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MEMORANDUM

TO: Gerald W. Bowes, Ph.D., Manager
Cal/EPA Scientific Peer Review Program
Office of Research, Planning and Performance
State Water Resources Control Board

FROM: Jeff Wong, Ph.D.
Chief Scientist
Department of Toxic Substances Control

DATE: January 30, 2012

SUBJECT: REQUEST FOR EXTERNAL PEER REVIEW FOR SAFER CONSUMER PRODUCTS REGULATIONS

This memorandum is a request for you to initiate the process to obtain reviewers through the University of California to provide external peer review for the scientific policy portions of the proposed regulations for Safer Consumer Products. The regulatory adoption process for these proposed regulations will begin in February 2012 and is projected to become final by December 31, 2012.

The following is a list of the attachments associated with this request:

- **Attachment 1:** Summary of Proposed Regulations. Attachment 1 provides a brief background that has led the Department of Toxic Substances Control (DTSC) to propose regulations for Safer Consumer Products. The plain English version of the proposed regulations that provides major aspects of the proposed regulations are found at:
[http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-
Informal-Draft-Summary-10312011.pdf](http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-Informal-Draft-Summary-10312011.pdf)
- **Attachment 2:** Scientific Factors: Peer Review Points. Attachment 2 contains the four (4) points that DTSC is requesting comments from the peer reviewer.

- **Attachment 3:** Individuals Involved in the Development of the Safer Consumer Product Regulations.
- **Attachment 3-A:** Previous External Scientific Peer Reviewers. Attachment 3-A identifies the individuals who previously served as external peer reviewers or have current commitments with DTSC for the Safer Consumer Product regulations.
- **Attachment 4:** Excerpts from Draft Regulations for Safer Consumer Products. Attachment 4 contains the pertinent portions of the proposed regulations that are the subject of this peer review request. For regulatory context the peer reviewer may wish to view the entire text at:
[http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-
Informal-Draft-10312011.pdf](http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-
Informal-Draft-10312011.pdf)
- **Attachment 4-A:** Section 69502.2 Chemicals of Concern Identification. This table provides additional context for peer review point #1 in Attachment 2.
- **Attachment 5:** Flow Chart for the Regulations for Safer Consumer Products. Attachment 5 provides the overall big picture for the flow of the proposed regulations. The portions of the proposed regulations that are subject to the peer review are the chemical identification, prioritization, and the alternatives assessment processes.

To obtain additional information on DTSC's efforts to accelerate the quest for safer consumer products in the Green Chemistry Initiative, please visit:

<http://www.dtsc.ca.gov/SCPRegulations.cfm>

DTSC is requesting that the external peer reviewers complete their review within 30 days. It is extremely important that the peer reviewers conduct their review as expeditiously as possible in order for DTSC to finalize these regulations by December 31, 2012.

The following peer reviewers with experience in environmental policy and the following expertise are appropriate to review the regulations:

- General toxicology, including chemical hazard assessments tools, such as Green Screen, USEPA's Design for the Environment
- Materials science, product design, manufacturing practices, and familiarization with material properties involved in common consumer products
- Alternatives Assessments and related tools, including life cycle analysis, life cycle thinking, with emphasis on consumer products

Should you have further questions, you may contact me at (916) 322-0504 or at jwong@dtsc.ca.gov.

Attachment 1 Summary of Proposed Regulations

Background:

In 2008 Governor Arnold Schwarzenegger signed [Assembly Bill 1879 \(Feuer\)](#), which became Chapter 559 (stats. of 2008). This law directs DTSC to adopt regulations to establish a process to reach an aspirational goal that encourages the manufacture of safer consumer products through innovation and the use of safer or less hazardous chemicals. In 2010 DTSC proceeded with regulations and on December 23, 2010, CalEPA recommended that DTSC take additional time to work out stakeholder concerns (see: <http://www.dtsc.ca.gov/upload/GRSP-12-23-2010.pdf>). On October 31, 2011, DTSC released the informal draft Safer Consumer Product regulations.

The statutory mandate for external scientific peer review ([Health and Safety Code section 57004](#)) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices. The proposed regulations are process in nature and have a scientific foundation but are not in the traditional sense of scientific peer review as in a risk assessment or development of a regulatory threshold.

To provide the peer reviewer the context of these process regulations, please refer to the plain English version of the Summary of Informal Draft Regulations for the Safer Consumer Products (dated October 31, 2011) at:

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-Informal-Draft-Summary-10312011.pdf>. Significant changes from the 2010 version of the regulations and the current informal draft regulations are found at:
<http://dtsc.ca.gov/upload/SCPRegulationsInformal-DraftSignificantChanges.pdf>

Objective:

The statute requires DTSC's Safer Consumer Products Regulations to establish a process to identify and prioritize chemicals in consumer products that are of concern, and develop a process for manufacturers to evaluate potential alternative designs to those products.

Manufacturers subject to the regulation must evaluate the hazardous chemicals in their consumer products through the Alternatives Assessment process described in the Safer Consumer Products Regulations in efforts to reduce the use of or exposure to such chemicals. These regulations provide a framework to encourage voluntary manufacturer actions to produce safer consumer products and avoid potential regulation.

The draft regulations have narrative, rather than weighted, decision making criteria for DTSC to identify products with hazardous chemicals (referred to as Priority Products) and for manufacturers to select alternative product designs. The narrative standards in the regulations are flexible and dynamic to accommodate case by case evaluations and will also allow for future incorporation of scientific advances and new chemical hazard information. Additionally, the regulations must remain flexible to adapt to the future changes in consumer products and a variety of manufacturing processes so that the Alternatives Assessment can promote innovation. To ensure transparency in the

Attachment 1 Summary of Proposed Regulations

implementation of these regulations, there are several instances where DTSC is required to host stakeholder workshops and post publically available information regarding the regulated community. Also, DTSC must provide guidance materials to assist in performing the Alternatives Assessment. Prior to the release of the first guidance document, stakeholder input will be solicited.

Regulatory Summary:

The plain English version of the Summary of Informal Draft Regulations for the Safer Consumer Products (dated October 31, 2011) at:

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-Informal-Draft-Summary-10312011.pdf> provides a plain English summary of the complete process. DTSC is developing a four step regulatory process that:

- (1) Yields an informational list of chemicals that have been identified by an authoritative organization or reliable information to exhibit a hazard trait (as defined by [Chapter 54. Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data, Title 22, California Code of Regulations.](#)) or shown by reliable information to demonstrate the occurrence of the chemical in the public or environment (as defined in the Department's proposed regulations). These chemicals are referred to as Chemicals of Concern (COC) after they have been identified, subjected to stakeholder input, and finalized by DTSC.
- (2) Allows DTSC to identify candidate products that contain a COC(s), and may be finalized as Priority Products following stakeholder input.
- (3) Requires manufacturers to examine their Priority Products and their potential alternative products through an Alternatives Assessment (as defined in the Department's proposed regulations) and identify the selected alternative product, if any. Copies of the completed Alternatives Assessment Reports, excluding trade secret information, will be made publically available.
- (4) Designates Regulatory Response options for DTSC to impose on to manufacturers based on their product selection in the Alternatives Assessment process.

Of these four process steps, it is the first three steps that the reviewer is asked to provide a scientific peer review.

Attachment 2
Scientific Factors
Peer Review Points

The statute mandate for external scientific peer review (Health and Safety Code section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices.

We request that you make this determination for each of the following points that constitute the scientific basis of the proposed regulatory action. An explanatory statement is provided for each issue to focus the review. In each point, section [25252 of the Health and Safety Code](#) provides the authority and basis for developing the proposed regulatory text that is the focus of this peer review.

1. The use of the chemicals lists developed by the sources named in the regulations identifies chemicals with hazard traits that have public health and environmental concerns to produce an initial Chemicals of Concern (CoC) list. (See Attachment 4 and 4-A)

The overarching criterion in identifying a Chemical of Concern (CoC) is that the chemical exhibits a hazard trait or an environmental or toxicological endpoint as identified in [Chapter 54. Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data, Title 22, California Code of Regulations](#). The important terms to consider are (1) "chemical," (2) "hazard trait," and (3) the substances named on the identified lists in section 69502.2(a). A substance on the identified lists must be a chemical and exhibit a hazard trait. The intent of incorporating the identified lists is to begin the Safer Consumer Products program with an initial CoC list that utilizes the work conducted by other governmental agencies, "authoritative organizations" (as defined in [section 69401.2\(b\), Chapter 54, Title 22](#)), and studies that meet the definition of "reliable information" or "reliable information demonstrating the occurrence, or potential occurrence, or exposures to a chemical."

Using the lists developed by others streamlines efforts to develop a CoC list as well as develops a robust list of chemicals that will send signals to the marketplace to avoid regrettable substitutions when manufacturers voluntarily replace CoCs in products, especially as DTSC will start out with a small number of Priority Products.

Subsection (a)(1) identifies lists that government agencies, or "authoritative organizations," developed to require regulatory action on a chemical to safeguard the public or the environment. The chemical lists are derived from California, state, country, and international governmental agencies and organizations sources. Some of these lists include "nonchemicals," such as nutrients, soil, or bacteria; however, it is the intent of DTSC to curate the informational CoC list to remove "nonchemicals," and chemicals that are excluded by law (e.g., pesticides).

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Subsection (a)(2) identifies chemical lists that were found by authoritative organizations to have human or environmental exposure and includes chemicals that are found in the environment or receptors, including humans, through environmental monitoring or biomonitoring data and reports. The authoritative organizations generated these lists include voluntary agreements with stakeholders to advise voluntary chemical action to reduce or eliminate these chemicals due to their potential exposures to public and environment.

This subsection intends to include emerging chemicals of concern where the chemical may be prevalent or persistent, but have incomplete toxicity information. The weight of evidence based on reliable information demonstrating the exposure or potential exposure is used to substantiate the need for the chemical listed as a CoC. For example PBDEs were found to be persistent in studies conducted by the DTSC's Environmental Chemistry Laboratory in the early 2000's, but scientific studies were insufficient to definitively identify a hazard trait. Years later, additional scientific studies showed that some forms of PDBEs cause kidney toxicity and warranted chemical action.

Subsection (a)(3) include chemicals that exhibit a hazard trait based on the definition of reliable information, even though they may be generated by under the auspices of "authoritative organizations." These chemicals are important to include in the initial CoC list because they are used by governmental agencies are a source of "reliable information" to identify hazard traits and assess hazards in environmental media or consumer products. These chemicals exhibit hazard traits such as carcinogenicity and neurotoxicity that are important to stakeholders and the intent of the AB1879 (2008).

2. Use of the initial product prioritization criteria in the chemical and product prioritization process in Article 3 are sufficient to identify all types of consumer products with CoCs as potential Priority Products. Use of the key prioritization criteria considers those critical factors which identify the potential Priority Products during the initial phase as high priority.

Article 2 produces a list of CoCs. Article 3 incorporates prioritization of a CoC and a product that contains a CoC in an interactive fashion to identify Priority Products that would undergo an Alternatives Analysis. The process of identifying a potential Priority Product may start with the CoC or the product depending on the information available. In either case, both the adverse impacts of the CoC and potential exposure of the CoC in the product are considered before the CoC/product combination are proposed and finalized as Priority Products.

For instance the CoC list could be culled and those that exhibit considerable adverse effects, especially to sensitive subpopulations, may be targeted for information on their volume in commerce, and use in manufacturing. Research could then proceed on to

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the types of products that use these “CoCs of higher concern” to determine exposure potential in consumer products.

Conversely, using the potential exposure criteria, product research may show certain types of product categories have a high likelihood of exposure routes. Further research and information requests to manufacturers, albeit voluntary, into ingredients may indicate the presence of CoC(s) in the product category which would warrant listing as a Priority Product.

In both instances, the interplay of CoC and product is considered – adverse effect of the CoC and exposure potential of the CoC based on product’s life cycle. These potential Priority Products would undergo an evaluation of the “Key Prioritization Criteria” in section 69503.2(b), to determine which of these candidates for Priority Products should be given “higher priority” and undergo the public listing process in section 69503.3. Please note that the Key Prioritization Criteria are different for assembled and formulated products.

- 3. Application of a de minimis level by adding the concentrations of CoCs that have the same hazard trait or environmental or toxicological endpoint, referred as “cumulative concentration,” in the proposed regulations is scientifically understood and adequately protects public health and the environment.**

De minimis is defined in section 69501.2(a)(25) as 0.01% for certain chemical hazard traits and for others as 0.1%. De minimis used in these regulations determine whether the Priority Product will undergo an Alternatives Assessment. De minimis itself is not a measure a safety but an administrative convenience, and it is DTSC’s intent to incorporate safety in a de minimis level when a case-by-case evaluation and modification to the de minimis level for the CoC in the Priority Product is conducted and undergoes a public process for the rationale to raise or lower the de minimis level. However in lieu of a case by case de minimis level, is there another more justifiable approach to de minimis that DTSC could consider that does not create a significant workload?

The current approach allows a manufacturer with a Priority Product with multiple CoCs to provide a de minimis exemption notice (and not be subject to an Alternatives Analysis) by comparing the de minimis level with the sum of the CoC concentrations that have the same hazard trait or environmental or toxic endpoint. By adding CoCs with the same hazard trait, rather than apply the de minimis to each CoC with the same hazard trait, DTSC is allowing for a cautious approach.

- 4. The definitions of the various “adverse” impacts and general usage of the term “adverse” impacts is used throughout the regulations. Within the context of the definitional and general use of the term “adverse” impacts in**

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the regulations and when scientific information is available, a qualitative or quantitative determination of adverse impact can be made, and is adequately protective of public health and the environment.

Sections 69301.2(a)(2)-(8) provides a number of definitions for adverse impacts. These terms are used in the regulatory language to consider when identifying CoCs, prioritizing Priority Products, conducting Alternative Assessments, and assigning Regulatory Responses. The definitions are used within their regulatory context to determine “adverse.” When information or data is available, a qualitative or quantitative determination can be made to substantiate and describe the “adverse” impacts and to explain them during the public process prior to listing the CoCs and Priority Products.

During the Alternatives Analysis, it is intended to provide guidance specific to the Priority Product to describe the expectations of DTSC to address “adverse” impacts, which will lead to the appropriate Regulatory Response after the Alternative is chosen. The various uses of “adverse” as they apply to Alternatives Analysis within the highlighted regulations in Attachment 4 adequately convey the intent of what adverse means in regulations. The regulations with the guidance that will be developed to provide DTSC’s expectations for “adverse” impacts in the Alternative Analysis will be used to help with compliance.

The Big Picture

Reviewers are not limited to addressing only the specific issues presented above, and area asked to contemplate the following questions:

- (a) In reading the supporting documentation in Attachment 4 and proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the proposed rule not described above? If so, please comment with respect to the statute language given above.
- (b) Taken as a whole, is the scientific portion of the proposed rule based upon sound scientific knowledge, methods, and practices?

Reviewers should also note that some proposed actions may rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statute requirement for absolute scientific rigor. In these situations, the proposed course of action is favored over no action.

The preceding guidance will ensure that reviewers have the opportunity to comment on all aspects of the scientific basis of the proposed DTSC action. At the same time, reviewers also should recognize that DTSC has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed rule. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that relevant to the central regulatory elements being proposed

Attachment 3

Individuals Involved in the Development of the Safer Consumer Product Regulations

The Green Ribbon Science Panel members who act in an advisory capacity to these regulations are the following:

Ann Blake, Ph. D., Environmental & Public Health Consulting
William F. Carroll, Ph.D., Occidental Chemical Corporation
Jae Choi, Ph.D., Avaya Corporation
Bruce R. Cords, Ph.D., Ecolab Inc.
George P. Daston, Ph.D., The Procter & Gamble Company
B. Tod Delaney, Ph.D., First Environment, Inc.
Richard Denison, Ph.D., Environmental Defense Fund
Arthur Fong, Ph.D., IBM Corporation
Kenneth Geiser, Ph.D., University Massachusetts-Lowell
Lauren Heine, Ph.D., Lauren Heine Group, LLC
Dale Johnson, Ph.D., UC Berkeley
Michael Kirschner, Design Chain Associates, LLC
Richard Liroff, Ph.D., Investor Environmental Health Network
Timothy F. Malloy, J.D., UCLA School of Law
H. Scott Matthews, Ph.D., Carnegie Mellon University
Roger McFadden, Staples, Inc.
Kelly D. Moran, Ph.D., TDC Environmental, LLC
Oladele A. Ogunseitan, Ph.D., M.P.H., University of California, Irvine
Robert Peoples, Ph.D., ACS Green Chemistry Institute
Julia Quint, Ph.D., California Department of Public Health
Debbie Raphael, M.A., San Francisco Department of the Environment
Julie M. Schoenung, Ph.D., University of California, Davis
Megan R. Schwarzman, MD, M.P.H., University of California, Berkeley
Anne Wallin, Ph.D., The Dow Chemical Company
Joseph H. Guth, J.D., Ph.D., Science & Environmental Health Network
Michael P. Wilson, Ph.D., M.P.H., University of California, Berkeley
Julie B. Zimmerman, Ph.D., Yale University

These Individuals have current commitments that involve the Safer Consumer Product regulations:

John Applegate

Nicholas Ashford, Ph.D., J.D., Massachusetts Institute of Technology

Norman L. Christensen, Ph.D., Duke University

Paul Locke, Dr.PH., J.D., M.P.H., Johns Hopkins Bloomberg School of Public Health

Joel Tickner, ScD, Assistant Professor, University of Massachusetts Lowell

Attachment 3

Individuals Involved in the Development of the Safer Consumer Product Regulations

The Science Advisory Panel members served as advisors for the Green Chemistry Initiative Report that led to the enactment of AB 1879, the legislation that provided the authority for the Safer Consumer Product regulations. The panel members are the following:

John Warner, Ph.D., (Chair), The Warner Babcock Institute for Green Chemistry
John R. Balmes, M.D. (Vice-Chair), University of California, San Francisco and Berkeley
Paul Anastas, Ph.D., Yale University
Nicholas Ashford, Ph.D., J.D., Massachusetts Institute of Technology
Eric Beckman, Ph.D., University of Pittsburgh
William F. Carroll, Jr., Ph.D., Occidental Chemical Corporation
Gail Charnley, Ph.D., HealthRisk Strategies
Richard A. Denison, Ph.D., Environmental Defense Fund
Daryl Ditz, Ph.D., Center for International Environmental Law
Michael Dourson, Ph.D., DABT, ATS, Toxicology Excellence for Risk Assessment
Ken Geiser, Ph.D., University Massachusetts-Lowell
Lynn Goldman, M.D., M.P.H., John Hopkins Bloomberg School of Public Health
John D. Graham, Ph.D., Dean, Pardee RAND Graduate School
Neil C. Hawkins, Ph.D., The Dow Chemical Company
Lauren Heine, Ph.D., Clean Production Action: Lauren Heine Group LLC
Vistas M. Karbhari, Ph.D., University of California, San Diego
John Peterson Myers, Ph. D., Environmental Health Sciences
Mary O'Brien, Ph. D., Grand Canyon Trust
Michael Wilson, Ph. D., M.P.H., University of California, Berkeley
Katy Wolfe, Ph.D., Institute for Research and Technical Assistance
Berry Trost, Ph. D., Stanford University

Attachment 3-A
Previous External Scientific Peer Reviewers (2010)

The following individuals have provided peer review to DTSC on the previous draft regulations in 2010 at:

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/SCPA-Archives.cfm>.

The external peer reviews for the 2010 Safer Consumer Product Alternative regulations are at

http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA_15Day_Notice_Attachment_2.pdf.

Norman L. Christensen, Ph.D., Professor of Ecology and Founding Dean, Nicholas School of the Environment, Duke University

Terrence Collins, Ph.D., Teresa Heinz Professor of Green Chemistry, Department of Chemistry, Carnegie Mellon University.

Paul Locke, DrPH, JD, MPH, Associate Professor, Department of Environmental Health Sciences, Johns Hopkins Bloomberg School of Public Health

Joel Tickner, ScD, Assistant Professor, Department of Community Health and Sustainability, School of Health and Environment, University of Massachusetts Lowell

Reviewers through the Cal/EPA Scientific Peer Review Program:

William H. Farland, Ph.D, ATS, Professor, Environmental and Radiological Health Sciences, Office of the Vice President for Research, Colorado State University.

George M. Gray, Ph.D, Professor, Department of Environmental and Occupational Health, Director, Center for Risk Science and Public Health, George Washington University, School of Public Health and Health Services.

Ortwin Renn, Ph.D., Professor and Chair of Environmental Sociology and Technology Assessment, Stuttgart University, Germany.

**Attachment 4
Regulation Excerpts**

1 **§ 69501.2. Definitions.**

2 (a) When used in this chapter, the following terms have the meanings specified in this
3 section:

4
5 (1) “Accreditation body” means an organization that meets the requirements of section
6 69508.2 and administers a program designed to train, evaluate, assist, and certify assessors.

7
8 (2) “Adverse air quality impacts” means air emissions of any of the air contaminants
9 listed below:

10 (A) California Toxic Air Contaminants;

11 (B) Greenhouse gases, which means any of the following gases:

12 1. Carbon dioxide;

13 2. Hydrofluorocarbons;

14 3. Methane;

15 4. Nitrogen trifluoride;

16 5. Nitrous oxide;

17 6. Perfluorocarbons;

18 7. Sulfur hexafluoride;

19 (C) Nitrogen oxides;

20 (D) Particulate matter, with an aerodynamic diameter of ten (10) micrometers or less;

21 (E) Stratospheric ozone-depleting compounds;

22 (F) Sulfur oxides; or

23 (G) Tropospheric ozone-forming compounds.

24
25 (3) “Adverse ecological impacts” means any of the following direct or indirect effects on
26 living organisms and their environments:

27 (A) Acute or chronic toxicity to aquatic, avian, or terrestrial animal or plant species;

28 (B) Adverse impacts on aquatic and terrestrial ecosystems;

29 (C) Deterioration or loss of environmentally sensitive habitats;

30 (D) Impacts that cause population loss, reductions in biodiversity, or changes in
31 ecological communities;

32 (E) Impacts that cause vegetation contamination or damage;

33 (F) Impairment of the ability of an endangered or threatened species to survive or
34 reproduce; or

35 (G) Any other impact specified in article 4 of chapter 54.

36
37 (4) “Adverse environmental impacts” means any of the following:

38 (A) Adverse air quality impacts;

39 (B) Adverse ecological impacts;

40 (C) Adverse soil quality impacts; or

41 (D) Adverse water quality impacts.

1 (5) "Adverse public health impacts" means impacts that directly or indirectly cause any
2 of the toxicological effects on public health listed in articles 2 and 3 of chapter 54.

3
4 (6) "Adverse soil quality impacts" means any of the following effects on soil function or
5 soil chemical, physical, or biological characteristics or properties:

6 (A) Biological contamination;

7 (B) Chemical contamination;

8 (C) Compaction or other structural changes;

9 (D) Erosion;

10 (E) Loss of organic matter; or

11 (F) Soil sealing, meaning the covering of the soil surface with a layer of impervious
12 material or changing the nature of the soil so that it behaves as an impermeable medium.

13
14 (7) "Adverse waste and end-of-life impacts" means adverse impacts associated with any
15 of the following:

16 (A) The amount of waste and byproducts generated, and any special handling required
17 for the waste and byproducts, during the life cycle of the Priority Product and each alternative
18 being considered;

19 (B) Disposal, treatment, or use of waste and byproducts, including solid waste,
20 wastewater and storm water discharge streams; or

21 (C) Disposal of the Priority Product in the trash, down the sewer, or down the storm
22 drain that interferes with the proper operation of solid waste, wastewater, or storm water
23 treatment facilities, and that may result in the release of Chemicals of Concern to the
24 environment.

25
26 (8) "Adverse water quality impacts" means any of the following adverse effects on the
27 beneficial uses, as specified in Water Code section 13050(f) or adopted in a Water Quality
28 Control Plan pursuant to article 3 of chapter 3 and/or article 3 of chapter 4 of division 7 of the
29 Water Code, of the waters of the State, which include groundwater, fresh water, brackish
30 water, marsh lands, wetlands, or coastal bodies or systems:

31 (A) Increase in biological oxygen demand;

32 (B) Increase in chemical oxygen demand;

33 (C) Increase in temperature;

34 (D) Increase in total dissolved solids; or

35 (E) Introduction of, or increase in, any of the following:

36 1. Chemicals identified as priority toxic pollutants for California pursuant to section
37 303(c) of the federal Clean Water Act;

38 2. Pollutants listed by California or the United States Environmental Protection Agency
39 for one or more water bodies in California pursuant to section 303(d) of the federal Clean
40 Water Act;

41 3. Chemicals for which primary Maximum Contaminant Levels (MCLs) have been
42 established under the federal Safe Drinking Water Act;

1 4. Pollutants requiring monitoring and reporting in waste discharges to land that have
2 Notification Levels (NLs) specified under the Waste Discharge and Water Reuse
3 Requirements (WDRs/WRRs) of the Porter-Cologne Water Quality Control Act; or

4 5. Chemicals for which OEHHA has published public health goals for drinking water.
5

6 (9) "Alternative" means any of the following:

7 (A) Removal of Chemical(s) of Concern in a Priority Product, with or without adding or
8 increasing the concentration of a substitute chemical;

9 (B) Reformulation or redesign of a product and/or manufacturing process to reduce or
10 eliminate the concentration of Chemical(s) of Concern in the Priority Product;

11 (C) Redesign of the product and/or manufacturing process, using different materials to
12 reduce the potential for public health and/or environmental exposures to Chemical(s) of
13 Concern in Priority Product; or

14 (D) Any other change to a Priority Product or a manufacturing process that reduces the
15 potential for adverse public health and/or environmental impacts or exposures associated with
16 the Chemical(s) of Concern in the Priority Product.
17

18 (25) "De minimis level" means a concentration equal to whichever of the following is
19 applicable:

20 (A) 0.01% by weight for chemicals exhibiting any of the following hazard traits or environmental
21 or toxicological endpoints specified by OEHHA pursuant to title 22, California Code of
22 Regulations, division 4.5, chapter 54:

23 1. Bioaccumulation;

24 2. Carcinogenicity, as defined in section 69402.1, that meets one or more of the criteria
25 in section 69402.2(a);

26 3. Developmental toxicity, as defined in section 69402.3, that meets one or more of the
27 criteria in section 69402.4(a);

28 4. Endocrine toxicity, as defined in section 69403.3, that meets one or more of the
29 criteria in section 69403.17(a);

30 5. Genotoxicity, as defined in section 69403.5, that meets one or more of the criteria in
31 section 69403.17(a);

32 6. Immunotoxicity, as defined in section 69403.8, that meets one or more of the criteria
33 in section 69403.17(a);

34 7. Neurotoxicity, as defined in section 69403.12, that meets one or more of the criteria
35 in section 69403.17(a);

36 8. Persistence; or

37 9. Reproductive toxicity, as defined in section 69402.5, that meets one or more of the
38 criteria in section 69402.6(a).

39 (B) 0.1% by weight for chemicals that do not exhibit any of the hazard traits or
40 environmental or toxicological endpoints listed in subparagraph (A).

41 (C) The de minimis level concentration specified by the Department pursuant to section
42 69503.4(c).
43
44

45 Article 2. Chemicals of Concern Identification Process

1

2 § 69502. General.

3 (a) This article identifies Chemicals of Concern, and specifies the process by which the
4 Department may identify additional Chemicals of Concern.

5 (b) The Department may use, but is not limited to using, information obtained and/or
6 reviewed pursuant to section 69501.5 to perform its duties under this article.

7

8 NOTE: Authority cited: Sections 25252 and 58012, Health and Safety Code. Reference:
9 Section 25252, Health and Safety Code.

10

11 § 69502.1. Applicability.

12 This article applies to all chemicals that exhibit a hazard trait or an environmental or
13 toxicological endpoint, and that may be present in products placed into the stream of
14 commerce in California.

15

16 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
17 Reference: Sections 25252 and 25257.1, Health and Safety Code.

18

19 § 69502.2. Chemicals of Concern Identification.

20 (a) Initial Chemicals of Concern List. As of the effective date of these regulations, a
21 chemical is identified as a Chemical of Concern, if it exhibits a hazard trait or an environmental
22 or toxicological endpoint, and meets one or more of the following criteria:

23 (1) The chemical is identified as exhibiting a hazard trait on one or more of the following
24 lists:

25 (A) California Safe Cosmetics Program's Chemicals Known or Suspected to Cause
26 Cancer or Reproductive Toxicity;

27 (B) California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65);

28 (C) Canadian Environmental Protection Act Environmental Registry's Persistent,
29 Bioaccumulative, and Inherently Toxic to the Environment (CEPA PBT);

30 (D) Category A and B Carcinogens, Report on Carcinogens, US Department of Health
31 and Human Services, Public Health Service, National Toxicology Program;

32 (E) Chemicals for which primary Maximum Contaminant Levels (MCLs) have been
33 established under the federal Safe Drinking Water Act;

34 (F) European Chemical Substances Information System Persistent Bioaccumulating
35 Toxins (ESIS PBT);

36 (G) European Commission Category 1 and Category 2 endocrine disruptors;

37 (H) European Union Directive on Dangerous Substances (Directive 67/548/EEC),
38 Category 1 Carcinogens and Category 1 Reproductive toxins;

39 (I) European Union EC 1272/2008 Annex VI, Category 1A and 1B carcinogens,
40 Category 1A and 1B reproductive toxins, and Category 1A and 1B mutagens;

41 (J) International Agency for Research on Cancer (IARC), Groups 1, 2A, and 2B
42 carcinogens;

- 1 (K) Pollutants listed by California or the US EPA for one or more water bodies in
2 California pursuant to section 303(d) of the federal Clean Water Act;
- 3 (L) Pollutants requiring monitoring and reporting in waste discharges to land that have
4 Notification Levels (NLs) specified under the Waste Discharge and Water Reuse
5 Requirements (WDRs/WRRs) of the Porter-Cologne Water Quality Control Act;
- 6 (M) Priority toxic pollutants for California pursuant to section 303(c) of the federal Clean
7 Water Act;
- 8 (N) US EPA Toxics Release Inventory Persistent, Bioaccumulative and Toxic
9 Chemicals; and/or
- 10 (O) Washington Department of Ecology Persistent, Bioaccumulative, Toxic Chemicals.
- 11 (2) The chemical is identified by one or more of the following lists based on exposures
12 or environmental or toxicological endpoints:
- 13 (A) National Report on Human Exposure to Environmental Chemicals, Center for
14 Disease Control;
- 15 (B) OSPAR List of Chemicals for Priority Action;
- 16 (C) OSPAR List of Substances of Possible Concern; and/or
- 17 (D) US EPA National Waste Minimization Program list of Persistent Bioaccumulative
18 and Toxic Priority Chemicals.
- 19 (3) The chemical is identified by one or more of the following sources of reliable
20 information:
- 21 (A) Grandjean & Landrigan identification of neurotoxicants;
- 22 (B) National Toxicology Program, Office of Health Assessment and Translation (formerly
23 the Center for the Evaluation of Risks to Human Reproduction (CERHR)) reports; and/or
- 24 (C) US EPA Integrated Risk Information System (IRIS) identification of carcinogens.
- 25 (b) Additions to the Chemicals of Concern List. In addition to the chemicals identified as
26 Chemicals of Concern pursuant to subsection (a), the Department may identify chemicals, that
27 exhibit one or more hazard traits or environmental or toxicological endpoints, as Chemicals of
28 Concern by considering the following factors for which information is available:
- 29 (1) Potential Chemical Adverse Impacts.
- 30 (A) The potential for the chemical to cause adverse public health and/or environmental
31 impacts, considering:
- 32 1. The chemical's hazard traits and environmental or toxicological endpoints, and
33 modes of action;
- 34 2. The chemical's aggregate effects;
- 35 3. The chemical's cumulative effects with other Chemicals of Concern with similar
36 modes of action;
- 37 4. The chemical's physicochemical properties;
- 38 5. The chemical's environmental fate properties; and
- 39 6. The populations and/or environmental receptors that are potentially adversely
40 impacted.

1 (B) The Department shall give special consideration to the type and severity of potential
2 adverse impact(s) and the potency of the chemical associated with the adverse impact(s) for
3 all of the following:

4 1. Children, pregnant women, and other sensitive subpopulations;
5 2. Environmentally sensitive habitats, endangered and threatened species, and
6 environments in California that have been designated as impaired by a California State or
7 federal regulatory agency; and

8 3. Widespread adverse public health and/or environmental impacts.

9 (2) Potential Exposures. The potential public and/or environmental exposures to the
10 chemical in quantities that could result in adverse impacts, considering relevant reliable
11 information that indicates the possibility for public or environmental exposures to the chemical,
12 and reliable information demonstrating the occurrence, or potential occurrence, of exposures
13 to the chemical.

14 (3) Availability of Information. The availability of reliable information to substantiate the
15 potential adverse impacts and exposures.

16 (4) Safer Alternatives. The Department may adjust the prioritization prior to listing a
17 chemical as a Chemical of Concern by considering whether there is a readily available safer
18 alternative chemical that is functionally acceptable for one or more common uses of the
19 chemical in consumer products.

20
21 NOTE: Authority cited: Sections 25252 and 58012, Health and Safety Code. Reference:
22 Sections 25252 and 25257.1, Health and Safety Code.

23 24 25 **Article 3. Chemicals of Concern and Consumer Product Prioritization Process**

26 27 **§ 69503. General.**

28 (a) This article specifies the process by which the Department shall evaluate and
29 prioritize products containing Chemicals of Concern.

30 (b) The Department may use, but is not limited to using, information obtained and/or
31 reviewed pursuant to section 69501.5 to perform its duties under this article.

32
33 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
34 Reference: Sections 25252 and 25253, Health and Safety Code.

35 36 **§ 69503.1. Applicability.**

37 Except as provided otherwise in section 69501(b), this article applies to all products that
38 contain one or more Chemicals of Concern, and that may be placed into the stream of
39 commerce as a consumer product in California.

40
41 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
42 Reference: Sections 25251, 25252, 25253, and 25257.1, Health and Safety Code.

§ 69503.2. Priority Products Prioritization.

(a) Product Prioritization Criteria. The Department will evaluate products to determine the potential adverse impacts and potential exposures by considering the factors listed in paragraphs (1) through (3) for which information is available. Based on that evaluation the Department may identify and list as Priority Products, consistent with the provisions of subsections (b) and (c) and the procedures specified in section 69503.3, products that it determines to be of high priority.

(1) Potential Adverse Impacts and Exposures. The Department shall consider the potential adverse public health and environmental impacts posed by the Chemical(s) of Concern in a product due to potential exposures during the manufacture, useful life, and end-of-life disposal or management of the product. The evaluation of the potential adverse impacts and exposures shall consider both of the following:

(A) Potential Adverse Impacts from Chemicals of Concern.

1. The potential for the Chemical(s) of Concern in a product to cause adverse public health and/or environmental impacts, considering:

a. The Chemical(s) of Concern's hazard trait(s) and environmental and toxicological endpoint(s), and mode(s) of action;

b. The Chemical(s) of Concern's aggregate effects;

c. The Chemical(s) of Concern's cumulative effects with other Chemicals of Concern with similar modes of action;

d. The Chemical(s) of Concern's physicochemical properties;

e. The Chemical(s) of Concern's environmental fate properties; and

f. The populations and/or environmental receptors that are potentially adversely impacted.

2. The Department shall give special consideration to the type and severity of potential adverse impact(s), and the potency of the chemical(s) associated with the adverse impact(s), for all of the following:

a. Children, pregnant women, and other sensitive subpopulations;

b. Environmentally sensitive habitats, endangered and threatened species, and environments in California that have been designated as impaired by a State or federal regulatory agency; and

c. Widespread adverse public health and/or environmental impacts.

(B) Potential Exposures. The potential for public and/or environmental exposures to the Chemical(s) of Concern in the product in quantities that could result in adverse impacts, considering:

1. Market presence information for the product;

2. Relevant reliable information that indicates the possibility for public or environmental exposures to the Chemical(s) of Concern in the product, and reliable information demonstrating the occurrence, or potential occurrence, of exposures to the Chemical(s) of Concern in the product;

3. Information concerning the household presence of the product, and other products containing the same Chemical(s) of Concern that is/are the basis for the Priority Product

1 listing, including the number of such of products, how common their household presence is,
2 the frequency of use, and the concentration of the chemical in those products; and

3 4. The potential for public or environmental exposures to the Chemical(s) of Concern in
4 the product, during the useful life of the product and end-of-life disposal or management of the
5 product, considering:

6 a. Manufacturing, use, storage, transportation, and end-of-life management practices
7 and the locations of these practices;

8 b. The types of uses that could result in public exposure to the Chemical(s) of Concern
9 in the product, considering:

10 i. Household and recreational use;

11 ii. Sensitive subpopulation potential use or exposure at locations frequented by
12 members of sensitive subpopulations; and

13 iii. Workers, customers, clients, and members of the general public who use, or
14 otherwise come in contact with, the product or releases from the product in the home,
15 workplace, or other location;

16 c. Frequency and duration of exposure for each use scenario and end-of-life scenario;

17 d. Containment of the Chemical(s) of Concern within the product, and engineering and
18 administrative controls; and

19 e. Potential for release into, migration from, or distribution across environmental media,
20 and potential for accumulation and persistence in biological and/or environmental components
21 or systems of the Chemical(s) of Concern or its/their degradation products, considering the
22 environmental fate properties of the Chemical(s) of Concern and its/their degradation products.

23 (2) Availability of Information. The Department shall consider the availability of reliable
24 information to substantiate the potential adverse impacts and exposures.

25 (3) Other Regulatory Programs. The Department shall consider the scope of federal
26 and/or other California State regulatory programs, and any applicable international trade
27 agreements ratified by the United States Senate, under which the product or the Chemical(s)
28 of Concern in the product is/are regulated, and the extent to which these other regulatory
29 requirements address, and provide adequate protections with respect to, the same adverse
30 public health and environmental impacts and exposure pathways that are being considered as
31 a potential basis for the product being listed as a Priority Product.

32 (b) Key Prioritization Criteria. In using the factors specified in subsection (a) to prioritize
33 products, the Department shall give priority to products meeting one or more of the following
34 criteria:

35 (1) The Chemical(s) of Concern in the product have a significant potential to cause
36 adverse public health and environmental impacts;

37 (2) The product is widely distributed in commerce, and widely used by consumers;

38 (3) There is a significant potential for public and environmental exposures to the
39 Chemical(s) of Concern in the product in quantities that can result in adverse public health or
40 environmental impacts;

41 (4) For assembled products, the product contains one or more Chemical(s) of Concern
42 that may present potential exposure(s) through inhalation or dermal contact in quantities that
43 can result in adverse public health or environmental impacts; and/or

1 (5) For formulated products, the product is intended to be:

2 (A) Applied directly to the body;

3 (B) Dispersed as an aerosol or a vapor; or

4 (C) Applied to hard surfaces with the likelihood of runoff or volatilization.

5 (c) Process for Consideration of the Prioritization Factors.

6 (1) Potential Adverse Impacts and Exposures and Availability of Information. The
7 Department shall begin the product prioritization process by evaluating products based on the
8 factors specified in subsection (a)(1) in conjunction with subsection (a)(2).

9 (2) Other Regulatory Programs. Having considered the potential adverse impacts and
10 the potential exposures for the product and its Chemical(s) of Concern, the Department shall
11 then determine which of these potential adverse impacts and exposures are addressed by
12 consideration of subsection (a)(3), and adjust the prioritization accordingly.

13 (3) Priority Products. Products determined to be of high priority after completion of the
14 steps specified in paragraphs (1) and (2) may be listed as Priority Products.

15 (4) Safer Alternative. The Department may, at its discretion, consider whether there is a
16 readily available safer alternative, that is functionally acceptable and technologically and
17 economically viable, to further adjust the prioritization prior to listing a product as a Priority
18 Product.

19 (5) Key Prioritization Factors. Prior to issuing the proposed and final Priority Products
20 lists, the Department shall review the list for consistency with subsection (b), and make
21 adjustments as needed.

22
23 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.

24 Reference: Sections 25252, 25253, and 25257.1, Health and Safety Code.

25
26 **§ 69503.4. De Minimis Exemption.**

27 (a) A responsible entity is exempt from the requirements of article 5 with respect to a
28 product that is listed as a Priority Product and that meets the criteria for a de minimis
29 exemption specified in subsection (b), if one of the responsible entities for the product submits
30 a complete and timely De Minimis Exemption Notification to the Department pursuant to
31 section 69503.5, unless subsection (d) or (e) of section 69503.5 applies.

32 (b) A de minimis exemption applies only to products meeting one of the following criteria
33 as of the date of the applicable Priority Products listing or the date the product is first placed
34 into the stream of commerce in California, whichever is later:

35 (1) For a formulated product, the cumulative concentration in the product of all
36 Chemicals of Concern that are a basis for the Priority Products listing and that exhibit the same
37 hazard trait, or environmental or toxicological endpoint, and mode of action does not exceed
38 the de minimis level.

39 (2) For an assembled product, the cumulative concentration in each component that is a
40 basis for the Priority Products listing, of all Chemicals of Concern that are a basis for the
41 Priority Products listing and that exhibit the same hazard trait, or environmental or toxicological
42 endpoint, and mode of action does not exceed the de minimis level.

1 (c)(1) The Department may specify a de minimis level that is lower or higher than the level
2 specified in subparagraph (A) or (B) of section 69501.2(a)(25) for the Chemical of Concern in
3 the Priority Product, if the Department determines based on available information that a lower
4 or higher de minimis level is warranted.

5 (2) The Department may specify a lower de minimis level if one or both of the following
6 criteria apply:

7 (A) The Chemical of Concern is found in concentrations at or below the level specified in
8 subparagraph (A) or (B) of section 69501.2(a)(25), whichever is applicable, in products that are
9 common and are frequently used, and reliable information shows that, even when individual
10 product concentrations of the Chemical of Concern are below the de minimis level, there is the
11 potential for adverse impacts from potential exposures to the Chemical of Concern, or releases
12 of the Chemical of Concern, due to one or more of the following:

- 13 1. Potential aggregate or cumulative exposures;
- 14 2. The inherent potency of the Chemical of Concern;
- 15 3. Potential bioaccumulation; or
- 16 4. The unintended presence of the Chemical of Concern in organs, tissues, or fluids.

17 (B) Reliable information shows the Chemical of Concern poses, or potentially poses,
18 adverse impacts in concentrations at or below the level specified in subparagraph (A) or (B) of
19 section 69501.2(a)(25), whichever is applicable.

20 (3)(A) The Department may specify a higher de minimis level if all of the following criteria
21 apply:

- 22 1. The source of the Chemical of Concern is one of the following:
 - 23 a. A naturally occurring contaminant in raw materials that are common and are
24 frequently used to manufacture the product;
 - 25 b. Air or water frequently used as a processing agent or an ingredient to manufacture
26 the product;
 - 27 c. A contaminant in recycled materials that are common and are frequently used to
28 manufacture the product; or
 - 29 d. A processing agent or intermediate frequently used to promote certain chemical or
30 physical changes during manufacturing, and the incidental retention of a residue is not desired
31 or intended;
- 32 2. The concentration of the Chemical of Concern in the Priority Product does not
33 exceed the concentration of the Chemical of Concern in the source; and
- 34 3. The Chemical of Concern cannot reasonably be removed from the product.

35 (B) The Department may not specify a higher de minimis level if this would result in
36 increased adverse public health or environmental impacts.

37
38 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
39 Reference: Sections 25252 and 25253, Health and Safety Code.

40
41 **§ 69503.5. De Minimis Exemption Notifications.**

- 1 (a) A De Minimis Exemption Notification required under section 69503.4(a) must be
2 submitted to the Department within sixty (60) days after the product is listed as a Priority
3 Product. The notification must include all of the following:
- 4 (1) Name of, and contact information for, the person submitting the De Minimis
5 Exemption Notification.
- 6 (2) Name of, and contact information for, the manufacturer and the importer(s), if
7 applicable.
- 8 (3) Name of, and contact information for, all responsible entities for the product, to the
9 extent known.
- 10 (4) The source of the Chemical(s) of Concern in the product.
- 11 (5) Information concerning any attempts taken to eliminate or reduce the amount of the
12 Chemical(s) of Concern in the product.
- 13 (6) The maximum concentration at which the Chemical(s) of Concern is/are present in
14 the product, and a listing and description of all information used to determine and substantiate
15 this concentration. A description must be included of whichever of the following is applicable:
- 16 (A) For a formulated product, the maximum concentration in the product of each
17 Chemical of Concern that is a basis for the Priority Product listing, and a description of the
18 information used to detect and measure this concentration.
- 19 (B) For an assembled product, the maximum concentration in each component, that is a
20 basis for the Priority Product listing, of each Chemical of Concern that is a basis for the Priority
21 Product listing, and a description of the information used to detect and measure this
22 concentration.
- 23 (7) Laboratory analytical testing protocols and results used to detect and measure the
24 concentration of the Chemical of Concern in the product, including quality control and quality
25 assurance protocols and information concerning the testing laboratory.
- 26 (8) A demonstration and certification that the responsible entity does and will continue to
27 meet the criteria, assumptions, and conditions that are the basis for the exemption.
- 28 (b) The responsible entity bears the burden of proof to demonstrate that the
29 concentration of the Chemical(s) of Concern in the Priority Product does not exceed the
30 applicable de minimis level, and will not pose a potential adverse public health or
31 environmental impact.
- 32 (c) If any of the information listed in subsection (a) significantly changes, a revised De
33 Minimis Exemption Notification shall be submitted to the Department within thirty (30) days of
34 the change.
- 35 (d) If the product no longer meets the criteria for a de minimis exemption specified in
36 section 69503.4, the responsible entity shall notify the Department of this change within thirty
37 (30) days of the change, and shall submit a Preliminary AA Report to the Department within
38 180 days after the change.
- 39 (e) The exemption provided under section 69503.4(a) does not apply if the Department
40 determines, and notifies the person who submitted the De Minimis Exemption Notification, that
41 the information or findings contained in the notification are inaccurate, invalid, or inadequate to
42 support a de minimis exemption.
- 43

1 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
2 Reference: Sections 25252 and 25253, Health and Safety Code.

3 4 **Article 4. Petition for Inclusion of a Chemical or Product in the Identification and** 5 **Prioritization Processes**

6 7 **§ 69504. Applicability and Petition Contents.**

8 (a) Any person may petition the Department to evaluate a claim that a chemical or a
9 product that contains a chemical should be listed as a Chemical of Concern or a Priority
10 Product, whichever is applicable, using the processes specified in articles 2 and 3 of this
11 chapter. The Petition must include all of the following:

12 (1) The name of, and contact information for, both of the following persons:

13 (A) The petitioner; and

14 (B) The person responsible for the contents of the petition, if different from the petitioner,
15 and the affiliation of this person with the petitioner;

16 (2) A description of the chemical and/or product that is the subject of the petition;

17 (3) A description of the uses and applications of the chemical and/or product;

18 (4) The basis for the petition, including an analysis of potential adverse public health
19 and/or environmental impacts associated with the chemical and/or product;

20 (5) Reliable information supporting the petition; and

21 (6) The identity of any known manufacturers and importers of the chemical or product.

22 (b) Within sixty (60) days after receiving a petition, the Department shall review the
23 petition and shall designate the petition complete if it contains all of the items specified in
24 subsection (a). If the Department determines that a petition is complete, the Department shall
25 notify the petitioner that it will conduct a technical review to determine whether to grant or deny
26 the petition on its merits. If the Department determines that the petition is incomplete, the
27 Department shall notify the petitioner of this determination and shall specify the basis for the
28 determination.

29 (c) The Department is not prohibited from requesting additional information during the
30 technical review conducted pursuant to section 69504.1 due to determining a petition to be
31 complete pursuant to subsection (b).

32
33 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
34 Reference: Sections 25252 and 25253, Health and Safety Code.

35 36 **Article 5. Alternatives Assessments**

37 38 **§ 69505. Guidance Materials.**

39 (a) Before finalizing the initial list of Priority Products pursuant to section 69503.3, the
40 Department shall make available on its website guidance materials to assist persons in
41 performing AAs in accordance with this article. The Department shall periodically revise and
42 update the guidance materials.

1 (b) The Department shall also post on its website AAs that the Department is aware of,
2 and that are available in the public domain at no cost and are supported by reliable
3 information. The posting shall indicate, for each AA, the name of the person that prepared the
4 AA.

5
6 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
7 Sections 25252 and 25253, Health and Safety Code.
8

9 **§ 69505.1. Alternatives Assessments: General Provisions.**

10 (a)(1) The requirements of this article applicable to a responsible entity may be fulfilled by
11 the responsible entity, or by a person acting on behalf of or in lieu of the responsible entity.

12 (2) Except as otherwise provided in subsections (b) and (e), a responsible entity for a
13 product that contains one or more Chemicals of Concern that is/are the basis for designation
14 as a Priority Product shall conduct an AA for the Priority Product, and shall comply with all
15 applicable requirements of this article.

16 (3) A responsible entity subject to the requirements of paragraph (2) shall prepare, sign,
17 and submit to the Department a Preliminary AA Report and a Final AA Report, meeting the
18 requirements of section 69505.5, as follows:

19 (A) Except as provided in subsection (b), the responsible entity shall submit the
20 Preliminary AA Report no later than 180 days after the date the product is listed on the final
21 Priority Products list posted on the Department's website, unless the Department specifies a
22 different due date for the product in the Priority Products list.

23 (B) Except as provided in subsection (b), the responsible entity shall submit the Final AA
24 Report no later than twelve (12) months after the date the Department issues a notice of
25 compliance for the Preliminary AA Report, unless the responsible entity requests, pursuant to
26 section 69505.3(b)(4), and the Department approves, pursuant to section 69505.6(a)(3), a
27 longer period of time.

28 (b) The requirements of this article do not apply to any of the following:

29 (1) A product that is no longer placed into the stream of commerce in California by any
30 person on and after the date that the product is listed as a Priority Product.

31 (2) A bulk chemical that is placed into the stream of commerce in California and that
32 meets the definition of a "consumer product", as defined in Health and Safety Code section
33 25251, but that is not packaged for sale to, or end use by, a retail consumer.

34 (3) A product that meets the de minimis exemption criteria specified in section 69503.4,
35 if a complete and timely De Minimis Exemption Notification has been submitted to the
36 Department satisfying the requirements of section 69503.5, unless subsection (d) or (e) of
37 section 69503.5 applies.

38 (c)(1) A responsible entity may request a one-time extension to the submission deadline
39 for the Preliminary or Final AA Report, or both, if the extension request is based on
40 circumstances that could not reasonably be anticipated or controlled by the responsible entity.
41 The Department must receive the extension request at least sixty (60) days before the
42 applicable due date.

- 1 (2) The extension request must include all of the following:
- 2 (A) The name of, and contact information for, the person filing the extension request;
- 3 (B) The name of, and contact information for, the responsible entity(ies) on whose
4 behalf the Preliminary and Final AA Reports will be submitted;
- 5 (C) If different from subparagraphs (A) and (B), the name of, and contact information for,
6 the manufacturer and the importer, if applicable, of the product;
- 7 (D) Information identifying and describing the Priority Product and, if applicable, the
8 component(s) subject to the AA requirement, including the brand name(s) and product
9 name(s) under which the Priority Product is placed into the stream of commerce in California;
- 10 (E) The due date for the Preliminary or Final AA Report, as applicable;
- 11 (F) The amount of additional time requested, not to exceed ninety (90) days; and
- 12 (G) The reason the extension is needed.
- 13 (3) The Department shall approve or deny, in whole or in part, the extension request,
14 and notify the person submitting the extension request of the decision, within thirty (30) days of
15 receipt of the extension request. Failure by the Department to issue a decision within thirty
16 (30) days does not constitute an approval of the extension request. The one-time extension
17 for a Preliminary or Final AA Report, or both, shall not exceed ninety (90) days.
- 18 (d) Each AA completed after January 1, 2015 shall be performed, and each Preliminary
19 and Final AA Report submitted after January 1, 2015 shall be prepared, by or under the
20 responsible charge of one or more assessor(s) certified pursuant to article 8 for the appropriate
21 product type or industry sector.
- 22 (e) A responsible entity may fulfill the requirements of subsection (a) by submitting to
23 the Department a report for a previously completed AA for the Priority Product, if the
24 Department determines that the report is substantially equivalent to the Final AA Report
25 requirements of section 69505.5 and that the report contains sufficient information for the
26 Department to identify the most appropriate regulatory response(s) pursuant to article 6.
- 27 (1) A responsible entity submitting a report pursuant to this subsection shall submit the
28 report no later than the deadline for submitting a Preliminary AA Report, pursuant to
29 subsection (a)(3)(A), except that a one-time extension may be requested pursuant to
30 subsection (c).
- 31 (2) A responsible entity submitting an existing report pursuant to this subsection may
32 supplement the report with additional information to render the report substantially equivalent
33 to the Final AA Report requirements of section 69505.5.
- 34 (f) A responsible entity conducting an AA, pursuant to subsection (a), shall consider all
35 relevant information made available on the Department's website, including any relevant public
36 comments, and any additional information or technical assistance the Department may provide
37 regarding alternatives assessments. The responsible entity shall summarize these efforts in
38 the AA Report.
- 39 (g) Notwithstanding any other provision of this chapter, failure of the Department to
40 make a compliance determination within sixty (60) days from receipt of the Preliminary or Final
41 AA Report, or failure of the Director to respond to an appeal submitted under section 69507.2

1 within sixty (60) days, shall not cause a Preliminary or Final AA Report to be deemed
2 compliant.

3
4 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
5 Sections 25252 and 25253, Health and Safety Code.

6
7 **§ 69505.2. Assessment of Priority Products and Alternatives.**

8 (a)(1) The AA required to be performed pursuant to section 69505.1(a) shall be conducted
9 in two stages, as specified in sections 69505.3 and 69505.4.

10 (2) The responsible entity shall complete the first stage of the AA, and submit a
11 Preliminary AA Report that complies with sections 69505.1(a)(3)(A) and 69505.5.

12 (3) The responsible entity shall next complete the second stage of the AA, and submit a
13 Final AA Report that complies with sections 69505.1(a)(3)(B) and 69505.5.

14 (b) A responsible entity may use an AA process that differs from the process specified
15 in sections 69505.3 and 69505.4, if all of the following requirements are met:

16 (1) The responsible entity's alternate process provides the information needed to
17 prepare an AA Report that substantially meets the requirements of section 69505.5.

18 (2) The responsible entity's alternate process compares the Priority Product and the
19 alternatives using, at a minimum, the same factors, and associated exposure pathways and life
20 cycle segments, specified in sections 69505.3 and 69505.4.

21 (3) The responsible entity submits a work plan to the Department with sufficient
22 information to demonstrate that the alternate process will meet the requirements of paragraphs
23 (1) and (2), and sufficient information for the Department to specify an appropriate due date for
24 submittal of the Final AA Report. The due date shall be eighteen (18) months after the date the
25 Department issues a notice of compliance for the work plan, unless the responsible entity
26 requests, pursuant to section 69505.3(b)(4), and the Department approves, pursuant to section
27 69505.6(a)(3), a longer period of time. The additional time shall not exceed thirty (30) months
28 after the Department issues a notice of compliance for the work plan. The work plan must be
29 submitted to the Department no later than sixty (60) days after the product is included on the
30 Priority Products list. Upon receipt of a work plan pursuant to this subsection, the Department
31 shall follow the steps specified for the review of Preliminary AA Reports in section 69505.6(a).

32 (4) The responsible entity submits a Final AA Report to the Department that
33 substantially meets the requirements of section 69505.5 by the due date specified by the
34 Department pursuant to paragraph (3).

35
36 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
37 Sections 25252, 25253, and 25257, Health and Safety Code.

38
39 **§ 69505.3. Alternatives Assessment: First Stage.**

40 (a) All references in this section to "Chemical(s) of Concern" mean the Chemical(s) of
41 Concern that is/are the basis for the product being identified as a Priority Product.

42 (b) The first stage of the AA shall include all of the following steps:

43 (1) Step 1, Identification of Product Requirements.

1 (A) The responsible entity shall identify the function, performance, technical feasibility,
2 and legal requirements associated with the Priority Product that must be met by potential
3 alternatives.

4 (B) The responsible entity shall identify the function of the Chemical(s) of Concern in
5 meeting the Priority Product's function, performance, technical feasibility, and legal
6 requirements.

7 (C)1. The responsible entity shall determine if the Chemical(s) of Concern or substitute
8 chemical(s) is/are necessary to meet the Priority Product's function, performance, technical
9 feasibility, and legal requirements.

10 2. If the responsible entity determines that neither the Chemical(s) of Concern nor
11 substitute chemical(s) is/are necessary to meet the Priority Product's function, performance,
12 technical feasibility, and legal requirements, the responsible entity shall evaluate as one of the
13 alternatives to the Priority Product the removal of the Chemical(s) of Concern from the Priority
14 Product without the addition of substitute chemical(s).

15 (2) Step 2, Identification of Alternatives.

16 (A) In addition to the alternative identified pursuant to paragraph (1)(C)2., if applicable,
17 the responsible entity shall identify alternatives for consideration that meet the product
18 requirements identified pursuant to paragraph (1)(A) for the Priority Product, and that eliminate
19 or reduce the concentration of the Chemical(s) of Concern in the Priority Product and/or
20 reduce the potential for public and/or environmental exposures to the Chemical(s) of Concern
21 in the Priority Product. The responsible entity shall research available information that may
22 identify existing potentially viable alternatives, including information posted on the
23 Department's website pursuant to section 69505(b). The responsible entity shall include in the
24 AA consideration of any identified existing potentially viable alternatives.

25 (B) The comparison of the Priority Product and any alternative that does not involve the
26 addition of a substitute chemical does not require completion of the step specified in paragraph
27 (3).

28 (3) Step 3, Initial Screening of Alternative Chemicals.

29 For those alternatives being considered that involve substituting the Chemical(s) of
30 Concern with other chemical(s), the responsible entity shall do all of the following:

31 (A) Collect and use available information to identify the adverse public health and
32 environmental impacts associated with each chemical being considered as a possible
33 alternative to the Chemical(s) of Concern in the Priority Product;

34 (B) Compare each of the potential alternative chemicals with the Chemical(s) of
35 Concern in the Priority Product, using the information collected and evaluated pursuant to
36 subparagraph (A);

37 (C)1. Eliminate from further consideration in the AA any alternative chemical(s) that the
38 responsible entity determines may pose greater adverse public health and/or environmental
39 impacts than the Chemical(s) of Concern.

40 2. Subparagraph 1. does not apply to a chemical that poses both greater and lesser
41 individual adverse impacts relative to the Chemical(s) of Concern. However, a responsible

1 entity is not required to retain, for further consideration in the AA, a chemical that poses both
2 greater and lesser individual adverse impacts relative to the Chemical(s) of Concern.

3 (4) Step 4, Next Steps.

4 The responsible entity shall develop a work plan and proposed implementation schedule for
5 completion of the second AA stage, as specified in section 69505.4, and preparation of the
6 Final AA Report. The work plan must specify the proposed submission date for the Final AA
7 Report, and must ensure that the Final AA Report will be submitted to the Department no later
8 than twelve (12) months after the Department issues a notice of compliance for the Preliminary
9 AA Report. The responsible entity may request approval from the Department for a longer
10 period of time to submit the Final AA Report, not to exceed twenty-four (24) months from the
11 date the Department issues a notice of compliance for the Preliminary AA Report. Such a
12 request must include a detailed explanation as to why the additional time is needed. If the
13 Priority Products list identifies more than one component that must be included in the AA for
14 the Priority Product, separate submission dates may be proposed for each component.

15
16 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
17 Sections 25252, 25253, and 25257, Health and Safety Code.

18
19 **§ 69505.4. Alternatives Assessment: Second Stage.**

20 The second stage of the AA shall include all of the following steps:

21 (a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.

22 (1) A factor, in conjunction with an associated exposure pathway and life cycle segment,
23 is relevant if it would constitute both:

24 (A) A demonstrable contribution to the adverse impacts of the Priority Product and/or
25 one or more alternatives under consideration; and

26 (B) A demonstrable difference between two or more of the alternatives being
27 considered, including the Priority Product.

28 (2) The responsible entity shall collect and use available quantitative information,
29 supplemented by available qualitative information and analysis, to identify the factors listed
30 below, and the associated exposure pathways and life cycle segments, that are relevant for
31 the comparison of the Priority Product and the alternatives still under consideration after
32 completion of the first AA stage as specified in section 69505.3:

33 (A) Multimedia life cycle impacts and chemical hazards, for chemical ingredients known
34 to be in the Priority Product and the alternatives being considered based on available
35 information:

36 1. Physical chemical hazards;

37 2. Adverse public health impacts;

38 3. Adverse environmental impacts;

39 4. Physicochemical properties;

40 5. Environmental fate properties;

41 6. Materials and resource consumption impacts; and

42 7. Adverse waste and end-of-life impacts.

43 (B) Product function and performance:

- 1 1. Useful life of the Priority Product, and that of the potential alternatives;
- 2 2. Functional and performance comparison of each alternative relative to the Priority
- 3 Product; and
- 4 3. Technological and economic feasibility of each alternative. As part of a
- 5 determination of whether a “technologically and economically feasible alternative” exists, the
- 6 responsible entity shall consider all of the following, to the extent applicable:
 - 7 a. The extent to which a functionally acceptable alternative is currently available in the
 - 8 marketplace;
 - 9 b. The affordability of any currently available functionally acceptable alternative; and
 - 10 c. The purchase price differential between the Priority Product and the alternative.
- 11 (C) Economic impacts. The responsible entity’s evaluation and comparison of economic
- 12 impacts shall take into account both internalized and externalized costs during the life cycle of
- 13 the Priority Product and all alternatives being considered, and shall include an evaluation of
- 14 the range of projected costs. Evaluation and comparison of externalized costs shall include
- 15 costs to government agencies, the public, businesses, and consumers.
- 16 (3) The responsible entity’s identification of relevant exposure pathways shall consider
- 17 both of the following:
 - 18 (A) Chemical quantity information:
 - 19 1. Quantities of the Chemical(s) of Concern or alternative chemical(s) necessary to
 - 20 manufacture the Priority Product, or alternative; and
 - 21 2. Estimated volume and/or mass of the Chemical(s) of Concern or substitute
 - 22 chemical(s) that is/are or would be placed into the stream of commerce in California as a result
 - 23 of the Priority Product or potential alternatives.
 - 24 (B) Exposure potential factors specified in subsections (a)(1)(B), (b)(4), and (b)(5) of
 - 25 section 69503.2.
 - 26 (b) Step 2, Comparison of the Priority Product and Alternatives.
 - 27 The responsible entity shall use available quantitative information, supplemented by
 - 28 available qualitative information and analysis, to evaluate and compare the Priority Product
 - 29 and each of the alternatives under consideration with respect to each relevant factor and
 - 30 associated exposure pathways and life cycle segments identified pursuant to subsection (a).
 - 31 The responsible entity shall compare each alternative with the Priority Product and with each
 - 32 of the other alternatives being considered.
 - 33 (c) Step 3, Alternative Selection Decision.
 - 34 The responsible entity shall select the alternative that will replace or modify the Priority
 - 35 Product, unless the decision is to retain the existing Priority Product. The selection of an
 - 36 alternative or the decision to retain the Priority Product shall be based on and supported by the
 - 37 comparative analysis conducted pursuant to subsection (b).

38

39 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
40 Sections 25252, 25253, and 25257, Health and Safety Code.

41

42 **Article 6. Regulatory Responses**

43

1 **§ 69506. Applicability.**

2 The requirements of this article apply to any alternative selected pursuant to section
3 69505.4(c) that is placed into the stream of commerce in California. These requirements also
4 apply to the Priority Product if an alternative is not selected, or if the Priority Product will
5 remain in commerce pending development and distribution of the selected alternative.
6

7 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
8 Section 25253, Health and Safety Code.
9

10 **§ 69506.1. AA Report Supplemental Information Requirements.**

11 (a) The Department may at any time require the responsible entity to provide any
12 information supplementary to the Final AA Report that the Department determines is
13 necessary to determine and ensure implementation of one or more regulatory responses
14 imposed pursuant to this article. The responsible entity shall provide this information within the
15 time period specified by the Department.

16 (b) The Department may at any time require the responsible entity to obtain or develop
17 information to fill one or more of the information gaps identified in the Final AA Report,
18 pursuant to section 69505.5(h)(2), if the Department determines this information is needed to
19 re-evaluate, pursuant to section 69506.6(d), the initial regulatory response(s) imposed for the
20 selected alternative or for the Priority Product that remains in commerce. The responsible
21 entity shall provide this information within the time period specified by the Department.
22

23 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
24 Section 25253, Health and Safety Code.
25

26 **§ 69506.2. No Additional Regulatory Response Required.**

27 No regulatory response under sections 69506.3 through 69506.6 is required for the
28 selected alternative, if the Department determines, after review of the Final AA Report, that
29 both of the following criteria are met:

30 (a) The selected alternative does not contain a Chemical of Concern in a concentration
31 exceeding the de minimis level; and, if the selected alternative contains multiple Chemicals of
32 Concern, the total concentration of all Chemicals of Concern exhibiting the same hazard trait,
33 or environmental or toxicological endpoint, and mode of action does not exceed the de minimis
34 level.

35 (b) The selected alternative does not pose significant potential adverse public health or
36 environmental impacts.
37

38 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
39 Section 25253, Health and Safety Code.
40

41 **§ 69506.3. Product Information for Consumers.**

1 (a)(1) Except as provided in paragraph (2), during the time that a selected alternative
2 product, or a Priority Product for which an alternative is not selected, is offered for sale in
3 California, the responsible entity shall ensure that all of the following information is made
4 available to the consumer prior to any exposure to the Chemical(s) of Concern.

5 (A) Manufacturer's name and importer's name, if applicable;

6 (B) Brand name(s) and product name(s), and description of the product;

7 (C) A list of, and common names for, all Chemicals of Concern known, based on
8 available information, to be in the product;

9 (D) Identification of any end-of-life management program for this product, and any end-
10 of-life management requirements specified by law;

11 (E) Any safe handling procedures needed to protect public health or the environment
12 during the useful life of the product and instructions for the proper end-of-life disposal or
13 management; and

14 (F) The manufacturer's website address and the importer's website address, if
15 applicable, where the consumer can obtain additional information about the product, the
16 potential adverse public health and/or environmental impacts posed by the product, and proper
17 end-of-life disposal or management of the product.

18 (2) Paragraph (1) does not apply to a selected alternative product that does not contain
19 a Chemical of Concern in a concentration exceeding the level specified in section 69506.2(a).

20 (b) The requirements of subsection (a) shall be met by making the required information
21 available to consumers, in easily seen, legible, and understandable formats, by both:

22 (1) Posting the information in a prominent place on the manufacturer's website and the
23 importer's website, if applicable; and

24 (2) Using one or more of the following means of informing consumers of this information
25 at the point of sale:

26 (A) Providing the required information on the product packaging or in a manual that is
27 accessible without breaking the product seal; or

28 (B) Posting the information in a prominent place at the point of retail display.

29 (c) A responsible entity that has a product subject to the requirements of subsections
30 (a) and (b) shall ensure that these requirements are fully implemented for that product no later
31 than twelve (12) months after the Department issues a notice of compliance for the Final AA
32 Report for the product.

33
34 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
35 Section 25253, Health and Safety Code.

36 37 **§ 69506.4. End-of-Life Management Requirements.**

38 (a) Except as provided in section 69506.2, a responsible entity for a selected
39 alternative, or a Priority Product for which an alternative is not selected, that is sold or
40 otherwise made available to consumers as a finished product and is required to be managed
41 as a hazardous waste in California at the end of its useful life, shall ensure that both of the
42 following requirements are met:

1 (1) The information required by section 69506.3 shall be provided for the product.
2 Additionally, the product information must state that the product must be disposed of or
3 otherwise managed as a hazardous waste at the end of its useful life.

4 (2) No later than two (2) years after the Department issues a notice of compliance for
5 the Final AA Report for the product, the responsible entity shall fund, establish, and maintain
6 an end-of-life management program for the product. The program must comply with all of the
7 following requirements:

8 (A) A comprehensive product stewardship plan must be developed and maintained, and
9 must include all of the following:

10 1. A list of, and contact information for, participating manufacturers and importers and,
11 if applicable, other participating persons.

12 2. The scope of products to be covered by the plan.

13 3. The roles and responsibilities for manufacturers, importers, retailers, consumers,
14 and government throughout the life cycle of the product.

15 4. Identification and description of collection systems that will be used.

16 5. End-of-life management information, including what steps will be taken to ensure
17 management that complies with all applicable federal and California State and local laws, and
18 addresses any adverse multimedia impacts.

19 6. Anticipated resource needs and a description of the financing mechanism to
20 implement and sustain the plan, including identification of any third-party product stewardship
21 organization collecting and administering a fee to fund the stewardship program. The
22 responsible entity for the product shall provide a financial guarantee mechanism for a
23 sustainable end-of-life management program for the product. Multiple responsible entities may
24 form a third-party product stewardship organization, funded by participating manufacturers and
25 other responsible entities, to provide local services to collect, recycle, or otherwise
26 appropriately manage covered products at the end-of-life.

27 7. Program performance measures for:

28 a. Increasing the capture rate of covered products at the end-of-life; and

29 b. Increasing recyclability.

30 8. Public education, outreach, and communications plans.

31 9. Public and stakeholder consultation activities during preparation, and periodic review
32 and updating, of the plan.

33 10. Reporting and evaluation procedures.

34 (B) The product stewardship program and plan for collecting and, if applicable, recycling
35 the product shall be developed in consultation with California retailers and potential collection
36 sites. The collection program must include one or both of the following:

37 1. Collection mechanisms; and

38 2. Compensation to retailers and other persons who agree to administer or participate
39 in the collection program.

40 (C) The responsible entity shall post a copy of the product stewardship plan on its
41 website, and provide a link to the posting to the Department for posting on its website.

1 (D) The responsible entity for a product subject to the requirements of this section shall,
2 every two (2) years from the date the end-of-life management program is required to be
3 implemented, ensure that a report is provided to the Department. The report must include both
4 of the following:

5 1. The amount of products placed into the stream of commerce in California over the
6 previous two-year period, by total tonnage; and

7 2. The number of products recovered over the same two-year period, by total tonnage.

8 (b) Upon request, the responsible entity shall provide to the Department a copy of the
9 product stewardship plan required under this section.

10 (c) A responsible entity subject to the requirements of this section may request the
11 Department's approval to substitute an alternative end-of-life management program that
12 achieves, to the maximum extent feasible, the same results as the program required by this
13 section. A responsible entity may not substitute an alternative end-of-life management plan for
14 the plan specified in this section unless it receives written approval from the Department.

15 (d) A responsible entity subject to the requirements of this section may request an
16 exemption from the requirement to provide an end-of-life management program by
17 demonstrating to the Department's satisfaction in the Final AA Report that an end-of-life
18 management program cannot feasibly be implemented for the product.

19
20 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
21 Section 25253, Health and Safety Code.

22 23 **§ 69506.5. Product Sales Prohibition.**

24 (a) Except as provided in section 69506.2 and subsection (c), the requirements of
25 subsection (b) apply to a selected alternative that contains one or more Chemical(s) of
26 Concern, or a Priority Product for which an alternative is not selected, if the Department
27 notifies the responsible entity, pursuant to section 69506.8, that the Department has
28 determined that a safer alternative exists that does not contain a Chemical of Concern and that
29 is both functionally acceptable and technologically and economically feasible.

30 (b) Effective one (1) year after the Department issues a notification pursuant to
31 subsection (a), unless the Department specifies a shorter period of time in the notification, any
32 responsible entity for the product that is the subject of the notification shall cease to place the
33 product into the stream of commerce in California. The responsible entity shall also ensure
34 that an inventory recall program for the product is implemented and completed within three (3)
35 years after the notification is issued by the Department, unless the Department specifies a
36 shorter period of time in the notification.

37 (c) A product that is the subject of a notification issued by the Department pursuant to
38 subsection (a) is not subject to the requirements of subsection (b) if all of the following
39 requirements are met:

40 (1) Within sixty (60) days after the notification is issued by the Department, the
41 responsible entity notifies the Department of its intent to submit a revised Final AA Report that
42 selects an alternative that does not contain a Chemical of Concern;

1 (2) Within one (1) year after the notification is issued by the Department, unless the
2 Department specifies a shorter period of time in the notification, the Department receives a
3 Final AA Report that selects an alternative that does not contain a Chemical of Concern and
4 that fully meets the requirements of section 69505.5; and

5 (3) The product containing one or more Chemical(s) of Concern is completely removed
6 from commerce in California, and an inventory recall in California is completed, by the date
7 specified by the Department in the notice of compliance or notice of disapproval for the Final
8 AA Report submitted under paragraph (2), or in a separate notice issued by the Department
9 under section 69505.6(c)(1). The due date shall be no longer than three (3) years after the
10 Department issues the notice.

11 (d)(1) The responsible entity may request a one-time extension to the due date for the
12 Final AA Report to be submitted under subsection (c)(2), pursuant to the procedures specified
13 in section 69505.1(c).

14 (2) If an extension is granted by the Department, one of the following requirements must
15 be met by the due date specified in the extension approval:

16 (A) A revised Final AA Report meeting the requirements of subsection (c)(2) shall be
17 submitted to the Department; or

18 (B) The requirements of subsection (b) shall be implemented.

19
20 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
21 Section 25253, Health and Safety Code.

22 23 **§ 69506.6. Other Regulatory Responses.**

24 (a) **Except as provided in section 69506.2, the Department may impose one or more of**
25 **the following regulatory responses that it determines are necessary to limit potential exposures**
26 **to, and reduce the level of potential adverse public health or environmental impacts posed by,**
27 **a selected alternative, or by a Priority Product for which an alternative is not selected or which**
28 **will remain in commerce in California pending development and distribution of the selected**
29 **alternative:**

30 (1) The Department may impose one or more of the regulatory responses specified in
31 sections 69506.1 and 69506.3 through 69506.5 to situations other than those situations
32 specified in sections 69506.1 and 69506.3 through 69506.5.

33 (2) The Department may impose one or more of the following regulatory responses to
34 any situation, including those situations specified in sections 69506.1 and 69506.3 through
35 69506.5:

36 (A) Requiring engineered safety measures to control access to, or limit exposure to, the
37 Chemical(s) of Concern in the product;

38 (B) Restricting the use of the Chemical(s) of Concern that is/are in the product;

39 (C) Requiring the responsible entity to initiate a research and development project, or
40 fund a challenge grant, that is pertinent to the Priority Product and that uses green chemistry
41 principles; and

1 (D) Requiring a new AA to be performed, and Preliminary and Final AA Reports to be
2 submitted to the Department in a specified time period.

3 (b) In accordance with the process specified in section 69506.8, the Department shall
4 notify known affected responsible entities of regulatory response determinations made
5 pursuant to this section, along with the implementation due date for the regulatory response
6 and the rationales for the regulatory response determination.

7 (c) In assigning a due date for completing a regulatory response required under this
8 section, the Department shall consider the complexity of implementing the regulatory
9 response.

10 (d) The Department may periodically re-evaluate each regulatory response imposed
11 under this section to determine if changes are needed based on changes in science or
12 technology, or other relevant information or facts that have accrued since the regulatory
13 response was selected, including information that fills one or more of the information gaps
14 identified in the Final AA Report pursuant to section 69505.5(h)(2).
15

16 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
17 Section 25253, Health and Safety Code.

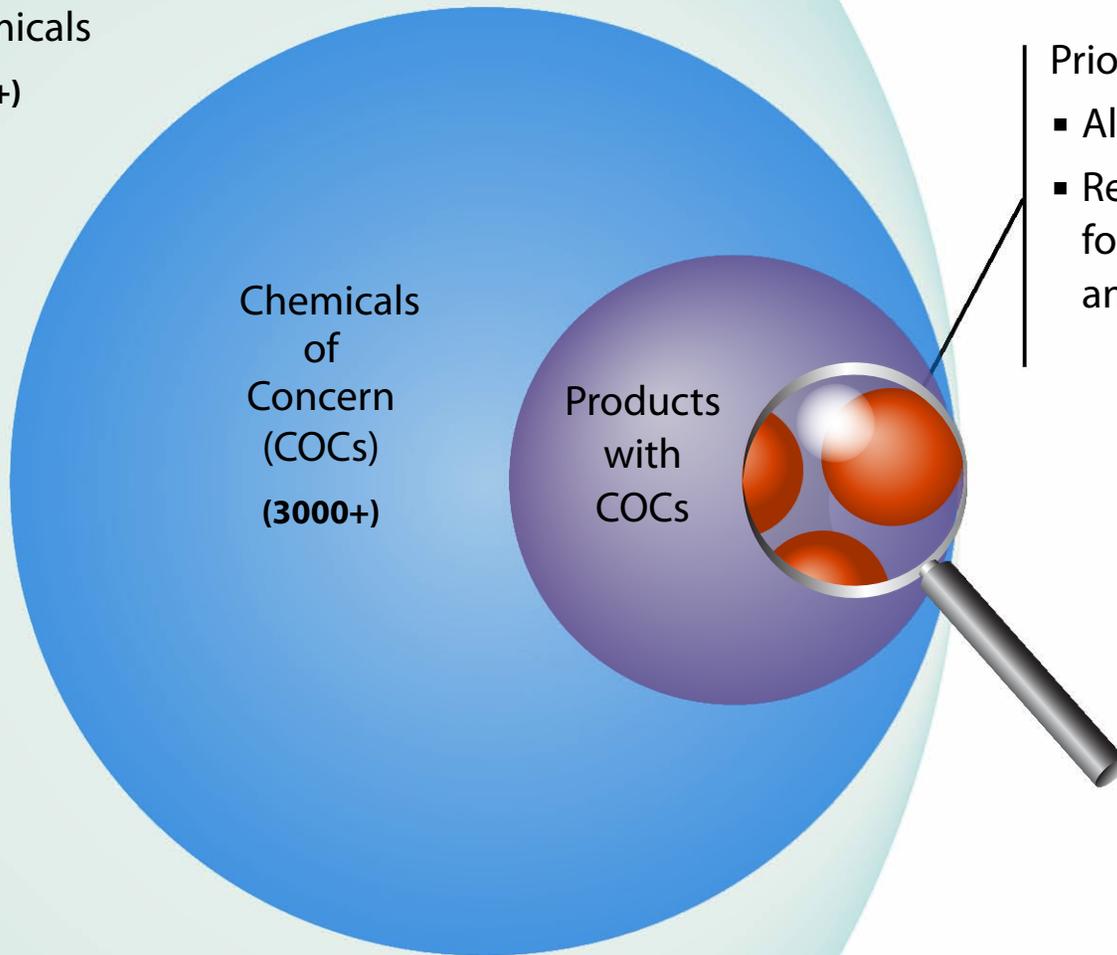
Section 69502.2. Chemicals of Concern Identification

§69502.2	Informal draft regulatory language	
(a)	<i>Initial Chemicals of Concern List. As of the effective date of these regulations, a chemical is identified as a Chemical of Concern, if it exhibits a hazard trait or an environmental or toxicological endpoint, and meets one or more of the following criteria:</i>	
<p>To facilitate effective and efficient implementation of the product/chemical prioritization process, the regulations themselves establish the initial list of Chemicals of Concern (COC) by drawing from three general sources of existing information that identify chemicals of concern. The three groups of chemical information sources used to establish the initial COC list meet the OEHHA and DTSC definitions of “authoritative organizations”, “reliable information”, and/or “reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical”. These information sources identify chemicals by either a hazard trait or an environmental or toxicological endpoint. The COC source lists named in the informal draft regulations are considered “authoritative” and “reliable”, are widely recognized nationally and internationally, and have been used to initiate actions for protection of public health and/or the environment.</p>		
(a)(1)	<i>The chemical is identified as exhibiting a hazard trait on one or more of the following lists:</i>	
	Chemical Sources for Initial COC List	Hazard Trait
(a)(1)(A)	California Safe Cosmetics Program’s Chemicals Known or Suspected to Cause Cancer or Reproductive Toxicity	Toxicological Hazard Traits: <ul style="list-style-type: none"> • Carcinogenicity • Reproductive Toxicity • Developmental Toxicity
(a)(1)(B)	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)	Toxicological Hazard Traits: <ul style="list-style-type: none"> • Carcinogenicity • Reproductive Toxicity • Developmental Toxicity
(a)(1)(C)	Canadian Environmental Protection Act Environmental Registry’s Persistent, Bioaccumulative, and Inherently Toxic to the Environment (CEPA PBiT)	Exposure Potential Hazard Traits: <ul style="list-style-type: none"> • Bioaccumulation • Persistence
(a)(1)(D)	Category A and B Carcinogens, Report on Carcinogens, US Department of Health and Human Services, Public Health Service, National Toxicology Program	Toxicological Hazard Trait: <ul style="list-style-type: none"> • Carcinogenicity
(a)(1)(E)	Chemicals for which primary Maximum Contaminant Levels (MCLs) have been established under the federal Safe Drinking Water Act	Various Toxicological Hazard Traits:
(a)(1)(F)	European Chemical Substances Information System Persistent Bioaccumulating Toxins (ESIS PBT)	Exposure Potential Hazard Traits: <ul style="list-style-type: none"> • Bioaccumulation • Persistence • Various Toxicological Hazard Traits
(a)(1)(G)	European Commission Category 1 and Category 2 endocrine disruptors	Toxicological Hazard Trait: <ul style="list-style-type: none"> • Endocrine Toxicity
(a)(1)(H)	European Union Directive on Dangerous Substances (Directive 67/548/EEC), Category 1 carcinogens and Category 1 reproductive toxins	This has been superseded by (a)(1)(I) – see below.
(a)(1)(I)	European Union EC 1272/2008 Annex VI, Category 1A and 1B carcinogens, Category 1A and 1B reproductive toxins, and Category 1A and 1B mutagens	Toxicological Hazard Traits: <ul style="list-style-type: none"> • Carcinogenicity • Reproductive Toxicity • Developmental Toxicity • Genotoxicity

	Chemical Sources for Initial COC List	Hazard Trait
(a)(1)(J)	International Agency for Research on Cancer (IARC), Groups 1, 2A, and 2B carcinogens	Toxicological Hazard Trait: <ul style="list-style-type: none"> • Carcinogenicity
(a)(1)(K)	Pollutants listed by California or the US EPA for one or more water bodies in California pursuant to section 303(d) of the federal Clean Water Act	Various: <ul style="list-style-type: none"> • Toxicological Hazard Traits • Environmental Hazard Traits • Exposure Potential Hazard Traits
(a)(1)(L)	Pollutants requiring monitoring and reporting in waste discharges to land that have Notification Levels (NLs) specified under the Waste Discharge and Water Reuse Requirements (WDRs/WRRs) of the Porter-Cologne Water Quality Control Act	Various Toxicological Hazard Traits
(a)(1)(M)	Priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act	Various: <ul style="list-style-type: none"> • Toxicological Hazard Traits • Environmental Hazard Traits • Exposure Potential Hazard Traits
(a)(1)(N)	US EPA Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals	Exposure Potential Hazard Traits: <ul style="list-style-type: none"> • Bioaccumulation • Persistence • Various Toxicological Hazard Traits
(a)(1)(O)	Washington Department of Ecology Persistent, Bioaccumulative, Toxic Chemicals	Exposure Potential Hazard Traits: <ul style="list-style-type: none"> • Bioaccumulation • Persistence • Various Toxicological Hazard Traits
(a)(2)	<i>The chemical is identified by one or more of the following lists based on exposures or environmental or toxicological endpoints:</i>	
	Chemical Sources for Initial COC List	Hazard Trait
(a)(2)(A)	National Report on Human Exposure to Environmental Chemicals, Center for Disease Control	Various Toxicological Hazard Traits: <ul style="list-style-type: none"> • Chemicals that are biomonitored are “reliable information demonstrating” exposure
(a)(2)(B)	OSPAR List of Chemicals for Priority Action	Environmental Hazard Traits
(a)(2)(C)	OSPAR List of Substances of Possible Concern	Environmental Hazard Traits
(a)(2)(D)	US EPA National Waste Minimization Program list of Persistent Bioaccumulative and Toxic Priority Chemicals	Exposure Potential Hazard Traits: <ul style="list-style-type: none"> • Bioaccumulation • Persistence • Various Toxicological Hazard Traits
(a)(3)	<i>The chemical is identified by one or more of the following sources of reliable information:</i>	
	Chemical Sources for Initial COC List	Hazard Trait
(a)(3)(A)	Grandjean & Landrigan identification of neurotoxicants	Toxicological Hazard Trait: <ul style="list-style-type: none"> • Neurotoxicity
(a)(3)(B)	National Toxicology Program, Office of Health Assessment and Translation (formerly the Center for the Evaluation of Risks to Human Reproduction (CERHR)) reports	Toxicological Hazard Traits: <ul style="list-style-type: none"> • Reproductive Toxicity • Developmental Toxicity
(a)(3)(C)	US EPA Integrated Risk Information System (IRIS) identification of carcinogens	Toxicological Hazard Trait: <ul style="list-style-type: none"> • Carcinogenicity

Overview: The Safer Consumer Products Regulations

All Chemicals
(100,000+)



Chemicals
of
Concern
(COCs)
(3000+)

Products
with
COCs

Priority Products Requiring:

- Alternatives Assessments
- Regulatory Response(s) for selected Alternative and/or Priority Product

How It Works: The Safer Consumer Products Regulations

