

INITIAL STATEMENT OF REASONS**Safer Consumer Product Alternatives**

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I. PROBLEM, REQUIREMENT OR OTHER CONDITION ADDRESSED

Health and Safety Code section 25252 requires the Department of Toxic Substances Control (DTSC), by January 1, 2011, to adopt regulations to establish a process by which chemicals or chemical ingredients in consumer products may be identified and prioritized for consideration as being Chemicals of Concern. This process is required to include, at a minimum, consideration of: (i) the volume of a chemical in commerce in California, (ii) the potential for exposure to a chemical in a consumer product, and (iii) potential effects on sensitive subpopulations, including infants and children.

Health and Safety Code section 25252 directs DTSC, in adopting these regulations, to develop criteria by which chemicals and their alternatives may be evaluated. These criteria must include, at a minimum, the hazard traits and environmental and toxicological endpoints that the Office of Environmental Health Hazard Assessment (OEHHA) is required to specify by January 1, 2011, pursuant to Health and Safety Code section 25256.1, for purposes of the Toxic Information Clearinghouse that DTSC is required to establish pursuant to Health and Safety Code section 25256.

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

Health and Safety Code section 25253 requires DTSC to adopt regulations, by January 1, 2011, that establish a process for evaluating Chemicals of Concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a Chemical of Concern. This section requires that these regulations establish a process that includes: (i) an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives; (ii) an evaluation of critical exposure pathways; and (iii) life cycle assessment tools that, at a minimum, take into consideration: product function or performance; useful life; materials and resource consumption; water conservation; water quality impacts; air emissions; production, in-use, and transportation energy inputs; energy efficiency; greenhouse gas emissions; waste and end-of-life disposal; public health impacts, including potential impacts to sensitive subpopulations, including infants and children; environmental impacts; and economic impacts.

Health and Safety Code section 25253 also requires that the regulations specify the range of regulatory responses that DTSC may take following the completion of an alternatives analysis, including, but not limited to, requiring: no regulatory response; additional information to be provided to DTSC; labeling or other types of product information; a restriction on, or prohibition of, the use of a Chemical of Concern in a consumer product; controlling access to or limiting

1 exposure to the Chemical of Concern in a consumer product; managing the product at the end
2 of its useful life; funding green chemistry challenge grants; and any other outcome DTSC
3 determines accomplishes the requirements of this statute.
4

5 **II. EFFORT TO AVOID DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS**

6

7 The proposed regulations do not duplicate or conflict with existing federal law. California's
8 Green Chemistry Initiative was developed, to a great extent, to address structural weaknesses
9 in the federal Toxic Substances Control Act of 1976 ("TSCA") (Title 15, United States Code,
10 section 2601 et seq). TSCA places the cost of obtaining data about chemical safety on the
11 United States Environmental Protection Agency (US EPA) rather than requiring chemical
12 companies to develop and submit such information. Consequently, information about the
13 80,000 chemicals in U.S. commerce is severely limited and there is little to no information on
14 the health or environmental effects of many of these chemicals.
15

16 In 1998, US EPA launched the voluntary High Production Volume (HPV) Challenge Program.
17 The goal of the program was to collect health and environmental effects data to provide the
18 public with basic hazard information, thus allowing the public to actively participate in
19 environmental decision-making. HPV chemicals are classified as those chemicals produced or
20 imported in the United States in quantities of 1 million pounds or more per year. The HPV
21 program has had varying levels of success – while some information has been collected on
22 approximately 2,500 chemicals, information on the overwhelming majority of chemicals used at
23 lesser quantities than 1 million pounds per year is still unknown.
24

25 Pending legislation to overhaul TSCA, the Safe Chemicals Act of 2010 (S.3209), and a House
26 Discussion Draft "Toxics Chemicals Safety Act of 2010" both incorporate Green Chemistry
27 principles in sections titled "Safer Alternatives and Green Chemistry and Engineering." Based
28 on the timelines specified in the draft legislative documents, it is anticipated that a federal
29 program similar or comparable to California's Green Chemistry Program will be delayed at
30 least five years.
31

32 **III. STUDIES RELIED ON**

33

34 The Safer Consumer Product Alternatives regulations implement one of six policy
35 recommendations in the final *California Green Chemistry Report* issued in December 2008.
36 The regulations build upon current environmental protection laws to shift the focus from end-of-
37 pipe cleanup or "cradle to grave" regulation to up-front design and prevention of harm, foster
38 innovation, and prompt market changes toward a sustainable economy. The six
39 recommendations ensure a comprehensive and collaborative approach to increase
40 accountability and effectiveness of environmental programs across state government for

1 evaluating risk, reducing exposure, encouraging less-toxic industrial processes, and identifying
2 safer alternatives.

3
4 Governor Arnold Schwarzenegger signed Assembly Bill 1879 (Feuer, Chapter 559, Statutes of
5 2008) and Senate Bill 509 (Simitian, Chapter 560, Statutes of 2008) on September 29, 2008,
6 laying the critical foundation for the Green Chemistry program. These bills provide the
7 authority and mandate to adopt the proposed regulations.

8

9 **IV. ALTERNATIVES CONSIDERED**

10

11 Available alternatives included the following:

12

13 **Chosen Alternative:** DTSC has determined that adding Chapter 53 to Division 4.5 of Title 22,
14 California Code of Regulations, Safer Consumer Product Alternatives, is the most effective and
15 least burdensome approach. It also provides the required flexibility to carry out the provisions
16 of Health and Safety Code (Health and Safety Code) sections 25252 and 25253. Because
17 these regulations were developed in tandem with interested parties to build a workable
18 program, but without compromising the safety of public health and the environment, DTSC has
19 chosen these regulations as the preferred alternative. In addition, the development of these
20 regulations has had the benefit of advice and counsel on scientific matters, various
21 recommendations on scientific approaches to chemical policy and differing suggestions for
22 implementation strategies from the legislatively-mandated Green Ribbon Science Panel.

23

24 This regulatory development process included active and continuous public and interested
25 party involvement that embraced transparency. This process began in 2009 with a series of
26 meetings with interested parties to identify regulatory concepts. Numerous meetings and
27 public workshops played a critical role in collecting additional concepts. After considering input
28 received during this phase, DTSC released a draft conceptual flowchart in the February 2010.
29 This conceptual flowchart became the genesis of the chosen alternative.

30

31 DTSC continued discussions with interested parties regarding a proposed regulatory
32 framework throughout much of 2010. The conceptual flowchart was soon followed by the
33 release of a detailed outline for the draft regulations. After receiving feedback from a wide
34 variety of interested parties (via email and website submissions, letters, and meetings) and the
35 Green Ribbon Science Panel on the detailed outline, DTSC released the draft regulations for
36 Safer Consumer Product Alternatives on June 23, 2010. Two half-day workshops were held to
37 receive comments on these regulations on July 7 and 8, 2010. Based on numerous letters,
38 comments, and meetings following the workshops, these regulations were developed for
39 adoption. All formal submissions from interested parties were posted on the DTSC public
40 website.

41

1 In consideration of the potential impact to small businesses, DTSC has included special
2 considerations to lessen potential economic consequences of coming into compliance with
3 these regulations for this portion of the market. At DTSC's discretion, a qualified small
4 business may have its compliance deadlines extended for these regulations. In addition, small
5 businesses may request consultative services from DTSC, for which DTSC must be
6 reimbursed. DTSC lacks the authority to provide any other considerations, such as loans or
7 grants, to lessen the impact to small businesses.

8
9 DTSC has developed these regulations based on substantial public and interested party input.
10 These regulations provide a workable regulatory infrastructure that will develop safer
11 consumer product alternatives for the citizens and marketplace of California. DTSC has
12 determined that these regulations are the chosen alternative.

13 14 **Rejected Alternatives:**

15
16 1. *Do Nothing.* DTSC rejected this option because Health and Safety Code sections 25252
17 and 25253 require that DTSC adopt regulations to address Chemicals of Concern in consumer
18 products. To do nothing would place Californians in jeopardy of continued exposure to
19 Chemicals of Concern in consumer products when the average U.S. consumer already comes
20 into contact with 100 chemicals per day.

21
22 To do nothing would also reject the California Legislature's direction to develop a broader,
23 more comprehensive approach to chemicals policy for the State of California following the
24 Green Chemistry Initiative's policy recommendation:

25
26 "Accelerate the Quest for Safer Products, creating a systematic, science-based
27 process to evaluate Chemicals of Concern and identify safer alternatives to ensure
28 product safety."

29
30 Therefore, DTSC has rejected this option.

31
32 2. *Product and Chemical Hazard Categories Prioritization Process to Develop Safer*
33 *Consumer Products.* While this alternative (described below) contains many conceptual merits
34 that appear in the chosen alternative, DTSC has determined that this alternative, in its original
35 form, is not viable.

36
37 To further develop this particular alternative, many meetings with interested parties were held
38 and DTSC evaluated numerous written comments and letters that were received in response
39 to this alternative. This process was a continuous process between DTSC and interested
40 parties and in the end, transformed this alternative into the chosen alternative.

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

11
12 Basic concepts from this original approach that remain in the chosen alternative include:
13 (1) chemical and product prioritization process that factors in the same public health and
14 environmental considerations, albeit a different prioritization pathway; (2) manufacturer
15 responsibility to develop safer consumer product alternatives and the requirements that must
16 be addressed in the alternatives assessment; and (3) DTSC-specified regulatory responses.

17
18 Some of the significant changes include: (1) an open and transparent process that includes a
19 public comment period prior to finalizing the lists of chemicals and products that must undergo
20 an alternatives analysis to examine ways to develop a safer consumer product; (2) small
21 business considerations; (3) specifically requiring DTSC to post on its website implementation
22 progress by making information available, that is not considered confidential information (trade
23 secret), as it is received or developed; (4) requiring an accredited assessor to review a
24 manufacturer's alternatives assessments; and (5) a petition process to request inclusion of a
25 chemical or product in the prioritization process.

26
27 The concerns expressed by a wide range of interested parties about the lack of specific DTSC
28 oversight have been addressed. Because much of this alternative no longer resembles the
29 chosen alternative, DTSC considers this a separate alternative that is rejected.

30
31
32

1 **V. DETAILED STATEMENT OF REASONS**

2
3 **Article 1. General**

4 **Section 69301. Applicability**

5 **Section 69301**, in its entirety, is necessary to describe the scope and purpose of Chapter 53.
6 This section is also necessary to establish the scope of the applicability of Chapter 53 by
7 specifying which products are and are not subject to its requirements.
8

9 **Section 69301(a)** specifies that Chapter 53: (i) sets out the process for identifying and
10 prioritizing Chemicals of Concern, and the process for the evaluation of alternatives to such
11 chemicals and consumer products containing them; and (ii) specifies the regulatory responses
12 that may apply to a consumer product after the evaluation of the chemical/product and
13 potential alternatives.
14

15 **Section 69301(b)(1)** specifies that Chapter 53 applies to all consumer products placed into the
16 stream of commerce in California, except as otherwise provided in paragraphs (2) and (3) of
17 this subsection, which are described below.
18

19 The applicability of these regulations to all consumer products “placed into the stream of
20 commerce in California,” as defined, is necessary to take into account current and anticipated
21 methods of selling or offering for sale consumer products containing a Chemical of Concern,
22 through mail order catalogs and Internet sales as well as traditional “brick and mortar” entities.
23 In addition, the term as defined includes products that are offered as promotional items with a
24 purchase and manufacturer “giveaways”. Some interested parties have expressed concern
25 over the vastness and scope of the regulations and have urged DTSC to narrow the scope to
26 make the universe of products subject to these regulations smaller. However, DTSC has
27 determined that consistency with existing statutory reach — both as to what is included and
28 excluded — is necessary and that exempting any other consumer products would not be in line
29 with the intent and purpose of the authorizing legislation, and would impermissibly shrink the
30 scope of consumer products set out in statute that are subject to the regulations.
31

32 DTSC notes that the public comment periods provided in the chemical and product
33 identification and prioritization processes specified in articles 2 and 3 provide ample
34 opportunity for interested parties to provide evidence to DTSC that one or more chemicals or
35 products being proposed for the Chemicals under Consideration, Priority Chemicals, Products
36 under Consideration, or Priority Products list should not be included on those lists.
37

38 **Section 69301 (b)(2)** exempts from the regulations any product that is statutorily exempted
39 from the definition of “consumer product” and any product that is placed into the stream of
40 commerce in this State solely for the manufacture of one or more statutorily-exempt products.
41 The statutory definition of “consumer product” and the exemptions from this definition are set

1 out in Health and Safety Code section 25251. Exemptions to the requirements in this chapter
2 are necessary in order for the scope of the regulations to be consistent with the authorizing
3 legislation.

4
5 Health and Safety Code section 25251 defines “consumer product” as a “product or part of the
6 product that is used, brought (*sic*), or leased for use by a person for any purposes.” In
7 accordance with Health and Safety Code section 25251, a consumer product does not include:
8 (1) a dangerous drug or device as defined in Section 4022 of the Business of (*sic*) Professions
9 Code; (2) dental restorative materials as defined in subdivision (b) of Section 1648.20 of the
10 Business and Professions Code; (3) a device as defined in Section 4023 of the Business and
11 Professions Code; (4) a food as defined in subdivision (a) of Section 109935; (5) the
12 packaging associated with any of the items specified in paragraph (1), (2), or (3); (6) a
13 pesticide as defined in Section 12753 of the Food and Agricultural Code or the Federal
14 Insecticide, Fungicide and Rodenticide Act (7 U.S.C. Sec. 136 and following); or (7) mercury-
15 containing lights defined as mercury-containing lamps, bulbs, tubes, or other electric devices
16 that provide functional illumination. (Mercury-containing devices are only exempted from these
17 regulations until December 31, 2011.)

18
19 **Section 69301(b)(3)** specifies that the regulations do not apply to any consumer product that
20 is manufactured or stored in, or transported through, California solely for use outside of
21 California. It also provides that the burden of proof in establishing that a consumer product
22 meets the above criteria is on the manufacturer of that consumer product. This provision is
23 necessary to clarify that Chapter 53, consistent with the intent of Health and Safety Code
24 section 25251, does not apply to any consumer product manufactured or stored in, or
25 transported through, California, but not actually placed into the stream of commerce in
26 California.

27
28 **Section 69301(c)** specifies that the requirements in the regulations that pertain to consumer
29 products or to chemicals or chemical ingredients in products do not apply to an unintentionally-
30 added chemical or chemical ingredient, whose presence in a product is not known to the
31 producer of the product, if all of the further specified criteria in this subsection are met.

32
33 **Section 69301(c)(1)** specifies the first of the four conditions that must be met for purposes of
34 the exemption provided in section 69301(c). Specifically, the producer, as defined, of the
35 consumer product must have exercised due diligence to become knowledgeable about any
36 chemical or chemical ingredient that might reasonably be expected to be present in the
37 product — whether intentionally or unintentionally — by taking reasonable steps to become
38 knowledgeable about the factors set out below, to the extent these factors are applicable:

- 39
40 (A) The source, composition, and types of chemicals that are in the items that go into the
41 consumer product or are associated with its production, and

1
2 (B) The manufacturing process itself, including likely chemical reactions during the
3 manufacturing process.
4

5 **Section 69301(c)(2)** specifies the second of the four conditions that must be met for purposes
6 of the exemption provided in section 69301(c). Specifically, the producer cannot reasonably
7 be expected to know about the presence of the unintentionally-added chemical or chemical
8 ingredient.
9

10 **Section 69301(c)(3)** specifies the third of the four conditions that must be met for purposes of
11 the exemption provided in section 69301(c). Specifically, the producer is required to provide
12 information, upon request, to DTSC that satisfies DTSC that the conditions of sections
13 69301(c)(1) and (c)(2) have been met.
14

15 **Section 69301(c)(4)** specifies the last of the four conditions that must be met for purposes of
16 the exemption provided in section 69301(c). Specifically, in the event the producer does have
17 knowledge about unintentionally-added chemicals or chemical ingredients in the consumer
18 product, the producer must provide such information, upon request, to DTSC and any known
19 responsible entity for the product.
20

21 **Section 69301.1. Guiding Principles**

22 **Section 69301.1** is necessary to establish the guiding principles that must be considered in
23 complying with the provisions of Chapter 53. In fulfilling requirements and responsibilities
24 under this chapter, DTSC, manufacturers, responsible entities and those acting on their behalf
25 must base analyses and determinations on the best scientific principles and practices, and
26 must be guided by the principles espoused in sections 69301.1(a) through (d).
27

28 Green Chemistry is a systematic scientific and engineering approach that seeks to reduce the
29 use of hazardous chemicals and the generation of toxic wastes by changing how society
30 designs, manufactures, and uses chemicals in processes and products. Rather than the
31 primary focus being on managing wastes at the product's end-of-life stage (or "cradle to
32 grave"), Green Chemistry shifts the focus to designing chemicals, processes, and goods that
33 have fewer or no adverse effects throughout their lifecycle ("cradle to cradle") on California's
34 people and environment. Stakeholders have repeatedly conveyed to DTSC that the Green
35 Chemistry approach offers substantial opportunity for the state through: better information;
36 innovation and new technology; new high-skill, high-wage jobs; stronger worker and consumer
37 protection; and a cleaner, healthier environment.
38

39 Green Chemistry represents a major paradigm shift that focuses on environmental protection
40 at the design stage of product and manufacturing processes. It is an innovative way to deal
41 with chemicals before they become hazards, with the goal of making chemicals and products

1 “benign by design”. Green chemistry is a preemptive strategy that reduces the use of toxic
2 substances before they contaminate the environment and our bodies. It is a marked departure
3 from the past, when society managed industrial and municipal wastes by disposal or
4 incineration. Green Chemistry seeks to dramatically reduce the use of toxic chemicals in the
5 first place, rather than merely manage the toxic chemical-tainted waste after its use and
6 disposal.

7
8 Green Chemistry focuses on improving the building blocks of manufacturing — the feedstocks
9 and the catalysts used to make things — so products can be engineered to be safer and more
10 easily reused and not persist in the environment. Green chemistry changes the design of
11 products and industrial processes so they do not threaten human health or the environment.¹
12 The guiding principles of sections 69301.1(a) through (d) reflect the guiding principles of the
13 final *California Green Chemistry Report*, which is the culmination of input from numerous and
14 varied interested parties.

15
16 **Section 69301.1(a)** states that green chemistry principles and life cycle thinking should be
17 considered throughout implementation of Chapter 53.

18
19 **Section 69301.1(b)** states that adverse impacts on public health and the environment that
20 may result from the production, use or end-of-life management of consumer products and
21 consumer product ingredients should be significantly reduced or eliminated, to the extent
22 technologically and economically feasible.

23
24 **Section 69301.1(c)** states that redesign of consumer products and manufacturing processes,
25 while maintaining or enhancing product function and performance, should be encouraged to
26 reduce adverse public health and environmental impacts of chemicals used in commerce, as
27 well as the overall costs of those impacts on the people of California. By way of example, it is
28 noted that the National Institutes of Health estimates that the annual cost of cancer in the U.S.
29 is approximately \$210 billion per year and rising 7% annually.²

30
31 **Section 69301.1(d)** states that chemical and consumer product prioritization processes should
32 seek to identify and give priority to those chemicals, and the consumer products that contain
33 them, that pose the greatest public health and environmental threats, are most prevalently
34 distributed in commerce and used by consumers, and for which there is the greatest potential
35 for consumers or environmental receptors to be exposed to the chemical in quantities that can
36 result in public health or environmental harm. These prioritization criteria advance the goals of
37 the authorizing statutes and are reflective of the best scientific approaches to these issues.

38

¹ California Green Chemistry Initiative, Final Report, December 2009.

² Fiduciary Guide to Toxic Chemical Risk, Jane Ambactheer, March 2007.

Section 69301.2. Definitions

Section 69301.2 is necessary to define terms which are used throughout Chapter 53, to avoid confusion and future disputes or litigation over the applicability of terms. The following terms have been defined: "AA Notification", "AA Report", "AA verification statement", "AA Work Plan", "Alternatives assessment", "Bioaccumulation", "California distributor", "California importer", "Carcinogen or reproductive toxin", "Chemical", "Chemical ingredient", "Chemical Hazard Assessment", "Chemical mixture", "Chemical of Concern", "Chemical Removal Confirmation Notification", "Chemical Removal Intent Notification", "Chemical substance", "Chemical Under Consideration", "Component", "Consumer Product", "Contact information", "Day", "De minimis exemption," "De minimis level", "Department", "Distributor", "Economic impacts", "End-of-life", "Energy efficiency", "Environment", "Environmental impact", "Exposure Potential Assessment", "Failure to Comply List", "Failure to Respond List", "Financial guarantee", "Functionally equivalent", "Greenhouse gas", "Green chemistry principles", "Hazard trait", "Importer", "Intentionally-added chemical or chemical ingredient", "Intermediate manufacturing process", "Inventory recall", "Life cycle", "Life cycle thinking", "Listserv", "Manufacturer", "Materials and resource consumption", "Multimedia Life Cycle Evaluation", "Nanomaterial", "Nanoscale", "Nanoscale phenomena", "Nanostructure", "Persistence", "Person", "Place into the stream of commerce in California", "Priority Chemical", "Priority Product", "Produce", "Producer", "Product function and performance", "Product Removal Confirmation Notification", "Product Removal Intent Notification", "Product stewardship", "Product Under Consideration", "Public health impacts", "Recycled material", "Release", "Reliable information", "Responsible entity", "Retailer", "Safer", "Sales outlet", "Selected alternative", "Sell or offer for sale", "Sensitive subpopulations", "Soil sealing", "State or local agency", "Supply chain", "Technologically and economically feasible alternative", "Threat", "Tier I Alternatives Assessment", "Tier I AA Report", "Tier II Alternatives Assessment", "Trade Secret", "Unintentionally-added chemical or chemical ingredient", "Useful life", "Water conservation", and "Water quality impacts".

Section 69301.3. Acronyms

Section 69301.3 includes a list of acronyms used throughout Chapter 53 and is necessary to facilitate discussion and avoid confusion. The following acronyms have been specified:

"AA" means Alternatives Assessment; "CEPA" means Canadian Environmental Protection Act; "CRNR" means California Regulatory Notice Register; "ECHA" means European Chemicals Agency; "IEC" means International Electrotechnical Commission; "ISO" means International Organization for Standardization; "NAICS" means North American Industry Classification System; "OEHHA" means Office of Environmental Health Hazard Assessment; "REACH" means Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation (EC) No. 1907/2006 of the European Parliament and Council; and "TSCA" means Toxic Substances Control Act.

Section 69301.4. Duty to Comply and Consequences for Non-Compliance

Section 69301.4, in its entirety, is necessary to set out the responsibilities for compliance with the requirements of Chapter 53, including information submittals, notifications, alternatives assessments, and regulatory responses; and to provide options for responsible entities. This section is also necessary to specify the consequences of non-compliance, including fines and penalties, as well as placement on DTSC's Failure to Comply List.

The regulations assign to the responsible entity, as defined, for a consumer product the requirement to comply with, or otherwise ensure compliance with, the provisions of Chapter 53 pertaining to: submission of chemical and product information pursuant to section 69301.6; Priority Product notification pursuant to section 69303.5, alternatives assessments pursuant to article 5, and regulatory responses pursuant to article 6. In lieu of complying with these requirements, the regulations give responsible entities the option to cease placing into the stream of commerce in California a product that is subject to these requirements.

Pursuant to section 69301.2(a)(67), "responsible entity" means any of the following persons:

- (A) The person who is the owner or licensee of the brand name or trademark under which the consumer product is placed into the stream of commerce in California;
- (B) A California importer, as defined, of the consumer product;
- (C) A California distributor, as defined, of the consumer product;
- (D) A retailer, as defined, of the consumer product;
- (E) Any other person who is party to a contractual agreement with a California importer, California distributor, or retailer concerning a consumer product that is placed into the stream of commerce in California, unless that contractual agreement specifically states that the consumer product shall not be placed into the stream of commerce in California.

A vast number of consumer products are placed into the stream of commerce in California by someone other than the actual producer of the product. In fact, most of the consumer products in California's stream of commerce are produced by persons that have no presence in California and in many cases no presence in the United States. Due to these circumstances, DTSC determined that the option of placing the duty to comply with these regulations on product producers was not viable or desirable for the following reasons:

- (1) DTSC's ability to implement the directives of Health and Safety Code sections 25252 and 25253 requires that DTSC be able to compel and enforce compliance with the

1 requirements of Chapter 53. In the case of the many product producers that have no
2 presence in California, DTSC has no practical, and in most cases no legal, ability to
3 compel such producers to comply with these requirements.
4

- 5 (2) In light of the practical and legal limitations identified above, placing the duty to comply
6 solely on product producers would create a significant unlevel playing field for
7 California product producers.
8

9 For these reasons it is necessary that the duty to comply with the requirements of Chapter 53
10 fall to responsible entities, as defined above. This is similar to the duty to comply approach
11 embodied in other California statutes and regulations that impose requirements on products
12 sold in California but produced both in-state and out-of-state (for example, California's Toxics
13 in Packaging Prevention Act, article 10.4 of chapter 6.5 of division 20 of the Health and Safety
14 Code).
15

16 **Section 69301.4(a)** *Submission of Chemical and Product Information*. This subsection
17 requires the responsible entity to comply with the requirements to make information available
18 to DTSC, upon request, pursuant to section 69301.6, except as otherwise discussed below.
19

20 **Section 69301.4(a)(1)** specifies that when DTSC requests information pursuant to section
21 69301.6, the responsible entity for a consumer product must make that information available to
22 DTSC by the date requested. This subsection also specifies that when a chemical is the
23 subject of the request (as opposed to a product), then a responsible entity for any product
24 containing the chemical must make the information available to DTSC. Both types of requests
25 may be satisfied by having a third party provide the information to DTSC by the date
26 requested. DTSC is also authorized to grant one 60-day extension to the date for producing
27 the requested information. This provision is necessary in order for DTSC to have a robust set
28 of information in carrying out its duties to identify and prioritize Chemicals of Concern in
29 consumer products. The 60-day extension provision provides some flexibility to DTSC to
30 establish deadlines for submission of information without unduly delaying its receipt by DTSC.
31

32 **Section 69301.4(a)(2)** creates an exception to the obligation established in section
33 69301.4(a)(1) to provide information to DTSC. The exception is conditional and is dependent
34 on one of three facts and circumstances occurring.
35

36 **Section 69301.4(a)(2)(A)** establishes the first condition that exempts a responsible entity from
37 complying with the information submission requirements of section 69301.6 --- if DTSC notifies
38 the responsible entity that the requested information has been made available to DTSC by
39 another person.
40

1 **Section 69301.4(a)(2)(B)** establishes the second condition that exempts a responsible entity
2 from complying with the information submission requirements of section 69301.6 --- if the
3 requested information is made available to DTSC by another person and the responsible entity
4 receives a notice from that person of the submittal and DTSC receives a copy of the
5 notification.

6
7 **Section 69301.4(a)(2)(C)** establishes the third condition that exempts a responsible entity from
8 complying with the information submission requirements of section 69301.6 --- if the
9 responsible entity complies with the requirements of section 69301.4(e).

10
11 **Section 69301.4(b) *Priority Product Notification.*** This subsection requires the responsible
12 entity to comply with the notification requirements in section 69303.5 unless one of the two
13 following conditions is met.

14
15 **Section 69301.4(b)(1)** establishes the first condition that exempts a responsible entity from
16 complying with the notification requirement of section 69303.5 --- if the manufacturer or
17 another person in the product supply chain provides the notification to DTSC.

18
19 **Section 69301.4(b)(2)** establishes the second condition that exempts a responsible entity from
20 complying with the notification requirement of section 69303.5 --- if the responsible entity
21 complies with the requirements of section 69301.4(e).

22
23 **Section 69301.4(c) *Alternatives Assessments.*** This subsection requires a responsible entity
24 to comply with the AA requirements specified in article 5, except as otherwise discussed
25 below.

26
27 **Section 69301.4(c)(1)** specifies that it is the responsible entity for a consumer product that
28 must comply with the requirements of article 5. The responsible entity may fulfill its obligations
29 under article 5 by ensuring that some other person fulfills the requirements for the particular
30 product within the applicable time lines.

31
32 **Section 69301.4(c)(2)** creates an exception to section 69301.4(c)(1). The responsible entity
33 does not have to comply with the requirements of article 5 if one of the three following
34 conditions is met.

35
36 **Section 69301.4(c)(2)(A)** establishes the first condition that exempts a responsible entity from
37 complying with the alternatives assessment requirements of article 5 --- if some other person
38 meets the article 5 requirements to the satisfaction of DTSC.

39

1 **Section 69301.4(c)(2)(B)** establishes the second condition that exempts a responsible entity
2 from complying with the alternatives assessment requirements of article 5 --- if DTSC has
3 granted a de minimis exception for the product pursuant to section 69305.3.
4

5 **Section 69301.4(c)(2)(C)** establishes the third condition that exempts a responsible entity from
6 complying with the alternatives assessment requirements of article 5 --- if the responsible
7 entity complies with the requirements of section 69301.4(e).
8

9 **Section 69301.4(d) *Regulatory Responses***. This subsection requires a responsible entity to
10 comply with the regulatory response requirements specified in article 6, except as otherwise
11 discussed below.
12

13 **Section 69301.4(d)(1)** specifies that the responsible entity is responsible for complying with
14 the requirements of article 6. The responsible entity may fulfill its obligations under article 6 by
15 ensuring that the applicable requirements of article 6 are satisfied within the requisite time
16 frame by another person.
17

18 **Section 69301.4(d)(2)** creates an exception to section 69301.4(d)(1). The responsible entity
19 does not have to comply with the requirements of article 6 if one of the following conditions is
20 met.
21

22 **Section 69301.4(d)(2)(A)** establishes the first condition that exempts a responsible entity from
23 complying with the regulatory response requirements of article 6 --- if the requirement has
24 already been fulfilled to the satisfaction of DTSC by another person.
25

26 **Section 69301.4(d)(2)(B)** establishes the second condition that exempts a responsible entity
27 from complying with the regulatory response requirements of article 6 --- if the responsible
28 entity complies with the requirements of section 69301.4(e).
29

30 **Section 69301.4(e) *Options for Responsible Entities***. This subsection specifies the
31 requirements that a responsible entity may fulfill in lieu of fulfilling the requirements of section
32 69301.6, section 69303.5, article 5, and/or article 6. The primary optional requirement is that
33 the responsible entity must cease to place the product (that is subject to these requirements)
34 into the stream of commerce in California. This provision, which has been suggested by
35 interested parties who are in product supply chains, is necessary to give responsible entities
36 who do not wish to comply with these requirements another viable option. Additionally, this
37 provision is necessary to enable DTSC to effectively implement Chapter 53 and the authorizing
38 statutes, as well as to provide a level playing field for those responsible entities who do expend
39 the time and resources to comply with these requirements.
40

1 **Section 69301.4(e)(1)** exempts a responsible entity that is not the manufacturer of the affected
2 product from compliance with section 69301.6, section 69303.5, article 5, and article 6 if the
3 responsible entity complies with all of the requirements specified in section 69301.4(e)(1)(A)
4 through (C).

5
6 **Section 69301.4(e)(1)(A)** requires that the responsible entity to have ceased placing the
7 affected product into the stream of commerce in California no later than thirty days after the
8 compliance date for the pertinent requirement, and to notify DTSC of this. In addition, the
9 responsible entity must upon request provide DTSC with any related information within the
10 time specified.

11
12 **Section 69301.4(e)(1)(B)** specifies the information that must be included in the notification
13 required pursuant to section 69301.4(e)(1)(A). That required information is as follows:

- 14
15 1. Name and contact information for the responsible entity;
- 16 2. Information regarding sales locations where the product is sold in California;
- 17 3. Name and contact information for the person immediately upstream in the supply chain
18 from the responsible entity;
- 19 4. Name and contact information for any other persons known by the responsible entity to
20 be in the supply chain for the product;
- 21 5. Brand names under which the product is placed into the stream of commerce in
22 California; and
- 23 6. Documentation establishing that the responsible entity was in a contractual relationship
24 with the person(s) supplying the product that requires the supplier(s) to ensure that all
25 products supplied under the contract are in compliance with all applicable provisions of
26 Chapter 53.

27
28 **Section 69301.4(e)(1)(C)** requires that the responsible entity has signed up for inclusion in
29 DTSC's listserv in order to be eligible for the exemption.

30
31 **Section 69301.4(e)(2)** specifies the condition that a responsible entity that is the manufacturer,
32 as defined, of the product must meet in order to be exempt from complying with sections
33 69301.6, 69303.5, article 5 and article 6. Specifically, the manufacturer must provide
34 documentation to DTSC to convince DTSC that the product is no longer being placed into the
35 stream of commerce in California by any person.

36
37 **Section 69301.4(f) *Failure to Comply List***. This subsection requires, and specifies the criteria
38 and process for, DTSC to issue notices of non-compliance and establish and maintain a
39 Failure to Comply List.
40

1 **Section 69301.4(f)(1)(A)** requires DTSC to issue a notice of non-compliance to all known
2 responsible entities for a product when DTSC determines that one or more requirements of the
3 regulations, as they apply to a specific chemical or product, have not been fulfilled. DTSC is
4 also required to send a copy of the notice to all other persons, known to DTSC, in the supply
5 chain for the product or chemical. This notice is necessary so that the affected responsible
6 entities are alerted to the non-compliance status of their product, giving them time to come into
7 compliance (or alternatively to comply with section 69301.4(e) or to dispute DTSC's
8 determination of non-compliance) before DTSC posts information concerning the
9 determination of non-compliance on the Failure to Comply List on DTSC's website.

10
11 **Section 69301.4(f)(1)(B)** specifies the contents of a notice issued pursuant to section
12 69301.4(f)(1)(A). The notice must describe the nature of the non-compliance and the fact that
13 DTSC intends to place information about the non-compliance determination on the Failure to
14 Comply List maintained on DTSC's website.

15
16 **Section 69301.4(f)(2)** specifies that no sooner than 45 days and no later than 90 days after
17 DTSC issues a notice of non-compliance, if the non-compliance has not been remedied and
18 there is no pending dispute under article 7, then DTSC will post information about the non-
19 compliance on its Failure to Comply List maintained on the DTSC website. A condition of non-
20 compliance is deemed remedied if DTSC determines that the requirements of section
21 69301.4(e)(2) have been satisfied.

22
23 **Section 69301.4(f)(3)** requires DTSC to maintain a Failure to Comply List on DTSC's website.
24 This provision gives interested parties and the general public important information about
25 which responsible entities, manufacturers, and products are not in compliance with these
26 regulations. It also specifies the information required to be posted. This provision is
27 necessary to keep responsible entities, in particular retailers, informed about the compliance
28 status of the products for which they are responsible. This provision also gives important
29 information to consumers to allow them to make informed decisions regarding consumer
30 products. It also helps to maintain a "level playing field" for responsible entities and
31 manufacturers that are in compliance with these regulations. The required information
32 includes:

- 33
34 (A) Identifying information for the product, including brand names under which the product
35 is placed into the stream of commerce in California;
36 (B) The requirements of the regulations and applicable due dates that are the basis for the
37 determination of non-compliance;
38 (C) Any Priority Chemicals known to be in the product;
39 (D) Name and contact information, if known, for the manufacturer, as identified on the
40 product label, and the distributor, if one is identified on the label;

- 1 (E) Name and contact information for any responsible entity that has been notified by
2 DTSC of the condition of non-compliance. But DTSC will not include information about
3 a responsible entity that has fully complied with section 69301.4(e)(1);
4 (F) Name and contact information for any other person who has received a notice from
5 DTSC under section 69301.4(f)(1); and
6 (G) The date the product is first listed on the Failure to Comply List.
7

8 **Section 69301.4(f)(4)** specifies that DTSC must remove a product and related information
9 from the Failure to Comply List if DTSC determines that the condition of non-compliance has
10 been fully remedied or that the requirements of section 69301.4(e)(2) have been satisfied. A
11 product and related information will also be removed from the Failure to Comply List if a
12 Chemical Removal Confirmation Notification or a Product Removal Confirmation Notification
13 has been submitted to DTSC, and the non-compliance is not related to section 69301.6.
14

15 **Section 69301.4(f)(5)** requires DTSC to remove information regarding a responsible entity
16 from the Failure to Comply List upon a determination by DTSC that the responsible entity has
17 complied with section 69301.4(e).
18

19 **Section 69301.4(g) Violations.** This subsection is necessary to make clear the additional
20 consequences for violations of Chapter 53.
21

22 **Section 69301.4(g)(1)** specifies that a person who fails to comply with any of the requirements
23 of Chapter 53 is subject to enforcement action by DTSC under its enforcement authority in
24 division 20, chapter 6.5, article 8 of the California Health and Safety Code.
25

26 **Section 69301.4(g)(2)** specifies that the fines and penalties provisions in article 8 of chapter
27 6.5 of division 20 of the Health and Safety Code, pertaining to false statements and
28 representations, apply to persons who intentionally or negligently make false statements or
29 false representations under Chapter 53.
30

31 **Section 69301.5. Information Submission and Retention Requirements**

32 **Section 69301.5**, in its entirety, is necessary to specify the requirements to submit information
33 to DTSC and to establish information and documentation requirements.
34

35 **Section 69301.5(a)** requires all documents and other information submitted to DTSC pursuant
36 to these regulations to be signed by an officer of the company and by the person(s) in charge
37 of preparing or overseeing the preparation of the document or information. In addition, all
38 documents, data and information must be in English and in an electronic format specified or
39 approved by DTSC. This section also specified the mailing address and email address to
40 which documents and information required under Chapter 53 are to be sent.
41

1 This provision is necessary to ensure information submitted to DTSC is easily accessed and
2 understood by DTSC employees. The requirement that all information must be submitted in
3 English safeguards DTSC from receiving voluminous information that must be translated into
4 English before being reviewed for completeness and compliance with the applicable
5 requirements. In addition, this provision lowers the cost to DTSC in implementing the
6 provisions of Chapter 53.

7
8 **Section 69301.5(b)** sets out a certification statement that must be included and signed in
9 conjunction with the submittal of certain key documents generated under the regulations. The
10 documents subject to the certification statement are: Chemical Removal Confirmation
11 Notifications, Chemical Removal Intent Notifications, Product Removal Confirmation
12 Notifications, Product Removal Intent Notifications, de minimis exemption requests, AA
13 notifications, AA Work Plans, AA Reports, Tier I AA Reports, AA verification statements,
14 documentation for designation pursuant to section 69308 or 69308.1 as a qualified third-party
15 assessment entity or a qualified in-house assessment entity, and documentation for
16 designation as an accrediting body pursuant to section 69308.2. The certification statement is
17 necessary in order to ensure such key submittals are accurate and to apprise parties signing
18 the statements of the applicable standards related to the documents' preparation.

19
20 **Section 69301.5(c)** sets out a three-year document retention provision, running from the date
21 a document was first required to have been obtained or prepared, but which has not been
22 required to be submitted to DTSC. This is necessary to ensure DTSC has continued access
23 for a reasonable period of time to information that may be needed to support fulfillment of
24 DTSC's responsibilities under Chapter 53.

25
26 **Section 69301.6. Chemical and Product Information**

27 **Section 69301.6**, in its entirety, is necessary to specify the process for DTSC to obtain and
28 review information on chemicals and products. Health and Safety Code section 25252
29 requires DTSC to adopt regulations that establish a process to identify and prioritize those
30 chemicals or chemical ingredients in consumer products that may be a Chemical of Concern.
31 The information required to be submitted to DTSC under this section will be requested only on
32 an as-needed basis to identify and prioritize chemicals and chemical ingredients in consumer
33 products. This information will enable DTSC to have a sound and robust process for
34 identifying and prioritizing Chemical of Concerns and consumer products that contain Priority
35 Chemicals. This information is necessary to ensure that decisions made by DTSC in carrying
36 out its responsibilities under Chapter 53 and Health and Safety Code section 25252 are fully
37 informed and based on sound science and other relevant information.

38
39 **Section 69301.6(a)(1)** specifies a process for DTSC to obtain and review data that DTSC
40 determines is necessary to carrying out its duties under the regulations.

1 **Section 69301.6(a)(2)** clarifies that DTSC is not precluded from using information gained
2 through means, other than those specified in this section, in implementing Chapter 53.

3
4 **Section 69301.6(a)(3)** provides that a person subject to chemical and/or product information
5 submittal requirements may satisfy those requirements by either: **(A)** submitting the
6 information to DTSC in an acceptable format; or **(B)** providing DTSC with electronic access to
7 the information in a format acceptable to DTSC — unless DTSC specifically requests submittal
8 of the information to DTSC.

9
10 **Section 69301.6(b)** sets up a sequential process that DTSC must follow in seeking to review
11 and/or obtain data and other information to carry out its duties under the authorizing statute
12 and Chapter 53. Later steps may only be used if the preceding step(s) did not lead to DTSC
13 getting the necessary information. The specified order to the steps is as follows:

14
15 **(1)** Use of data that is readily available, without a charge, in a usable format in the public
16 domain;

17
18 **(2)** Use of data that is readily available, but for which there is a charge, in a usable format
19 in the public domain to the extent resources are available to DTSC to pay for the
20 information;

21
22 **(3)** Requiring a responsible entity to make existing information available to DTSC under a
23 schedule specified by DTSC;

24
25 **(4)** Requiring a responsible entity to generate new data or information and to make that
26 information available to DTSC in accordance with a schedule specified by DTSC.

27
28 This hierarchical approach minimizes the unnecessary expenditure and use of resources by
29 DTSC and responsible entities. It allows for the most effective and efficient approach to
30 seeking necessary information.

31
32 **Section 69301.6(c)(1)** specifies the types of data or information that may be requested by
33 DTSC and that is required to be made available to DTSC. This information is necessary to
34 enable DTSC to appropriately identify and prioritize chemicals and consumer products:

35
36 **(A)** Chemical and product data and information specified in sections 69302.3 and 69303.

37
38 **(B)** Information describing the types, categories and classes of products that contain
39 Priority Chemicals.
40

1 (C) Identification of all intentionally-added chemicals and chemical ingredients in specified
2 consumer products, including quantities in the entire consumer product or component.

3
4 (D) Chemical and consumer product market data, including:

- 5
6 1. Volume or units sold in California,
7 2. Description of sales locations in California.
8 3. The intended uses of the product,
9 4. The targeted customer base(s), and
10 5. A description of the end-of-life management program, if any, for the product.

11
12 (E) Standard analytical chemistry protocols for the detection and measurement of a
13 chemical in products and in environmental and biological media. This information is
14 necessary in order to standardize the use of the analytical methods in analytical
15 laboratories to measure and detect the presence of the Chemical of Concern in
16 consumer products and in environmental and biological media.

17
18 (F) Information concerning a product that has been reformulated or redesigned to remove
19 or reduce the concentration of a Priority Chemical, or a product containing a chemical
20 that has been substituted for a product that contained a Priority Chemical. DTSC may
21 require the submittal of this information if the reformulation, redesign or replacement
22 occurred after DTSC listed the chemical. This information is necessary for DTSC to fill
23 data gaps, identify possible regrettable substitutes, and garner further information for
24 the chemical and product identification and prioritization processes.

25
26 **Section 69301.6(c)(2)** provides that the data and information submittal requirements specified
27 in section 69301.6(c)(1) may be satisfied by making data and information available to DTSC
28 that has been provided under the REACH, TSCA, or CEPA programs. That information must
29 still satisfy the pertinent provision of the regulations that is the subject of the information
30 request by DTSC.

31
32 **Section 69301.6(d)(1)** specifies that the information subject to the requirements of section
33 69301.6(b)(3) and (b)(4) is limited to data and information that pertain to either products in the
34 stream of commerce in California or chemicals in such products.

35
36 **Section 69301.6(d)(2)** specifies that when requesting information pursuant to section
37 69301.6(b)(3) or (b)(4), DTSC must make reasonable efforts to avoid requesting the same
38 information from multiple parties unless DTSC determines it has a reason to do so.

39
40 **Section 69301.6(d)(3)** provides that in addition to the information specified in section
41 69301.6(b)(3) and (b)(4), DTSC may also request any needed data or information directly from

1 the manufacturer of the pertinent chemical or product. If the manufacturer does not make the
2 requested information available to DTSC within the time requested, then DTSC will place the
3 name of the manufacturer and additional information about the request on DTSC's Failure to
4 Respond List posted on DTSC's website. If the manufacturer or another person provides the
5 requested information, then DTSC must remove the related entry from its Failure to Respond
6 List. This section allows DTSC to request information from the manufacturer who, in many
7 cases, will have more direct access to the needed information than would the responsible
8 entity. The Failure to Respond List is necessary to inform responsible entities, especially
9 retailers, and consumers about manufacturers who have chosen not to cooperate in providing
10 information needed by DTSC to properly identify and prioritize chemicals and products.

11
12 **Section 69301.6(e)** specifies the means by which DTSC may request that information be
13 made available to it. Those means are: **(1)** correspondence sent via U.S. mail or
14 electronically to an individual responsible entity or other person; or **(2)** data and information
15 call-ins on DTSC's website that are also noticed to those on any listservs established by DTSC
16 related to these regulations and also noticed in the CRNR. Unless otherwise specified by
17 DTSC, this second type of call-in applies to all responsible entities or manufacturers of a
18 specific chemical or product or group of chemicals or products.

19
20 **Section 69301.6(f)** allows any responsible entity or other person to provide reliable
21 information, as defined, to DTSC at any time for consideration by DTSC in the chemical and
22 product identification and prioritization processes. The provision allows the information to be in
23 support of a chemical or product to be included in, or excluded or removed from, the chemical
24 lists or product lists. DTSC is required to give good faith consideration to such information.

25
26 The term "reliable information" is used throughout the regulations to qualify the data sources
27 that will be acceptable to inform various parts of the prioritization and alternatives assessment
28 processes. Section 69301.6(a)(66) defines reliable information and lists sources of data,
29 studies, and information that is widely accepted by the scientific community. Data, studies and
30 information that come from these sources is acceptable and will be used by DTSC to evaluate
31 chemicals, products, alternatives assessments, and regulatory responses.

32 33 **Section 69301.7. Availability of Information on the DTSC's Website**

34 **Section 69301.7**, in its entirety, is necessary to specify the types of information that DTSC will
35 post on its website. In order to implement these regulations, making information available to
36 the public, consumers, responsible entities and other persons in the supply chain is critical.
37 This section clearly specifies the information that DTSC will post to assist responsible entities
38 in complying with the requirements of Chapter 53 may use for compliance. This information
39 will also assist the public and consumers to make informed choices regarding consumer
40 products.

1 **Section 69301.7(a)** requires that DTSC post on its website and update as needed all of the
2 information set out below. The availability of the documents and information listed below, and
3 updates thereto, will be noticed in the CRNR and to persons on any listservs established by
4 DTSC for purposes of implementing Chapter 53.

- 5 (1) Failure to Comply List;
- 6 (2) Failure to Respond List;
- 7 (3) Data and information Requests;
- 8 (4) Exemption determinations, including rescissions, made pursuant to sections 69302.1
9 and 69303.1, and supporting rationale;
- 10 (5) Proposed and final chemical lists and supporting rationale and documentation, copies
11 of written comments received regarding the proposed lists, and any responses DTSC
12 has chosen to provide;
- 13 (6) Proposed and final product lists, along with supporting rationale and documentation,
14 copies of written comments received regarding the proposed lists, and any responses
15 DTSC has chosen to provide;
- 16 (7) Petitions filed under article 4 that are deemed complete, and notices of decision and
17 statements of basis prepared by DTSC related to such petitions;
- 18 (8) Chemical Removal Confirmation Notifications, Chemical Removal Intent Notifications,
19 Product Removal Confirmation Notifications, and Product Removal Intent
20 Notifications;
- 21 (9) Due dates for the Tier II-A and Tier II-B AA Reports for each AA Work Plan;
- 22 (10) A list of extension requests approved for submittal of AA Work Plans and AA Reports;
- 23 (11) A list of de minimis exemption requests received by DTSC, as well as copies of
24 DTSC's notifications granting, denying, or rescinding a de minimis exemption;
- 25 (12) AA Report notices of completeness;
- 26 (13) Proposed and final regulatory response determinations, as well as copies of all written
27 comments received for a proposed determination and any responses DTSC has
28 chosen to provide;
- 29 (14) A list of regulatory response exemption requests submitted to DTSC, as well as copies
30 of DTSC's notifications granting, denying, or rescinding an exemption;
- 31 (15) Copies of all disputes and petitions for review filed with DTSC under article 7 and
32 copies of DTSC decisions on such filings; and
- 33 (16) A list of accrediting bodies whose designation as such has been rescinded by DTSC,
34 and a list of lead assessors whose accreditation has been rescinded.

35
36 **Section 69301.7(b)** specifies additional items that DTSC must post on its website and update
37 at least quarterly:

- 38 (1) A list of products determined by DTSC to contain a Chemical under Consideration or
39 Priority Chemical;
- 40 (2) AA guidance documents;
- 41 (3) AAs available in the public domain;

- 1 (4) AA notifications submitted to DTSC;
- 2 (5) A list of Tier I AAs performed by a qualified third party assessment entity or verified by
3 a third-party lead assessor and submitted to DTSC;
- 4 (6) A list of all AA Work Plans submitted to DTSC, as well as a full or redacted copy of
5 each AA Work Plan, including both the original AA Work Plan and the AA Work Plan
6 approved by DTSC if they are different;
- 7 (7) A list of all AA Reports submitted to DTSC, the executive summary for each AA
8 Report, the AA verification statement if applicable, and a full or redacted copy of each
9 AA Report, including the original submittal and the AA Report approved by DTSC if
10 different;
- 11 (8) Regulatory Response Report;
- 12 (9) Links to product stewardship plans provided to DTSC;
- 13 (10) A list of qualified third-party assessment entities and qualified in-house assessment
14 entities;
- 15 (11) A list of persons designated as accrediting bodies; and
- 16 (12) Findings of audits conducted by DTSC.

17

18 **Section 69301.7(c)** provides that all documents and information posted on DTSC's website
19 under section 69301.7 must include the date the item is posted and dates of any revised
20 postings. This is necessary because the time lines for complying with the requirements of
21 Chapter 53 are in some cases triggered by the date certain information is posted on DTSC's
22 website.

23

24 **Section 69301.8. Chemicals and Products Lists: Timelines and Sequencing**

25 **Section 69301.8** is necessary to establish the time lines and sequencing for the issuance of
26 the initial lists of: Chemicals under Consideration, Priority Chemicals, Products under
27 Consideration, and Priority Products. Establishing specific timelines and sequencing clarifies
28 when and how DTSC will propose and finalize the initial and subsequent chemical and product
29 lists.

30

31 This section is necessary so that the Chemicals of Concern identification and prioritization
32 process moves in an orderly fashion without undue delay. It also puts potentially affected
33 parties on notice of the time frames in which DTSC is operating. This section also gives DTSC
34 some flexibility in the manner/order in which it releases updates to the various lists.

35

36 **Section 69301.8(a)** sets out the schedule as follows: **(1)** the proposed initial list of Chemicals
37 under Consideration must be issued for public review and comment by June 1, 2011; **(2)** the
38 final version of the initial list of Chemicals under Consideration must be issued by March 1,
39 2012; **(3)** the proposed initial list of Priority Chemicals must be issued for review and comment
40 by July 1, 2012; **(4)** the proposed initial list of Products under Consideration must be issued for
41 public review and comment by March 1, 2013; **(5)** the proposed initial list of Priority Products

1 must be issued for public review and comment by September 1, 2013; and **(6)** the final version
2 of the initial list of Priority Products must be issued by December 1, 2013.

3
4 **Section 69301.8(b)** provides that when updating any of the chemical or product lists DTSC
5 may, in its discretion: **(1)** simultaneously or sequentially issue the updated and/or revised
6 Chemicals under Consideration list and Priority Chemicals list; and **(2)** simultaneously or
7 sequentially issue the updated and/or revised Products under Consideration list and Priority
8 Products list.

9
10 **Article 2. Chemical Prioritization Process**

11
12 Article 2, in its entirety, is necessary to fulfill the requirements of Health and Safety Code
13 section 25252, which require DTSC to establish a process to identify and prioritize chemicals
14 and chemical ingredients in consumer products that may be considered as Chemicals of
15 Concern. Health and Safety Code section 25252 requires that the identification and
16 prioritization process include, but not be limited to, consideration of a chemical's: (1) volume in
17 commerce in California; (2) potential for exposure to the chemical in a product; and (3)
18 potential effects on sensitive subpopulations.

19
20 Health and Safety Code section 25252 also requires DTSC to evaluate chemicals by
21 developing criteria that include, but are not limited to, traits, characteristics, and endpoints
22 (collectively referred to as hazard traits for purposes of this Statement of Reasons), developed
23 by OEHHA, for the Toxics Information Clearinghouse established under Health and Safety
24 Code section 25256.1.

25
26 DTSC is fulfilling the statutory requirement to establish a chemical identification and
27 prioritization process by identifying Chemicals of Concern and prioritizing each such chemical
28 as either a "Chemical under Consideration" or a "Priority Chemical". This is the first step in the
29 process leading up to the exploration and identification of safer alternative chemicals and
30 consumer products. The second step, addressed by article 3, identifies and prioritizes
31 products that contain Priority Chemicals in order to identify those products for which an
32 alternatives assessment must be undertaken pursuant to article 5, which is necessary to
33 implement Health and Safety Code section 25253.

34
35 Under the provisions of article 2, Chemicals of Concern will be identified and then prioritized
36 by:

- 37
38 (1) Identifying chemicals that exhibit one or more hazard traits as defined in section
39 69301.2, and that are reasonably expected to be present in consumer products, and
40

- 1 (2) Using prioritization factors specified in sections 69302.3 and 69302.4 to determine
2 which of the chemicals identified in step 1 will be identified as Chemicals of Concern,
3 and then prioritized by being placed on either the list of Chemicals under Consideration
4 or the list of Priority Chemicals.
5

6 To identify and prioritize a chemical as either a Chemical under Consideration or a Priority
7 Chemical, DTSC will use broad, overarching scientific factors to evaluate the chemical(s). For
8 the reasons discussed below, this approach was chosen rather than a static and rigid
9 regulatory approach of the type that requires the use of specified types of chemical toxicity
10 criteria or requires the use of a system for weighting toxicity information to produce a chemical
11 ranking system.
12

13 The broad, overarching scientific prioritization factors listed in these regulations are designed:
14 (1) to be flexible enough to accommodate the availability and type of chemical information
15 being evaluated; and (2) to stand the test of time by allowing DTSC to consider chemical
16 information based on advances in science and technology without constant updates to the
17 regulations. It is important to note that all the prioritization factors specified in article 2 may not
18 be applicable to a given chemical and that DTSC is not required to consider all the
19 prioritization factors for a given chemical. Providing an extensive list of prioritization factors is
20 necessary to accommodate prioritizing chemicals now and in the future when additional
21 scientific data may become available. This is necessary to avoid unnecessary delays in
22 developing chemical lists and to allow the implementation of the regulations to keep pace with
23 advances in science.
24

25 Because the rationale for identifying and listing a chemical as a Chemical under Consideration
26 or a Priority Chemical will be different for each chemical, DTSC: (1) may customize the
27 applicability and evaluation of broad, overarching scientific factors to consider for a chemical;
28 (2) will explain the rationale for listing a chemical as a Chemical under Consideration or a
29 Priority Chemical; and (3) will make the rationale and supporting information available to the
30 public for review and comment along with the proposed lists. Allowing the public to review and
31 comment provides an open and transparent process prior to finalizing the Chemical under
32 Consideration and Priority Chemical lists.
33

34 The rationale and supporting documentation may include the evaluation and consideration of
35 current scientific information, including any state of the art, or acceptable mechanisms used for
36 weighing scientific evidence or balancing toxicity and information and other factors to prioritize
37 a chemical as a Chemical under Consideration or Priority Chemical. In addition to the hazard
38 trait information, the prioritization factors include, for example, chemical and physical
39 properties, chemical use, chemical presence and prevalence in products, public health and
40 environmental impacts, and routes of exposure.
41

1 In summary, a chemical that exhibits a hazard trait and is reasonably expected to be present in
2 a product is subject to the identification and prioritization process for designation as a
3 Chemical under Consideration. Chemicals under Consideration that pose the greatest level of
4 threat to public health and/or the environment will be designated Priority Chemicals. Priority
5 Chemicals that are on a finalized list are then used to prioritize products under article 3,
6 Product Prioritization Process.

7 8 **Section 69302. General**

9 This section introduces the purpose of article 2 and is necessary to specify the process that
10 DTSC will use to identify and prioritize a chemical as a Priority Chemical. As part of this
11 process, DTSC will evaluate information from manufacturers and other sources to identify and
12 prioritize Priority Chemicals. DTSC may rely on information on chemicals obtained under
13 section 69301.6, but is not limited to information obtained under section 69301.6 in performing
14 its duties in article 2.

15 16 **Section 69302.1. Applicability**

17 **Section 69302.1**, in its entirety, is necessary to specify the scope of chemicals subject to the
18 chemical prioritization process.

19
20 **Section 69302.1(a)** identifies the conditions under which a chemical is subject to the chemical
21 prioritization process: (1) the chemical exhibits a hazard trait, and (2) the chemical is
22 reasonably expected to be in products placed into the stream of commerce in California.

23
24 The first point of entry into the prioritization process set out in article 2 is whether the chemical
25 exhibits a hazard trait. Health and Safety Code section 25252 requires DTSC to develop
26 criteria to evaluate chemicals. These criteria include, but are not limited to, hazard traits,
27 developed by OEHHA, that are included as data in the Toxics Information Clearinghouse
28 established under Health and Safety Code section 25256.1. For purposes of identifying
29 chemicals that exhibit a hazard trait, DTSC is using hazard traits developed by OEHHA.

30
31 Until OEHHA's hazard traits list is finalized, DTSC will use criteria, included in the definition of
32 hazard trait in section 69301.2(a)(39), that includes a chemical in the article 2 chemical
33 prioritization process only if the chemical is one of the following:

- 34
- 35 • Carcinogen or reproductive toxin as specified in section 69301.2(a)(9),
 - 36
 - 37 • Chemical listed as having mutagenic properties in the European Union Category 1A or
 - 38 1B, or
 - 39
 - 40 • Persistent bioaccumulative toxic chemical as determined by the United States
 - 41 Environmental Protection Agency.

1
2 Section 69301.2(a)(9) defines carcinogen or reproductive toxin as a chemical that is listed or
3 meets criteria established by specified sources that are viewed by the scientific community as
4 reliable sources.

5
6 The second criterion that a chemical must meet to be included in article 2 chemical
7 prioritization process is related to products. To be subject to the chemical prioritization
8 process, (1) the chemical must be reasonably expected to be present in a product, and (2) the
9 product must be placed into the stream of commerce in California.

10
11 Reasonably expected presence of a chemical in a product may be determined by any number
12 of methods, including for example, information submitted by the manufacturer, analytical
13 testing, product reports, mass balance calculations, third-party information, and the petition
14 process in article 4, among others.

15
16 The product must also be placed into the stream of commerce in California. This includes
17 Internet sales, storefront retail sales, promotional items and “giveaways”. A product purchased
18 outside of California and brought into California for personal use, including a product that is
19 purchased as a gift, is not considered to be “placed into the stream of commerce in California”.

20
21 **Section 69302.1(a)(1) and (2)** specify two conditions, which are summarized below, under
22 which a chemical that would otherwise be subject to the chemical prioritization process in
23 article 2 is exempted from that process.

24
25 These exemptions, together, are necessary to: (1) avoid duplication of regulation of chemicals
26 already regulated by other State or federal governmental agencies and to clarify and
27 implement the requirement in Health and Safety Code section 25257.1(c): “DTSC shall not
28 duplicate or adopt conflicting regulations for product categories already regulated or subject to
29 pending regulation consistent with the purposes of this article”; and (2) limit the scope of
30 chemicals subject to the prioritization process by only considering chemicals for which there is
31 one or more exposure pathways that could pose a threat to public health and/or the
32 environment.

33
34 **Section 69302.1(a)(1)** specifies that article 2 does not apply to a chemical if DTSC has
35 determined that the chemical is regulated by one or more federal and/or California state
36 regulatory programs that address for each life cycle segment the same public health and
37 environment threats as are addressed by these regulations and the authorizing statute. A
38 chemical that is regulated for less than its full life cycle is not exempt from article 2, nor does
39 regulatory authority over the chemical by a foreign country, another state or a local agency
40 qualify for the exemption since in these situations there is no jurisdictional or consistent
41 authority either in or throughout California

1
2 A chemical that is regulated by a single program or a combination of federal and California
3 state regulatory programs that span the chemical's entire life cycle may be exempted from
4 article 2. DTSC will assess each regulatory program to determine whether collectively public
5 health and the environment are protected from threats posed to the same extent as would be
6 achieved under these regulations and the authorizing statute. If DTSC determines there are
7 significant gaps in the scope of threats addressed by the other regulatory programs, the
8 chemical would not be eligible for this exemption. (See section 69302.3(h) for a related
9 discussion.)

10
11 By way of example, a chemical that might qualify for this type of chemical exemption is a fuel
12 additive that has undergone a "multimedia" evaluation as required by section 43830.8 of the
13 Health and Safety Code. Before adopting new specifications for chemical fuel additives, the
14 California Air Resources Board (CARB) is required to prepare a "multimedia" evaluation to
15 examine the relative risk posed by any newly proposed fuel additive to the State's resources,
16 human health and the environment. Section 43830.8 requires that a multimedia evaluation
17 must identify and evaluate any significant adverse impact on public health and the
18 environment, including air, water or soil that may result from the production, use, or disposal of
19 a motor vehicle fuel that may be used to meet CARB motor vehicle fuel specifications.

20
21 According to the Guidance Document and Recommendations on the Types of Scientific
22 Information Submitted by Applicants for California Fuels Environmental Multimedia
23 Evaluations, revised June 2008, (<http://www.arb.ca.gov/fuels/multimedia/080608guidance.pdf>),
24 potential additives must be evaluated. The evaluation not only includes engine performance
25 and emission requirements, but also includes considerations to health and environmental
26 criteria involving air emissions, cross environmental media transfer and associated health
27 risks, ozone formation potential, hazardous waste generation and management and surface
28 and groundwater contamination resulting from production, distribution, and use.

29
30 This multimedia evaluation process is a flexible approach and accounts for the unique factors
31 for each fuel additive. This process also incorporates an ongoing discussion with the fuel
32 additive's applicant and the California Environmental Protection Agency's Multimedia Working
33 Group (MMWG) for the following:

- 34
- 35 • Tier I: Technical consultation and peer review to establish the risk assessment elements
36 and issues. The MMWG provides technical consultation during development of Tier I
37 Work Plan including identification of key elements such as (1) chemical composition, (2)
38 manufacturing, transportation, and storage, (3) historical use of fuels and components,
39 and (4) risk assessment elements and issues (such as (a) physical, chemical, and
40 environmental toxicity and (b) like release scenarios into the environment). Scientific
41 peer review occurs at each of the Tiers.

- 1
- 2 • Tier II: Development and review of Multimedia Risk Assessment Protocol. The MMWG
- 3 provides technical consultation on Risk Assessment Design (including (a) approaches
- 4 to fill gaps in scientific knowledge and (b) use of fate and transport models to predict
- 5 movement in the environment and potential exposures.
- 6
- 7 • Tier III: Multimedia Risk Assessment Completion, Submittal, Review and
- 8 Recommendations. Independent scientific peer review of the Multimedia Risk
- 9 Assessment report and MMWG recommendations is conducted.

10

11 This is a rigorous multimedia, risk assessment that also incorporates the life cycle concepts to

12 provide policy makers with reliable information to make policy decisions regarding public health

13 and environmental protection. A chemical that is subject to this type of multimedia chemical

14 evaluation under another federal or California state regulatory program might be determined by

15 DTSC to not be subject to the chemical prioritization process under article 2.

16

17 **Section 69302.1(a)(2)** specifies that article 2 does not apply to a chemical if DTSC has

18 determined that there is no exposure pathway by which the chemical might pose a threat to

19 public health or the environment in California during the useful life or end-of-life management

20 of the chemical or any product containing the chemical. In general, chemical exposure

21 pathways involve:

- 22
- 23 • The transport media: the chemical movement through the environment,
 - 24 • The exposure point: public health or environmental contact with the chemical,
 - 25 • The exposure route: the chemical entrance into the body or environmental
 - 26 compartment,
 - 27 • The receptor population: the sector of human or environmental population affected.
- 28

29 A chemical that meets the criteria for this exemption from article 2 would meet the objective of

30 these regulations. That is, it does not pose a threat to public health or the environment that

31 needs to be reduced or eliminated.

32

33 **Section 69302.1(b)** is necessary to specify that DTSC may proceed with the chemical

34 identification and prioritization process without making a specific determination that a chemical

35 is exempt from that process. Section 69302.1(b) clarifies that in the absence of a specific

36 determination by DTSC that a chemical is exempt there is a presumption that the chemical

37 does not meet the conditions for an exemption. The provision further clarifies that the burden

38 to proof that a chemical is exempt from the chemical prioritization process is on the person

39 requesting a chemical exemption determination under section 69302.1(c).

40

1 **Section 69302.1(c)** is necessary to specify that the burden of proof that a chemical is exempt
2 from the chemical prioritization process is on the person seeking the exemption determination
3 from DTSC. The person seeking the determination must prove by clear and convincing
4 evidence that one or both of the exemptions set out in section 69302.1(a)(1) and (2) applies.

5
6 Evidence attempting to show that there is no chemical exposure pathway must include, to the
7 extent applicable, the results of any use and abuse tests, including assumptions and testing
8 methodologies, conducted for a federal or California State regulatory program.

9
10 **Sections 69302.1(d)** is necessary to allow DTSC, at its discretion, to re-evaluate and rescind
11 an exemption determination if DTSC finds that the facts or assumptions on which the
12 exemption was based were not valid at the time or are no longer valid.

13 **Section 69302.2. Chemical Lists**

14 **Section 69302.2**, in its entirety, is necessary to specify the chemical lists that will be prepared,
15 and the process DTSC will use to prepare and finalize the chemicals lists.

16
17
18 **Section 69302.2(a)** requires DTSC to prepare two chemicals lists: **(1)** Chemicals under
19 Consideration, and **(2)** Priority Chemicals. The list of Chemicals under Consideration will be
20 based on factors specified in section 69302.3, and the list of Priority Chemicals will be based
21 on the factors specified in section 69302.4.

22
23 The Chemical under Consideration list serves two functions. First, it serves as notification to
24 manufacturers that certain chemicals are being considered for listing as a Priority Chemical
25 and allows the manufacturers to redesign a product voluntarily. Second, it serves to identify
26 potential chemical data gaps, whether hazard trait information or product information, by
27 providing a pool of chemicals from which to obtain or generate additional information.

28
29 During informal workshops, interested parties have indicated that chemical data gaps exist and
30 that more information is needed to fill those data gaps in order to take appropriate action. In
31 evaluating Chemicals under Consideration, some of these data gaps will be identified. Some
32 of these gaps may be filled by requesting additional information from chemical companies;
33 others may be filled by research and short-term tests (rather than lengthy studies) that will
34 provide predictive indicators of chemical activity and hazards.

35
36 The Priority Chemicals list alerts manufacturers of the chemicals upon which DTSC will take
37 further regulatory action. The Priority Chemicals list places manufacturers on notice that if
38 their product contains a Priority Chemical, the product may be identified and prioritized as a
39 Priority Product. Until DTSC undergoes the Product Prioritization Process, a manufacturer
40 may voluntarily rethink the usage of the Priority Chemical in the product and redesign the

1 product. Placement on the Priority Products list signifies that the manufacturer must begin the
2 mandatory process to develop an alternatives assessment for the Priority Product.

3
4 **Section 69302.2(b)** specifies the public review and comment process that DTSC must follow
5 before finalizing the Chemicals under Consideration and Priority Chemicals lists. A notice
6 regarding the availability of the proposed list(s) will be sent to persons on listservs established
7 for this chapter, and will be published in the CRNR. Additionally, the proposed list(s) and
8 supporting documentation and the rationale for the identification and prioritization of the
9 chemicals on the lists will be made publicly available on DTSC's website for review and
10 comment, subject to article 10. The supporting information must include each proposed
11 chemical's hazard trait(s) and the potential exposure pathway(s). The notice must include: **(1)**
12 the time period during which comments may be submitted, **(2)** the method(s) for submitting
13 comments, and **(3)** whether any workshops will be held.

14
15 Section 69302.2(b) is necessary to ensure that the public and other interested parties have
16 input into the chemical listing process. This comment period is also necessary to provide
17 responsible entities another opportunity, in addition to that provided in section 69301.6(f), to
18 present information and data not previously considered to have a chemical added to or
19 removed from the proposed Chemicals under Consideration or Priority Chemicals list prior to
20 finalization of the lists.

21
22 **Section 69302.2(c)** specifies that after DTSC considers public comments, it will finalize and
23 post on its website the final Chemicals under Consideration and final Priority Chemicals lists.
24 DTSC may, at its discretion, respond to public comments.

25
26 **Section 69302.2(d)** requires the Chemicals under Consideration and Priority Chemicals lists to
27 be updated, as needed, to include additions to and/or deletions from prior lists.

28 **Section 69302.3. Chemicals under Consideration**

29 This section, in its entirety, is necessary to specify and describe the prioritization factors that
30 DTSC may consider when listing a chemical that meets the applicability criteria in section
31 69302.1 as a Chemical under Consideration.

32
33
34 It is important to note that the prioritization factors in the regulations take into account future
35 knowledge and scientific advancements for a chemical, and that DTSC is not required to
36 consider all the prioritization factors listed in this section for each chemical. DTSC will take
37 into consideration those factors that are applicable to each chemical and for which reliable
38 information is available. DTSC will provide the rationale and supporting documentation for
39 listing a chemical as a Chemical under Consideration and interested parties will have the
40 opportunity to comment on DTSC's rationale, pursuant to section 69302.2.

1 Health and Safety Code section 25252 requires DTSC to develop criteria for the evaluation of
2 chemicals. The criteria must include the hazard traits that OEHHA is developing for the Toxics
3 Information Clearinghouse established by Health and Safety Code section 25256.1. DTSC
4 also has the authority to use other hazard traits not identified by OEHHA to evaluate
5 chemicals. DTSC will take into account the hazard traits identified by OEHHA as prioritization
6 factors. But the hazard traits in this section precede OEHHA's finalized hazard traits list.
7 Section 69302.3(b)(25) may be used as a "catch all" for hazard traits that are not specifically
8 identified in this section but are identified in the final hazard traits lists OEHHA is developing
9 for inclusion in the Toxics Information Clearinghouse.

10
11 **Section 69302.3(a)(1) through (15)** are necessary to allow DTSC to consider chemical and
12 physical properties as potential hazard traits when identifying a Chemical under Consideration.
13 Chemical and physical properties provide DTSC basic information for a chemical and its
14 behavior during its manufacture and use. Chemical and physical properties may also be used,
15 to some extent, as predictive indicators of behavior in the humans, wildlife, ecosystems, and
16 the environment.

17
18 The specified properties are not an exhaustive list, but provide common chemical and physical
19 properties that may be used to evaluate a chemical and its potential public health and
20 environmental threats.

21
22 DTSC may consider as prioritization factors, to the extent applicable, density, dissociation
23 constant, explosiveness, flammability, flash point, granularity, melting or boiling point, oxidizing
24 properties, partition coefficient, stability in organic solvents and relevant degradation
25 byproducts, surface tension, vapor pressure, viscosity, water solubility, and other physical,
26 chemical, or quantum properties specific to nanomaterials.

27
28 **Section 69302.3(b)(1) through (26)** are necessary to allow DTSC to consider as chemical
29 prioritization factors adverse public health impacts. Section 69302.3(b) specifies that public
30 health impacts will include an evaluation and comparison of impacts resulting from a single,
31 intermittent or frequent use of or contact with the chemical through dermal, oral and inhalation
32 routes of exposure. The hazard traits and toxicological endpoint factors listed in this
33 subsection are not an exhaustive list of the adverse impacts to public health that may be
34 considered by DTSC in the chemical prioritization process.

35
36 **Section 69302.3(b)(1)** identifies acute or chronic toxicity as a chemical prioritization factor.
37 Single (acute) or repeated (intermittent or chronic) exposures to the chemical is a measure of
38 general toxicity to public health. Acute toxicity results in sudden or severe symptoms that
39 appear, change, or worsen rapidly as a result of exposure to a chemical. Intermittent toxicity
40 results in symptoms that may appear later after repeated exposures; while chronic toxicity
41 results in symptoms that appear over a longer period of time (i.e., latency period). Acute

1 symptoms may disappear once the chemical exposure is removed, while chronic symptoms
2 may have a longer duration. Intermittent symptoms may manifest as either acute or chronic
3 symptoms.

4
5 **Section 69302.3(b)(2)**, identifies bioaccumulation in humans as a chemical prioritization
6 factor. This may be shown by either biomonitoring data or scientifically sound predictive
7 chemical behavior, e.g., mercury behavior, and is a measure of exposure to a chemical.
8 Bioaccumulation occurs when a person absorbs the chemical at a rate greater than that at
9 which the substance is lost.

10
11 **Section 69302.3(b)(3)** identifies carcinogenicity as a chemical prioritization factor.
12 Carcinogenicity is a hazard trait that causes a toxicological endpoint that shows increased,
13 abnormal cell growth and is normally attributed to chemical, radionuclide or radiation exposure.
14 There are many types of specific cancers; this consideration is intended to capture all those
15 cancers as a consideration for listing a chemical as a Chemical under Consideration.

16
17 **Section 69302.3(b)(4)** identifies cardiovascular toxicity as a chemical prioritization factor.
18 Cardiovascular toxicity following chemical exposure is the adverse effects on the structure or
19 function of the heart or the vascular system. Manifestations of cardiovascular toxicity include
20 structural effects associated with functional damage and actual damage to the heart and blood
21 vessels related to the heart. Examples of damage to the heart and blood vessels related to the
22 heart include lesions leading to atherosclerosis or hypertension and inflammation to the heart;
23 functional effects including adverse changes in the ability of the cardiovascular system to
24 supply appropriate nutrients, metabolites, respiratory gases, or hormones.

25
26 **Section 69302.3(b)(5)** identifies dermatotoxicity as a chemical prioritization factor.
27 Dermatotoxicity is the occurrence of adverse effects on the structure or function of the skin
28 following exposure to a chemical. The skin serves as a barrier to the outside environment and
29 maintains the body's heat, fluid, and electrolyte balance. Some dermatotoxicity effects include,
30 but are not limited to, allergic sensitization, allergic reactions, acute or subacute irritation, or
31 photosensitivity.

32
33 **Section 69302.3(b)(6)** identifies developmental toxicity as a chemical prioritization factor.
34 Developmental toxicity is a hazard trait that causes adverse effects on a developing fetus or
35 child following exposure to a chemical substance to a parent prior to conception, during
36 prenatal development, or before maturity (e.g., lead causes developmental toxicity and is
37 caused by ingestion of lead). Effects can include birth defects, low birth weight, biological
38 dysfunctions, or psychological or behavioral deficits that manifest as the child grows.
39 Developmental toxicity is associated with sensitive subpopulations identified in Health and
40 Safety Code section 25252(a) (3).

41

1 **Section 69302.3(b)(7)** identifies the effects of electromagnetic radiation, including ionizing
2 radiation and non-ionizing radiation as a chemical prioritization factor. Electromagnetic
3 radiation may cause damage to organ tissue.
4

5 **Section 69302.3(b)(8)** identifies endocrine toxicity as a chemical prioritization factor.
6 Endocrine toxicity may result in an adverse effect (i.e., disruption) following exposure to a
7 chemical on the structure or function of the endocrine system, which produces hormones that
8 control a number of functions in humans. Endocrine disruption may produce adverse
9 developmental, reproductive, neurological, and immune effects in humans.
10

11 **Section 69302.3(b)(9)** identifies epigenetic toxicity as a chemical prioritization factor.
12 Epigenetic effects are changes in an organism that are caused by exposure to a chemical
13 without changing the underlying gene sequence; that is, non-genetic factors cause the
14 organism's genes to behave (or "express themselves") differently.
15

16 **Section 69302.3(b)(10)** identifies genotoxicity as a chemical prioritization factor. Genotoxic
17 effects due to chemical exposure cause damage to genetic information and express the
18 damage as gene mutations or chromosomal abnormalities.
19

20 **Section 69302.3(b)(11)** identifies hematotoxicity as a chemical prioritization factor. Impacts of
21 chemical exposures that cause hematotoxic effects (adverse effects on blood and blood
22 forming tissues) include changes in the number, types or lifetime of circulating blood cells;
23 decreased capacity of hemoglobin to transport oxygen; and increase or decrease in blood
24 clotting activity resulting from interference in platelet response or function or other causes.
25

26 **Section 69302.3(b)(12)** identifies hepatotoxicity as a chemical prioritization factor.
27 Hepatotoxicity affects the structure or functions of the liver, gall bladder, and gastrointestinal
28 tract and may cause liver damage, hepatitis, vascular changes, gall bladder disease, and
29 inflammation of the gastrointestinal epithelium.
30

31 **Section 69302.3(b)(13)** identifies immunotoxicity as a chemical prioritization factor.
32 Immunotoxicity is an adverse effect on the parts or function of the immune system following
33 exposure to a chemical substance. Toxicological endpoints include allergic sensitization, such
34 as delayed hypersensitivity, changes in immune cell numbers, suppression or enhancement of
35 the immune response, and initiation or worsening of autoimmunity.
36

37 **Section 69302.3(b)(14)** identifies musculoskeletal toxicity as a chemical prioritization factor.
38 Musculoskeletal toxicity causes adverse effects on the structure or function of the
39 musculoskeletal system, including bones, muscles, cartilage, tendons, ligaments, joints and
40 connective tissue following exposure to a chemical substance. Musculoskeletal toxicity may
41 be exhibited by arthritis, decreased joint movement; changes in mineral content of bone;

1 osteoporosis bone malformation or other skeletal growth disorders; abnormal bone mass or
2 density indices; tooth loss; fibromyalgia; and adverse muscle and neuromuscular function.

3
4 **Section 69302.3(b)(15)** identifies nephrotoxicity and other toxicity to the urinary system as a
5 chemical prioritization factor. Nephrotoxicity refers to adverse effects on the structure or
6 function of the kidney and components of the urinary system following exposure to a chemical
7 substance. Evaluating for nephrotoxicity includes, but is not limited, abnormal urine volume or
8 chemistry, pathological changes to the kidney, formation of calculi in the ureter or bladder, and
9 muscular or epithelial damage in the urinary bladder

10
11 **Section 69302.3(b)(16)** identifies neurotoxicity as a chemical prioritization factor. Following
12 exposure to a chemical, neurotoxic effects include an alteration of the normal activity of the
13 central or peripheral nervous system that causes damage to nervous tissue. Toxicological
14 endpoints may include impaired muscle control, behavioral changes, and impaired mental
15 faculties.

16
17 **Section 69302.3(b)(17)** identifies ocular toxicity as a chemical prioritization factor. Ocular
18 toxicity consists of adverse changes to the components or function of the visual system
19 following exposure to a chemical substance. Ocular toxicity effects include, but are not limited
20 to, iris, conjunctival, lens or corneal damage; abnormal reaction to light; damage to the eye lids
21 or nictitating membranes; functional or structural damage to the retina; and damage to or
22 functional abnormalities to the ocular portions of the central nervous system.

23
24 **Section 69302.3(b)(18)** identifies organ or tissue system toxicity as a chemical prioritization
25 factor. Chemical exposure that causes organ or tissue system toxicity may manifest itself as
26 negative effects on, or alternations to, the target organ and tissue system.

27
28 **Section 69302.3(b)(19)** identifies ototoxicity as a chemical prioritization factor. Ototoxicity
29 causes adverse effects on the structure or function of the inner ear or nerve, which could result
30 in temporary or permanent disturbances of hearing, balance, or both following exposure to a
31 chemical substance. Ototoxic effects include, but are not limited, hearing impairment,
32 abnormal balance, changes to cellular components of the inner ear, and change in auditory
33 response or electrical activity in the auditory areas of the brain.

34
35 **Section 69302.3(b)(20)** identifies chemical persistence as a chemical prioritization factor. The
36 ability of a chemical to remain in organic tissue and exist for a long period of time prior to its
37 release or elimination in humans may also be known as biopersistence.

38
39 **Section 69302.3(b)(21)** identifies reactivity in biological systems as a chemical prioritization
40 factor. Reactivity in biological systems is described as the occurrence of rapid reactions with
41 molecules in the body that lead to alterations in critical molecular function and, ultimately,

1 adverse health outcomes. Biological systems' reactivity include, but are not limited, to adverse
2 health effects resulting from covalent binding or oxidation of cellular macromolecules,
3 generation of reactive oxygen species or oxidative stress, or catalytic generation of hydroxyl
4 radicals.

5
6 **Section 69302.3(b)(22)** identifies reproductive toxicity as a chemical prioritization factor.
7 Reproductive toxicity caused by chemical exposure will interfere in some way with normal
8 reproduction and includes adverse effects on sexual function and fertility in adult males and
9 females.

10
11 **Section 69302.3(b)(23)** identifies respiratory effects as chemical prioritization factor.
12 Chemical exposures that cause adverse impacts to the respiratory system may include a
13 variety of acute and chronic pulmonary conditions, including local irritation, bronchitis,
14 pulmonary edema, emphysema, and cancer.

15
16 **Section 69302.3(b)(24)** identifies toxicokinetics as a chemical prioritization factor.
17 Toxicokinetics is the rate at which a chemical will enter the body and what happens to the
18 chemical and the body once the chemical is in the body.

19
20 **Section 69302.3(b)(25)** allows the consideration, as chemical prioritization factors, of those
21 hazard traits not specifically identified in this subsection, such as those that may be identified
22 by OEHHA that are not specifically identified above. This provision is also necessary to
23 address advancements in science and technology that detect or identify other hazard traits not
24 currently detectable.

25
26 **Section 69302.3(b)(26)** is necessary to clarify and make more specific the types of "potential
27 effects on sensitive subpopulations, including infants and children", as identified in Health and
28 Safety Code section 25252, that DTSC will consider when identifying a Chemical under
29 Consideration. Section 69301.2 further defines sensitive subpopulations and includes, but is
30 not limited to, pregnant women and the elderly.

31
32 **Section 69302.3(c)(1) through (7)** are necessary to allow DTSC to consider as chemical
33 prioritization factors adverse ecological impacts. Ecology is intertwined with human survival;
34 adverse impacts to the ecological system will impact public health. For example, chemicals
35 that affect plants or animals may affect public health through ingestion of the chemical;
36 chemicals that affect plant survival may adversely impact the delicate balance of nature that
37 may ultimately affect the balance of carbon dioxide and oxygen in the air. The factors listed in
38 this subsection are not an exhaustive list, but they provide common ecological factors to
39 consider when prioritizing a chemical as a Chemical under Consideration.

40

1 **Section 69302.3(c)(1)** identifies, as a chemical prioritization factor, acute or chronic toxicity in
2 aquatic, avian or terrestrial organisms. Acute or chronic toxic effects to these organisms may
3 have a direct effect on public health through ingestion as food, indirect effects through the food
4 chain or through other ecosystem impacts.

5
6 **Section 69302.3(c)(2)** identifies, as a chemical prioritization factor, adverse impacts to aquatic
7 ecosystems, including aquatic sediments. Adverse impacts to aquatic ecosystems will impact
8 aquatic life and may directly or indirectly impact public health.

9
10 **Section 69302.3(c)(3)** identifies, as a chemical prioritization factor, adverse impacts to
11 terrestrial ecosystems. Chemicals may cause adverse ecological terrestrial impacts that will
12 affect land-based organisms, including wildlife.

13
14 **Section 69302.3(c)(4)** identifies, as a chemical prioritization factor, adverse impacts to
15 environmentally sensitive habitats, including habitat loss or deterioration and other negative
16 impacts to sensitive habitats due to a chemical. Habitat loss or deterioration will impact the
17 organisms that depend on the habitat and may cause cascading effects that may upset the
18 balance in the ecosystem and may eventually impact public health.

19
20 **Section 69302.3(c)(5)** identifies, as a chemical prioritization factor, adverse impacts to
21 endangered or threatened species that negatively affect their ability to survive, reproduce, or
22 live in their habitats. Society has recognized and taken responsibility for the impact on certain
23 species in nature that are in danger of extinction.

24
25 **Section 69302.3(c)(6)** identifies, as a chemical prioritization factor, population loss, decline in
26 population diversity and changes in historical communities.

27
28 **Section 69302.3(c)(7)** identifies, as a chemical prioritization factor, vegetation contamination
29 or damage (including phytotoxicity).

30
31 **Section 69302.3(d)(1) through (5)** are necessary to allow DTSC to consider as chemical
32 prioritization factors adverse environmental impacts. Public health is impacted by chemical
33 environmental pollutants. Chemicals may cause environmental contamination through air,
34 water, and soil and the public may be exposed to the chemical through contact with
35 environmental media. The factors listed in this subsection are not an exhaustive list, but
36 provide common environmental factors to consider when prioritizing a chemical as a Chemical
37 under Consideration.

38
39 **Section 69302.3(d)(1)(A) through (J)** identify chemical traits as chemical prioritization factors.
40 Chemical activity in the environment may be evaluated using the specific chemical traits
41 identified in this subsection. This list is not an exhaustive list, but it provides common chemical

1 traits to evaluate and to inform the chemical prioritization process. Chemical trait information
2 includes field and laboratory scientific information, as well as predictive chemical behavior
3 using models to provide information on the chemical being considered, as well as, the
4 chemical degradation products and fate and transport data in environmental compartments.
5 Any chemical traits data and studies used will stem from reliable information as defined in
6 section 69301.2.

7
8 **Section 69302.3(d)(1)(A)** identifies, as a chemical prioritization factor, stability and persistence
9 in biological and environmental compartments. This chemical trait information is necessary to
10 evaluate how long the chemical will stay in the environment and in biological organisms,
11 including how the chemical or chemical degradation products may impact food chain
12 organisms.

13
14 **Section 69302.3(d)(1)(B)** identifies, as a chemical prioritization factor, fate and transport
15 among environmental compartments. This chemical trait information is necessary to evaluate
16 the mobility of the chemical between soil, water and air.

17
18 **Section 69302.3(d)(1)(C)** identifies bioaccumulation as a chemical prioritization factor.
19 Bioaccumulation is the net accumulation of a chemical in an organism or an environmental
20 compartment that absorbs the chemical at a rate greater than that at which the chemical is
21 lost.

22
23 **Section 69302.3(d)(1)(D)** identifies biodegradation as a chemical prioritization factor. Related
24 to stability and persistence, this chemical information will inform the chemical prioritization
25 process by evaluating what type of environmental conditions are necessary to break down the
26 chemical to benign or reusable chemical components.

27
28 **Section 69302.3(d)(1)(E)** identifies photodegradation as a chemical prioritization factor.
29 Related to the other chemical traits listed in this subsection, photodegradation will inform the
30 chemical prioritization process by evaluating what type of light or sunlight is required to break
31 down the chemical, or whether the photodegradation of the chemical itself may cause
32 chemical byproducts that are of concern.

33
34 **Section 69302.3(d)(1)(F)** identifies, as a chemical prioritization factor, transformation products
35 in environmental settings. Chemical transformation informs the chemical prioritization process
36 by providing data on whether the chemical is able to change its structure readily without other
37 chemicals or reagents present.

38
39 **Section 69302.3(d)(1)(G)** identifies hydrolysis half life as a chemical prioritization factor.
40 Chemical hydrolysis half life provides chemical trait information on how the chemical reacts in

1 the presence of water; specifically, how long it takes the chemical concentration to decrease
2 by half in the presence of water.

3
4 **Section 69302.3(d)(1)(H)** identifies, as a chemical prioritization factor, aerobic and anaerobic
5 soil half-lives. This provides data on how long it takes the chemical concentration to be
6 reduced by half by soil microbial activity in an oxygen (aerobic) and non-oxygen (anaerobic)
7 environment.

8
9 **Section 69302.3(d)(1)(I)** identifies, as a chemical prioritization factor, aerobic and anaerobic
10 sediment half-lives, which are similar to section 69302.3(d)(1)(H), but in soil sediments, which
11 are in water environments.

12
13 **Section 69302.3(d)(2)(A) through (H)** identify air quality impacts as chemical prioritization
14 factors. Air quality crosses over other prioritization factors listed in this section. These cross
15 over areas include: public health impacts due to respiratory effects, ecological impacts and
16 environmental impacts due to general air contamination as well as global warming potential.
17 But they are also called out separately here so that the evaluation process is comprehensive.

18
19 **Section 69302.3(d)(2)(A) and (B)** identify nitrogen oxides and sulfur oxides as chemical
20 prioritization factors. Chemicals that cause air emissions that result in nitrogen oxides and
21 sulfur oxides cause acid rain, which causes negative effects on the ecosystem and ozone,
22 which contributes to the greenhouse gas effect.

23
24 **Section 69302.3(d)(2)(C)** identifies toxic air contaminants as chemical prioritization factors.
25 Chemicals identified by the California Air Resources Board Air Toxics Program are monitored
26 and controlled as toxic air contaminants because they can cause public health effects.

27
28 **Section 69302.3(d)(2)(D)** identifies greenhouse gases as chemical prioritization factors.
29 Greenhouse gases are gases in the atmosphere that absorb and emit radiation within the
30 thermal infrared range, resulting in the greenhouse effect. Greenhouse gases include, but are
31 not limited to, carbon dioxide, methane, nitrous oxide, and ozone.

32
33 **Section 69302.3(d)(2)(E)** identifies secondary organic aerosols as chemical prioritization
34 factors. Secondary organic aerosols are those chemicals that could form or contribute to the
35 formation of secondary organic aerosols in the atmosphere. Secondary organic aerosol and
36 its formation are linked to air quality, public health, and the climate.

37
38 **Section 69302.3(d)(2)(F)** identifies stratospheric ozone-depleting compounds as chemical
39 prioritization factors.

40

1 **Section 69302.3(d)(2)(G)** identifies other ozone-forming compounds as chemical prioritization
2 factors.

3
4 **Section 69302.3(d)(2)(H)** identifies particulate matter as chemical prioritization factors.
5 Particulate matter may cause public health respiratory impacts and in small sizes may serve as
6 building blocks to secondary organic aerosols, which may contribute to greenhouse gases.

7
8 **Section 69302.3(d)(3)(A) through (J)** identify water quality impacts as chemical prioritization
9 factors. Water quality is directly and indirectly tied to public health and environmental impacts.

10
11 **Section 69302.3(d)(3)(A) through (C)** identify, as chemical prioritization factors, biological
12 oxygen demand, chemical oxygen demand and total dissolved solids which are determinants
13 of water quality and are common measures of water quality. Biological oxygen demand is one
14 of the most common measures of polluting organic material in water. Biological oxygen
15 demand indicates the amount of putrescible organic matter present in water. Therefore, a low
16 biological oxygen demand is an indicator of good quality water, while a high biological oxygen
17 demand indicates polluted water.

18
19 Chemical oxygen demand is a measure of the capacity of water to consume oxygen during the
20 decomposition of organic matter and the oxidation of inorganic chemicals such as ammonia
21 and nitrite. Chemical oxygen demand measurements are commonly made on samples of
22 waste waters or of natural waters contaminated by domestic or industrial wastes and may
23 provide information for water treatment activities.

24
25 Chemical oxygen demand is related to biochemical oxygen demand in that they both measure
26 the oxygen-demanding strength of waste waters, but do not necessarily measure the same
27 types of oxygen consumption. Biological oxygen demand measures the amount of oxygen
28 consumed by microbial oxidation and is most relevant to waters rich in organic matter.

29
30 Total dissolved solids tests measure the amount of all dissolved solids in the water. These
31 solids are primarily minerals and salts, but can also include organic matter. Total dissolved
32 solids usually apply to freshwater systems, as salinity comprises some of the ions measuring
33 total dissolved solids. The principal application of TDS is in the study of water quality for
34 streams, rivers and lakes. Although TDS is not generally considered a primary pollutant (e.g. it
35 is not deemed to be associated with health effects) it is used as an indication of aesthetic
36 characteristics of drinking water and as an aggregate indicator of the presence of a broad
37 array of chemical contaminants.

38
39 **Section 69302.3(d)(3)(D)** identifies, as chemical prioritization factors, chronic and acute
40 toxicity in water column and sediments as a water quality impact measure. Chronic and acute

1 toxicity refers to a chemical's ability to cause harmful effects in water and/or sediments after
2 repeated releases or a single release.

3
4 **Section 69302.3(d)(3)(E) through (H)** identify, as chemical prioritization factors, chemicals
5 and pollutants listed by other regulatory programs that are monitored or have standards
6 established for water quality. Chemicals that have been established to have an impact on
7 water quality are one of the factors in assessing water quality impacts when considering a
8 chemical as a Chemical under Consideration.

9
10 **Section 69302.3(d)(3)(I)** identifies, as a chemical prioritization factor, thermal pollution which
11 may cause degradation to the beneficial use of water. Thermal pollution is heat discharge into
12 waters that adversely affect or kill aquatic life and disrupt an ecosystem.

13
14 **Section 69302.3(d)(3)(J)** identifies, as a chemical prioritization factors, impacts to surface
15 water and groundwater not otherwise captured in this subsection. This is necessary to provide
16 DTSC specific authority to consider other water quality impacts when considering a chemical
17 as a Chemical under Consideration.

18
19 **Section 69302.3(d)(4)(A) through (H)** identify soil quality impacts as chemical prioritization
20 factors. These include chemical soil contamination and may be evaluated by the amount of
21 soil that is currently contaminated by the chemical.

22
23 Biological contamination may be caused by an increase of life forms due to the presence of the
24 chemical. For instance, there may be an unwanted increase of microorganisms due to the
25 presence of the chemical used as food or building blocks. Biological contamination may also
26 occur through unwanted chemical absorption or uptake of the chemical into plant or animal life.

27
28 Chemical contamination in the soil may also lead to the loss of biodiversity in the soil, as well
29 as the loss of organic matter. Erosion, soil compaction or other soil structural changes and soil
30 sealing also result from chemical contamination in the soil.

31
32 The loss of biodiversity and organic matter may be due to the chemical's direct (e.g., poisoning
33 or killing organic matter) or indirect "trickle down" effects on one organism leading to loss of
34 other organisms. The loss of biodiversity and organic matter may lead to soil compaction or
35 other soil structural changes, erosion and soil sealing.

36
37 Soil compaction and other soil structural changes are forms of physical degradation resulting in
38 distortion of the soil where biological activity, porosity and permeability are reduced, strength is
39 increased and soil structure partly destroyed. Compaction can reduce water infiltration
40 capacity and increase erosion risk by accelerating run-off.

41

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

6
7 **Section 69302.3(d)(5)** is necessary to allow DTSC to consider as chemical prioritization
8 factors other adverse impacts to the environment, not specifically identified above, including,
9 but not limited to, the release of heat, odor or radiation. This allows DTSC to consider future
10 information on chemicals that are not known or researched at this time.

11
12 **Section 69302.3(e)(1) through (6)** are necessary to allow DTSC to consider the dispersive
13 volume of the chemical in California, as required in Health and Safety Code section 25252.
14 The information obtained under this subsection allows DTSC to evaluate the volume and
15 distribution of the chemical in California. In the absence of specific chemical exposure data,
16 this information helps determine chemical exposure to public and environment and is a factor
17 to consider in identifying a Chemical under Consideration. "Dispersive volume" of chemicals in
18 California includes such information as: **(1)** projected annual sales of the chemical, **(2)** annual
19 regional distributions, **(3)** marketing and customer-targeted volumes, **(4)** volume of the
20 chemical in current use, **(5)** annual volume of the chemical used in products, and **(6)** controlled
21 distribution systems, if any.

22
23 **Section 69302.3(f)** is necessary to allow DTSC to consider the chemical exposure potential to
24 the public or the environment from common products containing the chemical during the
25 products' use and end-of-life disposal or management. Factors to consider include those listed
26 in section 69303.3(b).

27
28 **Section 69302.3(g)(1) through (3)** are necessary to clarify and make more specific the
29 consideration specified in Health and Safety Code section 25252: potential for exposure to the
30 chemical in a product. Types of evidence that DTSC may consider in evaluating exposure
31 potential are specified in this subsection. Evidence of chemical exposure may be linked to a
32 product by human biomonitoring, such as the California Environmental Contaminant
33 Biomonitoring Program, or data that indicates the presence in the indoor environment or
34 drinking water. Anecdotal evidence of the chemical presence in biomonitoring data, an indoor
35 environment or drinking water is not sufficient as a consideration for a Chemical under
36 Consideration, unless the anecdotal evidence is, or is verified, by reliable information.

37
38 **Section 69302.3(g)(4)** is necessary to specify that data that meets the definition of reliable
39 information and that shows the following is also a factor that may be considered in prioritizing
40 chemicals:

- 1 • The chemical or its degradation products are present in the California solid waste,
2 waste water or storm water streams, and pose public health or environmental threats,
- 3 • Significant public funds are required to clean up or mitigate the chemical threats to the
4 public health or the environment, and
- 5 • The chemical's presence in consumer products increases the cost of reusing or
6 recycling those products.

7
8 **Section 69302.3(g)(5)(A) through (F)** are necessary to allow DTSC to consider, in prioritizing
9 chemicals, estimates of fate and transport of a chemical or its degradation products based on
10 one or more of the following:

- 11
- 12 • Fugacity modeling, a chemical fate and transport multimedia model,
- 13 • Field studies in the environment,
- 14 • Observations and measurements conducted in the field, and
- 15 • Microcosm studies, which includes simulating an ecosystem in a laboratory setting.

16
17 Environmental or biological presence may also be estimated using a point source or market-
18 wide source term calculation, modeling or measurement, or a combination of these options.

19
20 **Section 69302.3(g)(6) through (8)** are necessary to allow DTSC to consider other relevant
21 chemical criteria not specifically identified in the prior subsections, including:

- 22
- 23 • Data that shows other chemical species that exhibit a hazard trait are formed during
 - 24 ○ breakdown of the chemical,
 - 25 ○ chemical transformation in an environmental setting, or
 - 26 ○ combination with other chemicals;
- 27 • Use of computational modeling for structural activity relations to predict chemical
28 behavior;
- 29 • Short term in-vitro bioassays to predict chemical behavior; and
- 30 • Computational modeling data that provides information for this section.

31
32 **Section 69302.3(h)(1)** is necessary to clarify that in the event that the section 69302.1(a)(1)
33 exemption does not apply, DTSC will consider how a chemical is regulated by other federal
34 and/or California governmental programs throughout the life cycle of the chemical and the
35 product and use this information in chemical prioritization, based upon consideration of how
36 closely these other regulatory programs match the scope and purpose of Chapter 53 and the
37 authorizing statutes.

38
39 For example, chemical A in the product is adequately regulated from its production to
40 consumer use, but the disposal causes an adverse environmental impact. Chemical B may

1 cause consumer exposure during use, but because it is not used in a workplace, it is not under
2 the regulatory oversight of federal or state Occupational Health and Safety Administration.
3 Factoring in all other prioritization factors, DTSC might conclude that chemical B is essentially
4 “unregulated” and is a higher-priority chemical than Chemical A.
5

6 **Section 69302.3(h)(2)** specifies that a chemical is not a Chemical of Concern, Chemical under
7 Consideration, or Priority Chemical if DTSC determines that the federal and/or California state
8 regulatory programs overseeing the chemical address the public health and environmental
9 threats addressed by these regulations and the authorizing statutes throughout the life cycle of
10 the chemical.

11 12 **Section 69302.4. Priority Chemicals**

13 This section, in its entirety, is necessary to specify and describe the prioritization factors that
14 DTSC may use to identify and list Priority Chemicals from the Chemicals under Consideration
15 list. It is possible that as DTSC evaluates a chemical for listing as a Chemical under
16 Consideration, DTSC will simultaneously be evaluating the chemical as a Priority Chemical as
17 well. DTSC will provide the rationale and supporting documentation for listing a chemical as a
18 Priority Chemical, and interested parties will have the opportunity to comment on DTSC’s
19 rationale pursuant to section 69302.2.
20

21 **Section 69302.4(a)** requires DTSC to prepare, from the list of Chemicals under Consideration,
22 a list of Priority Chemicals that are determined to be of highest priority based on consideration
23 of the factors specified in sections 69302.4(a)(1) through (a)(4), which are summarized below.
24

25 **Section 69302.4(a)(1)** specifies that DTSC may consider the relative degree of threat posed
26 by each chemical to public health or the environment based on consideration of pertinent
27 factors specified in section 69302.3.
28

29 **Section 69302.4(a)(2)** specifies that DTSC may consider the availability of reliable information
30 to substantiate the threat(s) posed by the chemical. Any data that is used to determine
31 whether a Chemical under Consideration becomes a Priority Chemical will be based on
32 reliable information, as defined, to substantiate the threats.
33

34 **Section 69302.4(a)(3)** specifies that DTSC may consider the availability of DTSC resources.
35 This is necessary to enable DTSC, in determining the types and number of chemicals to be
36 placed on the Priority Chemicals list, to take into consideration the availability of DTSC
37 resources needed to implement the provisions of Chapter 53 applicable to Priority Chemicals.
38

39 **Section 69302.4(b)(1)** specifies that in evaluating the relative degree of threat, pursuant to
40 section 69302.4(a)(1), DTSC must seek to identify and give priority to the chemicals that: (1)
41 pose the greatest public health and environmental threats; (2) are most prevalently distributed

1 in commerce and contained in products used by consumers, and (3) have the greatest
2 potential for chemical exposure to consumers or environmental receptors in quantities that can
3 result in public health or environmental harm. DTSC must consider both the potential for
4 exposure to the chemical and the potential harm resulting from potential exposures. This
5 paragraph, along with paragraph (2) and (3), which are summarized below, are necessary to
6 give responsible entities, manufacturers, the public and other interested parties a better
7 understanding as to how DTSC will use the prioritization factors specified in section 69302.3 to
8 identify and list Priority Chemicals.

9
10 **Section 69302.4(b)(2)** specifies the considerations for evaluating the potential for exposure
11 when determining the relative degree of threat. DTSC must consider at a minimum: **(A)**
12 market data for the chemical and products containing the chemical; **(B)** reliable information
13 that shows the occurrence of public health and environmental exposures; **(C)** information
14 concerning the presence of the chemical in products commonly found in households, including
15 the number of products, how often the product is used, and the chemical concentration in
16 those product; and **(D)** information showing the prevalence of the chemical in products that are
17 in the stream of commerce in California.

18
19 **Section 69302.4(b)(3)** specifies the considerations for evaluating the potential for harm when
20 determining the relative degree of threat, DTSC must at a minimum consider chemical potency
21 and resulting harm for: **(A)** children, pregnant women, and other sensitive subpopulations; and
22 **(B)** environmental receptors, especially environmentally sensitive habitats and endangered
23 and threatened species.

24
25 **Section 69302.4(c)** specifies that a chemical that exhibits no hazard trait other than
26 carcinogenicity or reproductive toxicity will not be listed as a Priority Chemical unless the
27 chemical is defined as a carcinogen or reproductive toxin under section 69301.2(a)(9). Section
28 69301.2(a)(9) defines carcinogen or reproductive toxin as a chemical that is listed or meets
29 criteria established by specified sources that are viewed by the scientific community as
30 reliable sources.

31
32 **Section 69302.4(d)** specifies the chemicals DTSC must consider in the first Chemical under
33 Consideration and Priority Chemical lists. The first chemical lists will come from those that are
34 identified as a:

- 35
36 (1) Cancer-causing chemical or a reproductive toxin as specified in section 69301.2(a)(9),
37 (2) Mutagenic chemical according to the European Union, or
38 (3) Persistent bioaccumulative toxin according the United States Environmental Protection
39 Agency.
40

1 Numerous interested parties have expressed concerns regarding the above limitations placed
2 on *initial* list of Priority Chemicals. However, by limiting the types of chemicals included in the
3 first list, resources are conserved because the focus is on chemicals where the science is
4 undisputed. The science and technology will be more readily capable of making the necessary
5 changes need to identify and develop safer alternatives to address the above-mentioned
6 chemicals, thus expediting the quest for safer alternatives. This will enable DTSC, as well as
7 responsible entities and manufacturers, to maximize the effective use of resources during the
8 early development and implementation of this new program.

9
10 **Section 69302.4(e)** makes it clear that in updating and revising the Chemical under
11 Consideration and Priority Chemical lists, DTSC may consider additional chemicals that do not
12 fall under one of the three categories specified above in Section 69302.4(e).

13
14 **Section 69302.5. Products Containing a Priority Chemical**

15 **Section 69302.5**, in its entirety, is necessary to specify the requirement for DTSC to post on its
16 website information concerning products determined by DTSC to contain a Priority Chemical.

17
18 **Section 69302.5(a)** requires DTSC to post information that identifies and describes products
19 that it determines contain or contained a Priority Chemical as of the date the applicable
20 chemical list is finalized.

21
22 This is necessary to alert responsible entities and manufacturers of products that, because
23 they are known to contain a Priority Chemical, may be considered by DTSC in the article 3
24 product prioritization process, and, if ultimately listed as a Priority Product, will be subject to
25 the article 5 Tier II AA requirements.

26
27 This list provides responsible entities and manufacturers the opportunity to get an early start
28 on evaluating their products and identifying safer alternatives before their product is potentially
29 listed as a Priority Product and, thus, subject to the Tier II AA requirements. This list also
30 serves to alert responsible entities and manufacturers that these products are subject to the
31 AA notification requirements of section 69305.1, if the product is reformulated or redesigned to
32 remove or reduce the concentration of the Priority Chemical in the product.

33
34 DTSC will not list, or will remove from the list, a product to which any of the following applies:

- 35
36 (1) A Chemical Removal Confirmation Notification or Product Removal Confirmation
37 Notice is submitted to DTSC,
38 (2) An AA Notification is submitted to DTSC under to section 69305.1, or
39 (3) The product is reformulated, redesigned or replaced as a result of a Tier II AA and the
40 information required under article 5 is submitted to DTSC.

1 **Section 69302.5(b)** is necessary to specify that DTSC will base its determination that a
2 product contains or contained a Priority Chemical based on: **(1)** reliable information; **(2)**
3 information from a responsible entity or manufacturer; or **(3)** product labeling, packaging, or
4 information sheet.

6 **Article 3. Product Prioritization Process**

8 Article 3, in its entirety, is necessary to establish the process to identify and prioritize products
9 that contain a Priority Chemical. This, in turn, is necessary to identify and prioritize as Priority
10 Products those products for which an alternatives assessment must be performed under article
11 5, as required by Health and Safety Code sections 25252 and 25253. Health and Safety Code
12 section 25253 requires DTSC to establish a process for evaluating Chemicals of Concern in
13 consumer products and their potential alternatives to determine how best to limit exposure or
14 to reduce the level of hazard posed by a Chemical of Concern. Health and Safety Code
15 section 25252 requires DTSC to develop the criteria by which chemicals and their alternatives
16 may be evaluated.

18 Identifying and prioritizing products that contain Priority Chemicals is an integral part of the
19 process for identifying and evaluating Chemicals of Concern and their alternatives. This is
20 because product-related factors (e.g., product design, types and volumes of uses, and
21 targeted customer bases) have a direct relationship to the factors specified in Health and
22 Safety Code section 25252 as the minimum factors to be used to identify and prioritize
23 Chemicals of Concern: (1) volume in commerce in California; (2) potential for exposure to the
24 chemical in a product; and (3) potential effects on sensitive subpopulations. In addition,
25 product-related factors are key to evaluating chemicals and alternatives to determine how to
26 limit exposure or to reduce the level of hazard posed by a chemical. Therefore, the product
27 prioritization process set out in article 3 is necessary to the fulfillment of DTSC's statutory
28 requirements under Health and Safety Code sections 25252 and 25253.

30 Upon identification of Priority Chemicals through the chemical prioritization process in article 2,
31 products that contain Priority Chemicals will be prioritized using a similar approach. Under the
32 provisions of article 3, products containing Priority Chemicals will be identified and then
33 prioritized by:

- 35 (1) Identifying consumer products that are reasonably expected to contain one or more
36 Priority Chemicals, and
- 38 (2) Using prioritization factors specified in sections 69303.3 and 69303.4 to determine
39 which of the products identified in step 1 will be identified and prioritized as either
40 Products under Consideration or Priority Products.

1 As in the chemical prioritization process, in order to identify and prioritize a product as either a
2 Product under Consideration or a Priority Product, DTSC will use broad, overarching scientific
3 factors to evaluate the product(s). The rationale for selecting this approach is the same as that
4 discussed in the statement of reasons for article 2.

5
6 As in the case of article 2, it is again noted that all the prioritization factors specified in article 3
7 may not be applicable to a given product and that DTSC is not required to consider all the
8 prioritization factors for a given product. As previously explained, providing an extensive list of
9 prioritization factors is necessary to accommodate prioritizing products now and in the future
10 when additional scientific and technological data may become available. This is necessary to
11 avoid unnecessary delays in developing products lists and to allow the implementation of the
12 regulations to keep pace with advances in science and technology.

13
14 The rationale for identifying and listing a product as a Product under Consideration or a Priority
15 Product will be different for each product, and so DTSC: (1) may customize the applicability
16 and evaluation of broad, overarching scientific factors to consider for a product; (2) will explain
17 the rationale for listing a product as a Product under Consideration or a Priority Product; and
18 (3) will make the rationale and supporting information available to the public for review and
19 comment along with the proposed lists. Allowing the public to review and comment provides
20 an open and transparent process prior to finalizing the Product under Consideration and
21 Priority Product lists.

22
23 The rationale and supporting documentation may include the evaluation and consideration of
24 current scientific information, including any state of the art, or acceptable mechanisms used for
25 weighing scientific evidence or balancing toxicity information and other factors to prioritize a
26 product as a Product under Consideration or Priority Product. Factors used to prioritize
27 products will include, for example, usage and prevalence of the product, and the potential for
28 the public and the environment to be exposed to the Priority Chemical in the product.

29
30 In summary, a product that contains a Priority Chemical is subject to the identification and
31 prioritization process for designation as a Product under Consideration. Products under
32 Consideration that pose the greatest level of threat to public health and/or the environment will
33 be designated as Priority Products. A Priority Product that is on a finalized list will be subject
34 to the alternatives assessment requirements of article 5.

35
36 **Section 69303. General**

37 This section introduces the purpose of article 3 and is necessary to specify the process that
38 DTSC will use to identify and prioritize products as Products under Consideration and Priority
39 Products. As part of this process, DTSC will evaluate information from manufacturers and
40 other sources to identify and prioritize Products under Consideration and Priority Products.

1 DTSC may rely on information on products obtained under section 69301.6, but is not limited
2 to information obtained under section 69301.6 in performing its duties in article 3.

3
4 **Section 69303.1. Applicability**

5 **Section 69303.1**, in its entirety, is necessary to specify the scope of chemicals subject to the
6 chemical prioritization process.

7
8 **Section 69303.1(a)** identifies the conditions under which a product is subject to the product
9 prioritization process: (1) the product contains a Priority Chemical, and (2) the product is
10 reasonably expected to be placed into the stream of commerce in California.

11
12 The first point of entry into the article 3 prioritization process is whether the product contains a
13 chemical that has been listed as a Priority Chemical under the process set out in article 2.

14
15 The presence of a Priority Chemical in a product may be determined by any number of
16 methods, including, for example, information submitted by the manufacturer, analytical testing,
17 product reports, mass balance calculations, third-party information, and the petition process in
18 article 4, among other reasonable methods.

19
20 The second criterion that a product must meet to be included in article 3 prioritization process
21 is whether the product is reasonably expected to be placed into the stream of commerce in
22 California. This includes Internet sales, storefront retail sales, promotional items and
23 “giveaways”. A product purchased outside of California and brought into California for
24 personal use, including a product that is purchased as a gift, is not considered to be “placed
25 into the stream of commerce in California”.

26
27 **Section 69303.1(a)(1) and (2)** specify two conditions, which are summarized below, under
28 which a product that would otherwise be subject to the product prioritization process in article 3
29 is exempted from that process.

30
31 These exemptions, together, are necessary to: (1) avoid duplication of regulation of products
32 already regulated by other State or federal governmental agencies and to clarify and
33 implement the requirement in Health and Safety Code section 25257.1(c): “DTSC shall not
34 duplicate or adopt conflicting regulations for product categories already regulated or subject to
35 pending regulation consistent with the purposes of this article”; and (2) limit the scope of
36 products subject to the prioritization process by only considering products for which there is
37 one or more exposure pathways that could pose a threat to public health and/or the
38 environment.

39
40 **Section 69303.1(a)(1)** specifies that article 3 does not apply to a product if DTSC has
41 determined that the product is regulated by one or more federal and/or California state

1 regulatory programs that address for each life cycle segment the same public health and
2 environment threats as are addressed by these regulations and the authorizing statute. A
3 product that is regulated for less than its full life cycle is not exempt from article 3, nor does
4 regulatory authority over the product by a foreign country, another state or a local agency
5 qualify for the exemption since in these situations there is no jurisdictional or consistent
6 authority either in or throughout California

7
8 A product that is regulated by a single program or a combination of federal and California state
9 regulatory programs that span the product's entire life cycle may be exempted from article 3.
10 DTSC will assess each regulatory program to determine whether collectively public health and
11 the environment are protected from threats posed to the same extent as would be achieved
12 under these regulations and the authorizing statute. If DTSC determines there are significant
13 gaps in the scope of threats addressed by the other regulatory programs, the product would
14 not eligible for this exemption. (See section 69303.3(h) for a related discussion.)

15
16 By way of example, a product that might qualify for this type of product exemption is a fuel
17 additive contained in an existing fuel or a new fuel that contains a Priority Chemical that has
18 undergone a "multimedia" evaluation. Before adopting new chemical additive to an existing
19 fuel or a new type of fuel, the CARB is required to prepare a "multimedia" evaluation to
20 examine the relative risk posed by any newly proposed fuel additive to the State's resources,
21 human health and the environment. Potential additives and new fuels must be evaluated not
22 only with regard to engine performance and emission requirements but also with consideration
23 of health and environmental criteria involving air emissions and associated health risks, ozone
24 formation potential, hazardous waste generation and management and surface and
25 groundwater contamination resulting from production, distribution, and use.

26
27 As described in these Statement of Reasons for section 69302.1(a)(1), the multimedia
28 evaluation is a rigorous process that is designed to provide policy makers with reliable
29 information regarding public health and environmental protection. A product that is subject to
30 this type of multimedia evaluation under another federal or California state regulatory program
31 might be determined by DTSC to not be subject to the product prioritization process under
32 article 3.

33
34 **Section 69303.1(a)(2)** specifies that article 3 does not apply to a product if DTSC has
35 determined that there is no exposure pathway by which the Priority Chemical in the product
36 might pose a threat to public health or the environment in California during the useful life of the
37 product or end-of-life management. In general, chemical exposure pathways involve:

- 38
39
- 40 • The transport media: the chemical movement through the environment
 - 41 • The exposure point: public health or environmental contact with the chemical
 - The exposure route: the chemical entrance into the body or environmental compartment

- 1 • The receptor population: the sector of human or environmental population affected.

2
3 The product prioritization factors for a Product under Consideration are essential in
4 determining chemical exposure pathways resulting from products for purposes of this
5 exemption. A product that meets the criteria for this exemption from article 3 would meet the
6 objective of these regulations. That is, it does not pose a threat to public health or the
7 environment that needs to be reduced or eliminated.

8
9 **Section 69303.1(b)** is necessary to specify that DTSC may proceed with the product
10 identification and prioritization process without making a specific determination that a product
11 is exempt from that process. Section 69303.1(b) clarifies that in the absence of a specific
12 determination by DTSC that a product is exempt there is a presumption that the product does
13 not meet the conditions for an exemption. The provision further clarifies that the burden to
14 proof that a product is exempt from the product prioritization process is on the person
15 requesting a product exemption determination under section 69303.1(c).

16
17 **Section 69303.1(c)** is necessary to specify that the burden of proof that a product is exempt
18 from the product prioritization process is on the person seeking the exemption determination
19 from DTSC. The person seeking the determination must prove by clear and convincing
20 evidence that one or both of the exemptions set out in section 69303.1(a)(1) and (2) applies.

21
22 Evidence attempting to show that there is no exposure pathway must include, to the extent
23 applicable, the results of any use and abuse tests, including assumptions and testing
24 methodologies, conducted for a federal and/or California state regulatory program.

25
26 **Sections 69303.1(d)** is necessary to allow DTSC, at its discretion, to re-evaluate and rescind
27 an exemption determination if DTSC finds that the facts or assumptions on which the
28 exemption was based were not valid at the time or are no longer valid.

29
30 **Section 69303.2. Product Lists**

31 **Section 69303.2**, in its entirety, is necessary to specify the products lists that will be prepared,
32 and the process DTSC will use to prepare and finalize the products lists.

33
34 **Section 69303.2(a)** requires DTSC to prepare two products lists: **(1)** Products under
35 Consideration, and **(2)** Priority Products. The list of Products under Consideration will be
36 based on factors specified in section 69303.3, and the list of Priority Products will be based on
37 the factors specified in section 69303.4.

38
39 The Products under Consideration list provides the responsible entity the opportunity to
40 anticipate the types of products that have the potential to eventually be listed Priority Products,
41 and to change or redesign the product voluntarily to remove or reduce the concentration of the

1 Priority Chemical in the product. Placement on the Priority Products list signifies that the
2 manufacturer must begin the mandatory process to develop an alternatives assessment for the
3 Priority Product.

4
5 **Section 69303.2(b)** specifies the public review and comment process that DTSC must follow
6 before finalizing the Products under Consideration and Priority Products lists. A notice
7 regarding the availability of the proposed list(s) will be sent to persons on listservs established
8 for this chapter, and will be published in the CRNR. Additionally, the proposed list(s) and
9 supporting documentation and the rationale for the identification and prioritization of the
10 products on the lists will be made publicly available on DTSC's website for review and
11 comment, subject to article 10. The supporting information must include the hazard trait(s) and
12 the potential exposure pathway(s) for the Priority Chemical that is the basis for a product being
13 listed as a Product under Consideration or a Priority Product. The notice must include: **(1)** the
14 time period during which comments may be submitted, **(2)** the method(s) for submitting
15 comments, and **(3)** whether any workshops will be held.

16
17 Section 69303.2(b) is necessary to ensure that the public and other interested parties have
18 input into the product listing process. This comment period is also necessary to provide
19 responsible entities another opportunity, in addition to that provided in section 69301.6(f), to
20 present information and data not previously considered to have a product added to or removed
21 from the proposed Products under Consideration or Priority Products list prior to finalization of
22 the lists.

23
24 **Section 69303.2(c)** specifies that after DTSC considers public comments, it will finalize and
25 post on its website the final Products under Consideration and final Priority Products lists.
26 DTSC may, at its discretion, respond to public comments.

27
28 **Section 69303.2(d)(1)** specifies that the proposed and final list of Priority Products must
29 include for each listed product, to the extent applicable, the following:

30
31 **(A)** DTSC's determination that a de minimis exemption, under section 69305.3, is not
32 allowed for the product. Supporting rationale, data and data sources for the
33 determination must also be included, subject to article 10.

34
35 **(B)** The component(s) of the Priority Product to which the de minimis concentration
36 applies, and which is the required minimum focus of the Tier II Alternatives Analysis for
37 the product.

38
39 **Section 69303.2(d)(2)** provides that if DTSC determines that a de minimis exemption may not
40 be considered for a Priority Product, then DTSC must provide its basis for making this

1 determination. This subsection also sets out a non-exhaustive list of factors that may serve as
2 the basis for DTSC's the determination.

3
4 **Section 69303.2(d)(2)(A)1.** specifies that one of the bases for a determination that a de
5 minimis exemption is not applicable is the existence of reliable information that shows the
6 Priority Chemical to be harmful or potentially harmful below the de minimis level.

7
8 **Section 69303.2(d)(2)(A)2.** specifies that, if section 69303.2(d)(2)(A)1. applies, DTSC may
9 specify a lower de minimis level for the product if reliable information shows the Priority
10 Chemical is not harmful at or below the lower level.

11
12 **Section 69303.2(d)(2)(B)** provides that DTSC may also base a determination that a de
13 minimis exemption is not applicable on the fact that numerous products that are commonly
14 used on a frequent basis contain the Priority Chemical at or below de minimis level
15 concentrations and the aggregate exposures to be harmful or potentially harmful.

16
17 **Section 69303.2(d)(3)** specifies that a de minimis exemption shall not be allowed at all for
18 chemicals, materials, or substances manufactured or engineered at the nanoscale, or which
19 contain nanostructures or are considered to be a nanomaterial. Because nano-related
20 materials operate and can be harmful or potentially harmful in such small sizes and small
21 quantities, a de minimis exemption is not appropriate.

22
23 **Section 69303.2(e)** specifies that an individual manufacturer's product, that is of a product
24 type listed by DTSC on the products lists, is not a Product under Consideration or Priority
25 Product if the product does not contain detectable concentrations of the Priority Chemical for
26 which the product type is listed. Additionally, a Tier II AA is not required for such a product.

27
28 **Section 69303.2(f)** requires the Products under Consideration and Priority Products lists to be
29 updated, as needed, to include additions to and/or deletions from prior lists, as well as
30 revisions to prior de minimis level determinations.

31 **Section 69303.3. Products under Consideration**

32 This section, in its entirety, is necessary to specify and describe the prioritization factors that
33 DTSC may consider when listing a product that contains a Priority Chemical as Product under
34 Consideration.
35

36
37 It is important to note that the prioritization factors in the regulations take into account future
38 knowledge and scientific advancements for chemicals and products, and that DTSC is not
39 required to consider all the prioritization factors listed in this section for each product. DTSC
40 will take into consideration those factors that are applicable to each product and for which
41 reliable information is available. DTSC will provide the rationale and supporting documentation

1 for listing a product as a Product under Consideration and interested parties will have the
2 opportunity to comment on DTSC's rationale, pursuant to section 69303.2.

3
4 **Section 69303.3(a)** is necessary to allow DTSC to consider the same information as in section
5 69302.3(e), but with an emphasis on evaluating this factor in relation to products. As with
6 section 69302.3(e), this information serves to evaluate the exposure potential for the Priority
7 Chemical in the product in the absence of specific exposure information. "Dispersive volume"
8 of products available in California includes such information as: **(1)** projected annual sales of
9 the product, **(2)** annual regional distribution, **(3)** marketing and customer-targeted volumes, **(4)**
10 volume of the product in current use, **(5)** percentage of the products estimated to contain the
11 Priority Chemical, **(6)** extrapolation of the data identified in (1) through (5) to estimate the
12 volume of the product's Priority Chemical in commerce in California, and **(7)** controlled
13 distribution systems, if any.

14
15 **Section 69303.3(b)** is necessary to allow DTSC to consider the potential for the public or the
16 environment to be exposed to a Priority Chemical from a product during its use and end-of-life
17 management. A non-exhaustive list of factors that may be used to evaluate the potential
18 exposure to the public or the environment includes:

- 19
20 **(1)** How well the Priority Chemical is physically contained or chemically bound in the
21 product, including the long-term integrity of the containment method,
22 **(2)** Whether there are engineering or administrative controls limiting access to the Priority
23 Chemical in the product,
24 **(3)** Whether there are any regulatory restrictions imposed by the federal government or the
25 State of California that reduce the potential for exposure, and
26 **(4)** How often and how long the public or the environment is exposed to the Priority
27 Chemical due to its presence in the product for each scenario involving product use
28 and end-of-life management.

29
30 Since the above list is non-exhaustive, other factors besides those listed may be used to
31 evaluate the potential for Priority Chemical exposure from the product.

32
33 **Section 69303.3(c)(1) through (6)** are necessary to allow DTSC to consider the types of
34 consumer uses of the product that may expose the public to adverse public health impacts as
35 specified in section 69302.3(a). A non-exhaustive list of factors set out in section 69303.3(c)
36 describes many scenarios to consider that may result in adverse health impacts due to Priority
37 Chemical exposure from products, including: **(1)** household use, **(2)** usage at various locations
38 that may cause exposure to sensitive subpopulations, **(3)** consumers coming into contact with
39 the product, **(4)** usage at businesses providing a service to clients, **(5)** persons who come into
40 contact with the product a specified service sector locales, and **(6)** the availability of the
41 product to consumers as a finished material, product or component. Products, materials or

1 components used solely or primarily in an intermediate manufacturing process or a research
2 and development program will be given lower priority in the product prioritization process. This
3 is necessary that highest priority is given to true consumer products.
4

5 **Section 69303.3(d)** is necessary to allow DTSC to consider, in the product prioritization
6 process, product uses and management and disposal practices that could result in releases
7 into the environment of the Priority Chemical in the product, which in turn could result in
8 adverse ecological and environmental impacts as specified in section 69302.3(c) and (d).

9 Factors that may be considered include: **(1)** use, storage, transportation and end-of-life
10 management practices and locations; and **(2)** the potential for release into, migration from or
11 distribution across environmental media, and the potential for accumulation or persistence in
12 biological or environmental compartments or systems of the Priority Chemical or its
13 degradation products. This is a non-exhaustive list of factors that DTSC may consider.
14

15 **Section 69303.3(e)** is necessary to allow DTSC to consider, in the product prioritization
16 process, the existence of data and other information relating to actual or potential public health
17 or environmental exposures to the Priority Chemical in the product. Data and information to be
18 considered are listed in section 69302.3(g).
19

20 **Section 69303.3(f)** is necessary to allow DTSC to consider, in the product prioritization
21 process, whether or not the product is required in California to be managed as a hazardous
22 waste at the end of its useful life.
23

24 **Section 69303(g)** is necessary to allow DTSC to consider whether the specific Priority
25 Chemical is required to be contained in the specific product pursuant to a federal or California
26 State law.
27

28 **Section 69303.3(h)(1)** is necessary to clarify that in the event that the section 69303.1(a)(1)
29 exemption does not apply, DTSC will consider how a product is regulated by other federal
30 and/or California governmental programs throughout the life cycle of the product and use this
31 information in product prioritization, based upon consideration of how closely these other
32 regulatory programs match the scope and purpose of Chapter 53 and the authorizing statutes.
33 The rationale for this subsection is the same as for the chemical prioritization factor in
34 discussed in section 69302.3(h), but is specific to a product that contains a Priority Chemical.
35

36 **Section 69303.3(h)(2)** specifies that a product is not a Product under Consideration or a
37 Priority Product if DTSC determines that the federal and/or California state regulatory
38 programs overseeing the product address the same public health and environmental threats
39 addressed by these regulations and the authorizing statutes throughout the life cycle of the
40 product.
41

1 **Section 69303.4. Priority Products**

2 This section, in its entirety, is necessary to specify and describe the prioritization factors that
3 DTSC may use to identify and list Priority Products from the Products under Consideration list.
4 It is possible that as DTSC evaluates a product for listing as a Product under Consideration,
5 DTSC will simultaneously be evaluating the product as a Priority Product as well. DTSC will
6 provide the rationale and supporting documentation for listing a product as a Priority Product,
7 and interested parties will have the opportunity to comment on DTSC's rationale pursuant to
8 section 69303.2.

9
10 **Section 69303.4(a)** requires DTSC to prepare, from the list of Products under Consideration, a
11 list of Priority Products that are determined to be of highest priority based on consideration of
12 the factors specified in sections 69303.4(a)(1) through (a)(4), which are summarized below.

13
14 **Section 69303.4(a)(1)** specifies that DTSC may consider the relative degree of threat posed
15 by each product, due to the Priority Chemical that is contained in the product, to public health
16 or the environment based on consideration of pertinent factors specified in section 69303.3.

17
18 Because different products containing the same Priority Chemical are likely to be
19 manufactured differently and have different physical forms (e.g., liquid or solid), the products
20 may behave, react, and cause public, ecological and environmental harm differently. DTSC
21 may use the relative degrees of threat posed by the Priority Chemical in the product to justify
22 listing it as a Priority Product. For example, the relative degree of threat of a Priority Chemical
23 to the environment may be greater for a Priority Product in powder form due to its ability to
24 disperse with the wind and contaminate a larger area of the environment than the same
25 Priority Product in solid form.

26
27 **Section 69303.4(a)(2)** specifies that DTSC may consider the availability of reliable information
28 to substantiate the threat(s) posed by the product. Any data that is used to determine whether
29 a Product under Consideration becomes a Priority Product will be based on reliable
30 information, as defined, to substantiate the threats.

31
32 **Section 69303.4(a)(3)** specifies that DTSC may consider the availability of an AA posted on
33 the DTSC's website pursuant to section 69305(b) that is relevant for the product or the Priority
34 Chemical in the product that substantially meets the requirements of article 5 pertaining to Tier
35 II AAs.

36
37 **Section 69303.4(a)(4)** specifies that DTSC may consider the availability of DTSC resources.
38 This is necessary to enable DTSC, in determining the types and number of products to be
39 placed on the Priority Products list, to take into consideration the availability of DTSC
40 resources needed to implement the provisions of Chapter 53 applicable to Priority Products.

41

1 **Section 69303.4(b)(1)** specifies that in evaluating the relative degree of threat, pursuant to
2 section 69303.4(a)(1), DTSC must seek to identify and give priority to the chemicals, and the
3 products that contain them, that: (1) pose the greatest public health and environmental threats;
4 (2) are most prevalently distributed in commerce and used by consumers, and (3) have the
5 greatest potential for chemical exposure to consumers or environmental receptors in quantities
6 that can result in public health or environmental harm. DTSC must consider both the potential
7 for exposure to the chemical in the product and the potential harm resulting from potential
8 exposures. This paragraph, along with paragraph (2) and (3), which are summarized below,
9 are necessary to give responsible entities, manufacturers, the public and other interested
10 parties a better understanding as to how DTSC will use the prioritization factors specified in
11 section 69303.3 to identify and list Priority Products.
12

13 **Section 69303.4(b)(2)** specifies the considerations for evaluating the potential for exposure
14 when determining the relative degree of threat. DTSC must consider at a minimum: **(A)**
15 market data for products containing the chemical; **(B)** reliable information that shows the
16 occurrence of public health and environmental exposures; **(C)** information concerning the
17 household presence of the product, and other products containing the same chemical,
18 including the number of products, how common is their household presence, how often the
19 product is used, and the chemical concentration in those product; and **(D)** information showing
20 the prevalence of the product in the stream of commerce in California.
21

22 **Section 69303.4(b)(3)** specifies the considerations for evaluating the potential for harm when
23 determining the relative degree of threat, DTSC must at a minimum consider chemical potency
24 and resulting harm for: **(A)** children, pregnant women, and other sensitive subpopulations; and
25 **(B)** environmental receptors, especially environmentally sensitive habitats and endangered
26 and threatened species.
27

28 **Section 69303.5. Priority Product Notification**

29 **Section 69303.5(a)(1)** requires each responsible entity for a Priority Product to notify DTSC
30 that its product is a Priority Product, within sixty (60) days after a product is listed as a Priority
31 Product. For Priority Products that are first manufactured, or first placed into the stream of
32 commerce in California after the date the product is listed as a Priority Product, the responsible
33 entity must provide this notice within thirty (30) days after the product is first placed into the
34 stream of commerce in California.
35

36 The notification requirement is necessary to inform DTSC which products and responsible
37 entities are subject to the next process step – the Tier II AA process. In addition, the
38 notification will enable DTSC to better assess the resources needed implement articles 5 and
39 6, as well as serving to focus audits and investigations on Priority Products for which the
40 required notification is not received.
41

1 **Section 69303.5(a)(1)(A) through (D)** are necessary to provide to DTSC contact information
2 and product information necessary to proceed to the next step in the process – the Tier II AAs.
3 The notification must include the following information:

- 4
- 5 (A) The name of, and contact information and applicable NAICS code(s) for, the
6 responsible entity and all persons involved in the product supply chain that are known
7 to the responsible entity;
 - 8 (B) The type and brand name of the Priority Product, and information that specifically
9 identifies the pertinent component, if applicable;
 - 10 (C) The name of, and contact information for, the person who will be complying with the
11 requirements of article 5 for the responsible entity, if that person is someone other than
12 the responsible entity; and
 - 13 (D) Whether the responsible entity or person who will be complying with the requirements
14 of article 5 will seek DTSC's approval for a de minimis exemption pursuant to section
15 69305.3, if a de minimis, if applicable.
- 16

17 **Section 69303.5(a)(2)** is necessary to specify that the Priority Product notification is not
18 required if a Chemical Removal Confirmation Notification or Product Removal Confirmation
19 Notification has been submitted to DTSC. These notifications apply to products from which the
20 Priority Chemical has been removed without substitution of another chemical, and products
21 that have been removed from the stream of commerce in California. As a result of these
22 actions, there is no longer any reason to address these products under these regulations.

23

24 **Section 69303.5(b)** is necessary to specify that if DTSC determines that the Priority Product
25 notification requirement has not been fulfilled for a Priority Product, DTSC will post this
26 information on the Failure to Comply List pursuant to section 69301.4(f).

27

28 **Section 69303.5(c)(1) through (8)** are necessary to specify that as certain information
29 becomes available to DTSC, this information will be added to the Priority Products list posted
30 on its website for each Priority Product. DTSC will maintain and update this information for as
31 long as the Priority Product continues to be placed in the stream of commerce in California.
32 This information includes the following:

- 33
- 34 (1) Product brand names;
 - 35 (2) Product producer and, if different, the manufacturer;
 - 36 (3) Responsible entities for each product, except for those responsible entities that have
37 complied with the requirements of section 69301.4(e);
 - 38 (4) Information on de minimis exemptions that have been granted by DTSC;
 - 39 (5) Information on Chemical Removal Confirmation Notifications and Product Removal
40 Confirmation Notifications submitted to DTSC;

- 1 **(6)** The identity of the person, if not the responsible entity, who will fulfill the requirements
2 of article 5;
- 3 **(7)** The due date for, and the date of receipt of, the AA Work Plan; and
- 4 **(8)** The due dates for, and the dates of receipt of, Tier II-A and Tier II-B AA Reports.

5

6 This provision is necessary to keep responsible entities informed as to what is being done by
7 whom and by when to fulfill the requirements of article 5 for their Priority Products. This
8 information is also of interest to the public.

9

10 **Article 4. Petition for Inclusion of a Chemical or Product in the Prioritization Process**

11

12 Article 4, in its entirety, is necessary to specify and describe the process for petitioning DTSC
13 to include a chemical or product in the prioritization process. The provisions in article 4 are
14 necessary to enable interested parties, i.e., individuals, industry, organizations, and
15 government to come forth and present information that demonstrates a chemical or product
16 poses a threat and should be evaluated for its potential listing as a Chemical under
17 Consideration, Priority Chemical, Product under Consideration, or Priority Product. The
18 provisions in article 4 provide the necessary latitude to increase the pace at which chemicals
19 or products enter into the prioritization process. This flexibility may become especially
20 important as science and technology begin to make advances where emerging information
21 demonstrates a cause for concern and the information is not readily available in the public
22 domain.

23

24 Although it is DTSC's intent to provide interested parties the opportunity to include chemicals
25 or the products in which they are contained into the prioritization process, the intent is not to
26 circumvent the technical review process. All chemicals and the products that contain them
27 must be evaluated via the article 2 and article 3 prioritization processes before a final decision
28 is made to include or not include them on a chemicals list and/or products list.

29

30 **Section 69304. Applicability and Petition Contents**

31 **69304** in its entirety, is necessary to specify the process to petition DTSC to include a chemical
32 or product in the prioritization processes.

33

34 **Section 69304(a)** allows any person, referred to as the petitioner, to petition DTSC to evaluate
35 a chemical or a consumer product using the chemical or product prioritization processes
36 specified in articles 2 and 3. The petition must be submitted to DTSC in accordance with the
37 requirements specified in section 69301.5 and must include the information specified in
38 sections 69304(a)(1) through 69304(a)(6). The information specified in sections 69304(a)(1)
39 through (a)(6), which are summarized below, is necessary for DTSC to make an informed
40 decision on the petition contents and contact the appropriate person for additional information
41 should it become necessary.

1
2 **Section 69304(a)(1)** requires that the name and contact information be provided to DTSC for
3 both: **(A)** the petitioner, **(B)** and the person responsible for the contents of the petition, if
4 different from the petitioner, along with this persons affiliation with the petitioner. This
5 information is necessary so that DTSC can notify the petitioner of its determination relative to
6 the petition, and in the event DTSC needs to contact either party to obtain additional
7 information.

8
9 **Section 69304(a)(2)** requires that the petition include a description of the chemical or product,
10 or both, which is the subject of the petition. Information on the chemical or product which is
11 the subject of the petition is necessary to assess the relevance of the information submitted.

12
13 **Section 69304(a)(3)** requires that the petition include the use(s) and application(s) of the
14 chemical or product, or both, which is the subject of the petition. Information on the application
15 of the chemical or product which is the subject of the petition is necessary to assess the
16 relevance of the information submitted.

17
18 **Section 69304(a)(4)** requires that the petition include the basis for the petition. Information on
19 the basis for the petition is necessary to assist DTSC in understanding the petitioner's rationale
20 for seeking to include the chemical or product in the prioritization process. This information is
21 necessary to deter petitions based on anecdotal information that has not been substantiated.

22
23 **Section 69304(a)(5)** requires that the petition include the supporting information, including, but
24 not limited to reliable information, as defined, for the basis of the petition. This information is
25 necessary to deter frivolous petitions.

26
27 **Section 69304(a)(6)** requires that the petition include the identity of any known manufacturers
28 of the chemical or product. Identification of known manufacturers in the petition is highly useful
29 and reduces costs to DTSC by eliminating the need for DTSC to subsequently identify the
30 manufacturers of the chemicals or products under evaluation in the petition. In addition,
31 identifying the manufactures will allow DTSC to request specific information from the
32 manufacturers and assist in filling in data gaps for any given chemical or product included in
33 the petition.

34
35 **Section 69304(b)** requires DTSC to respond within 60 days of receiving a petition, and to
36 designate the petition complete, if it contains the items specified in section 69304(a)(1) through
37 (6). If DTSC determines that the petition is complete, the petitioner will be notified, and the
38 petition will undergo a more thorough technical review to determine whether to grant or deny
39 the petition. If DTSC determines the petition to be incomplete, it will notify the petitioner and
40 provide the basis for this determination. These provisions are necessary to provide certainty to
41 petitioners as to when their petition will be acted upon for purposes of determining

1 completeness, and to ensure that DTSC provides necessary feedback to petitioners in
2 response to their petitions.

3
4 **Section 69304(c)** specifies that although DTSC may designate a petition complete, DTSC
5 may later request additional information during the technical review. This provision is
6 necessary to give DTSC the ability and flexibility to request information needed for the
7 technical review that was not readily apparent to be missing during the completeness review
8 conducted pursuant to section 69304.1.

9

10 **Section 69304.1. Technical Review of Petitions**

11 **Section 69304.1(a)** requires DTSC to prioritize the technical review of petitions determined to
12 be complete based on the comprehensiveness of the petitions and the availability of
13 resources. The highest priority must be given to petitions by federal and other California State
14 regulatory programs that relate to the petitioning agency's statutory and/or regulatory
15 mandates. This provision is necessary to allow DTSC to allocate the necessary resources
16 appropriately to review petitions in the event DTSC receives numerous petitions. Although
17 DTSC will conduct an initial completeness review of all incoming petitions, only those that pass
18 the initial review will be prioritized for the next step: the technical review.

19

20 **Section 69304.1(b)** requires DTSC to conduct a technical review of the petitions based on the
21 criteria specified in sections 69304.1(b)(1) through (b)(3). This provision is necessary to
22 ensure that DTSC's determination on each petition is a scientifically-based decision.

23

24 **Section 69304.1(b)(1)** requires DTSC to evaluate the comprehensiveness of the information
25 supporting the petition that pertains to the prioritization factors specified in sections 69302.3
26 and 69303.3. This requirement is necessary to ensure information is provided, to the
27 maximum extent possible, by the petitioner to facilitate the review of the chemical or product
28 that is the subject of the petition in the prioritization process in the event the petition is granted.

29

30 **Section 69304.1(b)(2)** requires DTSC to evaluate the quality of data and information
31 submitted to support the petition, including but not limited to reliable information, or data that
32 has been produced or reviewed and accepted by a State or local agency for compliance and
33 regulatory purposes. This requirement also is necessary to ensure information is provided, to
34 the maximum extent possible, by the petitioner to facilitate the review of the chemical or
35 product that is the subject of the petition in the prioritization process in the event the petition is
36 granted.

37

38 **Section 69304.1(b)(3)(A) and (B)** specify that DTSC will evaluate the availability of data and
39 information, other than the data and information submitted with the petition, needed to enable
40 DTSC to determine hazard traits exhibited by the chemical and evaluate the chemical or
41 product based on the factors in sections 69302.3 and 69303.3. This provision is necessary to

1 enable DTSC to consider in its determination to grant or deny a petition whether or not there is
2 adequate available information to evaluate the chemical or product under the article 2 and
3 article 3 prioritization processes.
4

5 **Section 69304.1(c)** specifies that DTSC may request that the petitioner provide additional
6 information to complete the technical review. The petitioner must provide, to the extent
7 available, the information within the time frame specified by DTSC. This provision is
8 necessary to provide DTSC the ability and flexibility to request additional information that is
9 needed to complete the technical review.
10

11 **Section 69304.1(d)(1) and (2)** specify that after completing the technical review, DTSC will
12 approve or deny the petition, prepare a notice of decision and a statement of basis explaining
13 the rationale for the decision, and notify the petitioner of its decision. This section is necessary
14 to inform the petitioner and the public of the petition, the decision rendered, and the basis for
15 DTSC's decision.
16

17 **Section 69304.1(e)** specifies that after granting a petition, DTSC will evaluate and, if
18 applicable, prioritize the chemical or the product in accordance with the prioritization processes
19 specified in articles 2 and/or 3. This provision is necessary to clarify that an approved petition
20 does not automatically place the chemical or product on a list, but that the chemical or product
21 must undergo the same prioritization process as other chemicals and products that DTSC
22 evaluates.
23

24 **Article 5. Alternatives Assessments**

25
26 Article 5, in its entirety, is necessary to provide the general and specific requirements to
27 conduct alternatives assessments (AA) for consumer products that are listed as Priority
28 Products under the prioritization process in article 3. Consumer products that are listed as
29 Priority Products are of concern due to the presence of a Priority Chemical in the consumer
30 product. The AA Work Plan and the subsequent AA Report, collectively the Tier II AA, will
31 establish the basis for identifying the most suitable alternative to the Priority Product (if there is
32 one) and the appropriate regulatory response under article 6. The various elements of this
33 article are necessary to provide consistency in the work products submitted by entities and to
34 allow for comparison of the data collected. Elements of this article are also crucial in
35 identifying data gaps for products that contain Priority Chemicals and identifying alternatives to
36 those chemicals. This article is necessary to clarify, implement, and make specific the
37 provisions of Health and Safety Code section 25253.
38

39 *Tiered Alternatives Assessments*

40 Health and Safety Code section 25253(b) specifies that DTSC may impose a range of
41 regulatory responses on a product after the Tier II AA has been completed. Numerous

1 interested parties have expressed a preference for a tiered AA approach that expedites
2 various products through the AA process without delaying the process so that the appropriate
3 regulatory response is swiftly achieved.
4

5 DTSC has evaluated the merits of the various proposals and has determined that the proposed
6 regulations strike a balance between addressing Chemicals of Concern in an expeditious
7 manner without unintentionally replacing those chemicals with regrettable substitutes due to
8 the lack of a robust alternative assessment. DTSC's regulations accommodate advancements
9 in science and technology without compromising the quality and amount of data collected to
10 move towards a safer alternative. The approach taken in the regulations is consistent with,
11 and is necessary to the implementation of, Health and Safety Code section 25253.
12

13 The regulation allows a manufacturer and/or responsible entity to begin reformulating and
14 improving upon products that contain a Chemical under Consideration well before the chemical
15 is listed as a Priority Chemical or the product is listed as a Priority Product. When the
16 manufacturer or responsible entity chooses to embark on such an early product reformulation
17 or redesign, this can be done without first performing a Tier II AA. However, the manufacturer
18 or responsible entity will be required to provide an AA Notification to DTSC, which must be
19 accompanied by a Tier I AA report, or other information describing the rationale for the
20 redesign or reformulation and hazard trait information for the original chemical and any
21 replacement chemical contained in the product. This information is necessary so that DTSC
22 can keep an eye out for any regrettable substitutions. If regrettable substitutions are found,
23 these will be addressed in future chemical and product prioritization processes.
24

25 This provision, which is only available to for products not yet listed as Priority Products, is
26 intended to provide an incentive to reformulate or redesign early in the process. Once a
27 product is included on the Priority Products list, the much more rigorous Tier II AA
28 requirements apply.
29

30 The Tier II AA process requires the manufacturer or responsible entity of a Priority Product to
31 prepare an AA Work Plan that contains the information specified in section 69305.4. A
32 responsible person in charge, required to be a lead assessor meeting the requirements of
33 section 69308.3, must prepare and implement the AA Work Plan, carry out the assessment
34 and evaluation of the data collected, and present the information in an AA Report in the format
35 specified in sections 69305.6 through 69305.8. The Tier II AA and the AA Report is divided
36 into two phases: the Tier II-A AA and the Tier II-B AA. The purpose of dividing the Tier II AA
37 into two phases is to allow the Tier II-A AA to inform the second phase, the Tier II-B AA.
38

39 The focus of the Tier II-A AA is a Chemical Hazard Assessment and, if determined to be
40 necessary, an Exposure Potential Assessment. The results of the Tier II-A AA are intended to

1 be used to refine as needed the scope and approach of the Tier II-B AA, and to potentially
2 screen out undesirable alternatives before moving on to the Tier II-B AA.

3
4 The focus of the Tier II-B AA is a Multimedia Life Cycle Evaluation. Because the completion of
5 the Tier II-B AA constitutes completion of the Tier II AA, the Tier II-B AA Report must identify,
6 and explain the rationale for, the selected alternative and present an implementation plan.

7 8 **Section 69305. Guidance Materials**

9 **Section 69305(a)** requires DTSC, prior to finalizing the initial list of Priority Chemicals pursuant
10 to section 69302.2, to prepare, and make available on its website, guidance materials to assist
11 persons in performing Tier II Alternatives Assessments (AA) that comply with the Chapter 53.
12 DTSC must periodically revise and update the guidance materials. This section is necessary
13 to provide technical assistance to manufacturers of consumer products with Priority Chemicals
14 that wish to begin seeking out alternatives to the Priority Chemical prior to a consumer product
15 being listed as a Product under Consideration or a Priority Product.

16
17 **Section 69305(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. The posting must indicate
19 the name of the entity that prepared the AA, and if the AA was prepared by a lead assessor
20 meeting the requirements of section 69308.3. Providing information on whether an AA was
21 performed by a lead assessor will assist a manufacturer and others to determine the reliability
22 of the information contained in the open source AA. This section is necessary to make
23 available easily accessible AA for consumer products that manufacturers may consider.
24 Posting open source AAs will also stimulate discussion to innovate and address complex
25 chemicals and product function redesign issues while simultaneously creating safer consumer
26 products.

27 28 **Section 69305.1. Alternatives Assessment Notifications and Tier I AA Reports**

29 This section, in its entirety, is necessary to establish and specify the process for AAs
30 performed for products that contain Chemicals of Concern but that have not been listed as
31 Priority Products. This section is necessary to clarify, implement, and make specific the
32 provisions of Health and Safety Code section 25253 as they apply to AAs for these products.

33
34 As explained above, this section allows a manufacturer and/or responsible to voluntarily
35 embark on early product reformulation or redesign, without first performing a Tier II AA. The
36 AA Notification is necessary so that DTSC can keep an eye out for any regrettable
37 substitutions, which could result from this type of less rigorous alternatives assessment. If
38 regrettable substitutions are found, these will be addressed in future chemical and product
39 prioritization processes.

1 **Section 69305.1(a)** requires a responsible entity to submit a notification to DTSC if, after a
2 chemical has been listed as a Chemical under Consideration or a Priority Chemical on the final
3 lists prepared pursuant to section 69302.2, any consumer product containing that chemical is
4 reformulated or redesigned to remove, or reduce the concentration of that chemical or the
5 original product has been replaced with another product. The responsible entity must provide
6 the notification before placing the reformulated, redesigned or replacement product into the
7 stream of commerce in California. The notification provided to DTSC must include all of the
8 information required in sections 69305.1(a)(1) through (a)(5), which are summarized below.

9
10 **Section 69305.1(a)(1) through (a)(5)** require that the notification submitted include: **(1)** the
11 responsible entity's name and contact information; **(2)** labeling information identifying and
12 describing the original product and the reformulated, redesigned or replaced product, including
13 the brand name(s) for both products; **(3)** the intended uses, and targeted customer base(s), for
14 the product; **(4)** the Chemical of Consideration or Priority Chemical removed from, or reduced
15 in, the product; and **(5)** a Tier I AA Report comparing the two products or all of the information
16 contained in sections 69305.1(a)(5)(A) through (a)(5)(C).

17
18 **Section 69305.1(a)(5)(A) through (a)(5)(C)** specify that in lieu of submitting a Tier I AA
19 Report, the following information must be provided: **(A)** information explaining the rationale for
20 and the factors considered in selecting the reformulation, redesign or substitution alternative;
21 **(B)** identification, and a qualitative or quantitative description, of any reduction(s) to adverse
22 public health or environmental impacts achieved by the reformulation, redesign or substitution;
23 and **(C)** identification of any hazard traits exhibited by the substitute chemical, if another
24 chemical was substituted for the Chemical under Consideration or Priority Chemical.

25
26 If a Tier I AA Report is submitted it must be based on the "The Green Screen for Safer Chemicals"
27 guidance document prepared by Clean Production Action, a non-profit organization that
28 collaborates with industry, government and other non-governmental organizations to design
29 and deliver strategic solutions for chemicals, sustainable materials and environmentally
30 preferable products. For additional information and the guidance document go to
31 <http://www.cleanproduction.org/Home.php>. Alternatively, for responsible entities choosing to
32 submit a Tier I AA Report to fulfill the requirements of section 69301.5(a)(5), the regulations
33 provide the flexibility for the use of other AA tools and/or methodologies if DTSC concurs those
34 tools and/or methodologies are substantially equivalent to the "Green Screen for Safer
35 Chemicals" or are otherwise acceptable for purposes of this requirement.

36
37 The Green Screen specifies four benchmarks that must be evaluated in the quest for safer
38 alternatives to Priority Chemicals. Each benchmark defines a progressively safer chemical:

- 39 • Benchmark 1: Avoid — chemical of high concern
- 40 • Benchmark 2: Use but search for safer substitutes
- 41 • Benchmark 3: Use but still opportunity for improvement

- 1 • Benchmark 4: Prefer — safer chemical

2
3 Each benchmark includes a set of criteria that a chemical, along with its known and predicted
4 breakdown products and metabolites, must meet. To progress from Benchmark 1 to
5 Benchmark 2, a chemical (and its breakdown products and metabolites) must meet all the
6 criteria specified under Benchmark 1. For example, a chemical (along with its breakdown
7 products and metabolites) that is a persistent bioaccumulative toxin would not pass beyond
8 Benchmark 1. Similarly, to progress from Benchmark 2 to Benchmark 3 and from Benchmark
9 3 to Benchmark 4, the chemical (along with its breakdown products and metabolites) must
10 meet all criteria specified under each respective benchmark. The criteria become increasingly
11 more demanding for environmental and human health and safety for each benchmark, with the
12 hazard criteria of Benchmark 4 representing the safest chemical.

13
14 **Section 69305.1(a)(5)(C)1. and 2.** specify that the information submitted in lieu of a Tier I AA
15 Report must identify the hazard traits based on criteria developed by DTSC or OEHHA, to the
16 extent such criteria are made available by DTSC or OEHHA. If relevant criteria have not yet
17 been provided by DTSC or OEHHA, reliable information shall be used to determine whether
18 the chemical exhibits a hazard trait.

19
20 **Section 69305.1(b)** specifies that the requirements of section 69305.1(a) do not apply to a
21 replacement product of an original product that was reformulated, redesigned, or to a chemical
22 that was substituted into a product as a result of the implementation of a selected alternative
23 identified in a Tier II AA Report submitted to DTSC.

24
25 **Section 69305.1(c)** specifies that the requirements of section 69305.1(a) do not apply if the
26 manufacturer of the product has submitted a Chemical Removal Confirmation Notification or a
27 Product Removal Confirmation Notification to DTSC.

28
29 **Section 69305.1(d)** specifies that the information submitted pursuant to section 69305.1(a),
30 will be taken into consideration by DTSC during the chemical prioritization process described
31 in article 2, and the subsequent product prioritization process, of article 3, and in the evaluation
32 of those prioritization factors related to exposure concerns and any other prioritization factors
33 that DTSC determines the information is pertinent to.

34
35 **Section 69305.1(e)** specifies that if the AA notification is accompanied by a Tier I AA Report
36 prepared by a qualified third-party assessment entity, or verified by a lead assessor meeting
37 the requirements of section 69305.2(c)(3)(B), DTSC must, if requested by the submitting party,
38 list the product that is the subject of the Tier I AA Report on DTSC's website. In addition, if
39 requested by the person submitting the AA Notification, DTSC must post on its website any
40 identifying descriptive information that the person submitting the AA Notification requests to be
41 posted on DTSC's website. This provision is intended to provide an incentive to manufacturers

1 and/or responsible entities that are proactive and reformulate early in the process to develop
2 safer alternatives to a product in commerce. A manufacturer or responsible entity may through
3 this provision request that DTSC post information regarding the salient aspects of the product
4 that has been reformulated and now replaces a product that contained a Chemical of Concern
5 to drive consumers to make use of the safer alternative in commerce. This provision is
6 necessary to encourage manufacturers to be proactive and to seek out information on a
7 chemical's hazard traits prior to using it in the products they manufacture.
8

9 **Section 69305.2. Tier II Alternatives Assessments: General Provisions**

10 This section, in its entirety, is necessary to specify the general requirements for Tier II AAs
11 which are required for Priority Products. This article is necessary to clarify, implement, and
12 make specific the provisions of Health and Safety Code section 25253 as they apply to AAs for
13 these products.
14

15 **Section 69305.2(a)(1)** requires, except as otherwise provided in sections 69305.2(d) and (f),
16 69301.4(c), 69303.2(e) and 69305.3, a responsible entity for a product that is listed as a
17 Priority Product to perform a Tier II AA for that Priority Product.
18

19 **Section 69305.2(a)(2)** requires a responsible entity subject to the requirements of section
20 69305.5.3 (a)(1), or a person fulfilling these requirements on behalf of, or in lieu of, the
21 responsible entity, to prepare, sign and submit to DTSC a Tier II AA Work Plan meeting the
22 requirements of section 69305.4 and a Tier II AA Report meeting the requirements of sections
23 69305.6 through 69305.8.
24

25 **Section 69305.2(a)(2)(A)** requires the Tier II AA Work Plan to be submitted no later than one
26 hundred and eighty (180) days following the date that the applicable final Priority Product
27 listing is posted on DTSC's website, except as provided in section 69305.2(b).
28

29 **Section 69305.2(a)(2)(B)** requires the Tier II AA Report, comprised of a Tier II-A AA Report
30 and a Tier II-B AA Report, to be submitted by the dates specified by DTSC pursuant to section
31 69305.4(b)(4), except as provided in section 69305.3(b). The Tier II AA Report is also referred
32 to an AA Report.
33

34 **Section 69305.2(b)(1)** allows a responsible entity, or a person fulfilling the requirements of this
35 article on behalf of, or in lieu of, the responsible entity, to request a one-time extension to the
36 submission deadline for the Tier II AA Work Plan and/or the AA Report. If an extension
37 request is made, it must be received no later than sixty (60) days before the due date for the
38 AA Work Plan or AA Report, as applicable. This provision is necessary to accommodate
39 reasonable and justified requested for time extension for completing AA Work Plans and AA
40 Reports.
41

1 **Section 69305.2(b)(2)** requires that if there is an extension request it must be submitted to
2 DTSC and must include the information specified in sections 69305.3(b)(2)(A) through (G),
3 which are summarized in the paragraphs below.
4

5 **Section 69305.2(b)(2)(A) through (G)** requires an extension request to include: **(A)** the name
6 of and contact information for the person filing the extension request; **(B)** the name of and
7 contact information for the person(s) on whose behalf the Tier II AA Work Plan and AA Report
8 will be submitted; **(C)** the name of and contact information for the manufacturer of the product
9 if different from the first two persons identified; **(D)** information identifying and describing the
10 Priority Product, including the brand name(s) under which the Priority Product is placed into
11 the stream of commerce in California; **(E)** the due date for the Tier II AA Work Plan or AA
12 Report, as applicable; **(F)** the amount of time requested, not to exceed the maximum extension
13 timeframes specified in section 69305.3(b)(3); and **(G)** the reason or justification for the
14 extension.
15

16 **Section 69305.2(b)(3)** requires DTSC within 30 days to approve, deny or approve in part an
17 extension request and to notify the person submitting the extension request of its decision.
18 Section 69305.3(b)(3) further specifies that the one-time extension for the Tier II AA Work Plan
19 must not exceed ninety (90) days, and the one-time extension for the AA Report shall not
20 exceed twelve (12) months.
21

22 **Section 69305.2(c)(1)(A) and (B)** requires the Tier II AA to be performed by, and the Tier II
23 AA Work Plan and AA Report prepared by, either a qualified third-party assessment entity
24 designated pursuant to section 69308 or a qualified in-house assessment entity designated
25 pursuant to section 69308.1. This provision is necessary to ensure that the AAs that are
26 submitted for review and implemented are prepared and conducted in a manner that is
27 technically sound and meets the requirements of this article.
28

29 **Section 69305.2(c)(2)** requires the responsible individual in charge of preparation of the Tier II
30 AA Work Plan and AA Report, and who conducts the AA, to be a lead assessor who meets the
31 requirements of section 69308.3 and to be accredited for a product type and/or industry sector
32 appropriate for the Tier II AA Report being performed. The lead assessor must be employed
33 by the qualified third-party assessment entity or qualified in-house assessment entity,
34 whichever is applicable. This provision is necessary to inform manufacturers and individuals
35 that the AA, AA Work Plan and AA report must be completed by an individual qualified to carry
36 out the requirements as specified. By specifying that only qualified individuals may conduct
37 and submit the necessary work products, the cost to the state is lowered, as the intensity of
38 review can be reduced.
39

40 **Section 69305.2(c)(3)(A)** requires a Tier II AA performed and AA Report prepared by a
41 qualified in-house assessment entity, to be reviewed and verified by a second lead assessor

1 who meets the requirements of section 69308.3, and is employed by a qualified third-party
2 assessment entity that did not participate in any way in the design or formulation of the AA
3 Work Plan, data gathering, analysis, or other aspects of the Tier II AA, or preparation of the AA
4 Report. The lead assessor that verifies the Tier II AA and AA Report must not have any
5 economic interest in any entity that manufacturers, or places into the stream of commerce in
6 California, a Chemical of Concern, Product under Consideration, or Priority Product. The
7 verifying lead assessor must perform the requirements specified in sections 69305.3(c)(3)(B)1.
8 through 69305.3(c)(3)(B)5., which are summarized below.

9
10 **Section 69305.2(c)(3)(B)1. through 5.** specifies that the lead assessor that verifies the Tier II
11 AA Work Plan and AA Report must do all of the following: **1.** verify compliance with the
12 requirements of article 5 and indicate the degree to which the guidance document(s) posted by
13 DTSC pursuant to section 69305(a) were used in conducting the AA; **2.** verify the proper
14 analysis of the product's or component's life cycle; **3.** verify the appropriate use of life cycle
15 assessment tools and methodologies; **4.** attest to the accuracy of the reported data; and **5.**
16 perform a final quality assurance review of the Tier II AA, AA Report, and of the data on which
17 the AA is based. This provision is necessary to provide a third-party review of the supporting
18 data and analysis and the basis for Tier II AA determinations on a Priority Product or
19 component, so as to give the public and DTSC greater assurance as to the quality, reliability
20 and integrity of the Tier II AA.

21
22 **Section 69305.2(c)(3)(C)** requires the verifying lead assessor to prepare an AA verification
23 statement documenting the verification process and findings. This provision is necessary to
24 ensure that responsible individuals in charge of verifying the contents of an AA under this
25 article officially states that the requirements of section 69305.3(c)(3)(A)1. through section
26 69305.3(c)(3)(A)5. were followed.

27
28 **Section 69305.2(c)(3)(D)** requires the verifying lead assessor to base the AA verification
29 statement solely on the factors listed in sections 69305.3(c)(3)(B)1. through section
30 69305.3(c)(3)(B)5. The selected alternative, or the decision not to select an alternative to the
31 Priority Product or component, as identified in the Tier II AA Report pursuant to section
32 69305.8(f), may not be a consideration factor in verifying the AA or preparing the AA
33 verification statement. This is necessary to ensure that the alternative selection decision rests
34 solely with the responsible entity or the manufacturer that must implement the decision.

35
36 **Section 69305.2(d)** allows a manufacturer to submit an existing report or study completed on
37 a Priority Product in lieu of complying with the requirements of preparing and conducting a Tier
38 II AA Work Plan and AA Report, if the report is substantially equivalent to the requirements of
39 sections 69305.6 through 69305.8 and that the report contains sufficient information to identify
40 the most appropriate regulatory response pursuant to article 6. This provision is necessary to

1 not only encourage manufacturers to use existing information to expedite the quest for safer
2 products, but also to comply with the goal and intent of Health and Safety Code section 25253.

3
4 **Section 69305.2(d)(1)** requires the report submitted pursuant to section 69305.3(d) to be
5 submitted no later than one hundred and eighty (180) days following the date that the
6 applicable final Priority Product listing is posted on DTSC's website. The section further
7 specifies that a one-time extension may be requested pursuant to section 69305.2(b). This
8 provision is necessary to allow DTSC an opportunity to evaluate existing reports or studies that
9 are submitted and determine if they contain the necessary contents. In the event the existing
10 report or study does not contain the necessary contents, DTSC will direct the manufacturer to
11 prepare an AA Work Plan, AA Report, or elements of the two to complete a Tier II AA for the
12 Priority Product.

13
14 **Section 69305.2(d)(2)** allows a manufacturer submitting an existing report or study pursuant to
15 section 69305.3(d) to submit supplemental information to render the information submitted
16 substantially equivalent to the requirements of sections 69305.6 through 69305.8. This
17 provision is necessary because some existing reports or studies may differ in content but can
18 be easily augmented with additional information to meet the requirements of article 5.

19
20 **Section 69305.2(d)(3)** specifies that if the existing report or study submitted pursuant to
21 section 69305.3(d) is not available in the public domain, the report or study shall be
22 accompanied by documentation demonstrating that the Tier II-AA Report was verified by a
23 lead assessor pursuant to section 69305.2(c)(3). This provision is necessary to give the public
24 and DTSC greater assurance as to the quality, reliability and integrity of the Tier II AA.

25
26 **Section 69305.2(e)** requires any person performing a Tier II AA, pursuant to section
27 69305.3(a), to consider all available relevant information made available on DTSC's website
28 and any additional information or technical assistance DTSC may provide regarding
29 alternatives assessments. These efforts must be summarized in the Tier II AA Report. This
30 provision is necessary to require manufacturers to, at a minimum, considering existing
31 knowledge and technological advances identifying and evaluating alternatives.

32
33 **Section 69305.2(f)(1)** specifies that the requirements of section 69305.2(a) pertaining to
34 submission of an AA Work Plan and performance of a Tier II AA do not apply if a Chemical
35 Removal Intent Notification and/or Chemical Removal Confirmation Notification, or a Product
36 Removal Intent Notification and/or Product Removal Confirmation Notification is submitted to
37 DTSC for the product prior to the due date for submitting the AA Work Plan. Further, if only a
38 Chemical Removal Intent Notification or Product Removal Intent Notification is submitted to
39 DTSC by that date, i.e. the date the AA Work Plan is due, one of the those items specified in
40 sections 69305.2(f)(1)(A) through (f)(1)(C) must be submitted to the DTSC by the date
41 specified in the respective sections. This provision allows a manufacturer or responsible entity

1 to elect to remove a Priority Chemical from a product or remove the product from commerce
2 without the need to develop an AA Work Plan or perform a Tier II AA. The manufacturer or
3 responsible entity must provide DTSC notification of its intent to remove the Priority Chemical
4 from a product or the Priority Product from California commerce within 180 days after a Priority
5 Product is listed.

6
7 **Section 69305.2(f)(1)(A)** requires a Chemical Removal Confirmation Notification to be
8 submitted no later than ninety (90) days after the date the Chemical Removal Intent
9 Notification or Product Removal Intent Notification was submitted. This provision requires that
10 within 90 days of having submitted the intent to remove a Priority Product from commerce or a
11 chemical from a Priority Product the manufacturer or responsible entity must provide DTSC a
12 Chemical Removal Confirmation Notification.

13
14 **Section 69305.2(f)(1)(B)** requires a Product Removal Confirmation Notification to be
15 submitted no later than ninety (90) days after the date the Chemical Removal Intent
16 Notification or Product Removal Intent Notification was submitted. This provision requires that
17 within 90 days of having submitted the intent to remove a Priority Product from commerce or a
18 chemical from a Priority Product, the manufacturer or responsible entity must provide DTSC a
19 Product Removal Confirmation Notification. This provision is intended to work in unison with
20 the provision contained in section 69305.2(f)(1)(A). Together, the two provisions provide
21 needed flexibility and effectively allow a manufacture to provide DTSC with a notice of intent to
22 remove either a Priority Product from commerce or a Priority Chemical from a product and
23 subsequently determine that they will instead do the other.

24
25 **Section 69305.2(f)(1)(C)** requires an AA Work Plan to be submitted by the due date for the AA
26 Work Plan or no later than ninety (90) days after the date the Chemical Removal Intent
27 Notification or Product Removal Intent Notification was submitted, whichever is later. An AA
28 Work Plan is due 180 days after a Priority Product is listed. A manufacturer or responsible
29 entity may instead, however, submit a Chemical Removal Intent Notification or Product
30 Removal Intent Notification within the 180-day time period. If the manufacturer does not
31 submit the Product Removal Confirmation Notification or Chemical Removal Confirmation
32 Notification within the time period specified in sections 69305.2(f)(1)(A) or (B), an AA Work
33 Plan must be submitted no later than 90 days after the notice of intent was submitted.

34
35 **Section 69305.2(f)(2)(A)** specifies that if an AA Work Plan has been submitted to DTSC, the
36 requirements of section 69305.2(a) pertaining to performance of a Tier II AA and submission of
37 an AA Report do not apply if a Chemical Removal Intent Notification and/or Chemical Removal
38 Confirmation Notification, or a Product Removal Intent Notification and/or Product Removal
39 Confirmation Notification, is submitted to DTSC for the product prior to the due date for
40 submitting the AA Report.

1 In the course of executing the AA Work Plan, manufacturers and/or responsible entities may
2 determine that they favor abandoning the use of a chemical or cease to manufacture a Priority
3 Product. This provision gives manufacturers and/or responsible entities the flexibility to elect
4 to remove a Priority Chemical or Priority Product from commerce after they have prepared,
5 submitted and received approval of an AA Work Plan. If only a Chemical Removal Intent
6 Notification or Product Removal Intent Notification has been submitted by the date the AA
7 Work Plan is due, the manufacturer or responsible entity must submit by the date specified one
8 of the documents specified in sections 69305.2 (f)(2)(A)1. through (f)(2)(A)3.

9
10 **Section 69305.2(f)(2)(A)1.** requires a Chemical Removal Confirmation Notification to be
11 submitted no later than ninety (90) days after the date the Chemical Removal Intent
12 Notification or Product Removal Intent Notification was submitted. To be eligible for the
13 exemption from the requirement to submit an AA Work Plan and conduct a Tier II AA the
14 manufacturer or responsible entity must submit a Chemical Removal Confirmation Notification
15 no later than 90 days after the Chemical Removal Intent Notification or Product Removal Intent
16 Notification was submitted.

17
18 **Section 69305.2(f)(2)(A)2.** requires a Product Removal Confirmation Notification to be
19 submitted no later than ninety (90) days after the date the Chemical Removal Intent
20 Notification or Product Removal Intent Notification was submitted. To be eligible for the
21 exemption from the requirement to submit an AA Work Plan and conduct a Tier II AA the
22 manufacturer or responsible entity must submit a Product Removal Confirmation Notification
23 no later than 90 days after the Chemical Removal Intent Notification or Product Removal Intent
24 Notification was submitted.

25
26 **Section 69305.2(f)(2)(A)3.** requires an AA Report to be submitted by the due date for the AA
27 Report or no later than ninety (90) days after the date the Chemical Removal Intent Notification
28 or Product Removal Intent Notification was submitted, whichever is later. If a Chemical
29 Removal Confirmation Notification or Product Removal Confirmation Notification is not
30 submitted then an AA Report must be submitted no later than 90 days after the date the
31 applicable Removal Intent Notification was submitted.

32
33 **Section 69305.2(f)(2)(B)** requires a Chemical Removal Confirmation Notification submitted
34 pursuant to subparagraph (A) to be accompanied by all of the information specified in sections
35 (f)(2)(B)1. through (f)(2)(B)3, which are summarized below. The information is necessary for
36 DTSC to assess the appropriateness of the information submitted and determine if an alternate
37 course of action is necessary.

38
39 **Section 69305.2(f)(2)(B)1. through 3.** require a Chemical Removal Confirmation Notification
40 to include: **1.** the intended uses, and targeted customer base(s), for the product; **2.** information
41 explaining the rationale for and the factors considered in the decision to remove the Chemical

1 under Consideration and/or Priority Chemical from the product, without adding any other
2 chemical to the product; and 3. identification, and a qualitative or quantitative description, of
3 any reduction to adverse public health or environmental impacts achieved by removing the
4 Chemical under Consideration and/or Priority Chemical from the product

5
6 **Section 69305.2(g)** specifies that DTSC's failure to make a completeness determination within
7 60 days from receipt of the applicable document, or failure of the Director to respond to a
8 request for review under section 69307.2 within 60 days, does no result in the Tier II AA Work
9 Plan or AA Report being deemed complete. This provision is needed to prevent the de facto
10 approval of an AA Work Plan or AA Report that does not comply with the applicable
11 requirements of Health and Safety Code section 25253 or article 5, in the event DTSC is
12 unable to act within the 60-day time period due to resource limitations or other reasons.

13 14 **Section 69305.3. De Minimis Exemption**

15 This section, in its entirety, is necessary to provide a manufacturer the opportunity to request
16 an exemption from article 5 for a product it manufactures, if the product is listed on the Priority
17 Product list and is not restricted from being eligible for an exemption. If a manufacturer
18 determines that its Priority Product contains a Priority Chemical at or below the de minimis
19 level listed by DTSC and the product is not restricted from being eligible for a de minimis
20 exemption request, then a de minimis exemption request may be filed. If DTSC grants the
21 exemption, the responsible entity is exempted from conducting a Tier II AA for its Priority
22 Product.

23
24 The section also prescribes the information that must be submitted to allow DTSC to grant the
25 de minimis exemption. This section is necessary to provide a manufacturer an opportunity to
26 request an exemption from article 5 if the quantity of the Priority Chemical in its product is
27 below the de minimis amount. This provision is necessary to allow DTSC and manufacturers
28 to focus their resources on those Priority Products that pose the greatest threats to public
29 health and the environment. The conditions for granting a de minimis exemption ensure that
30 exempted Priority Products do not pose such threats.

31
32 **Section 69305.3(a)** specifies that a responsible entity is exempt from the Tier II AA
33 requirements in article 5, if the manufacturer requests, and DTSC grants, a de minimis
34 exemption. If a de minimis exemption request is sought, it must be submitted to DTSC no later
35 than sixty (60) days after the product has been listed as a Priority Product, and must include all
36 of the information specified in sections 69305.3(a)(1) through (a)(7), which are summarized
37 below. This provision makes it known that a responsible entity must file an exemption request
38 and DTSC must grant the exemption before the Priority Product or component is exempted
39 from the Tier II AA requirements.

1
2 **Section 69305.3(a)(1) through (a)(7)** specify that a de minimis exemption request must
3 include: **(1)** the manufacturer's name and contact information; **(2)** the name of and contact
4 information for any responsible entity for the product, to the extent known to the manufacturer;
5 **(3)** information identifying and describing the product, including the brand name(s) under which
6 the product is made available for use in California, and information specifically identifying the
7 product component, if applicable; **(4)** the source and purpose of the Priority Chemical in the
8 product; **(5)** information concerning any attempts taken by the manufacturer to eliminate or
9 reduce the amount of the Priority Chemical in the product; **(6)** the maximum concentration at
10 which the Priority Chemical is present in the product, and a listing and description of all data
11 and other information used by the manufacturer to determine and substantiate this
12 concentration; and **(7)** a list of all federal and California state regulatory thresholds, intended to
13 protect public health or the environment, that are applicable to the chemical or the
14 chemical/product combination.

15
16 **Section 60305.3(b)** specifies that section 69305.3 (a) does not apply if DTSC has determined,
17 pursuant to section 69303.2(e)(3), that a de minimis exemption may not be considered for the
18 product.

19
20 **Section 69305.3(c)(1)** requires DTSC within 60 days of receiving a de minimis exemption
21 request, to issue a notice to the manufacturer with the information specified in sections Section
22 69305.3(c)(1)(A) through (c)(1)(C).

23
24 **Section 69305.3(c)(1)(A) through (c)(1)(C)** specifies that in its notice, DSTC may grant or
25 deny the de minimis exemption, or request additional information.

26
27 **Section 69305.3(c)(1)(C)1. and (C)2.** allow DTSC to request information including, but not
28 limited to, information concerning the source(s) of the Priority Chemical in the product, and
29 laboratory analytical testing protocols and results used to determine and substantiate the
30 concentration of the Priority Chemical in the product, including quality control and quality
31 assurance protocols and data and information concerning the testing laboratory.

32
33 **Section 69305.3(c)(2)** requires the manufacturer to provide any additional information
34 requested by DTSC within 30 days of receiving the request, unless prior to the due date for
35 submission the manufacturer requests and DTSC grants a one-time extension, which cannot
36 exceed an additional 30 days. If a request for additional information is not completely fulfilled,
37 DTSC must deny the de minimis exemption request. Within 60 days of receiving the
38 requested additional information, DTSC must issue a notice to the manufacturer either granting
39 or denying the de minimis exemption request.

40

1 **Section 69305.3(c)(3)** requires that a notice granting or denying a de minimis exemption
2 request include the basis for DTSC's decision.

3
4 **Section 69305.3(c)(4)** requires DTSC to send a copy of any notice to the manufacturer and to
5 any known responsible entity for the affected product.

6
7 **Section 69305.3(d)** requires a decision by DTSC to grant or deny a de minimis exemption
8 request to be governed by the conditions specified in sections 69305.3(d)(1) and (d)(2), which
9 are summarized below.

10
11 **Section 69305.3(d)(1)** requires that a de minimis exemption request be denied if the
12 manufacturer fails to demonstrate to DTSC's satisfaction that the concentration of the Priority
13 Chemical in the product does not exceed the applicable de minimis threshold.

14
15 **Section 69305.3(d)(2)(A)** requires that except as provided in section 69305.3(d)(2)(B), a de
16 minimis exemption request must be denied if DTSC has reliable information that shows the
17 Priority Chemical to be harmful or potentially harmful in concentrations below the de minimis
18 level.

19
20 **Section 69305.3(d)(2)(B)** provides that when DTSC has reliable information showing the
21 Priority Chemical to be harmful or potentially harmful at concentrations below the de minimis
22 level, DTSC may, at its discretion, grant a modified de minimis exemption if both conditions in
23 sections 69305.3(d)(2)(B)1. and 2. apply. Those conditions are summarized below.

24
25 **Section 69305.3(d)(2)(B)1. and 2.** specify that if **1.** reliable information identifies a specific
26 lower de minimis threshold for the Priority Chemical that is based on a scientific evaluation of
27 public health and environmental adverse impacts; and **2.** the information provided by the
28 manufacturer demonstrates to the satisfaction of DTSC that the concentration of the Priority
29 Chemical in the product does not exceed the de minimis threshold identified pursuant to
30 subparagraph (B)1., then it satisfies the two criteria for DTSC to consider setting a lower de
31 minimis level.

32
33 **Section 69305.3(d)(3)** specifies that DTSC may also deny a de minimis exemption request if
34 DTSC determines that the Priority Chemical is found at or below the de minimis level in
35 numerous consumer products that are commonly used on a frequent basis, and reliable
36 information shows these cumulative exposures to the Priority Chemical to be harmful or
37 potentially harmful even when individual product concentrations of the Priority Chemical are
38 below the de minimis level.

39
40 **Section 69305.3(e)** specifies that a de minimis exemption granted pursuant this section must
41 be rescinded if DTSC determines that the data or other information that DTSC relied upon in

1 granting the exemption was not, or is no longer, valid. If DTSC rescinds an exemption, DTSC
2 must notify the manufacturer and any responsible entity for the affected product, known to
3 DTSC.

4
5 **Section 69305.3(f)** requires all notices granting, denying or rescinding a de minimis exemption
6 request to include the basis for DTSC's decision.

7
8 **Section 69305.3(g)** specifies that if DTSC denies or rescinds a de minimis exemption provided
9 pursuant to section 69305.3, an AA Work Plan must be submitted for the affected product
10 within one hundred and eighty (180) days after DTSC posts the notice of denial or rescission
11 on its website. This is to ensure that a denied exemption request does not unduly delay
12 proceeding with the Tier II AA process for the subject Priority Product.

13 14 **Section 69305.4. Tier II Alternatives Assessment Work Plan**

15 This section, in its entirety, is necessary to specify narrative standards that are required to be
16 in an AA Work Plan and is consistent with the statutory requirements in Health and Safety
17 Code section 25253 that must be taken into account in an AA in order to adequately evaluate
18 the availability of potential alternatives. This section is necessary to ensure that the person
19 who will perform the Tier II AA has set out a plan that will lead to the performance of a Tier II
20 AA that meets the requirements of article 5, and to standardize the work products that are
21 submitted for DTSC's review.

22
23 **Section 69305.4(a)** specifies that the AA Work Plan submitted, pursuant to section
24 69305.2(b)(2) must be adequate to ensure that the Tier II AA and the Tier II AA Report will
25 provide sufficient detail to support the selection of an alternative, or a decision to retain the
26 existing Priority Product in lieu of an alternative, and selection of the appropriate regulatory
27 response(s), if any, upon completion of the Tier II AA. It further specifies that a Tier II AA Work
28 Plan must contain the contents specified in sections 69305.4(a)(1) through (a)(7), which are
29 summarized below. This provision is necessary because the details between AA Work Plans
30 and AA Reports will vary on a case by cases basis; however, the information that is provided
31 must be sufficient to allow the reader to understand the goal of the AA.

32
33 **Section 69305.4(a)(1)** requires the AA Work Plan to contain the "Preparer Information" which
34 must include the information specified in sections 69305.4(a)(1)(A) through (a)(1)(D), which
35 are summarized below. In this section, the names of the parties involved in funding, directing,
36 overseeing, preparing or reviewing the assessment must be included. Any organizations and
37 individuals that will be providing expert guidance or review for the AA must be identified,
38 including the name of, and qualifications and accreditation information for, the person in
39 charge under whose direction the AA Work Plan was prepared. This provision is necessary to
40 document the names of the individuals and the roles they played in preparing and finalizing the
41 AA Work Plan.

1
2 **Section 69305.4(a)(1)(A)** requires the name of and contact information for the person
3 submitting the Tier II AA Work Plan to be provided.

4
5 **Section 69305.4(a)(1)(B)** requires that, if applicable, the name and contact information for all
6 persons that the AA Work Plan is being submitted on behalf of, and their relationship to the
7 person identified in Section 69305.4(a)(1)(A) must be provided to DTSC. The information
8 required under this provision is necessary to: (1) provide the necessary contact information
9 should more information be necessary; and (2) document under whose direction the AA Work
10 Plan was completed.

11
12 **Section 69305.4(a)(1)(C)** requires the names of the parties that will be involved in funding,
13 directing, overseeing, preparing or reviewing the Tier II AA to be provided to DTSC.

14
15 **Section 69305.4(a)(1)(D)** requires any organizations and individuals anticipated to provide
16 expert guidance or review for the Tier II AA, including the name of, and qualifications and
17 accreditation information for, the person(s) in charge under whose direction the Tier II AA Work
18 Plan will be prepared and the Tier II AA will be conducted to be provided to DTSC.

19
20 **Section 69305.4(a)(2)** specifies the “Product Information” that must be included in the AA
21 Work Plan. It must include information identifying and describing the Priority Product and/or
22 component that is the subject of the AA Work Plan.

23
24 **Sections 69305.4(a)(2)(A) through (a)(2)(C)** requires that the AA Work Plan to include
25 information identifying and describing the Priority Product or component that is the subject of
26 the Tier II AA Work Plan, including: **(A)** the brand name(s) under which the product is placed
27 into the stream of commerce in California; **(B)** if applicable, the Priority Product component(s)
28 that will be the focus of the Tier II AA; and **(C)** identification of the Priority Chemical(s) that are
29 the basis for the product being listed as a Priority Product and any other Priority Chemical(s)
30 that are, or reasonably should be, known to be in the Priority Product.

31
32 **Section 69305.4(a)(3)** requires the AA Work Plan to include “Supply Chain Information,”
33 which must include the information specified in sections 69305.4(a)(3)(A) through (a)(3)(D),
34 which are summarized below.

35
36 **Section 69305.4(a)(3)(A) through (a)(3)(D)** specify that all of the following information
37 applicable to the product that is, or should reasonably be, known to the preparer of the AA
38 Work Plan must be included in the AA Work Plan, including: **(A)** the name and contact
39 information for the person identified on the product label as the manufacturer, and the person,
40 if any, identified as the distributor; **(B)** the name and contact information for the producer of the

1 product; **(C)** the name and contact information for all responsible entities for the product; and
2 **(D)** the name and contact information for any other person in the supply chain for the product.
3

4 **Section 69305.4(a)(4)** requires the AA Work Plan to specify the proposed “AA Goal and
5 Scope of Alternatives,” which includes the information specified in sections 69305.4(a)(4)(A)
6 through (a)(4)(E). These provisions are summarized below. The provisions of this section
7 establish the basis under which the Tier II AA will be performed. This information is necessary
8 because even when products are seemingly alike, the scope and objective of the Tier II AA
9 may differ. In specifying the AA Goal and Scope of Alternatives, latitude is given in sections
10 69305.4 (a)(4)(A) through 69305.4(a)(4)(D) to select the most appropriate goal and objective
11 for the product or product component subject to the Tier II AA.
12

13 **Section 69305.4(a)(4)(A)** allows for substitution of another chemical for the Priority Chemical
14 in the Priority Product or component, whichever is applicable, as the goal/scope of the AA
15 Work Plan. Under this option, a manufacturer may evaluate alternatives to replace the Priority
16 Chemical with another chemical that is less harmful or a chemical that is better understood.
17

18 **Section 69305.4(a)(4)(B)** allows for product and manufacturing process redesign to reduce
19 the concentration of the Priority Chemical in the product or product component as the
20 goal/scope of the AA Work Plan. Under this option, the manufacturer may elect to redesign a
21 product to contain less of a Priority Chemical, change its manufacturing process, or upgrade
22 the facility to accommodate safer alternatives.
23

24 **Section 69305.4(a)(4)(C)** allows for product or component redesign, using a different material,
25 for example, glass or ceramic in place of plastic, to address the Priority Chemical in a product
26 as the goal/scope of the AA Work Plan. Under this option, the manufacturer may evaluate
27 manufacturing a product with a different material to address any Priority Chemical(s) inherent
28 in a material.
29

30 **Section 69305.3(c)(4)(D)** allows for other approaches intended to meet the intent and
31 objectives of article 5 and Health and Safety Code section 25253(a). This section is necessary
32 to allow for innovation and advancements toward approaches not currently available.
33

34 **Section 69305.4(a)(5)(A)1. through 7.** specify that the AA Work Plan contain a “Scope of Life
35 Cycle Segments” identifying which life cycle segments are anticipated to be evaluated and
36 compared for the product and all of the alternatives. The approach provides the manufacturer
37 latitude in determining which of the seven segments will be included and addressed but
38 requires that the manufacturer explain the rationale for including, or not, any of the seven
39 segments, also known as stages, in a product’s life cycle. The seven segments in a products
40 life cycle include: **1.** raw materials mining, **2.** intermediary material processes, **3.** manufacturing
41 and packaging, **4.** distribution, transportation and marketing, **5.** use, **6.** product end-of-life, and

1 7. reuse and recycling. This provision is necessary to provide a manufacture the necessary
2 latitude in choosing the scope of the AA, while ensuring that the stages in a product's life cycle
3 are adequately addressed.
4

5 **Section 69305.4(a)(5)(B)** requires the AA Work Plan to explain the rationale for the omissions
6 of any life cycle segments, including an explanation of why an evaluation of the omitted life
7 cycle segment(s) is not necessary to comply with the requirements of Health and Safety Code
8 section 25253(a). The information requested through this provision is necessary for DTSC to
9 independently ascertain the validity of the assertions that are made.
10

11 **Section 69305.4(a)(6)** requires the AA Work Plan to include a section titled "Approach and
12 Methodology." This section must include the preparer's data-gathering approach for
13 addressing any data gaps related to the Priority Chemical. The manufacturer is allowed to use
14 existing data if it meets the objectives and scope of the AA Work Plan. The Tier II AA Work
15 Plan must also identify and briefly describe the approach and methodology that is anticipated
16 to be used for each major Tier II AA task, including, but not limited to the tasks indentified in
17 section 69305.5(a)(6)(A) through (a)(6)(F). These provisions are summarized below. The
18 approach and proposed methodology is a necessary component for an AA Work Plan to be
19 effective in carrying out the various deliverable and tasks and objectives. As such, these
20 elements are required to be included in the AA Work Plan that is submitted.
21

22 **Section 69305.4(a)(6)(A)** requires the AA Work Plan to identify and briefly describe the
23 approach and methodology that are anticipated to be used to identify the alternatives to be
24 evaluated.
25

26 **Section 69305.4(a)(6)(B)** requires the AA Work Plan to identify, and briefly describe the
27 approach and methodology that is anticipated to be used for determining which of the
28 Chemical Hazard Assessment, Exposure Potential Assessment, and Multimedia Life Cycle
29 Evaluation factors listed in section 69305.5 are pertinent to, and are anticipated to be used to
30 evaluate and compare, the product or product component and the alternatives.
31

32 **Section 69305.4(a)(6)(C)** requires the AA Work Plan to identify and briefly describe the
33 approach and methodology that are anticipated to be used for gathering and analyzing data
34 and other information.
35

36 **Section 69305.4(a)(6)(D)** requires the AA Work Plan to identify and briefly describe the
37 approach and methodology that are anticipated to be used for the data and information to
38 evaluate and compare the product or product component and all alternatives being considered.
39

1 **Section 69305.4(a)(6)(E)** requires the AA Work Plan to identify and briefly describe the
2 approach and methodology that are anticipated to be used for making the decision to select an
3 alternative or retain the Priority Product or component.
4

5 **Section 69305.4(a)(6)(F)** requires the AA Work Plan to identify and briefly describe the
6 approach and methodology that are anticipated to be used for preparing the AA Report.
7

8 **Section 69305.4(a)(7)** requires the AA Work Plan to include information on the “Schedule and
9 Deliverables”. The Tier II AA Work Plan must include a proposed schedule for completion of
10 each major Tier II AA task identified in the Tier II AA Work Plan. The schedule must specify
11 proposed dates for submitting information relating to any interim milestones and the proposed
12 completion dates for the Tier II-A and Tier II-B AA Reports pursuant to sections 69305.6
13 through 69305.8.
14

15 **Section 69305.4(b)(1)** requires DTSC, within 60 days of receiving the Tier II AA Work Plan, to
16 review the Tier II AA Work Plan for completeness and compliance with the requirements of this
17 section and issue a notice of its findings with either a notice of deficiency or notice of
18 completeness. The provisions of this section clarify the duration in which to expect a
19 determination from DTSC as to whether the AA Work Plan must be revised or can be
20 implement as submitted.
21

22 **Section 69305.4(b)(1)(A)** requires DTSC to issue a notice of deficiency if the AA Work Plan
23 fails to meet the requirements of section 69305.4.
24

25 **Section 69305.4(b)(1)(B)** requires DTSC to issue a notice of completeness if the AA Work
26 Plan meets the requirements of section 69305.4.
27

28 **Section 69305.4(b)(2)** requires DTSC in the notice of deficiency to specify the areas of
29 deficiency and a date, not to exceed 60 days from the date of the notice of deficiency, for
30 submitting the necessary information to complete the Tier II AA Work Plan. The person who
31 submitted the original Tier II AA Work Plan must submit a revised Tier II AA Work Plan within
32 the time specified and address the areas of deficiency.
33

34 **Section 69305.4(b)(3)** requires DTSC, within 60 days of receipt of the requested additional
35 information, to issue either a notice of completeness or a notice disapproving the Tier II AA
36 Work Plan. If the Tier II AA Work Plan is disapproved, DTSC must explain the basis for the
37 disapproval in the notice. A disapproved Tier II AA Work Plan is considered non-compliant
38 with the requirements of 69305(b)(2).
39

40 **Section 69305.4(b)(4)(A)** requires that if the Tier II AA Work Plan is determined to be
41 complete, DTSC must specify in the notice of completeness the dates for submitting the Tier II-

1 A AA and Tier II-B AA Reports. In assigning these due dates, DTSC is required to consider
2 the factors set out in sections Section 69305.5(b)(4)(A)1. and 2.

3
4 **Section 69305.4(b)(4)(A)1. and 2.** specify that in issuing due dates for the Tier II-A and Tier II-
5 B AA Reports, DTSC must take into account the complexity of the planned Tier II AA,
6 including, but not limited to, the scope of alternatives to be considered and the existence of
7 any applicable AAs available in the public domain and posted on DTSC's website that identify
8 one or more safer functionally equivalent and technologically and economically feasible
9 alternative(s).

10
11 **Section 69305.4(b)(4)(B)** requires that, except as provided in section 69305.2, the Tier II-A
12 and Tier II-B AA Reports must be submitted by the due dates specified in the notice of
13 completeness issued in accordance with section 69305.5(b)(4)(A). In addition, the Tier II-A
14 and Tier II-B AA Reports must be submitted simultaneously to DTSC and the verifying lead
15 assessor, if verification is required pursuant to section 69305.2(c)(3).

16
17 **Section 69305.4(b)(5)** requires all notices issued by DTSC pursuant to section 69305.5(b) to
18 be issued to the person who submitted the Tier II AA Work Plan, and a copy of the notice must
19 be sent by DTSC to all persons identified in the Tier II AA Work Plan pursuant to sections
20 69305.4(a)(1)(B) and 69305.4(a)(3).

21
22 **Section 69305.4(c)** specifies that if there is a significant change to the information contained in
23 an approved Tier II AA Work Plan, a notification must be provided to DTSC that identifies the
24 change(s) and briefly explains the rationale for the change(s).

25
26 **Section 69305.5. Tier II AA Evaluation and Comparison Process and Factors**

27 This section, in its entirety, is necessary to specify the Tier II AA contents, the evaluation and
28 comparison process for the product and potential alternatives, and factors to consider.

29
30 **Section 69305.5(a)(1)** specifies what must be included in a Tier II AA required pursuant to
31 section 69305(b). The Tier II AA is comprised of a Tier II-A and Tier II-B AA, which are
32 summarized below.

33
34 **Section 69305.5(a)(1)(A)** requires each Tier II-A AA to include a Chemical Hazard
35 Assessment and, except as provided in Section 69305.5(a)(2)(B), an Exposure Potential
36 Assessment. These two product evaluation and comparison processes are collectively
37 referred to as a Tier II-A AA.

38
39 **Section 69305.5(a)(1)(B)** requires a Multimedia Life Cycle Evaluation to be performed as part
40 of a Tier II AA. This is referred to as a Tier II-B AA.

41

1 **Section 69305.5(a)(2)(A)** requires a Chemical Hazard Assessment to be performed to
2 evaluate and compare the Priority Product and all alternatives initially identified for
3 consideration. This provision establishes the first assessment that must be conducted in
4 performing a Tier II AA.

5
6 **Section 69305.5(a)(2)(B)** specifies that following completion of a Chemical Hazard
7 Assessment evaluation and comparison, an Exposure Potential Assessment must be
8 performed to evaluate and compare the Priority Product and any alternative being considered
9 that contains a chemical that exhibits one or more hazard traits. An Exposure Potential
10 Assessment is not required if none of the alternatives being considered contain a chemical that
11 exhibits a hazard trait. This provision establishes the second assessment that must be carried
12 out in conducting and performing a Tier II-A AA.

13
14 **Section 69305.5(a)(2)(B)1.** requires the identification of hazard traits to be based on the
15 criteria developed by DTSC or OEHHA for determining when a chemical exhibits a hazard trait,
16 to the extent such criteria are made available by DTSC or OEHHA.

17
18 **Section 69305.5(a)(2)(B)2.** specifies that if relevant criteria have not yet been provided by
19 DTSC or OEHHA, reliable information must be used to determine if the chemical exhibits a
20 hazard trait.

21
22 **Section 69305.5(a)(2)(C)** specifies that the results of the Chemical Hazard Assessment or, if
23 applicable, the Exposure Potential Assessment, or both, may be used to screen out
24 alternatives before proceeding with the Multimedia Life Cycle Evaluation. At a minimum, an
25 alternative must be eliminated from further consideration if both section 69305.5(2)(C)1. and 2.
26 apply.

27
28 **Section 69305.5(a)(2)(C)1. and 2.** specify that an alternative must be eliminated from further
29 consideration if the person conducting the AA determines that: **1.** based on the Chemical
30 Hazard Assessment, potential exposures to the chemical in the alternative would pose a
31 greater threat of harm to public health or the environment than is posed by the Priority
32 Chemical in the Priority Product; and **2.** based on the Exposure Potential Assessment, that
33 there is the same or a greater potential for the public or the environment to be exposed to the
34 chemical in the alternative, than to be exposed to the Priority Chemical in the Priority Product,
35 during the product's useful life or end-of-life disposal or management. This provision provides
36 manufacturers and/or responsible entities flexibility in terminating the further evaluation or
37 consideration of an alternative if the alternative has proved to be worse than the Priority
38 Product or Priority Chemical that they are seeking to replace.

39
40 **Section 69305.5(a)(3)** requires the Priority Product or component and all alternatives being
41 considered to be evaluated and compared for the same set of life cycle segments, identified

1 pursuant to section 69305.5(a)(5)(A). The same methodologies, and a consistent set of
2 factors, must be used to evaluate and compare the Priority Product or component and all
3 alternatives being considered. In identifying the list of factors that will be used for this
4 evaluation and comparison, the person performing the Tier II AA must review the list of factors
5 specified in sections 60305.5(b) through (d) to determine which factors are pertinent to, and
6 will be used for, the evaluation and comparison. This provision requires that when a
7 manufacturer and/or responsible entity is evaluating alternatives for a Priority Product the
8 alternatives considered must be evaluated in the same depth and breadth so as not to make
9 decisions on varied data.

10
11 **Section 69305.5(b)** requires a “Chemical Hazard Assessment” to be conducted. The
12 minimum set of factors that to be reviewed to determine if they are pertinent for inclusion in the
13 Chemical Hazard Assessment Evaluation and comparison of the Priority Product or
14 component, and all alternatives being considered include the factors specified in sections
15 69305.6 (b)(1) through (4), which are summarized below. The factors contained in sections
16 69305.5(b)(1) through (b)(4) are essential in comparing the Priority Product and any
17 alternatives considered on an equal playing field so as not to presume one alternative is
18 advantageous over another.

19
20 **Section 69305.5(b)(1)** specifies that “Chemical Information” must be included and compared.
21 The chemical and physical properties to be considered, to the extent pertinent, for the Priority
22 Chemical contained in the Priority Product or component, and for any chemical that is being
23 considered as an alternative to the Priority Chemical, include, but are not limited to, those
24 properties listed in section 69302.3(a).

25
26 **Section 69305.5(b)(2)** specifies that “Public Health Impacts” must be included as part of the
27 chemical hazard assessment. Evaluation and comparison of public health impacts must
28 include, to the extent pertinent, consideration of impacts that may result from single,
29 intermittent or frequent use of, or contact with, the product, considering opportunities for
30 dermal, oral and inhalation exposures during product use or other stages in the life cycle of the
31 product. Factors to be considered, to the extent pertinent, include, but are not limited to, those
32 factors listed in section 69302.3(c). The information attained through this provision will allow
33 for a thorough assessment of the Priority Product or component and the alternatives being
34 considered so as to not trade one public health concern for another.

35
36 **Section 69305.5(b)(3)** specifies that “Ecological Impacts” must be included as part of the
37 chemical hazard assessment. Factors to be considered, to the extent pertinent, include, but
38 are not limited to, those factors listed in section 69302.3(e). The information attained through
39 this provision will allow for a thorough assessment of the Priority Product or component and
40 the alternatives being considered so as to not trade one ecological concern for another.

1 **Section 69305.5(b)(4)** specifies that “Chemical Traits Related to Environmental Impacts” must
2 be included in the chemical hazard assessment. Chemical traits to be considered, to the
3 extent pertinent, include, but are not limited to, those traits listed in section 69302.3(d)(1). The
4 information attained through this provision will allow for a thorough assessment of the Priority
5 Product or component and the alternatives being considered so as to not trade one
6 environmental concern for another.

7
8 **Section 69305.5(c)** requires an “Exposure Potential Assessment” to be conducted. The
9 minimum set of factors that must be reviewed to determine if they are pertinent for inclusion in
10 the Exposure Potential Assessment evaluation and comparison of the Priority Product or
11 component and all alternatives that are still under consideration following completion of the
12 Chemical Hazard Assessment include those factors specified in sections 69305.6(c)(1)
13 through (c)(4). The factors contained in sections 69305.5(c)(1) through (c)(4) are essential in
14 comparing the Priority Product and any alternatives considered on an equal playing field so as
15 not to presume one alternative is advantageous over another.

16
17 **Section 69305.5(c)(1)** requires the Exposure Potential Assessment to include an “Exposure
18 Limitations” evaluation. Factors to be considered, to the extent pertinent, in evaluating the
19 potential for the public or the environment to be exposed to the chemical that is contained in
20 the product during the product’s useful life and end-of-life disposal or management include, but
21 are not limited to, those factors listed in section 69303.3(b).

22
23 **Section 69305.5(c)(2)** requires the Exposure Potential Assessment to include a “Chemical
24 Quantity Information” evaluation. The chemical quantity Information must include those
25 specified in sections 69305.6(c)(2)(A) through (c)(2)(E), which are summarized below.

26
27 **Sections 69305.5(c)(2)(A)** specifies that the quantities of the Priority Chemical or alternative
28 chemical necessary to manufacture the Priority Product or component, or alternative, must be
29 included and evaluated.

30
31 **Sections 69305.5(c)(2)(B)** specifies that the concentration of the Priority Chemical in the
32 Priority Product or component and the corresponding concentration of any chemical
33 substitution must be included and evaluated.

34
35 **Sections 69305.5(c)(2)(C)** specifies that the volume or mass, or both, of the Priority Chemical
36 in the Priority Product or component and the corresponding volume or mass, or both, of any
37 potential chemical substitution must be included and evaluated.

38
39 **Sections 69305.5(c)(2)(D)** specifies that an extrapolation of the data identified in section
40 69305.5(c)(2)(A) through (C) to estimate the volume and/or mass of the Priority Chemical or

1 substitute chemical in commerce as a result of the product or product component must be
2 included and evaluated.

3
4 **Sections 69305.5(c)(2)(E)** specifies that the dispersive volume information, as it relates to the
5 volume of the chemical made available in commerce in California must be included and
6 evaluated. The evaluation may include but is not limited to: **1.** projected or actual sales; **2.**
7 regional distribution volumes, and **3.** marketing and customer targeted volumes.

8
9 **Section 69305.5(c)(3)** specifies that “Consumer Uses” must be included in the Exposure
10 Potential Assessment. Factors to be considered, to the extent pertinent, in evaluating the
11 types and extent of consumer uses that could result in public exposure to the chemical that is
12 contained in the product, and could result in adverse public health impacts, include but are not
13 limited to those factors listed in section 69303.3(c).

14
15 **Section 69305.5(c)(4)** specifies that “Environmental Releases” must be included in the
16 Exposure Potential Assessment. Factors to be considered, to the extent pertinent, in
17 evaluating product uses or management or disposal practices that could lead to releases to the
18 environment of the chemical that is contained in the product, and result in adverse
19 environmental impacts, include, but are not limited to, those factors listed in section
20 69303.3(d), which include use, storage, transportation and end-of-life management practices
21 and locations and potential for release into, migration from or distribution across environmental
22 media, and potential for accumulation or persistence in biological or environmental
23 compartments or systems of the chemical or its degradation products.

24
25 **Section 69305.5(d)** requires a Multimedia Life Cycle Evaluation to be conducted, and
26 specifies the minimum set of factors that must be reviewed to determine if they are pertinent
27 for inclusion in the Multimedia Life Cycle Evaluation comparison and evaluation of the Priority
28 Product or component and all alternatives that are still under consideration following
29 completion of the Chemical Hazard Assessment and, if applicable, the Exposure Potential
30 Assessment. The factors specified in sections 69305.5(d)(1) through (d)(4) are essential in
31 comparing the Priority Product and any alternatives considered on an equal playing field so as
32 not to presume one alternative is advantageous over another.

33
34 **Section 69305.5(d)(1)** requires the Multimedia Life Cycle Evaluation to include a “Product
35 Function and Performance” evaluation.

36
37 **Section 69305.5(d)(1)(A)** specifies that the function and performance factors attributed to the
38 Priority Chemical in the Priority Product or component, and any essential function and
39 performance attributes that must be met by any potential alternatives, must be included in the
40 Multimedia Life Cycle Evaluation.

41

1 **Section 69305.5(d)(1)(B)** specifies that the useful life, expressed in single use or number of
2 applications, days, months or years, of the Priority Product or component, and that of the
3 potential alternatives must be included in the Multimedia Life Cycle Evaluation.
4

5 **Section 69305.5(d)(1)(C)** specifies that the functional equivalency of each alternative relative
6 to the Priority Product or component, must be included in the Multimedia Life Cycle Evaluation.
7

8 **Section 69305.5(d)(1)(D)** specifies that the technological and economic feasibility of each
9 alternative must be included in the Multimedia Life Cycle Evaluation.
10

11 **Section 69305.5(d)(2)** specifies that the Multimedia Life Cycle Evaluation must include a
12 “Materials and Resource Consumption Impacts” evaluation, which must include: **(A)** water
13 consumption and conservation; **(B)** production, in-use, and transportation energy inputs; **(C)**
14 energy consumption and efficiency; and **(D)** reusability and recyclability.
15

16 **Section 69305.5(d)(3)** specifies that the Multimedia Life Cycle Evaluation must include an
17 “Environmental Impacts” evaluation. Sections 69305.5 (d)(3)(A) through (d)(3)(E) prescribes
18 the information that must be collected on the Priority Chemical and the alternatives to address
19 any incremental changes to Air Impacts, Ecological Impacts, Waste and End of Life Impacts,
20 and Water Quality Impacts. The information required in each of the subcategories, specified
21 below, is necessary to make informed decisions about the alternatives in comparison to the
22 Priority Chemical.
23

24 **Section 69305.5(d)(3)(A)** specifies that the Multimedia Life Cycle Evaluation must include, to
25 the extent pertinent, an air quality impacts evaluation by collecting and assessing data
26 regarding adverse impacts associated with air emissions, including the air contaminants listed
27 in section 69302.3(d)(2).
28

29 **Section 69305.5(d)(3)(B)** specifies that the Multimedia Life Cycle Evaluation must include a
30 water quality impacts evaluation by collection assessing data to document regarding adverse
31 impacts associated water quality, including the factors listed in section 69302.3(d)(3).
32

33 **Section 69305.5(d)(3)(C)** specifies that the Multimedia Life Cycle Evaluation must include, to
34 the extent pertinent, a soil quality impacts evaluation by collecting and assessing data
35 regarding adverse impacts associated with soil quality, including the factors listed in section
36 69302.3(d)(4).
37

38 **Section 69305.5(d)(3)(D)** specifies that the Multimedia Life Cycle Evaluation must include a
39 waste and end-of-life impacts evaluation by collecting and assessing data regarding any
40 incremental change in the amount of waste generated during manufacturing, and end-of-life of
41 the product. This includes adverse impacts associated with the amount of waste and

1 byproducts generated, and any special handling required for the waste and byproducts, during
2 the life cycle of the Priority Product and each alternative being considered. This also includes
3 an assessment of disposal, treatment or use of waste and byproducts, including solid waste,
4 wastewater and storm water discharge streams.
5

6 **Section 69305.5(d)(3)(E)** specifies that the Multimedia Life Cycle Evaluation must include
7 other environmental impacts not directly addressed through sections 69305.5(d)(3)(A) through
8 (d)(3)(D), such as release of heat, odor, or radiation.
9

10 **Section 69305.5(d)(4)** specifies that the Multimedia Life Cycle Evaluation must include a an
11 assessment of economic impacts associated with the Priority Product and any alternative
12 being considered. This includes any increase or decrease in jobs or businesses, of doing
13 business, and the costs of goods to consumers. Evaluation and comparison of economic
14 impacts must take into account both internalized and externalized costs during the life cycle of
15 the Priority Product or product component and all alternatives being considered, and shall
16 include an evaluation of the range of projected costs. Evaluation and comparison of
17 externalized costs must include costs to government agencies, the public, businesses, and
18 consumers.
19

20 **Section 69305.5(d)(4)(A)** specifies that the economic impacts assessment must include a
21 capital investment evaluation related to the Priority Chemical and any alternatives being
22 considered. Capital investment means the purchases of property, plant and equipment related
23 to the Priority Chemical or any of the alternatives being considered.
24

25 **Section 69305.5(d)(4)(B)** specifies that the economic impacts assessment must include a
26 cost for resources evaluation related to the Priority Chemical and any of the alternatives being
27 considered. Cost for resources includes people, equipment, facilities, funding, or anything else
28 required for the manufacturing of the Priority Product or component.
29

30 **Section 69305.5(d)(4)(C)** specifies that the economic impacts assessment must include an
31 energy costs evaluation related to the Priority Chemical and any of the alternatives being
32 considered. Energy costs includes the costs to produce, transmit and/or consume renewable
33 and non-renewable energy such as gas, oil, wind, solar, electrical, thermal, etc.
34

35 **Section 69305.5(d)(4)(D)** specifies that the economic impacts assessment must include a
36 non-compliance liability evaluation related to the Priority Chemical and any of the alternatives
37 being considered. Non-compliance liability includes the costs of doing business such as
38 preparation of the Tier II AA Work Plan and AA Reports, compliance with existing regulatory
39 and administrative requirements.
40

1 **Section 69305.5(d)(4)(E)** specifies that the economic impacts assessment must include an
2 operations and maintenance costs evaluation related to the Priority Chemical and any of the
3 alternatives being considered. Operation and maintenance costs include: insurance, regular
4 maintenance, repair, parts, and administration.

5
6 **Section 69305.5(d)(4)(F)** specifies that the economic impacts assessment must include a
7 waste disposal and treatment costs evaluation related to the Priority Chemical and any of the
8 alternatives considered must be described and included. Waste disposal costs include wastes
9 that are generated during the manufacturing of the Priority Product or any of its alternatives
10 and the costs to dispose of the Priority Product itself if it requires disposal at the end of life.
11 Treatment costs include: wastes that are generated and require treatment during the
12 manufacturing of the Priority Product or any of its alternatives and the costs the disposal of the
13 Priority Product itself if it requires disposal at the end of life.

14
15 **Section 69305.5(d)(4)(G)** specifies that the economic impacts assessment must include
16 evaluation of any other relevant financial investments or liabilities not listed above.

17
18 **Section 69305.5(e)** specifies that the requirement to evaluate the Priority Product, or
19 component, and all alternatives for the factors listed in sections 69305.6(d)(1) through (d)(3)
20 may be fulfilled by completing an ISO 14040, or equivalent, life cycle assessment.

21 22 **Section 69305.6. Tier II Alternatives Assessment Reports**

23 This section, in its entirety, is necessary to specify the requirements for Tier II AA Reports that
24 are submitted to DTSC.

25
26 **Section 69305.6(a)** requires the Tier II-A and Tier II-B AAs to be completed and the respective
27 AA Reports to be completed and submitted to DTSC by the dates specified in section
28 69305.4(b)(4), unless an extension has been requested and approved pursuant to section
29 69305.2(b).

30
31 **Section 69305.6(b)** requires that the Tier II-A and the Tier II-B AA Reports must include all of
32 the information specified in sections 69305.6(b)(1) through (b)(9), which are summarized
33 below.

34
35 **Section 69305.6(b)(1)** specifies that the Tier II Report must include the Preparer Information
36 specified in section 69305.7(b)(1)(A) through (b)(1)(C), which is summarized below.

37
38 **Section 69305.6(b)(1)(A)** specifies that the name of and contact information for the person
39 submitting the Report must be included in the Tier II AA Report.

1 **Section 69305.6(b)(1)(B)** specifies that, if applicable, the name of and contact information for
2 all persons on whose behalf that the Report is being submitted and their relationship to the
3 person identified in section 69305.7(b)(1)(A) must be included in the Tier II AA Report.
4

5 **Section 69305.6(b)(1)(C)** requires that the names of the parties that were involved in funding,
6 directing, overseeing, preparing or reviewing the Tier II AA be provided in the Tier II AA Report
7 be included in the Report. Any organizations and individuals that provided expert guidance or
8 review for the Tier II AA, including the name of, and qualifications and accreditation information
9 for, the person(s) in charge under whose direction the Tier II AA was conducted and the
10 Report was prepared are also required to be included.
11

12 **Section 69305.6(b)(2)** requires the Tier II AA Report to include a section titled “Acronyms” in
13 the report. An acronym list for the Report must be included to clarify the meanings of
14 abbreviated words.
15

16 **Section 69305.6(b)(3)** requires the Tier II AA Report to include a section titled “Manufacturer
17 Information”. Name and physical headquarters location of the manufacturer must be provided.
18 If the Tier II Report is prepared on behalf of a consortium of manufacturers or other persons in
19 the product’s supply chain, a list of the participants must be provided as well as their
20 corresponding contact information.
21

22 **Section 69305.6(b)(4)** requires the Tier II AA Report to contain a section titled “Facility
23 Description and Location.” A description and location of the facility(ies) where the Priority
24 Product or component is produced must be included. This description must also indicate the
25 proximity to raw or recycled materials that directly or indirectly influences the type and amount
26 of Priority Chemical contained in the Priority Product or component.
27

28 **Section 69305.6(b)(5)** requires the Tier II AA Report to include a section titled “Product
29 Information.” It must include information identifying and describing the Priority Product or
30 component that is the subject of the AA Report, including all of the information specified in
31 sections 69305.6(b)(5)(A) through (b)(5)(C), which are summarized below.
32

33 **Section 69305.6(b)(5)(A) through (b)(5)(C)** specifies that **(A)** the brand name(s) under which
34 the product is placed into the stream of commerce in California must be provided in the AA
35 Report. **(B)** If applicable, the Tier II Report must include the Priority Product component(s) that
36 are the focus of the Tier II AA, and **(C)** identification of the Priority Chemical(s) that are the
37 basis for the product being listed as a Priority Product and any other Priority Chemical(s) that
38 are, or reasonably should be, known to be in the Priority Product. The Tier II AA must, at a
39 minimum, focus on the product component(s) specified for the product in the Priority Products
40 List, but may be expanded to include additional product components or the entire product.
41

1 **Section 69305.6(b)(6)** requires the Tier II AA Report to contain a section titled “Supply Chain
2 Information.” The information applicable to the product that is, or should reasonably be, known
3 to the preparer of the Report that is specified in section 69305.6(b)(6)(A) through (D) must be
4 included. Those provisions are summarized below.
5

6 **Section 69305.6(b)(6)(A) through (b)(6)(D)** requires the Tier II AA Report to include: **(A)** the
7 name of, and contact information for, the person identified on the product label as the
8 manufacturer, and the person, if any, identified as the distributor; **(B)** the name of, and contact
9 information for, the producer of the product; **(C)** the name of, and contact information for, all
10 responsible entities for the product; and **(D)** the name of, and contact information for, any other
11 person in the supply chain for the product.
12

13 **Section 69305.6(b)(7)** requires the Tier II AA Report to include supporting Information for all
14 reference materials, studies, data and other information used as supporting information in
15 performance of the Tier II AA and preparation of the Tier II AA Report. The AA Report must
16 include a summary of the information reviewed and considered pursuant to section 69305.2(e)
17

18 **Section 69305.6(b)(8)** requires the Tier II AA Report to include an executive summary,
19 meeting the requirements of section 69305.9.
20

21 **Section 69305.6(b)(9)** requires the Tier II AA Report to include verification information. If an
22 AA verification statement is required pursuant to section 69305.2(c)(3), the AA Report must
23 include the information specified in sections 69305.6(b)(9)(A) through (C), which are
24 summarized below.
25

26 **Section 69305.6(b)(9)(A)** requires the identification and qualification information for the
27 verifying lead assessor and the qualified third-party assessment entity that employs the
28 verifying lead assessor to be provided with the Tier II AA Report.
29

30 **Section 69305.6(b)(9)(B)** specifies that a copy of the contractual agreement between the
31 preparer of the AA Report and the verifying lead assessor must be included with the Tier IIAA
32 Report.
33

34 **Section 69305.6(b)(9)(C)** specifies that the date by which the lead assessor’s AA verification
35 statement will be provided to DTSC, which must be not later than ninety (90) days after
36 submittal of the Tier II-A or Tier II-B AA Report, whichever is applicable.
37

38 **Section 69305.7. Tier II-A Alternatives Assessment Reports.**

39 This section, in its entirety, is necessary to specify that in addition to the information specified
40 in section 69305.6(b), the Tier II-A AA Report must also include all of the following specified in
41 section 69305.7(a) through (f), which are summarized below.

1
2 **Section 69305.7(a)** requires the Tier II-A AA Report to include a section titled “AA Goal and
3 Scope of Alternatives.” In this section, the AA Report must identify and briefly describe the
4 alternative(s) chosen to be evaluated and compared in the Tier II-A AA, and the rationale for
5 selecting these alternatives. If the scope of alternative types considered differs from the
6 anticipated scope identified in the AA Work Plan, the Report must note and explain the reason
7 for the change.

8
9 **Section 69305.7(b)** requires the Tier II-A AA Report to contain a section titled “Scope of Life
10 Cycle Segments”. The AA Report must identify which life cycle segments were chosen for
11 evaluation and comparison in the Tier II-A AA for the product and all alternatives. If not all life
12 cycle segments listed in section 69305.4(a)(5)(A) have been or will be evaluated and
13 compared, the AA Report must explain the rationale for the omissions, including an
14 explanation of why an evaluation of the omitted life cycle segments is not necessary to comply
15 with the requirements of Health and Safety Code section 25253(a).

16
17 **Section 69305.7(c)** requires the Tier II-A AA Report to contain a section titled “Approach and
18 Methodology for the Chemical Hazard Assessment and Exposure Potential Assessment (Tier
19 II-A AA)”. The AA Report must identify and describe the assessment tools, models, or
20 software used to conduct the Chemical Hazard Assessment and, if applicable, the Exposure
21 Potential Assessment, and discuss any limitations of these tools, models and software. The
22 AA Report must also identify any published methodologies or guidelines used, and any
23 deviations taken from the published methodologies or guidelines. The AA Report must also
24 identify, and briefly describe the approach and methodology used for each major Tier II-A AA
25 task, including as applicable, but not limited to, the tasks listed in section 69305.4(a)(6).

26
27 **Section 69305.7(d)** requires the Tier II-A AA Report to include a section titled “Chemical
28 Hazard Assessment.” The Report must include all of the information specified in Section
29 69305.7(d)(1) through (d)(3), which are summarized below.

30
31 **Section 69305.7(d)(1)** requires the Tier II-A AA Report to identify the factors listed in section
32 69305.5(b) that were used to evaluate and compare the Priority Product, or component, and all
33 alternatives considered, and the rationale for the selection of the evaluation and comparison
34 factors.

35
36 **Section 69305.7(d)(2)** requires the Tier II-A AA Report to include a comparative matrix, or
37 other format that provides the reviewer with an easily understood visual comparison, organized
38 in conformance with section 69305.5(b) that presents the information specified in section
39 69305.7(d)(2)(A) and (B).

40

1 **Section 69305.7(d)(2)(A)** requires the Tier II AA Report to present the data collected for each
2 factor evaluated and compared in the Chemical Hazard Assessment.

3
4 **Section 69305.7(d)(2)(B)** specifies that the Tier II AA Report must present comparative results
5 of the evaluation of the data presented in section 69305.7(d)(2)(A).

6
7 **Section 69305.7(d)(3)** requires the Tier II-A AA Report to include data relied on for any
8 determination that one or more alternatives being considered do not exhibit a hazard trait.
9 This information is not required for any alternative that will be evaluated using an Exposure
10 Potential Assessment.

11
12 **Section 69305.7(e)** requires the Tier II-A AA Report to include a section titled “Exposure
13 Potential Assessment.” If an Exposure Potential Assessment is required pursuant to section
14 69305.6(a)(2)(B), the report must include all of the information for the Exposure Potential
15 Assessment in sections 69305.7(e)(1) and (e)(2).

16
17 **Section 69305.7(e)(1)** specifies that the Tier II-A AA Report must identify the factors listed in
18 section 69305.5(c) that were used to evaluate and compare the Priority Product or component
19 and all alternatives considered, and the rationale for the selection of the evaluation and
20 comparison factors.

21
22 **Section 69305.7(e)(2)** specifies that the Tier II-A AA Report must include a comparative
23 matrix, or other format that provides the reviewer with an easily understood visual comparison,
24 organized in conformance with section 69305.5(c) that presents the information specified in
25 section 69305.7(e)(2)(A) and (B).

26
27 **Section 69305.7(e)(2)(A)** specifies that the Tier II AA Report must present the data collected
28 for each factor evaluated and compared in the Exposure Potential Assessment.

29
30 **Section 69305.7(e)(2)(B)** specifies that the Tier II AA Report must present comparative results
31 of the evaluation of the data presented in section 69305.7(e)(2)(A).

32
33 **Section 69305.7(f)** requires the Tier II-A AA Report to include a section titled “Adjustments to
34 the Tier II-B AA Work Plan.”

35
36 **Section 69305.7(f)(1)** specifies that the Tier II-A AA Report must include any adjustments to
37 the goal and scope of the alternatives assessment that will be evaluated and compared in the
38 Multimedia Life Cycle Evaluation (Tier II-B AA), based on the results of the Chemical Hazard
39 Assessment and, if applicable, the Exposure Potential Assessment, and the rationale for any
40 adjustments.

1 **Section 69305.7(f)(2)** specifies that the Tier II-A AA Report must include any adjustments to
2 the scope of the life cycle segments that will be considered in the multimedia life cycle
3 evaluation, based on the results of the Chemical Hazard Assessment and, if applicable, the
4 Exposure Potential Assessment, and the rationale for any adjustments.

5
6 **Section 69305.7(f)(3)** specifies that the Tier II-A AA Report must include any other changes to
7 the AA Work Plan for the Multimedia Life Cycle Evaluation, and the rationale for any changes.

8 9 **Section 69305.8. Tier II-B Alternatives Assessment Reports**

10 This section, in its entirety, is necessary to specify that in addition to the information specified
11 in section 69305.6(b), the Tier II-B AA Report must include the information specified in
12 sections 69305.8 (a) through (h), which are summarized below.

13
14 **Section 69305.8(a)** requires the Tier II-B AA Report to identify and explain any changes made
15 to the information submitted in the Tier II-A AA Report.

16
17 **Section 69305.8(b)** requires the Tier II-B AA Report to include a section titled “AA Goal and
18 Scope of Alternatives ” The Tier II-B AA Report must identify and describe the alternatives
19 chosen to be evaluated and compared in the Tier II-B AA, and the rationale for selecting these
20 alternatives. If the scope of alternatives considered differs from the anticipated scope
21 identified in the Tier II AA Work Plan and the Tier II-A AA Report the Tier II-B AA Report must
22 note and explain the reason for any changes.

23
24 **Section 69305.8(c)** requires the Tier II-B AA Report to include a section titled “Scope of Life
25 Cycle Segments. The Tier II-B AA Report must identify which life cycle segments were chosen
26 for evaluation and comparison for the product and all alternatives. If not all life cycle segments
27 listed in section 69305.4(a)(5) were evaluated and compared, the Tier II-B AA Report must
28 explain the rationale for the omissions, including an explanation of why an evaluation of the
29 omitted life cycle segments is not necessary to comply with the requirements of Health and
30 Safety Code section 25253(a). If the scope of life cycle segments considered differs from the
31 anticipated scope identified in the AA Work Plan, or differs from the life cycle segments
32 considered in the Tier II-A AA, the Tier II-B AA Report must note and explain the reason for
33 any changes.

34
35 **Section 69305.8(d)** requires the Tier II-B AA Report to include a section titled “Approach and
36 Methodology for the Multimedia Life Cycle Evaluation.” The Tier II-B AA Report must identify
37 and describe the assessment tools, models, or software used to conduct the Multimedia Life
38 Cycle Assessment, and discuss any limitations of these tools, models and software. The Tier
39 II-B AA Report must also identify any published methodologies or guidelines used, and any
40 deviations taken from the published methodologies or guidelines. The Tier II-B AA Report
41 must also identify, and briefly describe the approach and methodology used for each major

1 Tier II-B AA task, including as applicable, but not limited to, the tasks listed in section
2 69305.4(a)(6).

3
4 **Section 69305.8(e)** requires the Tier II-B AA Report to include a section titled “Multimedia Life
5 Cycle Evaluation,” and contain the information specified in sections 69305.8(e)(1) and (e)(2).

6
7 **Section 69305.8(e)(1)** requires the Tier II-B AA Report to identify the factors listed in section
8 69305.6(d) that were used to evaluate and compare the Priority Product, or component, and all
9 alternatives considered, and the rationale for the selection of those factors.

10
11 **Section 69305.8(e)(2)** requires the Tier II-A AA Report to include a comparative matrix, or
12 other format that provides the reviewer with an easily understood visual comparison, organized
13 in conformance with section 69305.5(d).

14
15 **Section 69305.8(e)(2)(A)** requires the Tier II AA Report to present the data collected for each
16 factor evaluated and compared in the Exposure Potential Assessment.

17
18 **Section 69305.8(e)(2)(B)** requires the Tier II AA Report to present comparative results of the
19 evaluation of the data presented in section 69305.8(e)(2)(A).

20
21 **Section 69305.8(f)** requires the Tier II-B AA Report to include a section titled “Selected
22 Alternative.” The Tier II-B AA Report must identify and describe the alternative, if any,
23 selected, and the rationale for the selection decision. This must include an assessment that
24 evaluates and compares the selected alternative against the Priority Product or component
25 and a detailed list and explanation of the reasons for the selection decision, or, alternatively,
26 for the decision not to select and implement an alternative to the Priority Product or
27 component, whichever is applicable. The Tier II-B AA Report must also include all of the
28 information specified in section 69305.8(f)(1) through (f)(3).

29
30 **Section 69305.8(f)(1)** requires the Tier II AA Report to provide the information specified in
31 section 69305.8(d)(1)(C) and (D) for the selected alternative. If no alternative is selected, the
32 information must be provided for each of the alternatives considered in the Tier II-B AA Report.

33
34 **Section 69305.8(f)(2)** requires the Tier II-B Report to demonstrate that the production, use
35 and disposal of the selected alternative, in conjunction with any regulatory response(s)
36 proposed pursuant to section 69305.5(h), will have no greater significant adverse impacts on
37 public health or the environment than the impacts associated with the Priority Product.

38
39 **Section 69305.8(f)(3)** requires the Tier II-B Report to include a list of all chemical ingredients
40 contained in the selected alternative and hazard trait information for any of those chemicals for
41 which hazard trait information has not already been provided to DTSC pursuant to Chapter 53.

1
2 **Section 69305.8(g)** requires the Tier II-B AA Report to include a section titled “Implementation
3 Plan.” A detailed plan, including key milestones and dates, for implementing the selected
4 alternative, if applicable, must be presented in the Tier II AA Report. The implementation plan
5 must include any steps necessary to ensure compliance with applicable federal, State or local
6 laws.

7
8 **Section 69305.8(h)** requires the Tier II-B AA Report to include a section titled “Proposed
9 Regulatory Responses.” The Tier II-B AA Report should identify regulatory response(s), if any,
10 that the person submitting the Report wishes to propose to best limit the exposure to, or
11 reduce the level of hazards posed by, any Priority Chemical that will be contained in the
12 selected alternative or that is contained in the Priority Product, if the decision resulting from the
13 Tier II AA is to retain the Priority Product.

14
15 **Section 69305.9. Tier II AA Report Executive Summary Required Contents**

16 **Section 69305.9(a)** is necessary to specify and require each Tier II-A and Tier II-B AA Report
17 to be accompanied by an executive summary. The executive summary, which DTSC must
18 post, in its entirety, on its website must be sufficient to convey to the public a general
19 understanding of the scope, goals and results of the Tier II-A AA or Tier II-B AA, whichever is
20 applicable, and allow a technically qualified person to make an independent assessment of the
21 findings presented in the AA Report.

22
23 **Section 69305.9(b)** is necessary to require the executive summary to be organized in
24 conformance with the organization of the Tier II-A or Tier II-B AA Report and to include, for
25 each section of the Report, a reiteration or detailed summary of the information presented in
26 the Report, but the preparer must not include in the executive summary any information
27 claimed as confidential under article 10.

28
29 **Section 69305.9(c)** is necessary to specify that if DTSC subsequently rejects a claim of
30 confidentiality, the preparer must, at DTSC’s request, submit a revised executive summary
31 within 30 days of the request to add any information for which a confidentiality claim is rejected
32 and which DTSC determines, and specifies in its request, must be included in the executive
33 summary.

34
35 **Section 69305.10. Department Review and Determination for Tier II AA Reports**

36 This section, in its entirety, is necessary to specify DTSC’s process for reviewing Tier II AA
37 Reports.

38
39 **Section 69305.10(a)** specifies that within sixty (60) days of receiving a Tier II-A or Tier II-B AA
40 Report and, if applicable, the AA verification statement for the AA Report, DTSC must review
41 the AA Report for completeness and compliance with the requirements of Health and Safety

1 Code section 25253(a) and article 5, and notify the person submitting the AA Report of DTSC's
2 finding. DTSC must notify the persons with either: **(1)** a notice of completeness, or **(2)** a notice
3 of deficiency.
4

5 **Section 69305.10(b)** requires DTSC to specify in any notice of deficiency the areas of
6 deficiency and the due date for submitting the necessary information to complete the AA
7 Report, which must be no later than ninety (90) days after the notice of deficiency is issued.
8

9 **Section 69305.10(b)(1)** requires the revised Tier II-A or Tier II-B AA Report to be submitted
10 within the time specified and to address all areas of deficiency. If requested, DTSC may, at its
11 discretion, approve a one-time extension not to exceed 60 days for submission of the revised
12 Tier II-A or Tier II-B AA Report to correct the deficiencies.
13

14 **Section 69305.10(b)(2)** specifies that within sixty (60) days of receipt of the requested
15 additional information, DTSC must notify the submitter of the information whether the
16 information submitted brings the AA Report into compliance with the requirements of Health
17 and Safety Code section 25253(a) and article 5, and either approve or disapprove the AA
18 Report for implementation.
19

20 **Section 69305.10(b)(3)** specifies that if DTSC again disapproves the AA Report, DTSC must
21 issue a second notice of deficiency and grant no more than 30 days for resubmission of the
22 requested information.
23

24 **Section 69305.10(b)(4)** specifies that if the submitter of the AA Report fails to adequately and
25 timely respond to two (2) notices of deficiency, the product must be placed on the Failure to
26 Comply List posted on DTSC's website pursuant to section 69301.4(f).
27

28 **Section 69305.10(c)** specifies that if the AA Report is determined to be complete, DTSC must
29 notify the person who submitted the Report of its determination.
30

31 **Section 69305.10(c)(1)** specifies that in the completeness determination notice, DTSC must
32 provide notice of DTSC's preliminary determination whether one or more of the regulatory
33 responses specified in sections 69306.3(e), 69306.4(b), 69306.5 or 69306.6 is required.
34

35 **Section 69305.10(c)(2)** specifies that if a regulatory response is required under section
36 69306.6, DTSC must specify the preliminary proposed due date for implementation of the
37 regulatory response.
38

39 **Section 69305.10(c)(3)** requires DTSC in assigning a deadline for completing a regulatory
40 response required by DTSC under section 69306.6, to consider the complexity of
41 implementing the regulatory response.

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Article 6. Regulatory Responses

Article 6, in its entirety, is necessary to specify the regulatory responses regimen that implement Health and Safety Code section 25253(b) and that apply to a consumer product after it has undergone an alternatives assessment that meets the requirements of the Tier II AA process in article 5. This article is necessary to clarify, implement, and make specific the provisions of Health and Safety Code section 25253.

Section 69306. Applicability

Section 69306(a) specifies that except as otherwise provided in section 69306(b), the requirements of article 6 apply to an alternative selected pursuant to section 69305.8(h), that is subsequently placed into the stream of commerce in California. It further provides, that these requirements also apply, to the extent applicable, to the Priority Product or component if an alternative is not selected, or if the Priority Product or component will remain in commerce pending development and distribution of the alternative consumer product or component, whichever is applicable. This section is necessary to inform responsible entities and interested parties of the applicability of the regulatory responses.

Section 69306(b)(1) is necessary to specify that the requirements of article 6 do not apply to a product if the manufacturer submits to DTSC, prior to the due date for implementing any regulatory response that would otherwise apply to the product, a Chemical Removal Confirmation Notification or a Product Removal Confirmation Notification. This provision gives manufacturers the opportunity to elect to remove a product or chemical from commerce in lieu carrying out the applicable regulatory response(s).

Section 69306(b)(2) is necessary to require a Chemical Removal Confirmation Notification that is submitted pursuant to section 69306(a)(1) to be accompanied by all of the following information: **(A)** the intended uses, and targeted customer base(s), for the product; **(B)** information explaining the rationale for and the factors considered in the decision to remove the Chemical under Consideration and/or Priority Chemical from the product, without adding any other chemicals to the product; and **(C)** identification, and a qualitative or quantitative description, of any reduction to adverse public health or environmental impact achieved by removing the Chemical under Consideration and/or Priority Chemical from the product. The information required under this section is necessary for DTSC to independently assess the appropriateness of the assertions made.

Section 69306.1. AA Report Supplemental Information Requirements

This section provides that DTSC may at any time request any information supplementary to the AA Report that DTSC determines is necessary to determine and ensure implementation of one or more regulatory responses imposed pursuant to article 6. The information requested by

1 DTSC must be provided, within the time period specified by the DTSC, by the person who is
2 the responsible entity for the Priority Product or component that is the subject of the AA
3 Report.

4
5 This provision is necessary to accommodate AA Reports that are substantially complete but
6 that require critical pieces of information to allow for an informed regulatory response
7 determination without necessitating rejection of an AA Report in its entirety.

8 9 **Section 69306.2. No Regulatory Response Required**

10 Section 69306.2 specifies that no regulatory response will be required for a selected
11 alternative if the AA Report provides information that demonstrates all of the following to
12 DTSC's satisfaction:

- 13
14 (a) The selected alternative does not contain a Priority Chemical at a concentration
15 exceeding the de minimis exemption specified in section 69301.2(a)(24) or specified
16 by DTSC pursuant to section 69303.2(d), whichever is applicable. If DTSC has
17 determined that a de minimis exemption does not apply to a product or chemical, the
18 responsible entity must demonstrate in the AA Report that the alternative does not
19 contain a chemical that exhibits a hazard trait at or above the detectable levels.
20
21 (b) The selected alternative does not present a significant threat to public health or the
22 environment.
23
24 (c) The Priority Product, which was the subject of the AA Report, will be completely
25 phased out, and recalled from commerce in California within three (3) years of the
26 date the AA Report is submitted to DTSC. This provision allows a responsible entity
27 up to 3 years to exhaust the existing inventory of a product for which an alternative
28 has been identified.

29
30 This section is necessary to clearly specify those circumstances under a regulatory response
31 is not needed to fulfill the requirements and intent of Chapter 53 and the authorizing statutes.

32 33 **Section 69306.3. Product Information for Consumers**

34 **Section 69306.3(a)** requires that the responsible entity make available the information
35 specified in sections 69306.3(a)(1) through 69306.3(a)(6) to consumers when the selected
36 alternative contains a Priority Chemical at levels that exceed the de minimis exemption level
37 specified in section 69301.2(a)(24), or the manufacturer does not select an alternative for a
38 Priority Product or component after the AA Report has been completed. This section is
39 necessary to provide retailers and consumers with the necessary information to make informed
40 purchasing decisions and project use and management for products that contain a Priority
41 Chemical. Informed decisions by consumers will help to drive the market to safer alternatives.

1
2 **Section 69306.3(a)(1)** requires that the manufacturer's name be made available. The
3 information specified is necessary to ensure that contact information is provided should
4 additional information be needed.

5
6 **Section 69306.3(a)(2)** requires identification of the brand name and description of the product.
7 This provision is necessary so that consumers know which product the information pertains to,
8 and to enable consumers to look up additional information about the product on the
9 manufacturer's website.

10
11 **Section 69306.3(a)(3)** requires that a list of the Priority Chemical(s) contained in the product
12 be provided. This provision is necessary to inform retailers and consumers of the necessary
13 information to make informed purchasing decisions for products that contain a Priority
14 Chemical.

15
16 **Section 69306.3(a)(4)** requires identification of any sensitive subpopulations should avoid
17 contact with or other exposure to the product. In some cases a particular subpopulation is
18 particularly vulnerable to Priority Chemical. For products containing such chemicals, the
19 product information must identify those subpopulations and provide the necessary information
20 about avoiding or limiting exposure to the product.

21
22 **Section 69306.3(a)(5)** requires identification of safe handling procedures needed to protect
23 public health or the environment during the useful life of the consumer product and proper end-
24 of-life disposal or management.

25
26 **Section 69306.3(a)(6)** requires that the manufacturer's website address where the consumer
27 can obtain additional information about the product, the threats posed by the product, and
28 proper end-of-life disposal or management of the product.

29
30 **Section 69306.3(b)** allows the requirements of section 69306.3(a) to be satisfied by including
31 an information sheet in the product packaging, printing the required information on the product
32 packaging, printing the information in a prominent place in the product manual if a hard copy
33 manual is packaged with the product, or posting the information in a prominent place at the
34 point of sale for products that are not packaged. This provision is necessary because not all
35 products will be of a size to be labeled or to contain packaging material.

36
37 **Section 69306.3(c)(1)** specifies that in addition to the requirements of sections 69306.3(a) and
38 69306.3 (b), whenever not precluded by the type or size of the product, a product subject to
39 section 69306.3(a) must be permanently marked or labeled with all of the information specified
40 in sections 69306.3(c)(1)(A) through 69306.3(c)(6)(F), summarized below, in a manner that is
41 easily seen, legible, and understandable to the consumer. This provision is necessary to

1 ensure that products that require special handling during use or end of life management are
2 properly marked so that the consumer can readily identify those products and properly manage
3 those products. The information required to be permanently marked or labeled on the product
4 include the following:

- 5
- 6 (A) The manufacturer's name,
 - 7 (B) Brand name of the product,
 - 8 (C) A statement that the product contains a Priority Chemical,
 - 9 (D) Any safe handling procedures needed to protect public health or the environment
10 during the useful life of the product and proper end-of-life disposal or management,
 - 11 (E) Identification of any end-of-life take back program for the product, and
 - 12 (F) The manufacturer's website address where the consumer can obtain additional
13 information about the product, the threats posed by the product, and proper end-of-life
14 disposal or management of the product.
- 15

16 The provisions in section 693063(c)(1)(A) through 69306.3(c)(1)(F) are necessary to ensure
17 that that responsible entities take into account the most practical and user friendly approach to
18 inform consumers about products that contain a Priority Chemical.

19

20 **Section 69306.3(c)(2)** specifies that if the size of the product precludes marking or labeling the
21 product with all of the information listed in section 69306.3(c)(1), the product must be marked
22 or labeled with as much of this information as the size of the product permits. This provision in
23 is necessary to ensure that that responsible entities take into account the most practical
24 approach to inform consumers about products that contain a Priority Chemical.

25

26 **Section 69306.3(d)** specifies that a responsible entity who has a product or component
27 subject to the labeling requirements of section 69306.3(a) through (c) must ensure that these
28 requirements are fully implemented for that product or component no later than twelve (12)
29 months after the applicable Tier II-B AA Report is submitted to DTSC. DTSC believes that the
30 12 month deadline for implementing this regulatory response is adequate and provides the
31 necessary amount of time to ensure that responsible entities do not unnecessarily delay taking
32 appropriate action.

33

34 **Section 69306.3(e)(1)** specifies that, except as provided in section 69306.2, the requirements
35 of sections 69306.3(a) through (c) also apply to a selected alternative when DTSC makes one
36 or more determinations specified below, and notifies the responsible entity and the
37 manufacturer of that determination:

- 38
- 39 (A) The information will promote significantly safer use, and the public health and
40 environmental threats posed by use of the product can be significantly mitigated by

1 providing the labeling information specified in sections 69306.3(a) through (c) to the
2 consumer,

3
4 **(B)** Product stewardship is necessary to mitigate adverse end-of-life impacts, or

5
6 **(C)** End-of-life reclamation of the product is necessary to conserve resources and mitigate
7 long term environmental damage as a result of ongoing virgin material extraction. This
8 provision is necessary to gradually make a move towards a more sustainable economy
9 that reuses existing and outdated products as feed stocks for the manufacturing of new
10 products.

11
12 **Section 69306.3 (e)(2)** specifies that a responsible entity for a product or component subject
13 to the requirements of section 69306.3(e) must fully comply with the requirements for that
14 product or component no later than twelve (12) months after being notified by DTSC of its
15 determination pursuant to section 69306.8(b), that the responsible entity's product or
16 component is subject to the requirements. Twelve (12) months is sufficient time to allow a
17 responsible entity to comply with the information dissemination requirements.

18 19 **Section 69306.4. End-of-Life Management Requirements**

20 This section, in its entirety, provides the criteria and management standards that apply to a
21 product that must be managed at the end of its useful life. The requirements of this section
22 apply to products that are required to be managed as hazardous waste at the end-of-life. The
23 requirements of this section, in their entirety, are necessary to build on the regulatory
24 requirements for products that must be handled as hazardous wastes at the end of their useful
25 life or that require management because of the use of raw materials that necessitate recovery
26 to lessen the impact to the environment.

27
28 Existing hazardous waste regulations do not apply to products that contain hazardous
29 materials at levels high enough to be regulated as hazardous wastes until the product reaches
30 the end of its useful life. Many of these products do not have end-of-life management
31 requirements in place and, thus, place a hardship on local and state governments and
32 ultimately taxpayers. Existing laws place the burden on government and taxpayers to manage
33 these products at the end of their useful lives. Given that products vary as will the Priority
34 Chemicals that they contain, the product stewardship plan that is developed must be on a
35 case-by-case basis and must take into account regional and demographic issues.

36
37 A study³ conducted through a grant from the California Department of Resources Recycling
38 and Recovery, concluded that approximately 50% of households that use batteries and

³ San Gabriel Valley Council of Governments, Household Battery and CFL Take Back Program, Telephone Survey Report, April 2010.

1 compact fluorescent light (CFL) bulbs dispose of them in the trash. Although the majority,
2 59%, of the respondents were aware that household batteries were considered hazardous
3 wastes only 3% handled them by taking them to a collection facility. The overwhelming
4 majority, 56%, disposed of them in the trash. Similarly 45% of households that use CFLs and
5 know they are hazardous wastes, disposed of them in the trash. Over a third of respondents,
6 37%, cited not knowing where to take the batteries or the CLF as the primary reason for not
7 disposing of them properly. This study illustrates the need for well thought out and
8 comprehensive take back programs that manage products at the end of life so that the
9 consumer outreach efforts are not left to state and local government.

10
11 Products that contain a Priority Chemical and have longer life spans, than the manufacturer or
12 responsible entity, should be well accounted for and a product stewardship organization that
13 collects and administers the program should be established when the products are
14 manufactured and distributed for use in California.

15
16 The requirements contained in section 69306.4(a)(2)(A) through 69306.4(a)(2)(F) establish the
17 product stewardship program that must be taken into account by manufacturers and
18 responsible entities who produce products that require end-of-life management. These
19 provisions are consistent with guidance recommendations proposed by the Association of
20 State and Territorial Solid Waste Officials (ASTSWMO), the California Department of
21 Resources, Recycling and Recovery, and the California Product Stewardship Council.

22
23 These provisions are meant to address not only the environmental impact of products but also
24 the fiscal impacts on local and state government. These provisions provide a comprehensive,
25 yet flexible method for managing products that have significant impacts on the environment.
26 The primary purpose of a product stewardship framework is to establish a consistent and
27 reliable process for identifying and selecting products over time that must be managed under a
28 product stewardship plan.

29
30 **Section 69306.4(a)** requires a responsible entity of a selected alternative or a Priority Product
31 or component for which the responsible entity does not select an alternative, which is required
32 to be managed as a hazardous waste at the end of its useful life to comply with the information
33 dissemination requirements in section 69306.4(a)(1) and establish, maintain and fund a take
34 back program pursuant to section 69306.4(a)(2). This provision is necessary to address
35 existing gaps in the law which place the burden of managing products that require end-of-life
36 management as hazardous waste on State and local governments, and, ultimately, on
37 taxpayers. By requiring an end-of-life management structure for these products, the ultimate
38 burden on consumers or taxpayers is significantly lessened because there is a systematic and
39 cohesive approach for collection of the products.

1 **Section 69306.4(a)(1)** requires that the responsible entity comply with the consumer product
2 information requirements specified in section 69306.3. In addition, the product information
3 must state that the product or component must be disposed of or otherwise managed as a
4 hazardous waste at the end of its useful life. The information requirements specified in this
5 provision are necessary to ensure consumers are aware of the requirements for end-of-life
6 management of the product.

7
8 **Section 69306.4(a)(2)** requires that the responsible entity, no later than two (2) years after
9 submitting the Tier II-B AA Report for the product to DTSC, establish, maintain and fund end-
10 of-life management programs, which comply with sections 69306.4(1)(2)(A) through (1)(2)(F),
11 summarized in the paragraphs below. Twelve (12) months is sufficient time to allow a
12 responsible entity to comply with the information dissemination requirements and development
13 of a Product Stewardship Plan and an additional 12 months is necessary to put into place the
14 necessary infrastructure for the end-of-life management programs.

15
16 **Section 69306.4(a)(2)(A)** requires that the responsible entity to develop, maintain, and post on
17 its website, a comprehensive Product Stewardship Plan that includes all of the following: **1.** list
18 of participating manufacturers and if applicable responsible entities; **2.** the scope of products to
19 be covered by the plan; **3.** the roles and responsibilities for manufacturers, retailers,
20 consumers and government throughout the life cycle of the product; **4.** identification of
21 collection system information; **5.** end-of-life management, including what steps will be taken to
22 ensure environmentally-sound management; **6.** anticipated resources and a financing
23 mechanism to implement and sustain the plan; **7.** program performance measures; **8.** public
24 outreach and communications plan; **9.** public and interested party consultation activities in
25 preparation of the plan; and **10.** reporting and evaluation procedures. Product-specific
26 stewardship plans are a necessary component to provide retailers, consumers, collection
27 facilities and local government with the necessary information to ensure a successful end-of-
28 life collection plan.

29
30 **Section 69306.4(a)(2)(A)1.** requires the Product Stewardship Plan include a list of
31 participating manufacturers and, if applicable, participating responsible entities. This provision
32 is necessary to identify which manufacturers are operating under the Product Stewardship
33 Plan. Should it become advantageous to the manufacturers involved, DTSC may bring
34 together the various manufacturers and interested parties to develop well thought out and
35 comprehensive programs for seemingly similar products, thus saving resources to all parties
36 involved.

37
38 **Section 69306.4(a)(2)(A)2.** requires the Product Stewardship Plan include the scope of
39 products to be covered by the plan, which shall include those products specified in sections
40 69306.4(a)(2)(A)2a through 2d., summarized in the paragraphs below. This provision is
41 necessary to ensure that the products covered by the plan are well identified and known.

1
2 **Section 69306.4(a)(2)(A)2.a.** requires the Product Stewardship Plan include the brand name
3 and description of the selected alternative, or Priority Product or component, which is being
4 managed under the product stewardship plan. The provision further identifies the brand
5 names and description of the products covered under the Product Stewardship Plan.
6

7 **Section 69306.4(a)(2)(A)2.b.** requires the Product Stewardship Plan to identify similar existing
8 products on the market that are marketed under other brand names that may be inadvertently
9 recovered by implementation of the product stewardship plan. This provision is necessary
10 because many products on the market are similar to other products. The Product Stewardship
11 Plan must take into account the number of products that could potentially be inadvertently
12 covered by the plan. Not taking all of the products into account could compromise the success
13 of a Product Stewardship Plan. In addition, it may prove to be advantageous to partner with
14 the manufacturers of the other products to develop one plan to cover all products, each
15 manufacturer paying its fair share into the development and management of the plan.
16

17 **Section 69306.4(a)(2)(A)2.c.** requires the Product Stewardship Plan to identify legacy
18 products, including brand names if available, that are no longer actively marketed at the time
19 the product stewardship plan is implemented. Similar to the provision above, the product
20 Stewardship Plan must take into account the number of products that are legacy products that
21 have not been recovered but may be recovered once the plan is in place. Not taking these
22 products into account could compromise the success of a Product Stewardship Plan.
23

24 **Section 69306.4(a)(2)(A)2.d.** requires the Product Stewardship Plan to identify the Plan's fair
25 share of orphan products, .i.e., products whose manufacturers or responsible entities are no
26 longer in existence, and their brand names if available. Similar to the provisions above, the
27 Product Stewardship Plan must take into account the number of orphan products that may be
28 recovered under the plan once the plan is in place. Not taking these products into account
29 could compromise the success of a Product Stewardship Plan.
30

31 **Section 69306.4(a)(2)(A)3.** requires the Product Stewardship Plan to identify and discuss the
32 roles and responsibilities for manufacturers, retailers, consumers and government throughout
33 the life cycle of the product. Defining roles that manufacturers and other entities will play is
34 essential to hold the various parties accountable and ensuring the success of the Product
35 Stewardship Plan. In addition, the role that government will play must be well defined to
36 determine if the roles defined are appropriate will ensure a more successful program. While
37 government can assist in bringing the various parties together, it is ultimately the responsibility
38 of the manufacturers and responsible entities to ensure the plan is well executed.
39

40 **Section 69306.4(a)(2)(A)3.a.** requires the manufacturer and responsible entity to incorporate
41 the stewardship program as a general cost of doing business through cost internalization or by

1 recovering costs through arrangements made with their distributors and retailers. This
2 provision is necessary to assess the planning and assumptions under which the plan is being
3 developed.

4
5 **Section 69306.4(a)(2)(A)3.b.** requires the Product Stewardship Plan to identify any third-party
6 product stewardship organization collecting and administering a fee to fund the stewardship
7 program. This provision is necessary to hold the various parties involved accountable for the
8 role and responsibilities that they have in carry out the requirements of a Product Stewardship
9 Plan.

10
11 **Section 69306.4(a)(2)(A)4.** requires the Product Stewardship Plan to include information on
12 the collection system being planned as part of the plan, which shall include identification of the
13 existing infrastructure, both regionally and statewide, the necessary infrastructure, not currently
14 in place, both regionally and statewide, and the minimum collection necessary to make the
15 recovery lucrative or cost effective. This provision is necessary to identify potential
16 opportunities that government may have in meeting a mutual need by the various interested
17 parties.

18
19 **Section 69306.4(a)(2)(A)5.** requires the Product Stewardship Plan to include end-of-life
20 management information, including what steps will be taken the various parties to ensure the
21 plan is carried out as intended to ensure environmentally-sound management that complies
22 with all applicable federal and California state and local laws. This provision is necessary to
23 assess the planning and assumptions under which the plan is being developed.

24
25 **Section 69306.4(a)(2)(A)6.** requires the Product Stewardship Plan to identify the anticipated
26 resources and financing mechanism to implement and sustain the plan. This provision is
27 necessary to access the planning and assumptions under which the plan is being developed.

28
29 **Section 69306.4(a)(2)(A)7.** requires the Product Stewardship Plan to include program
30 performance measures for increasing the capture rate of products at the end-of-life; increasing
31 recyclability i.e. reuse of product at end of life for feedstock to manufacture new products;
32 increasing product longevity for consumer use, and decreasing the use and volume of
33 packaging. This provision is necessary to hold all parties involved accountable for the success
34 of the program and identify areas that can be improved upon.

35
36 **Section 69306.4(a)(2)(A)8.** requires the Product Stewardship Plan to include a Public
37 outreach and communications plan. This provision is necessary to ensure that the Product
38 Stewardship Plan takes into account consumer awareness, a very necessary component of
39 ensuring a take back program is successful. As is evidenced by the study conducted by the
40 California Department of Resources Recycling and Recovery, consumer outreach and

1 awareness is crucial in achieving the necessary collection and recovery rates for a take back
2 program to be successful.

3
4 **Section 69306.4(a)(2)(A)9.** requires the Product Stewardship Plan to include public and
5 interested party consultation activities in preparation, and periodic review and updating, of the
6 plan. This provision establishes that interested party coordination and periodic updating and
7 reviewing is essential in having a cohesive Product Stewardship Plan.

8
9 **Section 69306.4(a)(2)(A)10.** requires the Product Stewardship Plan to include reporting and
10 evaluation procedures. This provision holds all parties involved accountable for the success of
11 the plan.

12
13 **Section 69306.4(a)(2)(B)** requires that the Product Stewardship Program to include
14 development and maintenance of a public education program geared towards the consumers
15 who are most likely to make use of the consumer product. This provision emphasizes that the
16 consumer outreach program should be tailored for the consumers who will most likely make
17 use of the product.

18
19 **Section 69306.4(a)(2)(C)** requires the Product Stewardship Program to be developed in
20 consultation with California retailers and potential collection sites. It further specifies that the
21 collection program include: **1.** collection mechanisms, including, but not limited to, placement
22 of collection bins at collection centers in visible and accessible locations for consumers; and **2.**
23 compensation to the retailers and other persons who agree to administer or participate in the
24 collection program.

25
26 **Section 69306.4(a)(2)(D)** requires the manufacturer or responsible entity of the consumer
27 product to provide a financial guarantee mechanism that ensures a sustainable end-of-life
28 management program for the consumer product. Multiple manufacturers and/or responsible
29 entities may form a third-party product stewardship organization funded by participating
30 manufacturers and responsible entities to provide local services to collect, recycle, or
31 otherwise appropriately manage the designated products.

32
33 This provision makes the manufacturer or responsible entity of the product responsible for
34 addressing the implications of a product they place on the market through the entire life cycle,
35 including ultimate disposition of that product at the end of its useful life. By placing this
36 responsibility on the manufacturer instead of requiring local governments to fund collection and
37 recovery programs for discarded products, the stewardship program will incorporate the cost of
38 disposal or recovery into the cost of the product, so those costs are borne jointly by the
39 producer and the consumer, not by government and taxpayers.

40

1 **Section 69306.4(a)(2)(E)** requires the responsible entity for a product subject to end-of-life
2 management requirements, every 2 years from the date the responsible entity is required to
3 have a take back program established, to provide a report to DTSC which covers: **1.** the
4 amount of products placed into the stream of commerce; and **2.** the amount of products
5 recovered for recycling over the two (2) year period by total tonnage. The stewardship
6 program is developed and implemented by the responsible entities and the privately owned
7 and run collection entities they employ. The report to DTSC is to ensure that performance
8 goals are being met. DTSC's role will be primarily one of oversight which can be efficiently
9 accomplished with relatively few public resources.

10
11 **Section 69306.4(b)(1)** specifies that, except as provided in section 69306.2, the requirements
12 of section 69306.4(a) also apply to a selected alternative to a Priority Product, or component,
13 that contains a Priority Chemical, or for a Priority Product for which the responsible entity does
14 not select an alternative, if DTSC determines that one or more of the requirement in section
15 69306.4 (b)(1)(A) through (C) apply and notifies the responsible entity and manufacturer of the
16 determination. This provision effectively requires that a selected alternative, Priority Product or
17 component that contains a Priority Chemical is subject to end-of-life management if DTSC
18 determines that a threat could be minimized, raw resources could be conserved or fiscal
19 impacts to state and local governments could be alleviated.

20
21 **Section 69306.4(b)(1)(A)** specifies that if DTSC determines there is a significant potential for
22 improper end-of-life handling or disposal practices that pose significant adverse public health
23 or environmental impacts, the responsible entity must comply with the information
24 dissemination requirements in section 69306.4(a)(1) and establish, maintain and fund a take
25 back program pursuant to section 69306.4(a)(2). Product stewardship is a great incentive for
26 innovation at the earliest stages of design because manufacturers must consider the end-of-
27 life impacts of their product during the earliest stages of design. As such, stewardship
28 programs create incentives for producers to redesign products to be less toxic, less bulky, and
29 lighter, as well as more recyclable.

30
31 **Section 69306.4(b)(1)(B)** specifies that if DTSC determines end-of-life reclamation of the
32 product is needed to conserve resources and mitigate long term environmental damage as a
33 result of continual virgin material extraction, the responsible entity must comply with the
34 information dissemination requirements in section 69306.4(a)(1) and establish, maintain and
35 fund a take back program pursuant to section 69306.4(a)(2). A product stewardship plan
36 provides the incentive for manufacturers to use materials that are easier to recycle or dispose
37 of at the end of life, thus, reducing material use and toxicity and increasing recycling. A
38 product stewardship plan will result in significant environmental, economic, energy and
39 greenhouse gas reduction benefits.

1 **Section 69306.4(b)(1)(C)** specifies that if DTSC determines there would be significant waste
2 management costs for local governments, ratepayers or taxpayers in the absence of a Product
3 Stewardship Program, the responsible entity must comply with the information dissemination
4 requirements in section 69306.4(a)(1) and establish, maintain and fund a take back program
5 pursuant to section 69306.4(a)(2). Absent a Product Stewardship Program, the burden of
6 managing the products at the end-of-life is placed on local governments to fund collection and
7 recovery programs for discarded Products. This provision allows DTSC to place the burden on
8 the manufacturers and responsible entities to incorporate the cost of disposal or recovery into
9 the cost of the product, so those costs are borne jointly by the producer and the consumer, not
10 by local government and taxpayers. Internalizing the costs of end-of-life management into the
11 cost of the product reduces the financial burden on communities.

12
13 **Section 69306.4(b)(2)** requires responsible entities subject to section 69306.4 (b) to establish,
14 maintain and fund an end-of-life management program beginning no later than two (2) years
15 after being notified of DTSC's determination pursuant to section 69306.8(b) that it is subject to
16 the requirements under this section. Twelve (12) months is sufficient time to allow a
17 responsible entity to comply with the information dissemination requirements and development
18 of a Product Stewardship Plan and an additional 12 months is necessary to put into place the
19 necessary infrastructure for the end-of-life management programs.

20
21 **Section 69306.4(c)** requires the Product Stewardship Plan required under section 69306.4 to
22 be submitted, upon request, for review by DTSC to ensure compliance with the requirements
23 of this section. This provision is necessary to establish that DTSC may request a copy of the
24 plan to ensure progress or compliance.

25
26 **Section 69306.4(d)** requires a copy of the Product Stewardship Plan required under section
27 69306.4 to be posted on the websites of the manufacturer and the responsible entity. A link to
28 these postings must be provided to DTSC for posting on DTSC's website. This provision is
29 necessary to make information as accessible as possible to all interested parties and the
30 general public.

31
32 **Section 69306.4(e)** specifies that a person subject to the requirements of this section may
33 request DTSC's approval to substitute an alternative end-of-life management program that
34 achieves the same results as the program required by this section. This provision is necessary
35 to provide latitude and flexibility in addressing an existing concern without limiting long-term
36 innovation.

37
38 **Section 69306.4(f)** specifies that a person subject to the requirements of section 69306.4 may
39 request an exemption by demonstrating to DTSC's satisfaction in the AA Report that an end-
40 of-life management program cannot feasibly be implemented for the product that is subject to

1 the requirements of this section. This provision is necessary to provide latitude in addressing
2 an existing concern that cannot be feasibly addressed through an existing approach.
3

4 **Section 69306.5. Product Sales Prohibition**

5 **Section 69306.5**, in its entirety, is necessary to specify the conditions and requirements for a
6 product sales ban.
7

8 **Section 69306.5(a)** specifies that, except as provided in section 69306.2 and section
9 69306.5(c), the requirements in section 69306.5(b) also apply to a selected alternative that
10 contains a Priority Chemical, or a Priority Product or component for which an alternative is not
11 selected, and for which DTSC determines, and notifies the responsible entity and
12 manufacturer, pursuant to section 69306.8, that a safer alternative exists that does not contain
13 a Priority Chemical and that is functionally equivalent and technologically and economically
14 feasible. This provision is necessary to prevent California from becoming a dumping ground
15 for products that contain Priority Chemicals. DTSC believes that once a safer alternative
16 exists, that is functionally equivalent and technologically and economically feasible, that
17 alternative should be made available for California consumers.
18

19 **Section 69306.5(b)** specifies that effective one (1) year after DTSC issues a notification
20 pursuant to section 69306.5(a), the product or component that is the subject of the notification
21 must not be placed into the stream of commerce in California, and the responsible entity or the
22 manufacturer must ensure that an inventory recall program for the product is completed within
23 two (2) years after being notified by DTSC. Twelve (12) months is sufficient time to allow a
24 responsible entity to comply with the information dissemination requirements by notifying all
25 affected retailers and an additional 12 months is necessary to recall and replace products on
26 the market. DTSC believes this provision will accommodate for any potential delays in making
27 a replacement product widely available.
28

29 **Section 69306.5(c)** specifies that a product or component that is the subject of a notification
30 by DTSC pursuant to section 69306.5(a) is not subject to the requirements of section
31 69306.5(b) if both the conditions in sections Section 69306.5(c)(1) and (c)(2) are met. This
32 provision is necessary to give the responsible entity or manufacturer the option to submit a
33 revised AA Report that selects a safer alternative in lieu of being subject to the requirements of
34 section 69306.5(b).
35

36 **Section 69306.5(c)(1)** specifies that within sixty (60) days after being notified by DTSC, the
37 responsible entity or the manufacturer wishing to submit a revised AA Report must notify
38 DTSC of its intent to submit a revised AA Report that selects an alternative that does not
39 contain a Priority Chemical. This provision is necessary to provide these responsible entities
40 and manufacturers with a second opportunity to select a safer alternative but within a time
41 frame that does not allow the alternatives selection process to be unduly extended.

1
2 **Section 69306.5(c)(2)** specifies that if within one (1) year after the notification, DTSC receives
3 a AA Report that selects an alternative that does not contain a Priority Chemical and that fully
4 meets the requirements of sections 69305.6 through 69305.8 then a product or component
5 subject to a notification under section 69306.5(a) is not subject to section 69306.5(b). A
6 manufacturer could potentially satisfy this requirement by revising pertinent sections of the AA
7 Report that was previously completed and submitted.

8
9 **Section 69306.5(d)(1)** specifies that a request may be submitted to DTSC for a one-time
10 extension of the due date for submitting the revised AA Report pursuant to section
11 69306.5(c)(2). The extension request must be received by DTSC no later than sixty (60) days
12 before the due date for the revised AA Report, and must include the information specified in
13 sections 69306.5 (d)(1)(a) through (d)(1)(F). This provision is necessary to provide latitude
14 and accommodate potential unexpected delays.

15
16 **Section 69306.5(d)(1)(A)** requires the request for a one-time extension for an AA report being
17 submitted pursuant to section 69305.5(d)(1) to include the name of and contact information for
18 the person filing the extension request. The information requested under this provision is
19 necessary in the event contact with the person filing the extension request is necessary.

20
21 **Section 69306.5(d)(1)(B)** requires the request for a one time extension for an AA report being
22 submitted pursuant to section 69305.5(d)(1) to include the name of and contact information for
23 the person(s) on whose behalf the revised AA Report will be submitted. The information
24 requested under this provision is necessary to enable DTSC to identify the principal on whose
25 behalf the request was made.

26
27 **Section 69306.5(d)(1)(C)** requires the request for a one time extension for an AA report being
28 submitted pursuant to section 69305.5(d)(1) to include, if different from the information
29 specified in sections 69306.5 (d)(1)(A) and (B), the name of and contact information for the
30 manufacturer of the product. The information requested under this provision is necessary to
31 enable DTSC to contact the manufacturers should it become necessary.

32
33 **Section 69306.5(d)(1)(D)** requires the request for a one time extension for an AA report being
34 submitted pursuant to section 69305.5(d)(1) to include the amount of time requested, which
35 cannot exceed ninety (90) days, This provision is twofold in its advantages: (1) it provides the
36 necessary flexibility for deadlines on the AA report should it become necessary due to an
37 unforeseen circumstance; and (2) it holds all parties accountable to date by which the AA
38 Report must be completed and submitted, before other provisions go into effect.

39
40 **Section 69306.5(d)(1)(E)** requires a request for a one time extension for an AA report being
41 submitted pursuant to section 69305.5(d)(1) to include the reason the extension is needed.

1 The information requested under this provision is necessary for DTSC to access the
2 reasonableness in the delays in submitting an AA Report.

3
4 **Section 69306.5(d)(1)(F)** requires the request for a one time extension for an AA report being
5 submitted pursuant to section 69305.5(d)(1) to include a copy of the notice issued by DTSC
6 pursuant to section 69306.5(a), and a copy of the notice of intent to submit a revised AA
7 report. This will assist DTSC in quickly determining to which product and responsible entity or
8 manufacturer the extension request pertains.

9
10 **Section 69306.5(d)(2)** requires DTSC within thirty (30) days of receipt to approve or deny the
11 extension request submitted pursuant to section 69306.5, and notify the person submitting the
12 extension request of its decision. The one-time extension for the revised AA Report may not
13 exceed ninety (90) days. The time period specified is sufficient for DTSC to review the
14 contents and basis for the extension request and provide a determination. This provision is
15 consistent with section 69306.5 (d)(1), the goal of which is to hold parties accountable for
16 submitting timely AA Reports.

17
18 **Section 69306.5(d)(3)** specifies that if an extension for an AA Report is approved by DTSC,
19 one of the requirements specified in sections 69306.5(d)(3)(A) or (d)(3)(B) must be met by the
20 due date specified by DTSC in the extension approval. Sections 69306.5(d)(3)(A) and
21 (d)(3)(B) are summarized below.

22
23 **Section 69306.5(d)(3)(A)** specifies that if an extension request for an AA Report is approved a
24 revised AA Report must be submitted that complies with section 69306.5(c)(2).

25
26 **Section 69306.5(d)(3)(B)** specifies that if an extension for an AA Report is approved and the
27 provisions of section 69306.5(d)(3)(A) are not complied with, then the requirements of section
28 68305.6(b) must be fully implemented.

29
30 **Section 69306.6. Other Regulatory Responses**

31 **Section 69306.6**, in its entirety, is necessary to specify when DTSC may require other
32 regulatory responses. This article is necessary to clarify, implement, and make specific the
33 provisions of Health and Safety Code section 25253(b).

34
35 **Section 69306.6(a)** specifies that in addition to the regulatory responses specified in sections
36 69306.1 and 69306.3 through 69306.5, and except as provided in section 69306.2, DTSC may
37 impose any of the regulatory responses specified in sections 69306.6 (a)(1) through (a)(2) that
38 DTSC determines are necessary to limit exposure to, and reduce the level of public health or
39 environmental hazards posed by, a selected alternative, or a Priority Product for which an
40 alternative is not selected. This provision is necessary to give DTSC the needed latitude in
41 evaluating products on a case-by-case basis and determining which of one or combination of

1 the regulatory responses will provide the necessary safeguards to products that contain a
2 Priority Chemical. The regulatory responses are consistent with Health and Safety Code
3 section 25253(b).

4
5 **Section 69306.6(a)(1)** specifies that DTSC may apply the regulatory responses set out in
6 sections 69306.3, 69306.4 and 69306.5 to scenarios other than the scenarios identified in
7 those sections. This provision is necessary to provide DTSC the necessary latitude and
8 discretionary authority to impose these requirements when determined necessary to protect
9 public health and the environment.

10
11 **Section 69306.6(a)(2)** specifies that DTSC may apply any of the regulatory responses in
12 sections (a)(2)(A) through (a)(2)(D) to any scenario, including those listed in sections 69306.3
13 through 69306.5. This provision is consistent with the enabling legislation. In addition, this
14 provision gives DTSC the needed latitude in evaluating products on a case-by-case basis and
15 in determining which of one or combination of the regulatory responses will provide the
16 necessary safeguards for products that contain a Priority Chemical. The regulatory responses
17 that may be imposed by DTSC under this section include:

- 18
- 19 (A) Requiring engineered safety measures to control access to or limit exposure to the
20 Priority Chemical in the product.
 - 21
 - 22 (B) Placing restrictions on the use of the Priority Chemical that is contained in the
23 consumer product.
 - 24
 - 25 (C) Requiring the responsible entity or manufacturer to initiate a green chemistry research
26 and development project or fund a green chemistry challenge grant. This provision
27 provides an incentive to manufacturers, responsible entities, investors or
28 entrepreneurs to seek innovative alternatives to address problems caused by existing
29 products and processes.
 - 30
 - 31 (D) Requiring a new Tier II AA to be performed and an AA Report be submitted to DTSC
32 no less than three (3) years after the date of the prior Tier II-B AA Report for the
33 Priority Product or component that was submitted to DTSC if either of the conditions
34 applies:
 - 35
 - 36 1. The prior AA Report did not identify or select an alternative product or
37 component, or
 - 38 2. DTSC becomes aware of a safer alternative that is functionally equivalent and
39 technologically and economically feasible.
 - 40

1 (E) Any other regulatory response that DTSC determines is necessary to limit exposure to
2 or otherwise reduce the hazards posed by the consumer product.
3

4 **Section 69306.6(b)** specifies that, in accordance with the process specified in section
5 69306.8, DTSC must notify affected manufacturers and responsible entities, known to DTSC of
6 regulatory response determinations made pursuant to this section along with an
7 implementation due date for the regulatory response and the rationale for the regulatory
8 response determination. This provision holds DTSC accountable for providing proper and
9 adequate notice to affected manufacturers and responsible entities of DTSC's regulatory
10 response determinations.
11

12 **Section 69306.6(c)** specifies that DTSC will periodically re-evaluate each regulatory response
13 imposed under this section to determine if any changes are needed based on any significant
14 changes in science, technology or other relevant information or facts that have occurred since
15 the regulatory response was selected. This provision holds DTSC accountable for regularly
16 reevaluating the regulatory responses and providing the necessary guidance to interested
17 parties for improvements as a result of advancements in science and technology.
18

19 **Section 69306.7. Exemption from Regulatory Response Requirements**

20 **Section 69306.7**, in its entirety, provides the conditions under which a manufacturer or
21 responsible entity is exempt from article 6, if the manufacturer or responsible entity requests
22 and DTSC grants an exemption. This article is necessary to clarify, implement, and make
23 specific the provisions of Health and Safety Code section 25257.1.
24

25 **Section 69306.7(a)** specifies that a selected alternative or Priority Product or component is
26 exempt from the requirements of article 6, if the responsible entity or the manufacturer
27 requests, and DTSC grants, an exemption. The exemption request must be submitted to
28 DTSC no later than the applicable periods specified in sections 69306.7(a)(1) or (a)(2).
29

30 **Section 69306.7(a)(1)** specifies that if an exemption request is being submitted, it must be
31 received within sixty (60) days after the responsible entity is notified by DTSC that a selected
32 alternative, or a Priority Product or component is subject to a regulatory response pursuant to
33 section 69306.6, or a determination under section 69306.3(e), 69306.4(b) or 69306.5. The
34 time period specified is sufficient time for a responsible entity to request an exemption, and
35 allows a determination to be made on the exemption request to be made in a timely manner so
36 as not to significantly delay implementation of the applicable regulatory response in the event
37 DTSC denies the requested exemption.
38

39 **Section 69306.7(a)(2)** specifies that if an exemption request is being submitted, it must be
40 received within sixty (60) days after a Tier II-B AA Report is submitted to DTSC for a product
41 subject to section 69306.3(a) through (c) or section 69306.4(a). The time period specified is

1 sufficient time for a responsible entity to request an exemption, and allows a determination to
2 be made on the exemption request to be made in a timely manner so as not to significantly
3 delay implementation of the applicable regulatory response in the event DTSC denies the
4 requested exemption.
5

6 **Section 69306.7(b)** specifies that the exemption request must include all of the information
7 specified in sections 69306.7(b)(1) through (b)(6), which are summarized below. The
8 information required in the specified sections is necessary for DTSC to make an informed
9 decision on whether or not to grant an exemption.
10

11 **Section 69306.7(b)(1)** specifies that the exemption request must include the name of and
12 contact information for the person filing the exemption request. The information requested is
13 necessary should contacting the person filing the request become necessary.
14

15 **Section 69306.7(b)(2)** specifies that the exemption request must include the name of and
16 contact information for the person(s) on whose behalf the exemption request is being
17 submitted. The information requested is necessary should contacting the person(s) on whose
18 behalf the exemption is filed become necessary.
19

20 **Section 69306.7(b)(3)** specifies that the exemption request must include the name of and
21 contact information for the manufacturer of the product if different from the persons identified in
22 section 69306.7(b)(1) and (b)(2). The information requested is necessary should contacting
23 the manufacturer of the product become necessary.
24

25 **Section 69306.7(b)(4)** specifies that the exemption request must include the name of and
26 contact information for any responsible entity for the product, to the extent known to the person
27 submitting the exemption request. The information requested is necessary should notifying the
28 responsible entity become necessary.
29

30 **Section 69306.7(b)(5)** specifies that the exemption request must include information
31 identifying and describing the product, including the brand name(s) under which the product is
32 placed into the stream of commerce in California, and information specifically identifying the
33 product component, if applicable. The Information requested under this provision is necessary
34 to distinguish the product under the exemption request from other products in commerce.
35

36 **Section 69306.7(b)(6)** specifies that the exemption request must include clear and convincing
37 evidence that demonstrates to DTSC's satisfaction that either or both of the conditions
38 specified in sections 69306.7(b)(6)(A) or (b)(6)(B) apply, which are summarized below. This
39 provision is necessary to advise those submitting exemption requests that the request must
40 provide well substantiated information for consideration for an exemption by DTSC.
41

1 **Section 69306.7(b)(6)(A)** provides for an exemption from the required regulatory response if
2 clear and convincing evidence demonstrates to DTSC's satisfaction that it would be in conflict
3 with a requirement of another California or federal regulatory program or an International Trade
4 Agreement ratified by the United States Senate, in such a way that the responsible entity or
5 manufacturer cannot reasonably be expected to comply with these requirements.
6

7 **Section 69306.7(b)(6)(B)** provides for an exemption from the required regulatory response if
8 clear and convincing evidence demonstrates to DTSC's satisfaction that it would substantially
9 duplicate a requirement of another California or federal regulatory program or an International
10 Trade Agreement ratified by the United States Senate.
11

12 **Section 69306.7(c)** specifies that within sixty (60) days of receiving an exemption request,
13 DTSC must issue a notice to the person who submitted the request granting or denying the
14 exemption request. A notice granting or denying an exemption request must include the basis
15 for DTSC's decision. A copy of the notice must also be sent to the product manufacturer and
16 any responsible entity known to DTSC.
17

18 **Section 69306.7(d)** requires an exemption request submitted pursuant to 69306.7(a) to be
19 denied if the request fails to demonstrate to DTSC's satisfaction that one or both of the criteria
20 specified in section 69306.7(a)(6) apply to the product or component. This provision is
21 necessary to inform those submitting an exemption request that if the information submitted is
22 not sufficient the request will be denied.
23

24 **Section 69306.7(e)** specifies that if the exemption request or DTSC's granting of an exemption
25 is based solely on the criteria specified in section 69306.7(a)(6)(A), DTSC may, at its
26 discretion, require implementation of a modified regulatory response that resolves the conflict
27 that is the basis for the exemption. This provision provides the necessary latitude to address a
28 conflict with another regulatory provision that is not known to DTSC at the time of the
29 application of a regulatory response.
30

31 **Section 69306.7(f)** specifies that an exemption granted pursuant this section will be rescinded
32 if DTSC determines that the facts and/or assumptions, that DTSC relied upon in granting the
33 exemption were not, or are no longer, valid. If DTSC rescinds an exemption, DTSC must
34 notify the person who submitted the exemption request and, if different, the manufacturer and
35 any responsible entity for the product, known to DTSC. This provision is necessary in the
36 event DTSC grants an exemption and is subsequently made aware of an erroneous
37 determination.
38

39 **Section 69306.7(g)** specifies that all notices issued under this section granting, denying or
40 rescinding an exemption must include a statement of basis for DTSC's decision. This

1 provision holds DTSC accountable for making known the basis of its decisions in granting,
2 denying or rescinding a determination for an exemption.
3

4 **Section 69306.8. Regulatory Response Determination Process**

5 **Section 69306.8(a)** specifies that prior to issuing a final regulatory response determination
6 notice pursuant to section 69306.3(e), 69306.4(b), 69306.5(a) or 69306.6(b), DTSC must
7 make the proposed regulatory response determination notice available on its website, for
8 public review and comment. DTSC must publish in the CRNR, send to persons on any
9 listserv(s) that DTSC establishes related to this chapter, and post on its website a notice
10 regarding the availability of the proposed regulatory response determination notice. This
11 notice must include the information specified in sections 69306.8(a)(1) through (a)(3),
12 summarized below. This provision is necessary to allow for public input into the regulatory
13 response determination process.
14

15 **Section 69306.8(a)(1)** requires the notice of a proposed regulatory response determination to
16 include the time period during which the public may submit comments.
17

18 **Section 69306.8(a)(2)** requires the notice of a proposed regulatory response determination to
19 include the method(s) for submitting comments to DTSC on the proposed regulatory response
20 determination notice.
21

22 **Section 69306.8(a)(3)** requires the notice of a proposed regulatory response determination to
23 include notification of any workshops, if DTSC determines one or more workshops are
24 necessary.
25

26 **Section 69306.8(b)** is necessary to specify that after review and consideration of public
27 comments on the proposed regulatory response determination notice, DTSC must finalize and
28 send to the product manufacturer and responsible entities, known to DTSC, the final regulatory
29 response determination notice. DTSC may, at its discretion, respond to some or all public
30 comments received. This provision holds DTSC accountable to take public input into account
31 in its final determination on applying regulatory responses.
32

33 **Section 69306.8(c)** is necessary to require all proposed and final regulatory response
34 determination notices to include the information specified in sections 69306.8(c)(1) through
35 (c)(4), which are summarized below.
36

37 **Section 69306.8(c)(1)** requires the final regulatory response determination notice to include a
38 description of the required regulatory response. The description of the regulatory response is
39 necessary so that interested parties are informed of the nature of the applicable regulatory
40 response.
41

1 **Section 69306.8(c)(2)** requires the final regulatory response determination notice to include
2 DTSC's basis for the required regulatory response. The basis for DTSC's determination for a
3 regulatory response is necessary to inform interested parties and the general public of the
4 rationale for selecting the regulatory response.

5
6 **Section 69306.8(c)(3)** requires the final regulatory response determination notice to include
7 the rationale, data and data sources, supporting DTSC's determination(s). The information
8 provided is subject to article 10's protections, processes, and limitations. The data and
9 DTSC's interpretation and rationale in arriving at a determination for a regulatory response are
10 necessary to inform interested parties and the general public of the rationale for selecting the
11 regulatory response.

12
13 **Section 69306.8(c)(4)** requires the final regulatory response determination notice to include
14 the implementation due date for any regulatory response imposed pursuant to section
15 69306.6. The date when a regulatory response goes into effect is necessary to establish the
16 date for compliance.

17 18 **Section 69306.9. Regulatory Response Report and Notifications**

19 **Section 69306.9**, in its entirety, is necessary to specify the requirements for a regulatory
20 response report and notifications.

21
22 **Section 69306.9(a)** requires a responsible entity for a product or component subject to a
23 regulatory response pursuant to article 6 to ensure that a notice is sent to retailers who sell the
24 product or component in California, informing the retailers of the applicability of the regulatory
25 response to the product or component. The notice must be sent to the retailers, and a copy
26 sent to DTSC. This provision is necessary to hold responsible entities accountable for
27 notifying California retailers of a determination that applies to a product that they manufacture
28 and place into the stream of commerce in California.

29
30 **Section 69306.9(a)(1)** requires that within thirty (30) days after receiving a final regulatory
31 response determination notice, pursuant to section 69306.8(b), for a product or component
32 pursuant to section 69306.3(e), 69306.4(b), 69306.5(a) or 69306.6(b), a responsible entity
33 must send a notice to retailers who sell the product or component in California, informing the
34 retailers of the applicability of the regulatory response to the product or component. A notice
35 must be sent simultaneously to DTSC.

36
37 **Section 69306.9(a)(2)** requires a responsible entity within thirty (30) days after a Tier II-B AA
38 Report is submitted to DTSC for a product or component subject to sections 69306.3(a)
39 through (c) or 69306.4(a), to send a notice be sent to retailers who sell the product or
40 component in California, informing the retailers of the applicability of the regulatory response to
41 the product or component. In conjunction with the section 69306.9, the notice must be sent

1 within 30 days after submitting a Tier II-B AA Report on a product that is subject to a regulatory
2 response.

3
4 **Section 69306.9(b)** requires the notice required in section 69306.9(a), that is sent to California
5 retailers and DTSC, to include all of the following information:
6

- 7 (1) The manufacturer's name and contact information,
- 8 (2) The responsible entity's name and contact information,
- 9 (3) The names of, and contact information for, any other persons in the supply chain for
10 the product known to the responsible entity,
- 11 (4) Information identifying and describing the original Priority Product or component, and
12 the selected alternative, including the brand name(s) under which the product or
13 component is placed into the stream of commerce in California, and
- 14 (5) A description of the required regulatory response and the due date for implementing
15 the regulatory response.

16
17 **Section 69306.9(c)** requires the responsible entity or the manufacturer to notify DTSC upon
18 completing implementation of the required regulatory response(s) and, if applicable, upon
19 completing development and introduction into the California market of the selected alternative.
20 The notification must include information describing how the regulatory response(s) was
21 implemented. If requested by DTSC, the responsible entity or the manufacturer must provide
22 periodic implementation status reports regarding the selected regulatory response(s). The
23 information provided to DTSC pursuant to this subsection must also be posted on the websites
24 of the manufacturer and responsible entity.

25
26 **Section 69306.9(d)(1)** requires DTSC to prepare and post on its website, and update at least
27 quarterly, a Regulatory Response Report that identifies the regulatory response or responses
28 for each selected alternative for a Priority Product. This is necessary to ensure that
29 responsible entities, manufacturers and other persons in the supply chain are fully informed as
30 to the requirements that apply to their products. This information will also be of interested to
31 consumers. The following information will be included in the Regulatory Response Report:
32

- 33 (A) The manufacturer's name and contact information,
- 34 (B) The names of, and contact information for, any persons in the supply chain for the
35 product known to DTSC,
- 36 (C) Information identifying and describing the original Priority Product or component, and
37 the selected alternative, including the brand name(s) under which the product or
38 component is placed into the stream of commerce in California,
- 39 (D) The due date and actual date for completing development and introduction into the
40 California market of the selected alternative, if any,
- 41 (E) The regulatory response(s),

- 1 (F) The applicable section in this article specifying the regulatory responses, and, in the
2 case of regulatory responses imposed based on a determination pursuant to section
3 69306.3(e), 69306.4(b), 69306.5(a) or 69306.6(a), the rationale for DTSC's
4 determination,
5 (G) The implementation due date, and the actual implementation date, for the regulatory
6 response, and
7 (H) Any other information provided to DTSC in the notice sent from the manufacturer to
8 California retailers pursuant to section 69306.9(b).

9
10 **Section 69306.9(d)(2)** specifies that DTSC must also include in the Regulatory Response
11 Report the information specified in sections 69306.9 (d)(1)(A) through (D) for each exemption
12 granted by DTSC.

13 14 **Article 7. Dispute Resolution Processes**

15 Article 7, in its entirety, specifies the processes available to responsible entities or
16 manufacturers who wish to dispute any of the enumerated actions or decisions of DTSC that
17 are subject to the dispute resolution procedures set out in this article. The provisions of the
18 article are necessary to allow responsible entities or manufacturers to bring further information
19 to the attention of DTSC that may persuade DTSC to make a different decision from the one
20 being disputed. The article provides for a transparent and inclusive process for seeking review
21 of important DTSC actions under this chapter. The article tailors the level of review to the
22 importance of the issue under review.

23 24 **Section 69307. Dispute Resolution**

25 **Section 69307(a)** is necessary to specify that article 7 applies to any responsible entity or
26 manufacturer that wants to dispute a decision of DTSC under Chapter 53 that applies to the
27 responsible entity's or manufacturer's product.

28
29 **Section 69307(b)** requires all parties to a dispute to use their best efforts to resolve disputes
30 informally. Article 7 is the sole means of administratively disputing a decision of DTSC under
31 these regulations. Therefore, failure of a manufacturer or responsible entity to make use of
32 these procedures to dispute an action or decision of DTSC will have waived its rights to further
33 dispute the matter administratively. This provision is necessary to avoid undue delay in
34 resolving disputes and to ensure that the parties proceed in an efficient fashion toward final
35 resolution of disputes.

36
37 **Section 69307(c)** provides that a disputed requirement is stayed (i.e. need not be complied
38 with) while the dispute is still being addressed under the provisions of article 7. This provision
39 is necessary to allow the party disputing the DTSC action to not have to carry out the disputed
40 requirement before having the dispute resolved.

41

Section 69307.1. Informal Dispute Resolution Procedures

Section 69307.1(a) is necessary to specify which issues being disputed are subject to informal dispute resolution, as opposed to the formal dispute resolution procedures set out in section 69307.3. This section specifies that a responsible entity or manufacturer may pursue informal dispute resolution under this section for any decision made by DTSC under Chapter 53 other than sections 69306.3(e), 69306.4(b), 69306.5, 69306.6, and 69306.7. Such informal disputes must be initiated within 15 days following the noticing or posting on DTSC's website of the action being disputed. Then, DTSC must allow the responsible entity or manufacturer filing the dispute to have the matter resolved within thirty (30) days of receiving the dispute. Failure to comply with the 15-day time frame renders DTSC's decision final.

Section 69307.1(b) provides that if a responsible entity or manufacturer disagrees with DTSC's decision following the informal dispute resolution process under section 69301.7(a), then the responsible entity or manufacturer may appeal to DTSC's director pursuant to section 69307.2. This provision is necessary to provide adequate opportunity for disputed matters to be resolved administratively.

Section 69307.2. Request for Further Review by the Director

Section 69307.2(a) specifies the information the responsible entity or manufacturer must supply to DTSC if it pursues a dispute with the Director of DTSC. The required information includes: the reason for seeking additional review and why the disputed decision is not in conformity with the regulations or is unreasonable. In addition, this section specifies additional supporting information required for review by DTSC's Director. This includes:

- (1) The original statement of dispute;
- (2) Supporting documents; and
- (3) Copies of DTSC's responses to the dispute.

This provision for information is necessary so that all parties are put on notice of what information is required for DTSC's Director to review an unresolved dispute, and to put the DTSC Director in a position to have the relevant information needed to make a decision.

Section 69307.2(b) sets the time frame for bringing a dispute to the DTSC Director at no more than thirty (30) days after the issuance of the informal dispute resolution decision under section 69307.1. This provision is necessary so that parties are on notice of the applicable deadlines for bringing an issue to the Director and so that disputes may be resolved efficiently.

Section 69307.2(c) specifies that either the Director or the Director's designee may make a decision on behalf of DTSC, but in either case that decision is to be made within sixty (60) days of receipt of the Director-level dispute. This section also confers authority for the Director or designee to grant or deny relief in whole or in part. If DTSC does not grant relief from the

1 disputed requirement(s), the decision must indicate the compliance date for any disputed item.
2 A decision under section 69307.2(c) is DTSC's final decision and is not subject to additional
3 dispute resolution. This section is necessary so that the parties know the applicable time
4 frames for a DTSC Director-level dispute to be decided, know who may make such a decision,
5 and that the decision does not have to be all or nothing. It is also necessary to ensure that
6 disputes are resolved efficiently.

7

8 **Section 69307.3. Formal Petition for Review Procedures**

9 **Section 69307.3** specifies which decisions or actions of DTSC are subject to the formal
10 dispute resolution procedures set out in Sections 69307.4 through 69307.7. The DTSC
11 decisions subject to these provisions are those arising under sections 69306.3(e), 69306.4(b),
12 69306.5, 69306.6, and 69306.7. This section also provides that these procedures do not
13 supplement the informal procedures set out in sections 69307.1 and 69307.2, but are in lieu of
14 those procedures. This section is necessary so that the affected parties will know which
15 procedures apply to which disputes.

16

17 **Section 69307.4. Time Lines for Petition**

18 **Section 69307.4** specifies that a responsible entity or manufacturer receiving a decision under
19 one of the enumerated sections of article 6 set out in section 69307.3 has thirty (30) days from
20 receipt of that decision to submit a petition for review to DTSC. If a dispute is not received
21 within the 30-day period, then DTSC's decision is final, and is not subject to further dispute
22 resolution procedures. This section is necessary so that responsible entities, manufacturers
23 and DTSC know which disputes are subject to formal dispute resolution procedures, the time
24 lines for a responsible entity or manufacturer to initiate such a dispute, and to keep the dispute
25 resolution process moving efficiently.

26

27 **Section 69307.5. Contents of Petition for Review**

28 **Section 69307.5** specifies that a petition initiating formal dispute resolution procedures must
29 include a statement of the reasons why the dispute is being filed. The statement must include:
30 **(a)** information demonstrating that DTSC's decision is clearly erroneous, or **(b)** a showing that
31 DTSC's decision is an exercise of discretion or an important policy consideration that makes
32 DTSC's review an appropriate exercise of discretion.

33

34 This provision is necessary so that the parties disputing a decision know what information is
35 required in their petitions and DTSC has a basis for making a decision on the petition.

36

37 **Section 69307.6. Department Review of Petitions**

38 **Section 69307.6(a)** specifies that DTSC has sixty (60) days from receipt of a petition filed
39 under Section 69307.4 to issue an order accepting or denying review of the petition. This
40 provision is necessary so that responsible entities, manufacturers and DTSC are aware of the

1 time frames for initially responding to the petition and to ensure the dispute resolution process
2 is efficient.

3
4 **Section 69307.6(b)** requires that an order under subsection (a) must specify when the briefs
5 are due from the responsible entity or manufacturer and DTSC. This provision is necessary so
6 that the parties know the applicable deadlines and to ensure that the dispute resolution
7 process is efficient.

8
9 **Section 69307.6(c)** specifies the effect of a denial of review under this section. The effect is a
10 final administrative decision which is effective on the date issued. In addition, this section
11 requires that an order denying review must specify the compliance date for the disputed item.
12 This provision is necessary so that the parties know the applicable deadlines and to ensure
13 that the dispute resolution process is efficient.

14
15 **Section 69307.6 (d)** specifies that DTSC has 180 days from the decision granting review to
16 conduct its review of the information in the briefs and to make a decision on the petition. This
17 provision is necessary so that the parties know the applicable deadlines and to ensure that the
18 dispute resolution process is efficient.

19
20 **Section 69307.6(d)(1)** specifies that if DTSC denies the petition, the final order must inform
21 the responsible entity or manufacturer of the date of compliance for the disputed issue(s).
22 DTSC's denial decision under this subsection constitutes a final decision and is not subject to
23 further dispute resolution procedures. This provision is necessary so that the parties know the
24 applicable deadlines and to ensure that the dispute resolution process is efficient.

25
26 **Section 69307.6 (d)(2)** specifies that if the final order grants any relief to the responsible entity
27 or manufacturer, then the matter is to be returned to DTSC staff involved with the substantive
28 issue(s) for re-evaluation. The order must tell the DTSC staff when the deadline is for
29 completion of the re-evaluation, but it cannot be more than 90 days from the date of the order.
30 The order may, but need not, provide additional guidance or criteria for the re-evaluation. This
31 provision is necessary so that the appropriate staff in DTSC is involved in the actual technical,
32 scientific decision-making and that it happens within a reasonable period of time.

33
34 **Section 69307.6 (e)** provides that a manufacturer may not seek judicial review of a decision by
35 DTSC unless and until DTSC issues a final order on the petition. This provision is necessary to
36 establish when a manufacturer has exhausted all administrative remedies and is able to
37 pursue judicial relief.

38

39 **Section 69307.7. Procedures for Department Review of Petitions**

40 **Section 69307.7(a)** specifies additional requirements that DTSC must comply with in
41 reviewing formal petitions for review brought under section 69307.4. This provision is

1 necessary to make it clear which decisions are subject to these additional requirements and
2 that they are supplemental to and not in lieu of the requirements applicable to formal dispute
3 resolution matters.

4
5 **Section 69307.7(b)** specifies 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 69307.6. This provision is necessary to ensure that there is objectivity and fairness on
8 the part of those in DTSC reviewing the petitions for review.

9
10 **Section 69307.7(c)** establishes a “firewall” between the DTSC staff involved in the decision-
11 making and review of petitions for review and those who made the initial decisions under
12 review. Unless DTSC staff involved in reviewing a petition simultaneously communicates with
13 the responsible entity or manufacturer or its representative on the matter under review, then
14 DTSC reviewing staff is barred from communicating with DTSC program staff regarding the
15 disputed issue(s). This provision is necessary to ensure that there is no ex parte
16 communication on the matters under review, keeping the dispute resolution process fair.

17 18 **Article 8. Accreditation and Qualification Requirements for Performance of** 19 **Alternatives Assessments**

20
21 Article 8, in its entirety, specifies the requirements for qualified third-party assessment entities,
22 qualified in-house assessment entities, accrediting bodies, and lead assessors, as well as the
23 process for attaining qualification and accreditation and provisions concerning the duration of
24 the qualification or accreditation, including renewal or termination for variance from the
25 specified requirements. These sections are necessary to ensure that alternatives
26 assessments are performed by persons with sufficient experience, expertise, and training in
27 order to promote reliability, auditability, and consistency. Additionally, these provisions, in
28 conjunction with section 69305.2(c)(3), are necessary to further ensure reliability and integrity
29 by requiring all alternatives assessments to be either performed by or verified by a third-party
30 that is unaffiliated with the manufacturer and responsible entity of the product being assessed.

31 32 **Section 69308. Requirements for Qualified Third-Party Assessment Entities**

33 **Section 69308**, in its entirety, is necessary to specify the requirements for qualified third-party
34 assessment entities.

35
36 **Section 69308(a)(1) through (4)**, specifies the information required to be submitted by an
37 entity seeking designation by DTSC as a qualified third-party assessment entity for the
38 purpose of performing or verifying AAs. Specifically, the application must include all of the
39 following:

- 40
41 (1) The applicant’s name and contact information;

- 1
- 2 **(2)** Identification of the combined qualifications of individuals, including lead assessors that
- 3 meet the requirements of section 69308.3, available within, or to, the entity, including
- 4 education, experience and subject matter competence and expertise;
- 5
- 6 **(3)** Documentation of the AA elements, inputs, assumptions, methodologies and
- 7 approaches used by the entity in performing AAs; and
- 8
- 9 **(4)** Demonstration of all of the following:
- 10 **(A)** Independence and lack of affiliation with any responsible entity, manufacturer,
- 11 group of manufacturers, or trade association;
- 12 **(B)** No economic interest in any entity that produces, sells or distributes any
- 13 Chemical of Concern or product containing a Chemical of Concern;
- 14 **(C)** Compliance with the standards of ISO 14040 or equivalent;
- 15 **(D)** Compliance with, and maintenance of, ISO/IEC Guide 65 accreditation; and
- 16 **(E)** Recordkeeping and document retention and retrieval capabilities sufficient to
- 17 facilitate DTSC audits.
- 18

19 **Section 69308(b)** requires DTSC to approve or deny the application for designation within

20 sixty (60) days of receipt. DTSC must notify the applicant of its decision. A notice of denial

21 must indicate the grounds for denial and, if applicable, the conditions the applicant must fulfill

22 to be designated or re-designated as a qualified entity.

23

24 **Section 69308(c)** specifies that if any of the information submitted pursuant to section

25 69308(a) changes, the updated information must be provided to DTSC within thirty (30) days

26 of the change.

27

28 **Section 69308(d)** limits the term of a designation to five (5) years; although, it may be

29 renewed upon application which must be submitted not less than ninety (90) days before

30 expiration.

31

32 **Section 69308(e)** specifies that an entity found to be negligently or willfully in violation of

33 Chapter 53 will lose its designation as a qualified third-party assessment entity for at least 10

34 years. At the end of 10 years, the entity may reapply for designation as a qualified third party

35 assessment entity.

36

37 **Section 69308.1. Requirements for Qualified In-House Assessment Entities**

38 **Section 69308.1** is necessary to specify the information to be submitted by a manufacturer, as

39 defined in section 69301.2 and section 69308.1(f), a consortium of manufacturers, a trade

40 association or a public-private partnership seeking designation by DTSC as a qualified in-

41 house assessment entity for the purpose of performing AAs. The requirements are the same

1 as those for a qualified third-party assessment entity specified in section 69308, above, except
2 that no showing of independence or lack of affiliation is required. Provisions pertaining to
3 DTSC action on the application, notification of changes, duration of designation, and for
4 renewal and loss of designation, are the same as for a qualified third-party assessment entity
5 specified in section 69308, above. However, if a qualified in-house assessment entity loses its
6 designation, during the period of disqualification, any Tier II AAs that the entity is required to
7 perform must be performed by an entity that is unaffiliated with the responsible entity or
8 manufacturer or any consortium, trade association or other partnership of which the
9 responsible entity or manufacturer is a member. This is necessary to provide sufficient
10 motivation for in-house assessment entities to comply with the requirements of article 5, and to
11 ensure the reliability and integrity of future AAs performed for products of any disqualified
12 entity.

13

14 **Section 69308.2. Requirements for Designated Accrediting Bodies**

15 This section, in its entirety, is necessary to ensure designated accrediting bodies properly
16 develop and accredit lead assessors, who are critical to the process of performing alternatives
17 assessments.

18

19 **Section 69308.2(a)** specifies the information to be submitted on the application to DTSC by a
20 person requesting to be designated as an accrediting body of lead assessors who meet the
21 requirements of section 69308.3. The required information includes: **(1)** applicant's name and
22 contact information; **(2)** applicant's institutional history; **(3)** product types and/or industry
23 sectors for which the applicant is proposing to accredit lead assessors; **(4)** description of the
24 accrediting body's lead assessor accreditation program that meets the requirements of section
25 69308.2(c); **(5)** the accrediting body's training curriculum that meets the requirements of
26 section 69308.2(c)(3) for initial lead assessor applicants, including course title, contents, hours,
27 and exam plan for each course; **(6)** the accrediting body's continuing education curriculum for
28 lead assessor re-accreditation, including the same elements as in paragraph (5); **(7)**
29 demonstrated qualifications and areas of expertise for those persons who develop the
30 curriculum; **(8)** a copy of the accrediting body's lead assessor application form meeting the
31 requirements of section 698308.2(c)(1); **(9)** a copy of the accrediting body's lead assessor
32 accreditation certification form meeting the requirements of section 69308.2(c)(4); **(10)**
33 information demonstrating ability to teach, and history of teaching, specified subject matters;
34 **(11)** disclosure of apparent or existing conflicts of interest; and **(12)** a certification statement
35 required by section 69301.5(b).

36

37 **Section 69308.2(b)** requires DTSC to approve or deny and application for designation, or
38 renewal of designation, within 60 days of receipt. DTSC must notify the applicant of its
39 decision. A notice of denial must state the grounds for denial and, if applicable, what the
40 applicant must do in order to be designated or re-designated.

41

1 **Section 69308.2(c)(1)** requires each lead assessor accreditation program to include written
2 application and admission procedures for both initial accreditation and biennial renewal of
3 accreditation. This includes requiring applicants to submit to the accrediting body an
4 application that includes the following: **(A)** applicant's name and contact information; **(B)** the
5 product type(s) and/or industry sector(s) for which the applicant is applying; **(C)** educational
6 experience meeting the requirements of section 69303.3(a)(1) substantiated by
7 documentation; **(D)** employment and other experience history meeting the requirements of
8 section 69308.3(a)(2) and required references; **(E)** any professional licenses, registrations or
9 other relevant credentials that the applicant holds; **(F)** for accreditation renewals,
10 documentation of completion of continuing education required under section 69308.3(a)(5);
11 and **(G)** a signed and dated certification statement containing prescribed content.

12
13 **Section 69308.2(c)(2)** requires each lead assessor accreditation program to include written
14 procedures for verifying an applicant's qualifying education and experience, including
15 verification of completion of continuing education requirements.

16
17 **Section 69308.2(c)(3)** requires each initial accreditation training program to be pertinent to the
18 type of work for which lead assessor accreditation will be offered, and to include all of the
19 following: **(A)** the requirements of Chapter 53; **(B)** training and case studies on principles and
20 practices of chemical hazard assessment, exposure potential assessment, and multimedia life
21 cycle evaluation; **(C)** training and case studies on identification of alternatives for consideration
22 in Tier II AAs; **(D)** training and case studies on identification of life cycle segments for
23 chemicals and products; and **(E)** training needed to attain expertise in specific fields necessary
24 to performing AAs.

25
26 **Section 69308.2(c)(4)** requires each lead assessor accreditation program to include the
27 issuance of written certificates for initial accreditation and re-accreditation. The certificate is to
28 be called "Certification of Accreditation as a Lead Assessor" and must include all of the
29 following: **(A)** lead assessor's name; **(B)** the product type(s) and/or industry sector(s) for which
30 the lead assessor is accredited; **(C)** date of issuance and date of expiration; **(D)** name and
31 contact information for accrediting body; **(E)** indication of initial or renewal accreditation; **(F)**
32 statement that the lead assessor meets the requirements of section 69308.3(a); and **(G)**
33 signature of the owner or officer of the accrediting body.

34
35 **Section 69308.2(c)(5)** requires each lead assessor accreditation program to include criteria
36 and procedures for denying an application for initial or renewed accreditation. Denial decisions
37 must be in writing, provided to the applicant, and provide the reasons for the denial. If
38 applicable, the applicant must be informed of the conditions the applicant must fulfill in order to
39 be accredited or re-accredited.

40

1 **Section 69308.2(c)(6)** requires each lead assessor accreditation program to include a
2 program to audit completed work performed by lead assessors accredited by the accrediting
3 body to ensure the quality and appropriateness of the work.
4

5 **Section 69308.2(c)(7)** requires each lead assessor accreditation program to include written
6 procedures for records retention.
7

8 **Section 69308.2(d)** requires each accrediting body to provide notification to DTSC, on at least
9 a quarterly basis, of the names and contact information of all lead assessors accredited by that
10 entity. The notification must also indicate the product type(s) and/or industry sectors for which
11 the lead assessor is accredited.
12

13 **Section 69308.2(e)** limits the duration of the designation of an accrediting body to no more
14 than five (5) years, subject to renewal, with a requirement that the renewal application must be
15 submitted not later than ninety (90) days before expiration of the designation and a provision
16 that extends the designation until DTSC makes a determination on the application.
17

18 **Section 69308.2(f)** prohibits trade secret or proprietary restrictions by the accrediting body for
19 its admission requirements, general curriculum, and educational approach. An accrediting
20 body may seek to have specific course information or life cycle assessment tools treated as
21 confidential information pursuant to article 10.
22

23 **Section 69308.2(g)** provides for rescission of a designation as an accrediting body: **(1)** upon
24 lapse of the designation period; **(2)** when a substantial number of lead assessors accredited by
25 it are found to be in violation of Chapter 53; **(3)** if the accrediting body is found to have
26 significantly deviated from the documentation submitted pursuant to subsection (b) of this
27 section; or **(4)** if DTSC finds the accrediting body to be negligent, fraudulent,
28 misrepresentative, or unethical in connection with their accreditation of lead assessors.
29

30 **Section 69308.3. Lead Assessor Accreditation**

31 This section, in its entirety, is necessary to ensure that lead assessors have sufficient training
32 and qualifications to perform alternatives assessments and to provide a disciplinary
33 mechanism for deviations from standards of the program or of professional behavior.
34

35 **Section 69308.3(a)(1) through (6)** require a responsible person in charge of performing or
36 verifying a Tier II AA or preparing an AA Work Plan or AA Report to be accredited by a
37 designated accrediting body for the product type(s) and/or industry sector appropriate to the
38 Tier II AA being performed or verified, and to meet all of the following requirements: **(1)** hold a
39 Bachelor's degree with a major in a scientific or engineering field from an accredited college or
40 university; **(2)** have the equivalent of three years professional experience performing AAs
41 and/or working in a scientific or engineering field --- post-graduate work in the performance of

1 AAs and/or in a scientific or engineering field from an accredited college or university may be
2 substituted for the required experience; **(3)** successfully complete a lead assessor
3 accreditation training program meeting the requirements of section 69308.2(c)(3) for initial
4 accreditation; **(4)** receive an initial “Certification of Accreditation as a Lead Assessor” meeting
5 the requirements of section 69308.2(c)(4) and issued by the accrediting body whose program
6 the lead assessor successfully completed; **(5)** maintain lead assessor accreditation status by
7 completing continuing education requirements, applying for re-accreditation, and receiving a
8 renewed certification; and **(6)** possess, and produce upon request, a current “Certification of
9 Accreditation as a Lead Assessor” meeting the requirements of section 69308.2(c)(4).

10
11 **Section 69308.3(b)** requires a lead assessor for whom the designated accrediting body’s
12 designation has been rescinded pursuant to section 69308.2(g)(2) through (g)(4) to apply for
13 reaccreditation by another designated accrediting body within 60 days after the rescission
14 decision is posted on DTSC’s website.

15
16 **Section 69308.3(c)** specifies that the accreditation of a lead assessor is subject to rescission
17 by the accrediting body or by DTSC for failure to comply with these regulations, or if DTSC or
18 the accrediting body finds the lead assessor to be negligent, fraudulent, misrepresentative, or
19 unethical in connection with their duties and responsibilities as a lead assessor. This provision
20 also requires the accrediting body to provide DTSC with the name and contact information for
21 any lead assessor whose accreditation is rescinded by the accrediting body, along with an
22 explanation for the rescission.

23 24 **Article 9. Audits**

25
26 Article 9, in its entirety, is necessary to authorize DTSC to conduct audits, as deemed
27 necessary and as resources permit, to ensure compliance with the goals and intent of articles
28 5 and 6. Audits will bring a systematic, disciplined approach to evaluate and improve the
29 effectiveness of the regulations.

30
31 Through the audits, DTSC will evaluate how different manufacturers or responsible entities
32 comply with the requirements and the decisions that they arrived at to uncover irregularities,
33 whether they are due to outright negligence or a result of laxity in following proper procedures.

34
35 Through audits, manufacturers and responsible entities will be held accountable by verifying
36 the reliability and integrity of the results of their work and alleviate the concern expressed by
37 numerous interested parties that manufacturers or responsible entities will default to less
38 costlier alternatives at the expense of seeking safer, less harmful alternatives. The results of
39 the audits, to the extent allowed by article 10, will be made public on DTSC’s website to hold
40 manufacturers and responsible entities accountable.

1 Audits will promote better management and decision-making, and thus more compliance
2 resulting in a more effective long term use of interested party resources. In the short term,
3 however, DTSC must prioritize the industry sectors that will be subject to audits to make the
4 most cost effective use of existing resources while providing the highest level of public health
5 and environmental protection.
6

7 **Section 69309. Audit of Alternatives Assessments and Regulatory Responses**

8 **Section 69309(a)** specifies that DTSC may audit Tier I and Tier II AAs as resources permit.

9 This provision is necessary to provide DTSC the authority to audit the Tier I and Tier II AA
10 reports without restricting DTSC to a set number which may vary depending on the availability
11 of resources.
12

13 **Section 69309(b)(1) through (b)(5)** are necessary to specify that the scope of the audit must
14 include, but not be limited to, an examination of: **(1)** compliance with article 5 requirements; **(2)**
15 compliance with the scope and objective of the AA Work Plan during the conduct of the AA; **(3)**
16 data quality and adequacy of analysis; **(4)** implementation of the selected alternative, if
17 applicable; and **(5)** compliance with the applicable regulatory response(s) imposed pursuant to
18 article 6. Audits of the AA are a necessary element to determine whether DTSC agrees with
19 the manufacturer's findings upon close examination of the AA results and to establish best
20 management practices for the various industry sectors.
21

22 **Section 69309(c)(1) through (c)(2)** are necessary to specify that upon completion of an audit,
23 DTSC must notify the manufacturer(s) and or responsible entity(ies) of the audit findings and
24 inform the manufacturers of the process to dispute audit findings.
25

26 **Article 10. Confidentiality of Information**

27
28 Article 10, in its entirety, is necessary to set out the provisions for the treatment of information
29 submitted pursuant to this chapter and claimed to be confidential by the submitter. Certain
30 elements also provide specifically for the handling of trade secrets. As a whole, these
31 provisions address the statutory and regulatory authorities that apply to a claim of
32 confidentiality, the procedural requirements for making a claim, and how DTSC may review
33 such a claim. These provisions also include DTSC's interpretation of a key term.
34

35 Article 10 looks primarily to Health and Safety Code section 25257, and then to the existing
36 California Public Records Act (the "PRA"), as the major sources of authority for handling
37 confidential information, as defined, while incorporating limited new features that promote
38 faster and more efficient disclosure of information, such as the marking and indexing of all
39 confidential claims and upfront substantiation of trade secret claims. In keeping with this
40 article's deference to the existing PRA and interpretations thereof, DTSC intends to rely on

1 substantive criteria already established in statute and in case law for determining trade secret
2 justification, including that set out in Government Code section 6255.

3
4 The provisions of this article will be essential to DTSC's efficient and effective processing of
5 the large amount of valuable information expected to be claimed as confidential and any
6 subsequent requests for public disclosure of that information under the PRA. These provisions
7 will play a critical role in ensuring proper document handling, minimizing DTSC response times
8 and discouraging frivolous claims while promoting access to government records and
9 maintaining public trust through robust transparency.

10
11 **Section 69310. Confidentiality of Information**

12 **Section 69310(a)** specifies the relevant authorities guiding the treatment of confidential
13 information in general and trade secrets in particular. For trade secrets, Health and Safety
14 Code section 25257 and any other applicable code section are expected to be the primary
15 authority, supplemented by the PRA wherever it does not directly conflict with the foregoing.
16 All other confidential information will be controlled by the PRA and any other applicable statute.
17 In cases where an existing law, other than Health and Safety Code section 25257, specifically
18 addresses the treatment of trade secrets, the claimed information is expected to be subject
19 primarily to that specific provision, and supplemented first by Health and Safety Code section
20 25257 and then generally by the PRA to the extent its provisions are not in direct conflict with
21 Health and Safety Code section 25257 and/or other specific provisions operating as the
22 primary authority.

23
24 Because article 10 was structured to address all manner of confidential information in addition
25 to trade secrets, submissions under AB 1879 (Stats. 2008, Ch. 559) may include a variety of
26 confidentiality claims. The single system for processing all of those claims described here is
27 necessary to promote administrative efficiency under the program while minimizing the risk of
28 inadvertent disclosure. A comprehensive system is also necessary to increase transparency
29 and foster greater public access to information, in keeping with the spirit of Government Code
30 section 6253(e). This approach ensures consistency with the PRA, while implementing the full
31 vision of AB 1879 (Stats. 2008, Ch. 559).

32
33 **Section 69310(b)** defines the omnibus term "confidential information", which was created to
34 describe any kind of information for which a submitter wishes to claim confidentiality, including,
35 but not limited to, trade secrets. A generic definition for all types of confidential information is
36 necessary to facilitate other provisions of article 10 that improve DTSC's ability to process and
37 protect all confidential information submitted under Chapter 53 while furthering public
38 transparency.

Section 69310.1. Assertion of a Claim of Confidential Information

Section 69310.1(a) requires a submitter claiming confidential information to assert the claim at the time of submission either as a trade secret under this article or as another kind of confidential information exempted under the PRA.

Such assertion must specifically identify information subject to the claim, reference its legal or factual basis in both the claims index and the supporting information required by this article, and be made at the time of submission. These requirements are necessary to facilitate efficient processing of claims by making the existence and nature of a claim clear to DTSC staff at the outset. This will also promote speedy disclosure by identifying immediately the information that may be shared with the public.

Section 69310.1(a)(1) requires that a trade secret claim identify which portion of the information is claimed to be trade secret and provide its legal or factual basis, including reference to both Health and Safety Code section 25257 and any other relevant code section, which will be included in both the claims index and any supporting information required by this article. This is necessary to assist DTSC in processing claims efficiently by making the legal basis of the claim and the corresponding authorities clear to staff at the outset.

Section 69310.1(a)(2) requires that any other confidential information claim, except for a trade secret, must identify which portion of the information is claimed to be confidential and provide its legal or factual basis, including reference to the PRA and any other relevant code section, which will be included in both the claims index and any supporting information required by this article. This is necessary to assist DTSC in processing claims efficiently by making the legal basis of the claim and the corresponding authorities clear to staff at the outset.

Section 69310.1(b) requires that the submitter provide both a complete copy of the documentation being submitted, including any claimed confidential information, and a redacted copy that excludes confidential information. Submission of a full and redacted set of documents is necessary to greatly reduce the administrative burden on DTSC by providing a redacted copy that DTSC can release to the public without the time and expense of producing such a document internally. The net result is both cost savings to DTSC and shorter turn-around time in making information available to the public.

Section 69310.1(b)(1) requires the submission of a complete copy of the documentation, including claimed confidential information, for the use of DTSC. This is necessary to allow DTSC to review all relevant technical and scientific information in carrying out its duties under this program.

Section 69310.1(b)(2) requires the submission of a copy of the documentation with the claimed confidential information redacted, which may be released in full to the public. This

1 provision is necessary to allow for a fast and efficient release of all publicly available
2 information upon request.

3

4 **Section 69310.2. Marking and Indexing of Documents**

5 **Section 69310.2(a)** requires the submitter to conspicuously mark each page containing
6 confidential information with the words “Trade Secret” and/or “Confidential”. This provision is
7 necessary to make it clear to DTSC staff the claimed confidentiality status of each individual
8 page, thereby reducing the likelihood of inadvertent disclosure.

9

10 **Section 69310.2(b)** requires the submitter to provide a separate claims index that briefly
11 describes the kind of confidential information being claimed, the legal or factual basis for the
12 claim, and the location of the claimed information in the submitted document. This claims
13 index may be made available in full to the public. The claims index is necessary to further
14 transparency by making it easier for the public to quickly identify all data withheld as
15 confidential from a particular document. It also promotes better agency data collection by
16 summarizing all claims within a single document so that aggregate data on number and types
17 of claims can be quickly collected across multiple submissions.

18

19 **Section 69310.3. Safeguarding of Confidential Information**

20 **Section 69310.3(a)** makes clear that DTSC employees may not unlawfully disclose or misuse
21 confidential information that they come into contact with at work. This provision is meant to
22 supplement, not replace, any other existing restrictions or penalties for misuse or improper
23 disclosure. This provision is necessary to ensure proper protection of confidential information
24 entrusted to DTSC.

25

26 **Section 69310.3(b)** requires DTSC employees with access to confidential information to take
27 appropriate security measures. This provision is necessary to ensure proper protection of
28 confidential information.

29

30 **Section 69310.4. Support of a Claim of Trade Secret Protection**

31 **Section 69310.4(a)** requires a submitter of information claimed to be confidential who receives
32 a request from DTSC to substantiate a trade secret claim to do so at the time of submission or
33 within 10 days of a request for support, whichever is later. It is expected, though not required,
34 that DTSC will routinely request support of trade secret claims at the initial notification, before
35 any submission is received, which will effectively require substantiation at the time of
36 submission. If DTSC chooses to request substantiation after a submission has been made,
37 then the submitter will have 10 days from receipt of DTSC’s request to comply. This provision
38 is necessary to allow DTSC to ease its factual and legal burden in reviewing a claim of trade
39 secret, thereby expediting its review and, ultimately, the release of non-privileged information.

40

1 This section also specifies the various kinds of information that the submitter must provide to
2 DTSC in order to substantiate a claim. Those categories of required information are:

- 3
- 4 (1) The identity of the person making the claim, which is necessary to establish ownership
5 and authority over the claim;
- 6 (2) A brief description of the information for which trade secret protection is being claimed,
7 which is necessary to identify and establish the boundaries of the claim;
- 8 (3) The time period of the claim and justification for it, which may range from a brief to an
9 indefinite period depending on the rationale provided, and which is necessary to
10 ensure that the information is protected only for the period of time justified;
- 11 (4) The extent to which information is known inside of the business and whether or not
12 appropriate non-disclosure agreements are in place, which is relevant to establishing
13 that reasonable security measures have been taken;
- 14 (5) The extent to which information is known outside of the business and whether or not
15 appropriate non-disclosure agreements are in place, which are relevant to establishing
16 that reasonable security measures have been taken;
- 17 (6) The security measures taken and planned to restrict access and safeguard the
18 information, which are relevant to establishing that reasonable security measures
19 have been and will continue to be taken;
- 20 (7) The estimated value of the information to the company and competitors, which is
21 relevant to establishing the economic value of the information;
- 22 (8) The estimated cost and effort invested in developing the information, which is relevant
23 to establishing the economic value of the information;
- 24 (9) The estimated ease or difficulty with which information could be properly acquired or
25 duplicated, which is relevant to the validity of a trade secret claim, the ease of reverse
26 engineering, and the reasonableness of efforts to maintain secrecy;
- 27 (10) Any relevant government agency determinations, which helps ensure that DTSC is
28 fully aware of all relevant authorities;
- 29 (11) A description of the nature and extent of potential harm from disclosure, including an
30 explanation of causation, which is relevant to establishing the economic value of the
31 information;
- 32 (12) Certification of the substantiating information by the submitter's general counsel or
33 other knowledgeable executive, based on knowledge and belief and subject to
34 established penalties for perjury and the non-compliance penalties established by this
35 chapter, all of which are necessary to ensure clear, enforceable responsibility for the
36 accuracy of the claim and its substantiating information. The signed statement is
37 required to certify to: **(A)** the truth, accuracy and completeness of the information, in
38 order to dissuade incomplete or misleading claims; **(B)** the private nature of the
39 information, in order to dissuade claims that are technically void because their
40 constituent information is already in the public domain; and **(C)** that a reasonable
41 basis for the claim exists, in order to dissuade frivolous claims;

1 **(13)** Contact information, so that DTSC can immediately contact the appropriate person if
2 the claim is deficient or challenged.

3
4 The requirement for detailed substantiation of a trade secret claim is necessary to reduce the
5 incidence of inaccurate or frivolous claims. It is also necessary to ensure that DTSC has
6 immediate access to the necessary information if called upon to make a determination on the
7 proper justification of a trade secret claim, which reduces both administrative costs and
8 response time.

9
10 **Section 69310.4(b)** specifies that while certain substantiating information must be provided for
11 each trade secret claim, information that is identical between claims may be incorporated by
12 reference. The certification and contact information requirements need only be provided once
13 for the entire submission. This provision is necessary to streamline the substantiation
14 requirements in order to reduce the compliance burden for submitters.

15
16 **Section 69310.4(c)** requires that a substantiation document containing trade secret
17 information be supplied to DTSC in both complete and redacted form as required by section
18 69310.1(b) and marked as required by section 69310.2(a). However, information claimed to
19 be trade secret that is contained in the substantiation document need not itself be indexed as
20 required by section 69310.2(b) or substantiated as required by section 69310.4(a). This
21 provision is necessary to ensure that the substantiation information is treated properly and with
22 minimal administrative burden for DTSC. Furthermore, by not applying the substantiation
23 requirement to the substantiation documents themselves, submitters can use trade secret
24 information to make their case for confidentiality without creating an infinite substantiation loop.

25 26 **Section 69310.5. Departmental Review of Trade Secret Claims**

27 **Section 69310.5**, in its entirety, is necessary to specify and make transparent the procedures
28 for DTSC review of trade secret claims.

29
30 **Section 69310.5(a)** specifies that DTSC may, at its discretion and upon submission or any
31 time thereafter, review trade secret claims and substantiating information according to the
32 additional provisions of this section. This permits DTSC to review substantiation information
33 proactively, and take action, if necessary, to ensure that the substantiation information is both
34 complete and justifiable, which reduces the incentive for making frivolous claims.

35
36 **Section 69310.5(a)(1)** specifies that if DTSC finds the substantiating information to be
37 incomplete, then it must alert the submitter of the deficiency and require him or her to rectify
38 the deficiency within a time period specified by DTSC. If the submitter fails to do so, then
39 DTSC must notify the submitter by certified mail of their failure to comply, and after a 30-day
40 notice period, DTSC may treat the improperly claimed information as a public record. During
41 that 30-day notice period, the submitter may correct the deficiency or seek a legal remedy to

1 block its prospective release by DTSC. The overall purpose is to ensure timely completion of a
2 trade secret claim, while protecting the due process rights of the submitter.
3

4 **Section 69310.5(a)(2)** specifies that DTSC may independently review a trade secret claim for
5 sufficient justification, based on existing criteria established in statute and case law. If DTSC
6 finds that the claim is not sufficiently justified, then it must notify the submitter by certified mail
7 and give the submitter thirty (30) days to seek a legal remedy before DTSC may treat the
8 improperly claimed information as a public record. The overall purpose is to ensure timely
9 completion of a trade secret claim, while protecting the due process rights of the submitter.
10

11 **Section 69310.5(a)(3)** makes clear that only after the specified procedural requirements have
12 been met may DTSC treat the improperly claimed information as if no claim had been made,
13 which results in the information being available for disclosure to the public. This ensures that
14 DTSC provides proper notice of its decision and an opportunity to take further legal action to
15 the submitter before DTSC may release to the public information claimed as a trade secret.
16

17 **Section 69310.5(b)** specifies that, in the event that DTSC receives a request under the PRA
18 for information claimed as a trade secret, DTSC must review the claim for sufficient
19 justification, unless it previously completed a review under section 69310.5, according to
20 specified procedures. This lays out clear guidelines for DTSC to follow in the event of a PRA
21 request.
22

23 **Section 69310.5(b)(1)** requires DTSC to immediately notify a submitter that a PRA request
24 has been made for information claimed as a trade secret, and then conduct a review of the
25 claim unless such a review was previously completed and there is no reason for a further
26 review. This helps protect a submitter's due process rights while curtailing the possibility of
27 duplicative reviews.
28

29 **Section 69310.5(b)(2)** specifies that DTSC must make its determination whether or not trade
30 secret protection for the information is justified within sixty (60) days of receipt of a request for
31 disclosure, so long as the submitter has received at least thirty (30) days notice prior to the
32 determination. This ensures both a reasonably timely decision by DTSC and protection of the
33 submitter's due process rights.
34

35 **Section 69310.5(b)(3)** specifies that in the event that DTSC finds insufficient justification for
36 the trade secret claim, it must give the submitter thirty (30) days written notice prior to
37 disclosure. Again, this provision ensures that the submitter has adequate time to seek legal
38 redress if it disagrees with DTSC's decision that a trade secret claim was not sufficiently
39 justified.
40

1 **Section 69310.5(b)(4)** specifies that in the event DTSC finds the trade secret claim to be
2 justified, it must inform the requester in writing within ten (10) days after the decision. If the
3 requester takes further legal action to compel disclosure, DTSC must inform the submitter
4 immediately, and indicate that the information was not disclosed because justification was
5 found to provide trade secret protection. This section also makes clear that it is the sole
6 responsibility of the submitter to defend a trade secret claim before the court, and that DTSC
7 must not disclose the claimed information in question until final disposition of the matter. This
8 provision ensures that both requester and submitter receive timely information about the status
9 of the claim. It also makes explicitly clear that responsibility for litigation of a disputed claim
10 lies with the parties themselves and not with DTSC, which is crucial for keeping limited DTSC
11 resources focused on the work of the regulation itself.
12

13 **Section 69310.6. Hazard Trait Submissions**

14 **Section 69310.6(a)** clarifies that the terms of Health and Safety Code section 25257(f) are
15 interpreted by DTSC as precluding justification for withholding trade secret information
16 submitted to DTSC that pertains to a hazard trait for a chemical or chemical ingredient,
17 including, but not limited to, Chemicals of Concern and any alternatives thereto. The term
18 “hazardous trait submissions” used in Health and Safety Code section 25257(f) is treated as
19 synonymous with the term “hazard trait submissions”. This clarifying interpretation is
20 necessary to avoid confusion and future misunderstandings over the meaning of Health and
21 Safety Code section 25257(f), such as erroneous suggestions that trade secret protection
22 under the PRA might be available, or that the exclusion might not apply to a chosen
23 alternative.
24

25 **Section 69310.6(b)** further interprets the term “hazard trait submission” to mean any
26 information submitted to DTSC pertaining to any hazard trait for any chemical or chemical
27 ingredient, including but not limited to Chemicals of Concern and any chosen alternatives. The
28 term is also interpreted to include hazard trait information that identifies the manufacturer of
29 the product containing a Chemical of Concern or a chosen alternative, as well as the fact that a
30 particular Chemical of Concern or chosen alternative is present in a particular product. These
31 interpretations are central to the purpose of Health and Safety Code Section 25257(f) in
32 excluding hazard trait data from trade secret protection. This ensures that the public has
33 appropriate access to relevant health and safety information to facilitate more informed
34 consumer purchasing and use decisions.
35

36 The defined term “hazard trait submission” does not include hazard trait information that
37 uniquely identifies a chosen alternative if that identifying information is claimed as a trade
38 secret and non-confidential identifying information is used in its place. Also excluded from the
39 definition of “hazard trait submission” is hazard trait information that discloses manufacturing
40 processes. This interpretation is necessary to ensure that certain information not germane to

1 consumer decision-making but critical to the protection of intellectual property is not
2 inadvertently captured by the term and later disclosed to the public.

3 4 **Article 11. Small Business**

5 6 **Section 69311. Applicability**

7 This section, in its entirety, is necessary to specify which type and size of a business qualifies
8 as a “small business” and is, thus, eligible for treatment as such under this article. Article 11
9 implicitly acknowledges that small businesses are differently situated from large businesses.
10 The requirements of Chapter 53 may be more challenging for small businesses to fulfill than
11 for larger businesses. In light of that, DTSC has established some ability to work with small
12 businesses to aid in their compliance with the regulations and be somewhat flexible with the
13 time lines for compliance for small businesses.

14
15 **Section 69311(a)** defines a small business based on number of employees, amount of annual
16 gross sales receipts and status as independently owned and operated. This definition is
17 necessary to have clear rules about which businesses qualify as a small business under these
18 regulations.

19
20 **Section 69311(b)** provides that article 11 applies only to a responsible entity or manufacturer
21 that meets the definition of “small business” set out in section 69311(a). Section 69311(b) also
22 specifies the documentation that a business seeking to qualify as a small business must
23 provide to DTSC. That documentation must be sent to DTSC within 60 days after a product of
24 the responsible entity or manufacturer has been identified as a Priority Product. This
25 documentation is necessary to ensure that any business seeking to take advantage of the
26 provisions of article 11 does in fact meet the qualification criteria specified in section 69311(a).
27 The required documentation consists of:

- 28
29 (1) Copies of government records that confirm the size of the business as no more than 25
30 people or a signed declaration or affidavit as to this same fact; and
31
32 (2) Tax returns that document that the average annual gross receipts of the business did
33 not exceed \$1 million over the life of the business or the prior three (3) years,
34 whichever is shorter.

35 36 **Section 69311.1. Timelines**

37 This section confers authority on DTSC to extend any otherwise applicable deadline under
38 these regulations for a small business that qualifies as a small business under section 69311.
39 This provision is necessary to give DTSC flexibility in carrying out this program, especially as it
40 applies to small businesses that will have a relatively greater challenge than other businesses
41 in fulfilling the requirements of the regulations.

1

2 Section 69311.2. Consultation Services for Small Businesses

3 This section provides that a manufacturer or responsible entity that qualifies as a small
4 business and that is subject to the requirements of article 5 may request DTSC to provide
5 consultative services to assist the manufacturer or responsible entity in complying with article 5
6 requirements. This section requires DTSC to provide the requested consultative services, and
7 requires the business requesting the services to reimburse DTSC for any associated costs
8 pursuant to Health and Safety Code section 25201.9.

9

10 This section is necessary to assure a responsible entity or manufacturer that is a small
11 business that DTSC will provide consultative services, if requested, to assist the business in
12 complying with the requirements of article 5. This section is also necessary to ensure that any
13 business requesting such services is aware of its obligation to reimburse DTSC for costs
14 associated with provided the consultative services.

15

16 Article 12. Severability

17

18 Section 69312. Severability

19 Section 69312 specifies that if any of the provisions of Chapter 53, or the application of any of
20 these provision, is held to be invalid, that invalidity will not affect other provisions or
21 applications of Chapter 53 that can be given effect without the invalid provision or application.
22 The provisions are, thus, severable. This severability provision is necessary to ensure that
23 proper and lawful provisions of the regulations are not inappropriately invalidated due to the
24 invalidity of other distinct provisions.

25