treatment systems. These specific aspects of collection and treatment systems pose an  
42 exposure to the public and environment because without proper wastewater or storm water  
43 treatment or removal of the chemical of interest, exposure to the public, flora, and fauna will  
44 occur via the waters of California.

1 While the expenditure of funds to treat the chemical of interest is not directly related to  
2 exposure, it is an important consideration in that until funds are available to treat or remove the  
3 chemical of interest, exposures may occur. Along the same line of thought, expenditure of  
4 funds to remove or treat the chemical of interest in order to recycle or reuse wastewater sludge  
5 will potentially result in exposures to flora and fauna.

6  
7 Lastly, wastewater and storm water collection and treatment systems operate under a permit  
8 to protect public health and the environment. Prior to discharge into waterways, these  
9 treatment systems must meet certain discharge requirements. If the treatment system is not  
10 operating correctly as shown by either violations of their permit or exceedances of regulatory  
11 thresholds for chemicals being monitoring, the result is increased likelihood of exposures via  
12 the waters to the public and environment.

13  
14 **Section 69501.1(a)(54)** defines “**responsible entity**” to establish the person who is required  
15 to comply with these regulations. A responsible entity may be the manufacturer, the importer  
16 or the retailer of a consumer product. There are some provisions that are specific to retailers  
17 due to their status that is distinct from manufacturers and importers. But DTSC felt it was  
18 important to include retailers as responsible entities to ensure that there is at least one entity in  
19 the product supply/sales chain that has responsibility for carrying out various duties under  
20 these regulations and that is under the jurisdiction of DTSC. That is, both the manufacturer  
21 and importer may be headquartered outside of California, but all retailers affected by these  
22 regulations are in California.

23  
24 This definition is not limited to the manufacturer, importer, or retailer of a Priority Product  
25 because the responsible entity is also required to comply with regulatory responses, if any,  
26 imposed by DTSC. And the regulatory response may pertain to an alternative to the original  
27 Priority Product. Therefore, the term “responsible entity” is not tied to the term “Priority  
28 Product.” Rather, it is tied to the term “consumer product.”

29  
30 **Section 69501.1(a)(55)** defines “**retailer**” to mean a person to whom a consumer product is  
31 delivered or sold for purposes of sale or distribution by the person to a consumer. This does  
32 not include wholesalers or suppliers that normally sell their products to another business. This  
33 definition is consistent with typical usage of this term in the world of commerce.

34  
35 **Section 69501.1(a)(56)** defines “**safer alternative**” to mean an alternative that limits  
36 exposure or reduces the level of hazard posed by a Chemical of Concern in a consumer  
37 product. “Alternative” is already defined in Section 69501.1 (a)(11). The term “safer  
38 alternative” advances the intent of enabling statute to develop consumer products that are  
39 incremental improvements over time, thus, moving toward “safer” products and not the  
40 requirement to arrive at completely “safe” product, if not technologically or economically  
41 feasible.

42  
43 **Section 69501.1(a)(57)** defines “**sales outlet**” to mean any place at which consumer products  
44 are sold, supplied, or offered for sale directly to consumers in California. Disclosure of sales  
45 outlets is required to be provided in the final alternatives analysis report and in various

1 notifications in the regulations, including the Priority Product Removal Notification, Priority  
2 Product Replacement Notification, and Priority Product Cease Ordering Notification. Again,  
3 this information is relevant and helpful to DTSC in its efforts to determine sales volume in  
4 California of a consumer product, which is one of the statutorily required criteria for identifying  
5 and prioritizing chemicals and products.

6  
7 **Section 69501.1(a)(58)** defines “**sensitive subpopulations**” to identify subgroups that are at  
8 greater risk of adverse health effects when exposed to one or more Chemicals of Concern.  
9 This definition implements the statutory mandate that the regulations establish a prioritization  
10 process that includes consideration of the potential effects on sensitive subpopulations,  
11 including infants and children. The term “sensitive population” is defined more broadly than  
12 the statutory language, as is allowed by the statute.

13  
14 “Sensitive subpopulations” can be thought of as groups of individuals who respond biologically  
15 at lower levels of exposure to a contaminant or who have more serious health consequences  
16 than the general population. This definition that DTSC has crafted addresses important factors  
17 to be considered including: life stages, gender, genetic traits, health status and exposure. As  
18 there is no universally accepted definition of the term “sensitive subpopulation,” the definition  
19 used is intended for the purposes of this regulation and furthers the purposes of the  
20 authorizing statute to protect “sensitive subpopulations”. It is also consistent with a broad,  
21 health-protective approach to protect the most vulnerable members of society as DTSC adopts  
22 and implements these regulations.

23  
24 This definition also includes those individuals who have a greater risk of adverse health effects  
25 because of a serious illness or due to the nature of their occupation. Exposures to Chemicals  
26 of Concern may exacerbate existing serious or chronic illness or disease thereby increasing an  
27 individual’s susceptibility to adverse health impacts. For example, individuals with asthma,  
28 bronchitis, emphysema, or other upper respiratory illness are often more susceptible to  
29 adverse health effects caused by poor air quality. Some workers experience chemical  
30 exposures at higher levels and or longer duration than the general public. Individuals living  
31 next to manufacturing sites can be exposed as product are manufactured, stored or  
32 transported through their communities.

33  
34 DTSC may identify additions to the Chemicals of Concern lists and give special consideration  
35 under Article 2 to a chemical if it contributes or causes adverse impacts to sensitive  
36 subpopulations. Sensitive subpopulations are also given special consideration when products  
37 are prioritized under Article 3.

38  
39 **Section 69501.1(a)(59)** defines “**technically and economically feasible alternative**” to  
40 make specific the reference specified in the enabling statute, Health and Safety Code section  
41 25253(a)(2), and referred to in Article 5. It requires a responsible entity to take into account  
42 and evaluate the product function or performance of the Priority Product in comparison to any  
43 alternative that is considered.

1 As part of a determination of whether an alternative meets the function and performance of the  
2 Priority Product, an alternative needs to meet the criteria as a “technically and economically  
3 feasible alternative”. This criterion includes the technical ability to develop and produce the  
4 alternative and the economic viability of the alternative to be a profitable. The responsible  
5 entity must consider the following, to the extent applicable:

6 **(A)** The extent to which a functionally acceptable alternative is currently available in the  
7 marketplace; and

8 **(B)** The effect on the operating margin of the manufacturer.

9  
10 Together these factors reflect marketplace realities and business realities in determining  
11 whether there is a technically and economically viable alternative to a Priority Product.

12  
13 **Section 69501.1(a)(60)** defines “**trade secret**” to mean the same as the definition in Civil  
14 Code section 3426.1(d). “Trade secret” means information, including a formula, pattern,  
15 compilation, program, device, method, technique, or process, that: (1) Derives independent  
16 economic value, actual or potential, from not being generally known to the public or to other  
17 persons who can obtain economic value from its disclosure or use; and (2) Is the subject of  
18 efforts that are reasonable under the circumstances to maintain its secrecy.

19  
20 This definition in the California Civil Code is a codification of the Uniform Trade Secrets Act,  
21 which has been enacted into law by many states. DTSC has chosen to adopt this frequently  
22 used definition into these regulations for several reasons. The usage is consistent with other  
23 uses in California regulatory regimes, is flexible enough to be suitable for these regulations,  
24 and has a substantial body of law and guidance developed regarding its application.

25  
26 (The California Public Records Act requires state agencies to provide public records to any  
27 member of the public. These “public records” includes any writing containing information  
28 relating to the conduct of the public's business prepared, owned, used, or retained by any state  
29 or local agency regardless of physical form or characteristics. However, trade secrets are not  
30 considered public records under this law.)

31  
32 **Section 69501.1(a)(61)** defines “**useful life**” to make specific the provision in Health and  
33 Safety Code section 25253 (a)(2) and Article 5 requiring a responsible entity to take into  
34 account and evaluate the useful life of the Priority Product in comparison to any alternative that  
35 is considered.

### 36 37 **§ 69501.2. Duty to Comply and Consequences for Non-Compliance**

38  
39 **Section 69501.2**, in its entirety, sets out the responsibilities for compliance with the  
40 requirements of Chapter 55, and provides certain compliance options for responsible entities.  
41 This section also specifies the consequences of non-compliance, which is the placement of the  
42 responsible entity’s name on DTSC’s Failure to Comply List.

43  
44 A “responsible entity” means any manufacturer, importer or retailer of the consumer product  
45 (§ 69501.1(a)(56)). A vast number of consumer products are placed into the stream of

1 commerce in California by someone other than the actual manufacturer of the product. In fact,  
2 most of the consumer products in California’s stream of commerce are manufactured by  
3 persons that have no presence in California and in many cases no presence in the United  
4 States. Due to these circumstances, DTSC determined that the option of placing the duty to  
5 comply with these regulations solely on the product’s manufacturer was not viable or desirable  
6 for the following reasons:

- 7 (1) DTSC’s ability to implement the directives of Health and Safety Code sections 25252  
8 and 25253 requires that DTSC be able to compel and enforce compliance with the  
9 requirements of Chapter 55. In the case of the many product manufacturers that  
10 have no presence in California, DTSC has no practical, and in most cases no legal,  
11 ability to compel such manufacturers to comply with these requirements.
- 12 (2) In light of the practical and legal limitations identified above, placing the duty to  
13 comply solely on product manufacturers would create a significantly uneven playing  
14 field for California product manufacturers.

15  
16 Consequently, it is necessary that the duty to comply with the requirements of Chapter 55 fall  
17 to responsible entities, as defined in these regulations. This is similar to the duty to comply  
18 approach embodied in other California statutes and regulations that impose requirements on  
19 products that are sold in California but manufactured both in-state and out-of-state (for  
20 example, California’s Toxics in Packaging Prevention Act, Article 10.4 of Chapter 6.5 of  
21 division 20 of the Health and Safety Code). For example, although the manufacturer, the  
22 packer, or the distributor can comply with label requirements pursuant to the Fair Packaging  
23 and Labeling Act, the law only requires a single entity to be identified on the packaging. These  
24 regulations also set up an appropriate hierarchy regarding which of the responsible entities has  
25 the primary and secondary duty to comply. That hierarchy is discussed in greater detail below.

26  
27 **Section 69501.2(a)** *Duty to Comply* provides an approach that consists of two tiers for fulfilling  
28 the requirements of section 69501.5 (Chemical and Product Information), section 69503.7  
29 (Priority Product Notification), Article 5 (Alternatives Analysis and AA reports), and Article 6  
30 (Regulatory Response). The first tier consists of the options available to the manufacturer and  
31 the importer; the second tier consists of options for the retailer.

32  
33 **Section 69501.2(a)(1)** specifies that a manufacturer has the principal duty to comply with all  
34 the requirements of this Chapter, then the requirements fall on the importer. A retailer will be  
35 notified by DTSC when the manufacturer and the importer have failed to comply. The retailer  
36 can then determine if it will cease ordering the product or take on the responsibility for  
37 complying with the alternative assessment, all the required submittals, and any imposed  
38 regulatory response.

39  
40 **Section 69501.2(a)(2)** creates an additional option for manufacturers, importers or retailers to  
41 have a consortium, trade associations, public partnership, or any other entity to act on their  
42 behalf. This provision grants an appropriate amount of flexibility to responsible entities  
43 regarding how they can best carry out their duties as responsible entities. It will allow for a  
44 more efficient use of resources in complying with these regulations.

1 **Section 69501.2(b) *Manufacturer or Importer Options.*** Once a consumer product is listed as a  
2 Priority Product, the manufacturer and the importer have the primary duty to comply with the  
3 requirements of this Chapter, including but not limited to, section 69501.4 (Chemical and  
4 Product Information), section 69503.7 (Priority Product Notifications), Article 5 (Alternatives  
5 Analysis and AA reports), and Article 6 (Regulatory Responses). This subsection specifies two  
6 options that a manufacturer or an importer can utilize in lieu of fulfilling these requirements.  
7 The first option (§ 69501.2(b)(1)) is to remove the Priority Product from the stream of  
8 commerce in California and the second option (§ 69501.2(b)(2)) is to replace the Priority  
9 Product with another consumer product.

10  
11 This provision, which has been suggested by interested parties who are in product supply  
12 chains, gives responsible entities who do not wish to comply with these requirements other  
13 viable options for achieving the statutory goal of safer consumer products. Additionally, this  
14 provision enables DTSC to effectively implement these regulations and the authorizing  
15 statutes, as well as to provide a level playing field for those responsible entities who do expend  
16 the time and resources to comply with these requirements.

17  
18 **Section 69501.2(b)(1) *Manufacturer or Importer Options- Priority Product Removal Notification***  
19 *(from the California market).* The primary optional requirement is that the responsible entity  
20 must cease to place the Priority Product that is subject to these requirements into the stream  
21 of commerce in California.

22  
23 The responsible entity may submit a Priority Product Removal Notification any time after the  
24 Priority Product is listed but before the Final Alternatives Analysis Report is due, as long as the  
25 responsible entity meets all regulatory obligations required up to that date. These regulatory  
26 requirements include the Priority Product Notification, and the Preliminary Alternatives Analysis  
27 report. For example, a manufacturer may submit this notification before the Priority Product  
28 Notification is due, or if the Priority Product Notification has been submitted, a manufacturer  
29 may submit this notification before the Preliminary AA Report is due. The latest this  
30 notification may be submitted before the Final AA Report is due.

31  
32 This notification is not a requirement for all manufacturers or importers of consumer products  
33 that contain a Chemical of Concern. This notification provides an option for those  
34 manufacturers or importers that choose not to proceed with an Alternative Analysis for a  
35 Priority Product and have availed themselves of either of these two options. Furthermore, it  
36 provides DTSC with information regarding Priority Products that are no longer in commercial  
37 distribution in California.

38  
39 **Section 69501.2(b)(1)(A) through(D)** specifies the information that must be included in the  
40 notification required under section 69501.3(b)(1). That required information is as follows:  
41 **(A)** Name and contact information for the manufacturer or importer;  
42 **(B)** Name and contact information for all persons in California, other than the final purchaser or  
43 lessee, to whom the manufacturer or importer directly sold the product within the prior  
44 twelve months;

- 1 (C) Identification and location of the manufacturer's or the importer's retail sales outlets where  
2 the manufacturer or importer sold, supplied, or offered for sale the product in California, if  
3 applicable; and  
4 (D) Information describing the product, including the brand name(s) and product name(s)  
5 under which the product was placed into the stream of commerce in California.  
6

7 The name of the manufacturer (or importer) and the name of the contact person in California  
8 are required to establish the identity of the responsible entity. This information will allow DTSC  
9 to communicate with the manufacturers and importers of affected Priority Products. The  
10 information regarding sales outlets will allow for verification of the removal of these Priority  
11 Products from the stream of commerce in California. The brand names or product names will  
12 be used to identify the Priority Products in California.  
13

14 **Section 69501.2(b)(2)(A) *Manufacturer or Importer Options- Priority Product Replacement***  
15 *Notification.* DTSC anticipates that some responsible entities may choose to remove their  
16 Priority Product from the California market and then reintroduce the same or similar product  
17 under a new name with the same Chemical of Concern that was the basis for the listing as a  
18 Priority Product. This notification is required to be submitted within 30 days after the  
19 replacement product is introduced into California. The term replacement product does not  
20 apply to the alternatives that are evaluated in an Alternatives Analysis.  
21

22 **Section 69501.2(b)(2)(A)1. through 6.** specifies the information that must be included in the  
23 Priority Product Replacement Notification required under section 69501.3(b)(2). That required  
24 information is as follows:

- 25 1. Name and contact information for the manufacturer or importer;
- 26 2. The name of, and contact information for, all persons in California, other than the final  
27 purchaser or lessee, to whom the manufacturer or importer directly sold the product  
28 within the prior twelve (12) months;
- 29 3. Identification and location of the manufacturer's or the importer's retail sales outlets  
30 where the manufacturer or importer sold, supplied, or offered for sale the product in  
31 California, if applicable;
- 32 4. Information describing the Priority Product that is replaced by the new product, including  
33 the brand name(s) and product name(s) under which the Priority Product was placed  
34 into the stream of commerce in California;
- 35 5. Information describing the new product that replaces the Priority Product, including the  
36 brand name(s) and product name(s) under which the product is placed into the stream  
37 of commerce in California, and the Chemical(s) of Concern in the new product; and  
38 6. A copy of the notice provided under paragraph (1).  
39

40 This information will establish the identity of the manufacturer or importer, the contact person  
41 in California, the sales outlets for the Priority Product, and the new replacement consumer  
42 product. This information will allow DTSC to verify the replacement of these Priority Products  
43 from the stream of commerce in California. The brand names or product names will be used to  
44 identify the replacement products. This notification also requires that the Priority Product  
45 Removal Notification be submitted for the Priority Product. DTSC has determined that this is

1 the appropriate type and amount of information that will allow it to track what responsible  
2 entities are doing under the regulations and to monitor compliance.

3  
4 **Section 69501.2(b)(2)(B)** The Priority Product Replacement Notification does not apply to a  
5 replacement product that is an alternative is selected under section 69505.4(c) or identified in  
6 the Final AA Report under section 69505.5(j).

7  
8 **Section 69501.2(c) *Retailer Options*.** This subsection specifies the two options that are  
9 available to the retailer in lieu of fulfilling the requirements of section 69501.5 (Chemical and  
10 Product Information), section 69503.7 (Priority Product Notification), and Article 5 (Alternatives  
11 Analysis and AA reports). DTSC has tailored the options for compliance by retailers to the  
12 unique role that retailers play in product manufacture, distribution and sale. That is, unlike  
13 manufacturers and importers, retailers merely provide the consumer products for sale to the  
14 ultimate consumer/purchaser. Nonetheless, due to the fact that the manufacturer and importer  
15 may be beyond the jurisdictional reach of DTSC, DTSC felt it necessary to include retailers as  
16 responsible entities, but give them more flexible means of complying with these regulations.

17  
18 **Section 69501.2(c)(1)** Once DTSC has provided notice to the retailer that the manufacturer  
19 and the importer have failed to comply, the retailer has various options. The retailer can check  
20 DTSC's website to verify whether the manufacturer or importer have rectified the failure to  
21 comply or the retailer can verify if the manufacturer or importer have submitted a Priority  
22 Product Removal Notification or the Priority Product Replacement Notification.

23  
24 **Section 69501.2(c)(2)** The second option is that the retailer must cease ordering the product  
25 and submit a notification to DTSC within ninety days after DTSC has notified the retailer that  
26 the manufacturer and importer have failed to comply with a specific requirement. Again, DTSC  
27 has tailored this option to coincide with the role played by the retailer.

28  
29 **Section 69501.2(c)(2)(B)1. through 6.** Specifies the information that must be included in the  
30 notification required under section 69501.2(c)(2)(B). The required information is as follows:

- 31 1. The retailer's name and contact information;
- 32 2. The manufacturer's and the importer's, if applicable, name and contact information;
- 33 3. Identification and location of the retailer's sales outlets where the product is sold,  
34 supplied, or offered for sale in California;
- 35 4. The name of, and contact information for, the person immediately upstream from the  
36 retailer in the supply chain for the product;
- 37 5. Information describing the product, including the brand name(s) and product name(s)  
38 under which the retailer placed the product into the stream of commerce in California;  
39 and
- 40 6. A statement certifying that the retailer will not re-initiate ordering the product unless and  
41 until information posted on DTSC's website indicates that the non-compliance has been  
42 remedied.

43  
44 This information will establish the identity of the retailer(s), manufacturer and importer, their  
45 contact persons, the sales outlets for the Priority Product, the name of the person immediately

1 upstream from the retailer, product description and brand names. A statement is also required  
2 from the retailer to certify that the retailer will not re-initiate the ordering of the Priority Products  
3 until information is posted on DTSC's website that the manufacturer or importer has remedied  
4 the non-compliance. All of this is aimed at tracking and ensuring compliance with the  
5 requirements of these regulations.

6  
7 **Section 69501.2(d) Failure to Comply List.** This subsection requires, and specifies the criteria  
8 and process for, DTSC to issue notices of non-compliance and establish and maintain a  
9 Failure to Comply List. In addition to the Failure to Comply List, DTSC has the authority under  
10 Article 8 of Chapter 6.5 of Division 20 of the Health and Safety Code to enforce any of the  
11 provision of these regulations. This includes the issuance of orders imposing administrative  
12 penalties, the referral of violations to prosecutors for civil or criminal prosecution, the  
13 settlement of cases, and the adoption of enforcement policies and standards related to those  
14 matters. DTSC is convinced that it cannot ensure compliance with these regulations unless it  
15 makes known to interested parties the names of responsible parties that are out of compliance  
16 and may pursue various types of enforcement for violation of these regulations.

17  
18 **Section 69501.2(d)(1)(A)** requires DTSC to issue a notice of non-compliance to all known  
19 responsible entities for a product when DTSC determines that one or more requirements of the  
20 regulations, as they apply to a specific chemical or product, have not been fulfilled. DTSC is  
21 also required to send a copy of the notice to all other persons, known to DTSC, in the supply  
22 chain for the product or chemical. This notice is necessary so that the affected responsible  
23 entities are alerted to the non-compliance status of their product, giving them time to come into  
24 compliance (or alternatively to comply with section 69501.3(b) or to dispute DTSC's  
25 determination of non-compliance) before DTSC posts information concerning the  
26 determination of non-compliance on the Failure to Comply List on DTSC's website.

27  
28 **Section 69501.2(d)(1)(B)** specifies the contents of a notice issued pursuant to section  
29 69501.2(d)(1)(A). The notice must describe the nature of the non-compliance and the fact that  
30 DTSC intends to place information about the non-compliance determination on the Failure to  
31 Comply List maintained on DTSC's website. This provision ensures that there is consistency  
32 in the content of the Notices of Non-compliance and that the recipient is aware of the  
33 provisions for which DTSC has determines the recipient is out of compliance.

34  
35 **Section 69501.2(d)(2)** specifies that no sooner than 45 days and no later than 90 days after  
36 DTSC issues a notice of non-compliance, if the non-compliance has not been remedied and  
37 there is no pending dispute under Article 7, then DTSC will post information about the non-  
38 compliance on its Failure to Comply List maintained on the DTSC website. A condition of non-  
39 compliance is deemed remedied if DTSC determines that the requirements of section  
40 69501.3(b)(1) have been satisfied or the condition of non-compliance has been fully remedied.  
41 This provision is an appropriate check and balance on DTSC's ability to post information about  
42 a responsible entity being out of compliance with the regulations.

1 **Section 69501.2(d)(3)** provides a responsible entity temporary relief if the responsible entity  
2 has requested a dispute resolution for a posting on the Failure to Comply List. Unless DTSC  
3 had such a provision, dispute resolution could be a moot avenue of relief.

4  
5 **Section 69501.2(d)(4)** requires DTSC to maintain a Failure to Comply List on DTSC's website.  
6 This provision gives interested parties and the general public important information about  
7 which responsible entities, manufacturers, and products are not in compliance with these  
8 regulations. It also specifies the information required to be posted. This provision is  
9 necessary to keep responsible entities, in particular retailers, informed about the compliance  
10 status of the products for which they are responsible. This provision also gives important  
11 information to consumers to allow them to make informed decisions regarding consumer  
12 products. It also helps to maintain a "level playing field" for responsible entities and  
13 manufacturers that are in compliance with these regulations. The required information  
14 includes:

- 15 **(A)** Information identifying and describing the product, including the brand name(s) and  
16 product name(s) under which the product is placed into the stream of commerce in  
17 California;
- 18 **(B)** The requirement(s) of this Chapter, and the applicable due date(s), that are the basis for  
19 the notice of non-compliance;
- 20 **(C)** A statement placing retailers of the product on notice of the failure to comply by the  
21 manufacturer(s) and the importer(s), if applicable, pursuant to subsection (a)(1), including  
22 identification of the requirement with which the retailer shall comply and the timeframe for  
23 compliance, which will be no less than ninety (90) days after the notice is posted on  
24 DTSC's website;
- 25 **(D)** The Chemical(s) of Concern known to be in the product;
- 26 **(E)** The name of and, if known, the contact information for the person listed on the product  
27 label as the manufacturer and the person, if any, listed as the distributor;
- 28 **(F)** The name of, and contact information for, any manufacturer or importer that has been  
29 notified by DTSC, under paragraph (1);
- 30 **(G)** The name of, and contact information for, retailers of the product known to DTSC who  
31 have not fully complied with the requirements of subsection (c); and
- 32 **(H)** The date the product is first listed on the Failure to Comply List.

33  
34 DTSC has determined that this information is the appropriate amount and type of information  
35 that it needs to post on the Failure to Comply List in order to keep interested parties and the  
36 general public apprised about the nature of the non-compliance being described.

37  
38 **Section 69501.2(d)(5)** specifies that DTSC must remove a product and related information  
39 from the Failure to Comply List if DTSC determines that the condition of non-compliance has  
40 been fully remedied or that the requirements of subsection (b)(1) have been satisfied. A  
41 product and related information will also be removed from the Failure to Comply List if a  
42 Chemical Removal Confirmation Notification or a Product Removal Confirmation Notification  
43 has been submitted to DTSC, and the non-compliance is not related to section 69501.5.

1 **Section 69501.2(d)(6)** requires DTSC to remove information regarding a responsible entity  
2 from the Failure to Comply List upon a determination by DTSC that the retailer has complied  
3 with subsection 69501.3(c). This is a common sense provision to keep the Failure to Comply  
4 List current.

### 6 **§ 69501.3. Information Submission and Retention Requirements**

8 **Section 69501.3**, in its entirety, specifies the requirements for submitting information to DTSC  
9 and it establishes information and documentation requirements.

11 **Section 69501.3(a)** provides that all information that a responsible entity is required to submit  
12 to DTSC under these regulations must be signed by the responsible individual in charge of  
13 preparing or overseeing the preparation of the information and by the owner, or an officer of  
14 the company, or an authorized representative. This requirement improves the credibility and  
15 reliability of the documents submitted to DTSC. It is consistent with other regulatory regimes  
16 that have limited governmental oversight or auditing capabilities.

18 **Section 69501.3(b)** requires all information submitted to DTSC must be in English and in an  
19 electronic format specified or approved by DTSC. This provision is intended to ensure  
20 information submitted to DTSC is easily accessed and understood by DTSC employees. The  
21 requirement that all information must be submitted in English safeguards DTSC from receiving  
22 voluminous information that must be translated into English before being reviewed for  
23 completeness and compliance with the applicable requirements. In addition, this provision  
24 lowers the cost to DTSC in implementing the provisions of these regulations.

26 **Section 69501.3(c)** sets out a certification statement that must be included and signed in  
27 conjunction with the submittal of certain key documents generated under the regulations. The  
28 documents subject to the certification statement are:

- 29 • Priority Product Removal Notifications;
- 30 • Priority Product Replacement Notifications;
- 31 • Priority Product Cease Ordering Notifications;
- 32 • Alternatives Analysis Threshold Exemption Notifications;
- 33 • Chemical of Concern Removal Notifications;
- 34 • Preliminary and Final AA Reports
- 35 • Submissions of information claimed to constitute trade secrets;
- 36 • Documentation for designation as an accrediting body pursuant to section 69508.2.

38 The certification statement is necessary in order to ensure such key submittals are accurate  
39 and to apprise parties signing the statements of the applicable standards related to the  
40 documents' preparation. The signature requirement by an owner or officer with specific  
41 responsibilities related to these notifications helps ensure the integrity and accuracy of these  
42 submittals.

44 **Section 69501.3(d)** sets out a three-year document retention provision, running from the date  
45 a document was first required to have been obtained or prepared, but which has not been

1 required to be submitted to DTSC. This is necessary to ensure DTSC has continued access  
2 for a reasonable period of time to information that may be needed to support fulfillment of  
3 DTSC's responsibilities under these regulations.

#### 4 5 **§ 69501.4. Chemical and Product Information**

6  
7 **Section 69501.4**, in its entirety, specifies the process for DTSC to obtain and review  
8 information on chemicals and products. Health and Safety Code section 25252 requires DTSC  
9 to adopt regulations that establish a process to identify and prioritize those chemicals or  
10 chemical ingredients in consumer products that may be a Chemical of Concern. DTSC has  
11 concluded that it will need to engage in information-gathering activities to support and inform  
12 the chemical and product prioritization processes. DTSC itself does not have the necessary  
13 information or personnel resources to administer this program without gathering information  
14 from various sources.

15  
16 **Section 69501.4(a)** specifies the means and methods that DTSC must use to obtain and/or  
17 review information that it determines is necessary to identify and prioritize chemicals and  
18 chemical ingredients in consumer products. This information will enable DTSC to have a  
19 sound and robust process for identifying and prioritizing Chemicals of Concern and consumer  
20 products that contain priority chemicals. This information is useful to help ensure that  
21 decisions made by DTSC in carrying out its responsibilities under these regulations and Health  
22 and Safety Code section 25252 are fully informed and based on sound science and other  
23 relevant information. This approach will minimize the unnecessary expenditure and use of  
24 resources by DTSC and responsible entities. It allows for the most effective and efficient  
25 approach to seeking necessary information. The methods DTSC may use are as follows:

- 26 (1) Obtain and/or review information in the public domain that is readily available in a usable  
27 format, without a subscription or other charge;  
28 (2) Obtain and/or review information in the public domain that is readily available in a usable  
29 format, with a subscription or other charge, to the extent resources are available to pay the  
30 required costs;  
31 (3) Request a responsible entity or a chemical manufacturer or importer to make existing  
32 information available to DTSC, in accordance with a schedule specified by DTSC; and/or  
33 (4) Request a responsible entity or a chemical manufacturer or importer to generate new  
34 information and provide it to DTSC, in accordance with a schedule specified by DTSC.

35  
36 **Section 69501.4(b)** specifies the means by which DTSC may request that information be  
37 made available to it. Those means are:

- 38 (1) Correspondence sent via U.S. mail or electronically to an individual responsible entity or  
39 other person; or  
40 (2) Information call-ins on DTSC's website that are also noticed to those on any electronic  
41 mailing lists established by DTSC related to these regulations. These methods are  
42 reasonably calculated to be efficient and effective methods of seeking relevant information.

43  
44 **Section 69501.4(c)(1) *Response Status List*** requires DTSC to maintain a Response Status  
45 List on DTSC's website. Under section 69501.4, DTSC may request information from

1 responsible entities that it determines is necessary to implement this regulation. The  
2 Response Status List will give interested parties and the general public the status of various  
3 requests and provide additional information as to whether the responsible entity has submitted  
4 the requested information in a timely manner, has failed to provide the requested information  
5 within the time specified, or has demonstrated that the information is not available or cannot be  
6 produced. DTSC is of the opinion that publishing the status of responses will encourage  
7 parties to provide requested information to DTSC. This, in turn, will promote program  
8 effectiveness and efficiencies.

9  
10 **Section 69501.4(c)(1)(A)** specifies that when a request for information is submitted to DTSC  
11 within the time specified, the submittal may be listed on the Response Status List as a “Timely  
12 Submittal”. This provision is self-explanatory.

13  
14 **Section 69501.4(c)(1)(B)** specifies that when a request for information is not submitted within  
15 the time specified, the submittal may be listed as either “Late Submittal or No Submittal”.  
16 Again, this provision is basically self-explanatory.

17  
18 **Section 69501.4(c)(1)(C)** specifies that when a responsible entity has demonstrated to  
19 DTSC’s satisfaction that the responsible entity does not have the information or cannot  
20 produce the information requested, the request may be listed as “Information not Available.”  
21 DTSC thought it was important to distinguish parties that were unable, as opposed to unwilling,  
22 to provide requested information. Interested parties may well be interested in this distinction,  
23 too.

24  
25 **Section 69501.4(c)(2)** specifies the information required to be posted on the Response Status  
26 List. This provision is intended to keep the public, in particular retailers, informed about the  
27 compliance status of the chemical or product information. This provision also gives important  
28 information to consumers to allow them to make informed decisions regarding consumer  
29 products. The required information includes the identification of the chemical manufacturer or  
30 importer, the chemical or product which is the subject of the request, and any updates to the  
31 status of the Response Status List.

32  
33 **Section 69501.4(c)(3)** This provision requires DTSC to update its website upon determining  
34 that the responsible entity, chemical manufacturer, importer, or other person has taken some  
35 action that results in changed status under paragraph (1). This requirement is intended to  
36 ensure that DTSC’s website is up-to-date and conveys accurate information about the program  
37 to interested parties and the general public.

38  
39 **Section 69501.4(d)** *Safer Consumer Products Partner Recognition List* provides recognition  
40 for responsible entities that voluntarily provide information to DTSC that advances the quest for  
41 safer consumer products and will be maintained on DTSC’s website. This provision rewards  
42 the entities that voluntarily expend their resources to assist DTSC in obtaining information  
43 helpful in its regulatory tasks.

1 **Section 69501.4(d)(1)** provides that responsible entities that voluntarily completed an  
2 Alternatives Analysis will be placed on this list and will have the Alternatives Analysis posted  
3 on DTSC’s website. This provision encourages parties to complete Alternatives Analyses  
4 without being compelled to do so. It also makes sure that this information is made available to  
5 interested parties and the general public.

6  
7 **Section 69501.4(d)(2)** specifies that responsible entities that have voluntarily provided  
8 information that is helpful to DTSC in fulfilling its regulatory requirements will be placed on this  
9 list with an explanation of how this information advances the quest for safer consumer  
10 products. As with the above paragraph, this provision encourages voluntary participation in  
11 this program and makes the information generated available to the public.

### 12 **§ 69501.5. Availability of Information on the DTSC’s Website**

13  
14  
15 **Section 69501.5**, in its entirety, is necessary to specify the types of information that DTSC will  
16 post on its website. In order to implement these regulations, making information available to  
17 the public, consumers, responsible entities and other persons in the supply chain is critical.  
18 This section clearly specifies the information that DTSC will post to assist responsible entities  
19 in complying with the requirements of Chapter 55 may use for compliance. This information  
20 will also assist the public and consumers to make informed choices regarding consumer  
21 products.

22  
23 **Section 69501.5(a)** requires that DTSC post on its website and update as needed all of the  
24 information set out below. The availability of the documents and information listed below, and  
25 updates thereto, will be sent to persons on any electronic mailing lists established by DTSC for  
26 purposes of implementing Chapter 55.

- 27  
28 (1) The Failure to Comply List prepared under section 69501.2(d).  
29 (2) Requests for information made under section 69501.4.  
30 (3) Proposed and final Chemicals of Concern and Priority Products lists and revisions to the  
31 lists, supporting rationale and documentation, prepared under sections 69502.3 and  
32 69503.4, copies of all written comments received during the public comment period for the  
33 proposed list, and copies of any written responses DTSC provides to the comments.  
34 (4) Petitions designated as complete under section 69504(c), and notices of decision and  
35 statements of basis prepared by DTSC under section 69504.1(d).  
36 (5) A list of extension requests approved for submission of the Preliminary and Final AA  
37 Reports.  
38 (6) AA Report notices of compliance, notices of deficiency, notices of disapproval, and notices  
39 of ongoing review issued under section 69505.6.  
40 (7) Proposed and final regulatory response determination notices issued by DTSC under  
41 section 69505.6(c) and Article 6, copies of all written comments received during the public  
42 comment period for a proposed notice, and copies of any written responses DTSC provides  
43 to the comments.

- 1 **(8)** A list of regulatory response exemption requests submitted to DTSC under section  
2 69506.11, and copies of all notifications issued by DTSC granting, denying, or rescinding a  
3 regulatory response exemption.
- 4 **(9)** Copies of all disputes and Requests for Review filed with DTSC under Article 7, and copies  
5 of all DTSC decisions, and notices of ongoing review, issued in response to disputes and  
6 Requests for Review.
- 7 **(10)** A list of accreditation bodies whose designation has been revoked by DTSC under section  
8 69508.3(d) or (g), and a list of certified assessors whose certification has been reprovved,  
9 suspended, place on probation, or revoked under section 69508.

10  
11 **Section 69501.5(b)** specifies additional items that DTSC must post on its website and update  
12 as appropriate:

- 13 **(1)** The Response Status List prepared under section 69501.4.
- 14 **(2)** The Safer Consumer Products Partner Recognition List prepared under section 69501.4.
- 15 **(3)** As the following information becomes available, DTSC shall add it to the Priority Products  
16 list for each product that is a Priority Product, and maintain and update this information for  
17 as long as the Priority Product continues to be placed into the stream of commerce in  
18 California:
- 19 **(A)** Brand name(s) and product name(s) for the product;
- 20 **(B)** Product manufacturer(s) and importers, except for those manufacturers or importers that  
21 have complied with the requirements of section 69501.2(b);
- 22 **(C)** Other responsible entities for the product, except for the responsible entities that have  
23 complied with the requirements of section 69501.2(c);
- 24 **(D)** The identity of the person that has been identified as being the person that will fulfill the  
25 requirements of Article 5;
- 26 **(E)** The due dates for, and dates of receipt of, each Preliminary AA Report and Final AA  
27 Report; and
- 28 **(F)** Lists of, and copies of, all of the following that have been submitted to the DTSC for each  
29 product:
- 30 1. Priority Product Notifications;
  - 31 2. Alternatives Analysis Threshold Exemption Notifications, and notices submitted to  
32 DTSC under subsections (c) and (d) of section 69503.6, and notices issued by DTSC  
33 under section 69503.6(e);
  - 34 3. Priority Product Removal Notifications, and, when applicable, the associated Priority  
35 Product Replacement Notifications;
  - 36 4. Chemical of Concern Removal Notifications; and
  - 37 5. Priority Product Cease Ordering Notifications.
- 38
- 39 **(4)** Guidance documents prepared by DTSC under section 69505(a).
- 40 **(5)** AAs made available by DTSC under section 69505(b).
- 41 **(6)** A list of all Preliminary AA Reports, Final AA Reports, Abridged AA Reports, and Alternate  
42 Process AA Work Plans that have been submitted to DTSC under Article 5, the executive  
43 summary for each document, and a full or redacted copy of each document, including both  
44 the originally submitted document and the document approved by DTSC, if different.

- 1 (7) A list and copies of all notification issued by DTSC, and all documents submitted to DTSC,  
2 under section 69506.6.
- 3 (8) Links to product stewardship plans, substitute end-of-life management programs,  
4 exemptions from end-of-life management program requirements, and copies of annual end-  
5 of-life program reports.
- 6 (9) The Regulatory Response Summary prepared and updated under section 69506.12(d).
- 7 (10) A list of entities that have been designated as accreditation bodies under section 69508.3,  
8 and a list of certified assessors who have been accredited under section 69508. DTSC  
9 shall update these lists whenever an accreditation body's designation is revoked, or an  
10 assessor's certification is reprovod, suspended, placed on probation, or revoked.
- 11 (11) Findings of audits conducted by DTSC under section 69509.

12  
13 **Section 69501.5(c)** requires that all documents and information posted on DTSC's website  
14 under these regulations must include the date the item is posted and dates of any revised  
15 postings. This is intended to keep the information current and reliable for use by the public. In  
16 addition, compliance with the requirements of Chapter 55 is in some cases triggered by the  
17 date certain information is posted on DTSC's website.

1 **Article 2. Chemical of Concern Identification Process**

2  
3 **Article 2** in its entirety, implements, clarifies, and make specific the process for Chemicals of  
4 Concern identification and listing, which is Step 1 of a four-step process that is a continuous,  
5 science-based, and an iterative process that identifies safer consumer product alternatives.  
6 Step 2 is in Article 3, the Chemicals of Concern and Consumer Products Prioritization Process.  
7 These first two steps of the process, not only serve to require manufacturers to identify safer  
8 consumer product alternatives through the Alternatives Analysis process in Article 5 (Step 3 of  
9 the process), but will also serve as a market driver for manufacturers to voluntarily develop  
10 safer consumer products as more fully described in the Informative Digest.

11  
12 *Statutory Requirements and Intent*

13 The discussion here, which provides background information on the identification and  
14 prioritization processes, applies to both chemicals and products – Articles 2 and 3. The  
15 chemical and product identification and prioritization processes established in these  
16 regulations are in response to the directives in Health and Safety Code sections 25252 and  
17 25253 and the overarching legislative intent of the “Green Chemistry” statutes embodied in  
18 Health and Safety Code section 25255(a).

19  
20 Health and Safety Code section 25252 requires DTSC to “establish a process to identify and  
21 prioritize those chemicals or chemical ingredients in consumer products that may be  
22 considered as a Chemical of Concern”. Health and Safety Code section 25252 also requires  
23 DTSC to:

- 24 (1) Establish an identification and prioritization process that includes, but is not limited to, the  
25 following:
- 26 a. Volume of the chemical in commerce in California;
  - 27 b. The potential for exposure to the chemical in the consumer product; and
  - 28 c. Potential effects on sensitive subpopulations, including infants and children.
- 29 (2) Evaluate chemicals and their alternatives by developing criteria that include, but are not  
30 limited to, traits, characteristics, and endpoints (collectively referred to as “hazard traits” for  
31 purposes of this Statement of Reasons), developed by the Office of Environmental Health  
32 Hazard Assessment (OEHHA), for the Toxics Information Clearinghouse established under  
33 Health and Safety Code section 25256.1.
- 34 (3) Use, to the extent feasible, “available information from other nations, governments, and  
35 authoritative bodies that have undertaken similar chemical prioritization processes”. (Note:  
36 DTSC is not limited to the use of such information only.)

37  
38 Health and Safety Code section 25253(a), in pertinent part, requires DTSC to “establish a  
39 process for evaluating Chemicals of Concern in consumer products, and their potential  
40 alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by  
41 a Chemical of Concern”.

42  
43 Health and Safety Code section 25255(a) states that the goal of the statute is “significantly  
44 reducing adverse health and environmental impacts of chemicals used in commerce, as well

1 as the overall costs of those impacts to the state’s society, by encouraging the redesign of  
2 consumer products, manufacturing processes, and approaches”.

3  
4 DTSC sought to interpret, clarify and make specific the sections above, consistent with the  
5 overarching legislative intent. In so doing, DTSC consulted with the Green Ribbon Science  
6 Panel (GRSP), which DTSC was required to establish under Health and Safety Code section  
7 25254. DTSC also reviewed stakeholder comments in response to an informal draft of the  
8 regulations. The regulations in Articles 2 and 3 reflect DTSC’s consideration of the GRSP and  
9 stakeholder comments, in meeting the authorizing statute requirement to establish the  
10 identification and prioritization processes.

11  
12 (1) Article 2 identifies an initial list of chemicals as Chemicals of Concern using the criterion  
13 that a chemical must exhibit a hazard trait as defined and described in Chapter 54, Green  
14 Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant  
15 Data, Title 22, California Code of Regulations (Chapter 54). Article 2 also establishes a  
16 process to identify additional chemicals as Chemicals of Concern and to make revisions to  
17 the Chemicals of Concern list.

18 (2) Article 3 prioritizes Chemicals of Concern in consumer products resulting in a list of Priority  
19 Products by evaluating the hazard trait(s) exhibited by the Chemical of Concern and their  
20 ability to contribute to or cause adverse impacts due to exposure to the Chemical of  
21 Concern in the consumer product.

### 22 23 *Identification and Prioritization Process Development*

24 In developing the identification and prioritization processes set out in Articles 2 and 3, DTSC  
25 consulted the GRSP. The GRSP was established in accordance with Health and Safety Code  
26 section 25254 to advise DTSC in the adoption of these regulations and related matters. DTSC  
27 provided various topics, including chemical and product identification and prioritization  
28 processes, and their associated underlying scientific principles, to the GRSP for discussion.  
29 The objective in consulting with the GRSP was not to reach a consensus among GRSP  
30 members on the various topics, but to obtain scientific insights based on each GRSP  
31 member’s area of expertise for DTSC to consider during the development of these regulations.

32  
33 Various options and expert opinions were provided by the GRSP to identify and prioritize  
34 chemicals and products, from a methodical, stepwise process to combining certain steps. One  
35 option discussed by the GRSP identified and prioritized Chemicals of Concern in two steps –  
36 (1) an identification process that produces a larger list of Chemicals under Consideration and  
37 then (2) a prioritization process that would yield a smaller number of Chemicals of Concern.  
38 Similarly, consumer products would undergo a two-step identification and prioritization  
39 processes – (1) identification of products that contain Chemicals of Concern, followed by a (2)  
40 prioritization process to list a smaller number of products as Priority Products. These Priority  
41 Products would then be subject to an Alternatives Analysis.

42  
43 A variation of the consumer product process combines the identification and prioritization  
44 processes together, which would be more efficient than a discrete two-step process.  
45 Efficiencies would be gained since the information needed to identify and prioritize products

1 containing Chemicals of Concern would most likely be from the same information source, i.e.,  
2 the manufacturer or in the public domain.

3  
4 The GRSP also discussed an option that combined the chemical and product identification and  
5 prioritization processes, which provides for additional efficiencies. As DTSC examined these  
6 various options discussed by the GRSP, it became apparent that prioritizing chemicals is very  
7 much dependent on information about both chemicals and products. Information about a  
8 chemical informs the identification and prioritization of the product and information about the  
9 product informs the chemical prioritization process.

10  
11 For example, consider the three factors in the authorizing statute that DTSC must take into  
12 account to “establish a process to identify and prioritize” Chemicals of Concern in consumer  
13 products: (1) volume of the chemical in commerce in California, (2) potential for exposure to  
14 the chemical in the product and (3) potential effects on sensitive subpopulations. *Chemical*  
15 *information* and data is needed to inform the factors regarding volume and potential effects on  
16 sensitive subpopulations. However, *consumer products information* is needed to evaluate the  
17 potential for exposure to the chemical in the consumer product. Consumer product use,  
18 physical form and the chemical concentration and function in the consumer product influence  
19 the potential for exposure to the chemical in the consumer product, as well as the potential  
20 effects on sensitive subpopulations. Additionally, information regarding the chemical volume in  
21 commerce in California, while available through the federal Toxic Substances Control Act  
22 (TSCA), may not be as accurate for DTSCs purposes as the volume of the “Chemical of  
23 Concern” in consumer products in California for prioritization purposes.

24  
25 Chemical prioritization cannot be done practically without at least some consumer product  
26 information. It is apparent that evaluating Chemicals of Concern in consumer products, and  
27 the alternatives being considered, to determine how best to limit exposure pursuant to Health  
28 and Safety Code section 25253, cannot be done without identifying the consumer product. In  
29 order to meet the authorizing statute’s intent and mandate, information regarding consumer  
30 products need to be incorporated into the chemical identification and prioritization processes in  
31 the regulations.

32  
33 DTSC sought to meet the authorizing statutory requirements, taking into consideration  
34 stakeholders’ input, by making policy decisions that incorporate science, practicality, efficiency  
35 and transparency. The resulting process is set out in Article 2 to identify Chemicals of  
36 Concern and in Article 3 to prioritize Chemicals of Concern in consumer products, and to list  
37 those as Priority Products.

### 38 *Narrative versus Prescriptive Processes*

39  
40 As discussed above, it became apparent to DTSC that prioritization of Chemicals of Concern  
41 and consumer products that contain Chemicals of Concern could not be done apart from each  
42 other, in isolation, but needed to be done together. Evaluating and balancing information on  
43 both chemicals and products based on available information allows for flexible decision-making  
44 to propose Priority Products for listing. Along that same line of thought, the identification of  
45 Chemicals of Concern, based on their hazard traits, is also not done without relevant toxicity

1 profile information and an evaluation of exposures, where consumer products-related  
2 information may be extremely helpful.

3  
4 A prescriptive process for identifying and prioritizing chemicals and products, with rigid criteria  
5 for DTSC to evaluate and make decisions, may provide a greater level of predictability and  
6 certainty to manufacturers who wish to evaluate their chemicals and consumer products --  
7 especially for chemicals and products not yet listed as Chemicals of Concern or Priority  
8 Products. DTSC appreciates the fact that some manufacturers wish to take proactive steps to  
9 examine alternatives to a consumer product before the consumer product is subject to these  
10 regulations. DTSC recognizes the value these regulations may serve as a market driver for  
11 manufacturers to voluntarily step up and develop safer consumer products, use safer  
12 alternative chemicals, or redesign the manufacturing process or the consumer product.

13  
14 While there is some value in greater certainty and predictability with a prescriptive process  
15 than with a narrative approach, there may also be some negative consequences as well. More  
16 specifically, by definition, a prescriptive process for decision-making entails a fairly rigid  
17 adherence to a set of steps and/or specific weighting of various factors or criteria. This, in turn,  
18 can be challenging to DTSC, especially since it greatly limits DTSC to bring its particular  
19 expertise and judgment to bear on a decision. A prescriptive process would only reflect  
20 decisions based on current science and understanding and creates the possibility that the  
21 current process in place ignores new science and understanding for future decisions. While  
22 regulations may be amended to reflect new science, by the time the regulations are amended,  
23 the regulations may need further amendment because the science has progressed again.  
24 There is valid concern that under a prescriptive approach, DTSC will constantly be behind new  
25 science and understanding, will constantly be amending regulations, and will be strapped into  
26 making regulatory decisions knowing that the regulatory process will not allow consideration of  
27 new scientific understanding of chemicals and products.

28  
29 In addition, there is a lack of knowledge and experience with a regulatory program of this  
30 scope and breadth since this regulatory program is the first of its kind in the nation. The GRSP  
31 and DTSC recognized that the processes in regulations need a measure of predictability and  
32 certainty. But the regulations also need to remain relevant and appropriate as the Safer  
33 Consumer Product program grows and matures with the need to incorporate advances in  
34 science, knowledge, and experience. Regulatory decisions need to be informed by the best  
35 scientific information and approaches available. For that reason, DTSC is not specifying a  
36 prescriptive process with numerical weighting or ranking system for chemicals and products,  
37 but is instead using a narrative approach that allows DTSC to use best available scientific  
38 information and practices to identify and prioritize chemicals and products.

39  
40 DTSC recognizes that before decisions are made final, stakeholders need to examine the  
41 rationale, data, and information sources that led DTSC to the decisions made. Transparency  
42 and stakeholder input (public comment period and a workshop) are built into Articles 2 and 3  
43 by requiring DTSC to provide its rationale for proposing to remove or add additional Chemicals  
44 of Concern and Priority Products. To address stakeholders' concerns about the lack of  
45 predictability in listing Chemicals of Concern, the regulations establish an initial list of

1 Chemicals of Concern (~1,200 chemicals) that are based on the work already done by other  
2 authoritative organizations. An informational list will be posted on DTSC's website within 30  
3 days of the effective date of the regulations. However, a person does not need to wait for the  
4 publication of the informational list since the chemical lists are identified in regulations.  
5

6 Also, after the initial Priority Products have been listed, DTSC will develop a periodic work plan  
7 to identify product categories for evaluation as Priority Products. In addition, up until 2016,  
8 DTSC will limit the Chemicals of Concern present in Priority Products to those that meet  
9 certain criteria (~200 chemicals). The Priority Product Work Plan will reflect the amount of  
10 available resources DTSC has to implement the Safer Consumer Products program. The  
11 Priority Products Work Plan will provide another measure of certainty and predictability to  
12 manufacturers who wish to take voluntary actions regarding their chemicals and products  
13 outside of the compulsory aspects of these regulations.  
14

15 DTSC has designed the regulations in Articles 2 and 3 to be pertinent, transparent and flexible:  
16 (1) to accommodate the availability and type of chemical and product information being  
17 considered and evaluated and (2) to stand the test of time by allowing DTSC to consider  
18 chemical information based on advances in science and technology.  
19

20 This Statement of Reasons outlines the rationale for the identification and prioritization process  
21 for Chemicals of Concern and Priority Products. As with any new process, periodic  
22 examination and evaluation of the practicality, meaningfulness, protectiveness and technical  
23 soundness of the processes set out in these regulations will be necessary. This will allow  
24 DTSC to make any course corrections, which will be critical to the success of the Safer  
25 Consumer Products program.  
26

## 27 **§ 69502. General**

28

29 **Section 69502(a)** specifies the purpose and scope of Article 2: it identifies Chemicals of  
30 Concern and specifies the process that DTSC may use to identify additional Chemicals of  
31 Concern, as required by the authorizing statute. This provision informs responsible entities  
32 and other interested parties of the process that DTSC will follow in identifying Chemicals of  
33 Concern.  
34

35 **Section 69502(b)** specifies that as part of the Chemicals of Concern identification process,  
36 DTSC will evaluate information from manufacturers and other sources. DTSC may rely on  
37 information about chemicals obtained under section 69501.4, but is not limited to solely using  
38 information obtained under section 69501.4 in performing its duties under Article 2. Providing  
39 DTSC with maximum latitude and flexibility to seek out and utilize a broad range of scientific  
40 data and other information ensures that the chemicals identification process and the resulting  
41 Chemicals of Concern list are based on sound science.  
42

### 43 **§ 69502.1. Applicability**

44

1 **Section 69502.1** specifies the scope of chemicals subject to the Chemicals of Concern  
2 identification process. The scope specified in the regulation is consistent with, and is  
3 necessary to implement, the broad scope of chemicals and products captured by the  
4 authorizing statute.

5  
6 This section identifies the conditions under which a chemical is subject to the identification  
7 process: (1) the chemical exhibits a hazard trait or an environmental or toxicological endpoint;  
8 and (2) the chemical is in products that are placed into the stream of commerce in California.  
9 The terms “hazard trait” and “environmental or toxicological endpoint” are defined in Article 1.

10  
11 According to Title 22, California Code of Regulations, Divisions 4.5, Chapter 54 (Chapter 54), a  
12 hazard trait must be supported by evidence that the chemical exhibits an adverse  
13 environmental or toxicological endpoint, which is shown by well conducted studies pursuant to  
14 Chapter 54. In some instances, a chemical may not exhibit a hazard trait even though  
15 research and well conducted studies, as defined in Chapter 54, section 69401.2(i), have been  
16 conducted, because the studies are inconclusive. In other cases, the chemical’s mechanism  
17 to cause an adverse toxicological or environmental endpoint is not known and a hazard trait  
18 cannot be assigned to the chemical.

19  
20 It is DTSC’s intent to verify the hazard trait or environmental or toxicological endpoint  
21 associated with the specific chemical before the informational list of Chemicals of Concern is  
22 posted on DTSC’s website. However, it may come to DTSC’s attention that the hazard trait  
23 associated with the chemical does not meet the definition of “hazard trait” set out Chapter 54,  
24 especially if new scientific information shows that a chemical does not exhibit a given hazard  
25 trait. In response to this situation, DTSC will review the information and take appropriate  
26 action on the Chemicals of Concern list according to the process set out in section 69502.3.

27  
28 For example, disregarding the point that dichlorodiphenyltrichloroethane (DDT) is banned,  
29 DDT is an organochlorine insecticide that is linked to eggshell thinning and affects wildlife  
30 survival. Eggshell thinning is an adverse environmental (i.e., ecological) impact, but the  
31 mechanism that causes eggshell thinning is not known and assigning a hazard trait linked to  
32 DDT based on eggshell thinning may be difficult. However, DDT is considered a persistent  
33 organic pollutant with toxic effects and environmental persistence is an exposure potential  
34 hazard trait pursuant to Chapter 54, section 69405.3. But assigning DDT the environmental  
35 persistence hazard trait that is linked to eggshell thinning in birds is debatable. Rather than  
36 debate the mechanism that causes eggshell thinning and assign a hazard trait, for purposes of  
37 identifying a Chemical of Concern, a chemical that exhibits a toxicological or environmental  
38 endpoint is reason enough to be identified as a Chemical of Concern. If new science leads to  
39 the conclusion that DDT’s mechanism related to eggshell thinning is linked to the ability to  
40 reproduce (i.e., reproductive toxicity hazard trait), DTSC will add the reproductive toxicity  
41 hazard trait to DDT. If, however, new science leads to the conclusion that DDT has nothing to  
42 do with eggshell thinning and that environmental persistence is not an issue, then DTSC will  
43 take appropriate action to remove DDT from the Chemical of Concern list.

44  
45 **§ 69502.2. Chemicals of Concern Identification**

1  
2 **Section 69502.2**, in its entirety, clarifies and makes specific the criteria used to identify the  
3 initial list of chemicals and to add any additional chemicals to the initial list as Chemicals of  
4 Concern.

5  
6 **Section 69502.2(a)** specifies the criteria for the initial Chemicals of Concern list. A chemical is  
7 a Chemical of Concern if it exhibits a hazard trait or an environmental or toxicological endpoint  
8 and is listed on one or more of the enumerated authoritative organizations' lists.

9  
10 This section establishes, as of the effective date of the regulations, a robust list of an estimated  
11 1,200 Chemicals of Concern, based on work already done by authoritative organizations. The  
12 Chemicals of Concern estimate reflects the removal of non-chemicals (i.e., nutrients) and  
13 duplicate chemicals that appear on more than one list. Prior to posting an informational  
14 Chemicals of Concern list on DTSC's website, the known pesticides and pharmaceuticals will  
15 be identified, since under specific conditions they are statutorily excluded from the definition of  
16 "consumer product". And, thus, they are outside the reach of the Safer Consumer Products  
17 program (Health and Safety Code section 25251). By having a robust list of Chemicals of  
18 Concern, the regulations send immediate signals to the marketplace about chemicals subject  
19 to this program. Consumers will be more informed about the Chemicals of Concern that may  
20 be present in the products they purchase and manufacturers, importers, and retailers (also  
21 referred to as responsible entities) may take voluntary actions on the chemicals in their quest  
22 for safer consumer products.

23  
24 For example, some companies, such as Wal-Mart and Staples, are using chemical lists for  
25 disclosure purposes or to restrict products containing certain chemicals for purchase at their  
26 retail stores. Others, such as the automotive industry, through their use of the Global  
27 Automotive Declarable Substance List (GADSL), use chemical lists to implement their quest  
28 for safer consumer products. Manufacturers who wish to begin proactive efforts and  
29 voluntarily redesign of their products may use this initial list of Chemicals of Concern as part of  
30 their process to make decisions regarding potential chemical alternatives or substitutions to  
31 consider. This, in turn, may also reduce the possibility of regrettable substitutions.

32  
33 Health and Safety Code section 25252(b)(2) requires that DTSC use, to the maximum extent  
34 feasible, available information from other authoritative bodies, i.e., "organizations", that have  
35 undertaken similar chemical prioritization processes. It is important to note that DTSC relies  
36 on this foundational definition of "authoritative organization", to support the first step in the  
37 prioritization process, that is, the identification of Chemicals of Concern. By relying on other  
38 authoritative organizations' work, recommendations and regulations that support protecting  
39 human health or the environment to identify the initial list of Chemicals of Concern, DTSC is  
40 able to maximize resources, minimizing time and costs to California. The Safer Consumer  
41 Products program is "jumpstarted" by starting with a robust initial list of Chemicals of Concern  
42 and to immediately start evaluating consumer products containing Chemicals of Concern to  
43 create the first Priority Products list.

1 DTSC considered the GRSP’s advice, public comments, and input from other state agencies,  
2 including the California Department of Public Health, California Air Resources Board, State  
3 Water Resources Control Board and OEHHA in establishing this list of sources for identifying  
4 Chemicals of Concern. In addition, DTSC employed the following criteria, which were not  
5 applied in a rigid or weighted fashion for all the reasons set out in the above section  
6 *Identification and Prioritization Process Development.*

7  
8 In identifying the chemical hazard traits for the initial Chemicals of Concern list, a type of  
9 chemical “prioritization” occurred. That is, Chapter 54 identifies many hazard traits, but only a  
10 select few were identified for the initial Chemicals of Concern list established in these  
11 regulations. The criteria DTSC considered to identify the sources of Chemicals of Concern  
12 with hazard traits for the initial Chemicals of Concern list are below (in no particular order).

#### 13 14 Chemical List and Hazard Trait Criteria

- 15 • The chemical list was supported, sponsored and/or developed by an authoritative  
16 organization, such as, a state, federal, or international agency, to protect public health  
17 or the environment. For example, the chemicals/chemical list:
  - 18 ○ was adopted as part of a regulatory scheme with an enforcement component;
  - 19 ○ exhibit a hazard trait based on the authoritative organization’s determination; or
  - 20 ○ is used to support or make policy or risk management decisions to protect public  
21 health and the environment.
- 22 • The chemical list was developed to prevent or limit exposures to public health and the  
23 environment. For example, the chemical list was developed to drive action plans to  
24 prevent pollution in environment.
- 25 • Harmonization and consistency with chemical lists and hazard traits identified by the  
26 States of Washington, Maine, and Minnesota with similar chemical programs.
- 27 • The chemicals on the list meets “strong evidence” or “evidence” for the toxicological and  
28 environmental hazard traits, as specified in Chapter 54
- 29 • The chemical list is reviewed and updated periodically.

30  
31 DTSC endeavored to start program implementation with hazard traits, chemicals and chemical  
32 lists that were generally in agreement with the recommendation of the GRSP and stakeholders  
33 to allow all parties to learn, gain experience, build a knowledge base, and make informed  
34 decisions before full scale implementation of these regulations. In examining the criteria for  
35 the chemical lists and hazard traits, a balance was struck. That is, in some cases, the  
36 chemical hazard trait became the driver to identify a chemical list. In other cases, the principal  
37 purpose or function of the chemical list became the driver to identify the chemical list. And in  
38 some cases, the criteria naturally paired the hazard trait with the chemical list. For example,  
39 for chemicals that are carcinogens, reproductive or developmental toxins, the California  
40 Proposition 65 list naturally comes to mind as an authoritative organization. In all cases, the  
41 chemicals on the lists meet criteria as strong evidence for toxicological hazard traits or as  
42 evidence for the exposure potential hazard trait in Chapter 54 and the chemical lists are  
43 reviewed and updated periodically.

1 Other factors influencing the identification of chemical hazard traits or chemical lists are the  
2 following:

- 3 • DTSC sought to have a “manageable” number of Chemicals of Concern on the initial list  
4 that would provide DTSC with a robust list of chemicals without having to add  
5 Chemicals of Concern in the early implementation years. This robust list also provides  
6 an adequate market signal to industry about chemicals that are of concern in consumer  
7 products and provides DTSC with a pool of chemicals from which Priority Products may  
8 be listed for Alternatives Analysis, and allow all parties to learn, gain experience, build  
9 knowledge base, and make informed decisions before full scale program  
10 implementation.
- 11 • DTSC considered the availability of state resources to implement the Safer Consumer  
12 Products program.
- 13 • The chemical list adds value to the initial Chemicals of Concern list; that is, the given  
14 chemical list does not excessively duplicate chemicals that are already named by other  
15 chemical lists.
- 16 • DTSC sought to identify chemical hazard traits that may yield partnerships with other  
17 California, state and national chemical programs to leverage resources and achieve  
18 results benefiting common goals – preventing exposures to harmful chemicals in  
19 consumer products.

20  
21 Using the criteria for identifying chemical lists and chemical hazard traits, DTSC identified and  
22 essentially “prioritized” the following chemical hazard traits for the initial list of Chemicals of  
23 Concern. It is noted that some chemicals may be listed for more than one hazard trait or a  
24 hazard trait that is not listed below; however, for purposes of identifying the initial Chemicals of  
25 Concern, these hazard traits were identified.

#### 26 27 Hazard Traits Identified for the Initial Chemicals of Concern List

- 28 • Carcinogenicity
- 29 • Developmental toxicity
- 30 • Reproductive toxicity
- 31 • Genotoxicity (mutagenicity)
- 32 • Endocrine Toxicity
- 33 • Neurotoxicity
- 34 • Bioaccumulation
- 35 • Environmental Persistence.

36  
37 The sources of chemicals listed in this section and their applicable listing criteria are  
38 summarized in Tables 2.1 and 2.2.

**Table 2.1 Section 69502.2(a)(1) Chemical List and Criteria**

Section 69502.2	Criteria #	1: Authoritative organization				3	4	5
	Chemical List	Hazard Trait	Regulatory Basis	Enforcement Consequences	Policy or Risk Management Decisions.	Harmonize	Strong Evidence	Updated
(a)(1)	The chemical is one or more of the following types of chemicals that are identified as exhibiting a hazard trait or an environmental or toxicological endpoint on one or more of the following lists:							
(A)	CA Proposition 65	Carcinogenicity, Developmental Reproductive	X	X	X	X	X	X
(B)	EU CMR	Carcinogenicity Mutagenicity Reproductive	X	X	X	X	X	X
(C)	EC Category 1 endocrine disruptors	Endocrine Toxicity			X	X	X	X
(D)	IRIS neurotoxicity	Neurotoxicity			X	X	X	X
(E)	IRIS carcinogens	Carcinogenicity			X	X	X	X
(F)	12 <sup>th</sup> Report on Carcinogens	Carcinogenicity			X	X	X	X
(G)	ESIS PBT	Persistence, Bioaccumulation	X	X	X	X	X	X
(H)	CEPA PBiT	Persistence, Bioaccumulation	X	X	X	X	X	X
(I)	IARC	Carcinogenicity			X	X	X	X
(J)	Neurotoxicants ATSDR	Neurotoxicity			X	X	X	X
(K)	US EPA National Waste Minimization Program PBTs	Persistence, Bioaccumulation			X	X	X	X
(L)	NTP OHAT Reproductive and Developmental Toxicants	Reproductive Developmental			X	X	X	X
(M)	TRI PBTs	Persistence Bioaccumulation	X	X		X	X	X
(N)	Washington PBTs	Persistence Bioaccumulation	X		X	X	X	X

Criteria #	Chemical List Criteria
1	The chemical list was supported, sponsored and/or developed by an authoritative organization, such as, a state, federal, or international agency, to protect public health or the environment. For example, the chemicals/chemical list: <ul style="list-style-type: none"> <li>•is adopted as part of a regulatory scheme and may have enforcement consequences;</li> <li>•exhibit a hazard trait based on the authoritative organization’s determination;</li> <li>•is used to support or make policy or risk management decisions to protect public health and the environment;</li> </ul>
2	The chemical list was developed to prevent or limit potential exposures to public health and the environment
3	Harmonization and consistency with chemical lists and hazard traits identified by the States of Washington, Maine, and Minnesota with similar chemical programs.
4	The chemicals on the list meets “strong evidence” or “evidence” for the toxicological and environmental hazard traits, as specified in Chapter 54
5	The chemical list is reviewed and updated periodically (not meant to be a static list)

**Table 2.2 Section 69502.2(a)(2) Chemical List and Criteria**

Section 69502.2	Criteria #	1: Authoritative organization				2	3	5
	Chemical List	Hazard Trait*	Regulatory Basis	Enforcement Consequences	Supports Policy or Risk Management Decisions.	Media/Receptor	Harmonize	Updated
(a)(2)	The chemical is one or more of the following types of chemicals							
(A)	CA Notification Levels	Various	X	X		Water/Human		X
(B)	CA Maximum Contaminant Levels (MCLs)	Various	X	X		Water/Human		X
(C)	CA Toxic Air Contaminants	Various		X		Air/Human	X	X
(D)	303(c)	Various	X	X		Water/Environment		X
(E)	OEHHA REL	"noncancer endpoints" (Various)	X		X	Air/Human		X
(F)	California Biomonitoring Program Priority Chemicals	Various	X		X	Unknown/Human		X
(G)	Fourth National Report on Human Exposure to Environmental Chemicals	Various			X	Unknown/Human	X	X
(H)	OSPAR List of Chemicals for Priority Action Part A	Persistence, Bioaccumulation			X	Water/Environment	X	X

\* "Various" indicates that the specific hazard traits of the chemicals on the list will be noted on the informational Chemicals of Concern list that DTSC will make available within 30 days of the effective date of these regulations [section 69502.3(a)].

Criteria #	Chemical List Criteria
1	The chemical list was supported, sponsored and/or developed by an authoritative organization, such as, a state, federal, or international agency, to protect public health or the environment. For example, the chemicals/chemical list: <ul style="list-style-type: none"> <li>•is adopted as part of a regulatory scheme and may have enforcement consequences;</li> <li>•exhibit a hazard trait based on the authoritative organization's determination;</li> <li>•is used to support or make policy or risk management decisions to protect public health and the environment;</li> </ul>
2	The chemical list was developed to prevent or limit potential exposures to public health and the environment
3	Harmonization and consistency with chemical lists and hazard traits identified by the States of Washington, Maine, and Minnesota with similar chemical programs.
4	The chemicals on the list meets "strong evidence" or "evidence" for the toxicological and environmental hazard traits, as specified in Chapter 54
5	The chemical list is reviewed and updated periodically (not meant to be a static list)

1 Table 2.3 provides a broad, general comparison of the different jurisdictions and their  
 2 Chemical Lists and the number of chemicals (in parentheses) on those lists. The Chemical  
 3 Lists are conceptually similar to the initial list of Chemicals of Concern, but are used for a  
 4 variety of purposes, such as chemical data reporting or data gathering. The Chemical Lists  
 5 from Washington, Maine, and Minnesota are most similar in their intent or purpose to the initial  
 6 list of Chemicals of Concern.

7  
 8 Table 2.3: Chemical List Comparison

Jurisdiction	Broad List	Focused List
Washington	High Priority Chemicals (~2,000)	Chemicals of High Concern for Children (~66)
Maine	Chemicals of Concern (~1,400)	Chemicals of High Concern (~70)
Minnesota	Chemicals of High Concern (~1,700)	Priority Chemicals (~9)
Canada	Priority Chemicals (~4,300)	Highest Priority Chemicals (~200)
Australia	Priority Existing Chemicals for Assessment (~3,000)	Priority Chemicals (~800)
Europe	Restricted Substances List (~1,000)	Substances of Very High Concern (~84) <sup>1</sup>
Japan	Monitored Chemicals (~1,550)	Priority Chemicals (~88) reporting
USEPA	Candidate List (~345)	TSCA Work Plan Chemicals (~83)
California	Chemicals of Concern (~1,200) <sup>2</sup>	Chemicals of Concern Work Plan** (~200) <sup>3</sup>

9 <sup>1</sup> not a subset of the Restricted Substances List

10 <sup>2</sup> estimated number of Chemicals of Concern excluding pesticides and drugs

11 <sup>3</sup> estimated number of Chemicals of Concern; see Statement of Reasons for section 69503.3(g)

12  
 13 **Section 69502.2(a)(1)** specifies that the chemicals exhibiting a hazard trait or an  
 14 environmental or toxicological endpoint on one of the included chemical lists is a Chemical of  
 15 Concern. Table 2.1 summarizes subsection (a)(1) chemical lists sources, their hazard traits  
 16 and criteria that each chemical list meets. The principal criterion that placed these chemical  
 17 lists together in subsection (a)(1) is that DTSC is accepting the chemical's hazard trait  
 18 identification by each authoritative organization that is responsible for the chemical list. The  
 19 chemicals on these chemical lists exhibit strong evidence for toxicological hazard traits and  
 20 evidence for the exposure potential hazard traits according to Chapter 54.

21  
 22 The Chemicals of Concern in subsection (a)(1) exhibit: (1) toxicological hazard traits of  
 23 carcinogenicity, developmental toxicity, reproductive toxicity, genotoxicity (mutagenicity),  
 24 neurotoxicity or endocrine toxicity or (2) exposure potential hazard traits of environmental  
 25 persistence and bioaccumulation.

26  
 27 The following subsections briefly describe the sources of each chemical list. It is noted that  
 28 "evidence" is used in some of the authoritative organization's descriptions to identify the  
 29 hazard traits. However, "evidence" is used as a general term unless specifically noted or  
 30 defined as meeting the definitions for a hazard trait in Chapter 54.

31  
 32 **Section 69502.2(a)(1)(A)** specifies that the chemicals listed as carcinogens, developmental  
 33 toxins and reproductive toxins on the California Safe Drinking Water and Toxic Enforcement  
 34 Act of 1986 (Proposition 65) list are Chemicals of Concern. Proposition 65 was enacted as a  
 35 California ballot initiative in November 1986 and was intended by its authors to protect  
 36 California citizens and the State's drinking water sources from chemicals known to cause

1 cancer, birth defects or other reproductive harm, and to inform citizens about exposures to  
2 such chemicals.

3  
4 Proposition 65 is an enforceable, regulatory program implemented by OEHHA, an authoritative  
5 organization, as the lead agency appointed by the Governor. The Proposition 65 list of  
6 chemicals is regularly maintained by OEHHA. The list also serves to inform other agencies on  
7 chemical policy to protect public health. Proposition 65 protects the public from carcinogens  
8 and reproductive toxins by requiring businesses to notify Californians about significant  
9 amounts of chemicals in the products they purchase, in their homes or workplaces, or that are  
10 released into the environment. By providing this information, Proposition 65 enables  
11 Californians to make informed decisions about protecting themselves from exposure to these  
12 chemicals. Proposition 65 also prohibits California businesses from knowingly discharging  
13 significant amounts of listed chemicals into sources of drinking water.

14  
15 OEHHA administers the Proposition 65 program and each year publishes an updated list of  
16 chemicals that are considered "Proposition 65 chemicals." Since 1987, the list has grown to  
17 about 800 chemical listings (Note: "chemical listings" is not synonymous with "chemicals".  
18 Many chemicals have multiple entries for distinct endpoints. For instance, lead is listed as  
19 causing: cancer, male reproductive harm, female reproductive harm, and developmental  
20 toxicity.) The listings are for chemicals that exhibit carcinogenic, developmental and/or  
21 reproductive toxicity. There are four principal ways for a chemical to be added to the  
22 Proposition 65 list.

- 23 • A chemical is listed if either of two independent committees of scientists and health  
24 professionals finds that the chemical has been clearly shown to cause cancer or birth  
25 defects or other reproductive harm. These two committees, the Carcinogen  
26 Identification Committee (CIC) and the Developmental and Reproductive Toxicant  
27 (DART) Identification Committee—are part of OEHHA's Science Advisory Board.  
28 OEHHA staff scientists evaluate all currently available scientific information on  
29 substances considered for placement on the Proposition 65 list and compile the relevant  
30 scientific evidence for the committees to review. The committees also consider public  
31 comments before making their decisions.
- 32 • A chemical is listed if an organization designated as an "authoritative body" by the CIC  
33 or DART Identification Committee has identified the chemical as causing cancer or birth  
34 defects or other reproductive harm. The following organizations have been designated  
35 as authoritative bodies: the U.S. Environmental Protection Agency, U.S. Food and Drug  
36 Administration (U.S. FDA), National Institute for Occupational Safety and Health,  
37 National Toxicology Program, and International Agency for Research on Cancer.
- 38 • A chemical is listed if an agency of the state or federal government requires that the  
39 chemical be labeled or identified as causing cancer or birth defects or other  
40 reproductive harm. Most chemicals listed in this manner are prescription drugs that are  
41 required by the U.S. FDA to contain warnings relating to cancer or birth defects or other  
42 reproductive harm.
- 43 • A chemical is listed if the chemical meets certain scientific criteria and is identified in the  
44 California Labor Code as causing cancer or birth defects or other reproductive harm.

1 This method established the initial chemical list following voter approval of Proposition  
2 65 in 1986 and continues to be used as a basis for listing as appropriate.

3  
4 **Section 69502.2(a)(1)(B)** specifies that Category 1A and 1B chemicals identified in the  
5 European Union European Commission 1272/2008 Annex VI due to carcinogenicity,  
6 reproductive toxicity, and/or mutagenicity are Chemicals of Concern.

7  
8 Annex VI is maintained by the European Chemicals Agency (ECHA), an international  
9 authoritative organization working with the European Commission and the European Union  
10 (EU) Member States for the safety of human health and the environment by identifying the  
11 needs for regulatory risk management at EU-wide level. Annex VI to Regulation European  
12 Commission (EC) No 1272/2008 includes lists of harmonized classification and labeling for  
13 certain substances or groups of substances that are legally binding within the EU. The  
14 classification and labeling system is the basis for a number of regulatory programs within the  
15 EU, making Annex VI an enforceable, regulatory list. Annex VI is updated on a regular basis  
16 and serves as an important tool for hazard communication and risk management to inform the  
17 EU programs the regulatory actions required for certain chemicals to protect public health.  
18 Currently, Annex VI has about 1,200 chemicals harmonized as Category 1A and 1B  
19 carcinogens, Category 1A and 1B reproductive toxins, and Category 1A and 1B mutagens,  
20 which are considered to exhibit the genotoxicity hazard trait under Chapter 54.

21  
22 The classification of a chemical's hazard trait is harmonized through a transparent, public  
23 process to ensure that the classification of the chemical is agreed upon and to ensure  
24 adequate risk management throughout the European Community. This could happen in three  
25 situations:

- 26 • When chemical suppliers provide multiple or contradictory classifications for the same  
27 chemical, which may be carcinogenic, mutagenic, toxic for reproduction or a respiratory  
28 sensitizer.
- 29 • When the substance is an active substance in biocidal or plant protection products.
- 30 • When Member States, manufacturers, importers and downstream users justify that a  
31 classification at the EU level is needed.

32  
33 A report is prepared for chemical classification harmonization and must contain sufficient  
34 information to make an independent assessment of various physical, toxicological and  
35 ecotoxicological hazards based on the information presented. A public comment period for 45  
36 days is held; after the comment period all comments received are forwarded to the Member  
37 State or those companies who had submitted the report for the purpose of viewing and  
38 responding to the public comments.

39  
40 The proposal, the comments and the response to comments are forwarded to the ECHA's Risk  
41 Assessment Committee. The Risk Assessment Committee, comprising experts from the  
42 Member States, issues a scientific opinion on the proposal, which will be forwarded to the EC.  
43 The EC, assisted by the Registration, Evaluation, Authorization and Restriction of Chemical  
44 substances (REACH) Regulatory Committee, consisting of representatives of the Member

1 States, will then decide on the proposed classification and labeling of the substance  
2 concerned. Once a decision is made, the harmonized classification appears in Annex VI.

3  
4 **Section 69502.2(a)(1)(C)** specifies that chemicals listed as Category 1 endocrine disruptors in  
5 the report, *Towards the establishment of a priority list of substances for further evaluation of*  
6 *their role in endocrine disruption - preparation of a candidate list of substances as a basis for*  
7 *priority setting* (ED Report), European Commission; DG Env, M0355008/1786Q/10/11/00, are  
8 Chemicals of Concern.

9  
10 Category 1 endocrine disruptors were identified by a group of experts in the ED Report, one in  
11 a series of studies sponsored by the European Commission, to develop a coherent approach  
12 to establish a list of priority substances to further study the chemicals and their role in  
13 endocrine disruption. This list is not meant to be static and the intent is to update the lists as  
14 scientific knowledge increases. Since the European Parliament adopted a Resolution calling  
15 upon the Commission to take action on the issue of endocrine disruptors in 1998, the  
16 Commission has published various staff working documents, which provide overviews of  
17 existing knowledge and of the challenges for risk assessment.

18  
19 From a total of 564 chemicals that had been suggested by various organizations or in  
20 published papers or reports as being suspected endocrine disruptors, 147 were considered  
21 likely to be either persistent in the environment or produced at high volumes. Of these 147  
22 chemicals, clear evidence of endocrine disrupting activity was noted for only 66. These 66 are  
23 the chemicals identified with the hazard trait of endocrine toxicity and are Chemicals of  
24 Concern. The different steps of the process to arrive at the 66 chemicals are briefly  
25 summarized below:

26  
27 Step 1 and 2: A working list of chemicals was compiled from various sources that listed  
28 suspected endocrine disruptors or described effects suggestive of endocrine disrupting activity  
29 for specific chemicals (564 chemicals). Then the information was reviewed to identify  
30 chemicals that might be either highly persistent in the environment (i.e. resistant to breakdown)  
31 or that are produced by industry at high volumes (i.e. more than 1,000 tons each year) as  
32 these would pose a greater likelihood for exposure to humans and animals (147 chemicals).

33  
34 Step 3: Using expert advice, information on the strength of evidence for endocrine disruption  
35 for the 147 chemicals was reviewed and chemicals were assigned to one of three categories:

- 36 • Category 1 - evidence of endocrine disrupting activity in at least one species using  
37 intact animals (66 chemicals are identified in this subparagraph);
- 38 • Category 2 - at least some in vitro evidence of biological activity related to endocrine  
39 disruption;
- 40 • Category 3 - no evidence of endocrine disrupting activity or no data available.

41  
42 Step 4 consisted of prioritizing the chemicals in the European Commission study, which is not  
43 used for purposes of identifying endocrine disruptors as Chemicals of Concern in Article 2, but  
44 may be used in the Article 3-prioritization process as reliable information demonstrating the  
45 occurrence of exposure. The 66 chemicals in Category 1 were reviewed, to decide, if it was

1 possible that humans or wildlife might actually be exposed. Highest concern was allotted to  
2 those where human or wildlife were expected to be exposed, medium concern related to those  
3 where humans were not expected to be exposed but wildlife could be, and lowest concern was  
4 scored for those where neither humans or wildlife were exposed.

5  
6 **Section 69502.2(a)(1)(D)** specifies that chemicals for which a Reference Dose or Reference  
7 Concentration has been developed based on neurotoxicity in the US EPA Integrated Risk  
8 Information System (IRIS) are Chemicals of Concern.

9  
10 The IRIS database contains information on human health effects that may result from  
11 exposure to various substances in the environment for more than 550 chemical substances.  
12 Approximately 20 chemicals have a Reference Dose or Reference Concentration based on  
13 neurotoxicity, a hazard trait that has not been recognized in the other lists. US EPA's IRIS  
14 database is a compilation of electronic reports on specific substances found in the environment  
15 and their potential to cause human health effects. IRIS was initially developed for US EPA  
16 staff in response to a growing demand for consistent information on substances for use in risk  
17 assessments, decision-making and regulatory activities. US EPA develops a list of substances  
18 for IRIS assessment on an annual basis. Through the continuously improving IRIS Program,  
19 US EPA provides the highest quality science-based human health assessments to support  
20 their regulatory activities.

21  
22 The Guidelines for Neurotoxicity Risk Assessment set forth principles and procedures to guide  
23 US EPA scientists in evaluating environmental contaminants that may pose neurotoxic risks,  
24 and inform US EPA decision makers and the public about these procedures. These Guidelines  
25 are the US EPA's first statement on setting principles and procedures to guide US EPA  
26 scientists in conducting neurotoxicity risk assessments. These Guidelines have been  
27 developed by a cross-Agency Technical Panel organized by the Risk Assessment Forum.

28  
29 A link between human exposure to some chemical substances and neurotoxicity has been  
30 firmly established. The Guidelines emphasize that risk assessments are conducted on a case-  
31 by-case basis. They stress that information is fully presented in US EPA risk assessment  
32 documents and that US EPA scientists identify the strengths and weaknesses of each  
33 assessment by describing uncertainties, assumptions, and limitations, as well as the scientific  
34 basis and rationale for each assessment. The Guidelines bridge gaps in risk assessment  
35 methodology and data by identifying these gaps and the importance of the missing information  
36 to the risk assessment process, encouraging research and analysis that will lead to new risk  
37 assessment methods and data. The Guidelines specifically note the special vulnerability of the  
38 nervous system of infants and children to environmentally relevant chemicals and provide  
39 guidance for the interpretation of data from developmental and reproductive studies involving  
40 assessment of nervous system structure and function.

41  
42 The Guidelines help develop a sound scientific basis for neurotoxicity risk assessment and  
43 promote consistency in the US EPA's assessment of nervous system effects. As in the case of  
44 earlier risk assessment guidelines, the principles articulated in these Guidelines will be  
45 incorporated into program-specific guidance and procedures. Risk assessment guidelines are

1 not regulations and do not impose legally binding requirements on US EPA, states, or the  
2 regulated community.

3  
4 **Section 69502.2(a)(1)(E)** specifies that chemicals that are identified as “carcinogenic to  
5 humans,” “likely to be carcinogenic to humans” or Group A, B1, or B2 carcinogens in the US  
6 EPA Integrated Risk Information System (IRIS) are Chemicals of Concern.

7  
8 IRIS is a compilation of electronic reports on specific substances found in the environment and  
9 their potential to cause human health effects. Out of the over 550 chemical substances in  
10 IRIS, approximately 90 are carcinogens. IRIS was initially developed for EPA staff in response  
11 to a growing demand for consistent information on substances for use in risk assessments,  
12 decision-making and regulatory activities. US EPA's IRIS, as discussed above, is a human  
13 health assessment program that evaluates risk information on effects that may result from  
14 exposure to environmental contaminants.

15  
16 **Section 69502.2(a)(1)(F)** specifies chemicals that are identified as “known to be” or  
17 “reasonably anticipated to be” a human carcinogen in the 12<sup>th</sup> Report on Carcinogens (RoC),  
18 US Department of Health and Human Services, Public Health Service, National Toxicology  
19 Program (June 10, 2011) are Chemicals of Concern.

20  
21 The RoC is a congressionally mandated, science-based, public health document that is  
22 prepared by the National Toxicology Program (NTP), an interagency program within Health  
23 and Human Services (HHS), on behalf of the Secretary of HHS. The report identifies agents,  
24 substances, mixtures, and exposure circumstances that are “known” or “reasonably  
25 anticipated” to cause cancer in humans. The RoC is published biennially and each edition of  
26 the report is cumulative, consisting of substances newly reviewed in addition to those listed in  
27 previous editions. To date, a total of twelve (12) RoCs have been published; the most recent,  
28 the 12<sup>th</sup> RoC, was released in 2011, and includes 240 listings, some of which are classes of  
29 related chemicals or agents. The RoC is used by regulatory agencies, as well as others, for  
30 policy and decision making.

31  
32 For each listed substance, the RoC contains a substance profile, which provides information  
33 on:

- 34 • cancer studies that support the listing—including those in humans, animals and on  
35 possible mechanisms of action
- 36 • potential sources of exposure to humans
- 37 • current Federal regulations to limit exposure

38  
39 Conclusions regarding carcinogenicity as “known to be” or “reasonably anticipated to be” a  
40 human carcinogen are based on scientific judgment, with consideration given to all relevant  
41 information. Relevant information includes, but is not limited to, dose response, route of  
42 exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub-populations,  
43 genetic effects, or other data relating to mechanism of action or factors that may be unique to a  
44 given substance. For example, there may be substances for which there is evidence of  
45 carcinogenicity in laboratory animals, but there are compelling data indicating that the agent

1 acts through mechanisms which do not operate in humans and would therefore not reasonably  
2 be anticipated to cause cancer in humans.

3  
4 **Section 69502.2(a)(1)(G)** specifies that chemicals that are identified as High Production  
5 Volume Persistent Bioaccumulating Toxins (PBTs) by the European Union (EU) are Chemicals  
6 of Concern [note: these chemicals are found on the European Chemical Substances  
7 Information System (ESIS)].

8  
9 The European Commission (EC) initiated an interim strategy to identify and address PBT  
10 chemicals. The criteria and steps to be identified as a PBT is rigorous and from an initial list of  
11 127 PBT chemicals, 28 chemicals met all of the criteria for being a PBT; 23 other chemicals  
12 are currently still under evaluation, and 66 chemicals evaluated did not meet all of the PBT  
13 criteria. Ten chemicals were deferred and not evaluated. Only those chemicals fulfilling the  
14 criteria as PBT are identified to be on the initial Chemicals of Concern list. Also note that even  
15 though only one hazard trait is required to be identified as a Chemical of Concern, for  
16 purposes of the initial Chemicals of Concern list, those chemicals identified met three hazard  
17 traits for listing under the EC criteria for PBT.

18  
19 Potential PBTs were identified by evaluating high production volume chemicals (at least 1,000  
20 tons produced or imported in EU by at least one Industry per year) that met certain screening  
21 criteria based on screening data and screening estimation techniques (QSARs) for high  
22 production volume chemicals. This process identified 127 chemicals, which underwent  
23 additional testing to evaluate whether they met the PBT criteria, as defined below:

- 24 • Persistence:
  - 25 ○ Half-life greater than 60 days in marine water;
  - 26 ○ Greater than 40 days in freshwater;
  - 27 ○ Greater than 180 days in marine sediment; or
  - 28 ○ Greater than 120 days in freshwater sediment;
- 29 • Bioaccumulative:
  - 30 ○ Bioconcentration factor (BCF) greater than 2,000 L/kg;
- 31 • Toxic:
  - 32 ○ Chronic No Observed Effect Concentration (NOEC) less than 0.01 mg/l;
  - 33 ○ Substance is classified as carcinogenic (category 1 or 2);
  - 34 ○ Mutagenic (category 1 or 2);
  - 35 ○ Toxic for reproduction (category 1, 2 or 3); or
  - 36 ○ There is other evidence of chronic toxicity, as identified by the classifications: T,  
37 R48, or Xn, R48 according to Directive 67/548/EEC.

38  
39 **Section 69502.2(a)(1)(H)** specifies that chemicals that are identified as Persistent,  
40 Bioaccumulative, and inherently Toxic (PBiT) to the environment by the Canadian  
41 Environmental Protection Act environmental registry(CEPA), Domestic Substances List are  
42 Chemicals of Concern.

43  
44 CEPA PBiT is a list of 397 substances that are Persistent, Bioaccumulative and inherently  
45 Toxic (PBiT) to non-human organisms, according to the categorization criteria used.  
46 Industrialized countries that are undertaking a similar categorization process tend to focus only

1 on chemicals that are used on a very large scale, such as the PBTs on HPV PBT EU list  
2 described above, while the CEPA PBiT list does not. As in the above HPV PBT EU list, even  
3 though only one hazard trait is required to be identified as a Chemical of Concern, these  
4 chemicals met DTSC's criteria met at least two hazard traits – persistence and  
5 bioaccumulation, in addition to CEPA's criteria for iT.

6  
7 Using information from Canadian industry, academic research and other countries,  
8 Government of Canada scientists from the Existing Substances Program at Health Canada  
9 and Environment Canada worked with partners in applying a set of rigorous tools to each of  
10 the approximately 23,000 chemical substances on the Domestic Substance List (DSL).

11  
12 The CEPA PBiT criteria used to identify suspected chemicals was a chemical is either (1)  
13 persistent or bioaccumulative and (2) inherently toxic to the environment. The criteria for PBiT  
14 are described below:

- 15 • **Persistent:** chemical substances that take a very long time to break down in the  
16 environment – sometimes many years. These substances can affect the environment  
17 for a long period of time. Because they last for so long, they can travel long distances  
18 and pollute a much wider area than those that break down quickly.
  - 19 ○ Half-life greater than or equal to 2 days in air;
  - 20 ○ Greater than or equal to 182 days in water;
  - 21 ○ Greater than or equal to 1 year in sediment; or
  - 22 ○ Greater than or equal to 182 days in soil.
- 23 • **Bioaccumulative:** chemical substances that can be stored in the organs, fat cells or  
24 blood of living organisms and remain for a long time. Over time, concentrations can  
25 build up and reach very high levels, and can also be transferred up the food chain.
  - 26 ○ Bioaccumulation Factor or Bioconcentration factor greater than or equal to 5,000,  
27 or Log  $K_{ow}$  greater than or equal to 5.
- 28 • **Inherently Toxic to non-human organisms (iT):** chemical substances that are known  
29 or suspected, through laboratory and other studies, to have a harmful effect on wildlife  
30 and the natural environment on which it depends. A substance is considered to exhibit  
31 acute toxicity to aquatic species (algae, invertebrates, fish) when the  $LC_{50}$  ( $EC_{50}$ ) is less  
32 than or equal to 1 mg/L, and chronic toxicity when the NOEC less than or equal to 0.1  
33 mg/L

34  
35 Substances meeting these criteria proceed to a screening assessment, and are then subject to  
36 one of the following outcomes:

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

42  
43 **Section 69502.2(a)(1)(I)** specifies that Groups 1, 2A, and 2B carcinogens identified by the  
44 International Agency for Research on Cancer (IARC), are Chemicals of Concern.

45 The International Agency for Research on Cancer (IARC) is part of the World Health  
46 Organization. IARC's mission is to coordinate and conduct research on the causes of human

1 cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer  
2 prevention and control. Public health agencies use this information as scientific support for  
3 their actions to prevent exposure to carcinogens and agents that may be carcinogens.

4  
5 Since 1971, more than 900 agents have been evaluated, of which more than 400 have been  
6 identified as Group 1, carcinogenic to humans, Group 2A, probably carcinogenic to humans, or  
7 Group 2B, possibly carcinogenic to humans. There are 107 Group 1 carcinogens, 61 Group 2A  
8 probable carcinogens, and 269 Group 2B possible carcinogens. There are 508 Group 3  
9 chemicals that are not classifiable as to its carcinogenicity to humans due to inadequate  
10 information available to review and one (1) Group 4 chemical that is probably not carcinogenic  
11 to humans. As new information or studies are available on these chemicals, the conclusion  
12 regarding its grouping may change and IARC is continually evaluating chemicals for  
13 carcinogenicity and reflecting updated evaluations through the monographs that are made  
14 available.

15  
16 Interdisciplinary working groups of expert scientists review the published studies and evaluate  
17 the weight of the evidence that an agent can increase the risk of cancer. The principles,  
18 procedures, and scientific criteria that guide the evaluations are described in the Preamble to  
19 the *IARC Monographs*. A summary of the groupings and evaluations is briefly provided below  
20 and while the term “evidence” is used in IARC evaluations, they are used in a different manner  
21 in Chapter 54, section 69402.2.

#### 22 23 Group 1: The agent is carcinogenic to humans.

24 This category is used when there is sufficient evidence of carcinogenicity in humans. An agent  
25 may be placed in this category when evidence of carcinogenicity in humans is less than  
26 sufficient but there is sufficient evidence of carcinogenicity in experimental animals and strong  
27 evidence in exposed humans that the agent acts through a relevant mechanism of  
28 carcinogenicity.

#### 29 30 Group 2.

31 This category includes agents for which, at one extreme, the degree of evidence of  
32 carcinogenicity in humans is almost sufficient, as well as those for which, at the other extreme,  
33 there are no human data but for which there is evidence of carcinogenicity in experimental  
34 animals. Agents are assigned to either Group 2A (probably carcinogenic to humans) or Group  
35 2B (possibly carcinogenic to humans) on the basis of epidemiological and experimental  
36 evidence of carcinogenicity and mechanistic and other relevant data. The terms probably  
37 carcinogenic and possibly carcinogenic have no quantitative significance and are used simply  
38 as descriptors of different levels of evidence of human carcinogenicity, with probably  
39 carcinogenic signifying a higher level of evidence than possibly carcinogenic.

#### 40 41 Group 3: The agent is not classifiable as to its carcinogenicity to humans.

42 This category is used most commonly for agents for which the evidence of carcinogenicity is  
43 inadequate in humans and inadequate or limited in experimental animals. Group 3 placement  
44 is not a determination of non-carcinogenicity or overall safety. It often means that further

1 research is needed, especially when exposures are widespread or the cancer data are  
2 consistent with differing interpretations.

3  
4 Group 4: The agent is probably not carcinogenic to humans.

5 This category is used for agents for which there is evidence suggesting lack of carcinogenicity  
6 in humans and in experimental animals.

7  
8 **Section 69502.2(a)(1)(J)** specifies that neurotoxicants identified in the Agency for Toxic  
9 Substances and Disease Registry's (ATSDR) Toxic Substances Portal, Health Effects of Toxic  
10 Substances and Carcinogens, Nervous System are Chemicals of Concern.

11  
12 ATSDR is a federal public health agency of the US Department of Health and Human  
13 Services. ATSDR serves the public by using science, taking public health actions, and  
14 providing health information to prevent harmful exposures and diseases related to toxic  
15 substances. This list identifies approximately 60 neurotoxins, a hazard trait that has not been  
16 heavily documented in the other lists.

17  
18 ATSDR is directed by congressional mandate to perform specific functions concerning the  
19 effect on public health of hazardous substances in the environment. These functions include:  
20 public health assessments of waste sites, health consultations concerning specific hazardous  
21 substances, health surveillance and registries, response to emergency releases of hazardous  
22 substances, applied research in support of public health assessments, information  
23 development and dissemination, and education and training concerning hazardous  
24 substances.

25  
26 ATSDR produces "toxicological profiles" for hazardous substances found at National Priorities  
27 List (NPL) sites. These hazardous substances are ranked based on frequency of occurrence  
28 at NPL sites, toxicity, and potential for human exposure. Toxicological profiles are developed  
29 from a priority list of 275 substances. ATSDR also prepares toxicological profiles for the  
30 Department of Defense (DOD) and the Department of Energy (DOE) on substances related to  
31 federal sites.

32  
33 Toxicological profiles are developed in two stages:

- 34 • Drafts: The toxicological profiles are first produced as drafts. ATSDR announces in the  
35 Federal Register the release of these draft profiles for a 90-day public comment period.  
36 Request draft toxicological profiles from ATSDR's Division of Toxicology and  
37 Environmental Medicine.
- 38 • Finals: After the 90-day comment period, ATSDR considers incorporating all comments  
39 into the documents. ATSDR finalizes the profiles and the National Technical  
40 Information Service (NTIS) distributes them.

41  
42 So far, 318 toxicological profiles have been published or are under development as "finals" or  
43 "drafts for public comment"; 291 profiles were published as finals; 136 profiles have been  
44 updated. Currently, 11 profiles are being revised based on public comments received; 6  
45 profiles under development. These profiles cover more than 250 substances.

1  
2 **Section 69502.2(a)(1)(K)** specifies that Persistent Bioaccumulative and Toxic Priority  
3 Chemicals identified by the US EPA National Waste Minimization Program are Chemicals of  
4 Concern.

5  
6 US EPA established the National Waste Minimization Program (NWM), which supports efforts  
7 to promote a more sustainable society, reduce the amounts of waste generated, and lower the  
8 toxicity and persistence of wastes that are generated. The NWM established a list of Priority  
9 Chemicals (PCs), which consists of 28 organic chemicals and chemical compounds and three  
10 (3) metals and metal compounds. Based on its review, EPA concluded that the chemicals are  
11 persistent, bioaccumulative, and toxic (PBTs). These metals are also a high priority in  
12 international waste minimization efforts to which the United States has made commitments.  
13 The NWM Program is voluntary in nature and US EPA is focusing its waste minimization  
14 efforts on the 31 PCs identified here. In addition, US EPA remains receptive to any waste  
15 minimization efforts, including efforts to address chemicals other than, or in addition to, these  
16 PCs.

17  
18 If these PCs cannot easily be eliminated or reduced at the source, the focus is on recovering  
19 or recycling them. The NWM PCs are currently being generated in industrial waste and are  
20 found in soil, sediment, ground water, surface water, air, and plant, animal, and human tissue  
21 as a result of past and present releases. The NWM PCs include: cadmium, lead, and mercury.  
22 These metals and their compounds are known to occur frequently in federal hazardous waste  
23 regulated industrial wastes and often meet Toxicity Characteristic criteria, meaning the waste  
24 streams they are found in must be managed under federal hazardous waste regulations.

25  
26 **Section 69502.2(a)(1)(L)** specifies that reproductive or developmental toxicants identified in  
27 Monographs on the Potential Human Reproductive and Developmental Effects (2003 - 2008),  
28 National Toxicology Program, Office of Health Assessment and Translation (formerly the  
29 Center for the Evaluation of Risks to Human Reproduction) are Chemicals of Concern.

30  
31 The National Toxicology Program (NTP) is an interagency program managed by the US  
32 Department of Health and Human Services (DHHS) whose mission is to evaluate agents of  
33 public health concern by developing and applying tools of modern toxicology and molecular  
34 biology.

35  
36 The NTP and the National Institute of Environmental Health Sciences established the NTP  
37 Office of Health Assessment and Translation (OHAT) to serve as an environmental health  
38 resource to the public and to regulatory and health agencies for policy and risk management  
39 decisions. This office conducts evaluations to assess the evidence that environmental  
40 chemicals, physical substances, or mixtures (collectively referred to as "substances") cause  
41 adverse health effects and provides opinions on whether these substances may be of concern  
42 given what is known about current human exposure levels. Assessments of potential adverse  
43 effects of environmental substances on reproduction or development carried out by the Center  
44 for the Evaluation of Risks to Human Reproduction from 1998-2010, are now be carried out by  
45 OHAT. The OHAT assessments are published as NTP Monographs.

1  
2 The NTP provides toxicological evaluation on substances of public health concern to provide a  
3 scientifically-based, uniform assessment of the evidence for reproductive and developmental  
4 toxicity of man-made or naturally occurring chemicals or chemical mixtures. Nominations of  
5 chemicals to be evaluated come through solicitations from the public and scientific  
6 communities, including industry, federal, state, and local governments, academia,  
7 environmental groups, citizens, and workers.

8  
9 **Section 69502.2(a)(1)(M)** specifies that chemicals that are identified on the US EPA Toxics  
10 Release Inventory (TRI) as Persistent, Bioaccumulative and Toxic (PBT) Chemicals that are  
11 subject to reporting under the Emergency Planning and Community Right-to-Know Act  
12 (EPCRA) section 313 are Chemicals of Concern.

13  
14 Approximately 18 chemicals were identified as PBTs when US EPA went through the process  
15 of identifying these chemicals. The criteria used by US EPA for environmental persistence and  
16 bioaccumulation hazard traits are consistent with the definition of “evidence” in Chapter 54.

17  
18 US EPA implements EPCRA, which requires businesses and other organizations to report  
19 chemical releases to the environment. The reporting thresholds are 25,000 pounds for the  
20 manufacture or processing of a chemical and 10,000 pounds for other use of the chemical. As  
21 part of this regulation, US EPA maintains the Toxics Release Inventory (TRI) database, which  
22 summarizes releases reported to EPA under this regulation to provide communities with  
23 information about toxic chemical releases and waste management activities and to support  
24 informed decision-making by industry, government, non-governmental organizations and the  
25 public. The chemical list for TRI is changed through the federal regulatory process, which in  
26 turn may affect the listing of PBT chemicals.

27  
28 US EPA lowered the reporting thresholds for TRI chemicals that are persistent,  
29 bioaccumulative, and toxic to 100 pounds, if a chemical on the TRI list met the criteria below:

- 30 • Persistent:
  - 31 ○ Half-life of 2 days for air or
  - 32 ○ 2 months for water, sediment, and soil
- 33 • Bioaccumulative:
  - 34 ○ Bioaccumulation or bioconcentration factor  $\geq 1,000$
- 35 • Toxic:
  - 36 ○ Moderately high to high chronic toxicity or
  - 37 ○ High ecotoxicity

38  
39 This resulted in the identification of four groups of chemicals, such as dioxins and dioxin- like  
40 compounds, mercury and lead compounds, and Polycyclic Aromatic Hydrocarbons (PAHs) and  
41 16 individual chemical species as PBTs.

42  
43 **Section 69502.2(a)(1)(N)** specifies that chemicals listed on the State of Washington  
44 Department of Ecology’s Persistent, Bioaccumulative, Toxic Chemicals identified in Chapter  
45 173-333 Washington Administrative Code (WAC) are Chemicals of Concern.

1  
2 Washington's goal in identifying PBTs in Chapter 173-333 WAC harmonizes with the objective  
3 of the Safer Consumer Products regulations, which is to reduce and phase-out PBT uses,  
4 releases and exposures. The Safer Consumer Products regulations aim is to limit exposures  
5 or reduce the level of hazard posed by Chemicals of Concern by requiring an Alternatives  
6 Analysis. The Alternatives Analysis may show that continued use of the Chemical of Concern  
7 is necessary – similarly, Washington recognizes that many factors will influence whether their  
8 reduction or phase-out goal for these PBTs can be attained and will vary depending on the  
9 PBT and the uses of the PBT.

10  
11 The Washington PBT list contains 17 chemicals, eight (8) chemical groups, and two (2) metals  
12 that were identified using the categorization criteria described below. The State of Washington  
13 will use its PBT list to develop chemical action plans to reduce and/or phase out PBTs,  
14 conduct ambient monitoring or biomonitoring to inform decision making, and encourage  
15 voluntary measures to reduce and/or phase out PBT uses. The Washington PBT list will also  
16 be reviewed and updated periodically.

17  
18 The criteria for identifying a chemical as a PBT are as follows:

19 Persistence. The chemical or chemical group can persist in the environment based on  
20 credible scientific information that:

- 21 • the half-life of the chemical in water, soil and sediments is greater than or equal to sixty  
22 days

23 Bioaccumulation. The bioconcentration factor or bioaccumulation factor in aquatic species for  
24 the chemical is greater than 1,000 or, in the absence of such data, that the log-octanol water  
25 partition coefficient (log K<sub>ow</sub>) is greater than five.

26 Toxicity. The chemical or chemical group:

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

34  
35 **Section 69502.2(a)(2)** specifies that a chemical that is one or more of the following types of  
36 chemicals as described is a Chemical of Concern. The chemicals identified in subsection  
37 (a)(2) are identified as Chemicals of Concern in order to address or prevent chemical  
38 contamination in environmental media, such as air and water and the exposures that may  
39 cause adverse impacts to public health or environment. Other chemicals that are identified for  
40 biomonitoring in humans are included to identify whether chemical exposure is occurring in  
41 humans. All of these chemicals are identified to inform public health agencies in policy and  
42 risk management decisions. In effect, the purpose of these chemical identifications became  
43 the driver to include the chemicals here as Chemicals of Concern. Because these chemicals  
44 were identified for a specific purpose (monitoring or reducing exposure/contamination), DTSC  
45 is relying on the authoritative organization's determination regarding exhibiting a hazard trait.

1 Table 2.2 provides a summary of the purpose (i.e., relevant media and receptor in criterion #2)  
2 as well as other listing criteria.

3  
4 These chemicals lists do not have hazard traits identified with the list that are easily  
5 accessible. It is DTSC's intent to verify the hazard trait or environmental or toxicological  
6 endpoint associated with the specific chemical before the informational list of Chemicals of  
7 Concern is posted on DTSC's website. However, it may come to DTSC's attention that the  
8 hazard trait associated with the chemical on these lists do not meet the definition of "hazard  
9 trait" set out in Chapter 54, especially given that some of the chemicals on these lists may  
10 have new scientific information shows that a chemical does not exhibit a given hazard trait. In  
11 response to this situation, DTSC will review the information and will not list the chemical on the  
12 informational Chemicals of Concern list or take appropriate action on the Chemicals of  
13 Concern list according to the process set out in section 69502.3.

14  
15 **Section 69502.2(a)(2)(A)** specifies that chemicals for which Notification Levels (NLs), as  
16 defined in Health and Safety Code Section 116455, have been established by the Department  
17 of Public Health are Chemicals of Concern.

18  
19 Notification Levels (NLs) are health-based advisory levels established by California  
20 Department of Public Health (CDPH) for chemicals in drinking water that lack Maximum  
21 Contaminant Levels (MCLs). When chemicals are found at concentrations greater than their  
22 NLs, certain requirements apply. State law (Health & Safety Code §116455) requires timely  
23 notification of the local governing bodies (e.g., city council, county board of supervisors, or  
24 both) by drinking water systems whenever an NL is exceeded in drinking water that is provided  
25 to consumers. The NLs serve to protect public health through notification requirements and,  
26 while not enforceable as drinking water standards, exceedance of a NL has enforcement  
27 consequences.

28  
29 **Section 69502.2(a)(2)(B)** specifies that chemicals for which primary MCLs have been  
30 established and adopted in Title 22, CCR, sections 64431 and 64444 are Chemicals of  
31 Concern.

32  
33 There are approximately 100 chemicals that have primary MCLs for drinking water, which are  
34 adopted as regulations by CDPH. MCLs are health protective drinking water standards to be  
35 met by public water systems. MCLs must be reviewed every five (5) years and take into  
36 account not only a chemical's health risks but also factors such as detectability and  
37 treatability, as well as costs of treatment. Health & Safety Code section 116365(a) requires  
38 CDPH to establish a contaminant's MCL at a level as close to its Public Health Goal (PHG) as  
39 is technically and economically feasible, placing primary emphasis on the protection of public  
40 health. The PHG is established by OEHHA through a human health risk assessment and is  
41 the contaminant's concentration in drinking water that does not pose any significant risk to  
42 health. MCLs are health protective, adopted in regulations and are enforceable.

43  
44 **Section 69502.2(a)(2)(C)** specifies that chemicals identified as Toxic Air Contaminants (TACs)  
45 under Title 22, CCR, sections 93000 and 93001, are Chemicals of Concern.

1  
2 The California Air Resources Board (CARB) regulates TACs through its Air Toxics Program to  
3 protect the public health by reducing TAC emissions and public exposure to TACs. This  
4 requires two separate steps. During the first step, risk assessment, the CARB identifies the  
5 highest risk substances. In the second or risk management step, the CARB and local air  
6 pollution control districts investigate and adopt measures requiring air toxics sources to  
7 minimize risk to public health.

8  
9 TAC means “an air pollutant which may cause or contribute to an increase in mortality or an  
10 increase in serious illness, or which may pose a present or potential hazard to human health.  
11 A substance that is listed as a hazardous air pollutant pursuant to subsection (b) of Section  
12 112 of the federal act (42 U.S.C. Sec. 7412(b)) is a toxic air contaminant.” (Health and Safety  
13 Code 39655(a)) Based on this definition, a TAC exhibits a toxicological endpoint and may be  
14 listed as a Chemical of Concern. Currently, there are over 200 substances listed as TACs;  
15 including 189 federal hazardous air pollutants. DTSC will identify the  
16 toxicological/environmental endpoint or the hazard trait before making available the Chemicals  
17 of Concern informational list. TACs are updated periodically and in selecting substances for  
18 review, the CARB considers criteria relating to "the risk of harm to public health, amount or  
19 potential amount of emissions, manner of, and exposure to, usage of the substance in  
20 California, persistence in the atmosphere, and ambient concentrations in the community"  
21 (Health and Safety Code section 39660(f)).  
22

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

31  
32 **Section 69502.2(a)(2)(D)** specifies that chemicals that are identified as priority toxic pollutants  
33 in the California Water Quality Control Plans (Basin Plans) under section 303(c) of the federal  
34 Clean Water Act and in section 131.38 of Title 40 of the Code of Federal Regulations are  
35 Chemicals of Concern.

36  
37 In order to preserve our water resources and prevent and control pollution to California waters,  
38 California Water Quality Control Plans are adopted under section 303(c) of the federal Clean  
39 Water Act. Section 303(c) requires states to develop water quality standards and review and  
40 update those standards every three years. Water quality standards must include designated  
41 uses of water bodies, water quality criteria that are necessary to protect those uses, expressed  
42 in either numeric or narrative form, and anti-degradation components. Because the Basin  
43 Plans identify priority pollutants that may impact water quality and cause toxicological and  
44 environmental endpoints to be exhibited, the chemicals that are priority pollutants in the Basin  
45 Plan may be listed as Chemicals of Concern. There are approximately 120 chemicals on this

1 list and DTSC will identify the toxicological/environmental endpoint or the hazard trait before  
2 making available the Chemicals of Concern informational list.

3  
4 **Section 69502.2(a)(2)(E)** specifies that chemicals that are identified with non-cancer  
5 endpoints and listed with an inhalation or oral Reference Exposure Level by OEHHA are  
6 Chemicals of Concern.

7  
8 OEHHA is responsible for conducting health risk assessments of chemical contaminants found  
9 in air and develops Reference Exposure Levels (RELs) for a variety of non-cancer health  
10 impacts. These RELs are required to be used in risk assessments for stationary sources for  
11 airborne emissions (California's Air Toxics Hot Spots program) and are the basis for regulatory  
12 action. There are approximately 100 RELs developed to date and DTSC will identify the  
13 specific hazard trait with the chemical before the informational list of Chemicals of Concern is  
14 posted on DTSC's website.

15  
16 **Section 69502.2(a)(2)(F)** specifies that Priority Chemicals that are identified under the  
17 California Environmental Contaminant Biomonitoring program are Chemicals of Concern. The  
18 Priority Chemicals were selected for the California Environmental Contaminant Biomonitoring  
19 program because there is a concern that humans are being exposed to harmful chemicals and  
20 causing a health risk or toxicological endpoint. There are approximately 200 chemicals on the  
21 California Biomonitoring Program.

22  
23 The selection of priority chemicals is a two-step process. The first step is to identify  
24 "designated chemicals" – those chemicals that should be considered for biomonitoring. The  
25 enabling legislation (Senate Bill 1379, Perata, Chapter 599, Stats. 2006) identified as the initial  
26 set of designated chemicals roughly 300 chemicals currently biomonitored by the U.S. Centers  
27 for Disease Control and Prevention (CDC). Additional designated chemicals were  
28 recommended by the Scientific Guidance Panel for inclusion in the program as designated  
29 chemicals.

30  
31 The second step is to identify "high priority" chemicals from the pool of "designated chemicals"  
32 to conduct biomonitoring in California. The Scientific Guidance Panel makes  
33 recommendations regarding which chemicals should be given priority from the pool of  
34 "designated chemicals" due to the limited resources in the California Biomonitoring program.  
35 Limited resources include the staff and instrumentation to analyze all of the designated  
36 chemicals as well as developing analytical methods.

37  
38 **Section 69502.2(a)(2)(G)** specifies that chemicals included in the *Fourth National Report on*  
39 *Human Exposure to Environmental Chemicals*, Updated Tables, published by the Centers for  
40 Disease Control and Prevention (CDC) are Chemicals of Concern.

41  
42 The CDC is a part of the U.S. Department of Health and Human Services and is one of the  
43 primary federal agencies for conducting and supporting public health activities in the United  
44 States. CDC is the principal federal agency that investigates threats to public health and the  
45 environment. The National Exposure Report is a series of ongoing assessments of the U.S.

1 population's exposure to environmental chemicals. Scientists measure chemicals or their  
2 metabolites in blood and urine samples obtained from a random sample of participants in  
3 CDC's National Health and Nutrition Examination Survey (NHANES). Data are presented for  
4 the population as a whole and for subgroups characterized by age, sex, and race or ethnicity.

5  
6 CDC's Environmental Health Laboratory develops analytical methods to measure synthetic  
7 and naturally occurring environmental chemicals in people. Currently, more than 300  
8 environmental chemicals or their metabolites are measured in human samples (e.g. urine,  
9 blood, serum, breast milk, and meconium) and reported in the National Exposure Report.

10  
11 The *Fourth National Report on Human Exposure to Environmental Chemicals*, Center for  
12 Disease Control, February 2009 was revised to include new and updated tables in February  
13 2012 (*Updated Tables*). The *Updated Tables, February 2012*, present data from the 2005-  
14 2006 and 2007-2008 survey periods and data for a few chemicals from the 2003-2004 survey  
15 period. The Updated Tables are cumulative and include data reported in earlier updates.

16 Specific public health uses of the exposure information in the *Fourth Report* are to:

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

27  
28 The CDC's Environmental Health Laboratory's biomonitoring program identifies potential  
29 chemicals to monitor based on solicitations from the public and other governmental agencies.  
30 Chemicals are selected based on:

- 31 • scientific data that suggests exposure in the United States population;
- 32 • the seriousness of health effects known or thought to result from some levels of  
33 exposure;
- 34 • the need to assess the efficacy of public health actions to reduce exposure to a  
35 chemical;
- 36 • the availability of an analytical method that is accurate, precise, sensitive, specific, and  
37 rapid;
- 38 • the availability of adequate blood or urine samples from the biomonitoring survey; and  
39 • the analytical cost to perform the analysis.

40  
41 The results of the biomonitoring program provide information to determine what proportion of  
42 the population has chemical levels above those associated with adverse health effects for  
43 chemicals with a known toxicity.

1 **Section 69502.2(a)(2)(H)** specifies that the chemicals listed in Part A of the Oslo and Paris  
2 Conventions for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)  
3 List of Chemicals for Priority Action (OSPAR List) Reference number 2004-12, are Chemicals  
4 of Concern.

5  
6 There are approximately 30 chemicals listed in Part A of the OSPAR List. The OSPAR  
7 Convention is the current legal instrument guiding international cooperation on the protection  
8 of the marine environment of the North-East Atlantic. In 2002, the OSPAR Convention  
9 adopted the OSPAR List to protect the marine environment, indicating that the chemicals on  
10 the OSPAR List exhibit an environmental hazard trait. There are currently 42 substances or  
11 groups of substances on the OSPAR List, of which OSPAR action is focused on the 29  
12 substances identified in Part A of the OSPAR List. For each of these substances or groups of  
13 substances, a background document is prepared to assess the uses and risks for the  
14 substance and to conclude what actions OSPAR should take to move towards the cessation  
15 target. These documents are reviewed periodically when new information is available,  
16 resulting in review statements or revised Background Documents, which may affect the risk  
17 evaluation and the recommended actions. OSPAR has adopted monitoring strategies for the  
18 hazardous substances for which background documents have been prepared. These describe  
19 information to be collected in order to monitor progress towards the cessation target.

20  
21 **Section 69502.2(b)** specifies the process for adding chemicals to the Chemicals of Concern  
22 list and provides that in order for a chemical to be identified as a Chemical of Concern, the  
23 chemical must exhibit a hazard trait or environmental or toxicological endpoints by considering  
24 reliable information on the factors in this section.

25  
26 It is important to note that DTSC is not required to consider all the factors listed in this section  
27 in every instance for a chemical to be identified as a Chemical of Concern, but DTSC is  
28 required to consider all those factors for which reliable information is available. Additionally, in  
29 accordance with section 69502.3, DTSC will make available the rationale and supporting  
30 information for proposed Chemicals of Concern prior to revising the list. The information that is  
31 to be used is set out in greater detail and explained below in describing the various paragraphs  
32 within Section 69502.2(b).

33  
34 **Section 69502.2(b)(1)** specifies that *Adverse Impacts* is one category of factors that DTSC  
35 may consider in deciding whether to add a chemical to the Chemicals of Concern List. This  
36 section identifies the chemical adverse impact factors that DTSC will consider in identifying  
37 and listing additional Chemicals of Concern.

38  
39 **Section 69502.2(b)(1)(A)** specifies the factors DTSC is to consider to evaluate the ability of  
40 the chemical to contribute to or cause adverse public health and/or environmental impacts  
41 using reliable information relevant to the factors set out in subparagraphs 1. through 8., that  
42 relate to the chemical's toxicity profile, physical properties and its mobility in the environment,  
43 discussed below:

- 1 1. One of the factors to consider in evaluating adverse impacts is the chemical's hazard  
2 trait(s) and/or environmental or toxicological endpoint(s). This factor was included as a  
3 very basic factor in determining whether or not a chemical should be a Chemical of  
4 Concern. It is also consistent with the statutory directive to take advantage of the work  
5 of other agencies in this field. In this case, it is the hazard traits identified in Chapter 54.  
6

7 DTSC will evaluate information from the scientific literature or documents that are  
8 already in existence from authoritative organizations to review the toxicity profile of a  
9 chemical, including what hazard traits the chemical has and what toxicological and  
10 environmental endpoints have been observed experimentally or in humans or in  
11 ecosystems. DTSC may also evaluate chemicals where there is a structurally similar  
12 chemical that has a fairly robust database from which one could infer from the structural  
13 similarity that the chemical may have the same toxicity profile. As the science develops,  
14 models may become more readily available that will systematically analyze for structural  
15 parts of molecules that are associated with specific toxicities, currently mostly cancer  
16 and genotoxicity models are targeted, but others are being developed.

- 17 2. The chemical's aggregate effects are a consideration in evaluating adverse impacts.  
18 Aggregate effects are the chemical's effects resulting from exposure to the same  
19 chemical from multiple sources. For example, exposure to DEHP, one of the more  
20 commonly used phthalate plasticizers, comes from a number of sources. All those  
21 exposure sources would be considered in assessing its ability to contribute or cause  
22 adverse public health impacts. This method of determining adverse public impact is an  
23 acceptable method for evaluating exposure and is used in developing public health  
24 goals for drinking water, accounting for exposure from sources of the chemical other  
25 than drinking water.
- 26 3. The chemical's cumulative effects with other chemicals with similar hazard traits and/or  
27 environmental or toxicological endpoints are factors to consider in evaluating adverse  
28 impacts. "Cumulative" refers to a chemical causing the same effects (i.e., hazard trait)  
29 in the organism from multiple chemicals. This factor is appropriate to consider in  
30 identifying a Chemical of Concern because some chemicals may not cause a toxic  
31 effect through exposure by itself, but combined with other chemical exposures will  
32 cause a toxic effect.

33  
34 For example, DEHP is only one of several phthalates in widespread use. Several  
35 phthalates exhibit reproductive and developmental toxicity, such as testosterone effects.  
36 In evaluating the public health impacts, widespread exposure to the other phthalates  
37 that produce the same toxic effect on testosterone would also be considered to  
38 determine the cumulative effects. And, to take it a step further, the cumulative effects of  
39 phthalates and other reproductive and developmental toxicants that act in the same way  
40 may be considered to evaluate the ability to contribute to or cause adverse impacts.

- 41 4. The chemical's physical hazards are a consideration in evaluating adverse impacts.  
42 Identifying the chemical's physical hazards as a factor to consider ensures that the  
43 chemical's combustion facilitation, explosivity and flammability are considered.  
44 Chemical properties that cause fire and explosive hazards contribute a physical hazard  
45 rather than a toxicity hazard, and are considered hazard traits as defined in Article 1. A

1 chemical that exhibits a physical hazard trait is eligible to be identified as a Chemical of  
2 Concern.

- 3 5. The chemical's physicochemical properties are a consideration in evaluating adverse  
4 impacts. The chemical's physicochemical properties provide DTSC basic information  
5 on a chemical and its behavior in manufacture and use. Physicochemical properties  
6 may also be used, to some extent, as predictive indicators of behavior in humans,  
7 wildlife, ecosystem, and the environment and may be used to evaluate a chemical and  
8 its adverse public health and environmental impacts.
- 9 6. The chemical's environmental fate is a consideration in evaluating adverse impacts.  
10 The chemical's environmental fate identifies a chemical's behavior and its exposure  
11 potential hazard trait, as defined in Chapter 54. Examples of the types of information  
12 that may be used to evaluate the chemical's environmental fate include field and  
13 laboratory scientific information, as well as predictive chemical behavior using models to  
14 provide information on the chemical being considered, as well as the chemical  
15 degradation products and fate and transport data in environmental compartments.

16  
17 The following is a non-exhaustive list of examples of tools or approaches that may be  
18 used to determine the chemical's ability to have an impact on the environment:

- 19 • Fugacity modeling, a chemical fate and transport multimedia model;
- 20 • Field studies in the environment;
- 21 • Observations and measurements conducted in the field; and
- 22 • Microcosm studies, which includes simulating an ecosystem in a laboratory setting.

23  
24 In addition, environmental or biological presence may also be estimated using a point  
25 source or market-wide source term calculation, modeling or measurement, or a  
26 combination of these options.

- 27 7. The chemical's ability to affect human populations and/or aquatic, avian, or terrestrial  
28 animal or plant organisms is a consideration in the evaluation of adverse impacts. This  
29 criterion is an appropriate indicator of a chemical's ability to cause harm to various  
30 human and animal organisms. This evaluation may include the chemical's impact to the  
31 receptors specifically identified resulting from a single, intermittent or chronic use or  
32 contact with the chemical through dermal, oral and inhalation routes of exposure.

33  
34 The hazard traits and toxicological endpoints in Chapter 54 are considered in  
35 conjunction with other chemical behaviors specified in subsections (b)(1)(A)(1) through  
36 (5) to ultimately determine the consequences to humans, aquatic, avian, terrestrial  
37 animals and plant organisms. For instance, mercury's bioaccumulation and toxicity is  
38 well documented and fish health advisories were issued by OEHHA due to potential  
39 mercury exposure from contaminated fish. This was one reason why regulatory actions  
40 were taken in the mid-2000s to ban and control the collection of mercury-containing  
41 consumer devices, such as fluorescent lamps, mercury- containing switches and  
42 thermostats.

- 43 8. The chemical's ability to degrade, form reaction products, or metabolize into another  
44 Chemical of Concern or a chemical that exhibits one or more hazard trait and/or  
45 toxicological endpoint is a consideration in the evaluation of adverse impacts. This

1 factor is important since not only may chemicals themselves be harmful, but their  
2 metabolites, degradation and reaction products may be as well. The original Chemical  
3 of Concern may not be detected any longer, but the adverse impact continues due to  
4 this factor. Types of data or information that may be considered includes:

- 5 • Data that shows other chemical species that exhibit a hazard trait are formed during:
  - 6 ○ breakdown of the chemical;
  - 7 ○ chemical transformation in an environmental setting; or
  - 8 ○ combined with other chemicals
- 9 • Use computational modeling for structural activity relations to predict chemical  
10 behavior
- 11 • Short term in-vitro bioassays to predict chemical behavior
- 12 • Computational modeling data that provides information for this section
- 13 • Information or data from public health and environmental agencies that are  
14 experiencing impacts to their responsibilities due chemical's ability to degrade,  
15 metabolize, form reaction products or transform into chemicals that are affecting  
16 public health and the environment.

17  
18 **Section 69502.2(b)(1)(B)1. through 4.** specifies that DTSC will give special consideration,  
19 based on reliable information, to the ability of the chemical to contribute to or cause adverse  
20 impacts to specific receptors and environmental conditions that may be especially sensitive to  
21 effects caused by a chemical.

22 **1. *Sensitive subpopulations.***

23 Health and Safety Code section 25252 requires DTSC to consider sensitive  
24 subpopulations as part of this program. The definition of "sensitive subpopulation" in  
25 these regulations provides examples of subgroups that may be at greater risk of  
26 adverse health impacts due to exposures to chemicals, but is not limited to those  
27 named in the definition. Other examples include: customers, women of child bearing  
28 age, workers in certain service industries, such as house cleaning or cosmetologists  
29 and other subgroups that may be exposed to a greater amount of chemicals than the  
30 general population.

31 **2. *Environmentally sensitive habitats.***

32 While environmentally sensitive habitats are not specifically identified in the authorizing  
33 statute, it is an important factor to consider when identifying a Chemical of Concern.  
34 Ecology is intertwined with human survival; adverse impacts to the ecological system  
35 will impact public health as well as the organisms living in the habitat. For example,  
36 chemicals that affect plants or animals may affect public health through ingestion of the  
37 chemical; chemicals that affect plant survival may adversely impact the delicate balance  
38 of nature that may ultimately affect the balance of carbon dioxide and oxygen in the air.  
39 Areas in California, such as wetlands, may be identified as an environmentally sensitive  
40 habitat through environmental impact reports, the regional water boards, California  
41 Department of Fish and Game (DFG), and other similar agencies or organizations.

42 **3. *Endangered and threatened plant and animal species may be listed by organizations,***  
43 ***such as the DFG, the United States Fish and Wildlife Service, other international***  
44 ***agencies or identified in environmental quality documents.***

1 The fact that a chemical's toxicity or behavior has an impact on endangered and  
2 threatened species is an important consideration when identifying a Chemical of  
3 Concern in order to preserve these species.

4 **4. *Environments in California that have been designated as impaired by a California State***  
5 ***or federal regulatory agency.***

6 A chemical may be identified as a Chemical of Concern based on its impact on impaired  
7 environments. For example, the regional water boards may identify the environment  
8 around water bodies and well as the water body itself as impaired due to chemicals  
9 found in the water and sediments. In these cases, the chemicals found to cause  
10 impairment to these environments may be given consideration in identifying a Chemical  
11 of Concern. Other federal or state agencies may also determine that environments that  
12 they protect and preserve are impacted by chemicals and deemed impaired; those  
13 chemicals will be given special consideration based on the impaired environment.

14  
15 **Section 69502.2(b)(1)(C)** specifies that DTSC will give special consideration to the ability of  
16 the chemical to contribute to or cause widespread adverse public health and/or environmental  
17 impacts if reliable information is available. Some examples of the types of information that  
18 would indicate widespread impacts include:

- 19 • Data that indicates that the chemical or its degradation products are present in the  
20 California solid waste, waste water or storm water streams, that pose public health or  
21 environmental threats;
- 22 • Chemical clean up or corrective action information from facilities that require permits to  
23 operate and handle chemicals;
- 24 • Significant public funds to clean up or mitigate the chemical threats to the public health  
25 or the environment;
- 26 • Chemical presence in consumer products that increases the cost of reusing or recycling  
27 the consumer product's materials; and
- 28 • Widespread usage of chemicals or consumer products containing the chemical.

29  
30 Also note that "reliable information" includes studies, information or reports conducted by or  
31 submitted to a local, state, national, or international government agency. The methods and  
32 analyses must be scientifically valid and conducted according to generally accepted principles.  
33 This would include monitoring data submitted to or conducted by local, state, or international  
34 government agencies that would indicate widespread impacts.

35  
36 **Section 69502.2(b)(2)** specifies that exposures to a chemical is a factor in identifying a  
37 Chemical of Concern. This criterion is appropriate for all the reasons set out above discussing  
38 the inclusion of (hazard trait and) exposure as the basis for identifying and prioritizing  
39 chemicals as Chemicals of Concern. DTSC is to consider reliable information regarding public  
40 or environmental exposures to the chemical and reliable information demonstrating the  
41 occurrence of exposures to the chemical.

42  
43 Evidence of chemical exposure may be shown by human biomonitoring, such as the Report on  
44 Human Exposure to Environmental Chemicals conducted by CDC or data that indicates the  
45 presence in the indoor environment, air, food or drinking water. Anecdotal evidence in and of

1 itself of the chemical's presence in biomonitoring data, an indoor environment or drinking water  
2 is not sufficient evidence for identification as a Chemical of Concern, unless the anecdotal  
3 evidence is, or is verified as, reliable information.

4  
5 Exposures in quantities that would result in adverse impacts may be shown, for example, by  
6 the California Environmental Contaminant Biomonitoring Program, which has identified priority  
7 chemicals that need to be monitored due to concern for human exposure and the priority  
8 chemical's toxic effects. This program, by way of identifying the priority chemicals, is  
9 considered reliable information of exposure to quantities that would result in adverse impact.  
10 When the biomonitoring results are published, the results will be considered reliable  
11 information demonstrating the occurrence of exposure.

12  
13 Authoritative organizations are also using the volume of chemical in commerce as a surrogate  
14 regarding exposure concerns. For instance, if only 10 pounds of a chemical are manufactured  
15 each year, there is much less chance of widespread exposure than if chemical manufacturers  
16 are producing 10 million pounds each year. However, in all cases, in order to know whether  
17 the exposure is "in quantities that would result in adverse impacts" the chemical's potency to  
18 produce toxic effects is needed. While chemical potency data are available for many  
19 chemicals, it is not for a great many chemicals. In those cases, other information, such as  
20 structural activity relationships, is needed to estimate chemical toxicity, in quantitative or semi-  
21 quantitative terms, to assess widespread exposure.

22  
23 **Section 69502.2(b)(3)** specifies that reliable information that is available to substantiate  
24 adverse impacts and exposures is a factor to consider in identifying a Chemical of Concern.  
25 The regulations specify that a greater amount of reliable information to substantiate adverse  
26 impacts and exposures, relative to other chemicals being evaluated, will be given a higher  
27 priority. This is appropriate because DTSC has limited resources to implement this program.  
28 The more robust the data set, the more likely DTSC can make an informed and appropriate  
29 prioritization decision. In addition, it is consistent with the approaches taken by other scientific  
30 organizations.

31  
32 **Section 69502.2(b)(4)** specifies that in addition to the factors specified in subsection (b)(1)  
33 through (3), DTSC may also consider the availability of a safer alternative chemical that is  
34 functionally acceptable for one or more common uses of the chemical in consumer products to  
35 identify a Chemical of Concern. While the adverse impacts are important considerations in  
36 identifying a chemical as a Chemical of Concern, DTSC believes that the decision to identify  
37 and prioritize a Chemical of Concern is appropriately influenced by the availability of safer  
38 alternative chemicals.

39  
40 For instance, there are many chemicals used in cleaning products where safer alternative  
41 chemicals have been used. These safer alternative chemicals may serve as substitutes in  
42 other products. In that case, DTSC may opt to identify the original chemical as a Chemical of  
43 Concern, after considering the other factors discussed above to increase the market presence  
44 of safer cleaning products, ultimately enhancing the safer alternatives' market presence and  
45 consumer acceptance, as well as leveling the playing field amongst manufacturers.

1  
2 **§ 69502.3. Chemicals of Concern List**  
3

4 **Section 69502.3(a)** specifies that an informational list of the initial Chemicals of Concern list  
5 will be made available within 30 days after the effective date of these regulations. This section  
6 provides responsible entities and other interested parties a list of Chemicals of Concern that  
7 DTSC is using to enter step 2 of the four-step process, Chemical of Concern and consumer  
8 product prioritization in Article 3. This informational list will also serve as a market signal to  
9 responsible entities as discussed in the introduction of Article 2. Additionally, it is DTSC's  
10 intent to verify the hazard trait associated with the chemical on some of the chemical lists  
11 where the purpose or objective of the chemical list became the driver for the chemical's listing.  
12

13 The Chemicals of Concern list will not be a static list, reflecting only those chemicals from  
14 chemical lists and sources identified in section 69502.2(a). It is DTSC's intent that as those  
15 chemical lists and sources change, DTSC will periodically update the Chemicals of Concern  
16 list using the procedures specified in subsections (c) and (d) and in compliance with the  
17 Administrative Procedure Act to the extent applicable.  
18

19 **Section 69502.3(b)** specifies that DTSC may make additions to or deletions from the  
20 Chemicals of Concern list using the factors specified in section 69502.2(b) and the procedures  
21 in subsections (c) and (d) of this section. This section makes it clear that the Chemicals of  
22 Concern list is not intended to be a one-time static list. It is intended to be revised to reflect  
23 updates in the science that forms the basis for the list. It also establishes the criteria and  
24 processes that DTSC must follow for updating and revising the Chemicals of Concern list.  
25

26 **Section 69502.3(c)(1) through (3)** specifies DTSC will make the proposed revisions to the  
27 Chemicals of Concern list available on its website, along with a bibliography of the supporting  
28 documentation. The documentation includes DTSC's rationale, data and information as well  
29 as the sources, to provide the public an understanding of the bases for DTSC's proposed  
30 listing decisions so that these parties can submit comments in response to these bases.  
31

32 Before DTSC finalizes the revisions to the Chemicals of Concern list, DTSC will hold at least  
33 one public workshop to provide an opportunity for public comments to the proposed revisions.  
34 A notice will be made available to the public regarding proposed revisions to the Chemicals of  
35 Concern list using the following methods:

- 36 • Electronic message to individuals on the electronic mailing list that the Department  
37 establishes; and
- 38 • Website posting of the notice regarding the availability of the proposed revisions to the  
39 list and supporting documentation.  
40

41 The notice will include the following:

- 42 • The last day for the public to submit written comments on the proposed revisions to the  
43 Chemicals of Concern list, which will be at least 45 days from the date the notice is sent  
44 to individuals on DTSC's electronic mailing list;
- 45 • The method(s) for submitting comments to the Department; and

- 1       • The date, time, and location of the public workshop(s).

2

3 The comment period provides interested parties an opportunity to present information and data  
4 not previously considered to have a chemical added to or removed from the Chemicals of  
5 Concern list prior to finalization of the list. The comment period provides an additional  
6 opportunity for responsible entities to provide comment and additional information to DTSC  
7 that may influence the Chemical of Concern listing.

8

9 **Section 69502.3(d)** specifies that after DTSC considers public comments, DTSC will finalize  
10 and post on its website the finalized revisions to the Chemicals of Concern list. At its own  
11 discretion, DTSC may, respond to public comments received during the comment period. To  
12 maximize the effective use of DTSC resources, DTSC has given itself the latitude to determine  
13 which comments merit a response.

### 1 **Article 3. Chemicals of Concern and Consumer Product Prioritization Process**

2  
3 **Article 3**, in its entirety, establishes the process to identify and prioritize products that contain  
4 a Chemical of Concern. Article 2 describes the first step in a four-step process to develop  
5 safer consumer product by establishing a process to identify chemicals as Chemicals of  
6 Concern; Article 3 contains the second process step - establishing a process to prioritize  
7 Chemicals of Concern in products and listing them as Priority Products.

8  
9 As described in the introduction to Article 2, the authorizing statute requires DTSC to identify  
10 and prioritize chemicals or chemicals ingredients in consumer products. For reasons  
11 discussed in the introduction to Article 2, DTSC has established a process to identify  
12 Chemicals of Concern in Article 2 and to prioritize Chemicals of Concern in consumer products  
13 as Priority Products in Article 3. Article 3 is necessary to clarify and make specific the  
14 provisions of Health and Safety Code sections 25252 and 25253, by establishing the process  
15 to prioritize Chemicals of Concern in consumer products as Priority Products.

16  
17 The regulations need to allow consideration of information from both Chemicals of Concern  
18 and consumer products. Evaluating and examining the information from both, based on the  
19 information available, will allow for flexible decision-making regarding which of the products  
20 that contain a Chemical of Concern should be listed as Priority Products. Along that same line  
21 of thought, the prioritization of Chemicals of Concern in consumer products is based on the  
22 interaction between the Chemical of Concern's physical and environmental or toxicological  
23 hazard traits and its presence in consumer products.

24  
25 As in the case of Article 2, it is again noted that not all the prioritization factors specified in  
26 Article 3 may be applicable to a given product and that DTSC is not required to consider all the  
27 prioritization factors for a given product, but to evaluate those that are relevant and available.  
28 As previously explained, using a narrative approach to prioritize Chemicals of Concern in  
29 consumer products as Priority Products is necessary to accommodate prioritizing Chemicals of  
30 Concern in products now and in the future when additional scientific and technological data  
31 may become available. This is necessary to avoid unnecessary delays that a prescriptive  
32 process may lock DTSC into when developing the Priority Products list. The narrative  
33 approach allows the implementation of the regulations to keep pace with advances in science  
34 and technology. This is not to say that DTSC will make decisions in a vacuum. On the  
35 contrary, as with listing Chemicals of Concern, DTSC is proposing a transparent public  
36 process for interested parties to examine DTSC's rationale, information, and sources of  
37 information and provide comments before DTSC finalizes the Priority Product list.

38  
39 Because the rationale for identifying and listing a product as a Priority Product will be different  
40 for each product, DTSC:

- 41 • may customize the applicability and evaluation of broad, overarching scientific factors to
- 42 consider for a product;
- 43 • will explain the rationale for listing a product as a Priority Product; and

- will make the rationale and supporting information available to the public for review and comment along with the proposed list. Allowing the public to review and comment provides an open and transparent process prior to finalizing the Priority Products list.

The rationale and supporting documentation may include the evaluation and consideration of current scientific information, including any state of the art, or acceptable mechanisms used for considering the weight of scientific evidence or balancing toxicity data and information and other factors to prioritize a product as a Priority Product. For example, DTSC may use a decision type matrix applied to the regulatory criteria to identify and prioritize candidate Priority Products with Chemicals of Concern that are carcinogens partially based on the carcinogens' potencies. DTSC may also use an entirely different method regarding the regulatory criteria to identify and prioritize candidate Priority Products with Chemicals of Concern that exhibit the "wildlife survival hazard trait". Using one common method to prioritize consumer products with dissimilar hazard traits, such as a human carcinogen, a chronic exposure issue, with wildlife survival, which may be an acute exposure issue, cannot be done without controversy. This situation reinforces DTSC's decision to use a narrative approach in the regulations that works hand in hand with a transparent public process before the Priority Products are finalized and listed.

## **§ 69503. General**

**Section 69503(a) and (b)** introduce the purpose of Article 3 and specify the process by which DTSC will evaluate and prioritize products containing Chemicals of Concern under this Article. DTSC may use, but is not limited to using, information obtained under section 69501.4 to perform its duties under this Article.

This section makes specific that as part of this process, DTSC will evaluate information from the public domain and other sources to identify products that contain Chemicals of Concern to prioritize them as Priority Products. DTSC may rely on information about products obtained from a responsible entity, importer or manufacturer under section 69501.4, but is not limited to using only that information in performing its duties under Article 3. Providing DTSC with maximum latitude and flexibility to seek out and utilize a broad range of scientific data and other information is necessary to ensure that this process and the resulting Priority Products list is based on sound science, reliable information, and relevant, dependable information.

### **§ 69503.1. Applicability**

**Section 69503.1** specifies that this Article applies to all products that contain one or more Chemicals of Concern, and that are placed into the stream of commerce in California. This section makes clear to all interested parties the scope of products that may be considered in the Chemicals of Concern and consumer product prioritization process. The scope specified in the regulation is consistent with, and is necessary to implement, the broad scope of the authorizing statute.

1 The first point of entry into the Article 3 prioritization process is that the product contains a  
2 Chemical of Concern identified and listed in Article 2. The second criterion that must be met is  
3 that a product containing a Chemical of Concern is placed into the stream of commerce in  
4 California. This provision is intended to ensure that the process is focused on those products  
5 that are of concern to the citizens and the environment of California.

## 7 **§ 69503.2. Priority Products Prioritization Factors**

8  
9 **Section 69503.2** specifies the factors DTSC will use to evaluate and prioritize Priority  
10 Products. The factors to consider emphasize the Chemical of Concern’s toxicity profile and  
11 the physical attributes exhibited by the Chemical of Concern in a consumer product, and  
12 exposure to the Chemical of Concern in the consumer products that would contribute or cause  
13 adverse impacts.

14  
15 This section provides a consistent set of factors for DTSC to consider in its evaluations and  
16 gives responsible entities, the public and other interested parties a better understanding of the  
17 prioritization factors that are considered in prioritizing Chemicals of Concern and identifying  
18 and prioritizing consumer products containing a Chemical of Concern as Priority Products.

19  
20 **Section 69503.2(a)** specifies that DTSC may evaluate products to determine their adverse  
21 impacts and associated exposures by considering the factors listed in section 69503.2(a)(1)  
22 through (3) for which information is available. Based on the evaluation, DTSC will determine  
23 which products are considered high priority and should be proposed and listed as Priority  
24 Products according the process laid out in later sections.

25  
26 This section provides responsible entities, stakeholders and interested parties predictability  
27 and certainty regarding the specific aspects DTSC will be evaluating to prioritize Chemicals of  
28 Concern in products to determine which products are of high priority and should be listed as  
29 Priority Products.

30  
31 It is important to note that DTSC is not required to consider all these factors, but those factors  
32 for which relevant information or, as applicable, reliable information is available.

33  
34 **Section 69503.2(a)(1)** specifies the factors that DTSC will consider to identify and list a Priority  
35 Product. DTSC is required to consider the adverse impacts due to exposures to the  
36 Chemicals of Concern in consumer products during its life cycle. That evaluation must  
37 consider: (1) the adverse impacts associated with the Chemical of Concern in the product and  
38 (2) the exposures to the Chemical of Concern in the product.

39  
40 This section specifies the factors DTSC will consider, guiding the prioritization of Chemicals of  
41 Concern in consumer products as candidates for listing as Priority Products. This section  
42 delineates that evaluating Chemicals of Concern in products is a two-fold evaluation – (1) the  
43 Chemical of Concern’s behavior in terms of its toxicity and physical profile in the product and  
44 (2) exposures to the Chemical of Concern in the product in quantities that may contribute to or  
45 cause enumerated adverse impacts.

1 In the early implementation stages of these regulations, consumer products and Chemicals of  
2 Concern that may be considered and evaluated under these prioritization factors may include  
3 those that may generate partnerships with other national and state agencies with common  
4 goals. In addition, DTSC may also solicit from other California state or local agencies those  
5 products or chemicals that are of concern to their environmental and public health  
6 responsibilities. DTSC may also internally examine candidate chemicals or consumer  
7 products that are of concern and that may contribute to or cause adverse impacts to public  
8 health and the environment.

9  
10 **Section 69503.2(a)(1)(A)1. through 3.** identify those adverse impacts associated with the  
11 Chemical(s) of Concern in consumer products that will be considered as part of the product  
12 identification and prioritization process. The factors to be considered in this section are the  
13 same as those listed in Article 2, section 69502.2(b)(1)(A) through (C), for Chemical of  
14 Concern identification, except that the evaluation in this subsection emphasizes the adverse  
15 impacts of Chemicals of Concern *in consumer products*.

16  
17 The reader is referred to Article 2, section 69502.2(b)(1)(A) through (C) of this Initial  
18 Statement of Reasons for further description of these factors. These sections evaluate the  
19 adverse impacts of a Chemical of Concern related to its presence in a product as a  
20 consideration for listing the product as a Priority Product. The information obtained from the  
21 Chemical of Concern identification is taken to the next level and DTSC evaluates how the  
22 Chemical of Concern's physical traits and toxicity profile may have an impact when it is in a  
23 consumer product. Additionally, when there are a number of products being evaluated at the  
24 same time and that contain the same Chemical of Concern, this information may, in balancing  
25 information throughout this section's entire evaluation process, serve to tip the scales to list  
26 one particular product, containing a Chemical of Concern, as a Priority Product over another.

27  
28 For instance, because different products that have the same function and contain the same  
29 Chemical of Concern may be manufactured differently and have different physical forms (e.g.,  
30 liquid or solid), the products may behave, react, and cause public health, ecological and  
31 environmental harm differently. DTSC will use this information to assess the exposure to the  
32 Chemical of Concern in these products and their ability to contribute to or cause adverse  
33 impacts as a basis for determining which products to list as Priority Products. For example,  
34 the Chemical of Concern's impact to terrestrial animal or plant organisms may be greater for a  
35 Priority Product in powder form due to its ability to disperse with the wind and contaminate a  
36 larger area of the environment than the same or similar Priority Product in larger solid form.

37  
38 **Section 69503.2(a)(1)(B)** specifies the second main factor to consider in prioritizing,  
39 identifying, and listing a Priority Product; that is, exposure to the Chemical of Concern. This  
40 provision also specifies factors to consider in establishing the exposure and the circumstances  
41 where exposures to the Chemical of Concern in the product may occur. It is noted that DTSC  
42 will use reasonable product uses to assess adverse impacts in these exposure scenarios.

43  
44 **Section 69503.2(a)(1)(B)1.a. through c.** Market presence information for the product may be  
45 used as a surrogate to assess exposure to the Chemical of Concern in the product. In

1 addition, specific subsets of market presence information may also be considered by DTSC as  
2 part of the prioritization process because the specified information is a further valuable  
3 surrogate for measures of actual exposure. These additional pieces of information include:

- 4 a. Statewide sales by volume;
- 5 b. Statewide sales by number of units; and
- 6 c. Intended product uses and age groups of targeted customer base(s).

7  
8 **Section 69503.2(a)(1)(B)2.** Reliable information regarding exposures to the Chemical(s) of  
9 Concern in the product to the public and/or aquatic, avian, or terrestrial animal or plant  
10 organisms is also considered as part of product prioritization. Relevant information may  
11 include, but is not limited to, the following to assess exposure:

- 12 • Monitoring data that indicates that the chemical or its degradation products are present  
13 in the California solid waste, waste water or storm water streams.
- 14 • Environmental media data that indicates the presence of the Chemical of Concern or its  
15 degradation products.
- 16 • Biomonitoring or environmental monitoring data showing the presence in humans or  
17 other biological organisms.
- 18 • Significant public funds to clean up or mitigate the Chemical of Concern, for example,  
19 soil clean up in order to protect public health or the environment.
- 20 • Data that shows other chemical species that exhibit a hazard trait are formed during:
  - 21 ○ breakdown of the chemical;
  - 22 ○ chemical transformation in an environmental setting; or
  - 23 ○ combined with other chemicals

24  
25 **Section 69503.2(a)(1)(B)3.** Information concerning the household presence of the product,  
26 and other products containing the same Chemical(s) of Concern, including the number of  
27 products, how common their household presence is, the frequency of use, and the  
28 concentration of the chemical in those products will also be considered by DTSC as part of  
29 prioritization. This information is necessary to assess aggregate exposure – the total exposure  
30 to the same Chemical of Concern from various sources of products that contain the Chemical  
31 of Concern that may contribute to or cause adverse effect to receptors using household  
32 products.

33  
34 Information concerning the household presence of the product is important with respect to  
35 public health exposures to the product and the Chemical of Concern in the product. DTSC  
36 acknowledges that in many cases this information will be difficult, if not impossible, to obtain. It  
37 is for this reason that the regulation only requires DTSC to consider this factor *to the extent*  
38 *that information is available*. This type of information will be sought by searching the public  
39 domain and requesting manufacturers to provide this information voluntarily through data call-  
40 ins conducted under Section 69501.4. DTSC may also consider using survey techniques to  
41 obtain this information.

42  
43 **Section 69503.2(a)(1)(B)4.** Exposures to the Chemical of Concern in the product to the public  
44 and/or aquatic, avian, or terrestrial animal or plant organisms during the product's life cycle is a  
45 consideration for identifying and prioritizing a Priority Product. The various scenarios

1 presented evaluate and assess the ability of the Chemical of Concern to contribute to or cause  
2 adverse impacts based on exposure to the product for possible listing as a Priority Product.

- 3 a. Exposures during manufacturing, use, storage, transportation, waste, and end-of-life  
4 management practices and the locations of these practices be assessed. This is one of  
5 the various scenarios to evaluate exposures that may cause adverse impacts to public  
6 health and environment. Releases of the Chemical of Concern in the product during  
7 product use, storage, transportation and end-of-life management practices can, and do,  
8 occur with varying degrees of frequency and at various life cycle stages and  
9 circumstances.

10  
11 Examples of considerations that may be used by DTSC to evaluate exposure by the  
12 public or the environment to the Chemical of Concern under this factor include, but are  
13 not limited to:

- 14 • How well the Chemical of Concern is physically contained or chemically bound in the  
15 product, including the long-term integrity of the containment method;  
16 • How the Chemical of Concern-containing product is managed to control exposure by  
17 the public or environment;  
18 • Whether there are any regulatory restrictions imposed by the federal government or  
19 the State of California to reduce or prevent chemical exposure;  
20 • Whether there are warnings or other precautions regarding the use of the product;  
21 and  
22 • How often and how long the Chemical of Concern from the product is exposed to the  
23 public or the environment for each scenario involving product use.

- 24  
25 b. Consideration also includes the types of uses that may result in public exposures to the  
26 Chemical of Concern in the product. This provision specifies that DTSC consider the  
27 types of consumer uses of the products that contain the Chemical of Concern that may  
28 expose the public and contribute to or cause adverse health impacts. The various  
29 scenarios for DTSC to consider include:

30 i. Household and recreational use, including:

- 31 • Household consumers using the product  
32 • Do-it-yourselfers  
33 • Hobbyists

34 ii. Sensitive subpopulation use or exposure at locations frequented by members  
35 of sensitive subpopulations, including service workers who may be using  
36 “household” products but at a greater than normal rate due to the service  
37 being provided. This sensitive subpopulation may also include, but is not  
38 limited to, household cleaning services workers or nail salon workers. Other  
39 sensitive populations may be found at locations, such as health care facilities,  
40 recreational facilities and day care facilities.

41 iii. Workers, customers, clients, and members of the general public who use, or  
42 otherwise come in contact with, the product or releases from the product in  
43 the home, workplace, or other locations. These locations may include those  
44 listed above, but would apply to all populations, not necessarily to just  
45 sensitive populations.

1  
2 These factors ensure that DTSC considers, in evaluating and prioritizing products  
3 that contain a Chemical of Concern, the types and extent of consumer uses of the  
4 product that may expose the public to the Chemical of Concern in the product, which  
5 in turn could result in adverse public health impacts. These scenarios may help  
6 provide an assessment of the types of individuals that may be exposed to the  
7 Chemical of Concern in the product, and the types of conditions surrounding uses  
8 that may lead to exposures.  
9

- 10 c. This subparagraph describes aspects of exposure related to subsection (a)(1)(B)4.a.,  
11 exposures during “manufacturing, use, storage, transportation, waste, and end-of-life”  
12 and in subsection (a)(1)(B)4.b.i. through iii., are to be assessed. Frequency, extent,  
13 level, and duration of exposure for each use scenario and end-of-life scenario are all  
14 factors to be considered. How often (frequency), the number of routes of exposure  
15 (extent), the concentration of the Chemical of Concern (level), and how long (duration)  
16 are factors to assess when determining exposure. In addition, repeated uses of the  
17 product containing the Chemical of Concern may vary and is considered to determine  
18 the aggregate exposure.  
19
- 20 d. Containment of the Chemical(s) of Concern within the product is another factor for  
21 DTSC to consider as part of prioritization. How the Chemical of Concern is contained or  
22 bound during the use of the product determines, in part, the amount of exposure that  
23 may occur. For instance, the Chemical of Concern may be a component inside a  
24 product and may not be accessible to the user, in which case, there is little to no  
25 exposure as a result of use of the product.  
26
- 27 e. Engineering and administrative controls are also exposure considerations. Some  
28 consumer products that contain Chemicals of Concern recommend precautionary  
29 measures or have warning labels regarding limiting or reducing exposures through  
30 engineering and administrative controls. These controls are into consideration when  
31 assessing exposures.  
32
- 33 f. Another factor for DTSC to consider in identifying, prioritizing, and listing a Priority  
34 Product is the ability of the Chemical of Concern or its degradation products to:
- 35 • be released into or migrate or distribute into environmental media; or
  - 36 • accumulate and persist in biological and/or environmental compartments or systems  
37 based on the environmental fate properties of the Chemical(s) of Concern or the  
38 degradation products.  
39

40 Subsection f. appropriately specifies that the Chemical of Concern’s ability to persist,  
41 bioaccumulate and move into different environmental compartments are exposure  
42 pathways that may contribute to or cause adverse impacts to the public and  
43 environment. Estimates of persistence, bioaccumulation, fate and transport of the  
44 chemical or its degradation products may be based on one or more of the following and  
45 may be used as a consideration for prioritizing, identifying, and listing a Priority Product:

- 1 • Fugacity modeling, a chemical fate and transport multimedia model;
- 2 • Field studies in the environment;
- 3 • Observations and measurements conducted in the field;
- 4 • Microcosm studies, which includes simulating an ecosystem in a laboratory setting;
- 5 • Use computational modeling for structural activity relations to predict chemical
- 6 behavior;
- 7 • Short term in-vitro bioassays to predict chemical behavior; and
- 8 • Computational modeling data.

9  
10 Environmental or biological presence may also be estimated using a point source or  
11 market-wide source term calculation, modeling or measurement, or a combination of  
12 these options.

13  
14 **Section 69503.2(a)(1)(B)5.** DTSC is also to consider product uses, disposal or discharge in a  
15 manner that could contribute to or cause adverse waste and end-of-life impacts. For example,  
16 if discharge or disposal is into the sewer, the Publicly Owned Treatment Works (POTW) may  
17 not be able to remove or treat the Chemical of Concern before it is discharged into California  
18 waters. All life depends on water and, consequently, there may be exposure to and adverse  
19 impacts from the Chemical of Concern. An indirect method that may be used to measure or  
20 quantify exposure is the POTW's cost to treat or remove the Chemical of Concern or its  
21 metabolites before the treated water is discharged into California waters. If treatment or  
22 removal is not conducted, the consequence is an increase in the likelihood of exposure to the  
23 public and the environment to the Chemical of Concern.

24  
25 **Section 69503.2(a)(2)** specifies that DTSC will consider the amount of information that is  
26 available to substantiate exposures to the Chemical of Concern. All other factors being equal,  
27 a product will be given a higher priority over other products being evaluated as Priority  
28 Products if there is a greater amount of information to substantiate adverse impacts and  
29 exposures. This will ensure that the proposed and final listing of Priority Products is based on  
30 sound data, information, and to the extent available, reliable information, biomonitoring or other  
31 exposure data, or modeling data. This data and information will be available to the public for  
32 review and comment prior to finalizing the Priority Product list.

33  
34 **Section 69503.2(a)(3)** specifies that DTSC is to consider the scope of other regulatory  
35 programs to address and provide adequate protection against the same adverse public health  
36 and environmental impacts being considered under these regulations. Other regulatory  
37 programs include federal, other California State regulatory programs, and applicable  
38 international agreements with the force of domestic law. This provision is intended to ensure  
39 that DTSC maximizes the effective use of its resources by focusing on those public health and  
40 environmental concerns that are not already being adequately addressed by another federal or  
41 California State regulatory program. It is also necessary to ensure consistency with Health  
42 and Safety Code section 25257.1.

43  
44 Health and Safety Code 25257.1(c) provides "DTSC shall not duplicate or adopt conflicting  
45 regulations for product categories already regulated or subject to pending regulation consistent

1 with the purposes of this Article.” DTSC has determined that federal or California regulatory  
2 agencies, or regulatory regimes created by legally binding treaty obligations will be considered  
3 under this provision. DTSC has precluded regulatory authority over the consumer product by a  
4 foreign country, another state or a local agency to qualify for the statutory exemption since in  
5 these situations there is no jurisdictional or consistent authority either in or throughout  
6 California.

7  
8 DTSC will assess each regulatory program to determine to what extent public health and the  
9 environment are protected from threats posed in comparison to the protection that would be  
10 achieved under these regulations and the authorizing statute. The more co-extensive the  
11 degree of protection under the collective application of the other programs is with the  
12 protection afforded under this program, the greater the likelihood that DTSC will not prioritize a  
13 chemical and/or product for further consideration under this program.

14  
15 For example, assume DTSC is evaluating two different products. Chemical A in one product is  
16 adequately regulated from its production through consumer use, but the disposal causes an  
17 adverse environmental impact. Chemical B in another product may cause consumer exposure  
18 during use, but because it is not used in a workplace, it is not under the regulatory oversight of  
19 federal or state Occupational Health and Safety Administration. Setting aside all other  
20 prioritization factors, DTSC may conclude that the product containing chemical B is largely  
21 “unregulated” and is a higher-priority than the product containing Chemical A. All other things  
22 being equal, the product containing chemical B might be proposed as a Priority Product based  
23 on this difference.

24  
25 By way of further example, a product that might qualify for low prioritization under these  
26 regulations is a fuel additive that has undergone a multimedia evaluation as required by  
27 section 43830.8 of the Health and Safety Code. Before adopting new specifications for  
28 chemical fuel additives, the California Air Resources Board (CARB) is required to prepare a  
29 multimedia evaluation to examine the relative risk posed by any newly proposed fuel additive  
30 to the State’s resources, human health and the environment. Section 43830.8 requires that a  
31 multimedia evaluation must identify and evaluate any significant adverse impact on public  
32 health and the environment, including air, water or soil that may result from the production,  
33 use, or disposal of a motor vehicle fuel that may be used to meet CARB motor vehicle fuel  
34 specifications.

35  
36 According to the Guidance Document and Recommendations on the Types of Scientific  
37 Information Submitted by Applicants for California Fuels Environmental Multimedia  
38 Evaluations, revised June 2008<sup>11</sup>, potential additives must be evaluated. The evaluation not  
39 only includes engine performance and emission requirements, but also includes considerations  
40 to health and environmental criteria involving air emissions, cross environmental media  
41 transfer and associated health risks, ozone formation potential, hazardous waste generation

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<sup>11</sup> <http://www.arb.ca.gov/fuels/multimedia/080608guidance.pdf>

1 and management and surface and groundwater contamination resulting from production,  
2 distribution, and use.

3  
4 This is a rigorous multimedia risk assessment that also incorporates the life cycle concepts to  
5 provide policy makers with reliable information to make policy decisions regarding public health  
6 and environmental protection. A consumer product that is subject to this type of multimedia  
7 chemical evaluation under another federal or California state regulatory program might be  
8 determined by DTSC to be of low priority under this Article.

9  
10 **Section 69503.2(b)** specifies further key factors to prioritize products that contain a Chemical  
11 of Concern. A product is given a higher priority over other products under evaluation if it meets  
12 both key prioritization factors. This section ensures that the process for identifying Priority  
13 Products for which an Alternatives Analysis will be required will lead to giving highest priority to  
14 the greatest chemical-associated threats to public health and the environment, as is called for  
15 by the authorizing statutes. The key prioritization factors are the following:

16 **(1)** The Chemical(s) of Concern in the product have a significant ability to contribute or cause  
17 adverse public health and environmental impacts. This consideration, includes, but is not  
18 limited to, the Chemical of Concern's toxicity, including the potency, and physicochemical  
19 profile, and its mobility in the environment.

20  
21 Potency refers to the chemical's dose to the receptor that will cause an adverse effect.  
22 Chemicals that cause an adverse effect in smaller doses are more potent than chemicals  
23 that cause the same adverse effect with a larger dose. The more potent the chemical, the  
24 more significant is its ability to contribute to or cause adverse public health and  
25 environmental impacts. The toxicity profile also considers the adverse effects on the  
26 sensitive subpopulations, environmental habitats, threatened/endangered wildlife, and  
27 impaired environments.

28  
29 Another aspect that determines whether a chemical has a significant ability to contribute or  
30 cause adverse public health and environmental impacts is the physicochemical properties  
31 of the chemical. These are chemical properties, such as vapor pressure, sorption  
32 coefficient for soil and sediment, etc., which determine the chemical's ability to move in the  
33 environment (air, water, soil) and result in chemical exposures to the receptor. The  
34 physicochemical properties are used in fate and transport mathematical models to predict  
35 chemical behavior and exposure concentrations to a receptor. The more mobile the  
36 chemical is, the more significant is its ability to cause exposures in quantities that contribute  
37 to or cause adverse public health and environmental impacts. The more mobile the  
38 chemical is in different types of environmental media, the more likely it is to result in  
39 adverse public health and environmental impacts.

40 **(2)** There is a significant ability for the public and/or aquatic, avian, or terrestrial animal or plant  
41 organisms to be exposed to the Chemical(s) of Concern in the product in quantities that  
42 would contribute to or cause adverse public health or environmental impacts. This may  
43 include consideration of how widely the product is distributed in commerce and how widely  
44 the product is used by consumers. This consideration takes into account information  
45 regarding all the exposure scenarios and evaluating the weight of evidence to determine

1 which product containing a Chemical of Concern should be listed as a Priority Product.  
2 This factor includes routes of exposure and disposition of the product during use and end of  
3 life.

4  
5 For example, a Chemical of Concern in a product that has multiple routes of exposure (e.g.,  
6 inhalation, ingestion, or dermal absorption) increases the chemical's ability to contribute or  
7 cause a toxic effect. This scenario would indicate a higher priority over other products with  
8 a Chemical of Concern that has a single route of exposure.

### 9 10 **§ 69503.3. Process to Evaluate Products Using the Prioritization Factors**

11  
12 **Section 69503.3**, in its entirety, specifies a stepwise process to evaluate the data and  
13 information gathered from the Priority Product Factors to establish and standardize the steps  
14 DTSC will take to prioritize products. This section also serves to provide the public, regulated  
15 entities, and other interested parties, a level of predictability and certainty regarding the  
16 methods that DTSC will use in proposing Priority Products.

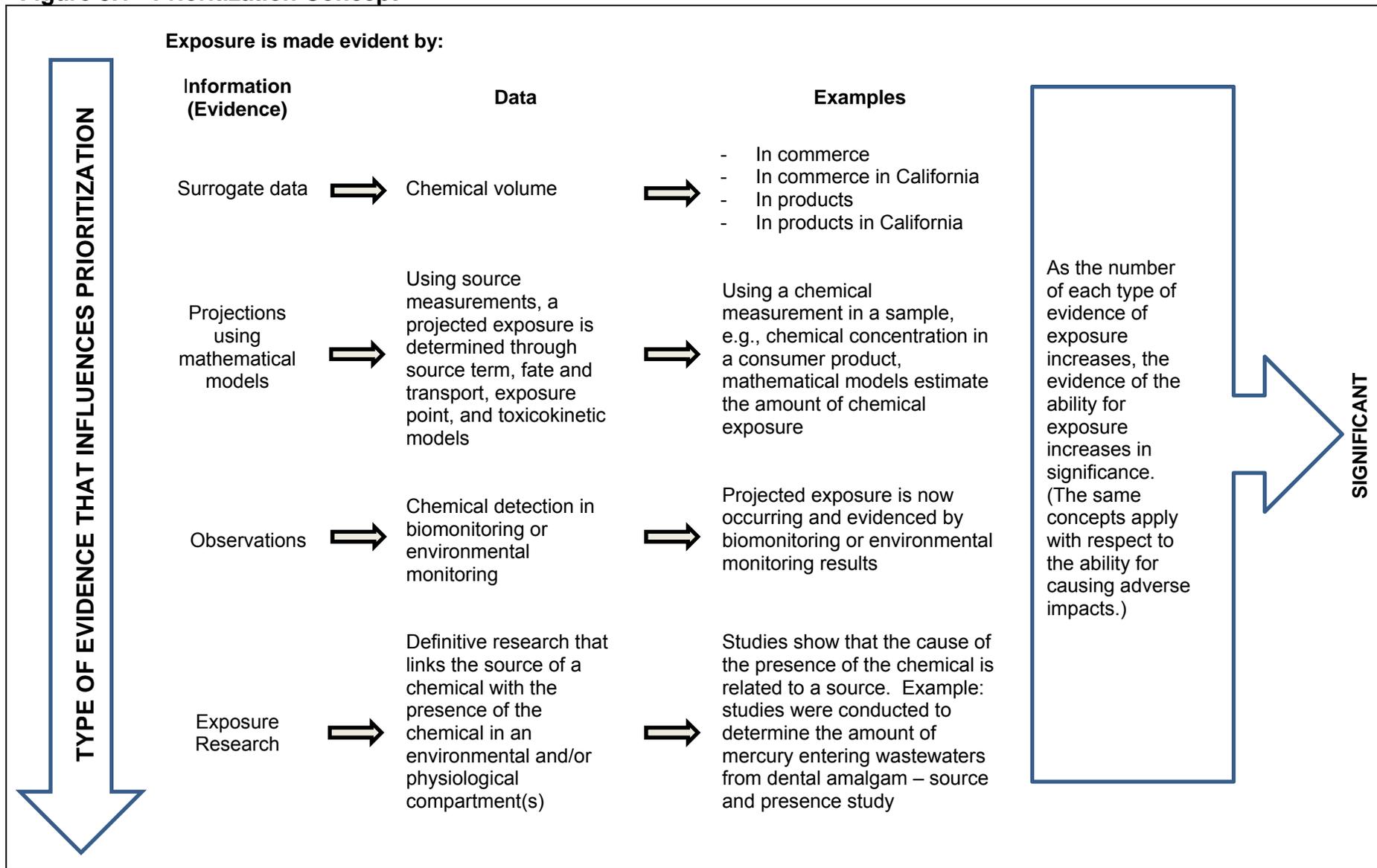
17  
18 It is important to note that the process to evaluate products using the prioritization factors is  
19 presented in a stepwise fashion, but it also incorporates a “reality check”. That is, the last step  
20 loops back to the Key Prioritization Factors to make adjustments as needed and to ensure that  
21 the proposed Priority Products have relevance to the Key Prioritization Factors.

22  
23 In some instances, the nature of the Chemical of Concern in the product may drive the listing  
24 as a Priority Product even though the exposure may be relatively small. This is especially true  
25 if the toxicity of the Chemical of Concern is high and the product sources of the Chemical of  
26 Concern are numerous. The resulting aggregate exposure may drive the Priority Product  
27 listing. In other cases, the exposure will drive the listing of the product even though the  
28 Chemical of Concern exhibits moderate toxicity, but its market presence and concentration in  
29 the product is relatively high.

30  
31 **Section 69503.3(a)** specifies that DTSC first consider the adverse Impacts and exposures  
32 based on available information. This section reflects DTSC's view that adverse impact and  
33 exposure are critical factors in the evaluation of products. It further reflects DTSC's view that it  
34 cannot afford the time or commitment of resources to conduct lengthy and costly research to  
35 determine the relative adverse impacts and exposure of products. Rather, DTSC will conduct  
36 its evaluation based on available information.

37  
38 Figure 3.1 - Prioritization Concept, provides a graphic representation of how some of the  
39 exposure factors specified in section 69503.2(a)(1)(B), might be used to prioritize products and  
40 how the significance of available information as described in section 69503.2(b) might be  
41 determined. It is important to know that this diagram shows conceptually how available  
42 information may be evaluated and used to inform which Priority Products to prioritize, but this  
43 diagram does not capture all the prioritization factors to consider. As each Priority Product  
44 listing is proposed, DTSC will provide stakeholders the rationale used to evaluate the relevant  
45 information to prioritize and propose Priority Products.

1 Figure 3.1 - Prioritization Concept



1 **Section 69503.3(b)** specifies that DTSC must consider other regulatory programs that may  
2 address the adverse impacts and exposures pathways of the Chemical of Concern in the  
3 product and adjust the prioritization accordingly.  
4

5 This provision mirrors section 69503.2(a)(3) and the accompanying portion of this Statement of  
6 Reasons and is intended to ensure consistency with Health and Safety Code section 25257.1,  
7 which precludes DTSC from regulating products in a manner that is duplicative of, or in conflict  
8 with, other existing regulatory programs. This section also takes into account pending  
9 regulatory action by another entity to determine whether DTSC actions would provide  
10 meaningful additional public health and environmental benefits in regards to adverse impacts  
11 and/or chemical exposure pathways.  
12

13 **Section 69503.3(c)** specifies that DTSC may list as a Priority Product one or more products  
14 determined to be of high priority after completion of the steps specified in subsections (a) and  
15 (b). This section emphasizes the step- wise faction DTSC will use to evaluate the Chemical of  
16 Concern in the product considering various exposure pathways and the chemical's ability to  
17 contribute to or cause adverse impacts.  
18

19 **Section 69503.3(d)** specifies that DTSC may consider the availability of a safer alternative  
20 during the prioritization process of products that contain a Chemical of Concern. This section  
21 is intended to provide DTSC the discretion to consider whether there is a readily available  
22 safer alternative that is functionally acceptable and technically and economically viable, to  
23 adjust the prioritization prior to listing a product as a Priority Product. More specifically, the  
24 existence of a known safer alternative makes the listing as a Priority Product more likely than if  
25 this were not the case. This provision allows DTSC to consider giving priority to a product  
26 based on publicly available information on safer alternatives. This, in turn, fosters the ability of  
27 the manufacturer to consider and to expeditiously complete the Alternatives Analysis process  
28 for the Priority Product to hasten the introduction of a safer product into the marketplace.  
29

30 **Section 69503.3(e)** specifies as a cross check, that DTSC revisit the key prioritization factors  
31 before issuing the proposed and final Priority Products lists. This step is necessary as a reality  
32 check to ensure that the proposed Priority Products have relevance to the Key Prioritization  
33 Factors and to make adjustments to the prioritization, as appropriate.  
34

35 **Section 69503.3(f)** specifies that by January 1, 2014, DTSC must issue a Priority Product  
36 Work Plan covering next three years. This is intended to provide a level of certainty and  
37 predictability to responsible entities and other stakeholders regarding the types of products that  
38 will be considered for evaluation prior to releasing a proposed Priority Product List. The work  
39 plan will include product categories, which may illustrate for example a level of detail  
40 comparable to the Family (i.e., Cleaning Products) or Class (i.e., Laundry) hierarchy level  
41 identified using the Global Product Classification (GPC) Standards<sup>12</sup> and a general

---

<sup>12</sup> <http://www.gs1.org/gdsn/gpc>

1 explanation, which may include exposure concerns, such as access to sensitive  
2 subpopulations. The work plan will plot a course for DTSC for three years.

3  
4 **Section 69503.3(f)(1)** allows for revisions to the work plan prior to work plan expiration to  
5 reflect necessary action on a chemical and/or product because of:

6 **(A)** statutory requirements,

7 **(B)** an Executive Order from the Governor, and

8 **(C)** petitions that have been granted under Article 4. It is noted here that the Priority Product  
9 Work Plan “legislative” revisions only occur when law is enacted that requires DTSC to take  
10 action. Also for clarification purposes, the Priority Product Work Plan is separate and apart  
11 from the Legislature’s authority to enact laws regarding chemicals and products.

12  
13 **Section 69503.3(f)(2)** provides stakeholders a minimum of one year to review and consider  
14 the subsequent three year Priority Product Work Plan prior to DTSC revising the proposed  
15 Priority Products list to ensure responsible entities have adequate time to review their  
16 products, formulations, and supply chain prior to entering the public comment period for a  
17 proposed Priority Product in section 69503.4(b).

18  
19 **Section 69503.3(f)(3)** requires DTSC to hold at least one or more workshops before issuing  
20 the work plan to provide stakeholders an opportunity for oral comment.

21  
22 **Section 69503.3(f)(4)** requires DTSC to send to persons on the electronic mailing list for these  
23 regulations and post on its website a notice of availability of each work plan and each revised  
24 work plan to provide responsible entities and other stakeholders the predictability and certainty  
25 for the next three year cycle to the extent possible.

26  
27 **Section 69503.3(f)(5)** clarifies that the Priority Product Work Plan does not include the initial  
28 list of up to five Priority Products that DTSC proposes within 180 days of the effective date of  
29 these regulations in section 69503.4(d).

30  
31 **Section 69503.3(g)** narrows the scope of Chemicals of Concern that DTSC may identify on  
32 the initial list of Priority Products as the basis for listing Priority Products to those Chemicals of  
33 Concern that meet both of the following criteria:

34 **(1)** Chemical criteria in section 69502.2(a)(1); and

35 **(2)** Chemical criteria in section 69502.2(a)(2).

36  
37 To address demands for certainty during early stages of implementation, until January 1, 2016,  
38 only those chemicals that have a hazard trait or toxicological or environmental endpoint listed  
39 on one or more of the authoritative organization’s chemical lists in 69502.2(a)(1), and that  
40 appears on an exposure or monitoring related chemical list in 69502.2(a)(2), may serve as the  
41 basis for a product being identified as a Priority Product.

42  
43 **§ 69503.4. Priority Products List**

1 **Section 69503.4(a)(1)** specifies the process by which DTSC will identify and prepare a list of  
2 products that, when they contain a Chemical of Concern, will be designated as Priority  
3 Products based on the factors specified in section 69503.2 and 69503.3. Placement on the  
4 Priority Products list signifies that the responsible entity must begin the process to develop an  
5 Alternatives Analysis for the Priority Product. This provision triggers the next step in the quest  
6 for safer products – the Article 5 Alternative Analysis.

7  
8 **Section 69503.4(a)(2)(A) through (D)** specify the information that DTSC must provide for  
9 each proposed and finalized Priority Product. This information is needed to provide the  
10 responsible entities with sufficient information to determine if their products are being proposed  
11 or finalized as Priority Products. This information also provides the public and other interested  
12 parties the basis for DTSC's proposed and final listing decisions so that these parties may  
13 submit comments during the comment period.

14  
15 For each listed product the following information shall be provided:

16 **(A)** The Chemical of Concern and the hazard trait(s) that is/are the basis for listing the product  
17 as a Priority Product.

18 **(B)1.** If applicable, the specific component or homogeneous material within a component to  
19 which the alternatives analysis threshold applies, and which is the minimum focus of the  
20 Alternatives Analysis. DTSC intends to be as specific as possible when products with  
21 multiple parts or components are identified as Priority Products to name the specific  
22 component or homogeneous material that is basis for the listing, and, thus, subject to  
23 the Alternatives Analysis. DTSC may, of course, name an entire multi-component  
24 product as a Priority Product when it is appropriate to do so. The Alternatives Analysis  
25 may apply to more than the specified component or homogeneous material, but at a  
26 minimum must address those identified by DTSC. Manufacturers are encouraged  
27 during the proposed Priority Product listing and public participation process to clarify  
28 any uniqueness that may pertain to their proposed Priority Product that may affect the  
29 listing.

30 **2.** For an alternatives analysis involving a highly durable product, DTSC is to specify and  
31 limit the number of components and/or homogenous materials in the component to ten  
32 or fewer per durable product every three years. This is to allow manufacturers of  
33 durable products (as defined in the next paragraph), such as the automobile industry,  
34 that have longer product development time frames to conduct the Alternatives Analysis.  
35 By limiting the components or homogeneous materials in the component as well as  
36 when the specified durable product is subject to an Alternatives Analysis, manufacturers  
37 are provided adequate time to address the durability requirements of the product.

38 **3.** For purposes of subparagraph 2., a highly durable product must meet all of the  
39 following:  
40 **a.** Have 100 or more manufactured components;  
41 **b.** Have a useful life or an average useful life of five or more years as shown by the  
42 manufacturer's information to consumers  
43 **c.** Is used more than one time, i.e., is not consumed, destroyed or discarded after a  
44 single use  
45

- 1       4. For purposes of subparagraph (B)2., durable product limitations as a Priority Product,  
2       does not apply to:
- 3           a. children’s products designed or intended for twelve (12) years old or younger as  
4           determined by consumer information or commonly recognized by consumers as  
5           intended for the age group, or
  - 6           b. products worn or placed on the human body, dispersed as an aerosol or vapor,  
7           or applied to hard surfaces with the likelihood of runoff or volatilization.

8  
9       **(C)** The due date for the Preliminary Alternatives Analysis Report. The default due date for the  
10       Preliminary Alternatives Analysis Report is 180 days from the date of listing a product as a  
11       Priority Product. However, based on each Priority Product’s uniqueness or DTSC’s  
12       resources, DTSC may specify a due date for the Preliminary Alternatives Analysis Report  
13       that is shorter or longer than the default.

14  
15       **Section 69503.4(b)** specifies the public review and comment process that DTSC must follow  
16       before finalizing the proposed Priority Products list. DTSC is required to make available on its  
17       website, for public review and comment, the proposed Priority Products list along with the  
18       rationale and a bibliography of supporting documentation, including the data and data sources.  
19       In addition, DTSC is required to hold one or more public workshops to provide opportunity for  
20       oral comments on the candidate products being considered as proposed Priority Products as  
21       well as the proposed Priority Products. DTSC believes that a robust public comment process  
22       leads to transparency and better decisions, which will in turn inspire more confidence in this  
23       program.

24  
25       Section 69503.4(b) ensures that the public and other interested parties have input into the  
26       Priority Product listing process. This comment period also provides responsible entities  
27       another opportunity, in addition to that provided in section 69501.4, to present information and  
28       data not previously considered to have a product added to or removed from the proposed  
29       Priority Products list prior to finalization of the list. The information that DTSC is required to  
30       provide in support of the proposed list provides the public and other interested parties an  
31       understanding of the bases for DTSC’s proposed listing decisions so that these parties can  
32       submit comments in response to these bases.

33  
34       DTSC is also required to hold one or more public workshops to provide an opportunity for the  
35       public to comment orally on the proposed list. DTSC must send to persons on any electronic  
36       mailing list(s) establishes for implementation of these regulations, and post on its website a  
37       notice regarding the availability of the proposed list and supporting documentation. The notice  
38       must include all of the following:

- 39       **(1)** The time period during which written comments may be submitted – the last day to submit  
40       comments is 45 days from the date of posting on the DTSC website and notification to  
41       parties on the electronic mailing list(s);
  - 42       **(2)** The method(s) for submitting comments; and
  - 43       **(3)** The date, time and location of the public workshop(s).
- 44

1 **Section 69503.4(c)** allows comments submitted on the proposed Priority Products list to  
2 include recommendations, along with supporting rationale and information pertaining to an  
3 alternatives analysis threshold for one or more of the proposed Priority Products. DTSC is  
4 required to consider these comments in setting the alternatives analysis threshold. This allows  
5 DTSC to take advantage of existing scientific information and data in the hands of interested  
6 parties and to have the benefit of that information before setting the alternatives analysis  
7 threshold. This will make for a more informed scientific decision than if DTSC set this level  
8 without the benefit of such information.

9  
10 **Section 69503.4(d)** specifies that DTSC, before finalizing the Priority Products list, will review  
11 all public comments. It also requires the final Priority Products list to include an alternatives  
12 analysis threshold for each Priority Product. Upon finalizing the Priority Products, DTSC must  
13 post the list on its website. DTSC may respond to some or all public comments received  
14 during the comment period. This section provides responsible entities with an official  
15 communication from DTSC regarding which products have been finalized as Priority Products  
16 and must undergo an Alternatives Analysis. To maximize the efficient and effective use of  
17 DTSC resources, it is necessary that DTSC be given the latitude to determine which  
18 comments merit a response.

19  
20 **Section 69503.4(e)** makes specific that the first list of proposed Priority Products is to be  
21 made available for public review and comment within 180 days after the effective date of these  
22 regulations. This section also specifies the initial list will consist of no more than five (5)  
23 Priority Products. This section provides regulated entities certainty regarding when to expect  
24 the initial proposed Priority Products and establishes a reasonable time frame for DTSC to  
25 publish the initial list of Priority Products. This section also assures regulated entities that  
26 during the initial stages of implementation, DTSC will be taking action on a relatively small  
27 number of Priority Products in order to gain experience and knowledge to refine  
28 implementation of these regulations.

29  
30 It is important to note that the initial number of Priority Products will be based on available  
31 resources to implement these regulations. It is DTSC's intent to make the most efficient use of  
32 resources, including considering strategies such as, staggering the dates when notifications  
33 and Alternatives Analysis Reports are due to DTSC.

34  
35 **Section 69503.4(f)** specifies that DTSC must review and revise, as appropriate, the Priority  
36 Products list at regular intervals of at least once every three (3) years. This section ensures  
37 that the Priority Products list is reviewed for progress, and that the Priority Product list does not  
38 remain stagnant. DTSC may choose to review the Priority Product list more often, but must do  
39 so at least once every three years. The review may indicate the Priority Products list is  
40 adequate and no revisions are needed. The review may also incorporate any petitions  
41 received under Article 4 to either add or remove a Priority Product.

42  
43 **Section 69503.4(g)** specifies that each responsible entity of a listed Priority Product must  
44 provide to DTSC one of four notifications within 60 days after the Priority Product is listed. A  
45 fifth notification, the Priority Product Replacement Notification, if applicable, is required at the

1 same time as the Priority Product Removal Notification or within 30 days when replacement  
2 product is placed in commerce in California.

3  
4 If a responsible entity introduces into California a Priority Product that meets the Priority  
5 Product listing after it has been listed (i.e., it is not a replacement product for the Priority  
6 Product), the responsible entity must submit a Priority Product Notification to DTSC within 60  
7 days of its introduction into the stream of commerce in California. In addition, the notifications  
8 in this subsection provide the public and other interested parties, information regarding the  
9 status of Priority Products that are on the market and their status in terms of being subject to  
10 the requirement to conduct an Alternatives Analysis. The notifications are:

11 **(1) Priority Product Notification**, as specified in section 69503.7.

12  
13 This notification requirement provides information to DTSC regarding which products and  
14 responsible entities are subject to the next process step – the Alternatives Analysis process.  
15 In an instance that a responsible entity submits a Priority Product notification within 60 days of  
16 being introduced into commerce in California (i.e., after the initial Priority Product listing), the  
17 same requirements and time allotments for conducting an Alternatives Analysis applies.

18  
19 The products included in notifications in subsections (f)(2) through (4) are not subject to an  
20 Alternatives Analysis. In addition, these alternate notifications are tailored to the status of the  
21 Priority Product under these regulations and allow DTSC and the public to monitor their status.  
22 They also allow DTSC to assess the resources needed to implement DTSC’s responsibilities  
23 for audits and investigations on Priority Products for which these notifications were received.

24  
25 The specified alternate notices are:

26 **(2) Alternatives Analysis Threshold Exemption Notification**, as specified in section 69503.6,  
27 and described later in the Article 3 Statement of Reasons;

28 **(3) Priority Product Removal Notification** and, if applicable, a Priority Product Replacement  
29 Notification, as specified in section 69501.2(b) and discussed in Article 1 of the Statement  
30 of Reasons; or

31 **(4) Chemical of Concern Removal Notification**, as specified in section 69505.1(g) and  
32 discussed in Article 5 of the Statement of Reasons.

### 33 34 **§ 69503.5 Alternatives Analysis Threshold Exemption**

35  
36 **Section 69503.5**, in its entirety, provides an exemption from the requirement of conducting an  
37 alternatives analysis for a Priority Product when specified criteria are met. The distinction  
38 between those Priority Products that are subject to the alternatives analysis and those that are  
39 exempt will be primarily based on the minimum detectable concentration for the Chemical of  
40 Concern and the difficulty of avoiding the presence of contaminants that are the source of the  
41 Chemical of Concern in the product.

42  
43 This alternatives analysis threshold (AA Threshold) exemption is not self-implementing; rather,  
44 it requires a notification to be submitted to DTSC. The term “de minimis” used in other draft  
45 regulations prepared by DTSC addressing Safer Consumer Products has been replaced with

1 the term “alternatives analysis threshold”. This was done to clarify DTSC’s rationale for  
2 including this concept. More specifically, it is a concentration below which there is an  
3 exemption from the duty to conduct an alternatives analysis and above which an alternatives  
4 analysis is required.

5  
6 Eliminating the use of the term “de minimis” is intended to minimize the possibility for confusion  
7 or misunderstanding that this threshold represents an insignificant or negligible risk, too small  
8 to be of concern. Risk, in the context of human health, is the probability of injury, disease, or  
9 death from exposure to a chemical.

10  
11 The public comment process related to Priority Products listing will provide transparency to  
12 stakeholders and will provide an opportunity to review and comment on setting the  
13 concentration for the AA Threshold exemption, among other issues. Stakeholders may  
14 provide evidence to address concerns about the uncertainty of a threshold for a given Priority  
15 Product or information on available analytical methods to document the exemption. (There is  
16 also a dispute resolution process under article 4 for responsible entities if they wish to dispute  
17 any decision made by DTSC.)

18  
19 This exemption will apply to both intentionally added chemicals and to unintentional by-  
20 products. Impurities in raw materials and by-products of reactions may be present at levels  
21 above the AA Thresholds. DTSC has determined that since the risks to public health and the  
22 environment are the same for intentionally and unintentionally added chemicals and from  
23 unintentional by products, such chemicals and the products to which they are relevant, are not  
24 appropriately exempted from these regulations. Rather, these factors are considered by DTSC  
25 in establishing the applicable AA Threshold.

26  
27 **Section 69503.5(a)** exempts a responsible entity from the duty to conduct an alternatives  
28 analysis if the criteria set out in subsection (b) below are met. In order to be eligible for the  
29 exemption, the responsible entity must submit a complete and timely Alternatives Analysis  
30 Threshold Exemption Notification (Exemption Notification) to DTSC pursuant to section  
31 69503.6. The exemption is subject to continuing compliance with subsections (c) and (d) of  
32 Section 69503.6, which are described in greater detail below. DTSC’s approval of the  
33 Exemption Notification is not required, but DTSC does have the authority to review and audit  
34 the information provided in the Exemption Notification.

35  
36 **Section 69503.5(b)** specifies the substantive criteria for the exemption. An AA Threshold  
37 exemption applies if the concentration each Chemical of Concern is less than or equal to the  
38 AA Threshold for the product, component(s), or homogeneous material(s) identified as the  
39 basis for the Priority Product listing. This condition must be met as of the date DTSC lists a  
40 Priority Product or when a Priority Product is first placed into the stream of commerce in  
41 California, whichever is later. If a Priority Product is introduced into the stream of commerce at  
42 a date that occurs after the Priority Product is listed, then the exemption will apply at this later  
43 date. A Priority Product may be listed due to the presence of one or more Chemicals of  
44 Concern. If there is only one Chemical of Concern, then only the single Chemical of Concern  
45 needs to be compared with the AA Threshold. If there is more than one Chemical of Concern,

1 then DTSC may specify a total concentration for each hazard trait or each environmental or  
2 toxicological endpoint. In this case, the concentration of each Chemical of Concern, that  
3 exhibits the same hazard trait, are added together, and this sum is then compared to the AA  
4 Threshold total for the hazard trait.

5  
6 **Section 69503.5(c)** requires DTSC to determine the AA Threshold for each of the Chemicals  
7 of Concern based on available reliable information. DTSC must consider the presence of  
8 unintended contaminants and laboratory analytical methodology in determining the appropriate  
9 AA Threshold. Alternatively, DTSC may develop an AA Threshold based on relevant  
10 information for the Chemical of Concern to ensure that the AA Threshold is protective of public  
11 health and the environment, as well as technically feasible.

12  
13 DTSC will not specify the AA Threshold at the time it proposes the Priority Product List.  
14 Instead, DTSC will request that recommendations with supporting rationale and information be  
15 submitted at the time of the public workshops and the public notice. DTSC will evaluate this  
16 information and publish the AA Threshold when DTSC posts the final Priority Product List.  
17 Public comment periods for the proposed Priority Products will provide stakeholders an  
18 opportunity to provide comments on the appropriateness of the AA Threshold. Any concerns  
19 regarding the proposed Chemicals of Concern, their hazard traits, available laboratory  
20 methods, detection limits, the complexity of the product, the component, or homogeneous  
21 material(s) within a component will be subject to public review and comment.

22  
23 **Section 69503.5(c)(1)**. The first set of criteria applies if the Chemical of Concern is an  
24 unintended contaminant that is present in the product. This contaminant may originate from  
25 the starting materials or be the result of secondary or incomplete reactions during the  
26 production process. While these impurities are present, they were not intentionally added.

27  
28 This provision allows DTSC to give consideration to those situations when it is not technically  
29 or economically feasible to remove the contaminants. The responsible entity will have to make  
30 reasonable effort to try to remove or avoid the presence of the contaminant. The provision  
31 limits the source of the contamination to the following specific circumstances which may be  
32 unavoidable and beyond the control of the responsible entity.

33  
34 **Section 69503.5(c)(1)(A)** specifies the source of the Chemical of Concern may be a naturally  
35 occurring contaminant in raw materials that are common and are frequently used to  
36 manufacture the product. Although impurities may be considered unavoidable, it may be  
37 technically feasible to reduce the content of these residues in the final product. Examples of  
38 naturally occurring Chemicals of Concern are heavy metals such as mercury, cadmium, lead,  
39 and arsenic.

40  
41 **Section 69503.5(c)(1)(B)** specifies the source of the Chemical of Concern may be air or water  
42 frequently used as a processing agent or an ingredient to manufacture the product. Water and  
43 air are both critical resources for manufacturing. Both have the potential to transmit chemical  
44 hazards to products during any process that involves direct contact with air or water, such as  
45 processing, heating, cooling, cleaning, etc. For example, chlorine, nitrates, pesticides, and

1 lead are just a few of the contaminants that can be found in some water supplies, and  
2 treatment technologies may be limited depending on the source of the water.

3  
4 **Section 69503.5(c)(1)(C)** specifies the source of the Chemical of Concern to be a contaminant  
5 in recycled materials that are common and are frequently used to manufacture the product. If  
6 the feedstock used is a recycled material, there may be great variability in the quality or there  
7 may be concerns that contaminants from post-consumer material may appear in the recycled  
8 material. Recovered material may contain some impurities which are unintended that have no  
9 function for the recycled material and do not change the chemical identity of the selected  
10 material. Recycling can never reach 100% purity and it is unavoidable that some small  
11 fractions of unintended contaminants are still present in the recycled material.

12  
13 Recycling materials conserves natural resources and energy, promotes sustainability, reduces  
14 disposal to landfills, and reduces the use of virgin material. Plastic bottles, paper, glass, and  
15 metal are a few materials that are commonly recycled. While encouraging the use of recycled  
16 content, this provision allows DTSC to consider the concentration of the contaminants in  
17 recycled materials when setting an AA Threshold.

18  
19 **Section 69503.5(c)(1)(D)** specifies the source of the Chemical of Concern to be a processing  
20 agent or intermediate frequently used to promote certain chemical or physical changes during  
21 manufacturing, and the incidental retention of a residue is not desired or intended. This allows  
22 for the possibility that minor amounts of the catalyst are lost in the reaction and may be a  
23 source of the Chemical of Concern in the Priority Product.

24  
25 **Section 69503.5(c)(2)(A)**. The second factor that DTSC must consider is the minimum  
26 concentration of the Chemical of Concern that can be detected in the Priority Product with  
27 available laboratory analytical methodology. This criterion essentially becomes the default AA  
28 Threshold if the Chemical of Concern is present as an intentionally added ingredient only.  
29 (That is, the factors in Paragraph (1) above are not relevant if there is no amount of  
30 unintentionally added Chemical of Concern in the product.)

31  
32 Current analytical techniques cannot detect down to a single molecule. At very low  
33 concentrations, it is impossible for analytical instruments to distinguish the difference between  
34 signals from analytes and signals created by the instrument. DTSC is proposing to set the  
35 minimum AA Threshold exemption using reasonable analytical detection limits which represent  
36 the lowest concentration levels the can be reliably detected within acceptable limits of  
37 precision and accuracy during routine laboratory operating conditions using appropriate  
38 methods. The detection limit is not the same as the quantitation limit, above which quantitative  
39 results may be obtained with a specified degree of confidence. Detection limits are matrix-,  
40 method-, and analyte- specific.

41  
42 This exemption criterion is necessary because a number of constituents have risk-based levels  
43 that are not analytically achievable in all matrices with existing analytical methods. The  
44 complexity of the matrix (the product), interference by other co-contaminants, strongly bound  
45 Chemicals of Concern to the matrix, or the rapid degradation of Chemicals of Concern during

1 the laboratory analysis are examples of conditions that will make analytical procedures  
2 extremely difficult.

3  
4 The ability to evaluate low-level data is critical when the detection limit exceeds a health based  
5 standard for a particular contaminant. Potentially harmful levels of the chemical may exist  
6 below our ability to detect them, making early detection of changes in the concentration of low-  
7 level contaminants using statistical evaluations of low-level data essential. The detection limit  
8 will allow for an AA Threshold that is lower and closer to risk-based benchmarks than using the  
9 quantitation limit. The detection limit will provide a less than a 1% chance of concluding that a  
10 chemical is present when it truly is not (a false positive).

11  
12 **Section 69503.5(c)(2)(B)** specifies that DTSC is proposing the detection limit as the minimum  
13 AA Threshold because a reliable, consistent detection of the constituent below the detection  
14 limit is not achievable. Making the minimum detection limit the lowest concentration for the  
15 exemption will assure that all exemption demonstrations will achieve acceptable analytical  
16 sensitivities.

17  
18 **Section 69503.5(c)(3)**. The third criterion for setting the AA Threshold level is the availability  
19 of reliable information that demonstrates that the concentration of the Chemical of Concern is  
20 protective of public health and/or the environment at higher concentration levels. DTSC may  
21 specify a different AA Threshold from that which would apply under paragraphs (1) and/or (2).  
22 If DTSC does so, it must consider the following relevant criteria.

23  
24 **Section 69503.5(c)(3)(A)**. *The inherent potency of the Chemical of Concern*. Toxicity is the  
25 capacity of a chemical to do damage or cause adverse effects. Potency is the measure of a  
26 chemical necessary to cause an effect. Potency is typically used to describe or measure  
27 effects, such as carcinogenic, mutagenic, reproductive toxicity and/or developmental toxicity.  
28 If a Chemical of Concern is not highly potent, this may require additional evaluation of the  
29 appropriateness of the AA Threshold value.

30  
31 **Section 69503.5(c)(3)(B)**. *Ability to bioaccumulate*. The ability to bioaccumulation is of  
32 concern because of biomagnifications in the environment. Bioaccumulation is of concern  
33 because small concentrations of chemicals in the environment can find their way into  
34 organisms in high enough dosages to cause problems. If the Chemical of Concern is  
35 bioaccumulative, it can be a source of high or frequent exposures in the environment.

36  
37 **Section 69503.5(c)(3)(C)**. *The unintended presence of the Chemical of Concern in organs,*  
38 *tissues, or fluids*. An individual's body burden of a pollutant is estimated by measuring the  
39 concentration of that substance in one or more tissues. Such measurements serve as  
40 indicators of recent or long-past chemical exposures. Body burdens integrate exposures that  
41 occur across time and reflect the accumulation of pollutants after metabolic and partitioning  
42 processes. Biomonitoring data can play a critical role in identifying novel hazards and high-risk

1 populations, tracking trends in human exposure, and characterizing exposure levels that pose  
2 health hazards.<sup>13</sup> Methods are lacking for interpreting what the presence of a chemical in  
3 organs, tissues, and fluids mean regarding health risks to an individual or population. The  
4 establishment of cause and effect in epidemiological studies and a thorough understanding of  
5 human dose response exist for only a few environmental chemicals. In the absence of these  
6 studies, DTSC considers the detection of Chemicals of Concern in organs, tissues, and fluids  
7 as demonstrating the occurrence of exposures, which may result in adverse impacts. Because  
8 the Chemicals of Concern that are the basis of the Priority Product have been prioritized based  
9 on hazard traits, the unintended presence of a Chemical of Concern in the body is a criterion  
10 that may be considered for setting the AA Threshold.

11  
12 **Section 69503.5(c)(3)(D).** *The presence or absence of a threshold dose response.* The  
13 dose-response is the relationship between dose and the proportion of individuals responding  
14 with an all or none effect. The threshold dose is a dose that is just sufficient to induce an  
15 adverse effect. This criterion will allow for consideration of threshold and no threshold dose  
16 responses to support raising or lowering the AA Threshold.

17  
18 Most types of adverse effects for any particular chemical only occur above a particular dose.  
19 Threshold refers to the established exposure values for chemicals, below which there would be  
20 no appreciable risk to human health. At low exposures, the body can usually tolerate some  
21 disturbance to its normal functions without any overt signs or symptoms of illness.

22  
23 Certain chemicals have toxic effects which can be triggered by exposure to very low amounts  
24 of a chemical and which can result in long-term illness or permanent damage. Carcinogens  
25 and mutagens are examples of hazard traits postulated as having no "threshold," and there is  
26 a probability of harm at any level of exposure.

27  
28 **Section 69503.5(c)(3)(E).** *The ability of the Chemical of Concern to contribute to or cause*  
29 *disproportionate adverse impacts on sensitive subpopulations and/or environmentally sensitive*  
30 *habitats.* These criteria are necessary to be consistent with the enabling statute. Sensitive  
31 subpopulations cannot tolerate chemical exposure as well as the general population. For  
32 example, children are more sensitive than adults are to chemical exposure because their  
33 bodies are creating new tissue, which is especially sensitive to exposure to chemical  
34 substances. During pregnancy, a woman's immune system has to work harder to protect both  
35 the mother and the baby and exposure to chemicals can affect the health of the unborn baby.  
36 If the Chemical of Concern does not affect sensitive populations or sensitive habitats, there  
37 may be justification to modify the AA Threshold.

38  

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<sup>13</sup> Thornton, Joseph W.; McCally, Michael; Houlihan, Jane; [Biomonitoring of industrial pollutants: health and policy implications of the chemical body burden](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1497458/pdf/12477912.pdf), Public Health Rep. 2002 Jul-Aug; 117(4): 315–323.  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1497458/pdf/12477912.pdf>

1 **Section 69503.5(c)(3)(F).** *Aggregate exposures to the Chemical of Concern.* The statutory  
2 language requires identification and prioritization process that considers the volume of the  
3 chemical in commerce in this state and the potential for exposure to the chemical in a  
4 consumer product. If a chemical is found in a product that is common and frequently used, the  
5 chemical may be present in higher than expected concentrations. A product used multiple  
6 times a day or if a product is commonly used in tandem with another product that also contains  
7 the Chemical of Concern will result in an exposure that is greater than a single use. Aggregate  
8 exposure, or exposure to a single chemical via multiple pathways, must also be considered if  
9 there is a known background source of the Chemical of Concern. The aggregate exposures  
10 are appropriately considered to ensure public health and environmental protectiveness.

11  
12 **Section 69503.5(c)(3)(G).** *Cumulative exposures to other Chemicals of Concern that exhibit*  
13 *the same hazard trait.* This criterion requires that the cumulative impacts of multiple  
14 Chemicals of Concern be considered when they exhibit the same hazard trait and /or  
15 environmental or toxicological endpoint. Unlike the criteria found in (F), this provision allows  
16 the effects of different chemicals to be assessed.

17  
18 **Section 69503.5(c)(3)(H).** *Any regulatory action threshold established by a governmental*  
19 *agency.* If a governmental agency establishes a level for a Chemical of Concern that is  
20 relevant, DTSC shall consider this reliable information. The statutory language requires that  
21 DTSC reference and use, to the maximum extent feasible, available information from other  
22 nations, governments, and authoritative bodies. Leveraging similar work and costs already  
23 incurred by those entities will minimize costs and maximize benefits for California.

24  
25 **Section 69503.5(d)** allows DTSC to include some flexibility to address the total concentration  
26 for multiple Chemicals of Concern with the AA Threshold. This may be necessary if the  
27 Chemicals of Concern that are the basis for the product being listed as a Priority Product  
28 exhibit the same hazard trait or adversely impact the same endpoint. For example, if DTSC  
29 sets the total AA Threshold for three Chemicals of Concern that exhibit the same hazard trait  
30 of an endocrine disruptor at 24 parts per million (ppm), then the responsible entity will have the  
31 flexibility to ensure compliance with the exemption threshold. A responsible entity may  
32 determine how each of the Chemicals of Concern will meet the total concentration of 24 ppm.  
33 For instance, the responsible entity may opt for each Chemical of Concern to be less than 8  
34 ppm or decide to eliminate one Chemical of Concern and make the other two less than 12  
35 ppm.

36  
37 **Section 69503.5(e)** allows DTSC to lower or raise a previously established AA Threshold  
38 based on new, or newly considered, information. This will be necessary as new scientific  
39 methods, new research, improved technology or tools, emerging fields of study, and new  
40 testing methodologies emerge or new reliable information is generated.

#### 41 42 **§ 69503.6. Alternatives Analysis Threshold Exemption Notifications**

43  
44 DTSC considered including a review and approval of the Alternative Analysis Threshold  
45 Exemption Notification, but decided that a self-implementing exemption with a notification to

1 DTSC would be less burdensome and more appropriate. DTSC's approach is to make the  
2 alternatives analysis threshold exemption conditional, based on the submittal of information  
3 about the maximum concentration of the Chemicals of Concern and laboratory testing  
4 information. Furthermore, the responsible entity bears the burden to demonstrate compliance  
5 with the alternatives analysis threshold and demonstrate that the Priority Products continues to  
6 meet the conditions of this exemption. If a product does not contain a Chemical of Concern, it  
7 is not subject to this notification. Only responsible entities for Priority Products that contain the  
8 Chemical of Concern that is the basis for its listing are required to submit an Alternatives  
9 Analysis Threshold Exemption Notification if they wish to be exempt from the alternatives  
10 analysis.

11  
12 **Section 69503.6(a)** requires that a responsible entity claiming an exemption from the duty to  
13 perform an alternatives analysis to submit the Alternatives Analysis Threshold Exemption  
14 Notification to DTSC within sixty days after the product is listed as a Priority Product. This time  
15 frame is consistent with the Priority Product Notification, which is also due sixty days after the  
16 Priority Product is listed. Together these two notifications will provide a comprehensive listing  
17 of products that contain the Chemical of Concern and their corresponding responsible entities.  
18 A Priority Product that contains a Chemical of Concern in concentrations below the alternatives  
19 analysis threshold is regulated less stringently because it meets the technical, policy, and  
20 scientific conditions found in section 69503.5. Although a Priority Product that contains a  
21 Chemical of Concern in concentrations below the alternatives analysis threshold is not subject  
22 to an alternatives analysis, it is subject to the requirements of the eligibility for an exemption.

23  
24 The notification must include all of the following:

- 25 **(1)** Name of, and contact information for, the person submitting the Alternatives Analysis  
26 Threshold Exemption Notification. If there are any questions about the content of the  
27 notification, this contact information is necessary.
- 28 **(2)** Name of, and contact information for, the manufacturer and the importer(s). DTSC will  
29 need to know the identity of the various manufacturers and importers that are the  
30 responsible entities for products claimed to be exempt from the alternatives analysis.
- 31 **(3)** Name of, and contact information for, all responsible entities for the product, to the extent  
32 known. This requirement includes any retailers that are known to the person submitting the  
33 notification.
- 34 **(4)** Information on the source of the Chemical(s) of Concern in the product. This exemption  
35 may be based on the source of the Chemical of Concern in the product; so, providing this  
36 information will serve to establish whether the Priority Product meets the conditions of this  
37 exemption.
- 38 **(5)** The maximum concentration at which the Chemical(s) of Concern is/are present in the  
39 product, component(s), or homogeneous material(s), whichever is applicable, and a listing  
40 and description of all information used to determine and substantiate this concentration. A  
41 notification must include the maximum concentration in the product of each Chemical of  
42 Concern and a description of the information used to detect and measure this  
43 concentration. This provision does not specify how to calculate the maximum  
44 concentration, but instead requires the responsible entity to describe how this requirement  
45 is met. This is performance-based requirement and allows a responsible entity to

1 determine the conformance of their product with these requirements. In the first instance,  
2 the responsible entity will determine testing frequency, number of samples, analytical  
3 sample preparations, analytical methods, and quality control.

4  
5 Please note that although there may be several ways to calculate the maximum  
6 contamination level of the Chemical of Concern, the maximum concentration level should  
7 not be confused with the average concentration of the chemical.

8 **(6)** Laboratory analytical testing protocols and results used to detect and measure the  
9 concentration of the Chemical of Concern in the product, including quality control and  
10 quality assurance protocols and information concerning the testing laboratory. This  
11 provision is not prescriptive in that it does not require specific analytical methodologies to  
12 prepare or analyze samples, but instead requires the responsible entity to include the  
13 quality control and quality assurance protocols regarding the testing of their products.  
14 There will be public comment opportunities when the Priority Product is proposed.  
15 Therefore, interested parties may comment on the adequacy of analytical techniques  
16 needed to meet the detection or quantitation limits in order to comply with this requirement.  
17 Many manufacturers supplement the information provided by suppliers with further  
18 analytical testing performed on behalf of the manufacture, even if the manufacturers rely on  
19 supplier certifications regarding purchased material content. Responsible entities should  
20 have a high degree of assurance about the content of their products to qualify for this  
21 exemption.

22 **(7)** Demonstration and certification that the responsible entity does and will continue to meet  
23 the criteria, assumptions, and conditions that are the basis for the exemption. There are  
24 many factors that may affect the criteria, assumptions, and conditions that are the basis for  
25 the exemption. Possible consideration here include: changes to the sources of the raw  
26 materials or recycled materials; the product's formulation; processing agents; any of the  
27 ingredients in the product; or the manufacturing location may require additional quality  
28 control or testing to verify continued compliance with the alternatives analysis threshold  
29 exemption. This provision is necessary because there is no expiration date for the  
30 alternatives analysis threshold exemption. In order to show continued eligibility for this  
31 exemption, a responsible entity must provide DTSC assurance of the continuing eligibility  
32 for this exemption. A responsible entity may choose to include documentation of how it will  
33 monitor its future operations to ensure continued eligibility for the exemption. When a  
34 Priority Product is significantly modified, a revised Exemption Notice is required. When a  
35 Priority Product fails to meet the conditions of the exemption, requirements such  
36 conducting an alternatives analysis and preparing related reports are triggered.

37  
38 **Section 69503.6(b)** requires that the responsible entity bear the burden of proof to  
39 demonstrate that the concentration of the Chemical(s) of Concern in the product or each  
40 component or homogeneous material, whichever is applicable, does not exceed the applicable  
41 alternatives analysis threshold. This provision clarifies that it is the responsible entity, and not  
42 DTSC, that has the burden of proof to show compliance with all the requirements of this  
43 conditional exemption for their product for as long as the exemption is claimed.

1 **Section 69503.6(c)** requires the responsible entity to submit to DTSC a revised Exemption  
2 Notification, if any of the information submitted in a previously submitted Exemption  
3 Notification significantly changes. A revised Exemption Notification must be submitted to  
4 DTSC within thirty days of a significant change.

5  
6 **Section 69503.6(d)** requires the responsible entity to submit a Priority Product Notification if  
7 the product no longer meets the criteria for an alternatives analysis threshold exemption. The  
8 notification is due within thirty days of the change in eligibility. Furthermore, the responsible  
9 entity is then required to submit a Preliminary AA Report to DTSC within 180 days of the  
10 change. Instead of submitting a Priority Product Notification and a Preliminary AA Report, a  
11 responsible entity may choose to submit either a Priority Product Removal Notification or  
12 Chemical of Concern Removal Notification within the same sixty days of the change.

13  
14 **Section 69503.6(e)** disallows the alternatives analysis threshold exemption if DTSC notifies  
15 the person who submitted the Exemption Notification that the information or findings contained  
16 in the notification are inaccurate, invalid, or inadequate to support an alternatives analysis  
17 threshold exemption. Although DTSC is not required to approve the Exemption Notification, if  
18 DTSC determines that the information or findings do not support the alternatives analysis  
19 threshold, the exemption may be invalidated by DTSC.

20  
21 **Section 69503.7** *Priority Product Notifications* reinforces and makes more specific the Priority  
22 Product notifications referenced in section 69503.4(g).

23  
24 **Section 69503.7(a)** provides that a Priority Product Notification is due to DTSC within 60 days  
25 of the Priority Product listing or within 60 days of the Priority Product introduction into  
26 California's stream of commerce; unless one of the following alternate notifications in section  
27 69503.4(f) was submitted to DTSC:

- 28 • Alternatives Analysis Threshold Exemption Notification;
- 29 • Priority Product Removal Notification and, if applicable, a Priority Product Replacement  
30 Notification; or
- 31 • Chemical of Concern Removal Notification.

32  
33 The Priority Product notification must include all of the following:

- 34 **(1)** The responsible entity's name and contact information, and a statement indicating whether  
35 the responsible entity is the product manufacturer, importer, or retailer;
- 36 **(2)** The type, brand name(s), and product name(s) of the Priority Product and, if applicable,  
37 information specifically identifying the component(s) or homogeneous material(s) triggering  
38 the product's listing as a Priority Product; and
- 39 **(3)** If applicable, the name of, and contact information for, the person that will be complying  
40 with the requirements of Article 5 on behalf of or in lieu of the responsible entity.

41  
42 It is important to reiterate that each manufacturer of a Priority Product is required to submit this  
43 notification. A consortium or trade association cannot provide this notification for the  
44 manufacturer; however, the information in subsection (a)(3) allows manufacturers to use trade  
45 associations or consortia to pool efforts to conduct the Alternatives Analysis in Article 5. This

1 notification requirement provides information to DTSC regarding the products and  
2 manufacturers that are subject to the next process step – the Alternatives Analysis process. In  
3 addition, the notification is needed to enable DTSC to better assess the resources needed  
4 implement Articles 5 and 6, as well as serving to focus audits and investigations on Priority  
5 Products for which the required notification or required Alternative Analysis reports has not  
6 been received.

7  
8 **Section 69503.7(b)** specifies that if DTSC determines that the notice requirements specified in  
9 subsection (a) have not been complied with for Priority Product, DTSC shall post this  
10 noncompliance on the Failure to Comply List under section 69501.3(d). This provision informs  
11 the public about the compliance status of responsible entities, which may be considered by  
12 consumers in making purchasing decisions and to implement related provisions of section  
13 69501.3, which are necessary to compel compliance with section 69503.4 and Article 5.

1 **Article 4. Petition Process for Identification and Prioritization of Chemicals and**  
2 **Products**

3  
4 **Article 4**, in its entirety, is necessary to specify the process for petitioning DTSC to include a  
5 chemical or product, or to delist a chemical or Priority Product, from the prioritization process.  
6 The provisions in Article 4 are necessary to enable interested parties, including individuals,  
7 industry, organizations, educational institutions, and government agencies, to present DTSC  
8 with information that demonstrates a chemical or product poses a threat, and should be  
9 evaluated for its potential listing as a Chemical of Concern or Priority Product. Conversely,  
10 Article 4 is necessary to provide a mechanism to remove a chemical and/or product from the  
11 prioritization process to reflect increased knowledge about, or a change in market  
12 circumstances with respect to, the chemical and/or product that was initially prioritized. The  
13 flexibility for DTSC to respond to stakeholder input, in crafting and maintaining its Chemicals of  
14 Concern and Priority Product lists, is especially important given that knowledge of the  
15 attributes of particular chemicals will increase over time. Similarly, safer chemical or  
16 engineering substitutes for known-hazardous chemicals will be developed over time; the  
17 consumer product marketplace will continue to evolve; and information about all of these  
18 factors is widely dispersed. Article 4 provides that all chemicals and products that petitioners  
19 propose for inclusion or delisting must be evaluated via the Article 2 and Article 3 identification  
20 and prioritization processes before a final decision is made on the merits of the petition.

21  
22 **§ 69504. Applicability and Petition Contents**

23  
24 **Section 69504**, in its entirety, is necessary to specify the process by which to petition DTSC  
25 to:

- 26 • include a chemical or product in the prioritization processes
- 27 • remove a chemical from the list of Chemicals of Concern or a product from the Priority  
28 Products list
- 29 • add chemicals on an existing chemicals list to the list of Chemicals of Concern
- 30 • establish or revise an alternatives analysis threshold for a Chemical of Concern in a  
31 Priority Product.

32  
33 **Section 69504(a)**, subject to the exception in subsection (b), allows a person (“petitioner”) to  
34 petition DTSC to evaluate a chemical or a consumer product or list of chemicals using the  
35 chemical identification or product prioritization processes specified in Articles 2 and/or 3. The  
36 petition must include the information specified in sections 69504(a)(1) through (6). The  
37 information specified in sections 69504(a)(1) through (6), summarized below, is necessary for  
38 DTSC to make an informed decision regarding the petition, and to contact the appropriate  
39 person should additional information be necessary.

40  
41 **Section 69504(a)(1)** requires that the name and contact information be provided to DTSC for  
42 both:

43 **(A)** The petitioner; and

44 **(B)** The person responsible for the contents of the petition, if different from the petitioner,

1 along with this person's affiliation with the petitioner.

2  
3 This information is necessary so that DTSC can notify the petitioner of its determination  
4 relative to the petition, and in the event DTSC needs to contact either party to obtain additional  
5 information about the petition.

6  
7 **Section 69504(a)(2)** requires that the petition include a description of the chemical or product,  
8 or both, which is/are the subject of the petition. This information is necessary to define the  
9 scope of the petition, and to assess the relevance of the information submitted.

10  
11 **Section 69504(a)(3)** requires that the petition include the use(s) and application(s) of the  
12 chemical or product, or both, which is/are the subject of the petition. This information is  
13 necessary to assess the relevance and completeness of the information submitted.

14  
15 **Section 69504(a)(4)** requires that the petition include the basis for the petition, which must  
16 include the scientific basis for the existence or absence of adverse public health and/or  
17 environmental impacts associated with the product or for the establishment or revision of an  
18 alternatives analysis threshold. This requirement works to ensure that DTSC gets quality  
19 petitions with some substantial basis for being filed.

20  
21 **Section 69504(a)(5)** requires that the petition include reliable information supporting this basis.  
22 Both requirements are intended to deter petitions based on limited and/or weak supporting  
23 data, and to insure that petitioners provide high quality, relevant information necessary for  
24 DTSC to assess the merits of their petition.

25  
26 **Section 69504(a)(6)** requires that the petition include the identity of any known manufacturers  
27 of the chemical or product. Identification of known manufacturers in the petition reduces costs  
28 to DTSC by eliminating the need for DTSC to determine these manufacturers, and facilitates  
29 DTSC's request of specific information from these manufacturers to assist in filling data gaps  
30 for any chemical or product included in the petition.

31  
32 **Section 69504(b)** creates an exception to the ability of a person to petition DTSC to remove a  
33 chemical from the list of Chemicals of Concern: a person may not petition DTSC seeking the  
34 removal of a Chemical of Concern identified as such in section 69502.2(a) unless the chemical  
35 is no longer listed on any of the lists identified in section 69502.2(a). This provision is  
36 necessary to preclude a wasteful expenditure of DTSC resources on petitions for removal of  
37 chemicals that have been well-established as possessing one or more hazard traits and are  
38 appropriately captured as Chemicals of Concern.

39  
40 **Section 69504(c)** requires DTSC to respond within 60 days of receiving a petition, and to  
41 designate the petition complete if it contains the items specified in section 69504(a)(1) through  
42 (6). If DTSC determines that the petition is complete, the petitioner will be notified, and the  
43 petition will undergo a substantive review to determine whether to grant or deny the petition on  
44 its merits. If DTSC determines the petition to be incomplete, it will notify the petitioner and  
45 provide the basis for this determination. These provisions are necessary to provide certainty to

1 petitioners as to when their petition will be acted upon for purposes of determining  
2 completeness, and to ensure that DTSC provides necessary feedback to petitioners in  
3 response to their petitions.

#### 4 5 **§ 69504.1. Merits Review of Petitions**

6  
7 **Section 69504.1(a)** requires DTSC to make decisions on whether to grant or deny a petition  
8 no later than the next regular update of the Chemicals of Concern or Priority Products List,  
9 whichever is applicable. In addition, it provides that DTSC will give high priority to petitions  
10 from federal or other California State agencies that relate to the petitioning agency's programs  
11 or authorities. This approach is consistent with the instructions within Health and Safety Code  
12 section 25252(b)(2) for DTSC to use information from other government bodies to the  
13 maximum extent feasible "to leverage the work and costs already incurred by those entities  
14 and to minimize costs and maximize benefits for the state's economy,". It will also assist  
15 federal and other California State regulatory programs in fulfilling their statutory and regulatory  
16 responsibilities. Both parts of this provision are necessary to provide DTSC with sufficient time  
17 to conduct a merits review of petitions, and to set petition-review priorities, in light of resource  
18 constraints. Although DTSC will conduct an initial completeness review of all incoming  
19 petitions, only those deemed complete will undergo a merits review.

20  
21 **Section 69504.1(b)** requires DTSC to conduct a merits review of petitions based on the  
22 criteria specified in sections 69504.1(b)(1) through (3). This provision is necessary to ensure  
23 that DTSC's determination on each petition is a scientifically based decision, and that  
24 petitioners and the general public know what criteria DTSC uses to evaluate petitions.

25  
26 **Section 69504.1(b)(1)** requires DTSC to evaluate the comprehensiveness of the information  
27 supporting the petition that pertains to the prioritization factors specified in sections 69502.3  
28 and/or 69503.3, and section 69504.1(b)(2) requires DTSC to evaluate the quality of information  
29 submitted to support the petition. These requirements are necessary to make effective use of  
30 DTSC resources, by ensuring that the petitioner provides a significant body of high-quality  
31 information wherever possible, to facilitate DTSC's scientific review of the chemical or product  
32 that is the subject of the petition.

33  
34 **Section 69504.1(b)(3)(A) and (B)** specify that DTSC will evaluate the availability of  
35 information, other than the data and information submitted with the petition, needed for DTSC  
36 to determine hazard traits exhibited by the chemical, and/or evaluate the chemical or product  
37 based on the factors specified in sections 69502.3 and/or 69503.3. These provisions enable  
38 DTSC to consider in its determination to grant or deny a petition whether there is adequate  
39 information available to evaluate the chemical or product under the Article 2 and Article 3  
40 identification and prioritization processes. Again, these provisions ensure that DTSC has a  
41 robust and balanced body of scientific information on which to base its decision, rather than  
42 relying exclusively on information provided by the petitioner.

43  
44 **Section 69504.1(c)** specifies that DTSC may request that the petitioner provide additional  
45 information to assist with the merits review. The petitioner must provide the information, to the

1 extent available, within the time frame specified by DTSC. This provision is necessary to  
2 provide DTSC the ability and flexibility to request additional information that is needed to  
3 complete the merits review.

4

5 **Section 69504.1(d)(1) and (2)** specify that after completing the merits review, DTSC will  
6 approve or deny the petition, prepare a notice of decision and a statement of basis explaining  
7 the rationale for the decision, and notify the petitioner of its decision. This section is necessary  
8 to inform the petitioner and the public of the petition, the decision rendered, and the basis for  
9 DTSC's decision.

1 **Article 5. Alternatives Analysis**

2  
3 **Article 5**, in its entirety, is necessary to clarify, implement, and make specific the provisions of  
4 Health and Safety Code section 25253. More specifically, this Article is necessary to specify  
5 the requirements applicable to conducting a comprehensive alternatives analysis (AA) for  
6 consumer products that are listed as Priority Products under Article 3. As described in Article  
7 3, consumer products that are listed as Priority Products are of concern due to the presence of  
8 one or more Chemical of Concern in the consumer product.

9  
10 Health and Safety Code section 25253(a)(2) requires these regulations to establish a process  
11 that includes an evaluation of the availability of potential alternatives and potential hazards  
12 posed by those alternatives, as well as an evaluation of critical exposure pathways. The  
13 process must include life cycle assessment tools that take into consideration, but are not  
14 limited to, all of the following:

- 15 (A) Product function or performance.
- 16 (B) Useful life.
- 17 (C) Materials and resource consumption.
- 18 (D) Water conservation.
- 19 (E) Water quality impacts.
- 20 (F) Air emissions.
- 21 (G) Production, in-use, and transportation energy inputs.
- 22 (H) Energy efficiency.
- 23 (I) Greenhouse gas emissions.
- 24 (J) Waste and end-of-life disposal.
- 25 (K) Public health impacts, including potential impacts to sensitive subpopulations,  
26 including infants and children.
- 27 (L) Environmental impacts.
- 28 (M) Economic impacts.

29  
30 The thirteen, (A) through (M), criteria listed in statute are embodied in the regulations and  
31 collectively address the life cycle impacts (i.e., from raw material extraction through materials  
32 processing, manufacture, distribution, use, repair and maintenance, and disposal or recycling)  
33 associated with the Priority Product or any alternative(s) considered. In accordance with  
34 Health and Safety Code section 25253 (a)(1), the regulations establish a process for  
35 evaluating Chemicals of Concern in consumer products, and their potential alternatives, to  
36 determine how best to limit exposure or to reduce the level of hazard posed by a Chemical of  
37 Concern. As such, the regulations establish a process for evaluating case- and/or chemical-  
38 specific consumer products.

39  
40 The thirteen criteria of section 25253(a)(2) comprise the contents of an AA- a systematic  
41 process for evaluating the life cycle impacts of a Priority Product and any alternatives  
42 considered. The concept of an AA is not new and parallels other popular life cycle assessment  
43 tools for evaluating and/or taking inventory of the impacts of products or services and are  
44 commonly known as *Life Cycle Assessment*, *Life Cycle Impacts*, *Life Cycle Inventory*, *Decision*  
45 *Analysis*, *Life Cycle Management*, or *Environmental Impact Assessment*. For consistency with

1 the authorizing statute, DTSC has retained the use of the term “alternatives analysis” used in  
2 Health and Safety Code section 25253(b).

3  
4 For simplicity and harmonization with commonly used life cycle assessment tools, the thirteen  
5 criteria have been grouped, where appropriate, to better align with criteria commonly taken into  
6 account by manufacturers who are faced with balancing choices and making tradeoffs when  
7 re-manufacturing a product to address a consumer or market need or demand. The AA  
8 process in the regulations, while divided into two stages, is consistent with commonly used life  
9 cycle assessment tools and requires:

- 10 • the goal and scope be identified,
- 11 • the relevant factors (i.e. inputs and outputs) for comparison be identified;
- 12 • assessment /comparison of the Priority Product and alternatives; and
- 13 • interpretation and summation of basis for conclusions and recommendations.

14  
15 The First and Second Stage AA, and the corresponding Preliminary and Final AA Reports,  
16 respectively, comprise the process for an evaluation of the availability of potential alternatives  
17 and address the impacts through a multimedia lifecycle evaluation. During the First Stage, the  
18 goal, scope and range of alternatives being considered in the AA must be identified. In the  
19 subsequent Second Stage the relevant factors are refined, compared, and assessed.  
20 Collectively, these processes and the accompanying reports establish the basis for identifying  
21 the most suitable alternative to the Priority Product, if any, and lay the foundation for imposition  
22 of the appropriate regulatory response(s) under Article 6.

23  
24 The First and Second Stage AA, contain five key steps that must be performed in order to  
25 progress to the subsequent step. The First Stage and Preliminary AA Report are intended to  
26 identify and report on existing or potential alternatives; whereas, the Second Stage and Final  
27 AA Report are intended to compare and report on the selected alternative(s). The Preliminary  
28 Report must include an implementation schedule for the Second Stage AA; the Final AA  
29 Report must include an implementation schedule for implementing the selected alternative and  
30 regulatory responses, if applicable.

<b>Table 1. Alternatives Analysis</b>		
<b>CONVENTIONAL AA</b>		<b>ABRIDGED AA</b>
<b>FIRST STAGE</b>	<b>SECOND STAGE</b>	
<b>Step 1:</b> Identification of Product Requirements & Function of Chemicals of Concern.	<b>Step 1:</b> Identification of Factors Relevant for Comparison of Alternatives.	<b>Step 1:</b> Identification of Product Requirements and Function of Chemicals of Concern.
<b>Step 2:</b> Identification of Alternatives.	<b>Step 2:</b> Comparison of the Priority Product & Alternatives	<b>Step 2:</b> Identification of Alternatives.
<b>Step 3:</b> Initial Screening of Alternative Chemicals.	<b>Step 3:</b> Alternative Selection Decision.	<b>Step 3:</b> Initial Screening of Alternative Chemicals.
<b>Step 4:</b> Consideration of Additional Information.	<b>Step 4:</b> Consideration of Additional Information.	<b>Step 4:</b> Identification of Factors Relevant for Comparison of Alternatives.
<b>Step 5:</b> Identification of Next Steps.	<b>Step 5:</b> Identification of Next Steps.	<b>Step 5:</b> Implementation Plan of Applicable Regulatory Responses including but not limited to initiation of research and development pertinent to Priority Product.

1

2 The regulations do not require that a specific alternative be selected, but instead embody the  
 3 goal of the authorizing statute, Health and Safety Code section 25255(a). That provision  
 4 states that the goal of the statute is “significantly reducing adverse health and environmental  
 5 impacts of chemicals used in commerce, as well as the overall costs of those impacts to the  
 6 state’s society, by encouraging the redesign of consumer products, manufacturing processes,  
 7 and approaches.”

8

9 It is anticipated that some alternatives may lend themselves to be quickly adopted and allow  
 10 for concurrent development of the alternative, and addressing other market requirements, such  
 11 as consumer acceptance, and costs while other alternatives will not. It is expected that at the  
 12 completion of the AA Reports, consisting of the Preliminary and Final AA Report, some  
 13 responsible entities will only require six (6) to twelve(12) months for making the alternative  
 14 available in the market place, while others may require twelve(12) to twenty-four (24) months.  
 15 As such, the regulations do not require that the alternative be ready for market distribution at  
 16 the completion of the AA Report, but require that the implementation plan include the  
 17 anticipated period from making the alternative available in the market place, if an alternative is  
 18 selected.

19

20 In addition, given that a functional alternative may not be readily available, the regulations  
 21 accommodate an Abridged AA, which truncates some of the steps in the First and Second  
 22 Stage to instead dedicate the responsible entities’ resources on further research and  
 23 development. The Abridged AA must be submitted by the due date of the pertinent

1 Preliminary AA Report and requires the responsible entity to expeditiously implement one or  
2 more of the regulatory responses until a safer functionally acceptable alternative is available.

#### 3 4 **§ 69505. Guidance Materials**

5  
6 **Section 69505(a)** requires DTSC, prior to finalizing the initial list of Priority Products under  
7 section 69303.3, to make available on its website guidance materials to assist persons in  
8 performing AAs that comply with Article 5. DTSC must periodically revise and update the AA  
9 guidance materials. This provision is necessary to require DTSC to provide technical guidance  
10 and assistance to parties that will be conducting AAs and preparing AA Reports. Without this  
11 provision, entities that become subject to the requirement to conduct an AA, and submit the  
12 related reports, will have insufficient time or ability to do so in a manner that complies with the  
13 regulations. Since this is a brand new endeavor for most all regulated entities, DTSC's  
14 guidance is essential to ensuring that the AAs are performed and reported on in a manner that  
15 is timely and in compliance with the regulations.

16  
17 **Section 69505(b)** requires that DTSC post on its website AAs that are available in the public  
18 domain, at no cost, and that are supported by "reliable information", as defined. The posting  
19 must indicate the name of the entity that prepared the AA. This provision is necessary to  
20 require DTSC to make available easily accessible AAs for consumer products that responsible  
21 entities may wish consider as they undertake their own AAs. As with the immediately  
22 preceding provision, this provision is necessary to allow for thoughtful, comprehensive, and  
23 appropriate AAs to be performed and reported on to DTSC in a timely manner.

#### 24 **§ 69505.1. Alternatives Analysis: General Provisions**

25 **Section 69505.1**, in its entirety, establishes the general provisions applicable to responsible  
26 entities that are subject to the AA requirements, and the persons who execute or manage the  
27 execution of the AA and the preparation of the corresponding reports. The Preliminary AA  
28 Report must be submitted to DTSC 180 days after the Priority Product is listed as such, unless  
29 DTSC specifies a different due date in the final Priority Products list. The Final AA report must  
30 be submitted to DTSC no later than 12 months after DTSC issues a notice of compliance for  
31 the Preliminary AA Report. A responsible entity, or person on their behalf, may request a one-  
32 time 90 day extension, on either or both the Preliminary and Final AA Report.

33  
34 Persons who execute or lead the execution of AAs must possess specified educational and  
35 profession requirements. On and after January 1, 2016, persons executing AAs must be  
36 certified by an accreditation body, as specified in Article 8. A responsible entity may submit a  
37 report previously prepared or a report prepared through a consortia that can be supplemented  
38 with additional information to be substantively equivalent to the Final AA report requirements.  
39 A responsible entity may choose not to perform an AA, but may instead elect to reformulate or  
40 redesign a Priority Product so that the addition of a new chemical is not necessary, but must  
41 submit a Chemical Removal Notification to DTSC by the date the Preliminary AA Report is  
42 due. Finally, the section provides that the requirements of Article 5 do not apply to products

1 that the responsible entity chooses to not place in the California market or to products that  
2 meet the Alternatives Analysis Threshold Exemption.

3  
4 **Section 69505.1(a)(1) and (2)** provide that all references in Article 5 to "Priority Product" mean  
5 the product, component(s) or homogenous material(s), unless otherwise specified, that is/are  
6 the basis for the product being listed as a Priority Product under Article 3. This provision is  
7 necessary to make clear that any use of the term "Priority Product" is the naming convention  
8 for the product, component or homogenous material that is the basis for the listing that is  
9 subject to the requirements under Article 5. A reference to a "product" means the product as a  
10 whole and not a distinct component. This provision allows DTSC to avoid unnecessary  
11 redundancy in describing the Article that is subject to the AA requirement.

12  
13 **Section 69505.1(b)** specifies two conditions under which the requirements of Article 5 do not  
14 apply. The requirements of Article 5 do not apply if:

- 15 (1) the Priority Product is no longer placed into the stream of commerce in California, or;  
16 (2) the Priority Product contains a Chemical of Concern at the alternative analysis threshold  
17 exemption criteria.

18  
19 The provision provides a necessary and logical exemption to the requirements of Article 5 if  
20 the responsible entity elects to no longer introduce the Priority Product into California  
21 commerce, or if the Chemical of Concern is at a concentration DTSC has determined is not of  
22 priority.

23  
24 **Section 69505.1(b)(1)** specifies that if a Priority Product is no longer placed into the stream of  
25 commerce in California by any person on and after the date that the product is listed as a  
26 Priority Product the responsible entity is exempt from the requirements of Article 5. This  
27 provision is necessary to make explicit that a responsible entity of a Priority Product that is not  
28 introduced into the state of California is not subject to the requirements.

29  
30 **Section 69505.1(b)(2)** specifies that a product that meets the alternative analysis threshold  
31 exemption criteria, specified in section 69503.4, is exempt from the requirements of Article 5.  
32 A responsible entity must submit a complete and timely alternative analysis exemption  
33 notification to DTSC that meets the requirements of section 69503.5, unless subsection (d) or  
34 (e) of section 69503.5 applies, in order to be eligible for the exemption. This provision is  
35 necessary to make explicit that a responsible entity of a Priority Product that contains a  
36 Chemical of Concern at the AA Threshold exemption criteria, and who submits the required  
37 notification documentation, is not subject to the requirement to conduct an AA.

38  
39 **Section 69505.1(c)(1)** specifies that the requirements of Article 5 applicable to a responsible  
40 entity may be fulfilled by the responsible entity, or by a person acting on behalf of or in lieu of  
41 the responsible entity. This provision provides the appropriate latitude to responsible entities  
42 for conducting the analysis in-house or through contract with a consultant acting on behalf of  
43 the responsible entity in complying with the requirements of Article 5.

1 **Section 69505.1(c)(2)** specifies that, except as provided in sections 69505.1(b),(f) and (g), a  
2 responsible entity for a product that contains one or more Chemical of Concern that is the  
3 basis for designation as a Priority Product shall conduct an AA for the Priority Product, and  
4 shall comply with all applicable requirements of Article 5. This section explicitly identifies the  
5 conditions that trigger a response by the responsibility entity to be in compliance with the  
6 requirements of Article 5.

7  
8 **Section 69505.1(c)(3)** requires a responsible entity, subject to the requirements of section  
9 69305.1 (c)(2), or a person fulfilling these requirements on behalf of, or in lieu of, the  
10 responsible entity, to prepare, sign and submit to DTSC a Preliminary AA Report and a Final  
11 AA Report. These reports must meet the requirements of section 69505.5, as further specified  
12 in section 69505.1(b)(3)(A), (B) or (C). This provision, along with the sections it references,  
13 specifies the time tables, process and deliverables for fulfillment of the AA requirements and  
14 ensures compliance.

15  
16 **Section 69505.1(c)(3)(A)** requires the Preliminary AA Report to be submitted no later than 180  
17 days following the date that the applicable final Priority Products listing is posted on DTSC's  
18 website, unless DTSC specifies a different due date for the product in the Priority Products list  
19 as provided in section 69503.3(a)(1)(D). Specifying a due date for the Preliminary AA Reports  
20 is necessary to ensure that: responsible entities know how long they have to submit the  
21 Preliminary AA Report; the AA process proceeds on a timely basis; and to put all responsible  
22 entities on a level playing field. Based on the information required to be included in the  
23 Preliminary AA Report, under section 69505.3, 180 days will, in most cases, provide a  
24 sufficient amount of time for preparation time of the Preliminary AA Report. An extension  
25 process is provided in section 69505.1(c)(1) to address those unusual situations for which one  
26 180 days is not adequate.

27  
28 As reflected in Table 2, below, the provisions contained in Articles 2 and 3, dictate an 18  
29 month period from the time the regulations are adopted and that provides signals to the market  
30 of the Chemicals of Concern and the products that they are contained in. Thirty (30) days after  
31 the effective date of the regulations DTSC will notice the first list of Chemicals of Concern.  
32 Manufacturers of products that contain any of the Chemicals of Concern can begin to asses:  
33 the quantities used in the products they manufacture; (2) whether the Chemical of Concern is  
34 necessary in the product and (3) alternatives to the Chemical of Concern.

35  
36 180 days after the effective date of the regulations, DTSC will identify products that contain the  
37 Chemicals of Concern and issue a public notice listing Priority Products. After a 45 day public  
38 comment period, DTSC will review the input received and finalize the Priority Products List of  
39 products that will require an Alternatives Analysis. If after public input, DTSC determines that  
40 a longer preparation time for the Preliminary AA is warranted, DTSC will include in its final  
41 Priority Products list the applicable time period for submittal of the Preliminary AA Report for  
42 the products listed.

1 **Table 2 - Timelines**

		2	
Signals to the Market Place (18 mo. or 1.5 yr. +)	}	30 days after SCP regs DTSC notices final Chemical of Concern list	3
		180 days after SCP regs DTSC notices draft Priority Product List	4
		45 days, <b>minimum</b> , Public Comment Period	5
		275 days to Final Chemical of Concern/PP List <sup>14</sup>	6
1030 Days 2.82 yrs.	}	<b>180 days after Chemical of Concern/PP list final - Preliminary AA</b>	7
		<b>60 days to review</b>	8
		<b>365 days after PAA is approved -Final AA</b>	9
		<b>60 days to review</b>	10
		<b>365 days after FAA is approved - Regulatory Responses</b>	11

12 The provisions of section 69505.1(b)(3)(A) are necessary to provide DTSC and responsible  
 13 entities the needed latitude in establishing the appropriate submittal timeframe for the  
 14 Preliminary AA Report. DTSC needs to be able to consider facts and circumstances that make  
 15 the default time frame of 180 days inappropriate. These facts and circumstances include, but  
 16 are not limited to, the complexity of the Priority Product being evaluated. A draft Priority  
 17 Product listing will be made available on DTSC’s website and will be subject to public input.  
 18 As such, responsible entities will be informed of the products being considered for evaluation  
 19 before they are listed and will have the opportunity to provide input in extending the due date  
 20 for the preliminary AA. In most instances the draft Priority Product list will be made available at  
 21 least 12 months before the list is final giving responsible entities ample time to begin collecting  
 22 information in the event that its product is listed in the final Priority Product list.

23  
 24 **Section 69505.1(c)(3)(B)** requires the Final AA report to be submitted no later than twelve (12)  
 25 months after the date DTSC issues a notice of compliance for the Preliminary AA Report,  
 26 unless DTSC grants an extension under other provisions cited. Specifying a due date for the  
 27 Final AA Report is necessary to ensure that:

- 28 • the responsible entities know the time frame for submitting the Final AA Report;
- 29 • responsible entities are kept on a level playing field; and
- 30 • the AA process is completed on a timely basis.

31  
 32 However, the provision also provides the necessary latitude for DTSC to grant an extension to  
 33 the submittal of the Final AA Report. This provision establishes a set time frame for submitting  
 34 the final AA, but also provides flexibility to accommodate more complex Priority Products that  
 35 require additional time in finalizing the Final AA report. Because entities are not required to fill  
 36 the data gaps associated with an alternative chemical under consideration 12 months or an  
 37 extension to 24 months is ample time to compile existing information and summarize its  
 38 findings.

---

<sup>14</sup> Estimated 9 month period for review and research of comments submitted, substantive changes may require additional 45-day comment period.

1 **Section 69505.1(c)(3)(C)** specifies that for a Priority Product that is *first* placed into the stream  
2 of commerce in California *after* the date the product is listed as a Priority Product, the  
3 Preliminary AA Report is due no later than 180 days after the product is first placed into the  
4 stream of commerce in California. This provision captures Priority Products that were not  
5 subject to the Priority Products List because they were not in the California stream of  
6 commerce at the time the list was published. The provision specifies an appropriate and  
7 comparable time frame applicable to other responsible entities for preparing and submitting a  
8 Preliminary AA Report to DTSC.

9  
10 **Section 69505.1(d)(1)** allows a responsible entity, or a person fulfilling the requirements of  
11 Article 5 for the responsible entity, to request a one-time, ninety (90) day extension to the  
12 deadline for the Preliminary or Final AA Report, or both. The extension request must be based  
13 on circumstances that could not reasonably be anticipated or controlled by the responsible  
14 entity. Any extension request must be received by DTSC no later than sixty (60) days before  
15 the applicable due date for the Preliminary or Final AA Report. This provision provides the  
16 appropriate latitude to DTSC to accommodate reasonable and justified requests for a time  
17 extension for completing Preliminary or Final AA Report, or both. The requirement to submit  
18 the request no later than sixty (60) days before the due date is necessary to provide DTSC  
19 with enough time to evaluate and reply to the request in a meaningful time frame. While longer  
20 than 60 days would be preferable, 60 days was chosen as the most workable for responsible  
21 entities and DTSC. In some cases, the circumstances necessitating an extension might not  
22 arise or be known until this late in the process.

23  
24 **Section 69505.1(d)(2)(A) through (G)** specifies that an extension request must include all of  
25 the following:

- 26 **(A)** The name of, and contact information for, the person filing the extension request;  
27 **(B)** The name of, and contact information for, the responsible entity(ies) on whose behalf the  
28 Preliminary and Final AA Reports will be submitted;  
29 **(C)** If different from subparagraphs (A) and (B), the name of, and contact information for, the  
30 manufacturer and the importer, if applicable, of the product;  
31 **(D)** Information identifying and describing the Priority Product and, if applicable, the  
32 component(s) or homogeneous materials(s) and its/their associated components(s) subject  
33 to the AA requirement, including the brand name(s) and product name(s) under which the  
34 Priority Product is placed into the stream of commerce in California;  
35 **(E)** The due date for the Preliminary or Final AA Report, as applicable;  
36 **(F)** The amount of additional time requested, not to exceed ninety (90) days; and  
37 **(G)** The reason the extension is needed, including an explanation as to why the circumstances  
38 necessitating the extension could not reasonable be anticipated or controlled by the  
39 responsible entity.

40  
41 These provisions ensure each extension request includes all of the information necessary for  
42 DTSC to:

- 43 • get in contact with the requesting entity, if necessary;
- 44 • appropriately consider the request; and
- 45 • evaluate whether a time extension is warranted.

1  
2 **Section 69505.1(d)(3)** requires DTSC to approve or deny, in whole or in part, an extension  
3 request within thirty (30) days of receipt, and to notify the person submitting the extension  
4 request of its decision. Failure by DTSC to issue a decision within thirty (30) days does not  
5 constitute an approval of the extension request. This provision confers appropriate latitude for  
6 DTSC to grant or deny the extension request to the extent warranted. It is also necessary to  
7 ensure that the request is responded to in a timely manner, while providing a sufficient amount  
8 of time for DTSC to review the contents and basis for the extension request and make a  
9 determination. Additionally, as stated above, placing a limit on the maximum extension time  
10 allowed is necessary to prevent extension requests from being used as a mechanism to  
11 indefinitely delay the AA process. Finally, this provision is necessary to that inadvertent error  
12 or delay by DTSC in responding to the request does not inappropriately result in an extension  
13 being granted.

14  
15 **Section 69505.1(e)** requires that all AAs performed and Preliminary and Final AA Reports  
16 submitted two years after the effective dates of the regulations shall be prepared by, or under  
17 the responsible charge of, one or more assessor(s) certified under Article 8 for the appropriate  
18 product type or industry sector. This provision ensures that AAs performed and AA Reports  
19 prepared meet an appropriate level of rigor and competency before being submitted to DTSC  
20 for review and approval. The phase-in date for this requirement ensures that the capacity for  
21 this type of work and the related certification process can occur. Under section 69505, DTSC  
22 must create the tools and guidance materials for complying with Article 5 requirements prior to  
23 finalizing the initial Priority Products list.

24  
25 DTSC anticipates an eighteen (18) month period from the date the regulations are adopted to  
26 the finalization of the first Priority Product list, and will simultaneously develop the guidance  
27 materials and tools necessary to complete an AA. The eighteen months include the draft  
28 Priority Product list, one 45-day public comment period, DTSC's review of the comments  
29 submitted and public noticing of the final Priority Product list. That will work to ensure the rigor  
30 and competency of the AAs until this requirement becomes applicable. DTSC will concurrently  
31 coordinate with USEPA and other technical consultants to review and approve accreditation  
32 body applications, develop and amend, as appropriate, curriculum and challenge tests prior to  
33 the date upon which work must be done by certified assessors.

34  
35 **Section 69505.1(f)** provides that a responsible entity, in lieu of performing a new AA and  
36 submitting a Preliminary and Final AA Report, may instead submit a report for a previously  
37 completed AA for the Priority Product or a report prepared through a consortium. The report  
38 must be substantially equivalent to the requirements for AA reports set out in section 69305.5  
39 and the report must contain sufficient information to identify the most appropriate regulatory  
40 response under Article 6. This provision makes allowances and recognizes the body of work  
41 that already exists, and will exist, regarding safer alternatives for certain chemicals and/or  
42 products. This provision provides clarity and latitude to responsible entities to use existing  
43 information to the extent suitable to expedite the quest for safer products.

1 **Section 69505.1(f)(1)** requires a report for a previously completed AA being submitted under  
2 section 69305.1(e) to be provided to DTSC no later than 180 days following the date that the  
3 applicable final Priority Products listing is posted on DTSC’s website. This section further  
4 specifies that a one-time extension may be requested under section 69305.1(c). This time line  
5 is consistent with the timeline for submitting a Preliminary AA Report if a new AA were being  
6 performed. Specifying a due date for submitting a report for a previously performed AA is  
7 necessary to ensure that: responsible entities know how long they have to submit Reports for  
8 previously prepared AAs; to keep responsible entities on a level playing field; and the AA  
9 process proceeds on a timely basis. In most cases, one hundred and eighty (180) days will  
10 provide a sufficient amount of time for submitting a report for a previously conducted AA, even  
11 if the report needs to be supplemented as specified in section 69305.1(e)(2). An extension  
12 process is provided in section 69305.1(b) to address those unique situation for which one  
13 hundred and eighty (180) days is not adequate.  
14

15 **Section 69505.1(f)(2)** specifies that a responsible entity submitting an existing report, under  
16 section 69305.1(e), may submit supplemental information to render the report substantially  
17 equivalent to the requirements of section 69505.5. This provision makes allowances for  
18 existing reports that may differ from the specific requirements of section 69505.5, but in a  
19 manner that such differences can be easily remedied with additional information. This  
20 provision also establishes an efficient and cost effective option for meeting the requirements  
21 and intent of Article 5 and the authorizing statute.  
22

23 **Section 69505.1(g)** allows a responsible entity to reformulate and remove the chemical(s) of  
24 concern after the Priority Product has been listed. The reformulated product, however, may  
25 not contain any Chemical of Concern or a substitute chemical. It further specifies that a  
26 responsible entity that elects to reformulate or redesign or replace the Priority Product shall  
27 submit a Chemical Removal Notification to DTSC before placing the reformulated, redesigned  
28 or alternative product into the stream of commerce in California. This provision provides  
29 responsible entities an incentive to elect to remove Chemical(s) of Concern that are not  
30 necessary for the product performance or function or when a readily available safer alternative  
31 exists without being required to undergo the process of conducting an AA. The provision  
32 allows reformulations, redesigns, or replacements to occur without unnecessary DTSC  
33 oversight when the revised product poses no risk of a “regrettable substitute”.  
34

35 **Section 69505.1(g)(1)** requires a responsible entity submitting a Chemical of Concern  
36 Removal Notification under this subsection to submit the notification no later than the deadline  
37 for submitting the Preliminary AA Report under section 69505.1(c)(3)(A). This provision makes  
38 specific the deadline for submitting a Chemical of Concern Removal Notification and is the  
39 same due date for the Preliminary AA Report. This provision affords responsible entities an  
40 opportunity to remove the Chemical of Concern from the Priority Product up until the deadline  
41 for submitting the Preliminary Report and thus no longer being subject to additional  
42 requirements.  
43

44 **Section 69505.1(g)(2)** requires the Chemical of Concern Removal Notification must include all  
45 of the following:

- 1 (A) The name of, and contact information for, the person submitting the notification;  
2 (B) The name of, and contact information for, the responsible entity(ies) on whose behalf the  
3 notification is being submitted;  
4 (C) If different from subparagraphs (A) and (B), the name of, and contact information for, the  
5 manufacturer and the importer of the product;  
6 (D) Information identifying and describing the original product and the reformulated product,  
7 including the brand name(s) and labeling information for both products;  
8 (E) The intended uses, and targeted customer base(s), for the product and the reformulated  
9 product;  
10 (F) The measures the responsible entity will take to ensure the product that contained the  
11 Chemical(s) of Concern is no longer placed into the stream of commerce in California; and  
12 (G) The Chemical(s) of Concern removed from the product, and both of the following:  
13 1. Information explaining the rationale and the factors considered in selecting the  
14 reformulation; and  
15 2. Laboratory analytical testing, quality control, and quality assurance protocols used to  
16 detect and measure the Chemical(s) of Concern in the product that ensures the  
17 Chemical(s) of Concern have been removed.  
18

19 This provision makes specific the information that must be provided to DTSC in a Chemical of  
20 Concern Removal Notification. More specifically, the responsible entity needs to know what is  
21 required for a complete submittal. And it is necessary for DTSC to have the prescribed  
22 information so that it can get in touch with the entity submitting the information if necessary  
23 and to make an informed evaluation of the information.  
24

25 **Section 69505.1(h)** requires any person performing an AA to consider all relevant information  
26 made available on DTSC's website and any additional information or technical assistance  
27 DTSC may provide regarding alternatives analysis. These efforts must be summarized in the  
28 AA Report. This provision is necessary to ensure that a responsible entity does not, knowingly  
29 or unknowingly, fail to utilize and take into consideration existing information that may be  
30 relevant to conducting an AA for a Priority Product.  
31

32 **Section 69505.1(i)**, specifies that DTSC's failure to make a compliance determination within  
33 60 days of receipt of the applicable document, or failure of the Director to respond to an appeal  
34 under Article 7 within 60 days, does not result in the AA Work Plan or AA Report being  
35 deemed in compliance with Article 5. This prevents the de facto, and potentially harmful,  
36 approval of a Preliminary or Final AA Report that does not comply with the applicable  
37 requirements of Health and Safety Code section 25253, or Article 5, in the event DTSC is  
38 unable to act within the 60-day time period due to resource limitations or other reasons.  
39

## 40 **§ 69505.2. Analysis of Priority Products and Alternatives**

41

42 **Section 69505.2**, specifies the general procedural steps that a responsible entity must follow  
43 to comply with the requirements of Article 5. A responsible entity must conduct an AA  
44 following the processes set out in sections 69505.3 and 69505.4 for a first and second stage  
45 AA, respectively. This must then be followed by the preparation of a Preliminary and Final AA

1 Report under section 69505.5. But a responsible may elect to use an Alternate AA process. A  
2 responsible entity electing to use and Alternate AA process must submit an AA work plan to  
3 DTSC for review. It must contain sufficient information to: demonstrate that the alternate  
4 process will meet the substantive requirements of sections 69505.3 and 69505.4 and for DTSC  
5 to establish the submittal date for the Final AA report.

6  
7 If after completion of the Final AA Report and prior to introducing the selected alternative into  
8 the market place, a responsible entity selects a different alternative the responsible entity must  
9 notify DTSC and submit a revised Final AA Report that identifies the differences between the  
10 two alternatives and rationale for the new selection. The revised Final AA report must be  
11 submitted 60 days prior to the introduction of the new alternative into the market place.

12 A final option available to responsible entities is the use of an Abridged AA Report. If after  
13 completion of the first stage AA, a responsible entity determines a functionally acceptable  
14 alternative is not available or feasible, the responsible entity may prepare and submit an  
15 Abridged AA Report. The Abridged AA Report must summarize the first stage AA findings  
16 under section 69505.5 and section 69505.4(a) of the second stage and summarize the findings  
17 under section 69505.5 in the Abridged AA Report. The use of the Abridged AA allows a  
18 responsible entity to move into the appropriate regulatory responses to limit or reduce any  
19 potential adverse impacts until a safer alternative is adequately researched and developed.

20  
21 **Section 69505.2(a)(1)** requires that the AA being performed under section 69505.1(c)(2) be  
22 conducted in two stages, as specified in section 69505.3 for first stage and section 69505.4 for  
23 second stage. This provision requires that responsible entities adequately assess and scope  
24 the breadth of the assessment that they plan to undertake, and submit it to DTSC for review  
25 before undertaking the second and final stage. It is necessary to have the Preliminary AA,  
26 including its work plan, be adequate to ensure that the AA and the AA Report will provide  
27 sufficient detail to support the selection of an alternative, or a decision to retain the existing  
28 Priority Product in lieu of an alternative, and selection of the appropriate regulatory  
29 response(s), if any, upon completion of the AA.

30  
31 **Section 69505.2(a)(2)** requires the responsible entity to complete the first stage of the AA, and  
32 submit a Preliminary AA Report within 180 days from the date the Priority Product was listed  
33 unless a different time is specified in the Priority Product listing. The Preliminary AA Report  
34 must include the contents specified in section 69505.5 and must be submitted for review as  
35 specified in section 69505.1(c)(3)(B). This provision establishes the content requirement and  
36 the time frame for completion of the first stage of the AA.

37  
38 **Section 69505.2(a)(3)** requires the responsible entity to complete the second stage of the AA,  
39 and submit a Final AA Report within 12 months from the date the preliminary AA is issued a  
40 notice of compliance unless DTSC has granted an extension. The Final AA Report must  
41 include the contents specified in section 69505.5. This provision ensures that responsible  
42 entities complete the second stage of the assessment in an appropriate time frame, and are  
43 required to provide sufficient information for DTSC to review the Final AA Report to determine  
44 whether the assessment complies with Article 5.

1 **Section 69505.2(b)** provides that after completion of the first four (4) steps of the first stage of  
2 the AA, under sections 69505.3(b)(1) through (4), a responsible entity that determines a  
3 functionally acceptable alternative is not available or feasible may prepare and submit an  
4 Abridged AA Report, in lieu of Preliminary and Final AA Reports. This provides appropriate  
5 latitude to the responsible entity conducting the AA and preparing the AA Reports. It also  
6 allows for a more efficient and effective use of DTSC's limited resources by providing for a  
7 more streamlined process while ensuring that key information is reviewed and evaluated by  
8 the responsible entity.

9  
10 **Section 69505.2(b)(1)** requires the responsible entity to summarize in the Abridged AA  
11 Report, the first stage AA findings required under section 69505.5. The first stage findings are  
12 critical in establishing the breadth and scope of the second stage AA, and consequently are  
13 the basis for either electing to submit an Abridged AA or conducting the second stage AA. The  
14 information upon which a responsible entity relied on to make its decision is necessary for  
15 DTSC to have an informed basis for evaluating the decision by the responsible entity.

16  
17 **Section 69505.2(b)(2)** requires the responsible entity to complete the first step of the second  
18 stage AA specified in section 69505.4(a) and summarize in the Abridged AA Report the  
19 findings. The provision in section 69505.2(b)(1), coupled with this provision, document and  
20 explain the relevant findings that establish the basis for a determination that a technically and  
21 economically alternative is not currently available. The Abridged AA Report documents the  
22 critical information gathered during the first and second stage AA that ensures the appropriate  
23 information is gathered to form the decision by the responsible entity. DTSC will use the  
24 information provided to determine if the appropriate decision was arrived at or identify, if  
25 appropriate, that a safer alternative is available in the market place.

26  
27 **Section 69505.2(b)(3)** requires the responsible entity to submit an Abridged AA Report to  
28 DTSC by the due date when the applicable Preliminary AA Report would be due, as specified  
29 in section 69505.1(c)(1)(A). The time period specified is consistent with the Preliminary AA  
30 Report timeframe, to provide consistency in the process so that compliance can be readily met  
31 by the responsible entity regardless of the approach undertaken.

32  
33 **Section 69505.2(b)(4)** specifies that the responsible entity must identify in the Abridged AA  
34 Report the milestones and dates for implementation of proposed regulatory responses, which  
35 must, at a minimum, include the advancement of Green Chemistry and Green Engineering  
36 under section 69506.9. In addition to the requirements under section 69506.9, a responsible  
37 entity may be required to identify other regulatory responses that will be put in place to limit or  
38 reduce exposure to Chemicals of Concern while safer alternatives are being pursued. This  
39 provision allows entities to pursue safer alternatives to a Priority Product while simultaneously  
40 addressing human health and environmental impacts until the safer alternative is introduced  
41 into the market.

42  
43 **Section 69505.2(c)** allows a responsible entity to use an AA process that differs from the first  
44 and second stage AA process if the process and report contents substantially comply with the  
45 requirements contained in the AA Reports under section 69505.5. Allowing responsible

1 entities to use an alternative process to the first and second stage AA process provides much  
2 needed flexibility in using their own existing assessment protocols, if available, and may  
3 reduce duplication of efforts or waste of resources. The alternate process must substantially  
4 meet the information gathering and/or analysis requirements in the first and second stage AA  
5 and be summarized in a Preliminary and Final AA Reports. To ensure compliance with Article  
6 5 requirements, DTSC will review the alternate AA process.

7  
8 **Section 69505.2(c)(1)** specifies that the responsible entity's alternate process must generate  
9 the information needed to prepare an AA Report that substantially meets the requirements of  
10 section 69505.5. The information that must be scoped and evaluated during the first and/or  
11 second stage, or both, must be scoped and evaluated under the alternate process used by the  
12 responsible entity. The information must then be summarized in a Preliminary and/or Final AA  
13 Report. This provision ensures that the scope and rigor of the alternate process substantially  
14 complies with the requirements in Article 5 that would otherwise apply.

15  
16 **Section 69505.2(c)(2)** requires the responsible entity's alternate process to compare the  
17 Priority Product and the alternatives using, at a minimum, the same factors, and, if applicable,  
18 the associated exposure pathways and life cycle segments specified in sections 69505.3 and  
19 69505.4. This provision is necessary to ensure that an alternative process used by a  
20 responsible entity complies with Article 5. This provision ensures that the scope and rigor of  
21 the alternate process substantially complies with the requirements in Article 5 that would  
22 otherwise apply.

23  
24 **Section 69505.2(c)(3)** requires the responsible entity to submit a work plan to DTSC with  
25 sufficient information to demonstrate that the alternate process will meet the requirements of  
26 sections 69505.2(c)(1) and (2), above, and sufficient information for DTSC to specify an  
27 appropriate due date for submittal of the Final AA Report. This provision ensures that prior to  
28 pursuing the alternative process, a responsible entity submit a work plan for DTSC review to  
29 ensure that the scope and rigor of the alternate process substantially complies with the  
30 requirements in Article 5.

31  
32 **Section 69505.2(c)(3)(A)** specifies that if the work plan submitted under 69505.2(b)(3)  
33 includes information for which trade secret protection is claimed, the responsible entity must  
34 also submit a redacted copy of the work plan. This provision ensures that information  
35 submitted to DTSC for compliance with the requirements of this Article is readily available for  
36 public review and does not require DTSC to expend any resources in redacting information  
37 claimed as confidential.

38  
39 **Section 69505.2(c)(3)(B)** requires the work plan submitted under section 69505.2(b)(3) to be  
40 accompanied by an executive summary that conveys to the public a general understanding of  
41 the work plan. The provision ensures that the information submitted to DTSC will be readily  
42 available for review by the public, is written in lay terms and does not require DTSC to expend  
43 any resources in clarifying the work plan.

1 **Section 69505.2(c)(3)(C)** specifies that the work plan for the alternative process must be  
2 submitted to DTSC no later than 60 days after the product is included on the Priority Products  
3 list. For a Priority Product that is first placed into the stream of commerce in California after  
4 the date the product is listed as a Priority Product, the responsible entity must submit the work  
5 plan no later than sixty (60) days after the product is first placed into the stream of commerce  
6 in California. Upon receipt of a work plan under this subsection, DTSC will follow the steps  
7 specified for the review of Preliminary AA Reports set out in section 69505.6(a). This provision  
8 ensures that an alternative process proposed by a responsible entity is evaluated for  
9 compliance with Article 5 requirements prior to the due date for the Preliminary AA Report. In  
10 the event that the determination is made that the alternate process does not meet the  
11 applicable requirements, the responsible entity has sufficient time to follow the process  
12 specified in these regulations without unnecessarily delaying assessment of the Priority  
13 Product. This also requires responsible entities for Priority Products first introduced into the  
14 stream of commerce in California after the publishing of the Priority Products list to submit a  
15 Preliminary Report within 60 days after the product is introduced and have a comparable time  
16 period to prepare and submit an alternate process work plan.

17  
18 **Section 69505.2(c)(3)(D)** specifies that the due date for the Final AA Report of an alternative  
19 process is 18 months after the date DTSC issues a notice of compliance for the work plan,  
20 unless DTSC grants an extension of time. The additional time cannot exceed 30 months from  
21 DTSC's issuance of a notice of compliance for the work plan. This provision ensures that an  
22 alternative process being used by a responsible entity conducting the AA is completed in an  
23 appropriate time frame. Without a deadline tailored to the alternate process there could be too  
24 little or too much time provided for conducting the alternate process AA.

25  
26 **Section 69505.2(c)(4)** specifies that the responsible entity must submit a Final AA Report to  
27 DTSC that substantially meets the requirements of section 69505.5 by the due date specified  
28 by DTSC under paragraph (3). This provision ensures that an alternative process used by a  
29 responsible entity complies with Article 5. That is, it is necessary that the Final AA Report be  
30 submitted in a timely fashion and substantially complies with the substantive requirements  
31 otherwise applicable to those following the conventional AA process.

32  
33 **Section 69505.2(d)(1)** allows a responsible entity to select a different alternative from the one  
34 identified in the Final AA Report submitted to DTSC, if the conditions of sections 69505.2(d)(1)  
35 (A) and (B) are met. This provision takes into account that changed facts or circumstances  
36 may cause some responsible entities to select a different alternative from the one identified in  
37 the Final AA Report. This type of flexibility is necessary to allow for the most appropriate  
38 alternative to be implemented by the responsible entity.

39  
40 **Section 69505.2(d)(1)(A)** requires the responsible entity to submit a revised Final AA Report  
41 that identifies and explains the differences in the information from the original Final AA Report  
42 to the revised Final AA Report. The responsible entity must also identify the information used  
43 to support the revisions to the Final AA Report. This provision allows responsible entities to  
44 adjust to facts and circumstances that warrant or justify a different analysis and/or conclusion  
45 from that reached by the responsible entity in the Final AA Report. It is necessary to have

1 flexibility so that, ultimately, a good outcome is reached—even if it is after the submittal of a  
2 Final AA Report.

3  
4 **Section 69505.2(d)(1)(B)** specifies the revised Final AA Report must be submitted to DTSC  
5 sixty (60) days prior to the introduction of the newly selected alternative. This provision  
6 requires that the responsible entity provide DTSC the appropriate notice and information prior  
7 to introducing an alternative to the Priority Product to prevent responsible entities from  
8 circumventing the process. The time frame specified is consistent with the last review of the  
9 Final AA Report.

10  
11 **Section 69505.2(d)(2)** requires a responsible entity to submit a revised AA Report if the  
12 selection decision in the original Final AA Report was to retain the Priority Product, and the  
13 responsible entity later decides to select an alternative to replace the Priority Product. This  
14 provision ensures that the information used by the responsible entity to substantiate a change  
15 in the final decision is made available to DTSC and the public.

### 16 17 **§ 69505.3. Alternatives Analysis: First Stage**

18  
19 **Section 69505.3**, in its entirety, specifies the process, scope and order for conducting a first  
20 stage alternatives analysis. The principal goal of the first stage and subsequent Preliminary  
21 AA report is to identify all potential alternatives to the Priority Product and eliminate those  
22 alternatives that pose greater aggregate or cumulative public health and environmental  
23 impacts than the Chemical of Concern. The first stage and subsequent Preliminary AA Report  
24 involves the gathering, organizing, and evaluating of the scientific and technical information  
25 necessary to decide whether a particular alternative is likely to constitute a potential  
26 alternative. The relevant information about an alternative is assembled for subsequent  
27 thorough evaluation in the second stage or Final AA Report. Under section 69503.2, one of  
28 the key prioritization factors to list a Priority Product is based on the Chemical of Concern's  
29 ability to cause adverse human health and environmental impacts. As such, alternatives to  
30 Priority Products must be preferable to the Priority Product and be evaluated first for their  
31 potential human health and environmental impacts. Other factors such as performance,  
32 consumer preference and economic impacts are, therefore, not evaluated as part of the first  
33 stage analysis. Those factors are deferred until the second stage when alternatives have been  
34 "short listed" for further consideration.

35  
36 **Section 69505.3(a)** specifies that all references to "Chemical(s) of Concern" mean the  
37 Chemical(s) of Concern that is/are the basis for the product being included on the Priority  
38 Products list. This provision clarifies the scope of what is captured by the use of the term  
39 "Chemicals of Concern" throughout the rest of Section 69505.3.

40  
41 **Section 69505.3(b)** requires the first stage of the AA to include the four steps specified in  
42 section 69505.3(b)(1) through (4). This provision establishes a sequential process for  
43 conducting the first stage of an AA and guides those conducting AAs in the manner in which  
44 the AA is to be performed. This provision ensures consistency in the information that is

1 gathered, evaluated and subsequently reported on thus limits the variability in the information  
2 that is submitted so that it can be appropriately reviewed and audited.

3  
4 **Section 69505.3(b)(1)** requires the *Identification of Product Requirements and Function of the*  
5 *Chemical of Concern* as the first step in the AA. This provision makes specific the first criterion  
6 that a responsible entity must take into account in evaluating alternatives for the Priority  
7 Product. Product requirements and the function or role that the Chemical(s) of Concern plays  
8 in the Priority Product is fundamental to knowing the alternatives that can or cannot be  
9 considered.

10  
11 **Section 69505.3(b)(1)(A)** requires that in identifying the product criteria the responsible entity  
12 must identify the function, performance, and legal requirements associated with the Priority  
13 Product that must be met by the alternatives being considered. This provision makes specific  
14 that in identifying and evaluating alternatives to the Priority Product the function, performance,  
15 technical feasibility, and legal requirements must be considered, evaluated and reported. The  
16 product function and related information serves as the basis in identifying viable alternatives.

17  
18 **Section 69505.3(b)(1)(B)** requires that in identifying the product criteria the responsible entity  
19 must identify the function of the Chemical(s) of Concern in meeting the Priority Product's  
20 function, performance, technical feasibility, and legal requirements. This provision ensures  
21 that responsible entities will evaluate, and later summarize in the Preliminary AA Report, the  
22 role of the Chemical of Concern in meeting the performance, technical feasibility, and legal  
23 requirements of a Priority Product to adequately evaluate potential alternatives. This  
24 information ensures an informed and appropriate comparison of the Chemical(s) of Concern  
25 and potential alternatives in meeting product function criteria.

26  
27 **Section 69505.3(b)(1)(C)1.** requires the responsible entity to determine if the Chemical(s) of  
28 Concern or substitute chemical(s) is/are necessary to meet the Priority Product's function,  
29 performance, technical feasibility, and legal requirements. This provision forces a responsible  
30 entity to evaluate and later summarize in the Preliminary AA Report whether the Chemical(s)  
31 of Concern or a substitute chemical is necessary to meet the function, performance, technical  
32 feasibility, and legal requirements of the Priority Product or any alternative that is being  
33 considered. An evaluation of the role the Chemical(s) of Concern play in the Priority Product is  
34 critical in identifying alternatives that play the same role however with less public health and  
35 environmental impacts. The determination of whether a Chemical of Concern is necessary is  
36 left up to the responsible entity; however, the rationale must be documented in the Preliminary  
37 and Final AA Report.

38  
39 **Section 69505.3(b)(1)(C)2.** requires that if the responsible entity determines that neither the  
40 Chemical(s) of Concern nor substitute chemical(s) is/are necessary to meet the Priority  
41 Product's function, performance, technical feasibility, and legal requirements, the responsible  
42 entity must evaluate as one of the alternatives to the Priority Product the removal of the  
43 Chemical(s) of Concern from the Priority Product without the addition of substitute chemical(s).  
44 This provision ensures that after determining that the neither the Chemical of Concern nor a  
45 substitute chemical is necessary, the responsible entity must consider evaluating the removal

1 of the Chemical of Concern without adding a different chemical. By requiring that an  
2 alternative without a substitute chemical be considered a comparison of tradeoffs can be  
3 evaluated.

4  
5 **Section 69505.3(b)(2)** requires the *Identification of Alternatives* as the second step in the AA.  
6 This provision ensures that after completing step 1, the responsible entity further evaluates the  
7 alternatives that meet the product's function and/or performance as part of Step two.

8  
9 **Section 69505.3(b)(2)(A)1.** requires that in addition to the evaluation of an alternative  
10 identified under section 69505.3(b)(1)(C)2., if applicable, the responsible entity must also  
11 identify other alternatives, as defined in section 69501.2(a)(11) that meet the product criteria  
12 identified under section 69505.3(b)(1)(A) for the Priority Product and that eliminate or reduce  
13 the concentration of the Chemical(s) of Concern in the Priority Product and/or reduce or restrict  
14 exposures to the Chemical(s) of Concern in the Priority Product. This provision ensures that  
15 the Preliminary Analysis will evaluate all alternatives that remove or reduce the amount of  
16 Chemical(s) of concern and/or reduce public health and environmental impacts and still meet  
17 the Priority Product's function performance technical feasibility and legal requirements.

18  
19 **Section 69505.3(b)(2)(A)2.** requires the responsible entity to research and take into account  
20 available information that may identify existing viable alternatives, for consideration in the AA,  
21 including information posted on DTSC's website under section 69505(b). This provision  
22 ensures that the preliminary assessment evaluates all existing alternatives that could be  
23 evaluated to remove or reduce the amount of chemical(s) of concern in a product. The AA  
24 must take into account existing and available relevant information to have a credible and  
25 valuable AA performed.

26  
27 **Section 69505.3(b)(2)(B)** specifies that alternatives that do not involve the addition of a  
28 substitute chemical do not require completion of step 3, Initial Screening of Chemicals. This  
29 provision makes specific that if a chemical substitute is not being considered, the screening of  
30 chemical substitutes is not necessary. For obvious reasons a responsible entity meeting the  
31 specified circumstances can proceed with step 4 of stage one.

32  
33 **Section 69505.3(b)(3)** requires the *Initial Screening of Alternative Chemicals* as the third step  
34 in the AA for those alternatives being considered that involve substituting the Chemical(s) of  
35 Concern with other chemical(s). This provision makes specific that for the alternatives that  
36 include replacement of a Chemical of Concern with another chemical, the Preliminary AA must  
37 include a comparison of the chemical's adverse public health and environmental impacts  
38 associated with each chemical being considered as a possible alternative to the Chemical(s) of  
39 concern in the Priority Product.

40  
41 **Section 69505.3(b)(3)(A)** requires the responsible entity to collect and use available  
42 information on hazard traits, toxicological and environmental endpoints and any other relevant  
43 data to identify for each chemical alternative being considered the impacts as specified in  
44 sections 69505.3(b)(3)(A)1. through 5. which include:

- 45     1. Adverse public health impact,

- 1       2. Adverse environmental impacts,
- 2       3. Environmental fate,
- 3       4. Physical chemical hazards, and
- 4       5. PhysiChemical of Concern chemical properties.

5  
6 This provision makes specific that for the alternatives that include replacement of a Chemical  
7 of Concern with another chemical, the Preliminary AA must include a comparison of the criteria  
8 specified in 1. through 5. The above criteria are crucial in evaluating chemicals for incremental  
9 improvements in one or more of the criteria. Chemical alternatives exhibiting an improvement  
10 in one or more of the criteria will naturally rise to the top for further evaluation.

11  
12 **Section 69505.3(b)(3)(B)** requires the responsible entity to compare the alternative chemicals  
13 being considered against the Chemical(s) of Concern in the Priority Product, using the  
14 information collected and evaluated under subparagraph (A). This provision ensures that the  
15 alternatives that rose to the top for incremental improvements are further evaluated by the  
16 responsible entity in subsequent phases of the AA.

17  
18 **Section 69505.3(b)(3)(C)** requires the responsible entity to eliminate from further  
19 consideration in the AA any alternative chemical(s) that the responsible entity determines  
20 poses equal or greater adverse public health and/or environmental impacts than the  
21 Chemical(s) of Concern. A chemical alternative that poses greater adverse public health  
22 and/or environmental impacts than the Chemical(s) of Concern should not be accorded further  
23 unnecessary consideration. A responsible entity may retain for further consideration  
24 chemical(s) that demonstrate less aggregate or cumulative impacts relative to the Chemical(s)  
25 of Concern. This provision is necessary to appropriately exclude from further consideration  
26 alternatives that are no better than the current Chemical of Concern in the Priority Product. It  
27 is also necessary in order to provide responsible entities latitude to further consider and  
28 evaluate alternatives that may represent an improvement in one of the hazard traits in  
29 comparison to that of Priority Product or Chemical of Concern that they are seeking to replace.

30  
31 **Section 69505.3(b)(4)** allows the *Consideration of Additional Information* as step four of the  
32 first stage of the AA. More specifically, a responsible entity may consider other relevant  
33 information and data not specifically requested or identified in section 69505.3(a)(1) through  
34 (3) and may include factors being considered in the second stage of the AA as part of its  
35 evaluation in the first stage AA. This provision provides responsible entities latitude in  
36 considering other factors that they consider relevant and significant in identifying viable  
37 alternatives.

38  
39 **Section 69505.3(b)(5)** requires the *Identification of Next Steps* as the fifth step of the first  
40 stage AA. The responsible entity must prepare and submit:

- 41 (A) a work plan and proposed implementation schedule for completion of the second stage  
42 AA, as specified in section 69505.4, and preparation and submittal of the Final AA Report;  
43 and
- 44 (B) a Preliminary AA Report.

1 This provision ensures that responsible entities prepare and submit a work plan and a  
2 Preliminary AA Report that contains the planning for completion of the second stage and Final  
3 AA Report. The information gathered and evaluated in the first stage AA and documented in  
4 the Preliminary AA Report will establish the scope of the second stage AA and Final AA  
5 Report.

#### 7 **§ 69505.4. Alternatives Analysis: Second Stage**

9 **Section 69505.4** in its entirety specifies the process, scope and order in conducting the  
10 second stage of the AA. The principal goal of the second stage and subsequent Final AA  
11 Report is to further evaluate the alternatives identified in the first stage. The second stage and  
12 companion Final AA Report requires the collection and use of available information and tools  
13 to identify the relevant factors and evaluate those factors to qualify or quantify the impacts  
14 posed by the alternatives being evaluated. The second stage simultaneously addresses the  
15 thirteen A-M criteria set out in statute and the multimedia lifecycle factors called for in statute.  
16 This section makes specific to responsible entities the procedural requirements and  
17 expectations in completing a second stage AA, after having completed the first stage of the  
18 AA.

20 **Section 69505.4(a)** requires the *Identification of Factors Relevant for Comparison of*  
21 *Alternatives* as the first step in the second stage of the AA. This provision requires that the  
22 responsible entity identify the factors that are relevant for comparison for the Priority Product  
23 and the alternatives being considered. It goes on to specify which factors are relevant. This is  
24 described in further detail below.

26 **Section 69505.4(a)(1)(A)** specifies that a factor is relevant if it would meet the criteria  
27 specified in 69505.4. (a)(1)(A) 1. and 2. This provision makes specific the criteria that make a  
28 factor relevant for comparison, and, is thus required to be identified. These factors are  
29 described in greater detail immediately below.

31 **Section 69505.4(a)(1)(A) 1.** provides one factor for determining a factor is relevant is that it  
32 makes a demonstrable contribution to the adverse public health, environmental, waste and  
33 end-of-life, and/or materials and resource consumption impacts of the Priority Product and/or  
34 one or more of the alternatives under consideration. This factor is intended to ensure that  
35 responsible entities do not devote time to factors that will not result in a difference from the  
36 Priority Product as it is or between various alternatives.

38 **Section 69505.4(a)(1)(A) 2.** specifies that there must also be a demonstrable difference in the  
39 factor's contribution to the impacts between two or more of the alternatives being considered in  
40 order for the factor to be relevant. This provision makes specific the criteria that must be met  
41 in order for a factor to be considered relevant and, thus, must be evaluated. By implication,  
42 the provision also specifies which factors are not relevant and, thus, need not be evaluated. In  
43 general, this provision is necessary to set an appropriate scope for the AA, i.e., one that  
44 focuses on relevant factors and to give certainty as to what those relevant factors are.

1 **Section 69505.4(a)(1)(B)** specifies that when making a determination under section  
2 69505.4(a)(1)(A), a responsible entity must include retaining the Priority Product as one of the  
3 alternatives being considered. This provision makes specific and establishes an appropriate  
4 scope of the alternatives that must be considered and evaluated.  
5

6 **Section 69505.4(a)(2)** requires the responsible entity to collect and use available quantitative  
7 information and analysis tools, supplemented by available qualitative information and analysis,  
8 to identify the factors contributing to the impacts listed in section 69505.4(a)(2)(A) and the  
9 associated exposure pathways and life cycle segments, that are relevant for the comparison of  
10 the Priority Product and the alternatives still under consideration after completion of the first AA  
11 stage as specified in section 69505.3. Section 69505.4(a)(2) further specifies that the factors  
12 contributing to the impacts in sections 69505.4(a)(2)(B) and (C) must be considered for all  
13 comparisons of the Priority Product and the alternatives being evaluated.  
14

15 This provision ensures that a responsible entity collects the available quantitative data on the  
16 Priority Product and the alternatives being considered and takes into account the available  
17 qualitative information to further refine the selection of the relevant factors to evaluate in the  
18 second stage of the AA. Requiring that a responsible entity conduct quantitative research is  
19 critical to quantifying the extent or magnitude of a potential problem. By requiring that the  
20 responsible entity supplement the quantitative research with qualitative research the potential  
21 problem can be better addressed by taking into account situational circumstances or nuances  
22 related to the problem at hand.  
23

24 **Section 69505.4(a)(2)(A)** requires that the responsible entity collect and use available  
25 information on the multimedia life cycle impacts and chemical hazards, for chemical  
26 ingredients known to be in the Priority Product and the alternatives being considered. The  
27 responsible entity must collect for the Priority Product and alternative being considered  
28 information related to:

- 29 1. adverse environmental impacts;
  - 30 2. adverse public health impacts ;
  - 31 3. adverse Waste and end-of-life impacts ;
  - 32 4. environmental fate;
  - 33 5. materials and resource consumption impacts;
  - 34 6. physical Chemical hazards; and
  - 35 7. PhysiChemical of Concernchemical properties.
- 36

37 The information collected under section 69505.4(a)(2)(A)1. through 7., comprise the factors to  
38 meet the goals of the authorizing statute. The elements contained in some of the thirteen,(A)  
39 through (M), criteria are addressed through this provision. Section 69505.4(a)(2)(A) coupled  
40 with the requirements of Section 69505.4(a)(2)(B) and (C) address the thirteen (A) through (M)  
41 criteria, in its entirety. Thus, these provisions ensure that the statutorily- required criteria are  
42 considered and evaluated as part of the AA.  
43

44 **Section 69505.4(a)(2)(B)** requires that the responsible entity collect and use available  
45 information on the product function and performance, meaning the principal use(s) or

1 applications of a product by a consumer, as intended by the manufacturer, including function  
2 and performance attributes, and legal requirement. The responsible entity must collect for the  
3 Priority Product and alternative being considered information related to:

- 4 1. useful life of the Priority Product, and that of the alternatives being considered;
- 5 2. comparison of function and performance for each alternative relative to the Priority  
6 Product, and each of the other alternatives being considered, and identification of the  
7 source and basis for the function and performance metrics used; and
- 8 3. a determination of whether a “technically and economically feasible alternative” exists.

9  
10 This provision, in combination with sections 69505.4(a)(2)(A) and (C), ensures that each AA  
11 incorporates consideration of all pertinent comparison and evaluation factors necessary to  
12 satisfy the goal and requirements of the authorizing statute.

13  
14 **Section 69505.4(a)(2)(C)** requires the responsible entity to evaluate and compare the  
15 economic impacts of the Priority Product and the alternatives being considered. If the  
16 responsible entity decides to retain the Priority Product, then the responsible entity’s evaluation  
17 and comparison of economic impacts must take into account all costs during the life cycle of  
18 the product and all alternatives being considered. A cost impact is an increase or decrease in  
19 one or more of the following:

- 20 1. Capital costs;
- 21 2. Consumer costs associated with the purchase or lease and use of the product;
- 22 3. Government agency, and public costs associated with the product;
- 23 4. Jobs or businesses costs;
- 24 5. Manufacturing costs;
- 25 6. Marketing costs;
- 26 7. Materials and resource consumption costs; and/or
- 27 8. Waste and end-of-life management costs.

28  
29 This provision, in combination with sections 69505.4(a)(2)(A) and (B), ensures that each AA  
30 incorporates consideration of all pertinent comparison and evaluation factors necessary to  
31 satisfy the goals and requirements of the authorizing statute.

32  
33 **Section 69505.4(a)(3)** requires the responsible entity to identify the relevant exposure  
34 pathways related to the chemical quantity in commerce and exposure potential as specified in  
35 section 69505.4(a)(3)(A) and (B). This provision ensures that the responsible entity identifies  
36 the relevant exposure pathways related to a chemical being used or under consideration to  
37 use; to assess the short and long-term ramifications of using the chemical. Sections  
38 69505.4(a)(3)(A) and (B) further elaborate on the types of information that must be identified to  
39 adequately assess the impacts of a chemical. Collectively, these requirements work to ensure  
40 that the AA is of appropriate scope and meets the statutorily-required criteria for consideration.

41  
42 **Section 69505.4(a)(3)(A)** requires that in identifying the relevant exposure pathways, the  
43 responsible entity must identify chemical quantity information related to:

- 44 1. quantities of the Chemical(s) of Concern or alternative chemical(s) necessary to  
45 manufacture the Priority Product, or alternative being considered; and

- 1       **2.** estimated volume and/or mass of the Chemical(s) of Concern or substitute chemical(s)  
2       that is/are or would be placed into the stream of commerce in California as a result of  
3       the Priority Product or alternatives being considered.  
4

5 This provision ensures that the AA addresses the quantities of a chemical being used or under  
6 consideration for use. This information is necessary to assess the short and long term  
7 ramifications of using a chemical and to comply with the statutory mandate that the AA  
8 address the thirteen (A) through (M) criteria.  
9

10 **Section 69505.4(a)(3)(B)** requires that in identifying the relevant exposure pathways the  
11 responsible entity identify the exposure factors specified in section 69503.2(a)(1)(B). The  
12 exposure pathways of section 69503.2(a)(1)(B) include the presence or prevalence of a  
13 product in the market and the exposure to the Chemical of Concern. This provision ensures  
14 that the responsible entity identify the relevant exposure pathways related to a chemical being  
15 used or under consideration for use to adequately assesses the impacts related to a chemical.  
16

17 **Section 69505.4(b)** requires the *Comparison of the Priority Product and Alternatives* as step  
18 two in the second stage of the AA. The responsible entity must use available quantitative  
19 information, supplemented by available qualitative information and analysis, to evaluate and  
20 compare the Priority Product and each of the alternatives under consideration with respect to  
21 each relevant factor and, where applicable, associated exposure pathways and life cycle  
22 segments identified under subsection (a). The responsible entity must compare each  
23 alternative with the Priority Product and with each of the other alternatives being considered.  
24 In its comparison of the Priority Product and the Alternatives, the responsible entity must  
25 address all of the requirements contained in section 69505.4(b)(1) through (8). The  
26 responsible entity must identify and/or document, as appropriate all of the following where  
27 available and appropriate for each of the relevant factors:

- 28 **(1)** Quantitative metrics, where available and appropriate, for each of the relevant factors  
29       identified under subsection (a)(2);  
30 **(2)** Qualitative metrics for any relevant factors for which quantitative metrics are not available  
31       or appropriate;  
32 **(3)** Available data for each metric for each alternative and the Priority Product;  
33 **(4)** Any absent or conflicting data regarding a relevant factor, and either or both of the  
34       following, as appropriate:  
35 **(A)** Available data that is most protective of public health and the environment, unless there  
36       are sound methodological reasons for rejecting such data; and/or  
37 **(B)** A value for the metric, using a method for dealing with data uncertainty due to absent or  
38       missing data that has been adopted by an authoritative organization, as defined in  
39       subsection (b) of section 69401.2, or generally accepted in peer reviewed literature.  
40  
41 **(5)** A description of the performance of the Priority Product and each alternative, with respect  
42       to each of the relevant factors;  
43 **(6)** Appropriate qualitative and/or quantitative relative weights for the relevant factors, and the  
44       rationale for the assignment of the relative weights;

- 1 (7) An evaluation of the overall performance of each alternative as compared to the Priority  
2 Product and the other alternatives, including discussion of the impact of the weight placed  
3 upon the relevant factors, the rationale for choosing the particular method for determining  
4 the overall evaluation and the sensitivity of the comparative evaluation to data uncertainty;  
5 and  
6 (8) Any other known evaluation of the Priority Product or one or more of the alternatives that  
7 comes to different conclusions, regarding the relative overall performance or public health  
8 and/or environmental impacts, and the reasons for the difference in the conclusions.  
9

10 This provision, in its entirety, ensures that a responsible entity adequately compares the  
11 impacts of a Priority Product to those of an alternative. To provide an equitable evaluation the  
12 responsible entity must evaluate both the Priority Product and alternatives considered in the  
13 same life cycle segments (i.e., from raw material extraction through materials processing,  
14 manufacture, distribution, use, repair and maintenance, and disposal or recycling). The criteria  
15 specified in sections 69505.4(b)(1) through (8) provide the necessary guidance to AA  
16 preparers and concrete direction for addressing data gaps. In addition, the analytic  
17 assumptions are made transparent and consistent.  
18

19 **Section 69505.4(c)** requires the *Selection of Alternative* as step three in the second stage of  
20 the AA. The section requires that the responsible entity select the alternative that will replace  
21 or modify the Priority Product, unless the decision is to retain the existing Priority Product.  
22 Further, the section requires that the selection of an alternative or the decision to retain the  
23 Priority Product shall be based on and supported by the comparative analysis conducted under  
24 section 69505.4(b). The responsible entity is required to select the alternative based on the  
25 findings of the alternatives assessment and must document the finding that supports the  
26 entity's decision. In general, this provision makes specific that the alternative selected must be  
27 based on a finding that it poses the safer alternative to any other "viable" alternative  
28 considered.  
29

30 **Section 69505.4(d)** allows the *Consideration of Additional Information*, as step four in the  
31 second stage of the AA. The responsible entity may include re-consideration of relevant  
32 information that was dismissed in the first stage and not specifically identified in the second  
33 stage AA in section 69505.4. This provision provides responsible entities latitude in  
34 reconsidering factors that were dismissed earlier and now determined to be relevant and  
35 significant in identifying viable alternatives.  
36

37 **Section 69505.4(e)** requires the *Identification of Next Steps* as step five of the second stage of  
38 the AA. The responsible entity must prepare and submit:

- 39 (1) a Final AA report that contains an implementation schedule for implementing the selected  
40 alternative and proposed regulatory responses, if applicable; and  
41 (2) a Final AA Report containing the information specified under section 69505.5.  
42

43 This provision ensures that the responsible entity considers the implementation schedule and  
44 allows the responsible entity to propose regulatory responses that would reduce, or eliminate  
45 any adverse human health and environmental impacts for DTSC's consideration. The Final

1 AA Report must contain the information specified in section 69505.5 to provide DTSC the  
2 necessary information on which to base its decision on the adequacy of the responsible  
3 entity's determination. Further, while the responsible entity "selects" the alternative, any  
4 regulatory response proposed is subject to DTSC review and approval, since regulatory  
5 responses are ultimately imposed by DTSC.

## 7 **§ 69505.5. Alternatives Assessment Reports**

9 **Section 69505.5**, in its entirety, provides the required contents of the Preliminary and Final AA  
10 Reports which are necessary to ensure that the AA has been thought thoroughly and  
11 adequately reported to ensure that the AA meets the requirements of this Article and the  
12 authorizing statute. It is also necessary to provide DTSC with the information necessary to  
13 adequately consider and evaluate the results of the AA and to put DTSC in a position to make  
14 an informed decision about which regulatory response(s), if any, it may impose.

16 **Section 69505.5(a)** specifies that all references in this section to "AA Reports" means the  
17 Preliminary AA and Final AA Report unless otherwise specified. This section is necessary to  
18 make specific that the requirements are applicable to both the Preliminary AA and Final AA  
19 Report without being unnecessarily repetitive, while ensuring both reports contain the relevant  
20 information.

22 **Section 69505.5(a)(1)** requires that the Preliminary and Final AA Reports include, as  
23 applicable, all of the information specified in sections 69505.5(b) through (k). This section is  
24 necessary to specify the required AA report contents. It is also necessary to ensure that all  
25 responsible entities know what the required contents are and to ensure that DTSC receives AA  
26 Reports that meet its needs.

28 **Section 69505.5(a)(2)** requires the responsible entity to include in the AA Reports sufficient  
29 information for DTSC to determine compliance with Article 5. This provision is necessary to  
30 ensure that each AA report submitted for DTSC review is complete and of the rigor necessary  
31 for DTSC to make an appropriate evaluation.

33 **Section 69505.5(a)(3)** requires the responsible entity to include in the Preliminary AA Report  
34 sufficient information for DTSC to determine the appropriate due date for submission of the  
35 Final AA Report. Responsible entities must fully describe in the Preliminary AA Report the  
36 planning undertaken to carrying out the subsequent stage to allow DTSC to make an informed  
37 decision about the deadline for submittal of the final AA Report.

39 **Section 69505.5(a)(4)** requires the responsible entity to include in the Final AA Report  
40 sufficient information for DTSC to determine the appropriate regulatory response(s), if any,  
41 under Article 6. Responsible entities must fully describe in the Final AA the findings and any  
42 limitations in carrying out the AA to adequately identify any logistical limitations and allow  
43 DTSC to identify the appropriate regulatory response(s).

1 **Section 69505.5(a)(5)** requires the responsible entity to identify and explain in the Final AA  
2 Report all differences in the information and analyses presented in the Preliminary AA Report  
3 and the Final AA Report. The responsible entity must also identify in the Final AA Report the  
4 information sources used to support changes from the Preliminary AA Report to the Final AA  
5 Report. This provision provides the responsible entity latitude in modifying the strategy that  
6 was planned during the Preliminary AA as a result of technical field limitations, or other  
7 unavoidable limitations that impacted the final implementation of the AA. It also allows the  
8 responsible entity to make necessary adjustments between the two reports based on what was  
9 learned during the first phase. It is necessary that such changes be explained so that DTSC  
10 can make an informed evaluation of the two reports and understand any differences between  
11 them.

12  
13 **Section 69505.5(a)(6)** requires that the responsible entity maximize the scope of information  
14 in the AA Report that can be made available to the public, while maintaining protection of  
15 legitimate trade secrets.

16  
17 **Section 69505.5(a)(6)(A)** requires a responsible entity who submits an AA Report containing  
18 information claimed to be a trade secret, a submit a separate publicly available AA Report that  
19 masks the claimed trade secret information only to the extent necessary to protect its  
20 confidential nature.

21  
22 **Section 69505.5(a)(6)(B)** specifies that if DTSC subsequently rejects a trade secret claim, the  
23 preparer of the AA report must, at DTSC's request, submit a revised publicly available AA  
24 Report. This report must be submitted within 30 days of the request, to add any information for  
25 which a trade secret claim is rejected; and which DTSC determines, and specifies in its  
26 request, must be included in the executive summary. This provision supports the objective of  
27 providing as much information as possible to the public and other interested parties regarding  
28 the AA, without infringing upon legitimate claims for protection of trade secrets.

29  
30 **Section 69505.5(b)** AA Reports submitted to DTSC be accompanied by an *Executive*  
31 *Summary*. The executive summary must contain sufficient information to convey to the public  
32 a general understanding of the scope and results of the AA. This provision facilitates the  
33 objective of providing as much information as possible to the public, in a manner that is tailored  
34 to those who are not experts in the field, and other interested parties regarding the AA without  
35 infringing upon legitimate claims for protection of trade secrets.

36  
37 **Section 69505.5(b)(1)** requires the Publicly Available AA Reports to be organized in  
38 conformance with the organization of the AA Report and to include, for each section of the AA  
39 Report, a reiteration or detailed summary of the information presented in the AA Report.  
40 However, the Publicly Available AA Report and executive summary must not include any  
41 information claimed as trade secret under Article 10. This provision facilitates the objective of  
42 providing as much information as possible, in a readily understandable format, to the public  
43 and other interested parties regarding the AA, without infringing upon legitimate claims for  
44 protection of trade secrets and confidential business information. In addition, it limits the

1 resources DTSC must devote to assembling documents for posting to DTSC's website since  
2 the reports will be submitted with redacted confidential information and ready for posting.

3  
4 **Section 69505.5(c)(1) through (3)** specifies that the AA Report must include the following  
5 *Preparer Information*:

- 6 (1) The name of, and contact information for, the person submitting the AA Report;  
7 (2) The name of, and contact information for, all persons on whose behalf the AA Report is  
8 being submitted; and  
9 (3) The names of the parties that were involved in funding, directing, overseeing, preparing or  
10 reviewing the AA, and any organizations and individuals that provided expert guidance or  
11 review for the AA.

12  
13 The information required under this provision is necessary in the event it becomes necessary  
14 for DTSC to contact the person submitting the report and those on whose behalf the AA is  
15 being prepared.

16  
17 **Section 69505.5(d)** requires that the AA reports contain *Responsible entity and Supply Chain*  
18 *Information* as follows:

- 19 (1) The name, contact information, and headquarters location of the manufacturer and  
20 importer, if applicable. If the AA Report is prepared on behalf of a consortium of  
21 manufacturers or other persons in the product's supply chain, a list of the participants must  
22 be provided as well as their corresponding contact information. This information is  
23 necessary should it become necessary to contact any of these entities.  
24 (2) The name of, and contact information for, any persons identified on the product label as the  
25 manufacturer. This information is necessary should contacting either of these persons  
26 become necessary, as well as to help identify the specific product that is the subject of the  
27 AA.  
28 (3) The name of, and contact information, for all persons in California, other than the final  
29 purchaser or lessee, to whom the manufacturer directly sold the product within the prior 12  
30 months. This information is necessary for DTSC to understand the product's supply chain  
31 and to assist DTSC in monitoring implementation of the AA selection decision and  
32 implementation of the required regulatory response, if any.  
33 (4) Identification and location of the manufacturer's retail sales outlets where the manufacturer  
34 sold, supplied or offered for sale the product in California, if applicable. This information is  
35 necessary for DTSC to understand the product's supply chain and to assist DTSC in  
36 monitoring implementation of the AA selection decision and implementation of the required  
37 regulatory response, if any.  
38 (5) The proximity of the places(s) of product manufacture to one or more source(s) of virgin or  
39 recycled materials that directly or indirectly influences the type and/or amount of Chemical  
40 of Concern contained in the Priority Product. This information is necessary to enable  
41 DTSC and other interested parties to understand how the location of the facility, relative to  
42 feedstock sources and product markets, affects various factors included in the AA Reports.

43  
44 **Section 69505.5(e)** requires the AA Report to include the following *Product Information*,  
45 identifying and describing the Priority Product that is the subject of the AA Report:

- 1 (1) The brand name(s) under which the product is placed into the stream of commerce in  
2 California. This information is necessary for DTSC to understand which products are  
3 captured by the AA Reports and to distinguish the product that is the subject of the AA from  
4 other similar products.
- 5 (2) If applicable, the component(s) and/or homogenous material(s) and its/their associated  
6 component(s) that is/are the focus of the AA.
- 7 (3) Identification of the Chemical(s) of Concern in the Priority Product that is/are the basis for  
8 the product being included on the Priority Product list, and any other Chemical(s) of  
9 Concern that is/are known, or reasonably should be known based on available information,  
10 to be in the product. This information is necessary so that DTSC and interested parties are  
11 fully informed as to the chemicals contained in the product that are of sufficient concern to  
12 have been listed by DTSC as Chemicals of Concern. More specifically, this information is  
13 necessary for DTSC to have sufficient information to make an informed evaluation of the  
14 AA Reports.
- 15 (4) The information specified in section 69505.3(b)(1), which includes the product criteria such  
16 as function, performance, technical feasibility and legal requirements of the product and the  
17 role and function that the Chemicals of Concern meet in the Priority Product. This  
18 information is necessary so that DTSC has that pertinent information available to it in order  
19 to make an informed evaluation of the AA Reports.

20  
21 **Section 69505.5(f)** requires the AA report to include information on the *Scope and*  
22 *Comparison of Alternatives*. The provision is necessary to provide DTSC and other interested  
23 stakeholders the necessary information to assess the AA Reports.

24  
25 **Section 69505.5(f)(1)(A)** requires the Preliminary AA Report to include all of the information  
26 evaluated and compared under section 69505.3(b), the initial screening of alternative  
27 chemicals, to replace the Chemical(s) of Concern in the Priority Product. That information  
28 must include at a minimum:

- 29 1. The information collected for the Chemical(s) of Concern and alternative chemical(s);  
30 and  
31 2. The comparative results of evaluating the information presented under subparagraph 1.  
32 This provision is necessary to ensure that information used in the initial screening of the  
33 alternatives is presented and set out in a format that is readily understood.

34  
35 **Section 69505.5(f)(1)(B)** requires the Preliminary AA report present the information required  
36 under section 69505.5(f)(1)(A) be presented in a matrix, or other format, that provides the  
37 reviewer with an easily understood visual comparison of the chemicals and their adverse  
38 impacts. This provision is necessary to ensure that information used in the initial screening of  
39 the alternatives be presented in a format that is readily understood.

40  
41 **Section 69505.5(f)(2)** requires the Final AA Report to include all of the information called for  
42 in paragraphs (A) and (B) for the evaluation and comparison of the Priority Product and its  
43 alternatives conducted under sections 69505.3(b) and 69505.4. The information used in the  
44 final screening of the alternatives considered must be presented in a format that is readily  
45 understood so that review and auditing of the findings is expeditious.

1  
2 **Section 69505.5(f)(2)(A)** requires that the Final AA Report include a matrix, or other format,  
3 that provides the reviewer with an easily understood visual comparison that presents all of the  
4 following, as applicable, for the evaluations conducted under sections 69505.3(b) and 69505.4:

- 5 1. The relevant exposure pathways and life cycle segments for each relevant comparison  
6 factor;
- 7 2. The information collected for each relevant factor, and associated exposure pathways  
8 and life cycle segments, for the Priority Product and each alternative considered; and
- 9 3. The comparative results of evaluating the information presented under subparagraph 2.

10  
11 This provision ensures the initial screening of alternatives conducted in the first stage of the AA  
12 be further considered and fully evaluated in the second stage of the AA. The relevant  
13 exposure pathways that are evaluated and compared will provide a multimedia evaluation on  
14 the impacts of the Priority Product and all alternatives being considered during each life cycle  
15 segment identified for consideration. This provision makes specific the key information that  
16 must be included in the Final AA Report and ensures it is presented in a readily  
17 understandable format.

18  
19 **Section 69505.5(f)(2)(B)** requires that the Final AA Report include a description, if applicable,  
20 of how safeguards provided by other federal and California State regulatory programs were  
21 considered in the AA, including identification of those programs and safeguards considered.  
22 This provision ensures other safeguards provided by federal and California state regulatory  
23 programs are taken into account to determine if those in place address the hazards posed by a  
24 selected alternative. This information is also necessary to allow DTSC to make an informed  
25 evaluation of the AA Report and to make an appropriate selection of regulatory response(s), if  
26 any.

27  
28 **Section 69505.5(f)(3)** requires the responsible entity to demonstrate in the Final AA Report  
29 that all of the requirements of section 69505.4(b) have been met. This provision ensures that  
30 the Priority Product and alternatives considered undergo a rigorous and thorough evaluation  
31 by the responsible entity in a manner that meets all of the enumerated criteria.

32  
33 **Section 69505.5(g)** requires that the AA report include information on the *Scope of Relevant*  
34 *Comparison Factors*. The Final AA Report must identify which factors, and associated  
35 exposure pathways and life cycle segments, were determined to be relevant, under section  
36 69505.4(a), for evaluation and comparison of the Priority Product and its alternatives. For  
37 each factor, exposure pathway, and life cycle segment determined not be relevant, the Final  
38 AA Report must explain the rationale and identify, and explain the pertinent findings of, the  
39 supporting information for this determination. This provision ensures the relevant information  
40 about the scope and contextual information about the factors considered is provided to DTSC  
41 and interested parties. This information, in turn, is necessary in order to make an informed  
42 evaluation of the AA Report.

43  
44 **Section 69505.5(h)** requires the AA report to include the *Methodology* used in the  
45 assessment. The AA Report must identify and describe the assessment tools, models, or

1 software used to conduct the AA, and discuss any limitations of these tools, models and  
2 software. The AA Report must also identify any published methodologies or guidelines used,  
3 and any deviations taken from the published methodologies or guidelines. The information  
4 required under this provision ensures the relevant background and contextual information is  
5 provided to DTSC and other interested parties so that an informed evaluation of the AA Report  
6 can be made.

7  
8 **Section 69505.5(i)(1)** requires the AA Report to provide information on *Supporting Information*  
9 used for the AA. Specifically, all information used as supporting information in performance of  
10 the AA and preparation of the AA Reports must be cited in the AA Reports and made available  
11 to DTSC, upon request. The AA Report must include a brief summary of the information  
12 reviewed and considered under section 69505.1(h). This information is necessary to ensure  
13 the basis of the information in the AA is maintained and can be reviewed by DTSC in the event  
14 DTSC or interested parties wish to get a better understanding of the information, data,  
15 assumptions, etc. that form a foundation for the AA and responsible entity's selection decision.

16  
17 **Section 69505.5(i)(2)** requires the Final AA Report to include the identification of information  
18 that is currently not available but, if available, could be used to:

- 19 **(A)** Validate information used for the first stage and second stage AA under sections  
20 69505.3(b), and 69505.4, respectively;  
21 **(B)** Address any uncertainties in the analyses conducted during the first stage and second  
22 stage AA under sections 69505.3(b) and 69505.4; and  
23 **(C)** Ensure that the list of chemical ingredients required to be identified for the Priority Product  
24 and its alternatives during the conduct of the AA and the preparation of the AA Reports is  
25 complete.

26  
27 While the regulations do not require data gaps be filled, there is the recognition that with  
28 additional information, whether readily available or not, better informed decisions can be made  
29 in scoping and subsequently addressing or validating uncertainties when comparing the  
30 Chemical(s) of Concern and any potential alternatives during the first and second stage AA.  
31 Although responsible entities are not required to fill informational data gaps as part of the AA,  
32 identification of the data gaps may be used to establish where additional scientific or technical  
33 work may be productive, individually or as a consortium, as part of a regulatory response in  
34 advancing green chemistry requirements contained in section 69506.9. More generally, this  
35 identification of data gaps is necessary to give DTSC a better basis for evaluating the AA  
36 Reports.

37  
38 **Section 69505.5(j)** requires the AA Report to include information on the *Selected*  
39 *Alternative(s)*. The AA Reports must identify and describe the alternatives chosen to be  
40 evaluated and compared, and explain the rationale for selecting and screening out specific  
41 alternatives at each stage of the alternative comparison process. This provision is necessary  
42 to ensure the relevant background and contextual information is provided to DTSC and other  
43 interested parties so that the scope of the AA is properly understood and DTSC may make an  
44 informed evaluation of the AA Reports.

1 **Section 69505.5(j)(1)** requires the Preliminary AA Report to identify and describe the  
2 alternatives, if any, selected for further evaluation in the second stage of the AA, and explain  
3 the rationale for the selection decision. The Preliminary AA Report identifies the viable  
4 alternatives that will be subsequently evaluated and thus establishes the scope of the second  
5 stage and Final AA.

6  
7 **Section 69505.5(j)(2)** requires the Final AA Report to provide information concerning the  
8 selected alternative, if any. Specifically, the Final AA Report must identify and describe the  
9 alternative, if any, selected, and the rationale for the selection decision. This must include an  
10 assessment that evaluates and compares the selected alternative against the Priority Product  
11 and a detailed list and explanation of the reasons for the selection decision, or, alternatively,  
12 for the decision not to select and implement an alternative to the Priority Product, whichever is  
13 applicable. The information required under this provision provides DTSC and other interested  
14 parties with an in-depth explanation of the rationale for the responsible entity's selection  
15 decision and is necessary for DTSC to make an informed evaluation of the AA Report. This  
16 information will then be used by DTSC to make an informed decision to determine the  
17 necessary regulatory response, if any.

18  
19 **Section 69505.5(j)(2)(A)** requires the Final AA Report to include information specified in  
20 section 69505.4(a)(2)(B) regarding product function and performance, for the selected  
21 alternative. If no alternative is selected, this information must be provided for each alternative  
22 considered. The information required under this provision provides DTSC and other interested  
23 parties the information evaluated and taken into account by the responsible entity in selecting  
24 an alternative and is necessary for DTSC to make an informed evaluation of the Final AA  
25 Report.

26  
27 **Section 69505.5(j)(2)(B)** specifies that the Final AA Report must explain the rationale for  
28 deciding to retain the Chemical(s) of Concern or to use a substitute chemical, whichever  
29 applies under section 69505.3(b)(1)(C)2., or if the selected alternative retains the Chemical(s)  
30 of Concern or uses a substitute chemical. The information required under this provision will  
31 inform DTSC and other interested parties of the basis for a responsible entity choosing to  
32 retain a Chemical of Concern or use a substitute chemical. This information is crucial for  
33 making an informed decision and for evaluating the Final AA Report.

34  
35 **Section 69505.5(j)(2)(C)** requires the Final AA Report to include a list of all chemical  
36 ingredients known, based on available information, to be in the selected alternative that differs  
37 from the chemical ingredients in the Priority Product or that are present in the selected  
38 alternative at a higher concentration than in the Priority Product, and all of the following  
39 information that is available for those chemicals:

- 40 1. Environmental fate;
- 41 2. Hazard trait(s) and environmental and toxicological endpoint(s) information for any of  
42 those chemicals for which such information has not already been provided to DTSC  
43 under this Chapter;
- 44 3. Information on the purity of the chemicals and identification of known impurities and  
45 additives in the chemical;

- 1 4. Physical chemical hazards;
- 2 5. PhysiChemical of Concern chemical properties; and
- 3 6. Substance identification information:
  - 4 a. Chemical abstract services number;
  - 5 b. Structural formula;
  - 6 c. Molecular weight;
  - 7 d. Synonyms;
  - 8 e. International Union of Pure and Applied Chemistry name;
  - 9 f. European Commission number;
  - 10 g. Registry of Toxic Effects of Chemical Substances number;
  - 11 h. International Union of Biochemistry and Molecular Biology number;
  - 12 i. Japan Ministry of International Trade and Industry number;
  - 13 j. Number assigned by the United Nations Experts on the Transport of Dangerous
  - 14 Goods;
  - 15 k. North America Department of Transportation number;
  - 16 l. European Inventory of Existing Commercial Chemical Substances number;
  - 17 m. European List of Notified Chemical Substances number;
  - 18 n. European Commission Directive 67/548/EEC No Longer Polymers number; and
  - 19 o. Other commonly recognized substance identification system numbers.

20  
21 The information required under this provision is necessary for DTSC to adequately assess  
22 likely adverse impacts that may occur as a result of a Chemical of Concern substitution. This  
23 is, again, a necessary piece of information in order to make an informed evaluation of the Final  
24 AA Report. Much of the substance identification information specified in sections 69505.5(j)  
25 (2)(C)6.a. through o. are naming conventions that are currently in use throughout the world.  
26 Although there are efforts underway to globally harmonize information related to chemicals, it  
27 is anticipated that the regulations will go into effect before those efforts are complete. As such,  
28 the regulations provide the needed latitude to allow responsible entities to identify the  
29 chemicals by other naming conventions.

30  
31 **Section 69505.5(k)** requires the AA Reports to identify and plan the *Next Steps* for the  
32 subsequent phase of the Preliminary or Final AA Report.

33  
34 **Section 69505.5(k)(1)** requires that the Preliminary AA Report include the work plan and  
35 proposed implementation schedule required to be prepared under section 69505.3(b)(5).

36  
37 **Section 69505.5(k)(1)(A)** specifies that the work plan and implementation schedule must  
38 specify the proposed submission date for the Final AA Report, and must ensure that the Final  
39 AA Report will be submitted to DTSC no later than twelve (12) months after the DTSC issues a  
40 notice of compliance for the Preliminary AA Report. The information required establishes the  
41 basis under which the AA will be performed and informs DTSC and other parties of the  
42 intended scope of the AA and/ AA Work Plan planned by the responsible entity. This  
43 information is critical in developing the proposed schedule for the AA and informing DTSC of  
44 the adequacy for the due date of the Final AA Report.

1 **Section 69505.5(k)(1)(B)** allows the responsible entity to request an extension for submittal of  
2 the Final AA Report, not to exceed twenty-four (24) months from the date DTSC issues a  
3 notice of compliance for the Preliminary AA Report. The extension request must include a  
4 detailed explanation of why additional time is needed. If the Priority Products list identifies  
5 more than one component that must be included in the AA for the Priority Product, separate  
6 submission dates may be proposed for each component or homogeneous material. In  
7 addition, this section provides, that if the responsible entity chooses to include additional  
8 components and/or homogeneous materials in the AA, separate submission dates may be  
9 proposed for each of those components and/or homogeneous materials. This provision  
10 provides necessary latitude to responsible entities when unforeseen circumstances are  
11 encountered that impact the submittal of the Final AA Report. In addition, it provides  
12 responsible entities the opportunity to conduct AA for individual components, if feasible, and  
13 not unnecessarily delay conducting the AA for all components simultaneously.

14  
15 **Section 69505.5(k)(2)** requires the Final AA Report include a detailed implementation plan, as  
16 specified in section 69505.4(d).

17  
18 **Section 69505.5(k)(2)(A)** the implementation plan must include key milestones and dates, for  
19 implementing the selected alternative, if applicable. The implementation plan must include any  
20 steps necessary to ensure compliance with applicable federal, state or local laws. This  
21 provision ensures that implementation of the selected alternative is done within a specific time  
22 frame, which will assist DTSC in monitoring and enforcing compliance with the Final AA Report  
23 and the requirements and intent of the statute.

24  
25 **Section 69505.5(k)(2)(B)** allows the Final AA Report to include information on any Proposed  
26 Regulatory Responses. Specifically, the Final AA Report may identify regulatory response(s)  
27 that would best limit the exposure to, or reduce the level of adverse public health and  
28 environmental impacts posed by, any Chemical of Concern that will be contained in the  
29 selected alternative or that is contained in the Priority Product, if the decision resulting from the  
30 AA is to retain the Priority Product. A responsible entity is allowed to provide DTSC with  
31 suggestions to consider in determining what regulatory response(s) may be appropriate, but is  
32 not required to do so. DTSC may take into account the regulatory responses proposed by the  
33 responsible entity and account for situational circumstances where the regulatory response  
34 proposed may address those circumstances.

## 35 36 **§ 69505.6. Department Review and Determinations for AA Reports**

37  
38 **Section 69505.6** in its entirety specifies the review and determination process that DTSC will  
39 use for both the Preliminary and Final AA Reports. The process contained in these provisions  
40 make it clear to responsible entities and other interested parties how DTSC will conduct its  
41 reviews and time frames that apply to various actions to be taken by DTSC.

42  
43 **Section 69505.6(a)(1)** specifies that within sixty (60) days of receiving a Preliminary AA  
44 Report, DTSC must review the Preliminary AA Report for compliance with Article 5, and issue  
45 a notice of compliance, a notice of deficiency, or a notice of ongoing review. The time frame

1 specified is necessary to keep the AA process moving along and not unduly delayed. Further,  
2 it allows responsible entities to plan for and expect a response from DTSC on their Preliminary  
3 AA Reports informing them of the two possible responses DTSC may make.

4  
5 **Section 69505.6(a)(2)(A)** requires that DTSC specify in a notice of deficiency the areas of  
6 deficiency and the due date for submitting the necessary information to complete the  
7 Preliminary AA Report. The due date for correcting the areas of deficiency may not exceed  
8 sixty (60) days from the date the notice of deficiency is issued. The responsible entity must  
9 submit a revised Preliminary AA Report within the time specified and address the areas of  
10 deficiency. The information, provided by DTSC, detailing the areas of deficiency is necessary  
11 to inform the responsible entity as to what needs to be remedied in order for their Preliminary  
12 AA Report to be deemed in compliance with Article 5. In addition, the time limitation is  
13 necessary to inform responsible entities of the maximum amount of time that DTSC will allow  
14 for remedying deficiencies before being found out of compliance. This ensures AA Reports  
15 are remedied on a timely basis so as to ensure that the AA process is not unduly delayed.

16  
17 **Section 69505.6(a)(2)(B)** requires DTSC within thirty (30) days of receipt of the additional  
18 information requested in the notice of deficiency, to issue a notice of compliance, a notice  
19 disapproving the Preliminary AA Report, or a notice of ongoing review. If the Preliminary AA  
20 Report is disapproved, DTSC must explain the basis for the disapproval in the notice. DTSC  
21 must also issue a notice of disapproval if a revised Preliminary AA Report is not submitted by  
22 the due date specified under section 69505.6(a)(A). A disapproved Preliminary AA Report is  
23 not in compliance with the requirements of section 69505.1(c)(2). This section obligates DTSC  
24 to respond to submittals of additional information on a timely basis so as not to unduly delay  
25 the AA process, and to ensure that responsible entities are informed of the basis in the event  
26 their Preliminary AA Report is disapproved. This section is also necessary to make it clear to  
27 all parties that a disapproved Preliminary AA Report constitutes non-compliance with the  
28 requirements of the regulations, which triggers various requirements on importers or retailers,  
29 as specified in section 69501.3.

30  
31 **Section 69505.6(a)(3)** requires that DTSC specify in a notice of compliance the date for  
32 submitting the Final AA Report. DTSC must specify a due date that is twelve (12) months from  
33 the date DTSC issues the notice of compliance, except that DTSC may specify more time for  
34 submission of the Final AA Report if it determines based on information in the Preliminary AA  
35 Report that more time is needed. DTSC may not establish a due date for the Final AA Report  
36 that is more than twenty-four (24) months from the date DTSC issues the notice of compliance  
37 for the Preliminary AA Report, except as provided in sections 69505.1(d) and 69505.5(k)(1)(C).  
38 DTSC needs some latitude in extending the due date for the final AA Report if available  
39 information demonstrates that 12 months will not be sufficient to complete the Final AA Report.

40  
41 **Section 69505.6(b)(1)** requires that within sixty (60) days of receiving a Final AA Report,  
42 DTSC review the AA Report for compliance with the requirements of this Article, and shall  
43 issue a notice of its findings with either a notice of compliance, a notice of deficiency, or notice  
44 of ongoing review. This section obligates DTSC to respond to submittals of additional

1 information on a timely basis so as not to unduly delay the AA process. It also ensures that  
2 responsible entities are informed of the acceptability or not of their Final AA Report.

3  
4 **Section 69505.6(b)(2)** requires that DTSC specify in a notice of deficiency the areas of  
5 deficiency and the due date, not to exceed sixty (60) days from the date the notice of  
6 deficiency is issued, for submitting the necessary information to complete the Final AA Report.  
7 The responsible entity shall submit a revised Final AA Report within the time specified and  
8 address all areas of deficiency. If requested by the responsible entity, DTSC may approve a  
9 one-time extension, of not more than sixty (60) days, for submission of the revised Final AA  
10 Report to correct the deficiencies. DTSC must inform the responsible entity as to what needs  
11 to be remedied in order for their Final AA Report to be deemed in compliance with Article 5 to  
12 achieve the maximum amount of compliance. This section informs responsible entities of the  
13 maximum amount of time that they can expect DTSC to allow for remedying deficiencies, to  
14 ensure that deficient AA Reports are remedied on a timely basis and not unduly delayed.

15  
16 **Section 69505.6(b)(3)** requires DTSC issue either a notice of compliance, a second notice of  
17 deficiency, or a notice of ongoing review within sixty (60) days of receipt of the requested  
18 additional information. DTSC must respond to submittals of additional information on a timely  
19 basis so as to ensure that the AA process and assignment of regulatory responses, if any, is  
20 not unduly delayed.

21  
22 **Section 69505.6(b)(3)(A)** specifies that if DTSC issues a second notice of deficiency, the  
23 notice must grant no more than thirty (30) days for resubmission of the requested information.  
24 Responsible entities are provided a final attempt in a timely fashion at rectifying any  
25 deficiencies prior to being found out of compliance with the requirements of Article 5 and  
26 triggering other requirements under section 69501.3.

27  
28 **Section 69505.6(b)(3)(B)** specifies that within sixty (60) days of receipt of the requested  
29 additional information, DTSC must issue either a notice of compliance, a notice of disapproval  
30 for the Final AA Report, or a notice of ongoing review. If the Final AA Report is disapproved,  
31 DTSC must explain the basis for the disapproval in the notice. DTSC shall also issue a notice  
32 of disapproval if a revised Final AA Report is not submitted by the due date specified under  
33 paragraph (2) or subparagraph (A), whichever is applicable. A disapproved Final AA Report is  
34 not in compliance with section 69505.1(d). DTSC must respond to submittals of additional  
35 information on a timely basis so as to ensure that the AA process and assignment of regulatory  
36 responses, if any, is not unduly delayed. It is also necessary to inform the responsible entities  
37 that if a Final AA Report is found to be deficient other requirements under section 69501.3 will  
38 be triggered.

39  
40 **Section 69505.6(c)(1)** specifies that if the Final AA Report is determined to be in compliance  
41 with this Article, DTSC must include in the notice of compliance, or in a separate notice sent to  
42 the manufacturer and all responsible entities known to DTSC, a notice of DTSC's proposed  
43 determination. This must be whether one or more of the regulatory responses specified in  
44 sections 69506.5, 69506.6, 69506.7, 69506.9, and/or 69506.10 is required. This section

1 notifies responsible entities of the range of regulatory responses that will be imposed on a  
2 Priority Product or its alternative.

3  
4 **Section 69505.6(c)(2)** specifies that if DTSC requires a regulatory response under sections  
5 69506.5, 69506.6, 69506.7, 69506.9, and/or 69506.10 is required, DTSC must specify the  
6 proposed due date for implementation of the regulatory response. In assigning a due date for  
7 completing a regulatory response, DTSC must consider the complexity of implementing the  
8 regulatory response. Given the regulations apply to a multitude of consumer products, some  
9 complex and others more simple in design, this section provides the necessary latitude in  
10 assigning deadlines for final implementation of the regulatory responses. DTSC may take into  
11 account the complexity of a product and determine based on feedback and working knowledge  
12 of the most appropriate deadline.

13  
14 **Section 69505.6(d)** requires that DTSC specify in a notice of ongoing review the estimated  
15 date by which DTSC expects to issue a notice of compliance or notice of deficiency. DTSC  
16 shall take into account its available resources and the complexity of the AA Report under  
17 review in estimating the date for issuance of a notice of compliance or notice of deficiency.

18  
19 **Section 69505.6(e)** specifies that all notices issued by DTSC under this section must be  
20 issued to the person who submitted the AA Report. Also, a copy of the notice must be sent by  
21 DTSC to all responsible entities on whose behalf the AA Report is being submitted and parties  
22 that were involved in funding, directing, overseeing, preparing, and/or reviewing the AA as  
23 identified in the AA Report under sections 69505.5 (c)(2) and (3). This section ensures that all  
24 persons particularly affected are notified of DTSC's determinations on AA Reports.

1 **Article 6. Regulatory Responses**

2  
3 **Article 6**, in its entirety, is necessary to implement, clarify, and make specific the provisions of  
4 Health and Safety Code section 25253(b). Specifically, the purpose of this Article is to  
5 delineate the criteria for regulatory responses that may be imposed on a Priority Product  
6 following completion of the alternatives assessment specified in Article 5. Because the  
7 consumer products subject to regulatory responses are as varied as, for example, a  
8 toothbrush, a rug, and an automobile part, this Article necessarily contains a broad menu of  
9 regulatory options. The purpose of this Article is to identify general sets of circumstances that  
10 will be more or less likely to give rise to specific regulatory responses, while preserving the  
11 Departmental flexibility necessary to implement appropriate regulatory measures on a case by  
12 case basis. This Article is also necessary to detail the process by which DTSC will impose  
13 regulatory responses.

14  
15 Health and Safety Code section 25253(b) requires these regulations to specify the range of  
16 regulatory responses that DTSC may impose following the completion of an alternatives  
17 analysis, including, but not limited to, any of the following actions:

- 18 (1) Not requiring any action;
- 19 (2) Imposing requirements to provide additional information needed to assess a  
20 Chemical of Concern and its potential alternatives;
- 21 (3) Imposing requirements on the labeling or other type of consumer product  
22 information;
- 23 (4) Imposing a restriction on the use of the Chemical of Concern in the consumer  
24 product;
- 25 (5) Prohibiting the use of the Chemical of Concern in the consumer product;
- 26 (6) Imposing requirements that control access to or limit exposure to the Chemical of  
27 Concern in the consumer product;
- 28 (7) Imposing requirements for the manufacturer to manage the product at the end of its  
29 useful life, including recycling or responsible disposal of the consumer product;
- 30 (8) Imposing a requirement to fund green chemistry challenge grants where no feasible  
31 safer alternative exists;
- 32 (9) Any other outcome DTSC determines accomplishes the requirements of the  
33 authorizing statute.

34  
35 The statute lists eight (8) types of regulatory responses that, at a minimum, must be included  
36 in the regulations. Additionally, Health and Safety Code section 25253(b)(9) authorizes DTSC  
37 to impose any other regulatory response that it determines accomplishes the requirements of  
38 the statute (Article 14 of Chapter 6.5 of division 20 of the Health and Safety Code).

39  
40 All of the statutorily listed regulatory responses are included in Article 6 of these regulations.  
41 For some of these responses, the regulations include language that provides necessary  
42 criteria to make the responses identified in the statute largely self-implementing. However,  
43 DTSC anticipates that many of the listed regulatory responses when imposed will need to be  
44 customized on a case- by- case basis in light of the nature of, and the uses of, the individual  
45 product. Therefore, for these case-by-case regulatory responses, the regulations include a

1 process for issuing a proposed regulatory response determination for public review and  
2 comment before DTSC makes its final regulatory response determination.

3 In specifying the criteria for, and the operation of, the regulatory responses, DTSC has sought  
4 to effectuate the legislative intent embodied in the following sections of the authorizing statute:

- 5 • Health and Safety Code section 25253(a)(1) sets forth the purpose of the alternatives  
6 analysis process, which is the step leading to the imposition of a regulatory response,  
7 as “to determine how best to limit exposure or to reduce the level of hazard posed by a  
8 Chemical of Concern.”
- 9 • Health and Safety Code section 25255(a) states that the overall goal of the authorizing  
10 statutes is “significantly reducing adverse health and environmental impacts of  
11 chemicals used in commerce, as well as the overall costs of those impacts to the state’s  
12 society, by encouraging the redesign of consumer products, manufacturing processes,  
13 and approaches.”

14  
15 All of the regulatory responses specified in Article 6 are intended to, and are necessary to: (i)  
16 limit exposure to Chemicals of Concern, (ii) reduce the level of hazard posed by Chemicals of  
17 Concern, and/or (iii) encourage the redesign of consumer products in a manner that reduces  
18 their adverse health and environmental impacts. The safer the selected alternative, the less  
19 stringent the regulatory response, if any, will be.

20  
21 **Section 69506. Regulatory Response Selection Principles**

22 Health and Safety Code section 25253(b) confers broad discretion on DTSC to select from  
23 among a large menu of regulatory responses to impose after completion of an Alternatives  
24 Analysis. Section 69506, in its entirety, is intended to, and is necessary to identify the  
25 overarching principles that will guide DTSC in selecting among the broad array of permissible  
26 regulatory responses. This increases the predictability of such responses for all stakeholders,  
27 helps guide DTSC program implementation staff, and increases the consistency of regulatory  
28 decision-making.

29  
30 **Section 69506(a)** states that as a general matter, when confronted with a Priority Product that  
31 has undergone an Alternatives Analysis, DTSC will impose regulatory responses that are  
32 designed to protect public health and the environment, and to maximize the use of those  
33 feasible product alternatives that pose the least toxic risk. This statement of principle gives  
34 effect to the statement of goals in Health and Safety Code Section 25255: “[T]he goals of this  
35 Article . . . [are] significantly reducing adverse health and environmental impacts of chemicals  
36 used in commerce, as well as the overall costs of these impacts to the state’s society, by  
37 encouraging the redesign of consumer products, manufacturing processes, and approaches.”

38  
39 **Section 69506(b)** states that DTSC must, in selecting regulatory responses, give preference  
40 to those that provide the greatest level of inherent protection from toxic risk, rather than relying  
41 on control systems to limit exposure to, or release of, Chemicals of Concern. This provision is  
42 likewise intended to make plain DTSC’s policy preference for, and duty under Health and  
43 Safety Code Section 25255(a) of, “encouraging the redesign of consumer products” as a  
44 means of reducing toxic risk, rather than merely encouraging the development of better control  
45 systems for existing products with known hazards.

1  
2 **Section 69506(c)** identifies five discretionary criteria that may inform DTSC’s selection of a  
3 regulatory response:

- 4 **(1)** The likely effectiveness of the response;
- 5 **(2)** The cost-effectiveness of the response as compared to other potential responses;
- 6 **(3)** The relative burdens that the response would place on DTSC, the regulated entities,  
7 product users, and the general public;
- 8 **(4)** Any unique or additional burdens placed upon sensitive subpopulations, and/or
- 9 **(5)** The ease and efficacy of enforcement.

10  
11 These criteria make clear that DTSC’s selection of regulatory responses may, when  
12 appropriate, be guided by its determination of the overall costs and benefits of regulation, and  
13 the equitable allocation of costs and benefits (factors (2) and (3)); that DTSC’s regulatory  
14 response selection may be based in part on pragmatic considerations relating to the ease of  
15 implementation and enforcement (factors (1) and (5)); and that DTSC’s response selection  
16 may be based on a focused effort to prevent further burdening sensitive subpopulations (factor  
17 4).

18  
19 This section identifies criteria not elsewhere enumerated that may cause DTSC to favor one  
20 regulatory response among a range of facially reasonable responses. DTSC’s consideration  
21 of particularized impacts on sensitive populations is consistent with Health and Safety Code  
22 section 25252(a)(3)’s instruction to consider, with respect to Chemicals of Concern, “potential  
23 effects on sensitive subpopulations.”

#### 24 25 **§ 69506.1. Applicability and Determination Process**

26  
27 **Section 69506.1** specifies when the requirements of Article 6 are triggered, and the process  
28 by which DTSC will provide an opportunity for affected responsible entities and other  
29 interested parties to review and comment on proposed product-specific, case by case  
30 regulatory response determinations before DTSC issues a final determination that must then  
31 be implemented by the responsible entity.

32  
33 **Section 69506.1(a)** specifies that the requirements of Article 6 apply to:

- 34 **(1)** an alternative selected under section 69505.4(c) that is placed into the stream of commerce  
35 in California. It further provides that these requirements also apply to
- 36 **(2)** the Priority Product if an alternative is not selected, or
- 37 **(3)** the Priority Product, if it will remain in commerce pending development and distribution of  
38 the alternative.

39  
40 This section informs responsible entities and interested parties of the scope of the applicability  
41 of Article 6. The ability to apply regulatory responses fulfills the requirements and purposes of  
42 the statute, and in particular, the provisions of Health and Safety Code sections 25253(a)(1)  
43 and 25255(a) discussed above.

1 **Section 69506.1(b)** specifies that prior to issuing a final regulatory response determination  
2 notice under section 69506.5, 69506.6, 69506.7, 69506.9 and/or 69506.10 DTSC must notify  
3 any known responsible entities and make the proposed regulatory response determination  
4 notice available on its web site for public review and comment. DTSC must hold one or more  
5 public workshops to provide an opportunity for oral comments on the proposed regulatory  
6 response determinations. In addition, DTSC must send the notice to individuals on the  
7 electronic mailing list that DTSC establishes related to this program, and must post on its  
8 website a notice regarding the availability of the proposed regulatory response determination.  
9 The notice must include all of the following information:

- 10 (1) The last day for the public to submit written comments, which shall be at least 45 days  
11 from the date the proposed regulatory responses are, sent to individuals on DTSC's  
12 electronic mailing list and posted on DTSC's website,  
13 (2) The method(s) for submitting comments, and  
14 (3) The date, time, and location of the public workshop(s).

15  
16 This provision provides the affected responsible entity and other interested parties an  
17 adequate opportunity to review and submit comments on proposed regulatory responses, and  
18 to ensure DTSC considers stakeholder input before any final determination is made.  
19

20 **Section 69506.1(c)** specifies that after review and consideration of public comments on the  
21 proposed regulatory response determination notice, DTSC must finalize the notice and send it  
22 to any known responsible entities. DTSC may respond to some or all public comments  
23 received. This section ensures that DTSC provides the responsible entity with proper notice of  
24 the final regulatory response determination that it is required to implement. It also ensures that  
25 DTSC considers all public comments received prior to finalizing its determination, while  
26 retaining the latitude to determine which comments require a response.  
27

28 **Section 69506.1(d)** specifies that all proposed and final regulatory response determination  
29 notices must include all of the following information:

- 30 (1) *A description of the required regulatory response.* This information ensures that interested  
31 parties are informed of the nature of the applicable regulatory response.  
32 (2) *The basis for DTSC's regulatory response determination.* This information ensures that the  
33 responsible entity and other interested parties are made aware of the rationale for the  
34 proposed (and final) regulatory response determination, and may comment on the  
35 determination and its basis. This information will also help future responsible entities  
36 anticipate the regulatory responses that might be imposed based on the alternatives they  
37 are considering during the AA process for their products, and consider this when making  
38 their alternative selection decision.  
39 (3) *The rationale, information, and information sources supporting DTSC's determination(s).*  
40 This provision is necessary for the same reasons as section 69506.8(c)(2).  
41 (4) *The implementation due date for any regulatory response imposed.* This provision  
42 establishes the compliance date for the responsible entity to implement the regulatory  
43 response, and informs other interested parties (for example, retailers and consumers) as to  
44 when they can expect to see the regulatory response implemented.  
45

1 **Section 69506.1(e)** specifies that in assigning a due date for completing a regulatory  
2 response, DTSC must consider the complexity of implementing the response. This provision  
3 provides necessary flexibility in establishing due dates for implementation of a regulatory  
4 response based on the broad range of consumer products that are within DTSC’s regulatory  
5 purview, and the highly variable lead times necessary to modify these products or undertake  
6 other required actions.

7  
8 **§ 69506.2. AA Report Supplemental Information Requirements**

9  
10 **Section 69506.2** in its entirety makes specific the regulatory response identified in Health  
11 and Safety Code section 25253(b)(2), which states that after completion of an Alternatives  
12 Analysis, DTSC may take the action of “[i]mposing requirements to provide additional  
13 information needed to assess a Chemical of Concern and its potential alternatives.”

14  
15 **Section 69506.2(a)** specifies that DTSC may, at any time, request any information  
16 supplementary to the AA Report that DTSC determines is necessary to determine and ensure  
17 implementation of one or more regulatory responses imposed under Article 6. The responsible  
18 entity must provide the requested information within the time period specified by DTSC. This  
19 provision is intended to accommodate AA Reports that are substantially complete, but that  
20 require critical information to allow for an informed regulatory response determination, without  
21 necessitating rejection of an AA Report in its entirety.

22  
23 **Section 69506.2(b)** allows DTSC to require the responsible entity to obtain or develop  
24 information, within a specified time frame, to fill data gaps identified in the final AA Report,  
25 under section 69505.5(i)(2), if DTSC determines it needs the information in order to reassess  
26 one or more initial regulatory responses imposed, under section 69506.10(b), for the selected  
27 alternative for a Priority Product that remains in commerce. The provision ensures that the  
28 responsible entity will provide the information within the time specified by DTSC.

29  
30 **§ 69506.3. No Regulatory Response Required**

31  
32 **Section 69506.3** specifies that no regulatory response under section 69506.4 through  
33 69506.10 will be required for a selected alternative if DTSC determines that a regulatory  
34 response is not necessary to prevent or limit adverse public health or environmental impacts.  
35 This section implements Health and Safety Code section 25253(b)(1), which provides that  
36 “[n]ot requiring any action” may be an appropriate regulatory response, and to clearly specify  
37 the circumstances under which no regulatory response will be required. The fulfillment of the  
38 criterion listed above is the only scenario under which no action will be required by operation of  
39 law (*i.e.*, in every case). DTSC anticipates, however, that there may occasionally be other  
40 individual circumstances in which it will determine, following the completion of an AA report,  
41 that a regulatory response is not needed.

42  
43 **§ 69506.4. Product Information for Consumers**

1 **Section 69506.4**, in its entirety, is necessary to implement and make specific Health and  
2 Safety Code section 25253(b)(3), which provides that permissible regulatory responses with  
3 respect to a consumer product include “[i]mposing requirements on the labeling or other type  
4 of consumer product information.” Additionally, this section achieves the requirements and  
5 purpose of the statute, and in particular the provisions of Health and Safety Code sections  
6 25253(a)(1) and 25255(a) discussed above. More specifically, this section clearly delineates  
7 those circumstances that will typically give rise to the regulatory requirement that a responsible  
8 entity make product information available to consumers, and identify the form and contents of  
9 the required consumer information.

10  
11 The duty to comply under section 69501.3(a) places the information provision requirement  
12 here principally on the manufacturer of a Priority Product or a replacement product. In the  
13 event that a manufacturer does not comply, the responsibility falls on the importer into the  
14 United States, of the Priority Product or replacement product. A retailer is only required to  
15 comply with the requirements if DTSC notifies the retailer that the manufacturer and importer  
16 have failed to comply.

17  
18 **Section 69506.4(a)(1)** requires that the information specified in paragraphs (A) through (F)  
19 must, within twelve (12) months of DTSC’s issuance of a notice of compliance for the Final AA  
20 Report, and for as long as a product is placed in the stream of commerce, be made available  
21 to consumers prior to any exposure to any Chemical(s) of Concern. This requirement applies  
22 to a product that is: a selected alternative; a Priority Product for which an alternative is not  
23 selected; or a Priority Product that is offered for sale in California pending development and  
24 distribution of the selected alternative. The information specified ensures that consumers have  
25 basic information about the product and the harmful chemicals it contains when making  
26 purchasing decisions. It also informs consumers about any required special handling or  
27 disposition requirements at the end of the useful life of the product.

28  
29 **Section 69506.4(a)(1)(A)** requires identification of the manufacturer’s name and importer’s  
30 name. This information allows DTSC to perform audits to determine compliance with this  
31 requirement. It also informs consumers of who is responsible for a specific product.

32  
33 **Section 69506.4(a)(1)(B)** requires that the brand name and description of the product be  
34 provided to the public. This provision ensures that consumers know which product the  
35 information pertains to, and enables consumers to look up additional information about the  
36 product on the manufacturer’s website.

37  
38 **Section 69506.4(a)(1)(C)** requires that a list of the Chemical(s) of Concern and the common  
39 names for those chemicals contained in the product be provided. This provision informs  
40 retailers and consumers of the information necessary to make informed purchasing and use  
41 decisions for products that contain a Chemical of Concern.

42  
43 **Section 69506.4(a)(1)(D)** requires identification of safe handling procedures needed to protect  
44 public health or the environment during the useful life of the consumer product, and proper  
45 end-of-life disposal or management, including precautions that consumers may take to prevent

1 or limit exposure to the Chemical(s) of Concern. This provision ensures that retailers and  
2 consumers are informed of precautions that consumers may take to prevent or limit exposure  
3 to the Chemical of Concern during product use, and are instructed in how to properly handle  
4 and dispose of the products.

5  
6 **Section 69506.4(a)(1)(E)** requires identification of any end-of-life management requirements  
7 specified by law and any existing end of life management programs for the product. This  
8 provision enables consumers considering purchase of the product to be made aware of any  
9 available options and restrictions for the product at the end of its useful life.

10  
11 **Section 69506.4(a)(1)(F)** requires identification of a manufacturer's website address where the  
12 consumer can obtain additional information about the product, the adverse public health and  
13 environmental impacts associated with the product, and proper end-of-life disposal or  
14 management of the product as identified in the AA Report for the product. This provision  
15 allows consumers to know where they can obtain additional information that is not made  
16 available with the product at the time of purchase, or that is subsequently updated or  
17 augmented.

18  
19 **Section 69506.4(a)(2)** provides that the requirements specified above in section 69506.4(a)(1)  
20 do not apply if the selected alternative does not contain a Chemical of Concern exceeding the  
21 controlling alternatives analysis threshold specified in section 69503.5. This provision  
22 precludes requiring manufacturers to give product information for a product that has a low  
23 concentration of the Chemical(s) of Concern and does not warrant specialized consumer  
24 product information under these regulations.

25  
26 **Section 69506.4(b)(1) and (2)** allow the responsible entity to satisfy the requirements of  
27 section 69506.4(a) by making the required information available to consumers in an easily  
28 understood, seen, and legible format; by posting the information in a prominent place on the  
29 manufacturer's website and the importer's website; and complying with one of the following:  
30 **(A)** Providing the required information at the point of sale, on the product packaging or in  
31 accompanying written material that is accessible without breaking the product seal; or  
32 **(B)** Posting the information in a prominent place at the point of retail display. For products  
33 offered for sale online, the point of retail display is/are the web page(s) on which the  
34 product is offered for sale.

35  
36 This section also specifies that, in all cases, the information must be easily seen, legible, and  
37 understandable to the consumer. This provision ensures that the required information is useful  
38 to the consumer and is made readily available and visible to the consumer prior to purchase,  
39 while at the same time providing flexibility in how this is achieved so as to accommodate the  
40 wide variability (for example, shape, size, structure and packaging) among the range of  
41 product types that may be subject to this regulatory response. This provision also reflects the  
42 reality that with respect to certain product types, on-product label requirements may be  
43 preempted by federal law, necessitating other means of providing the required information to  
44 consumers prior to purchase.

1 **§ 69506.5. Use Restrictions on Chemical(s) of Concern and Consumer Products**  
2

3 **Section 69506.5** is necessary, in its entirety, to implement Health and Safety Code section  
4 25253(b)(4), which provides that permissible regulatory responses to Priority Products include  
5 “[i]mposing a restriction on the use of the Chemical of Concern in the consumer product.” This  
6 section also contains a logical extension of this principle to allow imposition of a restriction on  
7 the sale or use of the product itself, consistent with the Health and Safety Code section  
8 25253(b)(9) authorization for DTSC to achieve “[a]ny other outcome the department  
9 determines accomplishes the requirements of this Article.”  
10

11 **Section 69506.5** specifies that after the responsible entity submits a Final AA report, DTSC  
12 may impose a use restriction on a Chemical of Concern in, and/or on the use of the Priority  
13 Product or selected alternative product, to reduce the ability of the product to contribute to or  
14 cause adverse public health and/or environmental impacts. The use restrictions specified in  
15 sections 69506.5(a)(1) through (6) may be imposed in combination, or in concert with other  
16 regulatory responses, if DTSC determines this approach will provide the necessary health and  
17 environmental safeguards. Paragraphs (1) through (6) described immediately below are all  
18 types of use restrictions that DTSC may, but will not necessarily, impose.  
19

20 **Section 69506.5(a)** specifies a use restriction that would limit the amount or concentration of  
21 the Chemicals of Concern permitted in a Priority Product or selected alternative product. Such  
22 use restrictions may be appropriate in instances when some amount of the Chemical of  
23 Concern appears to be functionally necessary, but a reduced concentration will reduce or  
24 eliminate adverse impacts.  
25

26 **Section 69506.5(b)** specifies a restriction on the settings in which a Priority Product or  
27 selected alternative product may be sold or used. As an example, restriction of a product to  
28 use in industrial or commercial settings may be appropriate when engineering controls – such  
29 as specialized ventilation equipment – are necessary to limit exposure to the Chemical of  
30 Concern. Such controls would not be feasible in a residential setting, and thus retail sale of  
31 the product for home use might be prohibited.  
32

33 **Section 69506.5(c)** specifies a use restriction on the form in which a Priority Product or  
34 selected alternative is sold. A restriction on sale of one or more product forms might consist,  
35 for example, of a restriction on the sale of a product in concentrated form; a restriction on the  
36 use of a certain dispensing apparatus, such as an aerosol can; or a requirement to include  
37 certain safety features in a product’s packaging, such as a child-proof seal, where such  
38 measures would reduce or eliminate the potential for exposure to the Chemical(s) of Concern.  
39

40 **Section 69506.5(d)** specifies a restriction on the persons who may purchase and/or use a  
41 Priority Product or selected alternative product. Such a restriction might include, for example,  
42 a requirement that the product is sold to adults only, or that it is sold only to licensed  
43 professional users.  
44

1 **Section 69506.5(e)** specifies a restriction that requires training of purchasers and/or users of a  
2 Priority Product or selected alternative that would preclude the sale of a product containing a  
3 Chemical of Concern to anyone who is not trained in safe use procedures.  
4

5 **Section 69506.5(f)** specifies any other use restriction that reduces the amount of, or ability of  
6 the Priority Product to contribute to or cause an exposure to, any Chemical(s) of Concern in a  
7 Priority Product or a selected alternative. The regulatory responses, specified in section  
8 69506.5(a)(1) through (6), give DTSC the needed latitude to evaluate products on a case by  
9 case basis. This allows them to determine whether one or more restrictions, short of a total  
10 product ban, will provide the necessary health and environmental safeguards with respect to  
11 products that contain a Chemical of Concern yet remain in the marketplace.  
12

### 13 **§ 69506.6. Product Sales Prohibition**

14

15 Consistent with Health and Safety Code section 25253(b)(5), which states that permissible  
16 regulatory responses to a Priority Product include “[p]rohibiting the use of the Chemical of  
17 Concern in the consumer product,” Section 69506.6, in its entirety, specifies the conditions and  
18 requirements for a product sales ban. This section also helps DTSC to effectuate the  
19 requirements and purposes of the statute, in particular the provisions of Health and Safety  
20 Code sections 25253(a)(1) and 25255(a) discussed above. More specifically, this section  
21 clearly identifies those circumstances that trigger a product sales ban, and provides an option  
22 for responsible entities that would otherwise be required to implement such a ban to instead  
23 submit a revised AA Report.  
24

25 **Section 69506.6(a)** specifies that the product sales prohibition may not be imposed on a  
26 product that does not contain any Chemical(s) of Concern above the applicable alternatives  
27 analysis threshold. This provision exempts products that do not contain any Chemical(s) of  
28 Concern above the applicable alternatives analysis threshold from the sales prohibition  
29 regulatory response. Products with Chemical(s) of Concern below the applicable threshold  
30 pose a lesser hazard than those that exceed this standard, and are, thus, appropriately  
31 precluded from this most drastic regulatory response.  
32

33 **Section 69506.6(b)** specifies that unless the conditions under sections 69506.3 or 69506.6(e)  
34 apply, the requirements of section 69506.6(c) apply to a selected alternative that contains one  
35 or more Chemical(s) of Concern, or a Priority Product for which an alternative is not selected, if  
36 DTSC determines and notifies the responsible entity as specified under section 69506.1, that  
37 there is a safer alternative that does not contain a Chemical of Concern and that is both  
38 functionally acceptable and technically and economically feasible. Section 69506.6(a) further  
39 specifies that in making its determination, DTSC must consider the exposure pathways that  
40 could contribute to or cause adverse public health and/or environmental impacts. This  
41 provision appropriately establishes the criteria for imposition of a product sales ban.  
42

43 **Section 69506.6(c)** specifies that any responsible entity that is the subject of a notification  
44 under section 69506.6(b) must cease placing a noticed product into the stream of commerce in  
45 California within one (1) year of the notification, unless the notification specifies a shorter time.

1 This provision is intended to motivate responsible entities to select, and make available  
2 expeditiously to California consumers, alternatives that do not contain a Chemical of Concern  
3 when a safer alternative exists that is functionally acceptable, and technologically and  
4 economically feasible and to achieve the statutory purpose of reducing the use of harmful  
5 chemicals in consumer products.

6  
7 **Section 69506.6(d)(1) and (2)** provide that DTSC may issue a notice under section 69506.1,  
8 prohibiting the sale of a Priority Product in California, notwithstanding the absence of presently  
9 identified safer and feasible alternatives, when the responsible entity is unable to demonstrate  
10 to DTSC's satisfaction that:

11 **(A)** the overall beneficial impact of the product significantly outweighs its aggregate adverse  
12 health and environmental effects, and

13 **(B)** administrative and/or engineering restrictions associated with the product will adequately  
14 protect human health and the environment.

15  
16 This provision specifies that the responsible entity shall cease to place the noticed product into  
17 the stream of commerce in California within one (1) year of the notification date, unless the  
18 notification specifies a shorter time. This provision reflects the reality that all products are  
19 ultimately not of equal social utility, and the level of chemical exposure risk that may be  
20 acceptable in, e.g., a lifesaving medical device or a safety-critical machine part may  
21 reasonably be higher than the level of chemical exposure risk acceptable in, e.g., a children's  
22 novelty item. This regulatory provision merely makes explicit what is generally implicit in  
23 product regulatory programs, namely, that the nature of regulation must be tailored in part to  
24 reflect the degree of societal necessity of maintaining a given product in the consumer  
25 marketplace.

26  
27 **Section 69506.6(d)(3) and (4)** specify that DTSC may issue a notice under section  
28 69506.6(d)(1), above, if the responsible entity does not provide the requested information  
29 within sixty (60) days or if the information submitted does not demonstrate the criteria under  
30 section 69506.6(d)(1)(A) and (B) have been met. Further, if a responsible entity is notified by  
31 DTSC under section 69506.6(d), the responsible entity must cease placing the product into the  
32 stream of commerce in California within one year after being notified by DTSC, unless DTSC  
33 specifies a shorter time period. These provisions, in combination with the provisions of section  
34 69506.6(d)(1) and (2), make explicit the requirements that a responsible entity must meet if it is  
35 notified that a product it manufactures may no longer be placed into the stream of commerce in  
36 California. A responsible entity is required to submit the requested information within the sixty  
37 (60) days; however, if the responsible entity exceeds that deadline or fails to make an  
38 adequate demonstration of the necessity of the product under review, the responsible entity  
39 must cease placing that product into the stream of commerce in California. The provisions  
40 provide sufficient latitude in allowing responsible entities to demonstrate the social utility of a  
41 product.

42  
43 **Section 69506.6(e)** specifies that a product that is the subject of a DTSC notification under  
44 section 69506.6(b) or (d) is not subject to the requirements of section 69506.6 (c) or (d)(4) if all  
45 of the conditions in section 69506.6(e)(1) through (3) are met. This provision gives a

1 responsible entity that wishes to avoid a product ban the opportunity to do so by investing the  
2 time and resources to provide a revised Final AA Report. This option fosters the goal of  
3 introducing safer products into the California marketplace.

4  
5 **Section 69506.6(e)(1)** specifies that, within sixty (60) days after being notified by DTSC under  
6 section 69506.6(b) or (d), a responsible entity wishing to avoid a product ban must notify  
7 DTSC of its intent to submit a revised Final AA Report that selects an alternative that does not  
8 contain a Chemical of Concern. This provision allows DTSC to be informed of the responsible  
9 entity's decision to submit a revised Final AA Report in lieu of implementing a product ban.  
10 This is necessary so that DTSC knows to monitor the responsible entity's compliance with the  
11 revised Final AA Report requirement rather than the product ban requirement.

12  
13 **Section 69506.6(e)(2)** specifies that a responsible entity wishing to avoid a product ban must  
14 submit a revised Final AA Report to DTSC within one (1) year after being notified by DTSC  
15 under section 69506.6(b) or (d), unless DTSC specifies a shorter time frame. The revised  
16 Final AA Report must select an alternative that does not contain a Chemical of Concern and  
17 that fully meets the requirements of section 69505.5. A manufacturer could satisfy this  
18 requirement by revising pertinent sections of a previously completed and submitted Final AA  
19 Report. This provision ensures that if the product ban is essentially waived, the responsible  
20 entity does in fact take the steps necessary to place a safer product into the California  
21 marketplace. This provision is also works to ensure that responsible entities given this second  
22 chance do not use it to unduly delay fulfillment of the condition tied to this second chance –  
23 submission of a revised Final AA Report.

24  
25 **Section 69506.6(e)(3)** specifies that a responsible entity wishing to avoid a product ban must  
26 completely remove the product containing a Chemical of Concern from commerce by the date  
27 specified by DTSC in the notice of compliance or a notice of disapproval for the revised Final  
28 AA Report. The product removal cannot be longer than three years after DTSC issues the  
29 notice. This provision ensures that products containing Chemicals of Concern sufficient to  
30 warrant a product ban are timely removed from the market.

31  
32 **69506.6(f)(1)** specifies that a responsible entity may request a one-time extension to the due  
33 date for the Final AA Report in section 69506.6(e)(2), under the procedures specified in  
34 section 69505.1(c). This provision provides needed flexibility to accommodate unexpected  
35 delays that warrant an extension.

36  
37 **69506.6 (f)(2)** specifies that if DTSC grants an extension, the responsible entity must satisfy  
38 one of the following requirements by the due date specified in the extension approval:

39 **(A)** Submit a revised Final AA Report meeting the requirements of subsection 69506.6 (e)(2)  
40 to DTSC, or

41 **(B)** Cease placing the product in the stream of commerce in California. This provision ensures  
42 that if the product ban is essentially waived, the responsible entity does in fact take the  
43 steps necessary to place a safer product into the California marketplace. This provision  
44 also ensures that responsible entities given this second chance do not use it to unduly

1 delay fulfillment of the condition tied to this second chance – submission of a revised Final  
2 AA Report.

#### 3 4 **§ 69506.7. Engineered Safety Measures or Administrative Controls**

5  
6 **Section 69506.7(a)** specifies that DTSC may, under subsection (b), impose requirements that  
7 control access to, or eliminate or reduce exposure to, Chemical(s) of Concern in a selected  
8 alternative product, or a Priority Product for which an alternative is not selected, through  
9 engineering or administrative controls that reduce the potential for health and/or environmental  
10 harm. For example, a Priority Product that may cause harmful indoor air emissions of a  
11 Chemical of Concern might be authorized for sale only upon proof that certain ventilation  
12 conditions exist in the setting in which it will be used (an engineering control), or a Priority  
13 Product might be required to be placed behind a store counter for sale, or dispensed only by  
14 an informed intermediary who can explain relevant risks to purchasers (forms of administrative  
15 control). This provision makes specific the provisions of Health and Safety Code section  
16 25253(b)(6), which authorizes DTSC to regulate a Priority Product by “[i]mposing requirements  
17 that control access to or limit exposure to the Chemical of Concern In the consumer product.”  
18

19 **69506.7(b)** specifies that DTSC may impose engineering or administrative controls to either  
20 integrally contain the Chemical of Concern within the structure of the product, or to limit  
21 exposure to the Chemical(s) of Concern, if any of the conditions in section 69506.7(b)(1)  
22 through (3) are met. This provision makes clear that DTSC may impose a requirement to  
23 redesign a product or engineer a process to completely enclose the hazard posed by a  
24 Chemical of Concern, and thereby reduce or eliminate exposure. Alternatively, or in addition,  
25 DTSC may mandate administrative measures to reduce risks associated with the Chemical of  
26 Concern in the setting in which the product is found during any portion of its lifecycle.  
27

28 **69506.7(b)(1)** specifies that if reliable information indicates the presence of a Chemical of  
29 Concern, or its degradate, metabolite or reaction product, in a particular subpopulation, DTSC  
30 may mandate an engineering or administrative control to prevent or reduce exposures to the  
31 Chemical of Concern. This provision identifies the data relevant to DTSC’s determination of  
32 when engineering and/or administrative controls may be required to protect sensitive  
33 subpopulations, as defined in section 69501.2(a)(68).  
34

35 **69506.7(b)(2)** specifies that if reliable information indicates an elevated level of the  
36 Chemical(s) of Concern in an indoor building or other enclosed environment, DTSC may  
37 mandate an engineering or administrative control to prevent or reduce exposures to the  
38 Chemical(s) of Concern. This provision makes clear that DTSC may use reliable information  
39 demonstrating the occurrence of exposure to a Chemical of Concern in a building or other  
40 enclosed environment as the basis for requiring engineered measures to reduce such  
41 exposure. An enclosed non-building environment may include, for example, the ordinarily  
42 inhabited space of a motor vehicle, train, ship, or airplane.  
43

44 **69506.7(b)(3)** specifies that if improper product handling of the Priority Product or alternative  
45 would increase the likelihood for release of, or exposure to, a Chemical(s) of Concern, DTSC

1 may require engineering and/or administrative control to better manage and track the Priority  
2 Product or alternative. As an example, existing California law requiring dismantling of certain  
3 appliances by Certified Appliance Recyclers to ensure proper treatment of hazardous materials  
4 therein. This provision provides DTSC with the ability to ensure that the product or its  
5 components are adequately managed during their useful life, disassembly, materials  
6 extraction, and/or recycling.

## 8 **§ 69506.8. End-of-Life Management Requirements**

9  
10 **Section 69506.8**, in its entirety, is necessary to implement and make specific Health and  
11 Safety Code section 25253(b)(7), which provides that DTSC may regulate a Priority Product by  
12 “Imposing requirements for the manufacturer to manage the product at the end of its useful life,  
13 including recycling or responsible disposal of the consumer product.” Additionally, this section  
14 allows DTSC to satisfy the requirements and purposes of the authorizing statute, and in  
15 particular Health and Safety Code sections 25253(a)(1) and 25255(a), as discussed above.  
16 More specifically, this section clearly demarcates those circumstances that trigger the  
17 regulatory response requiring a responsible entity to provide an end-of-life management  
18 program for a product, and to identify the required elements of the end-of-life management  
19 program.

20  
21 The requirements of this section apply to products that are required to be managed as  
22 hazardous waste at the end of product life. The requirements of this section are necessary to  
23 build on, but do not duplicate or conflict with, existing regulatory requirements for products that  
24 must be handled as hazardous wastes at the end of their useful life. For many of these  
25 products, there are no end-of-life management programs in place, whether mandatory or  
26 voluntary. This places a logistical burden and financial hardship on local and state agencies,  
27 and, ultimately, taxpayers, to provide for management of these products at the end of their  
28 useful lives.

29  
30 Additionally, the lack of an adequate end-of-life management program often leads to illegal  
31 end-of-life disposal practices that result in adverse public health and environmental impacts.  
32 As an example, only a small fraction of Californians dispose of their mercury-containing  
33 Compact Fluorescent Light (CFL) bulbs at a hazardous waste collection facility, as is required  
34 by law. This regulatory provision is necessary to describe the situations in which  
35 comprehensive product stewardship programs are most likely to be appropriate under these  
36 regulations, to specify the elements that must be included in a DTSC-mandated product  
37 stewardship program. These provisions are based on guidance provided by the Association of  
38 State and Territorial Solid Waste Officials; the California Department of Resources Recycling  
39 and Recovery; and the California Product Stewardship Council. These provisions are meant to  
40 address both the environmental impact of Priority Products, and the fiscal impacts of waste  
41 management on local and state governments and taxpayers. These provisions provide a  
42 comprehensive yet flexible method for managing products that may have significant adverse  
43 impacts on public health and the environment if not properly managed at end-of-life.

1 **Section 69506.8(a)** requires, with respect to a selected alternative, or a Priority Product for  
2 which the responsible entity does not select an alternative, that is sold to consumers as a  
3 finished product and is required to be managed as a hazardous waste at the end of its useful  
4 life, that a responsible entity:

5 **(1)** comply with the consumer product information requirements specified in section 69506.4;  
6 and

7 **(2)** establish, maintain, and fund an end-of-life management program, as further specified, no  
8 later than one (1) year after DTSC issues a notice of compliance.

9  
10 **Section 69506.8(a)(1)** requires that the responsible entity comply with the consumer product  
11 information requirements specified in section 69506.4. In addition, the product information  
12 must state that the product or component must be disposed of or otherwise managed as a  
13 hazardous waste at the end of its useful life. The information requirements in this provision are  
14 intended to ensure that consumers are aware of the requirements for safe use and end-of-life  
15 management of the product. Alerting consumers to issues related to the end-of-life  
16 management of a product should lead to higher compliance rates.

17  
18 **Section 69506.8(a)(2)** requires a responsible entity, no later than one (1) year after DTSC  
19 issues a notice of completeness for a Final AA Report, to establish, maintain, and fund an end-  
20 of-life management program for the product, as specified in sections 69506.8(a)(2)(A) through  
21 (D). Twelve (12) months is sufficient for a responsible entity to develop and disseminate  
22 information about its Product Stewardship Plan, and create the infrastructure for the end-of-life  
23 management program. This section is necessary to implement and make more specific Health  
24 and Safety Code section 25253(b)(7), which requires these regulations to include a regulatory  
25 response mandating that manufacturers to manage their products at end-of-life. Sections  
26 69506.8(a)(2)(A) through (D) are important to establish and inform responsible entities of the  
27 required elements for the end-of-life management program required under this section.

28  
29 **Section 69506.8(a)(2)(A)** requires the responsible entity to develop and submit to DTSC for  
30 approval a comprehensive product stewardship plan. Product-specific stewardship plans are  
31 necessary to provide retailers, consumers, collection facilities, and local government with the  
32 information required for a successful end-of-life collection plan. Product stewardship plans  
33 required under this section must include all of the following information:

- 34 1. A list of, and contact information for, participating manufacturers, importers and other  
35 participating persons. This provision is necessary to identify the manufacturers,  
36 importers, and other persons responsible for the product stewardship plan. DTSC may  
37 also convene the various manufacturers and interested parties to develop programs for  
38 similar products, thus saving resources for participating parties.
- 39 2. The scope of products to be covered by the plan. This provision is necessary to ensure  
40 that the range of products covered by the plan are well defined for the benefit of all  
41 affected parties, including DTSC, manufacturers, retailers, consumers, and other  
42 interested parties.
- 43 3. The roles and responsibilities for manufacturers, importers, retailers, consumers, and  
44 government throughout the life cycle of the product. Defining roles that manufacturers  
45 and other entities will play is essential to hold the various parties accountable and

1 ensure the success of the product stewardship plan. While government can assist in  
2 bringing the parties together, it is ultimately the responsibility of the responsible entities  
3 to ensure that the plan is effective in reaching stated goals.

- 4 4. Identification and description of the collection systems that will be used. This provision  
5 is necessary to identify potential opportunities for government and other entities to  
6 assist multiple responsible parties in meeting their mutual collection needs.
- 7 5. End-of-life management information, including what steps will be taken to ensure  
8 compliance with all applicable federal and California and local laws, and that addresses  
9 any adverse multimedia impacts. This provision is necessary to: (i) assess the  
10 assumptions underlying the plan, and (ii) ensure the plan has assessed and addressed  
11 applicable regulatory requirements, and any potential multimedia adverse  
12 environmental impacts.
- 13 6. Anticipated resource needs, and a description of the financing mechanism to implement  
14 and sustain the product stewardship program, including identification of any third-party  
15 product stewardship organization collecting and administering a fee to fund the  
16 program. This section provides that multiple responsible entities may form a third-party  
17 product stewardship organization, funded by participating manufacturers and  
18 responsible entities, to provide local services to collect, recycle, or otherwise  
19 appropriately manage the designated products.

20  
21 This provision enables DTSC to assess the financial assumptions under which the plan  
22 is being developed, and to ensure that responsibility for financing the product  
23 stewardship program is appropriately assigned to the manufacturer or other responsible  
24 entity. This provision makes a responsible entity responsible for addressing the  
25 implications of a product that it places on the market throughout the product's life cycle,  
26 including ultimate disposition at the end of product useful life. By placing this  
27 responsibility on the responsible entity, instead of requiring local governments to fund  
28 collection and recovery programs for discarded products, the product stewardship  
29 program will force internalization of the costs of collection and disposal or recovery, so  
30 those costs are borne jointly by the producer and the consumer – *i.e.*, the parties  
31 deriving direct benefit from the product's sale – rather than passed on to taxpayers.

- 32  
33 7. A financial guarantee provided by the responsible entity to ensure a sustainable end-of  
34 life management program for the product. This provision is necessary so that products  
35 for which special end-of-life management is necessary will be handled properly  
36 regardless of the financial health or ongoing business status of those in the supply  
37 chain. This provision has an analog in California's existing requirement that owners and  
38 operators of hazardous waste transfer, treatment, storage, and disposal facilities create  
39 a Closure Trust Fund to provide financial assurance for proper closure of their facility  
40 regardless of whether the entity remains in business. (Cal. Code Regs, tit. 22, §  
41 66264.143.) "Financial guarantee" means any mechanism, including the mechanisms  
42 described in Article 8 of Chapter 14, to ensure that adequate funding is available to pay  
43 for future end-of-life management costs for products placed into the stream of  
44 commerce in California
- 45 8. Program performance goals, which shall be quantitative to the extent feasible for:

- a. increasing the capture rate of products at the end-of-life; and
- b. increasing recyclability (*i.e.*, reuse of product at end of life for feedstock to manufacture new products).

This provision is necessary to hold all parties involved accountable for the success of the program, and to identify areas for improvement.

9. A description of how each program goal will be achieved. This provision is necessary to insure that the program is capable of meeting stated performance goals.
10. Public education, outreach, and communications plans. This provision is necessary to ensure that the product stewardship plan both takes into account and promotes consumer awareness, a critical component of the success of any end-of-life management program.
11. A description of public and stakeholder consultation activities during preparation, and periodic review and updating, of the plan. Consultation and coordination with interested parties is essential to developing a successful product stewardship program.
12. Reporting and evaluation procedures. This provision is necessary to ensure that the program includes features essential to continual program evaluation and improvement.

**Section 69506.8(a)(2)(B)** requires the product stewardship program and plan for collecting and, if applicable, recycling the product to be developed in consultation with California retailers and owners/operators of potential collection sites. It further specifies that the collection program must include:

1. Collection mechanisms; and
2. Compensation to retailers and other persons who agree to administer or participate in the collection program.

The establishment of effective and robust collection infrastructure is an essential element of an end-of-life management program. For many products, this will require establishing collection sites that are operated by businesses other than the responsible entity. In order to gain the cooperation and participation of these businesses, the program must provide compensation.

**Section 69506.8(a)(2)(C)** requires the responsible entity 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 they have access to basic information about the end of life program through the internet.

**Section 69506.8(a)(2)(D)** requires the responsible entity for a product subject to end-of-life management requirements to ensure that a report is provided to DTSC annually that includes:

1. The quantity, by tonnage, of products placed into the California stream of commerce in the previous two-year period; and

- 1       **2.** The quantity, by tonnage, of products recovered in that two-year period. The report to  
2       DTSC helps to ensure attainment of performance goals for the end-of-life management  
3       program.  
4

5       **Section 69506.8(b)** provides that multiple responsible entities may form a third-party product  
6       stewardship organization, funded by participating manufacturers and other responsible entities,  
7       to provide local services to collect, recycle, or otherwise appropriately manage covered  
8       products at the end-of-life. This provision is necessary to make it clear that a responsible  
9       entity may collaborate with other responsible entities to implement an end-of-life management  
10      program. The flexibility and critical mass that may result from collaboration are intended to  
11      make an effective program more likely than would requiring a responsible entity to act  
12      independently.  
13

14      **Section 69506.8(c)** specifies that a responsible entity subject to the requirements of this  
15      section may request DTSC's approval to substitute an alternative end-of-life management  
16      program that achieves, to the maximum extent possible, the same results as the program  
17      required by this section. This provision provides responsible entities the flexibility to use  
18      innovative and/or customized approaches to address the end-of-life management concerns  
19      associated with their products.  
20

21      **Section 69506.8(d)** specifies that a responsible entity subject to the requirements of section  
22      69506.8 may request an exemption, by demonstrating to DTSC's satisfaction in the AA Report  
23      that an end-of-life management program cannot feasibly be implemented for its product. This  
24      provision is expected to be invoked infrequently, but is necessary because there may be  
25      products that would otherwise be subject to the requirements of section 69506.8 for which an  
26      end-of-life management program cannot feasibly be implemented because of some unique  
27      characteristic of, or circumstance associated with, the product.  
28

## 29      **§ 69506.9. Advancement of Green Chemistry and Green Engineering** 30

31      **Section 69506.9** specifies that DTSC may require a manufacturer to initiate a research and  
32      development project or fund a challenge grant pertinent to the Priority Product. Such a project  
33      or grant would use green chemistry and/or green engineering principles to address one or  
34      more of the criteria in sections 69506.9(a) through (d). These criteria relate to:

- 35      **(a)** designing a safer alternative to a Priority Product, such as, for example, a product without  
36      Chemicals of Concern;  
37      **(b)** improving the performance of a Priority Product, such as, for example, by improving its  
38      function or extending its useful life;  
39      **(c)** decreasing the cost of a safer alternative to the Priority Product, such as, for example, by  
40      optimizing production methods or increasing the scale of production; or  
41      **(d)** increasing market penetration of a safer alternative to the Priority Product.  
42

43      This provision implements and make specific Health and Safety Code section 25253(b)(8),  
44      which provides that DTSC's regulatory responses to a Priority Product may include "[i]mposing

1 a requirement to fund green chemistry challenge grants where no feasible safer alternative  
2 exists."

#### 3 4 **§ 69506.10. Regulatory Response Selection and Re-Evaluation**

5  
6 **Section 69506.10(a)** allows DTSC to impose one or more regulatory responses specified in  
7 section 69506.2 and sections 69506.4 through 69506.9 to situations other than those specified  
8 in those sections. This provision provides DTSC latitude to address situations that arise in the  
9 future that may not be readily apparent at the time of regulations drafting.

10  
11 **Section 69506.10(b)** provides that DTSC will periodically reevaluate each regulatory response  
12 imposed under this section to determine if any changes are needed, based upon changed  
13 circumstances or information identified since a regulatory response was selected. The section  
14 further specifies that DTSC may require a new AA to be performed, and Preliminary and Final  
15 AA reports to be submitted to DTSC, within a specified time. This provision makes clear that  
16 regulatory responses are dynamic, and may periodically need to be revisited and adjusted in  
17 light of new scientific, market, or other information.

#### 18 19 **§ 69506.11. Exemption from Regulatory Response Requirements**

20  
21 **Section 69506.11**, in its entirety, specifies the conditions for, and process by which a  
22 responsible entity may obtain an exemption from the requirements of Article 6. It is intended to  
23 clarify, implement, and make specific the circumstances under which no regulatory responses  
24 will be triggered under Health and Safety Code section 25253(b).

25  
26 **Section 69506.11(a)** specifies that a product is exempt from the requirements of sections  
27 69506.4 through 69606.10 if the responsible entity requests, and DTSC grants, an exemption.  
28 The exemption request must be submitted to DTSC no later than whichever of the following  
29 dates is applicable:

30 **(1)** Sixty (60) days after DTSC issues a notice to the responsible entity under section  
31 69505.6(c); or

32 **(2)** Sixty (60) days after DTSC issues a notice of compliance for a Final AA Report for a  
33 product subject to sections 69506.4 or 69506.8.

34  
35 The time period specified is sufficient for a responsible entity to request an exemption, and  
36 ensures that the exemption request and response process are completed in a timely manner  
37 so as not to delay implementation of a regulatory response significantly if DTSC denies the  
38 requested exemption.

39  
40 **Section 69506.11(b)** specifies that the exemption request must include all of the following  
41 information:

42 **(1)** The name of, and contact information for, the person filing the request. This information is  
43 necessary should DTSC need to contact the filer.

- 1 (2) The name of, and contact information for, the person(s) on whose behalf the exemption  
2 request is being submitted. This information is necessary should DTSC need to contact the  
3 responsible entity on whose behalf the exemption is sought.
- 4 (3) The name of, and contact information for, the manufacturer and importer of the product (if  
5 different from the persons identified in (1) and (2). This information is necessary should  
6 DTSC need to contact the manufacturer or importer of the product.
- 7 (4) The name of, and contact information for, any other responsible entity for the product, to  
8 the extent known to the person submitting the exemption request. This information is  
9 necessary DTSC should need to notify the responsible entity.
- 10 (5) Information identifying and describing the product, including the brand name(s) under which  
11 the product is placed into the California stream of commerce, and, if applicable, information  
12 specifically identifying the product component and/or homogeneous material, and its/their  
13 associated component, if applicable, that would otherwise be subject to a regulatory  
14 response. This information is necessary to distinguish the product or component that is the  
15 subject of the exemption request from other similar products/components.
- 16 (6) Information that demonstrates to DTSC's satisfaction that one or both of the following  
17 conditions applies:
- 18 (A) The required or proposed regulatory response would conflict with a requirement of another  
19 California or federal regulatory program or an international trade agreement ratified by the  
20 United States Senate, in such a way that the responsible entity cannot reasonably be  
21 expected to comply with both requirements; and/or
- 22 (B) The required or proposed regulatory response substantially duplicates a requirement of  
23 another California or federal regulatory program or an international trade agreement ratified  
24 by the United States Senate, without conferring additional public health or environmental  
25 protection benefits.

26  
27 The information required by this section is necessary in order for DTSC to make a factually  
28 and legally informed decision as to whether to grant an exemption. Section 69506.11(b)(6), in  
29 particular, implements and conforms to the provisions of Health and Safety Code section  
30 25252(a)(2), which instructs DTSC to "leverage the work and costs already incurred" by other  
31 nations, governments, and authoritative bodies, and thereby "minimize costs and maximize  
32 benefits for the state's economy." Whether any DTSC regulatory response that would partially  
33 or wholly duplicate a substantive requirement imposed by another sovereign would confer  
34 "additional public health or environmental protection benefits" under section 69506.11(b)(6) will  
35 be determined in part by the ease and efficacy of state-level enforcement.

36  
37 **Section 69506.11(c)** specifies that within sixty (60) days of receiving an exemption request,  
38 DTSC must issue a notice to the person who submitted the request granting or denying it. A  
39 copy of the notice must also be sent to any responsible entity known to DTSC. This provision  
40 ensures that a determination is made on the exemption request in a timely manner so as not to  
41 significantly delay implementation of the applicable regulatory response in the event that DTSC  
42 denies the requested exemption. This provision also ensures that DTSC provides adequate  
43 notice to affected responsible entities regarding regulatory response exemption  
44 determinations.

45

1 **Section 69506.11(d)** specifies that if the exemption request or DTSC’s granting of an  
2 exemption is based solely on the criteria specified in section 69506.11(b)(6)(A), DTSC may  
3 require implementation of a modified regulatory response that resolves the identified conflict.  
4 This provision provides DTSC the flexibility to impose necessary regulatory responses, while at  
5 the same time resolving any potential conflict with another regulatory requirement unknown to,  
6 or insufficiently considered by, DTSC at the time of the initial regulatory response  
7 determination.

8  
9 **Section 69506.11(e)** specifies that an exemption granted pursuant this section will be revoked  
10 if DTSC determines that the facts and/or assumptions that DTSC relied upon in granting the  
11 exemption were not, or are no longer, valid. If DTSC rescinds an exemption, DTSC must  
12 notify the person who submitted the exemption request and any responsible entity known to  
13 DTSC. This provision makes clear that exemptions are not always permanent. Revocation  
14 may become necessary if the information submitted in the exemption request is subsequently  
15 determined to be erroneous, or if the facts upon which the exemption was based change so as  
16 to no longer support an exemption.

17  
18 **Section 69506.11(f)** specifies that all notices issued under this section granting, denying, or  
19 revoking an exemption must include a statement of the basis for DTSC’s decision, and a new  
20 date for compliance, if applicable. This provision ensures that DTSC provides adequate notice  
21 to affected responsible entities and other interested parties of the bases for DTSC’s  
22 determinations in response to regulatory response exemption requests.

## 23 24 **§ 69506.12. Regulatory Response Report and Notifications**

25  
26 **Section 69506.12**, in its entirety, is necessary to: (i) hold responsible entities accountable for  
27 timely implementation of required regulatory responses and, if applicable, their selected  
28 alternative products; (ii) ensure that retailers are made aware of regulatory responses that  
29 affect the products they sell; and (iii) ensure that DTSC is kept apprised of the implementation  
30 status of required regulatory responses and selected alternative products.

31  
32 **Section 69506.12(a)** requires, subject to specified exceptions, a responsible entity for a  
33 product subject to a regulatory response to send a notice to retailers who sell the products in  
34 California, informing them of the regulatory response applicable to the product. A copy of the  
35 notice must be sent to DTSC, so that DTSC knows that the responsible entity has complied  
36 with this requirement. To ensure that retailers are provided timely notice, this section requires  
37 the responsible entity to send the notice no later than whichever date is applicable:

- 38 **(1)** Thirty (30) days after receiving a final regulatory response determination notice, or  
39 **(2)** Thirty (30) days after DTSC issues a notice of compliance for a Final AA Report.

40  
41 This notification requirement is only necessary in the case of those regulatory responses that  
42 may have a direct or immediate impact on retail inventory, so that retailers can assess whether  
43 there are any actions they need or wish to take in light of the regulatory response. This  
44 provision does not apply with respect to the regulatory responses requiring a research and

1 development project, challenge grant, or new AA, as these regulatory responses do not have  
2 the potential to have a direct or immediate impact on retailers.

3  
4 **Section 69506.12(b)** specifies that the notice required under section 69506.12(a) must include  
5 all of the following information:

- 6 (1) Name of, and contact information for, the manufacturer and the importer;  
7 (2) Name of, and contact information for, the responsible entity, if different from the  
8 manufacturer or importer;  
9 (3) Information identifying and describing the original Priority Product or component, and the  
10 selected alternative, including the brand name(s) under which the product or component is  
11 placed into the stream of commerce in California, and the name(s) of any persons identified  
12 as the manufacturer ,importer and/or distributor on the product label; and  
13 (4) A description of the required regulatory response and the due date for implementation.

14  
15 All of the information required to be included in the notice is necessary to provide the retailer  
16 with adequate information to understand the regulatory response, the product it applies to, and  
17 the contact information for the entity responsible for implementing the regulatory response.

18  
19 **Section 69506.12(c)** requires the responsible entity to notify DTSC upon completing  
20 implementation of the required regulatory response(s) and, if applicable, upon completing  
21 development and introduction into the California market of the selected alternative. The  
22 notification must include information describing how the regulatory response(s) was/were  
23 implemented. If requested by DTSC, the responsible entity must provide periodic  
24 implementation status reports regarding the selected regulatory response(s). The information  
25 provided to DTSC under this subsection must also be posted on the responsible entity's  
26 website. This provision keeps DTSC, retailers, and other interested parties informed regarding  
27 the implementation status of required regulatory response(s) and the availability of alternative  
28 products in the marketplace. This information facilitates DTSC's compliance tracking, and its  
29 enforcement in the event that the responsible entity does not implement the regulatory  
30 response(s) by the specified due date.

31  
32 **Section 69506.12(d)(1)** requires DTSC to prepare and post on its website, and update at least  
33 semi-annually, a Regulatory Response Summary that identifies the regulatory response or  
34 responses for each selected alternative for a Priority Product, or for the Priority Product,  
35 whichever is applicable. The following information must be included in the Regulatory  
36 Response Summary:

- 37 (A) Name of, and contact information for, the manufacturer and importer;  
38 (B) The names of, and contact information for, any other responsible entities known to DTSC;  
39 (C) Information identifying and describing the original Priority Product, and the selected  
40 alternative, if any, including the brand name(s) under which the product is placed into the  
41 stream of commerce in California;  
42 (D) The due date and actual date for completing development and introduction into the  
43 California market of the selected alternative, if any;  
44 (E) The regulatory response(s), if any;  
45 (F) The applicable section in Article 6 specifying the regulatory responses;

- 1 **(G)** The implementation due date, and the actual implementation date, for the regulatory  
2 response; and  
3 **(H)** Any other information provided in the notice sent from the responsible entity to California  
4 retailers under section 69506.12 (a) and (b).  
5

6 This information is required to ensure that retailers and other persons in the product supply  
7 chain, including consumers, are kept fully informed as to the requirements that apply to  
8 specific products, and the implementation status for regulatory response(s).  
9

10 **Section 69506.12(d)(2)** specifies that DTSC must also include in the Regulatory Response  
11 Report the information specified in sections 69506.12 (d)(1)(A) through (D) for each exemption  
12 granted by DTSC under section 69506.11. This is necessary to inform retailers, others in the  
13 product supply chain, and other interested parties of products for which a regulatory response  
14 exemption has been granted.

1 **Article 7. Dispute Resolution Processes**

2  
3 **Article 7**, in its entirety, describes the processes available to responsible entities who wish to  
4 dispute any of the enumerated actions of DTSC that are subject to the administrative dispute  
5 resolution procedures set out in the Article. The provisions of the Article are necessary to  
6 allow responsible entities to bring further information to the attention of DTSC that may  
7 persuade DTSC to make a different decision from the one being disputed. The Article  
8 provides for a transparent and efficient process for seeking review of important DTSC actions  
9 under this Chapter. By providing for both informal and formal dispute resolution processes, the  
10 Article tailors the manner of review to the urgency of resolving the particular issue under  
11 review.

12  
13 **§ 69507. Dispute resolution**

14  
15 **Section 69507(a)** specifies that dispute resolution procedures, except as provide in section  
16 69507(c), are available for responsible entities only that are subject to actions taken by DTSC,  
17 and makes the procedures in this Article mandatory for those seeking administrative review of  
18 DTSC decisions.

19  
20 **Section 69507(b)** specifies that a responsible entity's failure to avail itself of the procedures in  
21 Article 7 constitutes a waiver of its right to further review of the disputed issue, either  
22 administratively or judicially, because the responsible entity has failed to exhaust its  
23 administrative remedies.

24  
25 **Section 69507(c)** identifies the following DTSC actions as categories of action for which  
26 administrative dispute resolution procedures are *not* available: any decision of DTSC made  
27 under Article 2, 4, or 10. Decisions made under these Articles are not appropriate for  
28 administrative dispute resolution. More specifically, Article 2 addresses Chemicals of Concern.  
29 The entire program hinges on this basic determination of what is and is not a Chemical of  
30 Concern. If a responsible entity could challenge this determination it could bring the whole  
31 program to a halt. In addition, no burdens are imposed on responsible entity by virtue of  
32 having a chemical identified as a Chemical of Concern. Article 4 establishes a petition  
33 process. DTSC could become overwhelmed and unable to administer the program if one  
34 could enter into dispute resolution regarding an adverse decision on a petition. Finally, Article  
35 10 sets out trade secret procedures and time frames. In effect, it has a stand-alone process  
36 for pursuing relief. And DTSC could not properly carry out its duties under the Public Records  
37 Act if it could not release records that were caught up in dispute resolution. Any party wishing  
38 to challenge such determinations must do so in trial court.

39  
40 **Section 69507(d)** specifies that any disputed requirement imposed by DTSC under this  
41 Chapter is stayed while the administrative dispute is pending, thus allowing the party disputing  
42 the DTSC action to postpone compliance until the administrative dispute resolution process is  
43 complete. This avoids prejudice to the responsible entity's interests while the matter is under  
44 review, and prevents the waste of resources that would occur were a responsible entity to

1 initiate changes that might be rendered unnecessary by any change in a departmental  
2 requirement as a result of review.

### 3 4 **§ 69507.1. Informal Dispute Resolution Procedures**

5  
6 **Section 69507.1(a)** specifies which issues being disputed, under this Chapter, are subject to  
7 informal dispute resolution, as opposed to the formal dispute resolution procedures set out in  
8 Section 69507.3. Disputes regarding decisions made by DTSC under sections 69506.5,  
9 69506.6, 69506.7, 69506.9, 69506.10, and 69506.11 are not eligible for informal dispute  
10 resolution. Informal dispute processes must be initiated within thirty (30) days following the  
11 noticing, or posting on DTSC's website, of the action being disputed. Then, DTSC must allow  
12 the responsible entity or manufacturer filing the dispute to have the matter resolved within 30  
13 days of receiving the dispute.

14  
15 **Section 69507.1(b)** provides that if a responsible entity disagrees with DTSC's decision  
16 following the informal dispute resolution process, the responsible entity may appeal to DTSC's  
17 director under section 69507.2. This provision is necessary inform the parties of the time  
18 frames that apply to dispute resolution, and which processes apply to various types of  
19 disputes.

### 20 21 **§ 69507.2. Appeal to the Director**

22  
23 **Section 69507.2(a)** specifies the information the responsible entity must supply to DTSC if the  
24 responsible entity appeals a dispute to the Director of DTSC. The required information  
25 includes: the reason for seeking additional review, and why the disputed decision is not in  
26 conformity with the regulations or is unreasonable. This section also specifies additional  
27 supporting information required for review by DTSC's Director, which includes:

- 28 **(1)** The original statement of dispute;  
29 **(2)** Supporting documents; and  
30 **(3)** Copies of DTSC's responses to the dispute.

31  
32 This information is required to put all parties on notice of what information is required for  
33 DTSC's Director to review an unresolved dispute, and to provide the DTSC Director with the  
34 information needed to make an informed decision.

35  
36 **Section 69507.2(b)** sets the time frame for bringing a dispute to the DTSC Director. An  
37 appeal must be made within 30 days after the issuance of the informal dispute resolution  
38 decision. This provision is necessary so that parties are on notice of the applicable deadlines  
39 for bringing an issue to the Director and so that disputes may be resolved efficiently.

40  
41 **Section 69507.2(c)** specifies that either the Director or Director's designee may make a  
42 decision on behalf of DTSC. In either case, that decision is to be made within 60 days of  
43 receipt of the appeal to the Director or DTSC may issue a notice of ongoing review if it has not  
44 made a decision. This section also confers authority for the Director or designee to grant or  
45 deny relief in whole or in part. If the relief sought is denied, DTSC must give a short

1 explanation of the basis for its decision. If the resulting decision is to hold the responsible  
2 entity or manufacturer to the disputed requirement, then the decision must indicate the date by  
3 which compliance is required.

4  
5 **Section 69507.2(d)** specifies that a decision made under subsection (c) is the last step in the  
6 administrative dispute resolution process, and it is not subject to further administrative dispute  
7 resolutions procedures. This section ensures that the parties know the applicable time frames  
8 for deciding an appeal to the DTSC Director, know who may make such a decision, and know  
9 the range of outcomes possible. It is also ensures that disputes are resolved efficiently, and  
10 the basis for their resolution communicated clearly.

11  
12 **Section 69507.2(e)** provides that DTSC must indicate in a notice of ongoing review the date  
13 by which it expects to make a decision. That estimation must take into account the complexity  
14 of the issue(s) raised and the availability of DTSC resources. This provision is intended to  
15 keep the dispute and appeal processes efficient and to keep the parties informed of status and  
16 anticipated resolution dates.

### 17 18 **§ 69507.3. Formal Dispute Resolution Procedures**

19  
20 **Section 69507.3** specifies which DTSC decisions are subject to the formal dispute resolution  
21 procedures set out in Sections 69507.4 through 69507.6, namely, those decisions through  
22 which DTSC requires a responsible entity to take one or more specific action(s) following  
23 completion of an alternatives assessment, which include decisions made under sections  
24 69506.5, 69506.6, 69506.7, 69506.9, 69506.10 and 69506.11. It provides that these  
25 procedures operate in lieu of informal dispute resolution procedures. This section is necessary  
26 to inform affected parties of which procedures apply to which disputes.

### 27 28 **§ 69507.4. Time Lines for Requests for Review**

29  
30 **Section 69507.4** specifies that a responsible entity receiving a decision under sections,  
31 69506.5, 69506.6, 69506.7, 69506.9, 69506.10 or 69506.11 has 30 days from receipt of that  
32 decision to submit a Request for Review to DTSC. If a Request for Review is not filed within  
33 the 30-day period, then DTSC's decision is final, and not subject to further administrative  
34 dispute resolution procedures. This section is necessary so that responsible entities and  
35 DTSC know which disputes are subject to formal dispute resolution procedures, the time lines  
36 for a responsible entity to initiate such a dispute, and to make clear what constitutes  
37 exhaustion of administrative remedies in the event that a responsible entity later seeks judicial  
38 review.

### 39 40 **§ 69507.5. Contents of Requests for Review**

41  
42 **Section 69507.5(a)** specifies that a Request for Review must include a statement of the  
43 reasons why the dispute is being filed. The request must include a showing the DTSC  
44 decision is based on:

45 **(a)** Erroneous facts, assumptions, approaches, or conclusions of law; or

1 (b) Public policy judgment that makes DTSC’s review an appropriate exercise of discretion.

2  
3 This provision is necessary so that responsible entities know what information is required in  
4 their Requests for Review, and DTSC understands that nature of the requestor’s grievance.

5  
6 **§ 69507.6. Department Procedures for Requests for Review**

7  
8 Provisions (a) through (d) of this section identify time frames for DTSC response to requests  
9 for review, and explain the effect of, and procedures associated with, a grant or denial of  
10 review. Collectively, these provisions work to ensure efficient handling of matters under review  
11 and to keep parties informed of the status and progress made regarding these matters.

12  
13 **Section 69507.6(a)** specifies that DTSC has 60 days from receipt of a Request for Review  
14 filed under Section 69507.4 to issue an order granting or denying the request, or a notice of  
15 ongoing review. This provision fosters timely and efficient resolution of matters under review.

16  
17 **Section 69507.6(b)** specifies the effect of a denial of review under this section. The effect is a  
18 final administrative decision, which is effective on the date issued.

19  
20 **Section 69507.6(b)(1)** requires that an order denying review must specify the date by which  
21 the Responsible entity must come into compliance with the requirements that were the subject  
22 of the Request for Review.

23  
24 **Section 69507.6(b)(2)** requires that DTSC include a short and plain description for its decision  
25 to deny a Request for Review.

26  
27 **Section 69507.6(c)** provides that an order granting review must specify when the briefs are  
28 due from the responsible entity and DTSC.

29  
30 **Section 69507.6(d)** specifies that DTSC has 180 days from the decision granting review to  
31 make a decision on the Request for Review or to issue a notice of ongoing review.

32  
33 **Section 69507.6(d)(1)** specifies that if DTSC denies the petition, the final order must inform  
34 the responsible entity of the date for compliance with the disputed decision(s). DTSC’s denial  
35 decision under this subsection constitutes a final decision and is not subject to further  
36 administrative dispute resolution procedures.

37  
38 **Section 69507.6(d)(2)** specifies that if the final order grants any relief to the responsible entity,  
39 then the matter is to be returned to DTSC staff involved with the substantive issue(s) for  
40 reevaluation. The order must specify a deadline for completion of the reevaluation by DTSC  
41 staff that is no more than 90 days from the date of the order. The order may, but need not,  
42 provide additional guidance or criteria for the re-evaluation. This provision is necessary so that  
43 appropriate DTSC staff members are involved in technical scientific decision-making, and that  
44 their reevaluation is concluded within a reasonable amount of time.

1 **Section 69507.6(e)** requires a notice of ongoing review to specify a time by which DTSC  
2 expects to make a decision. That estimate must take into account the complexity of the  
3 issue(s) under review and the availability of existing DTSC resources.

4

5 **Section 69507.6(f)** provides that no DTSC staff who participated in making or reviewing the  
6 disputed decision may participate in the decision-making or review of decisions made under  
7 Section 69507.6. This provision is necessary to ensure that DTSC's review is fair and  
8 objective.

9

10 **Section 69507.6(g)** establishes a firewall between DTSC staff involved in the decision-making  
11 and review of decisions under this section, and those staff that participated in the decision-  
12 making in dispute, unless they include the responsible entity or its representative in the  
13 communication. This provision is necessary to ensure that there is no ex parte communication  
14 regarding matters under review.

1 **Article 8. Accreditation Bodies and Certified Assessors**

2 **Article 8**, in its entirety, is necessary to specify the requirements for qualification, accreditation  
3 and renewal of persons engaged in the training, certifying, performing, and auditing of  
4 Alternatives Analyses AAs. The provisions of this Article are necessary to ensure that all  
5 persons involved in conducting and reporting on AAs possess the knowledge, experience and  
6 expertise in order to ensure the reliability and integrity of this process and the corresponding  
7 reports.

8  
9 In developing these regulations, DTSC considered and evaluated various alternatives that  
10 would:

- 11 • minimize the cost to the state;
- 12 • create capacity to perform the work called for, while simultaneously advancing the  
13 principles of green chemistry;
- 14 • ensure only persons with the relevant education and experience are permitted to  
15 perform and prepare AAs and related reports; and
- 16 • create public confidence in the results obtained in the AAs that are prepared and  
17 submitted to DTSC

18

19 In addition to the requirements set out in Article 8, DTSC considered the following alternatives  
20 in lieu of, or in combination with Article 8:

- 21 • Status quo, i.e. No Certification;
- 22 • Third Party Verification; and
- 23 • Peer Review Process.

24

25 By doing nothing or adopting the regulations without a certification process, DTSC would be  
26 required to conduct its outreach and training on AA through existing applicable and relevant  
27 mechanisms such as factsheets, mailers and workshops. Adoption of these regulations  
28 without including a certification process for assessors would:

- 29 • increase the amount of time required for DTSC's reviews of the work that is submitted;
- 30 • result in a lack of educational requirements and any person could prepare an AA;
- 31 • result in there being no mechanism to widely disseminate advancements in  
32 technologies and manufacturing practices; and
- 33 • result in a lack of consistency in quality and rigor in the preparation of AA.

34

35 A Third Party verification requirement for an AA would require that once a responsible entity  
36 has completed its AA, it would then submit the AA Reports to the third party organization to  
37 ensure compliance with the requirements of Article. The third party verification structure would  
38 necessitate some level of qualification and licensing of Third Party(ies) capable of successfully  
39 completing the assessment That is, additional qualification requirements beyond those set out  
40 in Article 8 would be necessary. Adoption of the regulations with third party verification would:

- 41 • increase the costs to responsible entities, as a result of paying for preparation of the AA  
42 and then verification of the AA;
- 43 • serve to increase public trust and confidence in the AAs conducted; and

- require adoption of the regulations with standards that must be met by a person or entity wishing to be qualified as a third party verifier.

A Peer Review process would require that upon completion of the AA, a responsible entity would submit the AA for review to one or more peers to ensure compliance with the requirements of Article 5. Given that some of the information contained in the AA may well be trade secret, submitting the AA to peer reviewers may be problematic. At a minimum, there would seem to be complexities related to confidentiality agreements. DTSC anticipates that responsible entities would want to submit their AAs to peer reviewers in redacted form. This, in turn, could have made it difficult for the peer reviewer(s) to conduct their evaluations.

Under a “pro bono” or voluntary peer review scenario, selection of the peer reviewers would be at the discretion of the responsible entity. DTSC has determined it would be extremely difficult, if not impossible to establish in regulation a voluntary peer review process. Under a “mandatory” peer review scenario, the requirements to qualify as a peer reviewer could be in regulation similar to the regulations in Title 16, CCR, Article 6, governing peer review for professional and vocational peer reviews. While those regulations pertain to peer reviews of work performed by certified public accountants, to be meaningful and ensure public trust the provisions contained in Article 8 would need to closely parallel those requirements. In fact, many of those requirements closely align with the requirements in Article 8 of these regulations.

Adoption of the Safer Consumer Products regulations with a “Peer Review” process could be in lieu of or in combination with the provisions of Article 8. A voluntary peer review process, in lieu of the requirements in Article 8, would essentially equate to the “No Certification” process discussed earlier. The regulations do not prevent a responsible entity from soliciting peer reviews prior to the submittal of their AA reports to DTSC. A mandatory Peer Review process would contain many of the same provisions in Article 8 and would require some administration by DTSC. That is, DTSC would be compelled to provide administrative and logistical support to the peer reviewers. DTSC’s experience has been that such support is time-consuming and expensive.

In summary, the other alternatives considered were rejected for one or more of the following:

- Costs to the state to implement the program in a practical and meaningful way;
- Delays in reviews and/or impediments to innovation;
- Costs to regulated entities to implement;
- Duplicative with little or no added value; and
- Potential to create distrust in AA findings.

In drafting Article 8, DTSC examined the requirements under the Professional Engineers Act (Business and Professions Code § 6700 – § 6799) and the California Home Energy Ratings System Program (Public Resources Code Section 25942). Both of these programs create the educational, training and work experience requirements for individuals certified or licensed under either of the programs. The provisions in Article 8 include analogs to the salient

1 provisions of those two programs. Article 8 provisions support DTSC’s goal of crafting  
2 regulations that meet the letter and spirit of the authorizing statute and can be carried out in a  
3 meaningful and practical way.

4  
5 Article 8, coupled with the auditing provisions in Article 9, provide DTSC sufficient oversight  
6 over the administration of the certification process and auditing of the work conducted by those  
7 certified to ensure reliable work products.

## 8 9 **§ 69508. Qualifications and Certification for Assessors**

10  
11 **Section 69508**, in its entirety, specifies the conditions and requirements for qualification as  
12 certified assessor, as well as the duration of the certification, and criteria and procedures for  
13 renewal or termination of certified assessor status. These provisions ensure that AA are  
14 performed by persons with sufficient experience, expertise, and training in order to promote  
15 reliability, auditability, and consistency of AAs and AA Reports and to provide a disciplinary  
16 mechanism for deviations from standards of the program or of professional behavior.

17  
18 **Section 69508(a)** specifies that an individual in responsible charge of conducting an AA and/or  
19 preparing a Preliminary or Final AA Report, or both, must meet the educational and experience  
20 requirements of section 69508(a)(1) and (2). This provision establishes the requisite  
21 educational and experience requirements for becoming a certified assessor and thus ensures  
22 that AAs are performed by persons with sufficient experience, expertise, and training to ensure  
23 reliability, minimize impact on state resources; expedite innovation and foster public trust in the  
24 AA process and AA Reports..

25  
26 **Section 69508(a)(1)** requires that an individual in responsible charge of conducting an AA  
27 and/ or preparing a preliminary or Final AA Report must possess a Bachelor’s degree with a  
28 major in a scientific or engineering field from an accredited college or university. This provision  
29 ensures persons conducting the AAs and preparing the AA reports possess the appropriate  
30 educational background and knowledge to ensure the reliability of the alternatives analyses  
31 and AA Reports.

32  
33 **Section 69508(a)(2)(A)** requires that an individual in responsible charge of conducting an AA  
34 and/or preparing a Preliminary or Final AA Report, or both, must have the equivalent of two(2)  
35 years of professional experience performing AAs and/or working in a scientific or engineering  
36 field. This provision ensures persons conducting the AAs and preparing the AA reports  
37 possess the education and knowledge to ensure reliability of the AAs and AA Reports.

38  
39 **Section 69508(a)(2)(B)** requires that an individual in charge of conducting an AA and/or  
40 preparing a Preliminary or Final AA Report must have completed post-graduate work in  
41 performing AAs or in a scientific or engineering field, or both. It further specifies that time may  
42 be substituted for post graduate work on a year-for-year basis for the experience required  
43 under section 69508(a)(2)(A) for post graduate work. This provision ensures persons  
44 conducting and preparing the AA reports possess the educational background and experience

1 to ensure reliability on the findings of the alternatives analysis, while at the same time  
2 providing some flexibility in how one may satisfy these requirements

3  
4 **Section 69508(b)** specifies that on and after two (2) years after the effective date of these  
5 regulations, an individual in responsible charge of conducting an AA and/or preparing a  
6 Preliminary or Final AA Report, or both, must successfully complete an assessor training  
7 program that is developed and delivered by an accreditation body, and successfully complete  
8 an exit exam that meets the requirements of section 69508.2(c)(5) and meet the requirements  
9 specified in section 69508(b)(1) through (3). This provision ensures persons conducting the  
10 AAs and preparing the alternatives analysis reports possess the educational and work  
11 experience to ensure reliability of the AA and related reports.

12  
13 **Section 69508(b)(1)** requires an individual in responsible charge of conducting an AA and/or  
14 preparing Preliminary or Final AA Reports, or both, must receive a “Certified Alternatives  
15 Assessor” certificate, meeting the requirements of section 69508.2(c)(6), issued by the  
16 accreditation body whose training program the assessor successfully completed under section  
17 69508(b)(3). This provision ensures persons conducting and preparing the AA reports  
18 possess a certification certifying that they have met the educational and training requirements  
19 before undertaking the preparation of an AA.

20  
21 **Section 69508(b)(2)** requires an individual in responsible charge of conducting AAs and/or  
22 preparing Preliminary or Final AA Reports to maintain certification by fulfilling the  
23 requirements of section 69508(b)(2)(A) through (C). This provision ensures persons  
24 conducting AAs and preparing the AA reports have been appropriately certified and possess a  
25 certification certifying that they have met the educational and training requirements before  
26 undertaking the preparation of an AA.

27  
28 **Section 69508(b)(2)(A)** requires an individual in responsible charge of conducting an AA  
29 and/or preparing Preliminary or Final AA Reports, or both, to renew his or her certification by  
30 completing at least 20 hours of continuing education during each two-year accreditation period,  
31 as required. This must be provided or verified by the accreditation body from which the  
32 assessor will seek re-certification upon expiration of the current certification. It further  
33 specifies, that continuing education may be education and/or training focused on one or more  
34 aspects of performing, conducting and verifying AAs or closely related topics and at least two  
35 (2) hours of continuing education must be in professional ethics. This provision ensures  
36 persons conducting and preparing the AA reports keep up with changes in principles and  
37 practices in the field of AAs.

38  
39 **Section 69508(b)(2)(B)** requires a responsible individual in charge of conducting an AA and/or  
40 preparing Preliminary or Final AA Reports, or both, to renew his or her certification by  
41 submitting a renewal application to the accreditation body at least thirty (30) days prior to the  
42 expiration of the assessor’s certification. If the assessor complies with the requirements of this  
43 subparagraph and subparagraph (A) of subsection (b), the license will remain in effect until the  
44 accreditation body makes a determination on the application for renewal. This provision  
45 ensures persons conducting and preparing the AA reports continue to receive the necessary

1 training and possess up to date knowledge and apply emerging standards to ensure reliability  
2 of the AA being prepared. This provision is also necessary to provide accreditation bodies an  
3 appropriate amount of time to review renewal applications from certified assessors.

4  
5 **Section 69508(b)(2)(C)** requires an individual in responsible charge of conducting AAs and/or  
6 preparing Preliminary or Final AA Reports, or both, to receive a renewed “Certified  
7 Alternatives Assessor” certificate that satisfies the requirements of section 69508.2(c)(6)  
8 issued by the accreditation body that provided or verified the assessor’s continuing education  
9 under subparagraph (A). This provision compels persons conducting and preparing the AA  
10 reports to receive the necessary training and possess up to date knowledge and apply  
11 emerging standards to ensure reliability of the AA being prepared.

12  
13 **Section 69508(b)(3)** requires an individual in responsible charge of conducting AAs and/or  
14 preparing Preliminary or Final AA Reports, or both, to possess, and to produce when  
15 requested, a current “Certified Alternatives Assessor” certificate meeting the requirements of  
16 section 69508.2(c)(6). This provision compels persons conducting and preparing the AA  
17 reports continue to receive the necessary training, possess up to date knowledge and apply  
18 emerging standards to ensure reliability of the alternatives analysis being prepared.

19  
20 **Section 69508(c)** allows an individual in responsible charge of conducting AAs and/or  
21 preparing Preliminary or Final AA Reports, or both, to take a challenge test developed by the  
22 accreditation body in lieu of the classroom training requirements specified in sections  
23 69508.2(c)(4) and (5). This can only occur if the applicant meets the competency  
24 requirements and/or possesses on-the-job training equivalent to that specified in section  
25 60508.2(c)(4)(A) through (E). This provision provides the necessary latitude to persons who  
26 are currently conducting and preparing AA reports and possess the education and background  
27 the opportunity to demonstrate competency without requiring these individuals to participate in  
28 additional classroom instruction.

29  
30 **Section 69508(d)** specifies that if DTSC revokes, under sections 69508.3 (g)(2), (3) or (4), the  
31 designation of the accreditation body from which the assessor obtained accreditation, the  
32 assessor must apply for re-certification from another accreditation body no later than sixty (60)  
33 days after information concerning the revocation is posted on DTSC’s website. This provision  
34 compels persons conducting and preparing the AA reports are re-certified by another  
35 accreditation body, in the event that the accreditation body that previously certified them is  
36 found to be out of compliance with the requirements of these regulations. As a result a  
37 certified assessor continues to be under the direction of a valid accreditation body.

38  
39 **Section 69508(e)** specifies that an assessor’s certificate is subject to reprimand, suspension,  
40 probation, or revocation by the accreditation body or DTSC, or both, for failure to comply with  
41 the requirements of Chapter 55, or if DTSC or the accreditation body finds the assessor has  
42 engaged in activities governed by Chapter 55 in a manner that is negligent, fraudulent, or  
43 otherwise unethical. It further specifies, the accreditation body must provide DTSC the name  
44 and contact information for any assessor whose certification is revoked, suspended, placed  
45 on probation or revoked by the accreditation body, and an explanation of the reasons for the

1 rescission. This provision establishes a disciplinary process for persons conducting AAs and  
2 preparing the AA reports who fail to adhere to the requirements of this Chapter. In the broader  
3 sense, this authority is necessary to ensure the integrity and credibility of the AA program.  
4

5 **Section 69508(f)** requires final decisions and a summary of actions which result in reprimand,  
6 suspension, probation, or revocation to be posted on DTSC's web site for five (5) years after  
7 the effective date of the decision. This provision ensures interested parties are apprised of the  
8 licensure status of assessors and ensures the integrity and credibility of the AA program.  
9

10 **Section 69508(g)(1)** specifies that a certified assessor may not be in charge of conducting an  
11 AA and/or preparing AA Reports if the certified assessor has an ownership interest in the  
12 responsible entity whose Priority Product is the subject of the AA. The regulation goes on to  
13 define an "ownership interest" as one in which the certified assessor, or his or her spouse,  
14 parent or child holds a position as an officer or director of the responsible entity or if any of  
15 these people holds an equity stake in the responsible entity in the amount of \$10,000 or more.  
16 This provision ensures that certified assessors do not have a significant financial interest in the  
17 business entity whose product is the subject of the AA. The \$10,000 figure reflects the fact  
18 that some ownership interests may be so small as to not preclude a certified assessor from  
19 performing the AA. The \$10,000 amount acknowledges inflation and changes in the market  
20 from the time of the passage of the Political Reform Act, which has lower base line reporting  
21 amounts.  
22

23 **Section 69508(g)(2)** specifies that section 69508(g)(1) applies only to third party certified  
24 assessors conducting AAs and/or preparing an AA Report under a contractual agreement with  
25 the responsible entity. The provision makes it clear that the above provision does not apply to  
26 "inside/in house" certified assessors.  
27

## 28 **§ 69508.1. Qualifications for Accreditation Bodies**

29  
30 **Section 69508.1** in its entirety specifies the conditions and requirements for qualification as an  
31 accreditation body, the duration of the accreditation and criteria and procedures for renewal.  
32 The provisions within this section ensure that persons performing AAs and preparing AA  
33 Reports are trained by entities with the appropriate capacity, ability, experience, and expertise.  
34 This, in turn, promotes reliability, auditability, and consistency of AAs and AA Reports.  
35

36 **Section 69508.1(a)** requires an entity wishing to be designated, or to renew designation, by  
37 DTSC as an accreditation body to certify assessors, to have on staff one or more individuals  
38 that, in combination, possess all of the requirements in sections 69508.1(a)(1) through (6).  
39 This provision ensures that the entities certifying persons to perform AAs have the appropriate  
40 capacity, ability, experience, and expertise. This, in turn, is necessary in order to promote  
41 reliability, auditability, and consistency of AAs and AA Reports.  
42

43 **Section 69508.1(a)(1)** requires an entity wishing to be designated, or to renew designation, by  
44 DTSC as an accreditation body to certify assessors, to have on staff one or more individuals  
45 with a post graduate degree in a scientific or engineering field from an accredited college or

1 university. This provision ensures that the entities certifying persons to perform AA have the  
2 appropriate educational background and expertise. This, in turn, promotes reliability,  
3 auditability, and consistency of AAs and AA Reports.

4  
5 **Section 69508.1(a)(2)** requires an entity wishing to be designated, or to renew designation, by  
6 DTSC as an accreditation body to certify assessors, to have on staff one or more individuals  
7 with the equivalent of four (4) years of professional experience performing AAs and/or working  
8 in a scientific or engineering field. Post-graduate work in the performance of AAs and/or in a  
9 scientific or engineering field, while attending an accredited college or university, may be  
10 substituted on a year-for-year basis for the required experience. This provision ensures that  
11 entities certifying persons to perform AA have the appropriate educational background and  
12 work experience. This, in turn, promotes reliability, auditability, and consistency of AAs and  
13 AA Reports.

14  
15 **Section 69508.1(a)(3)** requires an entity wishing to be designated, or to renew designation, by  
16 DTSC as an accreditation body to certify assessors, to have on staff one or more individuals  
17 with the ability to teach, and experience teaching, the principles and practices of performing  
18 AAs as specified in Article 5. This provision is necessary to ensure that entities certifying  
19 persons to perform AA are trained by entities with the educational background and expertise in  
20 order to promote reliability, auditability, and consistency.

21  
22 **Section 69508.1(a)(4)** requires an entity wishing to be designated, or to renew designation, by  
23 DTSC as an accreditation body to certify assessors, to have on staff one or more individuals  
24 with the ability to teach, and experience teaching, the application of life cycle analysis tools  
25 and methodologies relevant to products. This provision ensures that entities certifying persons  
26 to perform AA have the appropriate educational background and expertise. This, in turn,  
27 promotes reliability, auditability, and consistency of AAs and AA Reports.

28  
29 **Section 69508.1(a)(5)** requires an entity wishing to be designated, or to renew designation, by  
30 DTSC as an accreditation body, to certify assessors, to have on staff one or more individuals  
31 with the ability to teach and experience teaching, or have access to subject matter experts with  
32 the ability to teach and experience teaching. This must apply to all of the following subject  
33 areas:

34 **(A) Environmental Fate and Transport:**

35 The concept of environmental fate and transport encompasses the following:

- 36 1. Fundamental processes in natural and engineered systems, including inter-media  
37 transport of contaminants between environmental compartments (air, water, soil and  
38 biota), and chemical and biochemical transformations within these compartments;
  - 39 2. Principles of environmental reactions with emphasis on aquatic chemistry; reaction and  
40 phase equilibria; acid-base and carbonate systems; oxidation-reduction; colloids;  
41 organic contaminants classes, sources and fates; groundwater chemistry; and
  - 42 3. Topics concerning the environment: ecology, population dynamics, pollution micro-  
43 biology, aquatic biology, bio-concentration, limnology, stream sanitation, nutrient cycles,  
44 and toxicology atmospheric chemistry
- 45

1 **(B) Principles of Green Chemistry:**

2 The concept of green chemistry encompasses the following:

- 3 1. The study of all aspects and types of chemical processes, including synthesis, catalysis,  
4 analysis, monitoring, separations and reaction conditions that reduce impacts on human  
5 health and the environment through the reduction in, or elimination of, the use or  
6 generation of hazardous materials, including feedstock, re-agents, solvents, products,  
7 and by-products; and
- 8 2. Pollution Prevention and Cleaner production methods.

9  
10 **(C) Project Life Cycle Management:**

11 The concept of project life cycle management encompasses the following:

- 12 1. Environmental management of engineering projects from the research through the  
13 development, operation, maintenance and ultimate disposal phases; and
- 14 2. Impacts of exploitation of raw materials and energy resources, and transportation;  
15 pollution from use and ultimate disposal of products; economics of environmental  
16 resources.

17  
18 **(D) Public Health:**

19 The term public health encompasses the following:

- 20 1. Impact to sensitive populations including by not limited to the study of risk and factors,  
21 such as socioeconomic status, toxic environmental exposures, and behaviors that  
22 influence the distribution of disease in subpopulations;
- 23 2. Examination of the basic principles of epidemiology, their application to specific public  
24 health situations and criteria for critically evaluating epidemiology studies; and
- 25 3. Methods of evaluating the causative factors of disease and the assessment of  
26 epidemiological study designs and research activities.

27  
28 **(E) Professional Ethics**

29 The term professional ethics encompasses the following:

- 30 1. Analysis of ethical principles and dilemmas that may arise during the conduct and  
31 preparation of the AA and AA Reports;
- 32 2. Examination of the services provided and approaches to providing impartial, fair, and  
33 equitable services dedicated to the protection of the public health and environmental  
34 safety;
- 35 3. Fundamental standards that uphold the safety, health, and welfare of the public;
- 36 4. Standards and practices to ensure that services are performed only in areas of  
37 competency, statements made only in an objective and truthful manner, the assessor  
38 acting for each employer or client as faithful agents or trustees, and deceptive acts are  
39 avoided; and
- 40 5. Rules of practice and Professional Obligations that support the above.

41  
42 **(F) Toxicology and Comparative Risk Assessment**

43 The term toxicology and comparative risk assessment encompasses the following:

- 44 1. The toxic effects that hazardous chemicals have on biological systems, including: dose-  
45 response curves, mechanisms of toxicity, carcinogenesis, and reproductive hazards;

2. The risks associated with exposure to hazardous chemicals and instruction on how risk assessment fit into the risk management processes; and
3. Examination of common toxicological effects of chemicals on biological systems through inclusion of relevant case studies.

### **(G) Occupational Health and Safety**

The term occupational health and safety encompasses the following:

1. The principles, practices and methods for identifying, evaluating, preventing and reducing workplace chemical hazards;
2. Methods for measuring and evaluating chemical-related hazardous workplace conditions; and
3. Federal and state statutory and regulatory requirements regarding occupational health protection.

This provision ensures that entities certifying persons to perform AAs have the educational background and expertise in key areas that must be addressed in the AA. This, in turn, promotes reliability, auditability, and consistency of AAs and AA Reports.

**Section 69508.1(a)(6)** requires an entity wishing to be designated, or to renew designation, by DTSC as an accreditation body, to certify assessors, have one or more individuals on staff with the ability to teach and experience teaching, or have access to subject matter experts with the ability to teach and experience teaching. This must apply to three or more of the following subject areas:

#### **(A) Economics and financial planning for innovation**

The concept of “economics and financial planning for innovation includes:

1. An introduction to the core principles of economics, finance and accounting to understand the steps necessary to bring green chemistry innovations to market; and
2. Exploration of other relevant topics in business administration and sustainability, including business models, ecological economics, entrepreneurship and service design.

#### **(B) Environmental law**

The term “environmental law” encompasses the following:

1. Federal statutory and regulatory requirements regarding public health and environmental protection;
2. State statutory and regulatory requirements regarding public health and environmental protection; and
3. Public policy.

#### **(C) Research in emerging technologies**

The term “research in emerging technologies” encompasses:

1. Advances made in Materials Science, i.e., nanotechnology, and chemical engineering; and
2. Case studies in lessons learned, which must include the principles of design, manufacture, and use of classes of materials such as metals, ceramics,

1 semiconductors, polymers, and biomaterials that addresses fundamental energy,  
2 environmental, health, economic, and manufacturing issues relating to those materials.

#### 3 4 **(D) Sustainable practices**

5 The term “sustainable practices” includes:

- 6 1. The examination and fundamental qualities, attributes and competencies to manage  
7 resources in a responsible manner, with minimal impact on natural resources and  
8 climate;
- 9 2. Identification of scientific methods for measuring and auditing the effectiveness of eco-  
10 friendly practices that make improvements on the amount of resources expended on  
11 energy, transportation, water use, recycling, and natural resource through the life cycle  
12 of products, technologies and processes; and
- 13 3. Identification skills and tools to identify emerging issues and opportunities most  
14 pertinent to specific industries, establishing appropriate goals, developing and  
15 integrating new strategies and measuring performance.

16  
17 This provision ensures that entities certifying persons to perform AA have the appropriate  
18 educational background and expertise. This, in turn, promotes reliability, auditability, and  
19 consistency of AAs and AA Reports.

20  
21 **69508.1(b)** specifies that any entity that seeks designation as an accreditation body must be  
22 independent of, and may not hold any stock or ownership interest in, any consumer product  
23 manufacturing, importation, distribution, or retail business unless they are a college, university,  
24 as specified in section 69508.1(c).

25  
26 **69508.1(c)** makes specific that section 69508.1(b) does not apply to colleges, universities, or  
27 their subdivisions, that seek designation as an accreditation body.

#### 28 29 **§ 69508.2. Accreditation Body Designation Requirements**

30  
31 **Section 69508.2**, in its entirety, is necessary to specify the conditions and requirements for  
32 designation as an accreditation body, as well as to specify the duration of the accreditation  
33 status, specify the criteria and procedures for obtaining and renewing accreditation, and to  
34 establish a disciplinary program for accreditation bodies. These provisions ensure that  
35 persons performing AA are trained by entities with the appropriate capacity, experience, and  
36 expertise. This, in turn, promotes reliability, auditability, and consistency of AAs and AA  
37 Reports.

38  
39 **Section 69508.2(a)** specifies that an entity meeting the qualification requirements specified in  
40 section 69508.1 may apply to be designated by DTSC as an accreditation body to certify  
41 assessors. This provision establishes the designation requirements and informs entities  
42 wishing to be designated as an accreditation body, the requirements for doing so.

43  
44 **Section 69508.2(b)** specifies that the application to be a designated as an accreditation body  
45 or renew designation as an accreditation body must include all of the information called for in

1 section 69508.2(b)(1) through(4). This provision establishes appropriate designation  
2 requirements for accreditation bodies and informs entities wishing to be designated as an  
3 accreditation body, the requirements for doing so.

4  
5 **Section 69508.2(b)(1)** specifies the application to be a designated as an accreditation body or  
6 renew designation as an accreditation body must include the name of, and contact information  
7 for, the person(s) submitting the application. The information requested under this provision is  
8 necessary so that DTSC knows the identity of the applicant seeking designation as an  
9 accreditation body and so that it has a means of contacting the applicant should it need to do  
10 so.

11  
12 **Section 69508.2(b)(2)** specifies that the application to be a designated as an accreditation  
13 body or renew designation as an accreditation body must include a summary of the  
14 qualifications of the individuals meeting the requirements specified in section 69508.1. The  
15 summary must include: education, experience, and areas of subject matter competency, that  
16 are available within, or to, the entity for training and certifying individuals to perform AAs. The  
17 information requested under this provision is necessary for DTSC to review and verify the  
18 qualifications of the individuals within the applicant entity, to determine if the entity meets the  
19 education, experience, and breadth of knowledge required for training and certifying individuals  
20 to perform AAs.

21  
22 **Section 69508.2(b)(3)** specifies that the application to be a designated as an accreditation  
23 body or renew designation as an accreditation body must include documentation that the entity  
24 meets all of the qualification requirements specified in section 69508.1. The information  
25 requested under this provision is necessary for DTSC to obtain and verify the qualifications of  
26 the individuals, to determine if the entity meets the education, experience, and breadth of  
27 knowledge required for training and certifying individuals to perform AAs.

28  
29 **Section 69508.2(b)(4)** specifies that the application to be a designated as an accreditation  
30 body or renew designation as an accreditation body must include a detailed description of the  
31 accreditation program demonstrating that the program meets the requirements specified in  
32 section 69508.2(c). Information detailing the description of the training program is necessary  
33 for DTSC to verify that the curriculum and training program, demonstrate sufficient breadth and  
34 rigor for training and certifying individuals to perform AAs.

35  
36 **Section 69508.2(b)(4)(A)** specifies that the application to be a designated as an accreditation  
37 body or renew designation as an accreditation body must include the entity's training program  
38 for certification of assessors, including for each course the title, content description, hours, and  
39 exam plan. Information detailing the description of the training program is necessary for DTSC  
40 to verify the curriculum and training program meet the appropriate education, for training and  
41 certifying individuals to perform AAs.

42  
43 **Section 69508.2(b)(4)(B)** specifies that the application to be a designated as an accreditation  
44 body or renew designation as an accreditation body must include demonstration of  
45 qualifications and areas of expertise of the individuals responsible for developing the entity's

1 training curriculum, as evidenced by education, experience, professional licenses,  
2 registrations, or other relevant credentials. The information requested on the qualifications of  
3 the individuals conducting the training is necessary to verify and confirm the entity meets the  
4 appropriate education, experience, and breadth of knowledge for training and certifying  
5 individuals to perform AAs.

6  
7 **Section 69508.2(b)(4)(C)** specifies that the application to be a designated as an accreditation  
8 body or renew designation as an accreditation body must include the entity's continuing  
9 education curriculum for re-accreditation of assessors, including for each course the title,  
10 content description, hours, and exam plan. Information regarding the training curriculum for re-  
11 certification is verify that the continuing education curriculum and training program, meet the  
12 appropriate breadth and rigor for training and certifying individuals to perform AAs.

13  
14 **Section 69508.2(c)** requires that an accreditation body must include in its program, at a  
15 minimum, all of the requirements in section 69508.2(c)(1) through (8). This provision is  
16 necessary, in its entirety, to obtain the information on the curriculum and training program, to  
17 determine if the entity meets the education, experience, and breadth of knowledge for training  
18 and certifying individuals to perform AAs.

19  
20 **Section 69508.2(c)(1)** requires the accreditation body's program to include admission  
21 procedures. It further specifies that a summary of application requirements and admission  
22 procedures for certification and certification renewals must be included. The applicant must  
23 include all of the following:

- 24 **(A)** The applicant's name and contact information;
- 25 **(B)** The applicant's educational experience, which must meet the requirements of section  
26 69508(a)(1) and must be substantiated by submittal of transcripts or other equivalent  
27 records;
- 28 **(C)** The applicant's employment and other experience history, which must meet the  
29 requirements of section 69508(a)(2) and for which references must be provided;
- 30 **(D)** The professional licenses, registrations, or other relevant credentials that the applicant  
31 possesses;
- 32 **(E)** Documentation of completion of continuing education required under section 69508(b)(2),  
33 if the application is for certificate renewal; and
- 34 **(F)** A signed and dated certification statement that reads: "I certify under penalty of perjury that  
35 the information I have entered on this application is true and complete to the best of my  
36 knowledge. I further understand that any false or incomplete statements may result in my  
37 disqualification as a certified assessor. I authorize the employers and educational  
38 institutions identified on this application to release any information they may have  
39 concerning my employment or education to the accreditation body with which this  
40 application is filed and to the State of California."

41  
42 This provision ensures that the entities applying for accreditation have a comprehensive  
43 program for obtaining and evaluating the applicants': educational experience; employment and  
44 work experience; and professional licenses, registrations, or other relevant credentials that an  
45 applicant possesses. Further, this provision requires that the applicant sign a statement

1 attesting to the accuracy of the information that is submitted. Collectively, all of these  
2 requirements are necessary to ensure the accuracy of the information submitted to  
3 accreditation bodies by candidates for certified assessor.

4  
5 **Section 69508.2(c)(2)** requires the accreditation body's program to include the verification  
6 procedures. Written procedures must be included for verifying an applicant's qualifying  
7 education and experience, including verification of fulfillment of continuing education  
8 requirements. This provision ensures that verification procedures are in place to evaluate the  
9 applicant's: educational experience; employment and work experience; and professional  
10 licenses, registrations, or other relevant credentials that the applicant possesses.

11  
12 **Section 69508.2(c)(3)** requires the accreditation body's program to include denial criteria. A  
13 summary of the criteria and procedures for denying an applicant for certification or certification  
14 renewal must be included. Denial decisions must be provided to the applicant in writing and  
15 must state the grounds for denial and, if applicable, specify the conditions the applicant must  
16 fulfill in to order to be certified or re-certified as an assessor. This provision ensures that the  
17 entity's applying for designation as an accreditation body, have in place the criteria for  
18 denying certified assessor status for applicants failing to meet the requisite qualification,  
19 including educational and work experience.

20  
21 **Section 69508.2(c)(4)** requires the accreditation body's program to include the Training of  
22 Assessors. The training program must include classroom and on-the-job assistance and/or  
23 training of applicants. The training must incorporate classroom and/or on-the-job training in  
24 analysis of information and practical application of principles, at a minimum, in all of the  
25 following:

- 26 **(A)** The requirements of this Chapter, with an emphasis on the requirements of Articles 5, 6,  
27 and 10;
- 28 **(B)** Training and case studies on principles and practices of performing AAs as specified in  
29 Article 5, using life cycle analysis tools and methodologies, and life cycle thinking, which  
30 refers to the examination of public health and environmental impacts over a product's entire  
31 life cycle;
- 32 **(C)** Training and case studies on identification of alternatives for consideration in AAs;
- 33 **(D)** Training and case studies on identification of the life cycle segments and exposure  
34 pathways for chemicals and products; and
- 35 **(E)** Training needed for the attainment of expertise in specific fields necessary to the  
36 performance of AAs.

37  
38 This provision ensures that the entity's applying for designation as an accreditation body, have  
39 in place a comprehensive training program to certify or recertify assessors.

40  
41 **Section 69508.2(c)(5)** requires the accreditation body's program to include an evaluation and  
42 examination of assessors. The program must include:

- 43 **(A)** A DTSC-approved written and practical test or evaluation that demonstrates the applicant's  
44 competence in the training requirements specified in section 69508.2(4)(A) through (E);  
45 and

1 **(B)** A DTSC-approved challenge test developed by the accreditation body that may be used in  
2 lieu of the classroom training requirements specified in 69508(c) and written and practical  
3 tests for applicants that meet the competency requirements and/or possess on-the-job  
4 experience that is equivalent to the requirements specified in section 69508.2(4)(A) through  
5 (E).  
6

7 This provision ensures that the entities applying for designation as an accreditation body have  
8 in place the evaluation and examination of assessors prior to certifying as a certified assessor.  
9 The evaluation and examination of assessors must include a DTSC approved written and  
10 practical evaluation. In addition, the program must include a DTSC approved challenge test to  
11 be administered to applicants who possess the competency requirements that would be  
12 gained from attending the class instruction. These provisions establish the appropriateness of  
13 the “default” test to be administered by the accreditation body and provide qualified applicants  
14 the flexibility of an expedited certification process.  
15

16 **Section 69508.2(c)(6)(A)** requires the accreditation body’s program to include a certificate  
17 issuance. A certificate for initial certification and certification renewal that is entitled “Certified  
18 Alternatives Assessor” must include, at a minimum, all of the following:

- 19 1. Assessor’s name;
- 20 2. Certificate number;
- 21 3. Certification issuance date and expiration date;
- 22 4. Name and contact information of the accreditation body issuing the certificate;
- 23 5. An indication whether the certificate is for initial certification or a renewal;
- 24 6. The product type(s) and/or industry sector(s) for which the assessor is certified;
- 25 7. A statement that the assessor meets the requirements of section 69508(a) and (b); and
- 26 8. The signature of the owner or an officer of the accreditation body issuing the  
27 certification.  
28

29 This provision specifies the contents of a certificate that must be issued to the applicant and  
30 made available to DTSC and an interested party upon request. In addition, these  
31 requirements ensure consistency in the certificates issued by accreditation bodies. These  
32 certificates are necessary in order for DTSC and an interested party to verify that the assessor  
33 preparing and submitting an AA meets the educational an experience requirements of Article 8  
34 to conduct and prepare AA reports under Article 5.  
35

36 **Section 69508.2(c)(6)(B)** requires the accreditation body’s program to include requirements  
37 and a process for certification renewal every two (2) years. This provision ensures that the  
38 accreditation body has in place a certificate renewal process to ensure the continued  
39 qualification status of certified assessors.  
40

41 **Section 69508.2(c)(7)** requires the accreditation body’s program to include an assessor  
42 agreement and audit program. The program must require that certified assessors enter into an  
43 agreement with the accreditation body under which the assessors agree to:

- 44 **(A)** Provide AA services only in the areas of expertise in which the individual has  
45 demonstrated competence;

- 1 (B) Provide true and accurate analysis; and  
2 (C) Random auditing by the accreditation body or its consultants, subject to non-disclosure  
3 agreements as needed, to ensure the quality of work and proper application of tools by the  
4 assessor.  
5

6 This provision ensures that the accreditation body has in place an agreement and audit  
7 program to evaluate assessors. These provisions ensure the integrity of the certified assessor  
8 program and AAs conducted by them. They are also necessary to ensure that DTSC can  
9 properly perform its oversight function to ensure the integrity and rigor of the AA program.  
10

11 **Section 69508.2(c)(8)(A)** requires the accreditation body's program to include a record  
12 maintenance program. The accreditation body's program must maintain a database of the  
13 names of individuals whose applications were accepted or denied, names of individuals  
14 certified, their certificate numbers, and their certificate issuance and expiration dates. The  
15 database must also include copies of applications, verification information, audit records, and  
16 violations, if any. All records must be maintained for a minimum of five (5) years. This  
17 provision ensures that the accreditation body has in place an electronic record maintenance  
18 program of the names of individuals whose applications were accepted or denied, names of  
19 individuals certified, their certificate numbers, and their certificate issuance and expiration  
20 dates. This, in turn, is necessary for DTSC and interested parties to have confidence in the  
21 work done by the accreditation body and to keep track of the number and caliber of certified  
22 assessors available to do AA work.  
23

24 **Section 69508.2(c)(8)(B)** requires that upon the request by DTSC, but not more frequently  
25 than annually, an accreditation body must submit to DTSC sufficient information to facilitate  
26 audits by DTSC under Article 9. This provision ensures that the accreditation body provides  
27 DTSC with information that is necessary for DTSC to carry out its oversight duties under this  
28 program, including the Audit function specified in Article 9.  
29

### 30 **§ 69508.3. Accreditation Body Designation Process**

31  
32 **Section 69508.3**, in its entirety, is necessary to specify the process for designation as an  
33 accreditation body, as well as to specify the duration of the accreditation, the renewal process  
34 and to establish a disciplinary process. These provisions inform applicants for accreditation  
35 body status and other interested parties what the procedures and time frames are for  
36 processing accreditation body applications. They are also necessary to ensure that DTSC's  
37 actions are standardized and applied fairly.  
38

39 **Section 69508.3(a)** requires DTSC to review the application submitted under section 69508.2  
40 and approve or deny the request for designation as an accreditation body, within sixty (60)  
41 days of receiving the application. It further specifies that DTSC must notify the person  
42 submitting the application of its determination and must state the grounds for denial and, if  
43 applicable, specify the conditions the applicant must fulfill in order to be designated, or re-  
44 designated, as an accreditation body. This provision ensures that entities applying to be  
45 designated an accreditation body are informed of the procedures and requirements on DTSC

1 when it receives an application for accreditation body status. It also ensures that DTSC's  
2 actions are standardized and applied fairly.

3  
4 **Section 69508.3(b)** specifies if the information submitted under section 69508.2 changes, the  
5 person that submitted the application must provide updated written information to DTSC within  
6 thirty (30) days of the change. This provision ensures that DTSC is made aware of any  
7 changes that may affect the qualifications of an entity to serve as an accreditation body.

8  
9 **Section 69508.3(c)** specifies the designation as an accreditation body expires after a period of  
10 five (5) years, except that it may be renewed upon application by the accreditation body, under  
11 section 69508.2, not later than ninety (90) days before expiration of the existing designation.  
12 Applications for renewal of designation meeting the requirements of section 69508.2 will  
13 extend the expiring designation until DTSC makes a determination on the renewal application.  
14 This provision ensures that entities designated an accreditation body continue to meet the  
15 requirements for being an accreditation body. The renewal process provides DTSC a  
16 necessary means of ensuring that the entity may still qualify as an accreditation body.

17  
18 **Section 69508.3(d)** specifies if DTSC determines an accreditation body negligently or willfully  
19 in violation of this Chapter, DTSC must revoke the entity's designation as an accreditation  
20 body for a period of at least ten (10) years. After this period, the accreditation body may  
21 reapply to be designated as an accreditation body. This provision establishes the appropriate  
22 consequences for negligent or willful violation of these regulations and to put an accreditation  
23 body on notice of the minimum revocation time period for violations of this Chapter.

24  
25 **Section 69508.3(e)** specifies that an accreditation body may not claim trade secret protection  
26 for its general admission process, curriculum, and educational approach. This provision  
27 ensures that general admission processes, curriculum, and educational approach are must be  
28 provided to candidates wishing to become certified assessors and other interested parties.

29  
30 **Section 69508.3(f)** specifies that DTSC may periodically review the performance of an  
31 accreditation body to determine whether the accreditation body is in compliance with the  
32 requirements of Chapter 55. This review may include records review and/or interviews of  
33 assessors participating in the training and certification program. This provision authorizes  
34 specific oversight activities by DTSC to ensure the integrity of the accreditation body program  
35 and to put accreditation bodies on notice on the frequency and type of review to which they  
36 may be subject.

37  
38 **Section 69508.3(g) requires** DTSC to revoke a designation of an accreditation body if any of  
39 the following occur:

40 **(1)** The designation period has lapsed, and the accreditation body has not submitted a renewal  
41 application that meets the requirements of section 69508.2;

42 **(2)** A substantial number of individuals certified by the accreditation body as assessors are  
43 found to be in violation of Chapter 55;

- 1 (3) DTSC finds that the accreditation body has significantly deviated from the documentation  
2 submitted to DTSC under section 69508.2, or is out of compliance with the applicable  
3 requirements of Article 8; or  
4 (4) DTSC finds the accreditation body to have carried out its activities governed by this  
5 Chapter in a manner that is negligent, fraudulent, or is otherwise unethical.  
6

7 This provision establishes the mandatory authority and grounds for DTSC to revoke an  
8 accreditation body's designation/status. It is also necessary to put an accreditation body on  
9 notice of the conditions under which revocation of their accreditation is mandatory.  
10

#### 11 § 69508.4. Filing a Complaint

12  
13 **Section 69508.4(a)** provides that a person may file a complaint against an accreditation body  
14 or certified assessor and alleging a violation of Chapter 55 and specifies that the complaint  
15 must include the information specified in section 69508.4(a)(1) and (2). This provision makes  
16 specific the required contents of a complaint and procedures for a person making a claim that  
17 a designated accreditation body or certified assessor is in violation of Chapter 55.  
18

19 **Section 69508.4(a)(1)** specifies that a complaint alleging a violation by an accreditation body  
20 or certified assessor must include the name of, and contact information for, both of the  
21 following:

- 22 (A) The accreditation body or certified assessor that is the subject of the complaint, ("the  
23 subject"); and  
24 (B) The name and contact of the complainant, unless filing anonymously  
25

26 This provision makes specific the information that must be provided by a person making a  
27 claim that a designated accreditation body or certified assessor is in violation of Chapter 55.  
28 Section 69508.4(a)(1)(B) is necessary to allow a person the opportunity to make an  
29 anonymous submittal. This will avoid a chilling effect that could result if all complainants were  
30 required to identify themselves.  
31

32 **Section 69508.4(a)(2)** specifies that a complaint alleging a violation by an accreditation body  
33 or certified assessor must include a description of the complaint, including the particular  
34 requirements that are alleged to have been violated and the facts which the complainant relies  
35 upon to support the alleged violation. This provision ensures that complaints contain the  
36 essential information to allow DTSC to understand the essential nature of the complaint and to  
37 appropriately follow up on the complaint.  
38

39 **Section 69508.4(b)** requires DTSC within thirty (30) days of receiving a complaint, to review  
40 the complaint and determine if the complaint contains the items specified in subsection (a). If  
41 DTSC determines that a complaint is complete, DTSC must notify the complainant, unless  
42 submitted anonymously, that DTSC will conduct further review to determine whether a violation  
43 has occurred. If DTSC determines that the complaint is incomplete, it must notify the  
44 complainant and specify the basis for the determination. Anonymous complaints lacking  
45 sufficient information will be dismissed. This provision ensures a standardized complaint

1 process and makes specific the amount of time in which to expect a response from DTSC  
2 notifying the complainant that the complaint contains the required information and DTSC will  
3 pursue further investigation.

4  
5 **Section 69508.4(c)** specifies if the complaint substantially complies with the requirements of  
6 this section, DTSC must serve a copy to each subject of the complaint, together with an order  
7 requiring that the complaint be answered by the subject within thirty (30) days after the date of  
8 service. This provision ensures a standardized approach in processing complaints, to keep  
9 the complaint process moving and to require a response by the subject of the complaint.

10  
11 **Section 69508.4(d)** requires DTSC to review the information and documentation in the  
12 response from the subject of the complaint and may refer items to external subject matter  
13 experts for review and recommendations. This provision ensures DTSC will review and take  
14 into account the response from the subject of the complaint in order to ensure a fair complaint  
15 review process and to allow input from subject matter experts, when appropriate.

16  
17 **Section 69508.4(e)** requires that DTSC close a complaint if it determines there is insufficient  
18 evidence to determine whether or not a violation has occurred. This provision ensures an  
19 efficient complaint review process and informs interested parties that complaints with  
20 insufficient evidence will be closed.

21  
22 **Section 69508.4(f)** specifies upon a determination that a violation has occurred, DTSC must:  
23 **(1)** Warn the subject of the complaint by issuing a citation, and obtain compliance;  
24 **(2)** Pursue the violations under the Administrative Procedure Act; and/or  
25 **(3)** Refer the matter to the Attorney General or appropriate district attorney.

26  
27 This provision makes specific that DTSC has the authority to, and will pursue violations  
28 through the various mechanisms available to DTSC. It is also necessary to clarify that the  
29 actions that DTSC may take may be taken in combination, and is not limited to one of the  
30 actions to the exclusion of the others.

1 **Article 9. Audits**

2  
3 **Article 9**, in its entirety, is necessary to implement, clarify, and make specific the provisions of  
4 Article 14 of Chapter 6.5 of Division 20 of the Health and Safety Code. More specifically, this  
5 Article establishes an audit program that DTSC may administer to ensure the accuracy and  
6 integrity of actions performed under these regulations and of documents submitted to DTSC  
7 under these regulations. While various documents related to the Alternatives Analysis process  
8 in Article 5 are called out specifically, they are not the only actions or documents subject to  
9 DTSC's auditing. Rather, these items enumerated are a non-exhaustive list of some of the  
10 critical activities and documents that are subject to DTSC's audit to ensure the integrity of  
11 DTSC's safer consumer products program.

12  
13 **§ 69509. Audit of Materials Submitted to the Department and Regulatory Responses**

14  
15 **Section 69509** establishes the existence of DTSC's audit program so that responsible entities  
16 and other interested parties are aware that such a program exists and are put on notice as to  
17 its scope.

18  
19 **Section 69509(a)** sets out a non-exhaustive list of actions taken by or on behalf of responsible  
20 entities that may be subject to audit by DTSC. The non-exhaustive list establishes some of the  
21 important items that are subject to audit and to inform parties that these are not the only  
22 actions and documents subject to DTSC's audit.

23  
24 **Section 69509(b)** specifies the permissible scope of audits undertaken by DTSC. This  
25 provision puts interested parties on notice of the types of information and focus of audits that  
26 may be undertaken by DTSC.

27  
28 **Section 69509(c)** sets out the actions that DTSC is required to take after completing an audit.  
29 More specifically, DTSC must inform:

- 30
- the responsible entity(ies) of the audit findings; and
  - the process for disputing the audit findings.
- 31

32  
33 This ensures that responsible entities and other interested parties understand the process that  
34 DTSC will follow after completing audits conducted under these regulations.

1 **Article 10. Trade Secret Protection**

2  
3 **Article 10**, in its entirety, is necessary to detail requirements for the submission and handling  
4 of information submitted to DTSC under Chapter 55 that is claimed by the submitter to be  
5 protected from disclosure as Trade Secret material.

6  
7 Health and Safety Code section 25257(a) authorizes persons submitting information to DTSC  
8 to “identify a portion” thereof as trade secret (section 25257(a)); subsection (b) of Section  
9 25257 requires DTSC employees to “maintain the confidentiality of that trade secret”; and  
10 section 25257(c) provides that all information that is not identified as trade secret shall, to the  
11 extent consistent with other laws, “be available to the public,” including, “[t]he fact that  
12 information is claimed to be a trade secret.” Subsection (a) further provides that submitters  
13 must comply with any written request from DTSC for “support for the claim that . . . information  
14 is trade secret.” Article 10 implements these requirements by establishing mechanisms for  
15 insuring that trade secret claims are meritorious; insuring that genuinely trade secret material  
16 is well protected from inadvertent disclosure; and delineating clearly which information  
17 submitted under Chapter 55 may be publicly released, and in what time frame. The provisions  
18 of Article 10 also reduce administrative burdens on DTSC by outlining a clear process for the  
19 designation, handling, and evaluation of trade secrecy claims.

20  
21 Consistent with Health and Safety Code section 25257(a), these regulations – in Article 1,  
22 section § 69501.1 (“Definitions”), subsection (a)(62), incorporate by reference the definition of  
23 “trade secret” in the Uniform Trade Secrets Act, at Civil Code section 3426.1(d). This two-  
24 pronged definition requires that a person asserting a trade secrecy claim demonstrate both  
25 that the information sought to be protected has economic (*i.e.*, “trade”) value, and that  
26 reasonable efforts have been made to maintain its confidentiality (keep it “secret”). This  
27 definition is consistent with the trade secrecy definition in the California Public Records Act,  
28 Government Code section 6254.7, which is also referenced in Health and Safety Code section  
29 25257(a). It is also consistent with the broader definition of trade secrecy contained in the  
30 Restatement (Third) of Unfair Competition (Section 39), which is an authoritative treatise on  
31 the Model Uniform Trade Secrecy Act that has been adopted in California.

32  
33 **§ 69510. Assertion of a Claim of Trade Secret Protection**

34  
35 **Section 69510(a)** specifies that a person who asserts a claim of trade secret protection with  
36 respect to information submitted to DTSC under Chapter 55 will receive a written request from  
37 DTSC to furnish DTSC with all of the substantiating information in paragraphs (1) through (10)  
38 of subdivision (a). This provision implements Health and Safety Code Section 25257(a), which  
39 authorizes DTSC to make a written request for “support for the claim that . . . information is  
40 trade secret.” This provision also reflects DTSC’s determination that for reasons of both  
41 fairness to submitters and administrative efficiency, DTSC will in writing request substantive  
42 support for all trade secrecy claims. It is necessary for this support to address multiple factors,  
43 because “[i]t is not possible to state precise criteria for determining the existence of a trade  
44 secret,” (Restatement (Third) of Unfair Competition, Section 39); and because analysis of a

1 trade secrecy claim necessarily involves evaluating multiple relevant factors, no single one of  
2 which is determinative.

3  
4 **Section 69510(a)(1)** requires identification of the person asserting a trade secrecy claim,  
5 which is necessary to identify a point of contact for any issues that arise with respect to  
6 processing confidential documents, safeguarding confidential information, and any challenge  
7 to the trade secrecy claim.

8  
9 **Section 69510(a)(2)** requires a brief description of the nature of the information that is the  
10 subject of the claim. This provision works to demarcate the non-confidential and confidential  
11 portions of an information submittal, consistent with the instruction in 25257(c) to make public  
12 “[t]he fact that information is claimed to be a trade secret.”

13  
14 **Section 69510(a)(3)** requires an explanation of the extent to which the information is known by  
15 employees or others involved with the facility or business of the person, and whether or not  
16 those individuals are bound by non-disclosure agreements;

17  
18 **Section 69510(a)(4)** requires an explanation of the extent to which the information is known  
19 outside of the facility or business of the person, and whether or not individuals with such  
20 knowledge are bound by non-disclosure agreements; and

21  
22 **Section 69510(a)(5)** requires an explanation of the measures taken to restrict access to and  
23 safeguard the information, and whether or not the person plans to continue to use these  
24 measures. All three of these provisions in subsections (a)(3) through (5) assist DTSC in  
25 assessing whether, consistent with Civil Code section 3426.1(d), the submitter has made  
26 “efforts that are reasonable under the circumstances” to maintain the secrecy of the  
27 information at issue. As noted in the Restatement (Third) of Unfair Competition, Section 39,  
28 many forms of precaution may be taken to preserve secrecy, including, but not limited to, use  
29 of physical security measures, need-to-know policies, nondisclosure agreements, signs, and  
30 restrictive legends that communicate the confidential nature of the underlying information.

31  
32 **Section 69510(a)(6)** requires an explanation of the estimated value of the information to the  
33 claimant and the claimant’s competitors; and

34  
35 **Section 69510(a)(7)** requires an explanation of the estimated amount of effort or money  
36 expended by the claimant to develop the information. These two provisions, (a)(6) and (7),  
37 help DTSC assess whether, consistent with Civil Code section 3426.1(d), the information at  
38 issue has “independent economic value, actual or potential, from not being generally known” to  
39 the public or others who can benefit from it. Where precise value is difficult to ascribe to a  
40 trade secret, expenditures to develop that information provide a useful proxy. See  
41 Restatement (Third) of Unfair Competition, Comment (e) (“Although a trade secret may consist  
42 of information discovered fortuitously, a significant expenditure of time, money, or effort in the  
43 production of the information is evidence of value.”)

1 **Section 69510(a)(8)** requires an explanation of the estimated ease or difficulty with which the  
2 information could be properly acquired or duplicated by others, including, with respect to any  
3 chemical identity for which trade secrecy is claimed, an explanation of why the chemical  
4 identity is not readily discoverable through reverse engineering. DTSC included this provision  
5 because a determination whether information is “readily ascertainable through proper means”  
6 is central to the trade secrecy inquiry. (See Restatement (Third) of Unfair Competition,  
7 Comment (f)).

8  
9 In the case of chemical formulations, the ease or difficulty of determining a chemical’s identity  
10 through laboratory deformation (“reverse engineering”) is central to whether that identity is  
11 trade secret. (See, e.g., Cal. Civ. Code section 3426.1(a) (stating that reverse engineering is  
12 not alone a misappropriation of a trade secret)); Emergency Planning and Community Right to  
13 Know Act, 43 U.S.C. Section 11042(b)(4) (stating that a person claiming trade secrecy for a  
14 chemical identity must show that “[t]he chemical identity is not readily discoverable through  
15 reverse engineering”; *Worthington Compressors, Inc. v. Costle*, 662 F.2d 45, 52 (D.C. Cir.  
16 1981) (stating that “the cost of reverse engineering” is material to evaluating whether there will  
17 be “competitive harm resulting from disclosure.”)

18  
19 **Section 69510(a)(9)** requires that the submitter of claimed-secret information provide DTSC  
20 with copies of, or references to, any pertinent trade secret or other confidentiality  
21 determinations previously made by DTSC or other government agencies. This provision  
22 ensures consistent treatment of information within and among government agencies, and to  
23 streamline DTSC’s evaluation of a trade secrecy claim where other agencies have already  
24 made a confidentiality determination with respect to the same information.

25  
26 **Section 69510(a)(10)** requires an explanation of the nature and extent of harm that would be  
27 caused if the claimed-secret information were made public, including an explanation of the  
28 causal relationship between disclosure and the harmful effects claimed. Because trade-secret  
29 designation disserves both the public interest in access to information and the marketplace  
30 interest in promoting competition, this provision ensures that claims for trade secrecy are not  
31 frivolously asserted with respect to information that has minimal value to the submitter.

32  
33 The substantiation requirements in section 69510(a)(1) through (10) are also consistent with  
34 the suite of factors used to examine trade secrecy claims under the Restatement (Second) of  
35 Torts (2d section 757, comment( b); California case law (see, e.g., *Futurecraft Corp. v. Clary*  
36 *Corp.* (1962) 205 Cal.App.2d 279, 289); other California regulations (see Title 8, Cal. Code  
37 Regs., Section 5194, App. D); and formal Departmental policy regarding Public Records Act  
38 requests for trade secret information (DTSC Public Records Act Policy, dated October 8, 2003,  
39 Administrative Directive DO 1-03-10). Submitters are not precluded from providing to DTSC  
40 any other information they deem relevant to the justification of their trade-secrecy claim.

41  
42 **Section 69510(a)(11)** requires the signature of the submitter’s general counsel or other  
43 executive with knowledge of the preparation of the substantiating information to certify under  
44 penalty of perjury that:

45 **(A)** the substantiating information is true, accurate, and complete;

1 (B) the information for which trade secret protection is sought is not otherwise available to the  
2 public; and  
3 (C) there is a reasonable basis for the trade secret claim for the information subject to the  
4 claim. These three requirements are necessary to insure the submitter's careful internal  
5 review of and accountability for trade-secret claim justifications, and are expected to  
6 prevent the submission of frivolous or unsubstantiated claims of trade secrecy.  
7

8 **Section 69510(a)(12)** requires that contact information for the individual to be contacted if any  
9 of the information claimed as trade secret is the subject of a California Public Records Act  
10 request. DTSC needs this information so that it may contact the submitting party if DTSC has  
11 any questions about the claim of trade secret protection, and/or to carry out its duties under  
12 Section 69510.1.  
13

14 **Section 69510(b)** specifies that while certain substantiating information must be provided for  
15 each trade secret claim, information that is identical between or among claims may be  
16 incorporated by reference. This provision reduces the regulatory compliance burden for  
17 persons submitting multiple claims to DTSC under a claim of trade secret protection, and  
18 reduces the administrative burden on DTSC in reviewing redundant information.  
19

20 **Section 69510(c)** requires that a person who submits a claim of trade secret protection must  
21 also at the time of submission provide DTSC with:

- 22 (1) a complete copy of the documentation being submitted, including the information claimed  
23 as trade secret; and
- 24 (2) a redacted copy of the documentation being submitted, excluding the information claimed  
25 as trade secret.  
26

27 This section further provides that DTSC may provide a copy of the redacted version of  
28 information without further notice or procedure. This provision ensures an effective and  
29 efficient means for DTSC to provide information requested under the Public Records Act to  
30 parties requesting the information. Placing the burden for redacting submitted information on  
31 the party making the trade secret claim(s) is the best means of reducing errors and the  
32 possibility of DTSC's inadvertent release of confidential information.  
33

34 **Section 69510(d)** requires the submitter, at the time of submission, to conspicuously mark  
35 each page containing claimed confidential information with the words "Trade Secret." The  
36 requirement for conspicuous marking is makes it clear to DTSC staff the claimed trade secret  
37 status of each individual page, which will inform proper document handling and reduce the  
38 chances of inadvertent disclosure. This section also specifies that if no claim of trade secret  
39 protection is made at the time of submission, DTSC may make the submitted information  
40 available in full to the public without further notice. This provision makes it clear to the  
41 submitter the consequences of not making a claim of confidentiality at the time of submission,  
42 under Health and Safety Code section 25257(c).  
43

44 **Section 69510(e)** provides that if the documentation supporting a claim of trade secret  
45 protection contains information that itself is subject to a claim of trade secret protection, the

1 supporting documentation must be separately supplied for each claim and provided in both  
2 complete and redacted form, as specified in section 69510(c) but shall not itself require further  
3 supporting documentation. This provision ensures that the substantiation information is  
4 treated properly, and that DTSC's administrative burden is minimized. Furthermore, it is  
5 necessary so that the substantiation requirement not be applied to the justification documents  
6 themselves in order to avoid an infinite substantiation loop. However, any substantiation  
7 document submitted to DTSC becomes a public record subject to request under the Public  
8 Records Act (PRA). The substantiation document itself, if requested, would be subject to a  
9 standard review for disclosure, based upon the substance of the claim on its face and any  
10 additional information voluntarily supplied by the submitter.

11  
12 **Section 69510(f)** provides that, except as specified in section 69510.(g), trade secret  
13 protection may not be claimed for any health, safety, or environmental information in any  
14 hazard trait submission, or any chemical identity information associated with a hazard trait  
15 submission. This provision effectuates the intent of Health and Safety Code section 25257(f),  
16 which provides that trade-secret protection may not attach to "hazardous [stet] trait  
17 submissions for chemicals and chemical ingredients under this Article [14]." (In Article 1  
18 ("Definitions"), DTSC has assumed that the word "hazardous" is a typographical error, and that  
19 the Legislature intended to use the phrase "hazard trait submissions," which is consistent with  
20 the terminology used in companion bill Senate Bill 509. (Stats, 2008, Chapter 560) The  
21 regulatory requirement to allow public access to data regarding the hazards of specific  
22 chemicals and chemical ingredients is central to fulfilling the purpose of Health and Safety  
23 Code 25257, by informing the public about toxic risks associated with consumer products, and  
24 incentivizing manufacturers to reduce or eliminate those risks.

25  
26 Nonetheless, DTSC has acknowledged and accommodated the need for possible trade secret  
27 protection for chemical identity or chemical ingredient identity in very limited, specific  
28 circumstances. Those circumstances are set out in subdivision (g).

29  
30 **Section 69510(g)** provides a very limited exception to section 69510(f), by authorizing a  
31 specific instance in which trade secret designation may attach to the identity of a chemical or  
32 chemical ingredient. This is because to provide otherwise would disincentivize the investment  
33 in safer product chemistries that Health and Safety Code 25257 seeks to promote. Section  
34 69510(g) allows for the possibility of trade secret protection for chemical or chemical ingredient  
35 identity if the party seeking trade secret protection for this chemical identity meets one  
36 threshold criterion and three additional enumerated criteria. The threshold criterion is that the  
37 context for and subject of the claim of trade secrecy must be a proposed alternative to a  
38 Chemical of Concern in a Priority Product. In addition, the claimant must do all of the  
39 following:

- 40 (1) Demonstrate to DTSC's satisfaction that the subject of the claim is a new chemical or new  
41 use of an existing chemical that is not a Chemical of Concern;
- 42 (2) Convince DTSC through the submission of relevant specified types of data that the  
43 proposed alternative chemical or chemical ingredient is substantially safer than the current  
44 Chemical of Concern in the Priority Product; and

1 **(3)** Comply with the substantiation requirements specified for all trade secrecy claims made  
2 under this Article.

3  
4 This section is necessary to balance the competing interests of incentivizing and rewarding  
5 innovation with the public's right and need to know about the chemical composition of  
6 consumer products. The specific criteria that must be met in order for chemical or chemical  
7 ingredient identity to be accorded trade secret protection are crafted to limit the availability of  
8 the exception to those circumstances in which the need to encourage and reward market  
9 innovation outweighs the desire to maximize provision of information to the public. That is, the  
10 exception is limited to the introduction of a new chemical or new use of a chemical that is  
11 demonstrably safer than the existing Chemical of Concern in a Priority Product. In addition,  
12 there must be substantiation of the generally applicable indicia of trade secret status set out  
13 elsewhere in the regulations. Absent such a provision, companies designing safer chemicals  
14 for consumer product use would be denied the benefits of their investment, thereby  
15 disincentivizing innovation.

16  
17 **Section 69510(h)** builds on the requirements of section 69510(g). More specifically, any  
18 person making a claim of trade secrecy under section 69510(g) must, to the fullest extent  
19 consistent with a trade secret protection claim, provide DTSC with a non-confidential  
20 description of the nature of the chemical or chemical ingredient. This provision is necessary in  
21 order for DTSC to engage with members of the public in a general way about the substitute  
22 chemical or chemical ingredient, without undermining the potential trade secret protection of  
23 the proposed chemical alternative to the Chemical of Concern.

#### 24 25 **§ 69510.1. Department Review of Claims of Trade Secret Protection**

26  
27 **Section 69510.1(a)** provides that DTSC may review a trade secret claim upon receipt of the  
28 information claimed to be protected, or at any later time. This provision allows DTSC to be  
29 effective and efficient. This puts DTSC in a position of settling some potential disputes about  
30 what is and is not trade secret information before such information is even subject to a Public  
31 Records Act request. This then will aid prompt responses to Public Records Act requests. As  
32 such, this provision allows for efficient implementation of the regulations and compliance with  
33 obligations under the Public Records Act.

34  
35 **Section 69510.1(b)(1)** provides that if DTSC determines the information provided in support of  
36 a request for trade secret protection is incomplete or insufficiently responsive to allow DTSC to  
37 determine if the trade secret claim is valid, DTSC shall:

- 38 **(A)** Notify the submitter of DTSC's finding of insufficiency;  
39 **(B)** Identify the specific areas that are deficient;  
40 **(C)** Provide an explanation for the determination that the information is insufficient; and  
41 **(D)** Indicate the date by which the submitter must provide the requested information.

42  
43 **Section 69510.1(b)(2)** provides that if the submitting party fails to provide the requested  
44 information within the time specified, DTSC must, by certified mail, notify the submitter that it is  
45 out of compliance with Article 10, and that the information claimed to be trade secret is subject

1 to disclosure by DTSC thirty (30) days after the mailing of the notice. During the 30-day  
2 period, the submitter may seek judicial relief in specified forms that would preclude DTSC from  
3 releasing the claimed trade secret information. During the 30-day period, DTSC may not  
4 release the information claimed as trade secret. This provision ensures that DTSC has  
5 adequate information upon which to base its trade secrecy determination, and establishes an  
6 orderly process for resolving claims related to sufficiently justifying trade secrecy claims.  
7

8 **Section 69510.1(c)** provides that if DTSC determines the information claimed as trade secret  
9 does not meet the substantive criteria for trade secret protection, DTSC will notify the  
10 submitting party of its determination. Notice will be by certified mail. Similarly, as with section  
11 69510.1(b), DTSC will inform the submitting party 30 days from the date of the notice of  
12 DTSC's decision, the information will be regarded as a public record subject to disclosure.  
13 During the 30-day period, the submitting party may seek judicial intervention and relief  
14 attempting to prevent disclosure of the information claimed as trade secret. During this 30-day  
15 period, DTSC may not publicly release the information that is the subject to the claim of trade  
16 secret. This provision implements Health and Safety Code section 25257(c)(3), which requires  
17 DTSC to give 30 days' notice to the submitter of trade secret information before releasing any  
18 such records, and authorizes submitters to seek judicial intervention to prevent record release.  
19 This provision establishes a time frame and procedure for resolving disputed trade secrecy  
20 claims. It is also necessary to allow time for a claimant of trade secret protection that receives  
21 an adverse decision from DTSC in response to its claim to initiate legal action to get judicial  
22 review of the DTSC decision.  
23

24 **Section 69510.1(d)** provides that if a party claiming trade secret protection for information  
25 initiates an action under sections 69510(b) or (c), then DTSC is precluded from publicly  
26 releasing the information that is the subject of the trade secret claim until the judicial action,  
27 including any appeal, is resolved. This provision preserves the asserted trade secret  
28 protection of information submitted to DTSC, and thereby prevents any economic harm to the  
29 submitter, while a court case is pending.