DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS CHAPTER 55. SAFER CONSUMER PRODUCTS Amend the Table of Contents by adding chapter 55, articles 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12, and sections 69501, 69501.1, 69501.2, 69501.3, 69501.4, 69501.5, 69501.6, 69502, 69502.1, 69502.2, 69502.3, 69503, 69503.1, 69503.2, 69503.3, 69503.4, 69503.5, 69503.6, 69504, 69504.1, 69505, 69505.1, 69505.2, 69505.3, 69505.4, 69505.5, 69505.6, 69506, 69506.1, 69506.2, 69506.3, 69506.4, 69506.5, 69506.6, 69506.7, 69506.8, 69506.9, 69507, 69507.1, 69507.2, 69507.3, 69507.4, 69507.5, 69507.6, 69508, 69508.1, 69508.2, 69508.3, 69508.4, 69509, 69510, 69510.1, 59511, and 69512 through 69599 to division 4.5 of California Code of Regulations, title 22, to read: Table of Contents *** **Chapter 55. Safer Consumer Products** Article 1. General4 Purpose and Applicability......4 § 69501. § 69502. Article 3. Chemicals of Concern and Consumer Product Prioritization Process27 § 69503. General.27

1	Article 4. P	etition for Inclusion of a Chemical or Product in the Identification a	nd
2	Prioritization	n Processes	34
3	§ 69504.	Applicability and Petition Contents.	34
4	§ 69504.1.	Technical Review of Petitions	
5			
6	Article 5. A	Iternatives Assessments	
7	§ 69505.		
8	_	Alternatives Assessments: General Provisions.	
9	§ 69505.2.	Assessment of Priority Products and Alternatives	38
0	§ 69505.3.	Alternatives Assessment: First Stage	38
1	§ 69505.4.	Alternatives Assessment: Second Stage	40
12	§ 69505.5.	Alternatives Assessment Reports	41
13	§ 69505.6.	Department Review and Determinations for AA Reports	46
4 5	Article 6. R	egulatory Responses	47
16	§ 69506.		
7	§ 69506.1.	AA Report Supplemental Information Requirements	
8	_	No Additional Regulatory Response Required	
9		Product Information for Consumers	
20	•	End-of-Life Management Requirements	
21		Product Sales Prohibition.	
22	§ 69506.6.	Other Regulatory Responses	52
23	§ 69506.7.	Exemption from Regulatory Response Requirements	53
24	§ 69506.8.	Regulatory Response Determination Process	54
25	§ 69506.9.	Regulatory Response Report and Notifications	55
26 27	Article 7 D	ispute Resolution Processes	56
28	§ 69507.	Dispute Resolution.	
29	· ·	Informal Dispute Resolution Procedures	
30	_	Appeal to the Director	
31	•	Formal Dispute Resolution.	
32	•	Time Lines for Requests for Review	
33	-	Contents of Request for Review	
34	•	Department Procedures for Requests for Review	
35			
36		ccreditation Bodies and Certified Assessors	
37	§ 69508.	Qualification and Certification of Assessors.	
38	_	Qualifications for Accreditation Bodies.	
39	•	Accreditation Body Designation Requirements.	
10		Accreditation Bodies Designation Process	
11	§ 69508.4.	Filing a Complaint	65

1	Article 9. Audits	65
2	§ 69509. Audit of Alternatives Assessments and Regulatory Responses	
3		
4	Article 10. Trade Secret Protection	
5	§ 69510. Assertion of a Claim of Trade Secret Protection	
6	§ 69510.1. Department Review of Trade Secrecy Claims	67
7	Article 11 Coverability	ec
8 9	Article 11. Severability	
10	g 09311. Severability	00
11	Article 12. [Reserved]	68
12	§§ 69512 69599. [Reserved]	
13		
14		
15		
16	NOTE: References in these informal draft regulations to Chapter 54 and its sections (6940	1
17	through 69407.2) refer to OEHHA's draft regulations entitled "Green Chemistry Haz	zard
18	Traits for California's Toxics Information Clearinghouse" (dated October 7, 2011).	
19		
20		
21		
22		
23		
24		
25		
26 27		
28		
29		
30		
31		
32		
33		
34		
35		
36		
37		
38		
39		
40		
41		
42		

Add California Code of Regulations, title 22, division 4.5, chapter 55 to read:

Chapter 55. Safer Consumer Products

Article 1. General

§ 69501. Purpose and Applicability.

- (a) This chapter specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying potential alternatives for Priority Products to determine how best to limit potential exposures or the level of potential adverse impacts posed by the Chemical of Concern in the product. This chapter also specifies the regulatory responses that will be imposed by operation of article 6 or may be required by the Department following completion of an alternatives assessment.
- (b)(1) Except as provided in paragraphs (2) through (4), this chapter applies to all consumer products placed into the stream of commerce in California.
- (2) This chapter does not apply to any product that is exempted from the definition of "consumer product" specified in Health and Safety Code section 25251, or to any product that is placed into the stream of commerce in California solely for the manufacture of one or more of the products exempted from the definition of "consumer product" specified in Health and Safety Code section 25251.
- (3) This chapter does not apply to any consumer product manufactured or stored in, or transported through, California solely for use outside of California.
- (4)(A) This chapter does not apply to a consumer product that the Department determines is regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that, in combination:
- 1. Address the same adverse public health and environmental impacts and exposure pathways that would otherwise be the basis for the product being listed as a Priority Product; and
- 2. Provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product was listed as a Priority Product.
- (B) The Department may re-evaluate a determination previously made pursuant to this paragraph and rescind the determination if the Department finds that the facts and/or assumptions upon which the determination was based were not, or are no longer, valid.

- NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
- 39 Reference: Sections 25251, 25252, 25253, and 25257.1, Health and Safety Code.

§ 69501.1. Acronyms.

- 42 CEPA Canadian Environmental Protection Act
- 43 CRNR California Regulatory Notice Register

- 1 DOT Department of Transportation (US)
- 2 EC European Commission
- 3 ECHA European Chemicals Agency
- 4 EINECS European Inventory of Existing Commercial Chemical Substances
- 5 ELINCS European List of Notified Chemical Substances
- 6 EPA Environmental Protection Agency (US)
- 7 IUBMB International Union of Biochemistry and Molecular Biology
- 8 IUPAC International Union of Pure and Applied Chemistry
- 9 MITI Ministry of International Trade and Industry (Japan)
- 10 NLP No Longer Polymers
- 11 OECD Organization of Economic Cooperation and Development
- 12 OEHHA Office of Environmental Health Hazard Assessment
- 13 OSPAR Convention for the Protection of the Marine Environment for the Northeast Atlantic
- 14 REACH Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation
- 15 (EC) No. 1907/2006 of the European Parliament and the Council
- 16 RTECS Registry of Toxic Effects of Chemical Substances
- 17 TSCA Toxic Substances Control Act
- 18 UN United Nations
- 19 US United States

- 21 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
- 22 Reference: Sections 25252 and 25253, Health and Safety Code.

2324

§ 69501.2. Definitions.

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

2728

25

26

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

29 30 31

32

- (2) "Adverse air quality impacts" means air emissions of any of the air contaminants listed below:
- (A) California Toxic Air Contaminants;
- 34 (B) Greenhouse gases, which means any of the following gases:
- 35 1. Carbon dioxide:
- 36
 Hydrofluorocarbons:
- 37 3. Methane;
- 38 4. Nitrogen trifluoride;
- 39 5. Nitrous oxide:
- 40 6. Perfluorocarbons;
- 41 7. Sulfur hexafluoride:
- 42 (C) Nitrogen oxides;

- 1 (D) Particulate matter, with an aerodynamic diameter of ten (10) micrometers or less;
- 2 (E) Stratospheric ozone-depleting compounds;
- 3 (F) Sulfur oxides; or
 - (G) Tropospheric ozone-forming compounds.

7

8

9

10

11

12

13

14

15

- (3) "Adverse ecological impacts" means any of the following direct or indirect effects on living organisms and their environments:
 - (A) Acute or chronic toxicity to aquatic, avian, or terrestrial animal or plant species;
 - (B) Adverse impacts on aquatic and terrestrial ecosystems;
 - (C) Deterioration or loss of environmentally sensitive habitats;
- (D) Impacts that cause population loss, reductions in biodiversity, or changes in ecological communities;
 - (E) Impacts that cause vegetation contamination or damage;
- (F) Impairment of the ability of an endangered or threatened species to survive or reproduce; or
 - (G) Any other impact specified in article 4 of chapter 54.

16 17

- 18 (4) "Adverse environmental impacts" means any of the following:
- 19 (A) Adverse air quality impacts;
- 20 (B) Adverse ecological impacts;
- 21 (C) Adverse soil quality impacts; or
 - (D) Adverse water quality impacts.

222324

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

25 26

27

28 29

30

31

33

34

- (6) "Adverse soil quality impacts" means any of the following effects on soil function or soil chemical, physical, or biological characteristics or properties:
 - (A) Biological contamination;
 - (B) Chemical contamination;
 - (C) Compaction or other structural changes;
- 32 (D) Erosion;
 - (E) Loss of organic matter; or
 - (F) Soil sealing, meaning the covering of the soil surface with a layer of impervious material or changing the nature of the soil so that it behaves as an impermeable medium.

35 36 37

38

39

- (7) "Adverse waste and end-of-life impacts" means adverse impacts associated with any of the following:
- (A) The amount of waste and byproducts generated, and any special handling required for the waste and byproducts, during the life cycle of the Priority Product and each alternative being considered;

- 1 2
- 3
- 4 5 6
- 7
- 8 9
- 10 11 12
- 13
- 14 15
- 16
- 17
- 18 19
- 20 21
- 22 23
- 24 25 26
- 27 28
- 29 30

- 32 33 34
- 35 36 37 38
- 39 40 41

- Disposal, treatment, or use of waste and byproducts, including solid waste, (B) wastewater and storm water discharge streams; or
- Disposal of the Priority Product in the trash, down the sewer, or down the storm drain that interferes with the proper operation of solid waste, wastewater, or storm water treatment facilities, and that may result in the release of Chemicals of Concern to the environment.
- "Adverse water quality impacts" means any of the following adverse effects on the (8)beneficial uses, as specified in Water Code section 13050(f) or adopted in a Water Quality Control Plan pursuant to article 3 of chapter 3 and/or article 3 of chapter 4 of division 7 of the Water Code, of the waters of the State, which include groundwater, fresh water, brackish water, marsh lands, wetlands, or coastal bodies or systems:
 - (A) Increase in biological oxygen demand;
 - (B) Increase in chemical oxygen demand;
 - (C) Increase in temperature;
 - Increase in total dissolved solids; or (D)
 - (E) Introduction of, or increase in, any of the following:
- 1. Chemicals identified as priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act:
- Pollutants listed by California or the United States Environmental Protection Agency for one or more water bodies in California pursuant to section 303(d) of the federal Clean Water Act;
- 3. Chemicals for which primary Maximum Contaminant Levels (MCLs) have been established under the federal Safe Drinking Water Act;
- Pollutants requiring monitoring and reporting in waste discharges to land that have 4. Notification Levels (NLs) specified under the Waste Discharge and Water Reuse Requirements (WDRs/WRRs) of the Porter-Cologne Water Quality Control Act; or
 - 5. Chemicals for which OEHHA has published public health goals for drinking water.
 - "Alternative" means any of the following: (9)
- (A) Removal of Chemical(s) of Concern in a Priority Product, with or without adding or increasing the concentration of a substitute chemical;
- Reformulation or redesign of a product and/or manufacturing process to reduce or (B) eliminate the concentration of Chemical(s) of Concern in the Priority Product;
- Redesign of the product and/or manufacturing process, using different materials to reduce the potential for public health and/or environmental exposures to Chemical(s) of Concern in Priority Product; or
- Any other change to a Priority Product or a manufacturing process that reduces the (D) potential for adverse public health and/or environmental impacts or exposures associated with the Chemical(s) of Concern in the Priority Product.

- (10) "Alternatives assessment" or "AA" means an evaluation and comparison of a product and alternative products, pursuant to article 5.
- (11) "Aqueous hydrolysis half-life" means the time required for the concentration of a chemical to be reduced to one-half of its initial concentration after being introduced into water.
- (12) "Assembled product" means a heterogeneous product consisting of two or more components.
- (13) "Atmospheric oxidation rate" means the rate of change or degradation of a chemical through the interaction with oxygen in the atmosphere.
- (14) "Bioaccumulation" means the accumulation of a chemical substance in an organism, or an individual component of the environment, which absorbs the chemical at a rate greater than that at which the chemical is lost.
- (15) "Certified assessor" means an individual that is qualified by education, experience, and examination, and has been issued a certificate by an accreditation body, pursuant to article 8, to perform one or more of the functions or procedures used to conduct or audit an AA, or verify an AA Report.
- (16) "Chemical" means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.
 - (17) "Chemical identification and description information" means all of the following:
 - (A) Substance identification information;
- (B) Information on the purity of the chemical and identification of known impurities and additives in the chemical;
 - (C) Physicochemical properties; and
 - (D) Environmental fate properties.
 - (18) "Chemical ingredient" means a chemical in a consumer product.
- (19) "Chemical of Concern" means a chemical identified as a Chemical of Concern under section 69502.2(a), or a chemical listed by the Department pursuant to section 69502.3.
- (20)(A) "Component" means a uniquely identifiable part, piece, assembly or subassembly, system, or subsystem of a consumer product that:
 - 1. Is required to complete or finish an item;
 - 2. Performs a distinctive and necessary function in the operation of a system; or
 - 3. Is intended to be included as a part of a finished item.

- (B) "Component" does not include a chemical ingredient in a formulated consumer product.

- (21) "Consumer product" or "Product" means any of the following:
- (A) A "consumer product" as defined in Health and Safety Code section 25251;
- (B) A component that meets the definition of a "consumer product" as defined in Health and Safety Code section 25251; or
- (C) A component that is identified, pursuant to section 69503.3(a)(2)(C), as the minimum required focus of an AA.

(22) "Contact information" means mailing and electronic address, headquarters location, phone number(s), title(s) if applicable, and website address.

(23) "Day" means calendar day. Periods of time are calculated by excluding the first day and including the last; except that the last day is excluded if it is a Saturday, Sunday, or other holiday specified in Government Code section 6700.

(24) "De Minimis Exemption Notification" means a notification submitted to the Department pursuant to section 69503.5.

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

- (A) 0.01% by weight for chemicals exhibiting any of the following hazard traits or environmental or toxicological endpoints specified by OEHHA pursuant to title 22, California Code of Regulations, division 4.5, chapter 54:
- Bioaccumulation;
- 2. Carcinogenicity, as defined in section 69402.1, that meets one or more of the criteria in section 69402.2(a);
- 3. Developmental toxicity, as defined in section 69402.3, that meets one or more of the criteria in section 69402.4(a);
- 4. Endocrine toxicity, as defined in section 69403.3, that meets one or more of the criteria in section 69403.17(a);
- 5. Genotoxicity, as defined in section 69403.5, that meets one or more of the criteria in section 69403.17(a);
- 6. Immunotoxicity, as defined in section 69403.8, that meets one or more of the criteria in section 69403.17(a);
- 7. Neurotoxicity, as defined in section 69403.12, that meets one or more of the criteria in section 69403.17(a);
 - 8. Persistence; or
- 40 9. Reproductive toxicity, as defined in section 69402.5, that meets one or more of the criteria in section 69402.6(a).

- 1 (B) 0.1% by weight for chemicals that do not exhibit any of the hazard traits or environmental or toxicological endpoints listed in subparagraph (A).
 - (C) The de minimis level concentration specified by the Department pursuant to section 69503.4(c).

3

(26) "Department" means the Department of Toxic Substances Control.

6 7 8

9

10

- (27) "Economic impacts" means an increase or decrease in any of the following:
- (A) Capital investments;
 - (B) Cost of goods to consumers;
- 11 (C) Cost of marketing;
- 12 (D) Energy costs;
- 13 (E) Jobs or businesses;
 - (F) Operation and maintenance costs;
- 15 (G) Resource costs; or
- 16 (H) Waste disposal and/or treatment costs.

17 18

19

20

21

22

23

24

25

26

27

14

- (28) "Economic interest" in an entity means that an individual, or that individual's spouse or dependent child:
- (A) Has a direct or indirect investment worth two thousand dollars (\$2,000) or more in the entity;
- (B) Is a director, officer, partner, trustee, or employee, or holds a position of management in the entity;
 - (C) Receives a source of income from the entity; or
- (D) Has an economic interest, as defined in subparagraphs (A) through (C), in a business entity that is a parent or subsidiary, as defined in section 18703.1(d) of Title 2 of the California Code of Regulations, of, or is otherwise related to, the entity.

28 29

(29) "End-of-life" means the point when the product is discarded by the consumer or the end of the useful life of the product, whichever occurs first.

31 32

30

(30) "Energy efficiency" means the reduction of energy usage while maintaining a comparable level of service.

33 34 35

(31) "Environment" means the land, air, water, soil, minerals, flora, and fauna.

36 37

38

39

40

- (32) "Environmental fate properties" means all of the following:
- (A) Aerobic and anaerobic soil and sediment half-lives;
- (B) Aqueous hydrolysis half-life;
 - (C) Atmospheric oxidation rate;
 - (D) Bioaccumulation in organs and tissues;
- 42 (E) Biodegradation;

- (F) Mobility among and between individual components of the environment;
 - (G) Persistence; and
 - (H) Photodegradation.

(33) "Environmental or toxicological endpoint" means any environmental or toxicological endpoint identified by OEHHA, pursuant to Health and Safety Code section 25256.1, and specified in chapter 54.

(34) "Failure to Comply List" means the list prepared by the Department pursuant to section 69501.3(d).

(35) "Failure to Respond List" means the list prepared by the Department pursuant to section 69501.5.

(36) "Financial guarantee" means any mechanism to ensure that adequate funding is available to pay for future end-of-life management costs for products placed into the stream of commerce in California.

(37) "Formulated product" means a homogeneous product, often, but not always, intended to be consumed through use.

(38) "Functionally acceptable" means that a product that has been altered by a chemical or component substitution, or that has replaced another product, substantially equals or exceeds the performance and functionality of the original product.

(39) "Green chemistry principles" means the twelve principles of green chemistry specified in "Green Chemistry: Theory and Practice" (Anastas, P.T. and Warner, J.C.; Oxford University Press: New York, 1998, p. 30).

(40) "Hazard trait" means any hazard trait identified by the OEHHA, pursuant to Health and Safety Code section 25256.1, and specified in chapter 54.

(41) "Import" means to bring, or arrange to bring, a consumer product into the United States for purposes of placing the product into the stream of commerce. "Import" includes reimporting a consumer product manufactured or processed, in whole or in part, in the United States.

(42) "Importer" means a person who imports a consumer product into the United States.

(43) "Information" means data, documentation, records, graphs, reports, or any other depiction of specific pieces of knowledge.

- (44) "Inventory recall" means to cause the return, directly or indirectly, of a consumer product that has not been sold at retail back to the responsible entity or the manufacturer or importer of the consumer product.
- (45) "Legal requirements" means specifications and/or performance standards that a product is required to meet by federal or California law.
- (46) "Life cycle" means the sum of all activities in the course of a consumer product's entire life span, including raw materials extraction, resource inputs and other resource consumption, intermediate materials processes, manufacture, packaging, transportation, distribution, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal.
- (47) "Life cycle thinking" means the examination and consideration of public health and environmental impacts over a product's entire life cycle.
- (48) "Listserv" means an electronic mailing list that a person may subscribe to on the Department's website in order to automatically receive electronic notification of the posting of documents and other information on that website.
- (49) "Manufacture" means to make, produce, or assemble. "Manufacture" does not include any of the following actions, unless the action results in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product:
 - (A) Repair or refurbishment of an existing consumer product;
 - (B) Installation of standardized components to an existing consumer product; or
 - (C) Making non-material alterations to an existing consumer product.
- (50) "Manufacturer" means any person who manufactures a product, or any person that controls the specifications and design of, or use of materials in, a product.
 - (51) "Market presence information" means all of the following:
 - (A) Statewide sales by volume;
 - (B) Statewide sales by number of units; and
 - (C) Intended product use(s), and types and age groups of targeted customer base(s).
- (52)(A) "Materials and resource consumption" means the consumption of renewable and nonrenewable resources that are used for a consumer product during its life cycle.
- (B) Except as specified in subparagraph (C)2., a renewable resource is a resource that is capable of being replaced by natural processes at a rate equal to or faster than its consumption rate. Renewable resources include solar and wind energy, timber, agriculture, and water.

- (C) Both of the following are nonrenewable resources:
- 1. An inherently finite resource that is formed over long periods of geologic time. This includes petroleum, coal, metals (mined and recycled), minerals, and other finite resources; and
- 2. A resource that meets the definition of a renewable resource, specified in subparagraph (B), but the resource is consumed at a rate that exceeds the rate at which it is replaced such that its continued use may drive the resource to exhaustion.
- (53) "Materials and resource consumption impacts" means all of the following:
 - (A) Energy consumption and efficiency;
 - (B) Production, in-use, and transportation energy inputs;
 - (C) Reusability and recyclability; and
 - (D) Consumption and conservation of renewable and nonrenewable resource.
 - (54) "Mode of action" means the mechanism by which a chemical produces an effect on a living organism or in an environmental compartment.
 - (55) "Persistence" means the propensity for a chemical substance to exist in the environment in an unchanged form.
 - (56) "Person" has the same meaning as in Health and Safety Code section 25118.
 - (57) "Physical chemical hazards" means physical hazard traits specified in article 6 of chapter 54.
 - (58) "Physicochemical properties" means the physicochemical properties specified in section 69407.2.
 - (59)(A) "Place into the stream of commerce in California" means to sell, offer for sale, distribute, supply, or manufacture a consumer product for use in California.
 - (B) "Sale or offer for sale" means any transfer or offer to transfer for consideration of title or the right to use, by lease or sales contract, including transactions conducted and offers made through sales outlets, catalogs, or the Internet, or any other similar electronic means.
 - (60) "Priority Product" means a product listed by the Department pursuant to section 69503.3.
 - (61) "Processing agent" means a chemical used in a product manufacturing process to promote chemical or physical changes.
 - (62) "Product function and performance" means the principal use(s) or application(s) of a product by a consumer, as intended by the manufacturer, including function and performance attributes, and legal requirements.

(63)"Purity" means the relative freedom from extraneous matter in a product.

3 4

5

for the purpose of recycling the material as feedstock.

(64)

(65)

6 7

8 9

10 11

12 13

14

15 16

17 18

19 20

21 22 23

24 25

26 27 28

29 30 31

32 33 34

35

36 37

39 40

38

a chemical into the environment.

(66)"Reliable information" means well-conducted scientific studies, as defined in section 69401.2, or any other information that meets one or more of the following criteria:

"Recycled material" means a material that has been separated from a waste stream

"Release" means an intentional or unintentional liberation, emission, or discharge of

- Relied on or used by an authoritative organization, as defined in section 69401.2, to protect public health or the environment;
 - (B) Generated using one of the following:
- US Food and Drug Administration Good Laboratory Practices (Part 58 of Title 21 of 1. the Code of Federal Regulations):
- 2. US EPA's Office of Chemical Safety and Pollution Prevention Harmonized Test Guidelines:
 - 3. TSCA (Chapter 1 of Title 40 of the Code of Federal Regulations);
- 4. TSCA Testing Guidelines (Parts 798 and 799 of Title 40 of the Code of Federal Regulations);
 - (C) Published in scientifically peer reviewed reports or other literature;
 - (D) Published in a report of the US National Academies;
- Published in reports by international, federal, state and local agencies that (E) implement laws and programs governing chemicals;
- Developed, or reviewed and accepted, by an international organization, federal (F) agency, state agency, or local agency for compliance or other regulatory purposes; or
- Developed according to valid accepted testing protocols in which the test parameters documented are based on specific testing guidelines, or in which all parameters described are comparable to a guideline method, including:
 - 1. OECD Guidelines for Testing of Chemicals;
- 2. OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring;
 - 3. OECD Manual for Investigation of High Production Volume Chemicals;
- 4. REACH/ECHA Guidance on Information Requirements and Chemical Safety Assessment and Regulation (EC) No. 440/2008 of the European Parliament and the Council; or
- 5. CEPA Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers.

- (67) "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" means any of the following that are established by reliable information:
- (A) Monitoring data that shows the chemical to be present in household dust, indoor air, or drinking water, or on interior surfaces;
- (B) Monitoring data that shows the chemical to be present in, or released from, products used in or present in the home;
- (C) Environmental monitoring data, or environmental modeling results, that indicate environmental accumulation of a chemical;
- (D) California Environmental Contaminant Biomonitoring Program data, Center for Disease Control's National Health and Nutrition Evaluation Survey biomonitoring data, or other biomonitoring data, that show the chemical to be present in human organs, tissues, or fluids;
- (E) Reliable information that provides evidence that a chemical exhibits the lactational or transplacental transfer hazard trait specified in section 69405.5;
- (F) Environmental monitoring data that shows the accumulation of the chemical in aquatic, avian, animal, or plant species;
- (G) Exposure modeling that indicates exposure point concentration(s) associated with adverse public health or environmental impacts; or
- (H) Monitoring data indicating the presence of a chemical or its degradation products in California solid waste, wastewater, or storm water streams collected or managed by California State or local agencies in concentrations or volumes that:
 - 1. Present potential adverse public health or environmental impacts;
- 2. May require the expenditure of public funds to mitigate potential adverse public health or environmental impacts;
 - 3. Increase the costs of reusing or recycling materials containing the chemical; or
- 4. Interfere with the proper operation of solid waste, wastewater, or storm water treatment systems and may result in the discharge of the chemical to the environment.
 - (68) "Responsible entity" means any of the following:
 - (A) The manufacturer of a consumer product.
 - (B) The importer of a consumer product.
 - (C) The retailer of a consumer product.
- (69) "Retailer" means a person to whom a consumer product is delivered or sold for purposes of sale or distribution by the person to a consumer.
- (70) "Safer alternative" means an alternative that, in comparison with the existing Priority Product, reduces, avoids, or eliminates the use of, and/or potential exposures to, one or more Chemical(s) of Concern, so as to reduce potential adverse public health and environmental impacts.

(71) "Sales outlet" means any place at which consumer products are sold, supplied, or offered for sale directly to consumers in California.
 (72) "Sensitive subpopulations" means subgroups that comprise a meaningful portion of the general population that are identifiable as being at greater risk of adverse health effects

when exposed to one or more chemicals that exhibit a hazard trait or toxicological endpoint,

including, but not limited to, infants, children, pregnant women, elderly individuals, and

9 10 11

12

13

14

1

2

3

5

6

7 8

(73) "Substance identification information" means all of the following that are applicable:

individuals with a history of serious illness that renders them as being at greater risk of adverse

(A) Chemical abstract services number;

health effects when exposed to chemicals.

- (B) Structural formula;
 - (C) Molecular weight;
- 15 (D) Synonyms;
- 16 (E) IUPAC name;
- 17 (F) EC number;
- 18 (G) RTECS number;
- 19 (H) IUBMB number;
- 20 (I) MITI number;
- 21 (J) Number assigned by the UN Experts on the Transport of Dangerous Goods;
- 22 (K) North America DOT number;
- 23 (L) EINECS number;
- 24 (M) ELINCS number;
- 25 (N) NLP number; and
 - (O) Other commonly recognized substance identification system numbers.

262728

29

30

31

32

33

34

35

- (74) "Technologically and economically feasible alternative" means an alternative product or chemical for which:
- (A) The current technological knowledge, equipment, materials, and other resources available to the manufacturer are sufficient to develop and implement the alternative;
- (B) The manufacturer may earn a reasonable rate of return over a reasonable period of time after the alternative has been implemented; and
- (C) The alternative does not increase aggregate externalized costs to consumers, public health, and the environment.

36 37

(75) "Trade secret" means a "trade secret" as defined in Government Code section 6254.7(d).

39 40

38

(76) "Useful life" means the period of time during which a product can be used for its intended use, expressed in terms of a single use, number of applications, or days, months, or years of use.

- 1 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
- 2 Reference: Sections 25251, 25252, 25253, and 25257, Health and Safety Code, Section 1060,
- 3 Evidence Code, and Sections 3426 through 3426.11, inclusive, Civil Code.

§ 69501.3. Duty to Comply and Consequences of Non-Compliance.

- (a) Duty to Comply.
- (1) A manufacturer has the principal duty to comply with requirements applicable to a responsible entity. In the event a manufacturer does not comply, it shall be the duty of the importer, if any, to comply. A retailer is required to comply with the requirements applicable to a responsible entity only if the manufacturer and the importer, if applicable, have failed to comply and the Department notifies the retailer of the manufacturer's and the importer's, if applicable, non-compliance by posting the information on the Failure to Comply List, pursuant to subsection (d)(4)(C).
- (2) The requirements of this chapter applicable to a responsible entity may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, the responsible entity.
 - (b)(1) Manufacturer or Importer Option.

A responsible entity that is the manufacturer or importer of a product shall not be held responsible for complying with the requirements of this chapter applicable to a responsible entity if the manufacturer or importer provides a notice to the Department containing information demonstrating to the Department's satisfaction that the product is no longer placed into the stream of commerce in California. The notice shall include all of the following:

- (A) The name of, and contact information for, the manufacturer or the importer;
- (B) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months;
- (C) Identification and location of the manufacturer's or the importer's retail sales outlets where the manufacturer or importer sold, supplied, or offered for sale the product in California, if applicable; and
- (D) Information describing the product, including the brand name(s) and product name(s) under which the product was placed into the stream of commerce in California.
- (2) If the manufacturer or importer places into the stream of commerce in California a product that replaces, in terms of use and customer bases, the removed Priority Product and that contains the same or different Chemical(s) of Concern, the manufacturer or importer shall provide a notice to the Department at the same time as the notice required pursuant to paragraph (1) or within thirty (30) days after the replacement product is first placed into the stream of commerce in California, whichever is later. The notice shall include all of the following information:
 - (A) The manufacturer's or importer's name and contact information;
- (B) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months;

- (C) Identification and location of the manufacturer's or the importer's retail sales outlets where the manufacturer or importer sold, supplied, or offered for sale the product in California, if applicable;
- (D) Information describing the Priority Product that is replaced by the new product, including the brand name(s) and product name(s) under which the Priority Product was placed into the stream of commerce in California; and
- (E) Information describing the new product that replaces the Priority Product, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, and the Chemical(s) of Concern in the new product.
- (3) Paragraph (2) does not apply to a replacement product first placed into the stream of commerce in California prior to the issuance of the applicable proposed Priority Products list, unless there is a two-fold or greater increase in the sales of the replacement product in California within one year after the date of the notice required pursuant to paragraph (1).
 - (c) Retailer Option.

A retailer of a consumer product for which the Department has provided notice pursuant to subsection (a), shall not be held responsible for complying with the requirements specified in the notice if:

- (1) The manufacturer or importer complies with the requirement specified in the Department's notice, or fulfills the requirements of subsection (b), within sixty (60) days after the Department issues the notice; or
 - (2) The retailer complies with both of the following requirements:
- (A) The retailer ceases ordering the product no later than sixty (60) days after the Department has provided notice pursuant to subsection (a)(1); and
- (B) No later than sixty (60) days after the Department has provided notice pursuant to subsection (a)(1), the retailer notifies the Department that it has ceased ordering the product, and provides the following information to the Department:
 - 1. The retailer's name and contact information;
 - 2. The manufacturer's and the importer's, if applicable, name and contact information;
- 3. Identification and location of the retailer's sales outlets where the product is sold, supplied, or offered for sale in California;
- 4. The name of, and contact information for, the person immediately upstream from the retailer in the supply chain for the product;
- 5. Information describing the product, including the brand name(s) and product name(s) under which the retailer placed the product into the stream of commerce in California; and
- 6. A statement certifying that the retailer will not re-initiate ordering the product unless and until information posted on the Department's website indicates that the non-compliance has been remedied.
 - (d) Failure to Comply List.
- (1)(A) If the Department determines that one or more requirements of this chapter have not been complied with for a specific product, the Department shall issue a notice of non-compliance to the manufacturer and the importers, if applicable, for the product.

- - tl tl

(B)

Department's intent to place information concerning the determination of non-compliance on the Failure to Comply List on its website pursuant to paragraph (4).

(2) If the non-compliance has not been remedied to the satisfaction of the Department,

A notice of non-compliance shall describe the nature of the non-compliance and the

- (2) If the non-compliance has not been remedied to the satisfaction of the Department, the Department shall post information concerning the determination of non-compliance on the Failure to Comply List on its website pursuant to paragraph (4). The Department shall post the information on the Failure to Comply List not less than 45 days and not later than 90 days after issuing the notice of non-compliance. The non-compliance shall be deemed to be remedied if the Department determines that the requirements of subsection (b)(1) have been fulfilled, or that the condition of non-compliance has been fully remedied.
- (3) Paragraph (2) does not apply if there is pending dispute under article 7 concerning the notice of non-compliance.
- (4) The Department shall post and maintain on its website a Failure to Comply List that includes all of the following information for each product covered by a notice of non-compliance:
- (A) Information identifying and describing the product, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California;
- (B) The requirement(s) of this chapter, and the applicable due date(s), that are the basis for the notice of non-compliance:
- (C) A statement placing retailers of the product on notice of the failure to comply by the manufacturer(s) and the importer(s), if applicable, pursuant to subsection (a)(1), including identification of the requirement with which the retailer shall comply and the timeframe for compliance, which shall be no less than sixty (60) days after the notice is posted on the Department's website;
 - (D) The Chemical(s) of Concern known to be in the product;
- (E) The name of and, if known, the contact information for the person listed on the product label as the manufacturer and the person, if any, listed as the distributor;
- (F) The name of, and contact information for, any manufacturer or importer that has been notified by the Department, pursuant to paragraph (1);
- (G) The name of, and contact information for, retailers of the product known to the Department who have not fully complied with the requirements of subsection (c); and
 - (H) The date the product is first listed on the Failure to Comply List.
- (5) The Department shall remove a product, and the associated information, from the Failure to Comply List if the Department determines that the condition of non-compliance has been fully remedied, or that the requirements of subsection (b)(1) have been fulfilled.
- (6) The Department shall remove information concerning a retailer who is a responsible entity from the Failure to Comply List if the Department determines that the retailer has fully complied with the applicable requirements of subsection (c).
- NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
- 41 Reference: Sections 25252 and 25253, Health and Safety Code.

§ 69501.4. Information Submission and Retention Requirements.

- (a) All information required to be submitted to the Department by a responsible entity pursuant to the chapter must be signed by the responsible individual in charge of preparing or overseeing the preparation of the information and by the owner, or an officer of the company, or an authorized representative. All information submitted to the Department must be in English, and must be generated and submitted in a manner and in an electronic format specified by the Department.
- (b) All De Minimis Exemption Notifications, Preliminary and Final AA Reports, Priority Product Notifications, and submissions of information claimed to constitute trade secrets must include the following certification statement, signed by the owner or an officer, or authorized representative, of the entity submitting the document and by the responsible individual in charge of preparing, or overseeing the preparation of, the information:

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

(c) A person who is subject to a requirement to obtain or prepare information, but who is not required to submit the information to the Department or has not yet been requested to submit information to the Department, shall retain the information for a period of three (3) years following the date the person was required to obtain or prepare the information.

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

§ 69501.5. Chemical and Product Information.

- (a) The Department shall seek to obtain and/or review information that it determines is necessary to implement this chapter using one or more of the following approaches:
- (1) Obtain and/or review information in the public domain that is readily available in a usable format, without a subscription or other charge;
- (2) Obtain and/or review information in the public domain that is readily available in a usable format, with a subscription or other charge, to the extent resources are available to pay the required costs;
- (3) Request a responsible entity or a chemical manufacturer or importer to make existing information available to the Department, in accordance with a schedule specified by the Department; and/or
- (4) Request a responsible entity or a chemical manufacturer or importer to generate new information and provide it to the Department, in accordance with a schedule specified by the Department.

- (b) The Department may request that information be made available to it pursuant to this section by either or both of the following methods:

 (1) Correspondence sont to an individual responsible entity or chamical manufactures.
- (1) Correspondence sent to an individual responsible entity or chemical manufacturer electronically or by United States mail. Copies of the correspondence shall be posted on the Department's website; and/or
- (2) Information call-ins that, unless otherwise specified, apply to all responsible entities and/or all chemical manufacturers and importers of a specific chemical or product or group of chemicals or products. The Department shall post information call-ins on its website, provide notice to individuals on the listservs established by the Department related to this chapter, and provide notice in the CRNR.
- (c) The Department shall post on its website on the Failure to Respond List a notice that a responsible entity or a chemical manufacturer or importer has not made the requested information available to the Department, if that person, or person acting on behalf of or in lieu of that person, does not make the requested information available by the date specified by the Department, unless the responsible entity or the chemical manufacturer or importer demonstrates to the Department's satisfaction that is does not have and is unable to produce the requested information. The Department shall also post information identifying the responsible entity or the chemical manufacturer or importer, and the chemical or product that is the subject of the request. The Department shall remove this information from its website upon determining that the responsible entity, or the chemical manufacturer or importer, or another person has fulfilled the request for information.

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

§ 69501.6. Availability of Information on the Department's Website.

- (a) The Department shall post on its website, and update as appropriate, all of the information and documents listed below, except as otherwise provided in article 10. The Department shall also provide notice of the availability of these documents and information, including the availability of updates to the documents and information, in the CRNR and to individuals on the listserv(s) that the Department establishes related to this chapter.
 - (1) The Failure to Comply List prepared pursuant to section 69501.3(d).
 - (2) The Failure to Respond List prepared pursuant to section 69501.5(c).
 - (3) Requests for information made pursuant to section 69501.5.
- (4)(A) Exemption determinations made pursuant to section 69501(b)(4), and the rationales for the determinations; and
- (B) Determinations made pursuant to section 69501(b)(4), rescinding previously made exemption determinations.
- (5) Proposed and final Chemicals of Concern and Priority Products lists and revisions to the lists, supporting rationales and documentation, prepared pursuant to sections 69502.3 and 69503.3, copies of all written comments received during the public comment period for the proposed list, and copies of any written responses the Department provides to the comments.

- 1 As the following information becomes available, the Department shall add it to the Priority
- 2 Products list for each product that is a Priority Product, and maintain and update this
- information for as long as the Priority Product continues to be placed into the stream of commerce in California:
 - (A) Brand name(s) and product name(s) for the product;
 - (B) Product manufacturer(s) and importers, if applicable, except for those manufacturers or importers that have complied with the requirements of section 69501.3(b);
 - (C) Other responsible entities for the product, except for the responsible entities that have complied with the requirements of section 69501.3(c); and
 - (D) Whichever of the following is applicable:
 - 1. A link to the De Minimis Exemption Notification for the product, unless subsection (d) or (e) of section 69503.5 applies; or
 - 2.a. The identity of the person that has been identified as being the person that will fulfill the requirements of article 5; and
 - b. The due dates for, and the dates of receipt of, the Preliminary AA Report and the Final AA Report.
 - (6) Petitions designated as complete pursuant to section 69504(b), and notices of decision and statements of basis prepared by the Department pursuant to section 69504.1(d).
 - (7) The due date for each Preliminary and Final AA Report.
 - (8) A list of extension requests approved, pursuant to section 69505.1(c), for submission of the Preliminary and Final AA Reports.
 - (9) A list of, and copies of, Priority Product Notifications submitted to the Department under section 69503.6.
 - (10) A list of, and copies of, De Minimis Exemption Notifications submitted to the Department under section 69503.5(a), notices submitted to the Department under subsections (c) and (d) of section 69503.5, and notices issued by the Department under section 69503.5(e).
 - (11) AA Report notices of compliance and notices of deficiency issued pursuant to section 69505.6.
 - (12) Proposed and final regulatory response determination notices issued by the Department pursuant to article 6, copies of all written comments received during the public comment period for a proposed notice, and copies of any written responses the Department provides to the comments.
 - (13) A list of regulatory response exemption requests submitted to the Department pursuant to section 69506.7(a), and copies of all notifications issued by the Department granting, denying, or rescinding a regulatory response exemption pursuant to sections 69506.7(c) and 69506.7(e).
 - (14) Copies of all disputes and Requests for Review filed with the Department pursuant to article 7, and copies of all Department decisions issued in response to disputes and Requests for Review.

- (15) A list of accreditation bodies whose designation has been rescinded by the Department pursuant to section 69508.3(g), and a list of certified assessors whose accreditation has been rescinded pursuant to section 69508(c).
- (b) The Department shall also post on its website, and update as appropriate, all of the following information and documents, except as otherwise provided in article 10:
- (1) Information concerning notices submitted to the Department pursuant to section 69501.3 (b) and (c).
 - (2) Guidance documents prepared by the Department pursuant to section 69505(a).
 - (3) AAs made available by the Department pursuant to section 69505(b).
- (4) A list of all Preliminary AA Reports that have been submitted to the Department pursuant to article 5, the executive summary for each Preliminary AA Report, and a full or redacted copy of each Preliminary AA Report, including both the originally submitted Preliminary AA Report and the Preliminary AA Report approved by the Department, if different.
- (5) A list of all Final AA Reports that have been submitted to the Department pursuant to article 5, the executive summary for each Final AA Report, and a full or redacted copy of each Final AA Report, including both the originally submitted AA Report and the Final AA Report approved by the Department, if different.
- (6) A list of all work plans submitted to the Department pursuant to section 69505.2(b), and a full or redacted copy of each work plan, including both the originally submitted work plan and the work plan approved by the Department, if different.
- (7) The Regulatory Response Report prepared and updated pursuant to section 69506.9(d).
- (8) Links to product stewardship plans provided to the Department pursuant to section 69506.4(a)(2)(C).
- (9) A list of entities that have been designated as accreditation bodies pursuant to section 69508.3.
 - (10) A list of certified assessors who have been accredited pursuant to section 69508.
 - (11) Findings of audits conducted by the Department pursuant to section 69509.
- (c) All documents and information posted on the Department's website pursuant to this chapter shall include the date the document or information is first posted and the date(s) of any revised postings.

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

Article 2. Chemicals of Concern Identification Process

§ 69502. General.

- (a) This article identifies Chemicals of Concern, and specifies the process by which the Department may identify additional Chemicals of Concern.
- (b) The Department may use, but is not limited to using, information obtained and/or reviewed pursuant to section 69501.5 to perform its duties under this article.

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

3 4 5

6

7

§ 69502.1. Applicability.

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

8 9 10

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

111213

14

15 16

17

18

19

20

21

22

23

24

25

26

2728

29

30

31

32

33

34

35

36

37

38

§ 69502.2. Chemicals of Concern Identification.

- (a) 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:
- (1) The chemical is identified as exhibiting a hazard trait on one or more of the following lists:
- (A) California Safe Cosmetics Program's Chemicals Known or Suspected to Cause Cancer or Reproductive Toxicity;
 - (B) California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65);
- (C) Canadian Environmental Protection Act Environmental Registry's Persistent, Bioaccumulative, and Inherently Toxic to the Environment (CEPA PBiT);
- (D) Category A and B Carcinogens, Report on Carcinogens, US Department of Health and Human Services, Public Health Service, National Toxicology Program;
- (E) Chemicals for which primary Maximum Contaminant Levels (MCLs) have been established under the federal Safe Drinking Water Act;
- (F) European Chemical Substances Information System Persistent Bioaccumulating Toxins (ESIS PBT);
 - (G) European Commission Category 1 and Category 2 endocrine disruptors;
- (H) European Union Directive on Dangerous Substances (Directive 67/548/EEC), Category 1 Carcinogens and Category 1 Reproductive toxins;
- (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;
- (J) International Agency for Research on Cancer (IARC), Groups 1, 2A, and 2B carcinogens;
- (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;
- (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;

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18 19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

- 1 (M) Priority toxic pollutants for California pursuant to section 303(c) of the federal Clean 2 Water Act;
 - (N) US EPA Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals; and/or
 - (O) Washington Department of Ecology Persistent, Bioaccumulative, Toxic Chemicals.
 - (2) The chemical is identified by one or more of the following lists based on exposures or environmental or toxicological endpoints:
 - (A) National Report on Human Exposure to Environmental Chemicals, Center for Disease Control;
 - (B) OSPAR List of Chemicals for Priority Action;
 - (C) OSPAR List of Substances of Possible Concern; and/or
 - (D) US EPA National Waste Minimization Program list of Persistent Bioaccumulative and Toxic Priority Chemicals.
 - (3) The chemical is identified by one or more of the following sources of reliable information:
 - (A) Grandjean & Landrigan identification of neurotoxicants;
 - (B) National Toxicology Program, Office of Health Assessment and Translation (formerly the Center for the Evaluation of Risks to Human Reproduction (CERHR)) reports; and/or
 - (C) US EPA Integrated Risk Information System (IRIS) identification of carcinogens.
 - (b) Additions to the Chemicals of Concern List. In addition to the chemicals identified as Chemicals of Concern pursuant to subsection (a), the Department may identify chemicals, that exhibit one or more hazard traits or environmental or toxicological endpoints, as Chemicals of Concern by considering the following factors for which information is available:
 - (1) Potential Chemical Adverse Impacts.
 - (A) The potential for the chemical to cause adverse public health and/or environmental impacts, considering:
 - 1. The chemical's hazard traits and environmental or toxicological endpoints, and modes of action:
 - 2. The chemical's aggregate effects;
 - 3. The chemical's cumulative effects with other Chemicals of Concern with similar modes of action;
 - 4. The chemical's physicochemical properties;
 - 5. The chemical's environmental fate properties; and
 - 6. The populations and/or environmental receptors that are potentially adversely impacted.
 - (B) The Department shall give special consideration to the type and severity of potential adverse impact(s) and the potency of the chemical associated with the adverse impact(s) for all of the following:
 - 1. Children, pregnant women, and other sensitive subpopulations;
 - 2. Environmentally sensitive habitats, endangered and threatened species, and environments in California that have been designated as impaired by a California State or federal regulatory agency; and

- 1 2
- 3 4
- 5 6 7
- 8 9 10
- 11 12 13
- 15

- 16 17
- 18 19 20
- 21 22 23 24
- 25 26 27 28
- 29 30 31

32

- 33 34 35
- 36 37
- 38 39
- 40
- 41

- Widespread adverse public health and/or environmental impacts. 3.
- (2) Potential Exposures. The potential public and/or environmental exposures to the chemical in quantities that could result in adverse impacts, considering relevant reliable information that indicates the possibility for public or environmental exposures to the chemical, and reliable information demonstrating the occurrence, or potential occurrence, of exposures to the chemical.
- Availability of Information. The availability of reliable information to substantiate the (3)potential adverse impacts and exposures.
- Safer Alternatives. The Department may adjust the prioritization prior to listing a (4) chemical as a Chemical of Concern by considering whether there is a readily available safer alternative chemical that is functionally acceptable for one or more common uses of the chemical in consumer products.
- NOTE: Authority cited: Sections 25252 and 58012, Health and Safety Code. Reference: Sections 25252 and 25257.1, Health and Safety Code.

§ 69502.3. **Chemicals of Concern List.**

- An informational list of the chemicals identified as Chemicals of Concern pursuant to section 69502.2(a) shall be posted on the Department's website within thirty (30) days after the effective date of these regulations. The Department shall periodically update the list to reflect changes to the underlying lists and sources from which it is drawn, using the procedures specified in subsection (c) and (d).
- The Department may expand the Chemicals of Concern list pursuant to section 69502.2(b), using the procedures specified in subsections (c) and (d).
- The Department shall make proposed revisions to the Chemicals of Concern list available on its website for public review and comment, along with supporting documentation, including the Department's rationales, information, and information sources, prior to finalizing the revisions to the Chemicals of Concern list. The Department shall hold one or more public workshop(s) to provide an opportunity for oral comment on the proposed revisions to the list. The Department shall publish in the CRNR, send to individuals on the listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed revisions to the list and supporting documentation. The notice must include:
- (1) The last day for the public to submit written comments on the proposed revisions to the Chemicals of Concern list. The last day for submission of public comments shall be fortyfive (45) days from the date the availability of the proposed list is published in the CRNR;
 - The method(s) for submitting comments to the Department; and (2)
 - (3)The date, time, and location of the public workshop(s).
- The Department shall post the final revisions to the Chemicals of Concern list on its website after review of public comments. The Department may respond to some or all public comments received.

(e) The Department shall review and revise, as appropriate, the chemicals listed on the Chemicals of Concern list at least once every three (3) years using the procedures specified in this section. Revisions may include additions and deletions.

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

Article 3. Chemicals of Concern and Consumer Product Prioritization Process

§ 69503. General.

- (a) This article specifies the process by which the Department shall evaluate and prioritize products containing Chemicals of Concern.
- (b) The Department may use, but is not limited to using, information obtained and/or reviewed pursuant to section 69501.5 to perform its duties under this article.

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

§ 69503.1. Applicability.

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

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

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 listing, including the number of such of products, how common their household presence is, the frequency of use, and the concentration of the chemical in those products; and
- 4. The potential for public or environmental exposures to the Chemical(s) of Concern in the product, during the useful life of the product and end-of-life disposal or management of the product, considering:
- a. Manufacturing, use, storage, transportation, and end-of-life management practices and the locations of these practices;
- b. The types of uses that could result in public exposure to the Chemical(s) of Concern in the product, considering:
 - Household and recreational use:
- ii. Sensitive subpopulation potential use or exposure at locations frequented by members of sensitive subpopulations; and
- iii. Workers, customers, clients, and members of the general public who use, or otherwise come in contact with, the product or releases from the product in the home, workplace, or other location;
 - c. Frequency and duration of exposure for each use scenario and end-of-life scenario;
- d. Containment of the Chemical(s) of Concern within the product, and engineering and administrative controls; and

- e. Potential for release into, migration from, or distribution across environmental media, and potential for accumulation and persistence in biological and/or environmental components or systems of the Chemical(s) of Concern or its/their degradation products, considering the environmental fate properties of the Chemical(s) of Concern and its/their degradation products.
- (2) Availability of Information. The Department shall consider the availability of reliable information to substantiate the potential adverse impacts and exposures.
- (3) Other Regulatory Programs. The Department shall consider the scope of federal and/or other California State regulatory programs, and any applicable international trade agreements ratified by the United States Senate, under which the product or the Chemical(s) of Concern in the product is/are regulated, and the extent to which these other regulatory requirements address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a potential basis for the product being listed as a Priority Product.
- (b) Key Prioritization Criteria. In using the factors specified in subsection (a) to prioritize products, the Department shall give priority to products meeting one or more of the following criteria:
- (1) The Chemical(s) of Concern in the product have a significant potential to cause adverse public health and environmental impacts;
 - (2) The product is widely distributed in commerce, and widely used by consumers;
- (3) There is a significant potential for public and environmental exposures to the Chemical(s) of Concern in the product in quantities that can result in adverse public health or environmental impacts;
- (4) For assembled products, the product contains one or more Chemical(s) of Concern that may present potential exposure(s) through inhalation or dermal contact in quantities that can result in adverse public health or environmental impacts; and/or
 - (5) For formulated products, the product is intended to be:
 - (A) Applied directly to the body;
 - (B) Dispersed as an aerosol or a vapor; or
 - (C) Applied to hard surfaces with the likelihood of runoff or volatilization.
 - (c) Process for Consideration of the Prioritization Factors.
- (1) Potential Adverse Impacts and Exposures and Availability of Information. The Department shall begin the product prioritization process by evaluating products based on the factors specified in subsection (a)(1) in conjunction with subsection (a)(2).
- (2) Other Regulatory Programs. Having considered the potential adverse impacts and the potential exposures for the product and its Chemical(s) of Concern, the Department shall then determine which of these potential adverse impacts and exposures are addressed by consideration of subsection (a)(3), and adjust the prioritization accordingly.
- (3) Priority Products. Products determined to be of high priority after completion of the steps specified in paragraphs (1) and (2) may be listed as Priority Products.
- (4) Safer Alternative. The Department may, at its discretion, consider whether there is a readily available safer alternative, that is functionally acceptable and technologically and

economically viable, to further adjust the prioritization prior to listing a product as a Priority Product.

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

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

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

§ 69503.3. Priority Products List.

- (a)(1) The Department shall use the procedures specified in this section and the factors specified in section 69503.2 to identify and list products as Priority Products.
- (2) The Department shall specify in the proposed and final Priority Products lists the following for each listed product:
- (A) The Chemical(s) of Concern that is/are the basis for the product being listed as a Priority Product.
 - (B) The de minimis level for the Chemical(s) of Concern.
- (C) For each assembled product, the component(s) that is/are the basis for the product being listed as a Priority Product. This/these component(s) is/are the component(s) to which the de minimis level applies, and which is/are the required minimum focus of the AA.
- (D) The due date for submission of the Preliminary AA Report, required pursuant to article 5. The due date for the Preliminary AA Report shall be 180 days after the date the product is listed on the final Priority Products list, unless the Department specifies a shorter or longer period of time.
- (b) The Department shall make the proposed Priority Products list available on its website, for public review and comment, along with supporting documentation, including the Department's rationales, information, and information sources, prior to finalizing the Priority Products list. The Department shall hold one or more public workshop(s) to provide an opportunity for oral comment on the proposed list. The Department shall publish in the CRNR, send to individuals on the listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed list and supporting documentation. The notice must include:
- (1) The last day for the public to submit written comments on the proposed Priority Products list. The last day for submission of public comments shall be forty-five (45) days from the date the availability of the proposed list is published in the CRNR;
 - (2) The method(s) for submitting comments to the Department; and
 - (3) The date, time, and location of the public workshop(s).
- (c) The Department shall post the final Priority Products List on its website after review of public comments. The Department may respond to some or all public comments received.
- (d) The initial proposed list of Priority Products shall be made available for public review and comment pursuant to subsection (b) no later than 180 days after the effective date of these regulations.

- (e) The Department shall review and revise, as appropriate, the Priority Products list at least once every three (3) years, using the procedures specified in this section.
 - (f) Each responsible entity for a product listed on the Priority Products list shall provide to the Department a Priority Product Notification as specified in section 69503.6 or a De Minimis Exemption Notification as specified in section 69503.5 within sixty (60) days after the product is listed as a Priority Product.

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

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

§ 69503.4. De Minimis Exemption.

- (a) A responsible entity is exempt from the requirements of article 5 with respect to a product that is listed as a Priority Product and that meets the criteria for a de minimis exemption specified in subsection (b), if one of the responsible entities for the product submits a complete and timely De Minimis Exemption Notification to the Department pursuant to section 69503.5, unless subsection (d) or (e) of section 69503.5 applies.
- (b) A de minimis exemption applies only to products meeting one of the following criteria as of the date of the applicable Priority Products listing or the date the product is first placed into the stream of commerce in California, whichever is later:
- (1) For a formulated product, the cumulative concentration in the product of all Chemicals of Concern that are a basis for the Priority Products listing and that exhibit the same hazard trait, or environmental or toxicological endpoint, and mode of action does not exceed the de minimis level.
- (2) For an assembled product, the cumulative concentration in each component that is a basis for the Priority Products listing, of all Chemicals of Concern that are a basis for the Priority Products listing and that exhibit the same hazard trait, or environmental or toxicological endpoint, and mode of action does not exceed the de minimis level.
- (c)(1) The Department may specify a de minimis level that is lower or higher than the level specified in subparagraph (A) or (B) of section 69501.2(a)(25) for the Chemical of Concern in the Priority Product, if the Department determines based on available information that a lower or higher de minimis level is warranted.
- (2) The Department may specify a lower de minimis level if one or both of the following criteria apply:
- (A) The Chemical of Concern is found in concentrations at or below the level specified in subparagraph (A) or (B) of section 69501.2(a)(25), whichever is applicable, in products that are common and are frequently used, and reliable information shows that, even when individual product concentrations of the Chemical of Concern are below the de minimis level, there is the potential for adverse impacts from potential exposures to the Chemical of Concern, or releases of the Chemical of Concern, due to one or more of the following:
 - 1. Potential aggregate or cumulative exposures;
 - 2. The inherent potency of the Chemical of Concern;
 - 3. Potential bioaccumulation; or

- 4. The unintended presence of the Chemical of Concern in organs, tissues, or fluids.
- (B) Reliable information shows the Chemical of Concern poses, or potentially poses, adverse impacts in concentrations at or below the level specified in subparagraph (A) or (B) of section 69501.2(a)(25), whichever is applicable.
- (3)(A) The Department may specify a higher de minimis level if all of the following criteria apply:
 - 1. The source of the Chemical of Concern is one of the following:
- a. A naturally occurring contaminant in raw materials that are common and are frequently used to manufacture the product;
- b. Air or water frequently used as a processing agent or an ingredient to manufacture the product;
- c. A contaminant in recycled materials that are common and are frequently used to manufacture the product; or
- d. A processing agent or intermediate frequently used to promote certain chemical or physical changes during manufacturing, and the incidental retention of a residue is not desired or intended:
- 2. The concentration of the Chemical of Concern in the Priority Product does not exceed the concentration of the Chemical of Concern in the source; and
 - 3. The Chemical of Concern cannot reasonably be removed from the product.
- (B) The Department may not specify a higher de minimis level if this would result in increased adverse public health or environmental impacts.

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

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

§ 69503.5. De Minimis Exemption Notifications.

- (a) A De Minimis Exemption Notification required under section 69503.4(a) must be submitted to the Department within sixty (60) days after the product is listed as a Priority Product. The notification must include all of the following:
- (1) Name of, and contact information for, the person submitting the De Minimis Exemption Notification.
- (2) Name of, and contact information for, the manufacturer and the importer(s), if applicable.
- (3) Name of, and contact information for, all responsible entities for the product, to the extent known.
 - (4) The source of the Chemical(s) of Concern in the product.
- (5) Information concerning any attempts taken to eliminate or reduce the amount of the Chemical(s) of Concern in the product.
- (6) The maximum concentration at which the Chemical(s) of Concern is/are present in the product, and a listing and description of all information used to determine and substantiate this concentration. A description must be included of whichever of the following is applicable:
- (A) For a formulated product, the maximum concentration in the product of each Chemical of Concern that is a basis for the Priority Product listing, and a description of the information used to detect and measure this concentration.

- (B) For an assembled product, the maximum concentration in each component, that is a basis for the Priority Product listing, of each Chemical of Concern that is a basis for the Priority Product listing, and a description of the information used to detect and measure this concentration.
- (7) Laboratory analytical testing protocols and results used to detect and measure the concentration of the Chemical of Concern in the product, including quality control and quality assurance protocols and information concerning the testing laboratory.
- (8) A demonstration and certification that the responsible entity does and will continue to meet the criteria, assumptions, and conditions that are the basis for the exemption.
- (b) The responsible entity bears the burden of proof to demonstrate that the concentration of the Chemical(s) of Concern in the Priority Product does not exceed the applicable de minimis level, and will not pose a potential adverse public health or environmental impact.
- (c) If any of the information listed in subsection (a) significantly changes, a revised De Minimis Exemption Notification shall be submitted to the Department within thirty (30) days of the change.
- (d) If the product no longer meets the criteria for a de minimis exemption specified in section 69503.4, the responsible entity shall notify the Department of this change within thirty (30) days of the change, and shall submit a Preliminary AA Report to the Department within 180 days after the change.
- (e) The exemption provided under section 69503.4(a) does not apply if the Department determines, and notifies the person who submitted the De Minimis Exemption Notification, that the information or findings contained in the notification are inaccurate, invalid, or inadequate to support a de minimis exemption.

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

§ 69503.6. Priority Product Notifications.

- (a) Within sixty (60) days after a product is listed as a Priority Product, each responsible entity for such a Priority Product shall notify the Department that its product is a Priority Product, unless the responsible entity has submitted a De Minimis Exemption Notification pursuant to section 69503.5. For a Priority Product that is first manufactured or first placed into the stream of commerce in California after the date the product is listed as a Priority Product, the responsible entity shall provide the notice within sixty (60) days after the product is first placed into the stream of commerce in California. The notification shall include all of the following:
- (1) The responsible entity's name and contact information, and a statement indicating whether the responsible entity is the product manufacturer, importer, or retailer;
- (2) The type, brand name(s), and product name(s) of the Priority Product and, if applicable, information specifically identifying the component(s) triggering the product's listing as a Priority Product; and

- (3) If applicable, the name of, and contact information for, the person that will be complying with the requirements of article 5 on behalf of or in lieu of the responsible entity.
- (b) If the Department determines that the notice requirements specified in subsection (a) have not been complied with for a particular product that is a Priority Product, the Department shall post this information on the Failure to Comply List pursuant to section 69501.3(d).

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

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

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

§ 69504. Applicability and Petition Contents.

- (a) Any person may petition the Department to evaluate a claim that a chemical or a product that contains a chemical should be listed as a Chemical of Concern or a Priority Product, whichever is applicable, using the processes specified in articles 2 and 3 of this chapter. The Petition must include all of the following:
 - (1) The name of, and contact information for, both of the following persons:
 - (A) The petitioner; and
- (B) The person responsible for the contents of the petition, if different from the petitioner, and the affiliation of this person with the petitioner;
 - (2) A description of the chemical and/or product that is the subject of the petition;
 - (3) A description of the uses and applications of the chemical and/or product;
- (4) The basis for the petition, including an analysis of potential adverse public health and/or environmental impacts associated with the chemical and/or product;
 - (5) Reliable information supporting the petition; and
 - (6) The identity of any known manufacturers and importers of the chemical or product.
- (b) Within sixty (60) days after receiving a petition, the Department shall review the petition and shall designate the petition complete if it contains all of the items specified in subsection (a). If the Department determines that a petition is complete, the Department shall notify the petitioner that it will conduct a technical review to determine whether to grant or deny the petition on its merits. If the Department determines that the petition is incomplete, the Department shall notify the petitioner of this determination and shall specify the basis for the determination.

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

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

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

§ 69504.1. Technical Review of Petitions.

- (a) The Department shall prioritize the technical review of complete petitions based on their comprehensiveness. High priority shall be given to petitions by federal and other California State regulatory programs that relate to the petitioning agency's statutory and/or regulatory mandates.
- (b) The Department shall conduct a technical review of each complete petition to determine whether to grant or deny the petition on its merits based on:
- (1) The comprehensiveness of the information submitted that pertains to the factors specified in sections 69502.2 and/or 69503.2, as applicable;
 - (2) The quality of the information submitted; and
- (3) The availability of information, other than that submitted with the petition, that supports the petitioner's claims that:
- (A) The chemical exhibits one or more hazard traits or environmental or toxicological endpoints; and
- (B) An evaluation of the chemical and/or the product, based on the factors specified in sections 69502.2 and/or 69503.2, as applicable, indicates a potential for adverse public health and/or environmental impacts.
- (c) The Department may request that the petitioner provide additional information to complete the technical review within a timeframe specified by the Department.
 - (d) After completing the technical review, the Department shall do both of the following:
- (1) Prepare a notice of decision to grant or deny the petition and a statement explaining the basis for the decision; and
 - (2) Notify the petitioner of the decision.
- (e) After granting a petition, the Department shall evaluate and, if applicable, list the chemical and/or the product in accordance with the processes specified in articles 2 and/or 3.

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

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

Article 5. Alternatives Assessments

§ 69505. Guidance Materials.

- (a) Before finalizing the initial list of Priority Products pursuant to section 69503.3, the Department shall make available on its website guidance materials to assist persons in performing AAs in accordance with this article. The Department shall periodically revise and update the guidance materials.
- (b) The Department shall also post on its website AAs that the Department is aware of, and that are available in the public domain at no cost and are supported by reliable information. The posting shall indicate, for each AA, the name of the person that prepared the AA.

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

§ 69505.1. Alternatives Assessments: General Provisions.

- (a)(1) The requirements of this article applicable to a responsible entity may be fulfilled by the responsible entity, or by a person acting on behalf of or in lieu of the responsible entity.
- (2) Except as otherwise provided in subsections (b) and (e), a responsible entity for a product that contains one or more Chemicals of Concern that is/are the basis for designation as a Priority Product shall conduct an AA for the Priority Product, and shall comply with all applicable requirements of this article.
- (3) A responsible entity subject to the requirements of paragraph (2) shall prepare, sign, and submit to the Department a Preliminary AA Report and a Final AA Report, meeting the requirements of section 69505.5, as follows:
- (A) Except as provided in subsection (b), the responsible entity shall submit the Preliminary AA Report no later than 180 days after the date the product is listed on the final Priority Products list posted on the Department's website, unless the Department specifies a different due date for the product in the Priority Products list.
- (B) Except as provided in subsection (b), the responsible entity shall submit the Final AA Report no later than twelve (12) months after the date the Department issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests, pursuant to section 69505.3(b)(4), and the Department approves, pursuant to section 69505.6(a)(3), a longer period of time.
 - (b) The requirements of this article do not apply to any of the following:
- (1) A product that is no longer placed into the stream of commerce in California by any person on and after the date that the product is listed as a Priority Product.
- (2) A bulk chemical that is placed into the stream of commerce in California and that meets the definition of a "consumer product", as defined in Health and Safety Code section 25251, but that is not packaged for sale to, or end use by, a retail consumer.
- (3) A product that meets the de minimis exemption criteria specified in section 69503.4, if a complete and timely De Minimis Exemption Notification has been submitted to the Department satisfying the requirements of section 69503.5, unless subsection (d) or (e) of section 69503.5 applies.
- (c)(1) A responsible entity may request a one-time extension to the submission deadline for the Preliminary or Final AA Report, or both, if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. The Department must receive the extension request at least sixty (60) days before the applicable due date.
 - (2) The extension request must include all of the following:
 - (A) The name of, and contact information for, the person filing the extension request;
- (B) The name of, and contact information for, the responsible entity(ies) on whose behalf the Preliminary and Final AA Reports will be submitted;

- (C) If different from subparagraphs (A) and (B), the name of, and contact information for, the manufacturer and the importer, if applicable, of the product;
- (D) Information identifying and describing the Priority Product and, if applicable, the component(s) subject to the AA requirement, including the brand name(s) and product name(s) under which the Priority Product is placed into the stream of commerce in California;
 - (E) The due date for the Preliminary or Final AA Report, as applicable;
 - (F) The amount of additional time requested, not to exceed ninety (90) days; and
 - (G) The reason the extension is needed.
- (3) The Department shall approve or deny, in whole or in part, the extension request, and notify the person submitting the extension request of the decision, within thirty (30) days of receipt of the extension request. Failure by the Department to issue a decision within thirty (30) days does not constitute an approval of the extension request. The one-time extension for a Preliminary or Final AA Report, or both, shall not exceed ninety (90) days.
- (d) Each AA completed after January 1, 2015 shall be performed, and each Preliminary and Final AA Report submitted after January 1, 2015 shall be prepared, by or under the responsible charge of one or more assessor(s) certified pursuant to article 8 for the appropriate product type or industry sector.
- (e) A responsible entity may fulfill the requirements of subsection (a) by submitting to the Department a report for a previously completed AA for the Priority Product, if the Department determines that the report is substantially equivalent to the Final AA Report requirements of section 69505.5 and that the report contains sufficient information for the Department to identify the most appropriate regulatory response(s) pursuant to article 6.
- (1) A responsible entity submitting a report pursuant to this subsection shall submit the report no later than the deadline for submitting a Preliminary AA Report, pursuant to subsection (a)(3)(A), except that a one-time extension may be requested pursuant to subsection (c).
- (2) A responsible entity submitting an existing report pursuant to this subsection may supplement the report with additional information to render the report substantially equivalent to the Final AA Report requirements of section 69505.5.
- (f) A responsible entity conducting an AA, pursuant to subsection (a), shall consider all relevant information made available on the Department's website, including any relevant public comments, and any additional information or technical assistance the Department may provide regarding alternatives assessments. The responsible entity shall summarize these efforts in the AA Report.
- (g) Notwithstanding any other provision of this chapter, failure of the Department to make a compliance determination within sixty (60) days from receipt of the Preliminary or Final AA Report, or failure of the Director to respond to an appeal submitted under section 69507.2 within sixty (60) days, shall not cause a Preliminary or Final AA Report to be deemed compliant.
- 41 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference:
- 42 Sections 25252 and 25253, Health and Safety Code.

§ 69505.2. Assessment of Priority Products and Alternatives.

- (a)(1) The AA required to be performed pursuant to section 69505.1(a) shall be conducted in two stages, as specified in sections 69505.3 and 69505.4.
- (2) The responsible entity shall complete the first stage of the AA, and submit a Preliminary AA Report that complies with sections 69505.1(a)(3)(A) and 69505.5.
- (3) The responsible entity shall next complete the second stage of the AA, and submit a Final AA Report that complies with sections 69505.1(a)(3)(B) and 69505.5.
- (b) A responsible entity may use an AA process that differs from the process specified in sections 69505.3 and 69505.4, if all of the following requirements are met:
- (1) The responsible entity's alternate process provides the information needed to prepare an AA Report that substantially meets the requirements of section 69505.5.
- (2) The responsible entity's alternate process compares the Priority Product and the alternatives using, at a minimum, the same factors, and associated exposure pathways and life cycle segments, specified in sections 69505.3 and 69505.4.
- (3) The responsible entity submits a work plan to the Department with sufficient information to demonstrate that the alternate process will meet the requirements of paragraphs (1) and (2), and sufficient information for the Department to specify an appropriate due date for submittal of the Final AA Report The due date shall be eighteen (18) months after the date the Department issues a notice of compliance for the work plan, unless the responsible entity requests, pursuant to section 69505.3(b)(4), and the Department approves, pursuant to section 69505.6(a)(3), a longer period of time. The additional time shall not exceed thirty (30) months after the Department issues a notice of compliance for the work plan. The work plan must be submitted to the Department no later than sixty (60) days after the product is included on the Priority Products list. Upon receipt of a work plan pursuant to this subsection, the Department shall follow the steps specified for the review of Preliminary AA Reports in section 69505.6(a).
- (4) The responsible entity submits a Final AA Report to the Department that substantially meets the requirements of section 69505.5 by the due date specified by the Department pursuant to paragraph (3).

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

§ 69505.3. Alternatives Assessment: First Stage.

- (a) All references in this section to "Chemical(s) of Concern" mean the Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product.
 - (b) The first stage of the AA shall include all of the following steps:
 - (1) Step 1, Identification of Product Requirements.
- (A) The responsible entity shall identify the function, performance, technical feasibility, and legal requirements associated with the Priority Product that must be met by potential alternatives.

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

1

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

The responsible entity shall identify the function of the Chemical(s) of Concern in

- If the responsible entity determines that neither the Chemical(s) of Concern nor substitute chemical(s) is/are necessary to meet the Priority Product's function, performance, technical feasibility, and legal requirements, the responsible entity shall evaluate as one of the alternatives to the Priority Product the removal of the Chemical(s) of Concern from the Priority Product without the addition of substitute chemical(s).
 - Step 2, Identification of Alternatives. (2)
- (A) In addition to the alternative identified pursuant to paragraph (1)(C)2., if applicable, the responsible entity shall identify alternatives for consideration that meet the product requirements identified pursuant to paragraph (1)(A) for the Priority Product, and that eliminate or reduce the concentration of the Chemical(s) of Concern in the Priority Product and/or reduce the potential for public and/or environmental exposures to the Chemical(s) of Concern in the Priority Product. The responsible entity shall research available information that may identify existing potentially viable alternatives, including information posted on the Department's website pursuant to section 69505(b). The responsible entity shall include in the AA consideration of any identified existing potentially viable alternatives.
- The comparison of the Priority Product and any alternative that does not involve the addition of a substitute chemical does not require completion of the step specified in paragraph (3).
 - (3)Step 3, Initial Screening of Alternative Chemicals.

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

- Collect and use available information to identify the adverse public health and environmental impacts associated with each chemical being considered as a possible alternative to the Chemical(s) of Concern in the Priority Product;
- Compare each of the potential alternative chemicals with the Chemical(s) of Concern in the Priority Product, using the information collected and evaluated pursuant to subparagraph (A);
- (C)1. Eliminate from further consideration in the AA any alternative chemical(s) that the responsible entity determines may pose greater adverse public health and/or environmental impacts than the Chemical(s) of Concern.
- 2. Subparagraph 1. does not apply to a chemical that poses both greater and lesser individual adverse impacts relative to the Chemical(s) of Concern. However, a responsible entity is not required to retain, for further consideration in the AA, a chemical that poses both greater and lesser individual adverse impacts relative to the Chemical(s) of Concern.
 - (4) Step 4, Next Steps.
 - The responsible entity shall develop a work plan and proposed implementation schedule for

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

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

13 14 15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

40

41

§ 69505.4. Alternatives Assessment: Second Stage.

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

- (a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.
- (1) A factor, in conjunction with an associated exposure pathway and life cycle segment, is relevant if it would constitute both:
- (A) A demonstrable contribution to the adverse impacts of the Priority Product and/or one or more alternatives under consideration; and
- (B) A demonstrable difference between two or more of the alternatives being considered, including the Priority Product.
- (2) The responsible entity shall collect and use available quantitative information, supplemented by available qualitative information and analysis, to identify the factors listed below, and the associated exposure pathways and life cycle segments, that are relevant for the comparison of the Priority Product and the alternatives still under consideration after completion of the first AA stage as specified in section 69505.3:
- (A) Multimedia life cycle impacts and chemical hazards, for chemical ingredients known to be in the Priority Product and the alternatives being considered based on available information:
 - 1. Physical chemical hazards;
 - 2. Adverse public health impacts;
- Adverse environmental impacts;
- 4. Physicochemical properties;
 - 5. Environmental fate properties:
- 37 6. Materials and resource consumption impacts; and
- 38 7. Adverse waste and end-of-life impacts.
- 39 (B) Product function and performance:
 - 1. Useful life of the Priority Product, and that of the potential alternatives;
 - 2. Functional and performance comparison of each alternative relative to the Priority
- 42 Product; and

- 3. Technological and economic feasibility of each alternative. As part of a determination of whether a "technologically and economically feasible alternative" exists, the responsible entity shall consider all of the following, to the extent applicable:
- a. The extent to which a functionally acceptable alternative is currently available in the marketplace;
 - b. The affordability of any currently available functionally acceptable alternative; and
 - c. The purchase price differential between the Priority Product and the alternative.
- (C) Economic impacts. The responsible entity's evaluation and comparison of economic impacts shall take into account both internalized and externalized costs during the life cycle of the Priority Product and all alternatives being considered, and shall include an evaluation of the range of projected costs. Evaluation and comparison of externalized costs shall include costs to government agencies, the public, businesses, and consumers.
- (3) The responsible entity's identification of relevant exposure pathways shall consider both of the following:
 - (A) Chemical quantity information:
- 1. Quantities of the Chemical(s) of Concern or alternative chemical(s) necessary to manufacture the Priority Product, or alternative; and
- 2. Estimated volume and/or mass of the Chemical(s) of Concern or substitute chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product or potential alternatives.
- (B) Exposure potential factors specified in subsections (a)(1)(B), (b)(4), and (b)(5) of section 69503.2.
 - (b) Step 2, Comparison of the Priority Product and Alternatives.

The responsible entity shall use available quantitative information, supplemented by available qualitative information and analysis, to evaluate and compare the Priority Product and each of the alternatives under consideration with respect to each relevant factor and associated exposure pathways and life cycle segments identified pursuant to subsection (a). The responsible entity shall compare each alternative with the Priority Product and with each of the other alternatives being considered.

(c) Step 3, Alternative Selection Decision.

The responsible entity shall select the alternative that will replace or modify the Priority Product, unless the decision is to retain the existing Priority Product. The selection of an alternative or the decision to retain the Priority Product shall be based on and supported by the comparative analysis conducted pursuant to subsection (b).

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

§ 69505.5. Alternatives Assessment Reports.

- (a)(1) The Preliminary and Final AA Reports must include, as applicable, all of the information specified in subsections (b) through (n).
- (2) The responsible entity must include in both reports sufficient information for the Department to determine compliance with this article.

- (3) The responsible entity must include in the Preliminary AA Report sufficient information for the Department to assess the appropriateness of the due date for submission of the Final AA Report.
- (4) The responsible entity must include in the Final AA Report sufficient information for the Department to determine the appropriate regulatory response(s), if any, pursuant to article 6.
- (5) The responsible entity must identify and explain in the Final AA Report all differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report. The responsible entity must identify in the Final AA Report the information sources used to support changes from the Preliminary AA Report to the Final AA Report.
- (6) If the responsible entity selects a different alternative from the one identified in the Final AA Report submitted to the Department prior to introduction of the originally selected alternative into the California marketplace, the responsible entity shall submit a revised Final AA Report with an explanation of the change. The revised Final AA Report must be submitted to the Department within sixty (60) days after the date the responsible entity decides to select a different alternative. The responsible entity shall also submit a revised Final AA Report if the original alternative selection decision was to retain the Priority Product and the responsible entity later decides to select an alternative to replace the Priority Product.
- (b)(1) All AA Reports must be accompanied by an executive summary. The executive summary must be sufficient to convey to the public a general understanding of the scope and results of the AA.
- (2)(A) The executive summary must be organized in conformance with the organization of the AA Report and must include, for each section of the AA Report, a detailed summary of the information presented in the AA Report. The responsible entity may not include in the executive summary any information for which trade secret protection is claimed pursuant to article 10.
- (B) If the Department subsequently rejects a trade secret claim, the responsible entity shall, at the Department's request, submit a revised executive summary within thirty (30) days of the request to add any information for which a trade secret claim is rejected and which the Department determines, and specifies in its request, must be included in the executive summary.
 - (c) Preparer Information.
 - (1) The name of, and contact information for, the person submitting the AA Report;
- (2) If applicable, the name of, and contact information for, all responsible entities on whose behalf the AA Report is being submitted; and
- (3) The names of the parties that were involved in funding, directing, overseeing, preparing, and/or reviewing the AA, and the qualifications and certification information for the individual(s) in responsible charge under whose direction the AA was conducted and the AA Report was prepared.
 - (d) Supply Chain Information.
- (1) The name of, contact information for, and headquarters location of the manufacturer(s) and the importer, if applicable, and, if the AA Report is prepared on behalf of a

consortium of manufacturers or other persons in the Priority Product's supply chain, a list of the participants along with their corresponding contact information;

- (2) The name of, and contact information for, the person identified on the product label as the manufacturer, and the person, if any, identified as the distributor, if different from paragraph (1);
- (3) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the Priority Product within the prior twelve (12) months; and
- (4) Identification and location of the manufacturer's and/or importer's retail sales outlets where the manufacturer and/or importer sold, supplied, or offered for sale the product in California, if applicable.
- (e) Facility Description and Location. A description and location of the facility(ies) where the Priority Product is produced. This description must also indicate the proximity to raw or recycled materials that directly or indirectly influences the type and amount of Chemical(s) of Concern in the Priority Product.
- (f) Product Information. The following information identifying and describing the Priority Product that is the subject of the Final AA Report:
- (1) The brand name(s) and product name(s) under which the product is placed into the stream of commerce in California;
- (2) If applicable, the component(s) that is/are the focus of the AA. The AA shall, at a minimum, focus on the component(s) specified in section 69503.3(a)(2)(C), but may be expanded by the responsible entity to include additional components or the entire product;
- (3) Identification of the Chemical(s) of Concern in the product or component(s), whichever is applicable, that are the basis for the product being listed as a Priority Product, and any other Chemical(s) of Concern that is/are known, or reasonably should be known based on available information, to be in the Priority Product; and
 - (4) The information specified in section 69505.3(b)(1).
- (g) Methodology. The AA Report shall identify and describe the assessment tools, models, and software used to conduct the AA, and discuss any limitations of these tools, models, and software. The AA Report shall also identify any published methodologies or guidelines used, and any deviations taken from the published methodologies or guidelines.
 - (h) Supporting Information.
- (1) All information used as supporting information in performance of the AA and preparation of the AA Reports must be cited in the AA Reports and made available to the Department, upon request. The AA Reports shall include a brief summary of the information reviewed and considered pursuant to section 69505.1(f).
- (2) The Final AA Report must include the identification of unavailable reliable information that, if available, could be used to:
 - (A) Validate information used for purposes of sections 69505.3(b) and 69505.4;
- (B) Address any uncertainties in the analyses conducted pursuant to sections 69505.3(b) and 69505.4; and

- (C) Ensure that the list of chemical ingredients required to be identified for the Priority Product and its alternatives during the conduct of the AA and the preparation of the AA Reports is complete.
- (i) Scope of Alternatives. The AA Reports must identify and describe the alternatives chosen to be evaluated and compared, and explain the rationale for selecting and screening out specific alternatives at each stage of the alternatives comparison process.
- (j) Scope of Comparison Factors. The Final AA Report must identify which factors, and associated exposure pathways and life cycle segments, were determined to be relevant, pursuant to section 69505.4(a), for evaluation and comparison of the Priority Product and its alternatives. For each factor, exposure pathway, and life cycle segment determined not be relevant, the Final AA Report must explain the rationale and identify, and explain the pertinent findings of, the supporting information for this determination.
 - (k) Comparison of Alternatives.
- (1)(A) The Preliminary AA Report must include all of the following information for the evaluation and comparison, conducted pursuant to section 69505.3(b)(3), of the Chemical(s) of Concern in the Priority Product and possible alternative chemical(s):
- 1. The information collected for the Chemical(s) of Concern and alternative chemical(s); and
- 2. The comparative results of evaluating the information presented pursuant to subparagraph 1.
- (B) The information required under subparagraph (A) must be presented in a matrix, or other format, that provides the reviewer with an easily understood visual comparison of the chemicals and their adverse impacts.
- (2) The Final AA Report must include all of the following information for the evaluation and comparison of the Priority Product and its alternatives conducted pursuant to sections 69505.3(b)(3) and 69505.4(b):
- (A) A matrix, or other format, that provides the reviewer with an easily understood visual comparison that presents all of the following, as applicable, for the evaluations conducted pursuant to sections 69505.3(b)(3) and 69505.4(b):
- 1. The relevant exposure pathways and life cycle segments for each relevant comparison factor;
- 2. The information collected for each relevant factor, and associated exposure pathways and life cycle segments, for the Priority Product and each alternative considered; and
- 3. The comparative results of evaluating the information presented pursuant to subparagraph 2.
- (B) A description, if applicable, of how safeguards provided by other federal and California State regulatory programs were considered in the AA, including identification of those programs and safeguards considered.
- (I) Selected Alternative. The Final AA Report must identify and describe the alternative, if any, selected, and the rationale for the selection decision. The description of the selection decision must include an assessment that evaluates and compares the selected

alternative against the Priority Product and a detailed list and explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable. The Final AA Report must also include all of the following:

- (1) The information specified in section 69505.4(a)(2)(B) for the selected alternative. If no alternative is selected, this information must be provided for each alternative considered.
- (2) If section 69505.3(b)(1)(C)2. applies, and the selected alternative retains the Chemical(s) of Concern, that is/are the basis for the product being listed as a Priority Product, or uses substitute chemical(s), the Final AA Report must explain the rationales for deciding to retain the Chemical(s) of Concern or to use substitute chemical(s), whichever applies.
- (3) A demonstration that the manufacture, use, and disposal of the selected alternative, in conjunction with any regulatory response(s) proposed pursuant to subsection (n), will have no greater significant adverse public health or environmental impacts than the impacts associated with the Priority Product. For purposes of this paragraph only, "environment", as it pertains to California's environment, means "environment" as defined in section 21060.5 of the Public Resources Code.
- (4) A list of all chemical ingredients known, based on available information, to be in the selected alternative that differ from the chemical ingredients in the Priority Product or that are present in the selected alternative at a higher concentration than in the Priority Product, and both of the following for those chemicals:
 - (A) All available and applicable chemical identification and description information; and
- (B) Available hazard trait and environmental and toxicological endpoint information for any of those chemicals for which such information has not already been provided to the Department pursuant to this chapter.
 - (m) Implementation Plans.
- (1) The Preliminary AA Report must include the work plan and proposed implementation schedule required to be prepared pursuant to section 69505.3(b)(4).
- (2) The Final AA Report must include a detailed plan, including key milestones and dates, for implementing the selected alternative, if applicable. The implementation plan must include any steps necessary to ensure compliance with applicable federal, state, or local laws.
- (n) Proposed Regulatory Responses. The Final AA Report must include the identification of any regulatory response(s) that the responsible entity wishes to propose that would best limit the exposure to, or reduce the level of adverse public health and environmental impacts posed by, any Chemical of Concern that will be in the selected alternative or that is in the Priority Product if the decision resulting from the AA is to retain the Priority Product.

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

§ 69505.6. Department Review and Determinations for AA Reports.

- (a)(1) Within sixty (60) days of receiving a Preliminary AA Report, the Department shall review the Preliminary AA Report for compliance with this article, and issue a notice of its findings with either a notice of compliance or a notice of deficiency.
- (2)(A) The Department shall specify in a notice of deficiency the areas of deficiency and the due date for submitting the necessary information to complete the Preliminary AA Report. The due date for correcting the areas of deficiency may not exceed sixty (60) days from the date the notice of deficiency is issued. The responsible entity shall submit a revised Preliminary AA Report by the due date specified, and address the areas of deficiency.
- (B) Within thirty (30) days of receipt of the requested additional information, the Department shall issue either a notice of compliance or a notice disapproving the Preliminary AA Report. If the Preliminary AA Report is disapproved, the Department shall explain the basis for the disapproval in the notice. The Department shall also issue a notice of disapproval if a revised Preliminary AA Report is not submitted by the due date specified pursuant to subparagraph (A). A disapproved Preliminary AA Report is not in compliance with section 69505.1(a)(2).
- (3) The Department shall specify in a notice of compliance the date for submitting the Final AA Report. The Department shall specify a due date that is twelve (12) months from the date the Department issues the notice of compliance, except that the Department may specify more time for submission of the Final AA Report if it determines based on information in the Preliminary AA Report that more time is needed. The Department may not establish a due date for the Final AA Report that is more than twenty-four (24) months from the date the Department issues the notice of compliance for the Preliminary AA Report, except as provided in section 69505.1(c).
- (b)(1) Within sixty (60) days of receiving a Final AA Report, the Department shall review the AA Report for compliance with the requirements of this article, and shall issue a notice of its findings with either a notice of compliance or a notice of deficiency.
- (2) The Department shall specify in a notice of deficiency the areas of deficiency and the due date, not to exceed sixty (60) days from the date the notice of deficiency is issued, for submitting the necessary information to complete the Final AA Report. The responsible entity shall submit a revised Final AA Report within the time specified and address all areas of deficiency. If requested, the Department may, at its discretion, approve a one-time extension, of not more than sixty (60) days, for submission of the revised Final AA Report to correct the deficiencies.
- (3) Within sixty (60) days of receipt of the requested additional information, the Department shall issue either a notice of compliance or a second notice of deficiency.
- (A) If the Department issues a second notice of deficiency, the notice must grant no more than thirty (30) days for resubmission of the requested information.
- (B) Within sixty (60) days of receipt of the additional information requested under subparagraph (A), the Department shall issue either a notice of compliance or a notice of disapproval for the Final AA Report. If the Final AA Report is disapproved, the Department shall explain the basis for the disapproval in the notice. The Department shall also issue a

notice of disapproval if a revised Final AA Report is not submitted by the due date specified pursuant to paragraph (2) or subparagraph (A), whichever is applicable. A disapproved Final AA Report is not in compliance with section 69505.1(a)(2).

- (c)(1) If the Final AA Report is determined to be in compliance with this article, the Department shall include in the notice of compliance, or in a separate notice sent to the manufacturer and all responsible entities known to the Department, a notice of the Department's proposed determination whether one or more of the regulatory responses specified in sections 69506.5 and/or 69506.6 is/are required.
- (2) If the Department requires a regulatory response under section 69506.6, the Department shall specify the proposed due date for implementation of the regulatory response. In assigning a due date for completing a regulatory response required under section 69506.6, the Department shall consider the complexity of implementing the regulatory response.
- (d) All notices issued by the Department pursuant to this section shall be issued to the person who submitted the AA Report, and a copy of the notice shall be sent by the Department to all persons identified in the AA Report pursuant to subsections (c)(2) and (c)(3) of section 69505.5.

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

Article 6. Regulatory Responses

§ 69506. Applicability.

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

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

§ 69506.1. AA Report Supplemental Information Requirements.

- (a) The Department may at any time require the responsible entity to provide any information supplementary to the Final AA Report that the Department determines is necessary to determine and ensure implementation of one or more regulatory responses imposed pursuant to this article. The responsible entity shall provide this information within the time period specified by the Department.
- (b) The Department may at any time require the responsible entity to obtain or develop information to fill one or more of the information gaps identified in the Final AA Report, pursuant to section 69505.5(h)(2), if the Department determines this information is needed to re-evaluate, pursuant to section 69506.6(d), the initial regulatory response(s) imposed for the

selected alternative or for the Priority Product that remains in commerce. The responsible entity shall provide this information within the time period specified by the Department.

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

§ 69506.2. No Additional Regulatory Response Required.

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

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

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

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

§ 69506.3. Product Information for Consumers.

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

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

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

 (C) A list of, and common names for, all Chemicals of Concern known, based on available information, to be in the product;
(D) Identification of any end-of-life management program for this product, and any end-

 of-life management requirements specified by law;

(E) Any safe handling procedures needed to protect public health or the environment

 during the useful life of the product and instructions for the proper end-of-life disposal or management; and

(F) The manufacturer's website address and the importer's website address if

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

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

4

5

6

7

8

9

10

11

12

- The requirements of subsection (a) shall be met by making the required information (b) available to consumers, in easily seen, legible, and understandable formats, by both:
- Posting the information in a prominent place on the manufacturer's website and the importer's website, if applicable; and
- Using one or more of the following means of informing consumers of this information (2)at the point of sale:
- Providing the required information on the product packaging or in a manual that is (A) accessible without breaking the product seal; or
 - Posting the information in a prominent place at the point of retail display. (B)
- (c) A responsible entity that has a product subject to the requirements of subsections (a) and (b) shall ensure that these requirements are fully implemented for that product no later than twelve (12) months after the Department issues a notice of compliance for the Final AA Report for the product.

13 14 15

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

16 17 18

19

§ 69506.4. End-of-Life Management Requirements.

- 20 21 22 23
- Except as provided in section 69506.2, a responsible entity for a selected alternative, or a Priority Product for which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product and is required to be managed as a hazardous waste in California at the end of its useful life, shall ensure that both of the following requirements are met:
- 24 (1) 25 26
- The information required by section 69506.3 shall be provided for the product. Additionally, the product information must state that the product must be disposed of or otherwise managed as a hazardous waste at the end of its useful life.
- 28 29 30

27

- No later than two (2) years after the Department issues a notice of compliance for the Final AA Report for the product, the responsible entity shall fund, establish, and maintain an end-of-life management program for the product. The program must comply with all of the following requirements:
- 32 33

- (A) A comprehensive product stewardship plan must be developed and maintained, and must include all of the following:
- 34
- A list of, and contact information for, participating manufacturers and importers and, if applicable, other participating persons.
- 35
- 2. The scope of products to be covered by the plan.
- 36 37
- 3. The roles and responsibilities for manufacturers, importers, retailers, consumers, and government throughout the life cycle of the product.
- 38
- 4. Identification and description of collection systems that will be used.
- 39 40 41
- End-of-life management information, including what steps will be taken to ensure management that complies with all applicable federal and California State and local laws, and addresses any adverse multimedia impacts.

- 6. Anticipated resource needs and a description of the financing mechanism to implement and sustain the plan, including identification of any third-party product stewardship organization collecting and administering a fee to fund the stewardship program. The responsible entity for the product shall provide a financial guarantee mechanism for a sustainable end-of-life management program for the product. Multiple responsible entities may form a third-party product stewardship organization, funded by participating manufacturers and other responsible entities, to provide local services to collect, recycle, or otherwise appropriately manage covered products at the end-of-life.
 - 7. Program performance measures for:
 - a. Increasing the capture rate of covered products at the end-of-life; and
 - b. Increasing recyclability.
 - 8. Public education, outreach, and communications plans.
- 9. Public and stakeholder consultation activities during preparation, and periodic review and updating, of the plan.
 - 10. Reporting and evaluation procedures.
- (B) The product stewardship program and plan for collecting and, if applicable, recycling the product shall be developed in consultation with California retailers and potential collection sites. The collection program must include one or both of the following:
 - 1. Collection mechanisms; and
- 2. Compensation to retailers and other persons who agree to administer or participate in the collection program.
- (C) The responsible entity shall post a copy of the product stewardship plan on its website, and provide a link to the posting to the Department for posting on its website.
- (D) The responsible entity for a product subject to the requirements of this section shall, every two (2) years from the date the end-of-life management program is required to be implemented, ensure that a report is provided to the Department. The report must include both of the following:
- 1. The amount of products placed into the stream of commerce in California over the previous two-year period, by total tonnage; and
 - 2. The number of products recovered over the same two-year period, by total tonnage.
- (b) Upon request, the responsible entity shall provide to the Department a copy of the product stewardship plan required under this section.
- (c) A responsible entity subject to the requirements of this section may request the Department's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program required by this section. A responsible entity may not substitute an alternative end-of-life management plan for the plan specified in this section unless it receives written approval from the Department.
- (d) A responsible entity subject to the requirements of this section may request an exemption from the requirement to provide an end-of-life management program by demonstrating to the Department's satisfaction in the Final AA Report that an end-of-life management program cannot feasibly be implemented for the product.

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

§ 69506.5. Product Sales Prohibition.

- (a) Except as provided in section 69506.2 and subsection (c), the requirements of subsection (b) apply to a selected alternative that contains one or more Chemical(s) of Concern, or a Priority Product for which an alternative is not selected, if the Department notifies the responsible entity, pursuant to section 69506.8, that the Department has determined that a safer alternative exists that does not contain a Chemical of Concern and that is both functionally acceptable and technologically and economically feasible.
- (b) Effective one (1) year after the Department issues a notification pursuant to subsection (a), unless the Department specifies a shorter period of time in the notification, any responsible entity for the product that is the subject of the notification shall cease to place the product into the stream of commerce in California. The responsible entity shall also ensure that an inventory recall program for the product is implemented and completed within three (3) years after the notification is issued by the Department, unless the Department specifies a shorter period of time in the notification.
- (c) A product that is the subject of a notification issued by the Department pursuant to subsection (a) is not subject to the requirements of subsection (b) if all of the following requirements are met:
- (1) Within sixty (60) days after the notification is issued by the Department, the responsible entity notifies the Department of its intent to submit a revised Final AA Report that selects an alternative that does not contain a Chemical of Concern;
- (2) Within one (1) year after the notification is issued by the Department, unless the Department specifies a shorter period of time in the notification, the Department receives a Final AA Report that selects an alternative that does not contain a Chemical of Concern and that fully meets the requirements of section 69505.5; and
- (3) The product containing one or more Chemical(s) of Concern is completely removed from commerce in California, and an inventory recall in California is completed, by the date specified by the Department in the notice of compliance or notice of disapproval for the Final AA Report submitted under paragraph (2), or in a separate notice issued by the Department under section 69505.6(c)(1). The due date shall be no longer than three (3) years after the Department issues the notice.
- (d)(1) The responsible entity may request a one-time extension to the due date for the Final AA Report to be submitted under subsection (c)(2), pursuant to the procedures specified in section 69505.1(c).
- (2) If an extension is granted by the Department, one of the following requirements must be met by the due date specified in the extension approval:
- (A) A revised Final AA Report meeting the requirements of subsection (c)(2) shall be submitted to the Department; or
 - (B) The requirements of subsection (b) shall be implemented.

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

§ 69506.6. Other Regulatory Responses.

- (a) Except as provided in section 69506.2, the Department may impose one or more of the following regulatory responses that it determines are necessary to limit potential exposures to, and reduce the level of potential adverse public health or environmental impacts posed by, a selected alternative, or by a Priority Product for which an alternative is not selected or which will remain in commerce in California pending development and distribution of the selected alternative:
- (1) The Department may impose one or more of the regulatory responses specified in sections 69506.1 and 69506.3 through 69506.5 to situations other than those situations specified in sections 69506.1 and 69506.3 through 69506.5.
- (2) The Department may impose one or more of the following regulatory responses to any situation, including those situations specified in sections 69506.1 and 69506.3 through 69506.5:
- (A) Requiring engineered safety measures to control access to, or limit exposure to, the Chemical(s) of Concern in the product;
 - (B) Restricting the use of the Chemical(s) of Concern that is/are in the product;
- (C) Requiring the responsible entity to initiate a research and development project, or fund a challenge grant, that is pertinent to the Priority Product and that uses green chemistry principles; and
- (D) Requiring a new AA to be performed, and Preliminary and Final AA Reports to be submitted to the Department in a specified time period.
- (b) In accordance with the process specified in section 69506.8, the Department shall notify known affected responsible entities of regulatory response determinations made pursuant to this section, along with the implementation due date for the regulatory response and the rationales for the regulatory response determination.
- (c) In assigning a due date for completing a regulatory response required under this section, the Department shall consider the complexity of implementing the regulatory response.
- (d) The Department may periodically re-evaluate each regulatory response imposed under this section to determine if changes are needed based on changes in science or technology, or other relevant information or facts that have accrued since the regulatory response was selected, including information that fills one or more of the information gaps identified in the Final AA Report pursuant to section 69505.5(h)(2).

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

§ 69506.7. Exemption from Regulatory Response Requirements.

- (a) A selected alternative, or a Priority Product for which an alternative is not selected, is exempt from the requirements of this article, if the responsible entity requests, and the Department grants, an exemption. The responsible entity shall submit an exemption request to the Department no later than whichever of the following dates is applicable:
- (1) Sixty (60) days after the Department issues a notice to the responsible entity pursuant to section 69505.6(c); or
- (2) Sixty (60) days after the Department issues a notice of compliance for a Final AA Report for a product subject to sections 69506.3 or 69506.4.
- (b) An exemption request submitted pursuant to subsection (a) must include all of the following:
 - (1) The name of, and contact information for, the person filing the exemption request;
- (2) The name of, and contact information for, the responsible entity(ies) on whose behalf the exemption request is being submitted;
- (3) If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer and the importer, if applicable, of the product;
- (4) The name of, and contact information for, other responsible entities for the product, to the extent known to the person submitting the exemption request;
- (5) Information identifying and describing the product, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, and information specifically identifying the component, if applicable; and
- (6) Information that demonstrates to the Department's satisfaction that either or both of the following apply:
- (A) The required or proposed regulatory response would conflict with one or more requirements of another California or federal regulatory program or an international trade agreement ratified by the United States Senate, in such a way that the responsible entity cannot reasonably be expected to comply with both requirements; and/or
- (B) The required or proposed regulatory response substantially duplicates one or more requirements of another California or federal regulatory program or an international trade agreement ratified by the United States Senate, without conferring additional public health or environmental protection benefits.
- (c) Within sixty (60) days of receiving an exemption request, the Department shall issue a notice to the person who submitted the request granting or denying the exemption request. The Department shall send a copy of the notice to known responsible entities for the product.
- (d) If the exemption request or the Department's granting of the exemption is based solely on the criteria specified in subsection (b)(6)(A), the Department may require or propose implementation of a modified regulatory response that resolves the conflict that is the basis for the exemption.
- (e) The Department shall rescind an exemption granted pursuant to this section if the Department determines that the facts and/or assumptions that the Department relied upon in granting the exemption were not, or are no longer, valid. If the Department rescinds an

exemption, the Department shall notify the person who submitted the exemption request and known responsible entities for the product.

(f) The Department shall include in all notices granting, denying, or rescinding an exemption pursuant to this section a statement of basis for its decision.

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

§ 69506.8. Regulatory Response Determination Process.

- (a) Prior to issuing a final regulatory response determination notice pursuant to sections 69506.5(a) or 69506.6(b), the Department shall notify all known responsible entities for the product of the proposed regulatory response(s) pursuant to paragraphs (1) through (3) of section 69505.5(c), and make the proposed regulatory response determination notice available on its website, for public review and comment. The Department shall hold one or more public workshop(s) to provide an opportunity for oral comment on the proposed regulatory response determination. The Department shall publish in the CRNR, send to persons on the listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed regulatory response determination. This notice must include all of the following:
- (1) The last day for the public to submit written comments on the proposed regulatory response determination. The last day for submission of public comments shall be forty-five (45) days from the date the availability of the proposed regulatory response determination notice is published in the CRNR;
 - (2) The method(s) for submitting comments to the Department; and
 - (3) The date, time, and location of the public workshop(s).
- (b) After review and consideration of public comments on the proposed regulatory response determination, the Department shall finalize and send to known responsible entities the final regulatory response determination notice. The Department may respond to some or all public comments received.
- (c) All proposed and final regulatory response determination notices shall include all of the following:
 - (1) A description of the required regulatory response(s);
- (2) The Department's determination(s) that is/are the basis for the required regulatory response(s);
- (3) The rationales, information, and information sources supporting the Department's determination(s); and
 - (4) The implementation due date(s) for the regulatory response(s).

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

3 4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

§ 69506.9. Regulatory Response Report and Notifications.

- (a) A responsible entity subject to a regulatory response pursuant to this article, except for the regulatory responses specified in subparagraphs (C) and (D) of section 69506.6(a)(2), shall ensure that a notice is sent to retailers who sell the product in California, informing the retailers of the applicability of the regulatory response to the product. The notice shall be sent to the retailers, and a copy sent to the Department, no later than whichever of the following dates is applicable:
- Thirty (30) days after receiving a final regulatory response determination notice, (1) pursuant to section 69506.8(b), for a product subject to sections 69506.5(a) and/or 69506.6(b); or
- (2) Thirty (30) days after the Department issues a notice of compliance for a Final AA Report for a product subject to sections 69506.3 or 69506.4.
 - (b) The notice required pursuant to subdivision (a) shall include all of the following:
- (1) The name of, and contact information for, the manufacturer and the importer, if applicable;
- The responsible entity's name and contact information, if different from the (2) manufacturer or importer:
- Information identifying and describing the original Priority Product, and the selected (3)alternative, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, and the name(s) of any persons identified as the manufacturer and/or distributor on the product label; and
- A description of the required regulatory response(s) and the due date for implementing the regulatory response(s).
- The responsible entity shall notify the Department upon completing implementation of the required regulatory response(s) and, if applicable, upon completing development and introduction into the California marketplace of the selected alternative. The notification must include information describing how the regulatory response(s) was/were implemented. If requested by the Department, the responsible entity shall provide periodic implementation status reports regarding the selected regulatory response(s). The information provided to the Department pursuant to this subsection shall also be posted on the website of the responsible entity.
- (d)(1) The Department shall prepare and post on its website, and update at least semiannually, a Regulatory Response Report that identifies the regulatory response(s) for each selected alternative for a Priority Product, or for the Priority Product, whichever is applicable. The Regulatory Response Report must contain all of the following information:
- (A) The name and contact information for the manufacturer and the importer, if applicable;
 - (B) The names of, and contact information for, other known responsible entities;
- (C) Information identifying and describing the original Priority Product, and the selected alternative, if any, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California;

- (D) The due date and actual date for completing development and introduction into the California marketplace of the selected alternative, if any;
 - (E) The regulatory response(s), if any;
 - (F) The applicable section(s) in this article specifying the regulatory response(s);
- (G) The implementation due date(s), and the actual implementation date(s), for the regulatory response(s); and
- (H) Other information provided to the Department pursuant to subsections (a) through (b).
- (2) The Department shall also include in the Regulatory Response Report the information specified in paragraphs (1)(A) through (1)(D) for each exemption granted by the Department pursuant to section 69506.7.

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

Article 7. Dispute Resolution Processes

§ 69507. Dispute Resolution.

- (a) This article applies to any responsible entity that wishes to dispute a decision made by the Department pursuant to this chapter that applies to the responsible entity.
- (b) The procedures set out in this article are required for resolving disputes arising under this chapter. If the responsible entity fails to follow the procedures specified in this article for disputes subject to this article, it shall have waived its right to further contest the disputed issue administratively.
- (c) A requirement imposed by the Department pursuant to this chapter on a responsible entity, and any posting concerning the requirement on the Failure to Comply list pursuant to section 69501.3(d), shall be stayed during the pendency of a dispute concerning the requirement.

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

§ 69507.1. Informal Dispute Resolution Procedures.

(a) For a dispute regarding a decision made by the Department pursuant to the provisions of this chapter, other than sections 69506.5, 69506.6, and 69506.7, a responsible entity may, within fifteen (15) days following the notice or website posting of the Department's decision that is the basis of the dispute, request that the Department informally resolve the dispute. The Department shall provide the responsible entity with an opportunity to resolve the dispute informally within thirty (30) days of receiving the request for dispute resolution. If a request for informal dispute resolution is not received within fifteen (15) days of the notice or website posting of the Department's decision, the Department's decision is final and is not eligible for any dispute resolution procedures under this article.

- (b) If the responsible entity disagrees with the Department's decision following completion of the informal dispute resolution process, the responsible entity may appeal to the Director of the Department under section 69507.2.

- 5 NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
- 6 Reference: Sections 25252, 25253, and 25257.1, Health and Safety Code.

§ 69507.2. Appeal to the Director.

- (a) A responsible entity appealing the Department's decision following completion of the informal dispute resolution process shall submit information stating the basis for seeking further review, and the reasons why the decision does not comport with the requirements of this chapter or is otherwise unreasonable. The responsible entity shall also provide all of the following:
 - (1) The original statement of dispute;
 - (2) Supporting documents; and
 - (3) Copies of responses prepared by Department employees.
- (b) The appeal shall be made to the Department's Director within thirty (30) days after completion of the informal dispute resolution process under section 69507.1.
- (c) The Director or designee shall issue a decision granting or denying the relief sought in whole or in part within sixty (60) days after receipt of the request under this section. If the relief sought is denied, the decision shall specify the date by which the responsible entity shall comply with the requirements of this chapter that were in dispute. A decision issued pursuant to this subsection is the Department's final decision and is not subject to additional administrative dispute resolution.

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

§ 69507.3. Formal Dispute Resolution.

For all disputes regarding a decision made by the Department under sections 69506.5, 69506.6, or 69506.7, the procedures specified in sections 69507.4 through 69507.7 shall apply in lieu of the procedures set forth in sections 69507.1 and 60507.2.

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

§ 69507.4. Time Lines for Requests for Review.

Within thirty (30) days of a responsible entity receiving a determination from the Department under section 69506.5, 69506.6, or 69506.7, the responsible entity may submit a Request for Review to the Department to review such determination. If a Request for Review is not filed within this time period, the Department's determination is final and is not eligible for any dispute resolution procedures under this article.

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

§ 69507.5. Contents of Request for Review.

A Request for Review filed under section 69507.4 must include a statement of the reasons supporting the Request for Review, and, as applicable, a showing that the determination is based on:

- (a) Erroneous facts, assumptions, approaches, or conclusions of law; and/or
- (b) A policy judgment that the Department should, in its discretion, consider.

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

§ 69507.6. Department Procedures for Requests for Review.

- (a) Within sixty (60) days following the filing of a Request for Review under section 69507.4, the Department shall issue an order either granting or denying the Request for Review.
- (b) An order denying review shall constitute the Department's final decision and shall not be subject to additional administrative dispute resolution. The decision shall be effective on the date of the order. The order denying review shall specify the date by which the responsible entity shall comply with the requirements of this chapter that were the subject of the Request for Review.
- (c) An order granting review shall specify a schedule for briefing of the issues by the responsible entity and the Department.
- (d) The Department shall issue an order specifying its decision on the merits of the Request for Review within one hundred and eighty (180) days from the date it grants the Request for Review.
- (1) If the final order upholds the Department's decision under this chapter, the order is the Department's final decision and is not eligible for additional administrative dispute resolution. An order upholding the Department's original decision shall specify the date by which the responsible entity shall comply with the applicable requirements of this chapter.
- (2) If the final order grants the relief sought by the responsible entity, in whole or in part, the order must remand the decision that is the subject of the Request for Review to the responsible program within the Department for re-evaluation by a specified date. The date for completion of the re-evaluation must be no more than ninety (90) days from the date of the order. The order may also provide guidance or criteria for the re-evaluation.
- (e) No Department staff that participated in the decision that is the subject of the Request for Review filed under section 69507.4 may participate in decision-making or review of decisions made under this section.
- (f) No Department staff participating in decision-making or review of decisions made under this section may have communications about the Request for Review with the

Department staff that participated in the decision that is the subject of the Request for Review filed under section 69507.4, unless the Department simultaneously communicates with the responsible entity or its representative regarding the issues under discussion with Department staff.

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

Article 8. Accreditation Bodies and Certified Assessors

§ 69508. Qualification and Certification of Assessors.

- (a) On and after January 1, 2015, an individual in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, must be certified by an accreditation body, and must meet all of the following requirements:
- (1) Possess a Bachelor's degree with a major in a scientific or engineering field from an accredited college or university.
- (2)(A) Have the equivalent of four (4) years of professional experience performing AAs or working in a scientific or engineering field, or both.
- (B) Post-graduate work in the performance of AAs or in a scientific or engineering field, or both, may be substituted on a year-for-year basis for the experience required pursuant to subparagraph (A).
- (3)(A) Successfully complete an assessor training program that is developed and delivered by an accreditation body, and successful completion of an exit exam that meets the requirements of section 69308.2(c)(5).
- (B) Successful completion of an approved challenge test developed by the accreditation body may be used in lieu of the classroom training requirements and written and practical tests for applicants who meet the competency requirements and/or possess on-the-job training equivalent to that specified in section 60508.2(c)(4)(A) through (E).
- (4) Receive a "Certified Alternatives Assessor" certificate, that meets the requirements of section 69308.2(c)(6), and is issued by the accreditation body whose training program the assessor successfully completed pursuant to paragraph (3).
 - (5) Maintain certification by doing both of the following:
- (A) Complete at least 20 hours of continuing education during each two-year accreditation period, as required and provided by, or verified by, the accreditation body from which the assessor will seek re-certification upon expiration of their current certification. Continuing education may be education and/or training focused on one or more aspects of performing, conducting, and verifying AAs or closely related topics. At least two (2) hours of continuing education must be in professional ethics.
- (B) Submit a certificate renewal application to an accreditation body at least thirty (30) days prior to the expiration of the assessor's certification. If the assessor complies with the requirements of this subparagraph and subparagraph (A), the license will remain in effect unless the accreditation body denies the application for renewal.

- (C) Receive a renewed "Certified Alternatives Assessor" certificate that satisfies the requirements of section 69508.2(c)(6) and is issued by the accreditation body who provided or verified the assessor's continuing education pursuant to subparagraph (A).
- (6) Possess, and produce when requested, a current "Certified Alternatives Assessor" certificate meeting the requirements of section 69508.2(c)(6).
- (b) If the Department rescinds, pursuant to subsection (g)(2), (g)(3), or (g)(4) of section 69508.3, the designation of the accreditation body from which the assessor obtained accreditation, the assessor shall apply for re-certification from another accreditation body no later than sixty (60) days after information concerning the rescission is posted on the Department's website.
- (c) An assessor's certificate shall be subject to rescission by the accreditation body or the Department, or both, for failure to comply with the requirements of this chapter, or if the Department or the accreditation body finds the assessor has engaged in activities governed by this chapter in a manner that is negligent, fraudulent, or otherwise unethical. The accreditation body shall provide to the Department the name of, and contact information for, any assessor whose certification is rescinded by the accreditation body, and an explanation of the reasons for the rescission.

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

§ 69508.1. Qualifications for Accreditation Bodies.

- (a) An entity wishing to be designated, or to renew designation, by the Department as an accreditation body to certify assessors shall have on staff one or more individuals that, in combination, possess all of the following:
- (1) A post-graduate degree with a major in a scientific or engineering field from an accredited college or university.
- (2) The equivalent of four (4) years of professional experience performing AAs and/or working in a scientific or engineering field. Post-graduate work in the performance of AAs and/or in a scientific or engineering field, while attending an accredited college or university, may be substituted on a year-for-year basis for the required experience.
- (3) The ability to teach, and experience teaching, the principles and practices of performing AAs as specified in article 5.
- (4) The ability to teach, and experience teaching, the application of life cycle assessment tools and methodologies relevant to products.
- (5) The ability to teach, and experience teaching, or have access to subject matter experts with the ability to teach, and experience teaching, in one or more of the following:
 - (A) Chemistry;
 - (B) Chemical engineering;
 - (C) Environmental law;
 - (D) Toxicology;
 - (E) Public policy;
 - (F) Pollution prevention;
 - (G) Cleaner production methods;

- 1 (H) Environmental health;
 - (I) Public health;

- (J) Risk analysis;
 - (K) Materials science;
- (L) Nanotechnology;
 - (M) Chemical synthesis; and/or
 - (N) Maternal and child health.
- (b) An entity seeking accreditation may not have any economic interest in any responsible entity, manufacturer, consortium of manufacturers, or trade association, or any economic interest in any person that manufactures, sells, or distributes any Chemical of Concern or product containing a Chemical of Concern.

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

§ 69508.2. Accreditation Body Designation Requirements.

- (a) An entity meeting the qualification requirements specified in section 69508.1 may apply to be designated by the Department as an accreditation body to certify assessors.
- (b) The application to be designated as an accreditation body, or to renew designation as an accreditation body, must include all of the following:
 - (1) The name of, and contact information for, the person(s) submitting the application;
- (2) A summary of the qualifications of the individuals, meeting the requirements specified in section 69508.1, including education, experience, and areas of subject matter competency, that are available within, or to, the entity for training and certifying individuals to perform AAs;
- (3) Documentation that the entity meets all of the qualification requirements specified in section 69508.1; and
- (4)(A) A detailed description of the accreditation program demonstrating that the program meets the requirements specified in subsection (c);
- (B) The entity's training program for certification of applicants, including for each course the title, content description, hours, and exam plan;
- (C) Demonstrated qualifications and areas of expertise of the individuals responsible for developing the entity's training curriculum, as evidenced by education and experience, professional licenses, registrations, or other relevant credentials; and
- (D) The entity's continuing education curriculum for re-accreditation applicants, including for each course the title, content description, hours, and exam plan.
- (c) Each accreditation body shall include in its program, at a minimum, all of the following:
- (1) Admission procedures. A summary of application requirements and admission procedures for certification and certification renewal must be included. Required information includes all of the following:
 - (A) The applicant's name and contact information;

- (B) The applicant's educational experience, which must meet the requirements of section 69508(a)(1) and must be substantiated by submittal of transcripts or other equivalent records;
- (C) The applicant's employment and other experience history, which must meet the requirements of section 69508(a)(2) and for which references must be provided;
- (D) The professional licenses, registrations, or other relevant credentials that the applicant possesses:
- (E) Documentation of completion of continuing education required pursuant to section 69508(a)(5), if the application is for certification renewal; and
- (F) A signed and dated certification statement that reads: "I certify under penalty of perjury that the information I have entered on this application is true and complete to the best of my knowledge. I further understand that any false or incomplete statements may result in my disqualification as a certified alternatives assessor. I authorize the employers and educational institutions identified on this application to release any information they may have concerning my employment or education to the accreditation body with which this application is filed and to the State of California."
- (2) Verification Procedures. Written procedures must be included for verifying an applicant's qualifying education and experience, including verification of fulfillment of continuing education requirements.
- (3) Denial Criteria. A summary of the criteria and procedures for denying an applicant for certification or certification renewal must be included. Denial decisions must be provided to the applicant in writing and must state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be certified or re-certified as an assessor.
- (4) Training of Assessors. The training program must include classroom and on-the-job assistance and/or training of applicants. The training must incorporate classroom and/or on-the-job training in analysis of information and practical application of principles, at a minimum, in all of the following:
- (A) The requirements of this chapter, with an emphasis on the requirements of articles 5, 6, and 10;
- (B) Training and case studies on principles and practices of performing AAs as specified in article 5, using life cycle thinking and life cycle assessment tools and methodologies;
 - (C) Training and case studies on identification of alternatives for consideration in AAs;
- (D) Training and case studies on identification of the life cycle segments and exposure pathways for chemicals and products; and
- (E) Training needed for the attainment of expertise in specific fields necessary to the performance of AAs.
- (5) Evaluation and Examination of Assessors. The program must include both of the following:
- (A) A Department-approved written and practical test or evaluation developed by the accreditation body that demonstrates the applicant's competence in the training requirements specified in paragraphs (4)(A) through (4)(E); and
- (B) A Department-approved challenge test developed by the accreditation body that may be used in lieu of the classroom training requirements and written and practical tests for

- applicants that meet the competency requirements and/or possess on-the-job experience that is equivalent to the requirements specified in paragraphs (4)(A) through (4)(E).
 - (6)(A) Certificate Issuance. A certificate for initial certification and certification renewal that is entitled "Certified Alternatives Assessor" and includes, at a minimum, all of the following:
 - 1. Assessor's name;
 - 2. Certificate number;
 - 3. Certificate issuance date and expiration date;
 - 4. Name of, and contact information for, the accreditation body issuing the certificate;
 - 5. An indication as to whether the certificate is for initial certification or a renewal;
 - 6. The product type(s) and/or industry sector(s) for which the assessor is certified:
 - 7. A statement that the assessor meets the requirements of section 69508(a); and
 - 8. The signature of the owner or an officer of the accreditation body issuing the certification.
 - (B) The accreditation body's program must include requirements and a process for certification renewal every two (2) years.
- (7) Assessor Agreement and Audit Program. The program must require that certified assessors enter into an agreement with the accreditation body under which the assessors agree to all of the following:
- (A) Provide alternatives assessment services only in the areas of expertise in which the individual has demonstrated competence;
 - (B) Provide true and accurate analyses; and
- (C) Random auditing by the accreditation body or its consultants to ensure the quality of work and proper application of tools by the assessor.
- (8) Record Maintenance Program. The accreditation body shall maintain a database of the names of individuals whose applications were accepted or denied, names of individuals certified, their certificate numbers, and their certificate issuance and expiration dates. The database must also include copies of applications, verification information, audit records, and violations, if any. All records shall be maintained for a minimum of five (5) years.
- (A) The accreditation body shall submit electronically to the Department the name of, and contact information for, each assessor certified by the accreditation body, their certificate number, their certificate issuance and expiration dates, and the areas of expertise in which the assessor is certified. The accreditation body shall provide an electronic update of this information to the Department at least once a year.
- (B) Upon the request of the Department, but not more frequently than annually, an accreditation body shall submit to the Department sufficient information to facilitate audits by the Department pursuant to article 9.

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

§ 69508.3. Accreditation Bodies Designation Process.

- (a) The Department shall review the application submitted pursuant to section 69508.2 and approve or deny the request for designation as an accreditation body within sixty (60) days of receiving the application. The Department shall notify the person submitting the application of its determination. A notice of denial shall state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be designated, or re-designated, as an accreditation body.
- (b) If the information submitted pursuant to section 69508.2 changes, the person that submitted the application shall provide updated written information to the Department within thirty (30) days of the change.
- (c) A designation as an accreditation body expires after a period of five (5) years, except that it may be renewed upon application by the accreditation body, pursuant to section 69508.2, not later than ninety (90) days before expiration of the existing designation. Timely applications for renewal of designation, meeting the requirements of section 69508.2, shall extend the expiring designation until the Department makes a determination on the renewal application.
- (d) If an entity is found to be negligently or willfully in violation of this chapter, the entity shall lose its designation as an accreditation body for a period of at least ten (10) years. After this period, the entity may reapply to be designated as an accreditation body.
- (e) An accreditation body may not claim trade secret protection for its general admission process, curriculum, and educational approach.
- (f) The Department may annually review the performance of accreditation bodies to determine whether the accreditation bodies comply with the requirements of this chapter. This review may include records review and/or interviews of assessors participating in the training and certification program.
- (g) The Department shall rescind its designation of an accreditation body if one or more of the following occurs:
- (1) The designation period has lapsed, and the accreditation body has not submitted a timely renewal application that meets the requirements of section 69508.2;
- (2) A substantial number of individuals certified by the accreditation body as assessors are found by the Department to be in violation of this chapter;
- (3) The Department finds that the accreditation body has significantly deviated from the documentation submitted to the Department pursuant to section 69508.2, or is out of compliance with the applicable requirements of this article; and/or
- (4) The Department finds the accreditation body to have carried out its activities governed by this chapter in a manner that is negligent, fraudulent, or is otherwise unethical.

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

2

3

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30 31

32

33 34

35 36

37

38

39

40

41

§ 69508.4. Filing a Complaint.

- (a) A person may file a complaint alleging a violation of this chapter by an accreditation body and/or certified assessor. The complaint must be submitted to the Department in accordance with section 69501.4, and must include both of the following:
 - (1) The name of, and contact information for, both of the following:
- (A) The accreditation body or certified assessor that is the subject of the complaint, hereinafter referred to as the subject; and
 - (B) The complainant.
- (2) A description of the complaint, including the particular requirements that are alleged to have been violated and the facts which the complainant relies upon to support the alleged violation.
- (b) Within thirty (30) days of receiving a complaint, the Department shall review the complaint and determine if the complaint includes the items specified in subsection (a). If the Department determines that a complaint is complete, the Department shall notify the complainant that the Department will conduct further review to determine whether a violation has occurred. If the Department determines that the complaint is incomplete, it shall notify the complainant and specify the basis for the determination.
- (c) If the complaint substantially complies with the requirements of this section, the Department shall serve a copy to each subject, together with an order requiring that the complaint be answered by the subject within thirty days (30) after the date of service.
- (d) The Department shall review the information and documentation in the response from the subject and may refer items to external subject matter experts for review and recommendations.
- (e) If the Department determines there is insufficient evidence to determine whether or not a violation has occurred, the Department shall close the complaint.
 - (f) If the Department determines that a violation has occurred, the Department shall:
 - (1) Warn the subject by issuing a citation, and obtain compliance;
 - (2) Pursue the violations under the Administrative Procedure Act; and/or
 - (3) Refer the matter to the Attorney General or appropriate district attorney.

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

Article 9. Audits

§ 69509. Audit of Alternatives Assessments and Regulatory Responses.

- (a) The Department may audit AAs, AA Reports, and regulatory responses.
- (b) The scope of any audit may include an examination of one or more of the following:
- (1) Compliance with article 5 requirements;
- (2) Information quality and adequacy of analysis;
- (3) Implementation of the selected alternative, if applicable; and
- 42 (4) Compliance with the regulatory response(s) imposed pursuant to article 6, if any.

- (c) Upon completion of an audit, the Department shall:
- (1) Notify the responsible entity(ies) of the audit findings; and
- (2) Inform the responsible entity(ies) of the process to dispute audit findings.

1

2

NOTE: Authority cited: Sections 25253, and 58012, Health and Safety Code. Reference: Article 8 of Division 4.5 of Chapter 20 and Section 25253, Health and Safety Code.

6 7

Article 10. Trade Secret Protection

8 9 10

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

§ 69510. Assertion of a Claim of Trade Secret Protection.

- 1112 in13 th
- (a) A person who asserts a claim of trade secret protection with respect to documents or information submitted to the Department under this chapter will receive a written request from the Department to furnish the Department with all of the following supporting information:
 - (1) The identity of the person asserting the claim;
 - (2) A brief description of the nature of the information for which trade secret protection is being claimed;
 - (3) The period of time for which trade secret protection is claimed, and the justification for the period of time specified;
 - (4) The extent to which the information is known by employees or others involved with the facility or business of the person, and whether or not those individuals are bound by nondisclosure agreements;
 - (5) The extent to which the information is known outside of the facility or business of the person, and whether or not individuals with such knowledge are bound by non-disclosure agreements;
 - (6) The measures taken to restrict access to and safeguard the information, and whether or not the person plans to continue utilizing such measures;
 - (7) The estimated value of the information to the person and the person's competitors;
 - (8) The estimated amount of effort or money expended by the person in developing the information;
 - (9) The estimated ease or difficulty with which the information could be properly acquired or duplicated by others;
 - (10) Copies of, or references to, any pertinent trade secret or other confidentiality determinations previously made by the Department or other public agencies;
 - (11) A description of the nature and extent of harm that would be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed;
 - (12) The signature of the person's general counsel or other executive with knowledge of the preparation of the substantiating information, certifying under penalty of perjury and subject to the provisions of section 69501.4(b), and also based up on the knowledge and belief of the signatory, that:
 - (A) The substantiating information is true, accurate, and complete;

- (B) The information for which trade secret protection is claimed is not otherwise publicly available; and
 - (C) There is a reasonable basis to assert trade secret protection for the information so claimed; and
 - (13) Contact information for the individual to be contacted if part of the claimed information is requested to be disclosed under the California Public Records Act.
 - (b) The substantiating information required under subsections (a)(1) through (a)(11) shall be provided for each individual trade secret claim, although such information may be incorporated by reference to apply to multiple claims, as appropriate. The requirements of subsections (a)(12) and (a)(13) may be met once for all claims submitted at one time.
 - (c) A person who asserts a claim of trade secret protection shall also, at the time of submission, provide the Department with both of the following:
 - (1) A complete copy of the documentation being submitted, which shall include the information for which trade secret protection is claimed; and
 - (2) A redacted copy of the documentation being submitted, which shall exclude the information for which trade secret protection is claimed. The Department may make the redacted copy of the documentation available to the public at its discretion.
 - (d) A person who asserts a claim of trade secret protection shall make such assertion at the time of submission by marking the words "Trade Secret", conspicuously on each page containing the information for which trade secret protection is claimed. If no claim of trade secret protection is made at the time of submission, the Department may make the submitted information available in full to the public without further notice.
 - (e) If the documentation supporting a claim of trade secret protection contains information that is itself subject to a claim of trade secret protection, such supporting documentation shall be separately supplied in both complete and redacted form as required by subsection (c), and marked as required by subsection (d), but shall not itself require further supporting documentation. Such documentation shall be separate from documentation used to comply with other provisions of this chapter.
 - (f) Trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient.

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

§ 69510.1. Department Review of Trade Secrecy Claims.

- (a) Upon receipt of information submitted pursuant to this chapter that contains information identified as being subject to trade secret protection, or at any time thereafter, the Department may review the trade secret claim and supporting information for compliance with the requirements of this article.
- (b) If the Department determines that information provided in support of a request for trade secret protection is incomplete or insufficiently responsive, the Department shall notify the submitter of the Department's finding of deficiency, the specific area(s) of deficiency, an

- explanation as to why the Department has determined the information to be deficient, and the date by which the submitter must cure the deficiency. If the submitter fails to cure the deficiency within the timeframe specified, the Department shall notify the submitter by certified mail that the claimant is out of compliance with this article, and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department thirty (30) days after such notice is mailed. During this 30-day period, the submitter may seek judicial review by filing an action for a writ of mandate, injunction, protective order, or other appropriate relief. During this 30-day period, and for any longer period ordered by a court of law, the Department shall not publicly release or disclose the claimed trade secret information.
 - (c) If the Department determines that information provided in support of a request for trade secret protection does not meet the substantive criteria for trade secret designation, the Department shall notify the submitter by certified mail of its determination and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department thirty (30) days after such notice is mailed. During this 30-day period, the submitter may seek judicial review by filing an action for a writ of mandate, injunction, protective order, or other appropriate relief. During this 30-day period, and for any longer period ordered by a court of law, the Department shall not publicly release or disclose the claimed trade secret information.

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

Article 11. Severability

§ 69511. Severability.

If any provision(s) of this chapter, or the application thereof to any person or circumstances, is held invalid, such invalidity shall not affect other provisions or applications of this chapter that can be given effect without the invalid provision or application, and to that end the provisions of this chapter are severable.

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

34 Article 12. [Reserved]

36 §§ 69512 -- 69599. [Reserved]