**ATTACHMENT** TEXT OF PROPOSED REGULATIONS – ADDITIONAL POST-HEARING CHANGES **April 2013** Changes in this version reflect changes to the text of the January 2013 post-hearing changes to the text as originally proposed in July 2012. All of the text is new language to be added to the California Code of Regulations. The January 2013 post-hearing changes are indicated by single underline / strikeout. The additional April 2013 post-hearing changes are indicated by double underline / strikeout: Underline: Underlined text reflects new text. Strikeout: Strikeout text reflects deleted text. For ease of reading and referencing the proposed regulations, line numbers and table of content page numbers are added, but are not part of the actual regulatory text. NOTE: An unofficial version of the April 2013 revised proposed regulations, which shows only the April 2013 changes (in double underline and double strikeout), is available on the Department of Toxic Substances Control's website as a courtesy copy only. (In this unofficial version, the January 2013 post-hearing changes version is shown with no underlines.) Additionally, an unofficial "clean" version of the April 2013 revised proposed regulations is available on the Department of Toxic Substances Control's website as a courtesy copy only. 

1		DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS	
2		CHAPTER 55. SAFER CONSUMER PRODUCTS	
3	A a all the a .T		0 44 a.a.d
4	<b>Amend</b> the Table of Contents by adding chapter 55, articles 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, <del>11, and 10, 10, 10, 10, 10, 10, 10, 10, 10, 10,</del>		
5	1211, and sections 69501, 69501.1, 69501.2, 69501.3, 69501.4, 69501.5, 69502, 69502.1,		
6	69502.2, 69502.3, 69503, 69503.1, 69503.2, 69503.3, 69503.4, 69503.5, 69503.6, 69503.7,		
7	69504, 69504.1, 69505, 69505.1, 69505.2, 69505.3, 69505.4, 69505.5, 69505.6, <u>69505.7,</u>		
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10	69507.4, 69507.5, 69507.6, 69508, <del>69508.1, 69508.2, 69508.3, 69508.4,</del> 69509, <u>69509.1,</u>		
11	69510, 69510.1, and 69511, and 69512 through 69599 to division 4.5 of title 22 of the California		
12	Code of Regu	ulations <del>, title 22</del> , to read:	
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**Add** chapter 55 to division 4.5 of title 22 of the California Code of Regulations, title 22, division 4.5, chapter 55 to to read:

## **Chapter 55. Safer Consumer Products**

#### Article 1. General

(a)

### § 69501. Purpose and Applicability.

identifying chemicals as and prioritizing Priority Products and their Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying and analyzing alternatives to consider for Priority Products to determine how best to limiteliminate or reduce potential exposures to, or the level of potential adverse impacts posed by, the Chemical(s) of Concern in the product Priority Products. This chapter also specifies the regulatory responses that will be imposed by operation of article 6 or that may be required by

Safer Consumer Products Regulations. This chapter specifies the process for

#### (b)((b) Applicability and Non-Duplication.

the Department following completion of an alternatives analysis.

(1) Except as provided in paragraphs (2) and (3), 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)-)(A) This chapter does not apply to anya consumer product manufactured that the Department determines is regulated by one or stored in, more federal and/or transported through, California solely State regulatory program(s), and/or applicable treaties or international agreements with the force of domestic law, that, in combination:

1. Address the same potential adverse impacts, potential exposure pathways, and potential adverse waste and end-of-life effects that could otherwise be the basis for use outside of 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 were listed as a Priority Product.

(B) The Department may re-evaluate a determination previously made pursuant to under 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.

(c) Harmonization. Nothing in these regulations authorizes the Department to supersede the requirements of another California State or federal regulatory program.

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

42 Reference: Sections 25251, 25252, 25253, and 25257.1, Health and Safety Code.

#### § 69501.1. Definitions.

(a) <u>Terminology.</u> When used in this chapter, the following terms, <u>unless specified</u> otherwise, have the meanings specified in this section:

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(1) "AA Reports" means the Preliminary <u>AA Reports</u>, and/or Final AA Reports, collectivelydraft and/or final Abridged AA Reports, and/or AA Reports submitted for previously completed AAs, whichever is applicable. <u>As applicable</u>, "AA Report" also includes the AA Report Addendum for a Final AA Report or Abridged AA Report.

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(2) "Accreditation body" means an entity designated by the Department, under article 8, to administer a program designed to train, evaluate, assist, and certify assessors.

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(3) "Adverse air quality impacts" means <u>indoor or outdoor</u> air emissions of any of the air contaminants listed below that have the <u>abilitypotential</u> to result in adverse public health, ecological, soil quality, or water quality impacts:

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- (A) California Toxic Air Contaminants as specified in <u>Titletitle</u> 17, California Code of Regulations, sections 93000 through 93001;
  - (B) Greenhouse gases, which means any of the following gases:
- 20 1. Carbon dioxide;
  - Hydrofluorocarbons;
- 22 3. Methane:
- 23 4. Nitrogen trifluoride;
- 24 5. Nitrous oxide;
- 25 6. Perfluorocarbons;
  - 7. Sulfur hexafluoride; or
- 27 8. Gases that exhibit the global warming potential hazard trait, as specified in section 69405.4:
  - (C) Nitrogen oxides;
  - (D) Particulate matter that exhibits the particle size or fiber dimension hazard trait, as specified in section 69405.7;
  - (E) Chemical substances that exhibit the stratospheric ozone depletion potential hazard trait, as specified in section 69405.8;
    - (F) Sulfur oxides; or
  - (G) Tropospheric ozone-forming compounds, including compounds that exhibit the ambient ozone formation hazard trait, as specified in section 69405.1.

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- (43) "Adverse ecological impacts" means any of the following direct or indirect effects on living organisms and/or their environments:
- (A) Adverse <u>impacts effects</u> to aquatic, avian, or terrestrial animal or plant organisms or microbes, including:
  - 1. Acute or chronic toxicity;

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- 1 2. Changes in population size, reductions in biodiversity, or changes in ecological communities; and
  - 3. The ability of an endangered or threatened species to survive or reproduce;
  - (B) Adverse impacts effects on aquatic and terrestrial ecosystems including:
  - 1. Deterioration or loss of environmentally sensitive habitats;
  - 2. Impacts that contribute to or cause vegetation contamination or damage; and
  - 3. Adverse impacts on environments that have been designated as impaired by a California State or federal regulatory agency;
    - (C) Biological or chemical contamination of soils; or
  - (D) Any other adverse effect, as defined in section 69401.2(a), for environmental hazard traits and endpoints specified in article 4 of chapter 54.
    - (54) "Adverse environmental impacts" means any of the following:
    - (A) Adverse air quality impacts;
    - (B) Adverse ecological impacts;
    - (C) Adverse soil quality impacts;
      - (D) Adverse water quality impacts; or
  - (E) Exceedance of an enforceable California or federal regulatory standard relating to the protection of the environment.
  - (5) "Adverse impacts" means adverse public health impacts and/or adverse environmental impacts.
  - (6) "Adverse public health impacts" means any of the toxicological effects on public health specified in <u>articlesarticle</u> 2 or <u>article</u> 3 of chapter 54, or exceedance of an enforceable California or federal regulatory standard relating to the protection of public health. Public health includes occupational health.
  - (7) "Adverse public health and/or environmental impacts" or "adverse impacts" means adverse public health impacts and/or adverse environmental impacts, collectively.
  - (8 (7) "Adverse soil quality impacts" means any of the following effects on soil function or properties:
    - (A) Compaction or other structural changes;
    - (B) Erosion;
    - (C) Loss of organic matter; or
  - (D) Soil sealing, meaning the covering of the surface soil with a layer of impervious material or changing the nature of the soil so that it behaves as an impermeable medium.
  - (98) "Adverse waste and end-of-life impacts effects" means the waste materials and byproducts generated during the life cycle of the Priority Product and/or each alternative being considered, including degradates and reaction products a product, and the associated adverse

public health or environmental impacts effects due to anyone or more of, or a combination of,
 the following:

- (A) The volume or mass generated;
- (B) Any special handling requirements needed to mitigate adverse impacts;
- (C) <u>ImpactsEffects</u> on solid waste <u>and wastewater</u> disposal and treatment, including operation of solid waste <u>and wastewater</u> handling or treatment facilities, <u>and the ability to reuse</u> or recycle materials resulting from the treatment of solid waste and/or wastewater;
- (D) Discharge(s) or disposal(s) to storm drains or sewers, contributing to adverse impacts on that adversely affects operation of wastewater or storm water treatment facilities; or
- (E) Release(s) into the environment, as a result of solid waste handling, treatment, or disposal activities, or the discharge or disposal to storm drains or sewers, of either or both of the following:
  - 1. The Chemical(s) of Concern contained in the Priority Product or alternatives; and/or
- 2. Any other chemical contained in the alternatives that differs from the chemicals contained in the Priority Product product.

(109) "Adverse water quality impacts" means any of the following adverse effects on the beneficial uses of the waters of the State, which include groundwater, fresh water, brackish water, marsh lands, wetlands, or coastal bodies or systems, as specified in Water Code section 13050(f) or adopted in a Water Quality Control Plan under 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;
- (D) Increase in total dissolved solids; or
- (E) Introduction of, or increase in, any of the following:
- 1. Priority toxic-pollutants identified for California under section 303(c) of the federal Clean Water Act;
- 2. Pollutants listed by California or the <u>United States</u> Environmental Protection Agency for one or more water bodies in California under section 303(d) of the federal Clean Water Act;
- 3. Chemicals for which primary Maximum Contaminant Levels (MCLs)-have been established and adopted under Health and Safety Code section 116365(a),64431 or bysection 64444 of chapter 15 of title 22 of the Environmental Protection Agency under the federal Safe Drinking Water ActCalifornia Code of Regulations;
- 4. Chemicals for which Notification Levels (NLs) have been specified under Health and Safety Code section 116455; or
- 5. Chemicals for which public health goals for drinking water have been published under the California Safe Drinking Water Act (commencing with Health and Safety Code section 116270).

  $(44\underline{10})$  "Alternative" means any of the following:

- (A) Removal of Chemical(s) of Concern infrom a Priority Product, with or without adding a substitute chemical or increasing the concentrationuse of a chemical already contained in the productone or more replacement chemicals;
- (B) Reformulation or redesign of a Priority Product and/or manufacturing process to reduce or eliminate or reduce the concentration of Chemical(s) of Concern in the Priority Product;
- (C) Redesign of a Priority Product and/or manufacturing process<del>, using different</del> materials to reduce or restrict potential exposures to Chemical(s) of Concern in the Priority Product: or
- (D) Any other change to a Priority Product or a manufacturing process that reduces the <u>potential</u> adverse <u>public health and/or environmental impacts and/or potential</u> exposures associated with the Chemical(s) of Concern in the Priority Product, and/or the potential adverse waste and end-of-life effects associated with the Priority Product.

 $(42\underline{11})$  "Alternatives Analysis" or "AA" means an evaluation and comparison of a Priority Product and one or more alternatives to the product, under article 5.

- (12) "Alternatives Analysis Threshold" means whichever of the following is applicable:
- (A) <u>‡The Practical Quantitation Limit for a Chemical of Concern that is present in a Priority Product solely as a contaminant; or</u>
- (B) The applicable concentration, if any, specified by the Department under section 69503.5(c).
- (13) "Alternatives Analysis Threshold" means a concentration by weight specified by the Department under section 69503.5(c).
- (14) "Alternatives Analysis Threshold Exemption Notification" means a notification submitted to the Department under section 69503.669505.3.
- (1514) "Aqueous hydrolysis half-life" means the time required for the concentration of a chemical to be reduced to by one-half of its initial concentration after being introduced into water.
- (16(15) "Assemble" means to fit, join, put, or otherwise bring together components to create, repair, refurbish, maintain, or make non-material alterations to a consumer product.
- (16) "Assembler" means any person who assembles a product containing a component that is a product subject to the requirements of this chapter.
- (17) "Atmospheric oxidation rate" means the rate of change or degradation of a chemical through the interaction with oxygen in the atmosphere.

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(1718) "Bioaccumulation" means the following:

- (A) Accumulation of a chemical in an organism, tissues of an organism, or an individual biological compartment of the environment, which absorbs the chemical at a rate greater than that at which the chemical is lost; and
  - (B) Bioaccumulation bioaccumulation, as specified in section 69405.2.

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(18) "Certified assessor" means an individual that has been issued a "Certified Alternatives Assessor" certificate by an accreditation body, under article 8.

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(19(19) "Candidate Chemical" means a chemical that is a candidate for designation as a Chemical of Concern, and that is identified as a Candidate Chemical under section 69502.2.

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(20)(A) "Chemical" means either of the following:

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1. An organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any degradate, metabolite, or reaction product of a substance with a particular molecular identity;

19 or 20

2. A chemical ingredient, which means a substance comprising one or more of any substance, element, ion, uncombined radical, degradate, metabolite, or reaction productsubstances described in subparagraph 1.

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- (B) "Molecular identity" means the substance's <del>physicochemical</del> properties, <del>chemical</del> structure and <u>listed below:</u>
- Agglomeration state;
  - 2. Bulk density;
  - 3. Chemical composition, including surface coating;
  - 4. Crystal structure;
  - 5. Dispersability;
  - 6. Molecular structure;
- Particle density;
  - 8. Particle size and, size distribution, and surface area;
  - 9. Physical form and shape, at room temperature and surface structure, reactivity, and any other pressure;
    - 10. Physicochemical properties that are:
    - 11. Porosity;
  - 12. Solubility in water and biologically relevant to whether the substance would be a Chemical of Concern. fluids:

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- (2013. Surface charge; and
- 41 14. Surface reactivity.

(21)

69503.5(b)(2)(B).

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5	(22) "Chemical Removal Intent Notification" and "Chemical Removal Confirmation			
6	Notification" mean the notifications submitted to the Department under section			
7	<del>69502.3(b).</del> 69505.2(a)(1)(A)1.			
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9	(2123)(A) "Component" means a uniquely identifiable homogeneous material, part, piece,			
10	assembly, or subassembly, system, or subsystem that is a necessary or intended element of a			
11	consumer product-that:			
12	(A) Is required to complete or finish an item;			
13	(B) Performs a distinctive and necessary function in the operation of a system; or			
14	(C) Is intended to be included as a part of a finished item.			
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16	(22(B) "Homogeneous material" means either of the following:			
17	<ol> <li>One material of uniform composition throughout; or</li> </ol>			
18	2. A material, consisting of a combination of materials, that cannot be readily disjointed			
19	or separated into different materials by mechanical actions such as unscrewing, cutting,			
20	crushing, grinding, or abrasive processes.			
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22	(24)(A) "Consumer product" or "Product" means any of the following:			
23	1. A "consumer product" as defined in Health and Safety Code section 25251; or			
24	2. AWhen applicable, a component that meets the definition of aof an assembled			
25	"consumer product" specified in Health and Safety Code section 25251; or."			
26	3. A component, or a homogeneous material within a component, that is identified,			
27	under section 69503.4(a)(2)(B), as the minimum required focus of an AA.			
28	(B)1. "Consumer product" or "Product" does not mean any historic product.			
29	2. "Historic product" means a product that ceased to be manufactured prior to the date			
30	the product is listed as a Priority Product.			
31	(C) "Consumer product" or "Product" does not mean a product previously owned or			
32	leased by someone other than the manufacturer, importer, distributor, <u>assembler</u> , or retailer of			
33	the product.			
34	(2225) "Contact information" many mailing and alcotronic address address as books yorkers			
35	(2325) "Contact information" means mailing and electronic address addresses, headquarters			
36	location, phone number(s), title(s) if applicable, and website address.			
37	(24/26)(A) "Contaminant" magne a chemical that is not an intentionally added			
38 20	(24(26)(A) "Contaminant" means a chemical that is not an intentionally added			
39 10	ingredient in a product and the source(s) of the chemical in the product is/are one or more of the following:			
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+ 1 42	<ol> <li>A naturally occurring contaminant commonly found in raw materials that are frequently used to manufacture the product;</li> </ol>			
T <b>∠</b>	nequently used to manufacture the product,			

"Chemical of Concern" means a chemical identified Candidate Chemical that has

been designated as a Chemical of Concern under section 69502.2(a), or a chemical listed by

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  - the product;
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- Air or water frequently used as a processing agent or an ingredient to manufacture
- A contaminant commonly found in recycled materials that are frequently used to manufacture the product; and/or
- A processing agent, reactant, by-product, or intermediate frequently used to promote certain chemical or physical changes during manufacturing, and the incidental retention of a residue is not desired or intended.
- "Intentionally added ingredient" means a chemical that is deliberately used in the (B) manufacture of a product where the continued presence is desired in the final product to provide a specific characteristic, appearance, or quality.
- (C) "Processing agent" means a chemical used in a product manufacturing process to promote chemical or physical changes.
- "Recycled material" means a material that has been separated from a waste stream for the purpose of recycling the material as feedstock.
- (27)"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.
  - (2528) "Department" means the Department of Toxic Substances Control.
- (26(29) "Economically feasible" means that an alternative product or replacement chemical does not significantly reduce the manufacturer's operating margin.
- "End-of-life" means the point when thea product is discarded by the consumer or the (30)end of the useful life of the product, whichever occurs first.
  - (2731) "Environment" means the land, air, water, soil, minerals, flora, and fauna.
  - (2832) "Environmental fate" means all of the following:
  - (A) Aerobic and anaerobic half-lives;
  - (B) Aqueous hydrolysis half-life;
  - (C) Atmospheric oxidation rate:
  - (D) Bioaccumulation;
  - (E) Biodegradation:
  - (F) Mobility in environmental media, as specified in section 69405.6:
  - (G) Persistence; and
  - (H) Photodegradation.
- (2933) "Environmental or toxicological endpoint" means any environmental or toxicological endpoint specified in chapter 54.

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(3135) "Functionally acceptable" means that an alternative product meets both of the

(3034) "Failure to Comply List" means the list prepared by the Department under section

- following requirements:
  - (A) The product complies with all applicable legal requirements; and
- The product performs the functions of the original product sufficiently well that (B) consumers can be reasonably anticipated to accept the product in the marketplace.
  - (3236) "Hazard trait" means any hazard trait specified or defined in chapter 54.
- (3337) "Hazard trait submission" means any health, safety, or environmental study of, or health, safety, or environmental datainformation regarding, a chemical that has been submitted to any government agency for any purpose or is required to be submitted to the Department under this chapter or article 14 of chapter 6.5 of division 20 of the Health and Safety Code-or these regulations. When any study or datum indicates that a chemical manifests any hazard trait,. Precise chemical identity is part of any hazard trait submission, except as otherwise provided in section 69509(g).
  - (34) "Homogeneous material" means either of the following:
  - (A) One material of uniform composition throughout; or
- (B) A material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding, or abrasive processes.
- (35(38) "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- in California. "Import" includes reimporting a consumer-product manufactured or processed, in whole or in part, in the United States. "Import" does not include ordering a product manufactured outside of the United States if the product is ordered from a person located in the United States.
- (3639) "Importer" means a person who imports a consumer product into the United Statesproduct that is subject to the requirements of this chapter. "Importer" does not include a person that imports a product solely for use in that person's workplace if that product is not sold or distributed by that person to others.
- (3740) "Information" means data, documentation, records, graphs, reports, or any other depiction of specific pieces of knowledge.
- (3841) "Legal requirements" means specifications and/or, performance standards, and/or labeling requirements that a chemical, product, or product packaging is required to meet under federal or California law.

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39 chapter 54. 42

(3942) "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.

- (4043) "Manufacture" means to make, or produce, or assemble. "Manufacture" does not include anyacts that meet the definition 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: "assemble."
  - (A) Repair or refurbishment of an existing consumer product;
  - (B) Installation of standardized components to an existing consumer product; or
  - Making non-material alterations to an existing consumer product.
- (44)"Manufacturer" means any person who manufactures a product that is subject to the requirements of this chapter, or any person that controls the specifications and design of,
- ormanufacturing process for, or has the capacity to specify specifies the use of materials chemicals to be included in, such athe product.
- (4245)(A) "Materials and resource consumption" means the consumption of renewable and nonrenewable resources that are used for a consumer product throughout its life cycle.
- 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, including petroleum, coal, metals (mined and recycled), metals, 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 wouldwill drive the resource to exhaustion.
  - (4346) "Persistence" means environmental persistence, as specified in section 69405.3.
  - (4447) "Person" has the same meaning as in Health and Safety Code section 25118.
- (4548) "Physical chemical hazards" means physical hazard traits specified in article 6 of

1	(4649) "Physicochemical properties" means the physicochemical properties specified in			
2	section 69407.2.			
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4	(4750)(A) "PlacePlaced into the stream of commerce in California" means to sell, offer for			
5	sale, distribute, supply, or manufacturethat a consumer product has been sold, offered for sale,			
6	distributed, supplied, or manufactured in or for use in California as a finished product or as a			
7	component in an assembled product.			
8	(B) "SellSold or offeroffered for sale" means any transfer or offer to transfer for			
9	consideration of title or the right to use, by lease or sales contract, including, but not limited to,			
10	transactions conducted and offers made through sales outlets, catalogs, or the Internet, or any			
11	other similar electronic means.			
12				
13	(48(51)(A) "Potential" means that the phenomenon described is reasonably			
14	foreseeable based on reliable information.			
15	(B) Subparagraph (A) does not apply to the use of the term "potential' in paragraph (2)			
16	above or section 69502.2(a)(1)(M).			
17				
18	(52) "Practical Quantitation Limit" or "PQL" means the lowest concentration of a chemical			
19	that can be reliably measured within specified limits of precision and accuracy using routine			
20	laboratory operating procedures.			
21				
22	(53) "Priority Product" means a product-chemical combination identified and listed as a			
23	Priority Product by the Department under section 69503.45.			
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25	(49) "Processing agent" means a chemical used in a product manufacturing process to			
26	promote chemical or physical changes.			
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28	(50) "Recycled material" means a material that has been separated from a waste stream			
29	for the purpose of recycling the material as feedstock.			
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31	(51(54) "Product-Chemical Replacement Intent Notification" and "Product-Chemical			
32	Replacement Confirmation Notification" mean the notifications submitted to the Department			
33	under section 69505.2(a)(1)(A)3.			
34				
35	(55) "Product Removal Intent Notification" and "Product Removal Confirmation			
36	Notification" mean the notifications submitted to the Department under section			
37	69505.2(a)(1)(A)2.			
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"Release" means an intentional or unintentional liberation, emission, or discharge of

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a chemical into the environment.

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- (5257) "Reliable information" means a scientific study or other a scientific study or other scientific information that is one or more of trustworthy based on the following:
- (A)(A) The level of rigor attendant to the generation of the information, including, where relevant, the use of quality controls;
- (B) The degree to which the information has been independently reviewed by qualified disinterested parties;
- (C) The degree to which the information has been independently confirmed, correborated, or replicated; and/or
- (D) With respect to a scientific study, the fact that the study meets both of the following criteria in subparagraphs (A) and (B):
  - 1.(A) The study or other scientific information was:
  - <u>a.1.</u> Published in a scientifically peer reviewed report or other literature;
  - (B)b.2. Published in a report of the United States National Academies;
- (C)c.3. Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or
- (D)d.4. Conducted, developed, submitted, prepared for, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes.
- (532-(B) With respect to a scientific study, ∓the study design was appropriate to the hypothesis being tested, and sufficient to support the proposition(s) for which the study is presented to the Department.

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- (58) "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" means any of the following that meet the definition of reliable information:
  - (A) Monitoring data that shows the chemical to be any of the following:
  - 1. Present in household dust, indoor air, or drinking water, or on interior surfaces;
- 2. Present in, or released from, products used in or present in the homehomes, schools, or places of employment;
  - 3. Accumulative or persistent in the environment; or
  - 4. Accumulative in aquatic, avian, animal, or plant species.
- (B) Biomonitoring data <u>from one or both of the following sources</u> that show the chemical to be present in human organs, tissues, or fluids including data from either of the following:
  - 1. California Environmental Contaminant Biomonitoring Program; <u>and/</u>or
- 2, Center. United States Centers for Disease Control's Control and Prevention's National Health and Nutrition Evaluation Survey biomonitoring data.
  - (C) Evidence that a chemical exhibits the hazard trait for any of the following:
  - Bioaccumulation;
  - 2. Persistence; or
  - 3. Lactational or transplacental transfer, as specified in section 69405.5.
- 40 (D) Exposure or environmental modeling that indicates either one or both of the following:

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- 1 Exposure point concentration(s) associated with adverse public health or 1. 2 environmental impacts; or 3 Environmental accumulation of a chemical. 2. 4 (E) Monitoring data indicating the presence of a chemical or its degradation products in 5 California solid waste, wastewater, biosolids, or storm water streams collected or managed by 6 California State or local agencies in concentrations or volumes that: 7 8
  - Contribute Potentially contribute to or cause adverse public health or environmental impacts:
  - 2. Would require Require the expenditure of public funds to mitigate potential adverse public health or environmental impacts associated with the chemical or its degradation products;
  - 3. Increase the costs of reusing or recycling materials containing the chemical or its degradation products;
  - Interfere with the proper operation of solid waste, wastewater, or storm water treatment systems and result in the discharge of the chemical or its degradation products to the environment:
    - 5. Exceed regulatory thresholds for the chemical or its degradation products; or
  - 6. Result in violations of the permit issued to the facility responsible for managing solid waste, wastewater, biosolids or storm water streams.

(54(59) "Replacement Candidate Chemical" or "replacement chemical" means a Candidate Chemical or other chemical, whichever is applicable, that replaces, or is under consideration to replace, the Chemical(s) of Concern, in whole or in part, in an alternative to the Priority Product, and that is one of the following:

- A chemical that is not present in the Priority Product; or (A)
- A chemical that is <u>or would be present at a lowerin the alternative at a higher</u> concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern.
  - (60)"Responsible entity" means any of the following:
  - <del>(A)</del> The manufacturer of a consumer product.
  - (B) The importer of a consumer product.
  - (C) The retailer of a consumer product.

(55(A) Manufacturer;

- (B) Importer:
- (C) Assembler; or
- (D) Retailer.

"Retailer" means a person to whom a consumer product product that is subject to the requirements of this chapter is delivered or sold for purposes of sale or distribution by thethat person to a consumer.

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42 Duty to Comply. (a)

(5662) "Safer alternative" means an alternative that, in comparison with the existing Priority Product, reduces, avoids, or eliminates the use of, and/or another product or product manufacturing process, has reduced potential adverse impacts and/or potential exposures to, associated with one or more Candidate Chemical(s), Chemical(s) of Concern, so as to reduce adverse public health and environmental impacts and/or replacement chemicals, whichever is/are applicable.

(<del>57</del>63) "Sales outlet" means any place at which consumer products are sold, supplied, or offered for sale directly to consumers in California.

(5864) "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 and/or toxicological endpoint, including, but not limited to, infants, children, pregnant women, and elderly individuals. "Sensitive subpopulations" also include persons individuals at greater risk of adverse health effects when exposed to chemicals, because they are either individuals with a history of serious illness or greater exposures to chemicals, or workers with greater exposures to chemicals due to the nature of their occupation.

(5965) "Technically and economically feasible alternative" means an alternative product or chemical for which:

- (A) The that the technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period; and an alternative product or replacement chemical.
  - (B) The manufacturer's operating margin is not significantly reduced.
- (66)"Trade secret" means "Trade Secretsecret" as defined in Civil Code section 3426.1(d).
- (61<del>7</del>67) "Useful life" means the period of time during which a product can be used for itsas intended use, expressed in terms of a single use, number of applications, or days, months, or
- vears of use.
- NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25251, 25252, 25253, and 25257, Health and Safety Code, Section 1060,
- Evidence Code, and Sections 3426 through 3426.11, inclusive, Civil Code.
- § 69501.2. Duty to Comply and Consequences of Non-Compliance.

- (1)(A) 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 if the Department provides notice to the importer under subsection (c)(1). A retailer or assembler is required to comply with the requirements applicable to a responsible entity only if the manufacturer and the importer have failed to comply and the Department notifies provides notice to the retailer or assembler of such non-compliance by posting the information on the Failure to Comply List, under subsection (d)(4)(C).
- (B) Notwithstanding subparagraph (A), the provisions of sections 69505.2 and 69505.3 may only be fulfilled by the manufacturer.
- (C) The Department may not require any responsible entity other than the manufacturer to comply with a regulatory response under sections 69506.6 through 69506.8. However, if the manufacturer fails to comply and the Department provides notice under subparagraph (A), the importer shall cease to place the product into the stream of commerce in California and each retailer and assembler shall cease ordering the product, no later than ninety (90) days after the Department has provided such notice.
- (2) Except for the requirement to submit a notification under sections 69503.6<u>7</u>, 69505.2, or 69503.769505.3, the requirements of this chapter applicable to a responsible entity may be fulfilled by a consortium, trade association, public-private partnership, non-profit organization, or other entity acting on behalf of, or in lieuthe stead of, the responsible entity.
  - (b) ManufacturerRetailer and ImporterAssembler Options.
- (1) Priority Product Removal Notification. A responsible entity that is the manufacturer A retailer or importer of assembler who has received a product notice from the Department under subsection (a)(1)(A) is not responsible for complying with the applicable requirements of this chapter if the manufacturer or importer provides a written 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 be provided no later than the due date for compliance with the requirement. The notice must include all of the following information:
  - (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)(A) Priority Product Replacement Notification. If the manufacturer or importer places a product into the stream of commerce in California that replaces the removed Priority Product, in terms of use and customer bases, 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 provided under 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 must include all of the following information:

1. The manufacturer's or importer's name and contact information;

- 2. 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;
- 3. 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;
- 4. 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;
- 5. 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; and
  - 6. A copy of the notice provided under paragraph (1).
- (B) Subparagraph (A) does not apply to a replacement product that was the selected alternative from an AA conducted under article 5.
  - (c) Retailer Option.

A retailer of a consumer product for which the Department has provided notice under subsection (a)(1), 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 within ninety (90) days after the Department issues the notice; or
  - (2) The retailer <u>or assembler complies</u> with both of the following requirements:
- (A) The retailer or assembler ceases ordering the product no later than ninety (90) days after the Department has provided notice under subsection (a)(1)(A); and
- (B) No later than ninety (90) days after the Department has provided notice under subsection (a)(1)(A), the retailer <u>or assembler</u> submits a <u>Priority-Product Cease Ordering Notification to notifyinforming</u> the Department that <u>itthe retailer or assembler</u> has ceased ordering the product, and provides the following information to the Department:
- 1. The name of, and contact information for, the retailer or assembler, whichever is applicable;
  - 2. The name of, and contact information for, the manufacturer(s) and importer;(s);
- 3. Identification and location of the retailer's sales outlets where the product is sold, supplied, or offered for sale in California; if applicable;
- 4. The name of, and contact information for, the person immediately upstream from the retailer <u>or assembler</u>, as <u>applicable</u>, in the supply chain for the product;
- 5. Information describing the product, including and the brand name(s) and product name(s) under which the retailer placed theretailer's or assembler's product is placed into the

stream of commerce in California; and, and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used:

- 66. The length of time the retailer or assembler estimates will be needed to exhaust the remaining inventory of the Priority Product; and
- <u>7</u>. A statement certifying that the retailer <u>or assembler</u> 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.
  - (dc) 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 importersimporter(s) for the product.
- (B) A notice of non-compliance must include a description of the nature of the non-compliance, the steps necessary to achieve compliance, and the Department's intent to place information concerning the determination of non-compliance on the Failure to Comply List on its website under paragraph (4).
- (2) If the non-compliance has not been remedied to the satisfaction of the Department, within forty-five (45) days after the issuance of the notice of non-compliance, the Department shall post information concerning the determination of non-compliance on the Failure to Comply List on its website-under paragraph (4)... The Department shall post thethis information on the Failure to Comply List not less than forty-five (45) days and not later than ninety (90) days after issuing the notice of non-compliance. The non-compliance is deemed to be remedied when the Department determines either 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 <u>a</u> 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 and the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used;
- (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 productand, if applicable, assemblers on notice under subsection (a)(1)(A) of the failure to comply by the manufacturer(s) and the importer(s), under subsection (a)(1), including identification of the requirement with which the retailer and, if applicable, assembler shall comply and the timeframe for compliance, which willshall be no less than ninety (90) days after the notice is posted on the Department's website;
- (D) The Chemical(s) of Concern <u>and any other Candidate Chemical(s)</u> known to <u>the Department to be present in the product;</u>

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- The name of and, if known, the contact information for the any person(s) listed on the (E) product label as the manufacturer-and the person, if any, listed as the, importer, or distributor;
- The name of, and contact information for, any manufacturer or importer that has been notified noticed by the Department, under paragraph (1);
- The name of, and contact information for, retailers of the productand, if applicable, (G) assemblers known to the Department who have not fully complied with the requirements of subsection (eb); and
  - The date the product is first listed on the Failure to Comply List. (H)
- The Department shall remove a product, and the associated information, from the (5)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.
- The Department shall remove information concerning a retailer or an assembler from the Failure to Comply List if the Department determines that the retailer or assembler has fully complied with subsection (eb).

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

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

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

- Signatures. All information documents required to be submitted to the Department (a) by a responsible entity under thethis 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.
- Format. All information documents 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.
- (c) All Priority Product Removal Notifications, Priority Product Replacement Notifications, Priority Product Cease Ordering Notifications, Alternatives Analysis Threshold Exemption Notifications, Chemical of Concern Removal Notifications, AA Reports, and submissions of information claimed to constitute trade secrets(c) Certification Statement. All documents required to be submitted to the Department under this chapter must include the following certification statement, signed by the owner or an officer of the entity submitting the document, whose responsibilities include product development, product safety, or related responsibilities pertinent to the documents listed in this paragraph, and by the responsible individual in charge of preparing, or overseeing the preparation of, the information:

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"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 violation of law."

- (d) Due Dates. All provisions in this chapter requiring a document to be submitted to the Department within a specified time frame means that the document must be postmarked or submitted electronically by the end date of that time frame.
- (e) <u>Document Retention.</u> 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 <u>the information</u> 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.
- 12 Reference: Sections 25252 and 25253, Health and Safety Code.

#### § 69501.4. Chemical and Product Information.

- (a) (a)(1) Information Gathering.
- (1) 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:
- (4A) Obtain and/or review information in the public domain that is readily available in a usable format, without a subscription or other charge;
- (2B) 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<u>C</u>) Request a responsible entityone or a more product or chemical manufacturer or importermanufacturers, importers, assemblers, and/or retailers to make existing information available to the Department, in accordance with a schedule specified by the Department; and/or
- (4<u>D</u>) Request a <u>responsible entityone</u> or a <u>more product or chemical manufacturer or importer manufacturers, importers, assemblers, and/or retailers</u> to generate new information and provide it to the Department, in accordance with a schedule specified by the Department.
- (2) For purposes of this section, the terms "manufacturer", "importer", "assembler", and "retailer", mean the manufacturer, importer, assembler, and retailer of any product or chemical, not just those products or chemicals subject to the requirements of this chapter Priority

  Products or Candidate Chemicals, except for those products exempted from the definition of "consumer product" specified in Health and Safety Code section 25251.
- (b) <u>Information Requests.</u> The Department may request that information be made available to it under this section by either or both of the following methods:
- (1) Correspondence sent to an individual responsible entity or chemical manufacturer or importerperson electronically or by United States mail; and/or
- (2) Information call-ins that, unless otherwise specified, apply to all responsible entities and/or all chemical-manufacturers-and, importers, assemblers, and retailers, as applicable, of a specific chemical or product or group of chemicals or products. The Department shall post

- (c)(1) Response Status List.
- (1) The Department shall maintain and post on its website a Response Status List. The Response Status List shall be used to provide notice that a responsible entity or a chemical manufacturer or importer, or a person, who has been requested to provide information to the Department under this section, or someone acting on behalf of or in lieuthe stead of that entityperson, has done one of the following:
- (A) Made the information requested under this section available to the Department within the time specified by the Department;
- (B) Failed to make the information requested under this section available to the Department, within by the time periodue date specified by the Department; or
- (C) Demonstrated to the Department's satisfaction that it does not have and is unable to produce the requested information.
- (2) The information posted on the Response Status List shall include identification of the responsible entity or the chemical manufacturer or importer person and the chemical or product that is the subject of the request.
- (3) The Department shall update information on its website upon determining that the responsible entity or the chemical manufacturer or importer, or another person, a person has taken action to change its status under paragraph (1).
- (d) Safer Consumer Products Partner Recognition List. The Department shallmay maintain and post on its website a Safer Consumer Products Partner Recognition List identifying persons that have voluntarily provided the Department with information that advances the quest for safer consumer products. Persons identified on this list shallmay include, but are not limited to, persons that have done-one-or-both of the following:
- (1) Voluntarily completed an <u>alternative</u>alternatives analysis on a consumer product that has not been listed as a Priority Product; and/or
- (2) Voluntarily provided information that is helpful to the Department in implementing this chapter.

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

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

- (a) <u>Website Postings Requiring Noticing.</u> The Department shall post on its website, and update as appropriate, all of the information <del>and documents listed below. The Department shall also provide notice of the availability of these documents and the information, including the availability of updates to the <u>documents and</u> information, to <u>individuals persons</u> on the electronic mailing list(s) that the Department establishes related to this chapter.</del>
  - (1) The Failure to Comply List prepared under section 69501.2(d).
  - (2) Requests for information made under section 69501.4.

- (3)(A) Exemption determinations made under section 69501(b)(3)(A) and the rationale supporting those determinations; and
- (B) Determinations made under section 69501(b)(3)(B) rescinding previously-made exemption determinations and the rationale supporting those rescission determinations.
- (3)(4) <u>Priority Product Work Plans, Pproposed and final Candidate Chemicals of Concern</u> and Priority Products lists and revisions to the lists, supporting rationale and documentation, prepared under sections 69502.3 and 69503.4, copies of all written comments received during the public comment <u>periodperiods</u> for the proposed <u>listlists</u>, and copies of <u>any</u> written responses the Department provides to the comments.
- (4)(5) Petitions designated as complete under section 69504(c), and notices of decision and statements of basis prepared by the Department under section 69504.1(d).
  - (5)(6) A list of <u>due date</u> extension requests approved for submission of AA Reports.
- (6)(7) AA Report notices of <u>public review periods</u>, <u>notices of compliance</u>, notices of deficiency, notices of disapproval, and notices of ongoing review issued under section 69505.6.
- (7)(8) Proposed and final regulatory response determination notices issued by the Department-under section 69505.6(c) and article 6, copies of all written comments received during the public comment period for a proposed notice regulatory response determination, and copies of any written responses the Department provides to the comments.
- (8)(9) A list of regulatory response exemption requests submitted to the Department under section 69506.11, and copies of all notifications notices issued by the Department granting, denying, or rescinding a regulatory response exemption.
- (9)(10) Copies of all disputes and Requests for Review filed with the Department under article 7, and copies of all Department decisions, and notices of ongoing review, issued in response to disputes and Requests for Review.
- (10) A list of accreditation bodies whose designation has been revoked by the Department under section 69508.3(d) or (g), and a list of certified assessors whose certification has been reproved, suspended, place on probation, or revoked under section 69508 (e).
- (b) <u>(b) Additional Website Postings.</u> The Department shall also post on its website, and update as appropriate, all of the following information—and documents:
  - (1) The Response Status List prepared under section 69501.4(c).
- (2) The Any Safer Consumer Products Partner Recognition List prepared under section 69501.4(d).
- (3) As the following information becomes available, the Department shall add it to the Priority Products list, posted the information on the Department's website, 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, and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used;

- (B) Product manufacturer(s) and importers, except for those manufacturers or importers that have complied with the requirements of submitted a timely and compliant Confirmation Notification under section 6950169505.2(b);
- (C) Other responsible entities for the product, except for the responsible entities that have complied with the requirements of section 69501.2(eb);
- (D) The identity of the person that has been identified as being the person that who will fulfill the requirements of article 5, as reflected in the Priority Product Notification;
- (E) The due dates for, and dates of receipt of, each <u>Preliminaryapplicable</u> AA Report and <u>Finaleach Alternate Process</u> AA <u>ReportWork Plan</u>; and
- (F) Lists of, and copies of, all of the following that have been submitted to the Department for each product, including the date of receipt:
  - 1. Priority Product Notifications;
- 2. Alternatives Analysis Threshold Exemption Notifications, and notices notifications submitted to the Department under subsections (c) and (d) of section 69503.669505.3, and notices issued by the Department under section 69503.669505.3(e);
  - 3. Priority 3. Chemical Removal Intent and Confirmation Notifications;
- 4. Product Removal Intent and Confirmation Notifications, and, when applicable, the associated Priority:
  - Product-Chemical Replacement Notifications;
  - 4. Chemical of Concern RemovalIntent and Confirmation Notifications; and
- 5. Priority 6. Product Cease Ordering Notifications submitted to the Department under section 69501.2(b)(2).
  - (4) Guidance documents prepared by the Department under section 69505(a).
  - (5) AAs made available by the Department under section 69505(b).
- (6) A list of all Preliminary AA Reports, Final AA Reports, Abridged AA Reports, and Alternate Process AA Work Plans, and AA Progress Reports that have been submitted to the Department under article 5, the executive summary for each document, the date of receipt, and a full or redacted copy of each document, including both the originally submitted document and the document approved by the Department, if different.
- (7) Copies of all written public comments submitted to the Department under section 69505.8, and identification of those issues that the Department determines must be addressed in an AA Report Addendum.
- (7)(8) A list, and copies, of all notifications notices issued by the Department, and all documents submitted to the Department, under section 69506.65.
- (8)(9) Copies of, or links to, product stewardship plans, substitute end-of-life management programs, exemptions from end-of-life management program requirements, and copies of annual end-of-life management program reports.
- (9)(10) The Regulatory response notifications submitted to the Department under subsections (a) and (c) of section 69506.10, and the Regulatory Response Summary prepared and updated by the Department under section 69506.1210(d).
- (10) A list of entities that have been designated as accreditation bodies under section 69508.3, and a list of certified assessors who have been accredited under section 69508. The

- Department shall update these lists whenever an accreditation body's designation is revoked, or an assessor's certification is reproved, suspended, placed on probation, or revoked.
  - (11(10)(11) Findings of audits conducted by the Department under section 6950969508.
  - (c) <u>Website Posting Date.</u> All-documents and information posted on the Department's website under this chapter must include the date the document or information is first posted and the date(s) of any revised postings.

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

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# 12 Article 2. <u>Process for Identifying Candidate</u> Chemicals-of Concern Identification 13 Process

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#### § 69502. General.

- (a) This article identifies <u>Candidate</u> Chemicals <u>that can be considered under article 3 for designation as a Chemical of Concern</u>, and specifies the process by which the Department may identify additional Candidate Chemicals <u>of Concern</u>.
- (b) \_\_\_. The Department may use, but is not limited to using, information obtained and/or reviewed under section 69501.4 to perform its duties under this article.

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

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#### § 69502.1. Applicability.

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

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

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#### § 69502.2. Candidate Chemicals of Concern-Identification.

- (a) InitialCandidate Chemicals of Concern-List. As of the effective date of these regulations, a chemical is identified as a Candidate Chemical of Concern, if it exhibits a hazard trait and/or an environmental or toxicological endpoint, and meets one or both of the following criteria:
- (1) The chemical is one or more of the following types of chemicals that are identified as exhibiting a hazard trait or an environmental or toxicological endpoint(1) The chemical is on one or more of the lists specified below:

- (A) Chemicals known to cause cancer and/or reproductive toxicity that are listed under Health and Safety Code section 25249.8 of the California Safe Drinking Water and Toxic Enforcement Act of 1986;
- (B) Category Chemicals classified by the European Commission as carcinogens, mutagens, and/or reproductive toxicants Categories 1A and 1B chemicals identified in the European Union in Annex VI to Regulation (European Commission EC) 1272/2008 Annex VI due to carcinogenicity, reproductive toxicity, and/or mutagenicity;
- (C) Category 1 Chemicals included as Category 1 endocrine disruptors by the European Commission identified in the in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation (European Commission EC DG Env report, Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption, M0355008/1786Q/10/11/00) 1907/2006;
- (D) Chemicals for which a reference dose or reference concentration has been developed based on neurotoxicity in the United States Environmental Protection Agency's Integrated Risk Information System;
- (E) Chemicals that are identified as "carcinogenic to humans", "likely to be carcinogenic to humans", or <u>GroupGroups</u> A, B1, or B2 carcinogens in the United States Environmental Protection Agency's Integrated Risk Information System;
- (F) Chemicals that are identified as "known to be" or "reasonably anticipated to be" a human carcinogen in the 12th Report on Carcinogens, United States Department of Health and Human Services, Public Health Service, National Toxicology Program;
- (G) Chemicals that are identified as High Production Volume Persistent Bioaccumulating Toxins by the European Union;
- (G) Chemicals included as persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative by the European Commission in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation (European Commission EC) 1907/2006;
- (H) Chemicals that are identified as Persistent, Bioaccumulative, and Inherently Toxic to the environment by the Canadian Environmental Protection Act Environmental Registry Domestic Substances List;
- (I) Chemicals classified by the European Commission as respiratory sensitizers Category 1 in Annex VI to Regulation (European Commission EC) 1272/2008;
- (<u>J</u>) Groups 1, 2A, and 2B carcinogens identified by the International Agency for Research on Cancer;
- (J<u>K</u>) Neurotoxicants that are identified in the Agency for Toxic Substances and Disease Registry's Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, Nervous System;
- (<u>KL</u>) Persistent Bioaccumulative and Toxic Priority Chemicals that are identified by the United States Environmental Protection Agency's National Waste Minimization Program;
- (<u>LM</u>) Reproductive or developmental toxicants identified in Monographs on the Potential Human Reproductive and Developmental Effects, National Toxicology Program, Office of Health Assessment and Translation;

- (MN) United States Environmental Protection Agency's Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals that are subject to reporting under the Emergency Planning and Community Right-to-Know Act section 313; and/or
- (NO) Washington Department of Ecology's Persistent, Bioaccumulative, Toxic Chemicals identified in the Washington Administrative Code, title 173, chapter 173-333.
  - (2) The chemical is one or more of the following types of chemicals:
- (A) Chemicals for which Notification Levels, as defined in Health and Safety Code section 116455, have been established by the California Department of Public Health;
- (B) Chemicals for which primary Maximum Contaminant Levels have been established and adopted under <u>sections</u> 64431 or <u>section</u> 64444 of chapter 15 of <u>Titletitle</u> 22 of the California Code of Regulations;
- (C) Chemicals that are air pollutants that may contribute to or cause an increase in mortality or an increase in serious illness or which may pose a present or potential hazard to human health, and are identified as Toxic Air Contaminants under sections 93000 and 93001 of Titletitle 17 of the California Code of Regulations;
- (D) Chemicals that are identified as priority toxic pollutants in the California Water Quality Control Plans under section 303(c) of the federal Clean Water Act and in section 131.38 of Titletitle 40 of the Code of Federal Regulations, or identified as pollutants by California or the United States Environmental Protection Agency for one or more water bodies in California pursuant tounder section 303(d) of the federal Clean Water Act and section 130.7 of title 40 of the Code of Federal Regulations;
- (E) Chemicals that are identified with non-cancer endpoints and listed with an inhalation or oral Reference Exposure Level by the California Office of Environmental Health Hazard Assessment under Health and Safety Code section 44360(b)(2);
- (F) Priority Chemicals that are identified under the California Environmental Contaminant Biomonitoring Program;
- (G) Chemicals that are identified on the Centers for Disease Control and Prevention's Fourth National Report on Human Exposure to Environmental Chemicals and Updated Tables; and/or
- (H) Chemicals that are identified on Part A of the list of Chemicals for Priority Action, Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic.
- (b) Additions to the <u>Candidate</u> Chemicals <u>of Concern</u> List. In addition to the chemicals identified as <u>Candidate</u> Chemicals <u>of Concern</u> under subsection (a), the Department may identify <u>as Candidate Chemicals those</u> chemicals, <u>which</u> that exhibit one or more hazard traits <u>and/</u>or environmental or toxicological endpoints, <u>as Chemicals of Concern</u> by considering the following factors for which reliable information is available:
  - (1) Adverse Impacts.
- (A) The ability of the Department shall evaluate the potential for the chemical to contribute to or cause adverse public health and/or environmental impacts, considering reliable information relevant toone or more of the following factors:
  - 1. The chemical's hazard trait(s) and/or environmental or toxicological endpoint(s);

- The chemical's aggregate effects;
- 2 3. The chemical's cumulative effects with other chemicals with <u>the same or similar</u> 3 hazard trait(s) and/or environmental or toxicological endpoint(s);
  - 4. The chemical's physical chemical hazards;
  - 5. The chemical's physicochemical properties;
  - 65. The chemical's environmental fate;
  - 76. The human populations, and/or aquatic, avian, or terrestrial animal or plant organisms that would be adversely impacted; and for which the Candidate Chemical(s) has/have the potential to contribute to or cause adverse impacts; and/or
  - 87. The chemical's abilitypotential for the chemical to degrade, form reaction products, or metabolize into another <u>Candidate</u> Chemical of <u>Concern</u> or a chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints.
  - (B) Based on reliable information, the The Department shall give special consideration to the ability of potential for the chemical to contribute to or cause adverse impacts for the following:
    - 1. Sensitive subpopulations;
    - 2. Environmentally sensitive habitats;
  - 3. Endangered and threatened species; and listed by the California Department of Fish and Wildlife; and
  - 4. Environments in California that have been designated as impaired by a California State or federal regulatory agency.
  - (C) Based on reliable information, the The Department shall also give special consideration to the ability of potential for the chemical to contribute to or cause widespread adverse public health and/impacts.
  - (D) The Department may also evaluate and consider, based on reliable information, structurally or environmental impactsmechanistically similar chemicals for which there is a known toxicity profile.
  - (2) Exposures. The Department shall consider <u>potential</u> exposures to the chemical, <del>considering reliablebased on both of the following:</del>
    - (A) Reliable information regarding potential exposures to the chemical; and reliable
  - (B) Reliable information demonstrating the occurrence, or potential occurrence, of exposures to the chemical.
  - (3) Availability of Information. The Department shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts and potential exposures. In evaluating the quality of the available information, the Department shall consider, as applicable, the factors specified in section 69503.2(b)(1)(C).
  - (3) Availability of Information. The Department shall consider the extent of reliable information that is available to substantiate adverse impacts and exposures. All other factors being equal, a chemical for which there is a greater amount of reliable information to substantiate adverse impacts and exposures, relative to other chemicals being evaluated, shall be given higher priority for purposes of this subsection.

(4) Safer Alternatives. In addition to the factors specified in paragraphs (1) through (3), the Department may consider the availability of a safer alternative chemical that is functionally acceptable for one or more common uses of the chemical in consumer products in determining whether to list the chemical as a Chemical of Concern.

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

#### § 69502.3. <u>Candidate Chemicals of Concern List.</u>

- (a) <u>Informational List.</u> The Department shall post an informational list of the chemicals identified as <u>Candidate</u> Chemicals of <u>Concern</u> under section 69502.2(a) 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 subsections (c) and (d).
- (b) Revisions to the List. The Department may make additions to, or deletions from, the Candidate Chemicals of Concern list using the factors specified in section 69502.2(b) and the procedures specified in subsections (c) and (d).
- (c) <u>Public Notice of Proposed List Revisions.</u> The Department shall make proposed revisions to the <u>Candidate</u> Chemicals <u>of Concern</u> list available on its website for public review and comment, along with supporting documentation, including the Department's rationale and a bibliography of the supporting information and information sources, prior to finalizing the revisions to the <u>Candidate</u> Chemicals <u>of Concern</u> list. The Department shall hold one or more public workshop(s) to provide an opportunity for <u>oral</u> comment on the proposed revisions to the list. The Department shall send to <u>individualspersons</u> on the electronic mailing list(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 <u>all of the following</u>:
- (1) The last day for the public to submit written comments on the proposed revisions to the <u>Candidate</u> Chemicals <u>of Concern</u>-list. The last day for submission of public comments shall be no sooner than forty-five (45) days from the date the <u>notice of availability</u> of the proposed revisions <u>is posted on the Department's website or the date the notice</u> is sent to <u>individualspersons</u> on the electronic mailing list(s) that the Department establishes related to this chapter, <u>and posted onwhichever is</u> the <u>Department's website; later date.</u>
  - (2) The method(s) for submitting comments to the Department; and .
  - (3) The date, time, and location of the public workshop(s).
- (d) <u>Website Posting of Final List Revisions.</u> The Department shall post the final revisions to the <u>Candidate</u> Chemicals of <u>Concern</u> list on its website after review of public comments. The Department may respond to some or all public comments received.

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

# Article 3. Chemicals of ConcernProcess for Identifying and ConsumerPrioritizing Product-Prioritization Process-Chemical Combinations

#### § 69503. General.

- (a) This article specifies the process by which the Department shall evaluate identify and prioritize products containing Candidate Chemicals of Concern.
- (b) \_\_\_\_. The Department may use, but is not limited to using, information obtained and/or reviewed under section 69501.4 to perform its duties under this article.

- NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
- 11 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 <u>Candidate</u> Chemicals of <del>Concern,</del> and that are placed into the stream of commerce in California.

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

# § 69503.2. Priority Products Product-Chemical Identification and Prioritization Factors.

- (a) ProductKey Prioritization Factors. Principles. Any product-chemical combination identified and listed as a Priority Product must meet both of the following criteria:
- (1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
- (2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.
- (b) Identification and Prioritization Process. The Department may evaluate products identify and list as a Priority Product one or more product-chemical combinations that it determines to be of high priority. The Department's decision to identify and list a product-chemical combination as a Priority Product shall be based on an evaluation of the product-chemical combination to determine the its associated potential adverse impacts—and, potential exposures—associated with the product, and potential adverse waste and end-of-life effects by considering the factors listed described in paragraphs (1) through (3and (2) for which information is reasonably available. Based on this evaluation the The Department may identify and list as a Priority Product, consistent with the provisions of subsection (b) and the processes specified in sections 69503.3 and 69503.4, one or more products that it determines to be of high priority-additionally, in its discretion, consider paragraph (3).
- (1)(A) Adverse Impacts and Exposures. The Department shall consider begin the adverse public health and environmental product-chemical combination evaluation process by evaluating the potential adverse impacts posed by the Candidate Chemical(s) of Concern in

a<u>the</u> product due to <u>potential</u> exposures during the life cycle of the product. The <u>Department's</u>
 evaluation of <u>potential</u> adverse impacts and <u>potential</u> exposures <del>must consider both of the</del>
 following:

- (A) Adverse Impacts Associated with the Chemical(s) of Concern.
- 1. The abilityshall include consideration of one or more of the Chemical(s) of Concern in-factors listed in section 69503.3(a) and one or more of the factors listed in section 69503.3(b). The listing of a product-chemical combination as a Priority Product shall be based on one or more of the factors listed in section 69503.3(a) and one or more of the factors listed in section 69503.3(b), in addition to the other factors specified in this section.
- (B) Adverse Waste and End-of-Life Effects. The Department may also consider product uses, or discharges or disposals, in any manner that have the potential to contribute to or cause adverse public health and/or environmental impacts, considering reliable waste and end-of-life effects associated with the Candidate Chemical(s) in the product.
- (C) Availability of Information. The Department shall consider the extent and quality of information relevant to the following factors: that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. In evaluating the quality of the available information the Department shall consider, as applicable:
- 1. The level of rigor attendant to the generation of the information, including, when relevant, the use of quality controls;
- 2. The degree to which the information has been independently reviewed by qualified disinterested parties;
- 3. The degree to which the information has been independently confirmed, corroborated, or replicated;
- 4. The credentials and education and experience qualifications of the person(s) who prepared and/or reviewed the information; and
- 5. The degree to which the information is relevant for the purpose for which it is being considered by the Department.
- a. The Chemical(s) of Concern's(2) Other Regulatory Programs. The Department shall next consider the scope of other California State and federal laws and applicable treaties or international agreements with the force of domestic law under which the product or the Candidate Chemical(s) 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 potential adverse impacts and potential exposure pathways, and adverse waste and end-of-life effects, that are under consideration as a basis for the product-chemical combination being listed as a Priority Product. If a product is regulated by another entity with respect to the same potential adverse impacts and potential exposure pathways, and potential adverse waste and end-of-life effects, the Department may list such a product-chemical combination as a Priority Product only if it determines that the listing would meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts, and/or exposure pathways, and/or adverse waste and end-of-life effects that are the basis for the listing.
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#### § 69503.3. Adverse Impact and Exposure Factors.

- (a) Adverse Impacts.
- (1) In evaluating a product-chemical combination for possible listing as a Priority
  Product, the Department shall evaluate the potential for the Candidate Chemical(s) to
  contribute to or cause adverse impacts, by considering one or more of the following factors for
  which information is reasonably available:
- (A) The Candidate Chemical(s)' hazard trait(s) and/or environmental and or toxicological endpoint(s);
  - b.(B) The Candidate Chemical(s) of Concern's aggregate effects;
- e.(C) The <u>Candidate Chemical(s) of Concern's'</u> cumulative effects with other chemicals with the same or similar hazard trait(s) and/or environmental or toxicological endpoint(s);
  - d.(D) The Candidate Chemical(s) of Concern's physical chemical hazards;
  - e. The Chemical(s) of Concern's physicochemical properties;
  - f.(E) The Candidate Chemical(s)-of Concern's' environmental fate;
- g.(F) The human populations, and/or aquatic, avian, or terrestrial animal or plant organisms for which the <u>Candidate</u> Chemical(s) of <u>Concern</u>-has/have the <u>abilitypotential</u> to contribute to or cause adverse impacts; and/or
- h.(G) The potential for the Candidate Chemical(s) of Concern's ability to degrade, form reaction products, or metabolize into another Candidate Chemical of Concern or a chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints.
- (2. Based on reliable information, the ) The Department shall give special consideration to the ability of potential for the Candidate Chemical(s) of Concern in the product to contribute to or cause adverse impacts for the following:
  - a.(A) Sensitive subpopulations;
  - b.(B) Environmentally sensitive habitats;
- e-(C) Endangered and threatened species listed by the California Department of Fish and GameWildlife; and
- d.(D) Environments in California that have been designated as impaired by a <u>California</u> State or federal regulatory agency.
- (3. Based) The Department may also evaluate and consider, based on reliable information, the Department shall also give special consideration to the ability of the Chemical(s) of Concern in the product to contribute to or cause widespread adverse public health and/or environmental impacts associated with structurally or mechanistically similar chemicals for which there is a known toxicity profile.

- (Bb) Exposures. Exposures In evaluating a product-chemical combination for possible listing as a Priority Product, the Department shall evaluate the potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure(s) to the Candidate Chemical(s) of Concern in the product, by considering one or more of the following factors for which information is reasonably available:
  - (1.) Market presence information forof the product, including all of the following:
  - a.(A) Statewide sales by volume;
  - b.(B) Statewide sales by number of units; and/or
  - e.(C) Intended product use(s), and types and age groups of targeted customer base(s).
- (2. Reliable information regarding public and/) The occurrence, or aquatic, avian, or terrestrial animal or plant organism potential occurrence, of exposures to the Candidate Chemical(s) of Concern in the product, and reliable information demonstrating the occurrence of exposures to the Chemical(s) of Concern in the product.
- (3. Information concerning the) The household and workplace presence of the product, and other products containing the same Candidate Chemical(s) of Concern-that is/are the basis for considering the listing of the product-chemical combination as a Priority Product, 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.
- (4. Public and/or aquatic, avian, or terrestrial animal or plant organism) Potential exposures to the <u>Candidate</u> Chemical(s) of <u>Concern</u> in the product during the product's life cycle, considering:
- <del>a.</del>(A) Manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices;
- b. The types of uses that would contribute to or result in public exposure to the Chemical(s) of Concern in the product, considering:
- i(B) Whether the product is manufactured or stored in, or transported through, California solely for use outside of California;
- (C) Whether the product 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;
  - (D) The following types of uses:
  - 1. Household and recreational use;
- <u>ii2</u>. Sensitive subpopulation <u>potential</u> use of, or exposure to, the product-<u>at locations</u> frequented by members of sensitive subpopulations; and/or
- iii <u>3</u>. 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, workplacehomes, schools, workplaces, or other locations;
- e.(E) Frequency, extent, level, and duration of <u>potential</u> exposure for each use scenario and end-of-life scenario;
- d.(F) Containment of the <u>Candidate Chemical(s)</u> of <u>Concern</u> within the product, <u>including</u> potential accessibility to the <u>Candidate Chemical(s)</u> during the useful life of the product and the potential for releases of the <u>Candidate Chemical(s)</u> during the useful life and at the end-of-life;

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associated with the product; and/or

f.(H) The ability of potential for the Candidate Chemical(s) of Concern or its/their degradation products to be released into, migrate from, or distribute across environmental media, and the ability of potential for the Candidate Chemical(s) of Concern or its/their degradation products to accumulate and persist in biological and/or environmental compartments or systems.

e.(G) Engineering and administrative controls; and that reduce exposure concerns

- 5. Product uses, or discharges or disposals, in any manner that would contribute to or cause adverse waste and end-of-life impacts.
- (2) Availability of Information. The Department shall consider the extent of information that is available to substantiate adverse impacts and exposures. All other factors being equal, a product for which there is a greater amount of information to substantiate adverse impacts and exposures, relative to other products being evaluated, shall be given a higher priority for purposes of this subsection.
- (3) Other Regulatory Programs. The Department shall consider the scope of other California and federal laws, and international agreements with the force of domestic law, 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 basis for the product being listed as a Priority Product.
- (b) Key Prioritization Factors. The Department shall, based on available information, give priority to products meeting both of the following criteria:
- (1) The Chemical(s) of Concern in the product have a significant ability to contribute to or cause adverse public health and environmental impacts; and
- (2) There is a significant ability for the public and/or aquatic, avian, or terrestrial animal or plant organisms to be exposed to the Chemical(s) of Concern in the product in quantities that would contribute to or cause adverse public health or environmental impacts, which may include consideration of how widely the product is distributed in commerce and how widely the product is used by consumers.

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. Process to Evaluate Products Using the Prioritization Factors.

- (a) Adverse Impacts and Exposures and Availability of Information. The Department shall begin the product evaluation and identification process, specified in section 69503.2, by using available information to consider and evaluate the adverse impact and exposure factors specified in section 69503.2(a)(1), along with the extent of available information as specified in section 69503.2(a)(2).
- (b) Other Regulatory Programs. Having considered the adverse impacts and the exposure pathways associated with the product and its Chemical(s) of Concern, the Department shall then, in accordance with section 69503.2(a)(3), assess whether any of these

- adverse impacts and/or exposures pathways are adequately addressed by other California and federal laws, and international agreements with the force of domestic law. This assessment shall be based upon available information. If a product is regulated or is subject to pending regulation by another entity, with respect to one or more adverse impacts or exposure pathways, the Department shall adjust the prioritization of the product based on whether listing the product as a Priority Product would meaningfully enhance protection of public health and/or the environment with respect to the adverse impacts and/or exposure pathways associated with the product.
- (c) Priority Products. The Department may list as a Priority Product one or more products determined to be of high priority after completion of the steps specified in subsections (a) and (b).
- (d) Safer Alternative. The Department may, at its discretion, consider whether there is a readily available safer alternative, that is functionally acceptable and technically and economically feasible, to further adjust the prioritization prior to listing a product as a Priority Product.
- (e) Key Prioritization Factors. Prior to issuing the proposed and final Priority Products lists, the Department shall review and evaluate the list for consistency with the key prioritization factors specified in section 69503.2(b), and make adjustments as needed.

# § 69503.4. Priority Product Work Plan.

- (f)(a) Initial Work Plan. Within one (1) year after the effective date of these regulations. No later than January 1, 2014, the Department shall issue a Priority Product Work Plan that, except as provided in section 69503.6, identifies and describes the product categories that the Department will evaluate to identify productsproduct-chemical combinations to be added to the Priority Products list during the next-three (3) years, following the issuance of the work plan. The work plan must include a general explanation of the decision to select the identified product categories for evaluation during the life of the work plan.
- (1) Subsequent to the issuance of the work plan, the Department may revise the work plan to include one or more additional product categories if necessitated by any of the following:
- (A) The Department is required by statute to take action on a particular chemical or product, or both, prior to the expiration of the work plan;
- (B) The Department is required by a Governor's Executive Order to take action on a particular chemical or product, or both, prior to the expiration of the work plan; and/or
  - (C) The Department grants a petition under section 69504.1.
- (2) (b) Subsequent Work Plans. Subsequent work plans shall be issued by the Department no later than one (1) year before the three-year expiration date of the current work plan, and shall become effective upon expiration of the current work plan.
- (3) (c) Revisions to Work Plans. The Department may revise an adopted work plan to include one or more additional product categories if necessitated by either of the following:
- (1) The Department is legally required to take action on a particular chemical or product, or both, prior to the expiration of the work plan; and/or

- (2) The Department grants a petition under section 69504.1.
- (d) Public Input. Prior to issuing each work plan, the Department shall hold one or more public workshop(s) to provide an opportunity for oral comment.
- (4) <u>e) Public Notice.</u> The Department shall send to <u>individuals persons</u> on the electronic mailing list(s) that the Department establishes related to this chapter, and post on its website, a notice of the availability of each work plan, and each revised work plan.
  - (5) This subsection does not apply to the adoption of the initial list of Priority Products.
- (g) Initial Priority Products List(s). Prior to January 1, 2016, the Department may list a product as a Priority Product only if the product is being listed on the basis of one or more Chemical(s) of Concern in the product that meet both of the following criteria:
- (1) The chemical meets one or more of the criteria specified in subsection (a)(1) of section 69502.2; and
- (2) The chemical meets one or more of the criteria specified in subsection (a)(2) of section 69502.2.

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

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

#### § 69503.45. Priority Products List.

(a)() Listing Process.

- (1) The Department shall use the procedures specified in this section and the factors identification and prioritization criteria and process specified in sections 69503.2 and 69503.3 to identify and list products product-chemical combinations as Priority Products.
- (2) The Priority Products list shall be established and updated through rulemaking pursuant tounder the Administrative Procedure Act (commencing with Government Code section 11340). Except as provided in section 69503.6, the Department shall hold one or more public workshop(s) to provide an opportunity for comment on candidate product-chemical combinations prior to issuing a proposed Priority Products list.
- (b) <u>List Contents.</u> The Department shall specify in the proposed and final Priority Products lists the following for each listed product<u>-chemical combination</u>:
- (A) The Chemical(s) of Concern and the hazard trait(s) (1)(A) A description of the product-chemical combination that is sufficient for a responsible entity to determine whether one or more of its products is a Priority Product.
- (B) If the product-chemical combination is a component of one or more assembled products, a description of the known assembled product(s) in which the component is used shall be included.
- (2)(A) The Candidate Chemical(s) that is/are the basis for the product being listed as a Priority Product and the hazard traits and/or environmental or toxicological endpoints known to be associated with those chemicals.
- (B)1. If applicable, the component(s) and/or homogeneous material(s) within a component, to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the AA.

- 2. For each Priority Product that is a highly durable product, the Department shall in all cases specify the number of component(s) and/or homogeneous material(s) within a component to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the (B) For purposes of this chapter, a Candidate Chemical that is the basis for a product-chemical combination being listed as a Priority Product, as specified under paragraph (2)(A), is designated as a Chemical of Concern for that product. All references in this chapter to the Chemical(s) of Concern in an alternative product that is under consideration or is selected to replace a Priority Product mean the chemical(s) that is/are the Chemical(s) of Concern for that Priority Product.
  - (3) The due date for submission of the Preliminary AA Report required under article 5. The due date for the Preliminary AA. For each Report shall be 180 days after the date the product is listed highlyon the final Priority Products list, unless the Department specifies otherwise in the Priority Products list.
  - (c) Alternatives Analysis Threshold. The Department may, for one or more product-chemical combinations, specify in the proposed and/or final Priority Products list an Alternatives Analysis Threshold concentration for any Chemical of Concern that is an intentionally added ingredient. The Department may also specify an Alternatives Analysis Threshold concentration greater than the applicable PQL for any Chemical of Concern that is a contaminant.
    - (e)(d) Complex Durable Products.
  - (1) For a complex durable product, the Department shall specify nomay not list as Priority Products more than ten (10) components and/or homogenous materials percontained in that product everyin a three (3) years-year period.
  - 3.(2) For purposes of subparagraph 2., "highlyparagraph (1), "complex durable product" means a product that meets all of the following criteria:
    - a.(A) The product is assembled from 100 or more manufactured components;
  - b.(B) Manufacturers of the product routinely prepare information intended to be provided to consumers that indicates that the product has a useful life, or an average useful life, of five (5) or more years; and
    - e.(C) The product is typically not consumed, destroyed, or discarded after a single use.
  - 4. Subparagraph 2.(3) Paragraph (1) does not apply to either of the following types of products:
  - a-(A) Products designed or intended primarily for children twelve (12) years of age or younger, as determined by information made available to consumers or as determined by whether the product is commonly recognized by consumers as being primarily intended for use by a child twelve (12) years of age or younger; or
  - b.(B) Products intended to be worn or placed on the human body, dispersed as an aerosol or vapor, or applied.
    - (d)(e) Revisions to hard surfaces with the likelihood of runoff or volatilization.
  - (C) The due date for submission of the Preliminary AA Report, required under article 5. The due date for the Preliminary AA Report shall be 180 days after the date the product is

- (b) The Department shall hold one or more public workshop(s) to provide an opportunity for oral comment on candidate products being considered for the proposed Priority Products list. 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 rationale and a bibliography of the supporting 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 send to individuals on the electronic mailing list(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 all of the following:
- (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 no sooner than fortyfive (45) days from the date the availability of the proposed list is sent to individuals on the
  electronic mailing list(s) that the Department establishes related to this chapter, and posted on
  the Department's website;
  - (2) The method(s) for submitting comments to the Department; and
  - (3) The date, time, and location of the public workshop(s).
- (c) Comments submitted under subsection (b) on the proposed Priority Products list may also include recommendations, with supporting rationale and information, pertaining to an alternatives analysis threshold for one or more proposed Priority Products. Comments submitted under this subsection shall be considered by the Department in making its determination under section 69503.5(c).
- (d) The Department shall post the final Priority Products list on its website after review of public comments. The final Priority Products list shall include the alternatives analysis threshold for each Priority Product. The Department may respond to some or all public comments received.
- (e) The Department shall make the initial proposed list of Priority Products available for public review and comment under subsection (b) no later than 180 days after the effective date of these regulations. The initial list of Priority Products shall include no more than five (5) Priority Products.
- (f) Priority Products List. 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.
- (g) e)(f) Priority Product Notifications to the Department. EachAs specified in section 69503.7(a), the responsible entity for a product-chemical combination listed on the Priority Products list shall provide to the Department one of a Priority Product Notification to the following notifications Department within sixty (60) days after the product-chemical combination is listed as a Priority Product, or sixty (60) days after the product-chemical combination is first placed into the stream of commerce in California, whichever is later:

- 1 (1) Priority Product Notification, as specified, unless the Department specifies a later due date in section 69503.7;
  - (2) Alternatives Analysis Threshold Exemption Notification, as specified in section 69503.6;
  - (3) the Priority Product Removal Notification and, if Products list. If applicable, a Priority Product Replacement Notification, as specified the responsible entity may concurrently submit a notification under section 69505.2 or section 69505.3, or such notification may be submitted at a later date as provided in section 6950169505.2(b); or section 69505.3.
    - (4) Chemical of Concern Removal Notification, as specified in section 69505.1(g).

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

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

# § 69503.<del>5. Alternatives Analysis Threshold Exemption</del><u>6. Initial Priority Products</u> List.

- (a) A responsible entity is exempt from The following provisions apply only to the requirements initial list of article 5 with respect to Priority Products:
- (a) Scope of Candidate Chemicals. In the initial list of Priority Products, the Department may list a product that is listed as a Priority Product and that meets the only if one or more Candidate Chemical(s) that is/are the basis for listing the product meet one or more of the criteria for an alternatives analysis threshold exemption specified in subsection (b), if one of the responsible entities for the product submits a complete and timely Alternatives Analysis Threshold Exemption Notification to the Department under (1) of section 69503.6, unless 69502.2 and one or more of the criteria specified in subsection (d) or (ea)(2) of section 69503.669502.2. This subsection also applies—to any revisions to Priority Products list adopted prior to January 1, 2016.
- (b) To be eligible for an alternatives analysis threshold exemption, the concentration in the product, or in each component or homogeneous material identified under section 69503.4(a)(2)(B), whichever is applicable, of each Chemical of Concern that is/are the basis for the product being listed as a Priority Product must not exceed the applicable alternatives analysis threshold specified under subsection (c). If subsection (d) applies, the total concentration of all Chemicals of Concern to which the alternatives analysis threshold applies must not exceed that threshold. This condition must be met 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.
- (c) The Department shall specify an alternatives analysis threshold for each Chemical of Concern that is a basis for the product being listed as a Priority Product. In establishing an alternatives analysis threshold, the Department shall, except as provided in paragraph (3), take into consideration, based on available reliable information, the factors specified in paragraph (1), if relevant, and paragraph (2):

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- (1) The ease or difficulty of removing from the product, or otherwise avoiding the presence in the product of, the Chemical of Concern, if the source(s) of the Chemical of Concern is/are one or more 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; and/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)(A) The minimum concentration of the Chemical of Concern that can be detected with available laboratory analytical methodology.
- (B) The Department shall not specify an alternatives analysis threshold that is lower than the minimum detectable concentration for the Chemical of Concern.
- (3) Notwithstanding paragraphs (1) and (2)(A), the Department may specify an alternatives analysis threshold based on reliable information showing that the specified threshold will protect public health and/or the environment. In doing so, the Department shall consider the following factors that are relevant:
  - (A) The inherent potency of the Chemical of Concern;
  - (B) The ability of the Chemical of Concern to bioaccumulate;
  - (C) The unintended presence of the Chemical of Concern in organs, tissues, or fluids;
  - (D) The presence or absence of a threshold dose-response;
- (E) The ability of the Chemical of Concern to contribute to or cause disproportionate adverse impacts on sensitive subpopulations and/or environmentally sensitive habitats;
- (F) The degree to which the severity of adverse impacts associated with the Chemical of Concern is affected by aggregate exposures to the Chemical of Concern, if the Chemical of Concern is found in multiple common and frequently used products;
- (G) The degree to which the severity of adverse impacts associated with the Chemical of Concern is affected by cumulative exposures to other Chemicals of Concern that are the basis for the product being listed as a Priority Product and that exhibit the same hazard trait and/or environmental or toxicological endpoint(s); and/or
  - (H) Any relevant regulatory action threshold established by a government agency.
- (d) If multiple Chemicals of Concern that exhibit the same hazard trait and/or environmental or toxicological endpoint(s) are identified as the basis for the product being listed as a Priority Product, the Department may specify a single alternatives analysis threshold under subsection (c) that applies to the total concentration in the Priority Product of all such Chemicals of Concern.
- (e) The Department may lower or raise a previously established alternatives analysis threshold based on new, or newly considered, information.

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

#### § 69503.6. Alternatives Analysis Threshold Exemption Notifications.

- (a) A responsible entity claiming an alternatives analysis threshold exemption shall submit an Alternatives Analysis Threshold Exemption Notification, as required under section 69503.5(a), 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) The name of, and contact information for, the person submitting the Alternatives Analysis Threshold Exemption Notification.
  - (2) The name of, and contact information for, the manufacturer and importer(s).
- (3) The 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) The maximum concentration at which the Chemical(s) of Concern is/are present in the product, or in each component or homogeneous material, whichever is applicable, and a listing and description of all information used to determine and substantiate this concentration. The description must include the maximum concentration 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.
- (6) 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.
- (7) 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 product, or in each component or homogeneous material, whichever is applicable, does not exceed the applicable alternatives analysis threshold.
- (c) The responsible entity shall submit to the Department a revised Alternative Analysis Threshold Exemption Notification, if any of the information listed in subsection (a) significantly changes. A revised Alternatives Analysis Threshold Exemption Notification must be submitted to the Department within thirty (30) days of the change.
- (d) If the product no longer meets the criteria for an Alternatives Analysis Threshold exemption specified in section 69503.5, 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, unless the responsible entity submits a Priority Product Removal Notification or Chemical of Concern Removal Notification within sixty (60) days of the change.
- (e) The exemption provided under section 69503.5(a) does not apply if the Department determines, and notifies the person who submitted the Alternatives Analysis Threshold

- Exemption Notification, that the information or findings contained in the notification are inaccurate, invalid, or inadequate to support a alternatives analysis threshold exemption.
  - (b) Size of the List. The initial final list of Priority Products shall include no more than five (5) Priority Products. The list may identify more than one Chemical of Concern for each listed product.
  - (c) Initial Proposed Priority Products List. The Department shall make the initial proposed list of Priority Products available for public review and comment under section 69503.5 no later than 180 days after the effective date of these regulations.
    - (d) Procedural Exceptions.
  - (1) Priority Product Work Plan. Section 69503.4 does not apply to the adoption of the initial list of Priority Products.
  - (2) Workshops. The provisions of section 69503.5(a)(2) requiring the Department to hold one or more public workshop(s) prior to issuing the proposed Priority Products list do not apply to the initial list of Priority Products.

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

#### § 69503.7. Priority Product Notifications.

- (a) Notifications to the Department. Within sixty (60) days after a product-chemical combination is listed as a Priority Product, unless the Department specifies a later due date in the Priority Products list, each the responsible entity for such a Priority Product shall notify the Department that its product-chemical combination is a Priority Product, unless the responsible entity has submitted an alternate notification to the Department under section 69503.4 (g)(2) through (g)(4). For a Priority Product that is first manufactured or first placed into the stream of commerce in California after the date of the product is listed as a Priority Product listing, the responsible entity shall provide the Priority Product, or an alternate, notification Notification within sixty (60) days after the product is first placed into the stream of commerce in California. The notification must 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, <u>assembler</u>, or retailer;
- (2) The type, brand name(s), and product name(s) of the Priority Product, and, if applicable, information specifically identifying the the product is a component(s) and/of one or more assembled products, a description of the homogeneous material(s) and its/their associatedknown product(s) in which the component(s) identified under section 69503.4(a)(2)(B); and is used;
- (3) If applicable, the name of, and contact information for, the person that will be complying with the requirements of article 5 on behalf of or in lieuthe stead of the responsible entity-; and
- (b4) If the Department determines applicable, an indication that a notification is being submitted under section 69505.2 or section 69505.3 concurrently with the Priority Product Notification, or will be submitted later as provided in section 69505.2 or section 69505.3.

(b) Non-Compliance. A responsible entity is not in compliance with subsection (a) if the notice responsible entity fails to fully and timely meet the 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 under section 69501.2(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 Process for Identification and Prioritization of Chemicals and Products

# § 69504. Applicability and Petition Contents.

- (a) <u>Petition Process.</u> Except as provided in subsection (b), a person may petition the Department to add to or remove from the <u>Candidate</u> Chemicals of <u>Concern</u>-list one or more chemicals, or to add <u>to or remove from the lists specified in section 69502.2(a)</u> the entirety of an existing chemicals list to the <u>lists specified in section 69502.2(a)</u>. A person may also petition the Department to add to or remove from the Priority Products list a product, or to establish or revise an alternatives analysis threshold for a Chemical of Concern in a Priority Product.-chemical combination. A 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 <u>petition</u> contents of the <u>petition</u>, if different from the petitioner, and the affiliation of this person with the petitioner;
- (2) A description of the chemical and/or product<u>-chemical combination</u> that is the subject of the petition;
- (3) A description of the uses and applications of the chemical and/or product-chemical combination;
- (4) The basis for the petition, including an analysis of the scientific basis for the existence or absence of <u>potential</u> adverse <u>public healthimpacts</u>, <u>potential exposures</u>, and/or <u>environmental impacts</u> <u>potential adverse waste and end-of-life effects</u> associated with the chemical and/or product, <u>or for the establishment or revision of an alternatives analysis threshold</u>;-chemical combination;
  - (5) Reliable information Information supporting the petition; and
- (6) The identity of any known manufacturers and importers of the chemical or product-chemical combination.
  - (b(b) Limitations on Petitions.
- (1) A person may not petition the Department to delist any chemical identified as a <u>Candidate</u> Chemical of Concern-under section 69502.2(a), unless that chemical is no longer listed on any of the lists identified in section 69502.2(a).
- (2) A person may not petition the Department to remove an entire chemicals list from the lists specified in section 69502.2(a) until three (3) years after the effective date of these regulations.

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- A person may not petition the Department to remove a product-chemical combination from the Priority Products list until three (3) years after the date the productchemical combination was placed on the Priority Products list.
- (c) Completeness Review. 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 incomplete, the Department shall notify provide notice to the petitioner of this determination and shall specify the basis for the determination. If the Department determines that a petition is complete, the Department shall notify provide notice to the petitioner that it will conduct a merits review to determine whether to grant or deny the petition.
- NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
- Reference: Sections 25252 and 25253, Health and Safety Code.

#### § 69504.1. Merits Review of Petitions.

- Process and Timing. The Department shall determine whether to grant or deny a (a) complete petition in accordance with the criteria and processes specified in articles article 2 and/or article 3, as applicable. The Department shall make its determination no later than the next regular update of the Candidate Chemicals of Concernlist or Priority Products list, as applicable. The Department shall give high priority to responding to reviewing petitions by federal and other California State agencies that relate to the petitioning agency's statutory and/or regulatory authorities.
- Substantive Review. The Department's merits review of each complete petition shall, to the extent applicable, be based on:
- The comprehensiveness of the information submitted that pertains to the factors (1) specified in sections section 69502.2(b) and/or section 69503.2, as applicable;
  - The quality of the information submitted; and. (2)
- (3)The availability of information, other than that submitted with the petition, that supports the petitioner's claims that:
- (A) The chemical exhibits does or does not exhibit one or more hazard traits and/or environmental or toxicological endpoints; and
- An evaluation of the chemical and/or the product, based on the factors specified in sections section 69502.2(b) and/or section 69503.2, as applicable, indicates does not indicate potential adverse public health and/or environmental impacts and potential exposures, and, if applicable, adverse waste and end-of-life effects.
- For a petition to remove a chemical from the Candidate Chemicals list, whether the chemical has changed status on any source list(s) that led to its inclusion on the Candidate Chemicals list.
- (5) For a petition to remove an entire existing chemicals list from the lists specified in section 69502.2(a), whether the entity responsible for the underlying list still conducts its scientific assessments of chemicals in a manner that is substantially equivalent to, or as

rigorous as, the manner in which it conducted its scientific assessments at the time of the initial adoption of these regulations.

- (c) <u>Supplemental Information Requests.</u> The Department may request that the petitioner provide, <u>within a specified timeframe</u>, additional information to assist the merits review, <u>within a timeframe specified by the Department</u>.
  - (d) Notice of Decision. After completing the merits review, the Department shall:
- (1) Prepare provide a notice of to the petitioner of its decision to grant or deny the petition, and that includes a statement explaining the basis for the decision; and
  - (2) Notify the petitioner of the decision.

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

#### **Article 5.** Alternatives Analysis

#### § 69505. Guidance Materials.

- (a) <u>Guidance Materials.</u> Before finalizing the initial list of Priority Products <u>under section</u> 69503.4, the Department shall make available on its website guidance materials to assist persons in performing AAs <u>in accordance under</u> with this article. The Department shall periodically revise and update the guidance materials.
- (b) <u>Sample Alternatives Analyses.</u> The Department shall also post on its website <u>examples of AAs that the Department is aware of, and that are available in the public domain at no cost and are supported by reliable information.</u> The posting must indicate, for each AA, the name of the person or entity 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 Analysis: General Provisions.

(a)(1) All references in this article to "Priority Product" mean a product that has a been listed on the Priority Products list under Article 3, or, if applicable, the component(s) and/or homogeneous material(s) within a component in the product that are the focus of the AA. If applicable, the AA must at a minimum include those component(s) and/or homogeneous material(s) that is/are identified under section 69503.4(a)(2)(B). The responsible entity may elect to expand the focus of the AA to include additional components and/or homogeneous materials or the entire product.

- (2) All references in this article to "product" mean the product as a whole.
- (b) This article does not apply to either 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 included on the Priority Products list.
- (2) A Priority Product that meets the alternatives analysis threshold exemption criteria specified in section 69503.5, if a complete and timely Alternatives Analysis Threshold

Exemption Notification has been submitted to the Department satisfying the requirements of section 69503.6, unless subsection (d) or (e) of section 69503.6 applies.

- (c)(1) The requirements of this article applicable to a responsible entity may be fulfilled entirely by the responsible entity, or entirely by a person acting on behalf of or in lieu of the responsible entity. Alternatively, the responsible entity may choose to fulfill some requirements themselves with other requirements being fulfilled by a person acting on behalf of or in lieu of the responsible entity.
- (2(a) Applicability. This article does not apply to a product for which the notification requirements of section 69505.2 or section 69505.3 have been fully and timely met.
  - (b) AA Requirements.
- (<u>1</u>) Except as otherwise provided in <u>subsection (a) above and subsections (b), (f),c)</u> and (<u>g) andd) of section 69505.2 (b) and (c),4,</u> a responsible entity for a product that contains one or more Chemicals of Concern, that is/are the basis for inclusion of the product on thea Priority Product list, shall conduct an AA for the Priority Product, and shall comply with all applicable requirements of this article.
- (32) A responsible entity subject to the requirements of paragraph (21) shall prepare, sign, and submit to the Department AA Reports, meeting the requirements of section 69505.5, as follows:
- (A) Except as provided in subsection (d)(1), thec), a responsible entity shall submit the Preliminary AA Report to the Department 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 under section 69503.4(a)(2)(C).
- (B) Except as provided in subsection (d)(1), thec), a 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, under section 69505.5(k)(1), and the Department approves, under section 69505.6(a)(3), a longer period of time an extended due date.
- (C) For a product that is first placed into the stream of commerce in California after the date the product is listed on the Priority Products list, the due date for the Preliminary AA Report shall be 180 days after the product is first placed into the stream of commerce in California, unless the Department specifies a different due date in the Priority Products list.
- (d)((3) The requirements of this article applicable to a responsible entity may be fulfilled entirely or in part by the responsible entity, and/or entirely or in part by a person acting on behalf of or in the stead of the responsible entity. This paragraph does not apply to sections 69505.2 and 69505.3.
  - (c) AA Report Due Date Extension.
- (1) A responsible entity may request, and the Department may grant, a one-time extension of up to ninety (90) days to the submission deadline for either the Preliminary or Final AA Report, or both, or Alternate Process AA Work Plan if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible

entity. The extension request must be received 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 AA Reports will be submitted;
- (C) If different from subparagraphs (A) and (B), the name of, and contact information for, the manufacturer(s) and the importer(s) of the product;
- (D) Information identifying and describing the product, and, if applicable, the component(s) and/or homogeneous material(s) and its/their associated component(s) subject to the AA requirement, including responsible entity's Priority Product, and the brand name(s) and product name(s) under which the product Priority Product is placed into the stream of commerce in California, and, if the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;
  - (E) The due date for the Preliminary or Final AA Report, as applicable;
  - (F) The amount of additional time requested; and
- (G) The reason the extension is needed, including an explanation as to why the circumstances necessitating the extension could not reasonably be anticipated or controlled by the responsible entity.
- (3) The Department shall approve or deny, in whole or in part, the extension request, in whole or in part and notifyprovide notice to 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.
- (e) Each AA completed on and after the date that is two (2) years after the effective date of these regulations shall be performed by, or under the responsible charge of, one or more assessor(s) certified under article 8 for the appropriate product type or industry sector. Each Preliminary and Final AA Report submitted on and after the date that is two (2) years after the effective date of these regulations shall be prepared by, or under the responsible charge of, one or more assessor(s) certified under article 8 for the appropriate product type or industry sector.
- (f) A responsible entity may fulfill the requirements of subsection (c)(2) 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 regulatory response(s) under article 6.
- (1) A responsible entity submitting a report under this subsection shall submit the report no later than the deadline for submitting a Preliminary AA Report, under subsection (c)(3)(A), except that a one-time extension may be requested under subsection (d).
- (2) A responsible entity submitting an existing report under 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.

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- (g) Chemical of Concern Removal Notification. If a responsible entity reformulates the Priority Product to remove the Chemical(s) of Concern, that is/are the basis for the Priority Product listing, without adding a substitute chemical, the responsible entity may submit a Chemical of Concern Removal Notification to the Department in lieu of conducting an AA and submitting an AA Report.
- (1) A responsible entity submitting a Chemical of Concern Removal Notification under this subsection shall submit the notification no later than the deadline for submitting the Preliminary AA Report under subsection (c)(3)(A).
  - (2) The Chemical of Concern Removal Notification must include all of the following:
  - (A) The name of, and contact information for, the person submitting the notification;
- (B) The name of, and contact information for, the responsible entity(ies) on whose behalf the notification is being submitted;
- (C) If different from subparagraphs (A) and (B), the name of, and contact information for, the manufacturer and the importer of the product;
- (D) Information identifying and describing the original product and the reformulated product, including the brand name(s) and labeling information for both products;
- (E) The intended uses, and targeted customer base(s), for the product and the reformulated product:
- (F) The measures the responsible entity will take to ensure the product that contained the Chemical(s) of Concern is no longer placed into the stream of commerce in California; and
  - (G) The Chemical(s) of Concern removed from the product, and both of the following:
- Information explaining the rationale and the factors considered in selecting the reformulation; and
- 2. Laboratory analytical testing, quality control, and quality assurance protocols used to detect and measure the Chemical(s) of Concern in the product that ensures the Chemical(s) of Concern have been removed.
- (h) A responsible entity conducting an AA under this article(d) Consideration of Information-and Public Comments.\_(1)—A responsible entity conducting an AA 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 analysis. The responsible entity shall summarize these efforts in the AA Report Final AA Report or final Abridged AA Report, whichever is applicable.
- (i) (2) The Department shall post on its website a notice regarding the availability for public review and comment of each Preliminary AA Report, draft Abridged AA Report, and Alternate Process AA Work Plan submitted to the Department. The notice shall include the time period, not to exceed forty-five (45) days, during which the public may submit comments. and the method(s) for submitting comments. Any public comments on these documents must be submitted to the entity that submitted the document to the Department with a copy submitted simultaneously to the Department.
- (e) Compliance Status. Notwithstanding any other provision of this chapter, failure of the Department to make a compliance determination for a Preliminary or Final an AA Report or Alternate Process AA Work Plan within the applicable timeframe specified in section

- 1 69505.689, or failure of the Director or the Department to respond to an appeal or Request for
- 2 Review submitted under article 7 within sixty (60) days, shall not cause a Preliminary or
- Finalan AA Report or Alternate Process AA Work Plan to be deemed compliant with this article.

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

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- § 69505.2. Removal/Replacement Notifications in Lieu of Alternatives Analysis of .
  - (a) Applicability.
  - (1)(A) The requirements of this article do not apply to a responsible entity's Priority
- Products Product if the manufacturer of the Priority Product submits one of the following notifications to the Department no later than the due date for submitting the Preliminary AA

14 Report:

- 1. A Chemical Removal Intent and Alternatives. or Confirmation Notification that complies with subsections (b) and (c):
  - (2. A Product Removal Intent and/or Confirmation Notification that complies with subsections (b) and (d); or
  - 3. A Product-Chemical Replacement Intent and/or Confirmation Notification that complies with subsections (b) and (e).
  - (B) If only a)(Chemical Removal, Product Removal, or Product-Chemical Replacement Intent Notification is submitted to the Department by the date specified in subparagraph (A), within ninety (90) days of the submission date, or by the due date for the Preliminary AA Report, whichever is later, the manufacturer shall submit one of the following to the Department:
    - 1). A removal or replacement Confirmation Notification; or
- 2. A Preliminary AA Report, <del>draft</del>-Abridged AA Report, or Alternate Process AA Work Plan.
  - (2)(A) If a Preliminary AA Report, draft Abridged AA Report, or Alternate Process AA Work Plan has already been submitted to the Department, the requirements of this article pertaining to performance of a second stage AA and submission of a Final AA Report, or submission of a Final AA Report, do not apply if one of the notifications specified in paragraph (1)(A) is submitted to the Department prior to the due date for submitting the Final AA Report, whichever is applicable.
  - (B) If only a Chemical Removal, Product Removal, or Product-Chemical Replacement Intent Notification is submitted to the Department by the date specified in subparagraph (A), the manufacturer shall submit a removal or replacement Confirmation Notification; or a Final AA Report-or final Abridged AA Report, by the later of the following dates:
    - 1. Ninety (90) days after the Intent Notification is submitted; or
- 40 <u>2.</u> The AA required to be performed under due date for the Final AA Report-or final 41 Abridged AA Report, whichever is applicable.

- (3) A manufacturer is not in compliance with section 69505.1(b), if the manufacturer submits a notification under this section, in lieu of submitting the otherwise required AA Report(s), and that notification is not submitted by the applicable due date or does not fully meet the applicable content requirements specified in subsections (b) through (e).
- (b) Content Requirements for Intent and Confirmation Notifications. Chemical Removal, Product Removal, and Product-Chemical Replacement Intent and Confirmation Notifications must include:
  - (1) The name of, and contact information for, the person submitting the notification.
  - (2) The name of, and contact information for, any known responsible entity(ies).
- (3) If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer(s) and importer(s) of the product.
- (4) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer directly sold the Priority Product within the prior twelve (12) months.
- (5) Identification and location of the manufacturer's retail sales outlets where the manufacturer sold, supplied, or offered for sale the Priority Product in California, if applicable.
- (6) Information identifying and describing the Priority Product and the reformulated product, if applicable, and the brand name(s) and labeling information under which the Priority Product and the reformulated product, if applicable, are/were placed into the stream of commerce in California, and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used.
- (7) The intended uses, and targeted customer base(s), for the Priority Product and the reformulated product, if applicable.
  - (8) The measures the manufacturer will take, or has taken, to:
- (A) If applicable, provide information regarding the reformulated product to persons selling or distributing the Priority Product in California; and
- (B) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California.
- (9) For Chemical Removal Notifications and/or Product-Chemical Replacement
  Notifications, the Chemical(s) of Concern that will be; or have been; removed from the product; and, as applicable, the following information:
- (A) Information explaining the rationale and the factors considered in deciding to reformulate the product;
- (B) Laboratory analytical testing methodology and quality control and assurance protocols used or that will be used to confirm that the Chemical(s) of Concern has/have been removed, and identification of the testing laboratory;
- (C) Information demonstrating that the Chemical(s) of Concern has/have been removed from the product that was a Priority Product;
- (D) The name of the replacement chemical(s), the concentration of each replacement chemical in the reformulated product, and the hazard traits and/or environmental or toxicological endpoints known to be associated with the replacement chemical(s);

- (E) Laboratory analytical testing methodology and quality control <u>and assurance</u> protocols used or that will be used to measure the concentration of the replacement chemical(s) in the product, and identification of the testing laboratory; and
- (F) Information demonstrating that the replacement chemical(s) meet one of the following criteria:
  - 1. The replacement chemical(s) is/are not on the list of Candidate Chemicals; or
- 2. The replacement chemical(s) is/are Candidate Chemical(s) that <u>is/are already in use</u> to manufacture the same product, in lieu of the Chemical(s) of Concern, by the same or a different responsible entity. For purposes of this subsection, "same product" means a product that has the same <u>or similar product description as, or similar product description to, the Priority Product; has the same intended use(s) and targeted customer base(s) as the Priority Product.</u>
  - (10) The certification statement specified in subsection (c)(2), (d) or (e), as applicable.
- (c) Chemical Removal Notification Certification Statements. Chemical Removal Intent and Confirmation Notifications must include whichever of the following certification statements is applicable:
- (1) Chemical Removal Intent Notifications must include a statement certifying that the manufacturer intends to do all of the following within ninety (90) days of the date the notification is submitted to the Department:
- (A) Remove the Chemical(s) of Concern from the Priority Product without the use of one or more replacement chemicals or otherwise adding other chemicals to the product;
- (B) Provide information regarding the reformulated product to persons selling or distributing the Priority Product in California;
- (C) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California; and
- (D) Submit a Chemical Removal Confirmation Notification to the Department for the Priority Product.
- (2) Chemical Removal Confirmation Notifications must include a statement certifying that:
- (A) The Chemical(s) of Concern has/have been removed from the product that was a Priority Product without the use of one or more replacement chemicals or otherwise adding other chemicals to the product;
- (B) Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California; and
- (C) The manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California and will not resume doing so.
- (d) Product Removal Notification Certification Statements. Product Removal Intent and Confirmation Notifications must include whichever of the following certification statements is applicable:

- (1) Product Removal Intent Notifications must include a statement certifying that the manufacturer intends to do both of the following within ninety (90) days of the date the notification is submitted to the Department:
  - (A) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California; and
  - (B) Submit a Product Removal Confirmation Notification to the Department for the product.
  - (2) Product Removal Confirmation Notifications must include a statement certifying that the manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California.
  - (e) Product-Chemical Replacement Notification Certification Statements. Product-Chemical Replacement Intent and Confirmation Notifications must include whichever of the following certification statements is applicable:
  - (1) Product-Chemical Replacement Intent Notifications must include a statement certifying that the manufacturer intends to do all of the following within ninety (90) days of submission of the date the notification is submitted to the Department, the manufacturer intends to:
    - (A) Remove the Chemical(s) of Concern from the Priority Product;
- (B) Provide information regarding the reformulated product to persons selling or distributing the Priority Product enin California;
- (C) Cease fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California; and
- (D) Submit a Product-Chemical Replacement Confirmation Notification to the Department for the Priority Product.
- (2) Product-Chemical Replacement Confirmation Notifications must include a statement certifying that:
- (A) The Chemical(s) of Concern has/have been removed from the product that was a Priority Product:
- (B) The replacement chemical(s) meet the criteria specified in subparagraph 1. or subparagraph 2. of subsection (b)(9)(F);
- (C) Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product enin California; and
- (D) The manufacturer has ceased, and will not resume, fulfilling orders for the Priority Product from persons selling or distributing the Priority Product in California and will not resume doing so.
- NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.
- 40 <u>§ 69505.3. Alternatives Analysis Threshold Notification in Lieu of Alternatives</u>
  41 Analysis.

- (a) Notification Requirements. This article does not apply to a responsible entity's
   Priority Product for which the manufacturer submits an Alternatives Analysis Threshold
   Notification to the Department concurrently with the Priority Product Notification, or by the due
   date for the Preliminary AA Report for the Priority Product. Each notification must include:
  - (1) The name of, and contact information for, the person submitting the notification;
  - (2) The name of, and contact information for, any known responsible entity(ies);
  - (3) If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer(s) and importer(s) of the Priority Product;
  - (4)(A) A statement certifying that the Chemical(s) of Concern is/are present in the manufacturer's Priority Product only as contaminants and the concentration of each Chemical of Concern does not exceed the Alternatives Analysis ThresholdPQL for that chemical; or
  - (B) A statement certifying that the Chemical(s) of Concern does/do not exceed the Alternatives Analysis Threshold(s) specified by the Department under section 69503.5(c) for the Chemical(s) of Concern.
  - (5) <u>If applicable, <del>lidentification of the PQL for each Chemical of Concern in the Priority Product, and the information and method used to determine the PQL;</u></u></del>
    - (6) The source of the Chemical(s) of Concern in the Priority Product;
  - (7) Information identifying and describing the Priority Product, the brand name(s) and labeling information under which the Priority Product is placed into the stream of commerce in California, and, if the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;
  - (8) Laboratory analytical testing methodology and quality control and assurance protocols used to measure each Chemical of Concern in the Priority Product, and identification of the testing laboratory; and
  - (9) A demonstration and certification that the manufacturer meets and will continue to meet the criteria and conditions that are the basis for the exemption in this section.
  - (b) Burden of Proof. The manufacturer bears the burden of proof to demonstrate that the concentration of the Chemical(s) of Concern in its Priority Product does not exceed the applicable PQL Alternatives Analysis Threshold.
  - (c) Notification Revisions. If any of the information listed in subsection (a) changes significantly, the manufacturer shall submit to the Department a revised Alternatives Analysis Threshold Notification within thirty (30) days of the change.
  - (d) Change in Product's Exemption Status. If the Priority Product no longer meets the criteria for an Alternatives Analysis Threshold exemption, the manufacturer shall notify the Department of this change within thirty (30) days of the change, and shall submit to the Department a Preliminary AA Report or an applicable Intent and/or Confirmation Notification under section 69505.2 within 180 days of the change.
  - (e) Determination of Exemption Eligibility. The exemption in subsection (a) does not apply if the Department notifies the person who submitted the Alternatives Analysis Threshold Notification that the information contained in the notification is inaccurate or inadequate to support an Alternatives Analysis Threshold exemption.

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

## § 69505.4. Alternatives Analysis Process and Options.

- (a) AA Stages.
- (1) An AA must be conducted in two stages, as specified in sections 69505.3 and 69505.4.
- (2) The responsible entity shall <u>initially</u> complete the first stage of the AA, and submit a Preliminary AA Report that complies with sections 69505.1(c)(3b)(2)(A) and 69505.57.
- (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(c)(3b)(2)(B) and 69505.57.
- (b) <u>Abridged AA Reports.</u> After completion of completing the first four (4) five (5) steps of the first stage of the AA, under <u>pursuant tounder</u> subsections (b)(1a) through (b)(4de) of section 60505.369505.5, a responsible entity that determines a functionally acceptable and technically feasible alternative is not available or feasible may prepare and submit and final and Abridged AA Report Reports, in lieu of the Preliminary and Final AA Reports, if all of the following requirements are met:
- (1) The responsible entity summarizes, in the Abridged AA Report, the first stage AA findings in conformance with the applicable requirements of section 69505.57;
- (2) The responsible entity identifies the factors relevant for comparison of the Priority Product and the alternatives, under consideration as specified in section 69505.46(a), and summarizes, in the Abridged AA Report, its findings with respect to section 69505.46(a) in conformance with the applicable requirements of section 69505.57;
- (3)(2) The responsible entity submits an<u>an</u> draft-Abridged AA Report to the Department to the Department by the due date specified in section 69505.1(c)(3b)(2)(A), and submits a final Abridged AA Report by the due date specified by the Department under section 69505.8(b)(4); and
- (4)(3) The responsible entity specifies in the includes an implementation plan included in the draft and final Abridged AA Report that specifies the milestones and dates for implementation of proposed regulatory responses, which shall, at a minimum, include the regulatory responses required under sections 69506.93 and 69506.8.
  - (e(c) Alternate Process AA.
- (1) A responsible entity may use an AA process that differs from the process specified in sections 69505.35 and 69505.46, if all of the following requirements are met:
- (1<u>A</u>) The responsible entity's alternate process provides the information needed to prepare an<u>a Final</u> AA Report that substantially meets the requirements of complies with section 69505.<del>5</del>7.
- (2<u>B</u>) The responsible entity's alternate process compares the Priority Product and the alternatives <u>under consideration</u> using, at a minimum, the same <u>relevant</u> factors and, <u>wherewhen</u> applicable, associated exposure pathways and life cycle segments specified in sections 69505.35 and 69505.46.

- (3<u>C</u>) The responsible entity submits a work planan Alternate Process AA Work Plan to the Department with sufficient information to demonstrate that the alternate process will meet the requirements of paragraphs (1complies with subparagraphs (A) and (2B), and sufficient information for the Department to specify an appropriate due date for submittal of the Final AA Report.
- (A)1. The Alternate Process AA Work Plan shall include the information specified in subsections (c), (d), and (e) of section 69505.7.
- <u>2.</u> If the <u>work planAlternate Process AA Work Plan</u> includes information for which trade secret protection is claimed, the responsible entity shall also submit a redacted copy of the work plan<del>, which shall exclude the that <u>masksexcludes</u> that information for which trade secret protection is claimed.</del>
- (B)3. The work plan Alternate Process AA Work Plan shall be accompanied by an executive summary organized in conformance with the organization of the work plan that is sufficient to convey to the public a general understanding of the work plan.
- 1. The executive summary must be organized in conformance with the organization of the work plan. The responsible entity may not include in the executive summary, and that masksexcludes any information for which trade secret protection is claimed.
- 2. 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)1.D) The work plan must be Alternate Process AA Work Plan is 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 under this subsection, the Department shall follow the steps specified for the review of Preliminary AA Reports in section 69505.6(a).
- 2. For a product that is first placed into the stream of commerce in California after the date the product is included on the Priority Products list, the due date for the work plan Alternate Process AA Work Plan shall be due sixty (60) days after the product Priority Product is first placed into the stream of commerce in California the due date for the Priority Product Notification for the product.
- (<del>D)</del> <u>E)1. The responsible entity timely submits a Final AA Report to the Department that substantially complies with section 69505.7.</u>
- 2. The due date for the Final AA Report shall beis eighteen (18) months after the date the Department issues a notice of compliance for the work planAlternate Process AA Work Plan, unless the responsible entity requests, and receives Department approval of an extended due date using the procedures specified for Preliminary AA Reports in section 69505.7(k)(1)(B), or the Department otherwise approves an extended due date under section 69505.5(k)(1), and the Department approves, §9(b)(4)(A). If the Department approves an extended due date, the responsible entity shall provide a yearly progress report until the Final AA Report is submitted. Each progress report must provide all of the information specified in subparagraphs 1. through 6. of section 69505.7(k)(1)(A).

- 1 2 3
- 4 <u>within 180 days</u> after the Department issues athe notice of compliance for the work plan.
   5 disapproval.
- 5 <u>(</u>

- (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 under paragraph (3).
- (d)(1) A responsible entity may select a different alternative(d) Previously Completed AAs. A responsible entity may comply with section 69505.1(b) 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 69505.7 and contains sufficient information for the Department to determine any necessary regulatory response(s) under article 6. The previously completed AA may be either an AA conducted or obtained by the responsible entity or a publicly available AA.

If the Alternate Process AA Work Plan is disapproved by the Department under

section 69505.6(a89(b)(3), a longer period of time. The additional time shall not exceed thirty

(30) months the responsible entity shall submit a Preliminary AA Report to the Department

- (1) A responsible entity submitting a report under this subsection shall submit the report no later than the deadline for submitting a Preliminary AA Report, except that a one-time extension may be requested under section 69505.1(c).
- (2) A responsible entity submitting an existing report under this subsection may supplement the report with additional information to render the report substantially equivalent to the Final AA Report requirements of section 69505.7.
  - (e) Revised Alternative Selection Decision.
- (1) If after submitting the Final AA Report, the responsible entity selects one or more alternatives that differ from the onealternative(s) identified as the selected alternative(s) in the Final AA Report-submitted to, the Department, if both of the following requirements are met:
- (A) The responsible entity shall submit a revised Final AA Report that identifies and explains to the Department at least sixty (60) days prior to placing the newly selected alternative product(s) into the stream of commerce in California. The revised Final AA Report must explain the differences in the information from the original Final AA Report to the revised Final AA Report. The responsible entity shall, identify the information used to support the revisions to the Final AA Report.
- (B) The, and describe the rationale for selecting the different alternative(s). The Department shall review and make a compliance determination with respect to the revised Final AA Report must be submitted to the Department at least sixty (60) days prior to placing the selected alternative product into the stream of commerce in California. in accordance with the procedures and criteria set forth in section 69505.89.
  - (2) Paragraph (1) also applies if the:
- (A) The selection decision in the original Final AA Report was to retain the Priority Product, and the responsible entity later decides to select an alternative to replace the Priority Product-; or

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

#### § 69505.3. Alternatives Analysis: 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 included on the Priority Products list.
  - (b) The first stage of the AA shall include all of the following steps:
- (1) Step 1, Identification of Product Requirements and Function of Chemical(s) of Concern.
- (A) The responsible entity shall identify the function, performance, and legal requirements associated with the Priority Product that must be met by the alternatives being considered.
- (B) The responsible entity shall identify the function of the Chemical(s) of Concern in meeting the Priority Product's requirements identified under subparagraph (A).
- (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 requirements identified under subparagraph (A).
- 2. 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 requirements identified under subparagraph (A), 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).
  - (2) Step 2, Identification of Alternatives.
- (A)1. In addition to any alternative identified under paragraph (1)(C)2., the responsible entity shall identify alternatives that meet the definition of "alternative" under section 69501.1(a)(11) and meet the requirements identified under 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 or restrict exposures to the Chemical(s) of Concern in the Priority Product.
- 2. The responsible entity shall research available information, including information posted on the Department's website under section 69505(b), that may identify existing viable alternatives for consideration in the AA. The responsible entity shall consider any such identified alternatives in the AA.
- (B) Alternatives that do not involve the addition of a substitute chemical do not require completion of the steps 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:
- (A) Collect and use available information on hazard traits and toxicological and environmental endpoints, and any other relevant data, to identify all of the following for each alternative chemical being considered:
  - 1. Adverse public health impacts;

- 1 2. Adverse environmental impacts;
- 2 3. Environmental fate;

- 3 4. Physical chemical hazards; and
  - 5. Physicochemical properties;
  - (B) Compare each of the alternative chemicals being considered with the Chemical(s) of Concern in the Priority Product, using the information collected and evaluated under subparagraph (A); and
  - (C) Eliminate from further consideration in the AA any alternative chemical(s) that the responsible entity determines poses equal or greater adverse public health and/or environmental impacts than the Chemical(s) of Concern.
    - (4) Step 4, Consideration of Additional Information.

As part of the first stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified in this section. This may include consideration of the factors and information identified in section 69505.4.

- (5) Step 5, Identification of Next Steps.
- (A) The responsible entity shall prepare a work plan and proposed implementation schedule for completion of the second AA stage, as specified in section 69505.4, and preparation and submittal of the Final AA Report.
- (B) The responsible entity shall prepare and submit to the Department a Preliminary AA Report as specified under section 69505.5.

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

# § 69505.4. Alternatives Analysis: 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) A factor listed in paragraph (2)(A) in conjunction, where applicable, with an associated exposure pathway and life cycle segment is relevant if:
- 1. It makes a demonstrable contribution to one or more adverse public health, environmental, waste and end-of-life, and/or materials and resource consumption impacts of the Priority Product and/or one or more of the alternatives under consideration; and
- 2. There is a demonstrable difference in the factor's contribution to such impact(s) between two or more of the alternatives being considered.
- (B) For purposes of subparagraph (A), a responsible entity shall include retaining the Priority Product as one of the alternatives being considered.
- (2) The responsible entity shall collect and use available quantitative information and analysis tools, supplemented by available qualitative information and analysis tools, to identify the factors listed in subparagraph (A) and, where applicable, 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. The factors identified in subparagraphs (B) and (C) shall be considered 1 relevant for all comparisons of the Priority Product and the alternatives. 2
  - (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 on:
    - 1. Adverse environmental impacts;
    - Adverse public health impacts;
  - Adverse waste and end-of-life impacts;
- 4. Environmental fate; 9

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- 5. Materials and resource consumption impacts; 10
- 11 6. Physical chemical hazards; and
- 12 7. Physicochemical properties.
  - (B) Product function and performance, meaning 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. This evaluation shall include, at a minimum, all of the following:
    - 1. Useful life of the Priority Product, and that of the alternatives being considered;
  - 2. Comparison of function and performance for each alternative relative to the Priority Product and each of the other alternatives being considered, and identification of the source and basis for the function and performance metrics used; and
  - 3. A determination of whether a "technically and economically feasible alternative" exists.
  - (C) Economic impacts. The responsible entity shall evaluate and compare the economic impacts of the Priority Product and the alternatives. If the comparison of economic impacts leads to a determination later decides to retain the Priority Product, then the responsible entity shall take into account all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered. A cost impact is an increase or decrease in one or more of the following:
    - Capital;
    - Consumer costs associated with the purchase or lease and use of the product;
    - Government agency, public, and/or business costs associated with the product;
- 32 4. Jobs or businesses:
  - Manufacturing costs;
- 34 6. Marketing costs;
- 35 Materials and resource consumption costs; and/or
- 8. Waste and end-of-life management costs. 36
  - (3) The responsible entity's identification of relevant exposure pathways shall consider both of the following:
    - (A) Chemical quantity information:
- Quantities of the Chemical(s) of Concern or alternative chemical(s) necessary to 40 manufacture the Priority Product and each alternative being considered; 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 and each alternative being considered.
  - (B) Exposure factors specified in subsection (a)(1)(B) of section 69503.2.
  - (b) Step 2, Comparison of the Priority Product and Alternatives.

The responsible entity shall use available quantitative information and analyses, supplemented by available qualitative information and analyses, to evaluate and compare the Priority Product and each of the alternatives under consideration with respect to each relevant factor and, where applicable, associated exposure pathways and life cycle segments identified under subsection (a). The responsible entity shall compare each alternative with the Priority Product and with each of the other alternatives being considered. The responsible entity shall identify and/or document, as appropriate, all of the following information:

- (1) Quantitative metrics, where available and appropriate, for each of the relevant factors identified under subsection (a)(2):
- (2) Qualitative metrics for any relevant factors for which quantitative metrics are not available or appropriate;
- (3) Available data for each metric for the Priority Product and each alternative being considered;
- (4) Any absent or conflicting data regarding a relevant factor, and either or both of the following, as appropriate:
- (A) Available data that is most protective of public health and the environment, unless there are sound methodological reasons for rejecting such data; and/or
- (B) A value for the metric, using a method for dealing with data uncertainty due to absent or missing data that has been adopted by an authoritative organization, as defined in section 69401.2(b), or generally accepted in peer reviewed literature;
- (5) A description of the performance of the Priority Product and each alternative, with respect to each of the relevant factors;
- (6) Appropriate qualitative and/or quantitative relative weights for the relevant factors, and the rationale for the assignment of the relative weights;
- (7) An evaluation of the overall performance of each alternative as compared to the Priority Product and the other alternatives, including discussion of the impact of the weight placed upon the relevant factors, the rationale for choosing the particular method for determining the overall evaluation, and the sensitivity of the comparative evaluation to data uncertainty; and
- (8) Any other known evaluation of the Priority Product or one or more of the alternatives that comes to different conclusions, regarding the relative overall performance or public health and/or environmental impacts, and the reasons for the difference in the conclusions.
  - (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 under subsection (b).

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(d) Step 4, Consideration of Additional Information.

As part of the second stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified in this section. This may include reconsideration of the factors and information identified in section 69505.3.

- (e) Step 5, Identification of Next Steps.
- (1) The responsible entity shall prepare a Final AA report that contains an implementation schedule for implementing the in lieu of a previously selected alternative, if any, and/or proposed regulatory responses, if any. product.
- The responsible entity shall prepare and submit to the Department a requirements of this subsection only apply for three (3) years after the date the original Final AA Report is approved by the Department.
- Reformulation. Except as specified underprovided in section 69505.5.2, if prior to (f) submitting the Final AA Report for a Priority Product the responsible entity removes, or reduces the concentration of, the Chemical of Concern(s) and uses one or more replacement Candidate Chemical(s), the Alternatives Analysis evaluation and comparison shall include consideration of both the Priority Product and the reformulated product.

18 NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: 19 Sections 25252, 25253, and 25257, Health and Safety Code.

#### § 69505.5. Alternatives Analysis Reports: First Stage.

The first stage of the AA shall include the five (5)six (6) steps described below:

- (a) Step 1, Identification of Product Requirements and Function(s) of Chemical(s) of Concern.
- The responsible entity shall identify the functional, performance, and legal (1) requirements of the Priority Product that must also be met by the alternatives under consideration.
- (2) The responsible entity shall identify the role(s), if any, of the Chemical(s) of Concern in meeting the Priority Product's requirements identified under paragraph (1).
- (3)(A) The responsible entity shall determine if the Chemical(s) of Concern or alternative replacement chemical(s) is/are necessary to meet the Priority Product's requirements identified under paragraph (1).
- If the responsible entity determines that neither the Chemical(s) of Concern nor (B) alternative replacement chemical(s) is/are necessary to meet the Priority Product's requirements identified under paragraph (1), the responsible entity shall evaluate removal of the Chemical(s) of Concern from the Priority Product without the use of any replacement chemical(s) as one of the alternatives to the Priority Product. Alternatively, the responsible entity may submit Chemical Removal Intent and/or Confirmation Notifications to the Department in lieu of completing the Alternatives Analysis and submitting the required AA
- 39 40 Reports.
  - Step 2, Identification of Alternatives. (b)

- (1)(A) In addition to any alternative identified under subsection (a)(3)(B), the responsible entity shall identify and consider alternatives that meet the definition of "alternative" under section 69501.1 and meet the Priority Product's requirements identified under subsection (a)(1).
- (B) The responsible entity shall research and evaluate available information that identifies existing possibly viable alternatives for consideration in the AA. This research and evaluation shall include, but is not limited to, information posted on the Department's website. The responsible entity shall consider any identified alternative in the AA, or explain in the AA Report why such an alternative is not viable for consideration.
- (2) Alternatives that do not involve the use of one or more replacement chemicals, or otherwise adding chemicals to the product, do not require compliance with subsection (c).
  - (c) Step 3, Identification of Factors Relevant for Comparison of Alternatives.
- (1) A factor listed in paragraph (2), in conjunction with an associated exposure pathway and life cycle segment, if applicable, is relevant if:
- (A) The factor makes a material contribution to one or more adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, and/or materials and resource consumption impacts associated with the Priority Product and/or one or more alternatives under consideration; and
- (B) There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or between two or more alternatives.
- (2) The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors listed below and the associated exposure pathways and life cycle segments, if applicable, that are relevant for the comparison of the Priority Product and the alternatives under consideration:
  - (A) Adverse environmental impacts:
  - (B) Adverse public health impacts:
  - (C) Adverse waste and end-of-life effects;
  - (D) Environmental fate;
    - (E) Materials and resource consumption impacts:
- (F) Physical chemical hazards; and
  - (G) Physicochemical properties.
- (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 replacement chemical(s) necessary to manufacture the Priority Product and each alternative under consideration; and
- 2. Estimated volume and/or mass of the Chemical(s) of Concern or alternative replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product and each alternative under consideration.
  - (B) Exposure factors specified in section 69503.3(b).

- 1 (e)(d) Step 34, Initial Evaluation and Screening of Alternative Replacement Chemicals.
  - (1) For those alternatives under consideration that involve removing or reducing the concentration of the Chemical(s) of Concern and using one or more alternative replacement chemicals, or otherwise adding chemicals to the product, the responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to evaluate and compare each of the alternative replacement chemicals under consideration with the Chemical(s) of Concern in the Priority Product with respect to each of the following factors to the extent relevant:
  - (A) Use available information on hazard traits and environmental and toxicological endpoints and any other relevant information to identify the following for each alternative replacement chemical under consideration:
    - **1.**(A) Adverse environmental impacts:
    - <u>2-(B)</u> Adverse public health impacts:
    - 3-(C) Environmental fate;
    - 4.(D) Physical chemical hazards; and
  - 5-(E) Physicochemical properties.
  - (B) Compare each of the alternative replacement chemicals under consideration with the Chemical(s) of Concern in the Priority Product, using the information collected and evaluated under subparagraph (A).
  - (2) The responsible entity may eliminate from further consideration in the AA any alternative replacement chemical(s) that it determines has/have the potential to pose adverse impacts equal to or greater than those posed by the Chemical(s) of Concern.
    - (d)(e) Step 45, Consideration of Additional Information.

In the first stage of the AA, the responsible entity may consider pertinent factors and information not specifically identified in this section. This may include, but is not limited to, consideration of the factors and information specified in section 69505.6. A responsible entity may eliminate an alternative from further consideration based on the additional factors and information as long as the reason for its elimination is explained in the Preliminary AA Report and there are alternatives remaining to be evaluated in the second AA stage.

- (e)(f) Step 56, Preliminary AA Report Preparation.
- (1) The responsible entity shall prepare, for inclusion in the Preliminary AA Report, a work plan and proposed implementation schedule for completion of the second AA stage and preparation and submittal of the Final AA Report.
- (2) The responsible entity shall prepare and submit to the Department a Preliminary AA Report as specified in section 69505.7.
- NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code.
- 40 § 69505.6. Alternatives Analysis: Second Stage.

- After receiving approval of the Preliminary AA Report from the Department, the responsible entity shall compare the Priority Product with the alternatives still under consideration. The second stage of the AA shall include the five (5) steps described below:
  - (a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.
- (1) A factor listed in paragraph (2)(A), in conjunction with an associated exposure pathway and life cycle segment, if applicable, is relevant if:
- (A) The factor makes a material contribution to one or more adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, and/or materials and resource consumption impacts associated with the Priority Product and/or one or more alternatives under consideration: and
- (B) There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or between two or more alternatives.
- (2)(1) Adverse Impacts and Multimedia Life Cycle Impacts. The responsible entity shallmay use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors specified in subparagraph (A)re-evaluate the identification of factors and the associated exposure pathways and life cycle segments, if applicable, that are determined to be relevant under section 69505.5(c) for the comparison of the Priority Product and the alternatives still under consideration after completion of the first AA stage. The In addition to the factors determined to be relevant under this paragraph and/or section 69505.5(c), the factors identified specified in subparagraphs (B)(2) and (C)(3) are relevant for all comparisons of the Priority Product and the alternatives.
- (A) Multimedia life cycle impacts for the Priority Product and alternatives under consideration, and chemical hazards and adverse impacts for the Chemical(s) of Concern and any alternative replacement chemical(s) or other chemicals in the alternatives that differ from the chemicals in the Priority Product. This evaluation shall be based on available information, and shall include the following factors to the extent relevant:
  - Adverse environmental impacts;
  - 2. Adverse public health impacts:
  - 3. Adverse waste and end-of-life effects;
  - 4. Environmental fate:
  - Materials and resource consumption impacts;
  - 6. Physical chemical hazards; and
  - 7. Physicochemical properties.
- (B)(2) Product function and performance. The responsible entity shall identify the principal manufacturer-intended use(s) or application(s), the functional and performance attributes, and the applicable legal requirements for the Priority Product. The responsible entity shall, at a minimum, evaluate:
- 1. The useful life of the Priority Product, and that of the alternatives under consideration:
- 2. The function and performance of each alternative relative to the Priority Product and other alternatives under consideration; and

1 <u>3. Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.</u>

(C)(3) Economic impacts.

- 1. The responsible entity shall evaluate, monetize, and compare for the relevant exposure pathways and life cycle segments the following impacts of the Priority Product and the alternatives:
  - a. Public health and environmental costs; and
- b. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.
- 2. If the responsible entity's alternative selection decision is to retain the Priority
  Product based in whole or in part on internal cost impacts, this decision must be explained in
  the Final AA Report. The Final AA Report must include a quantified comparison of the internal
  cost impacts of the Priority Product and the alternatives, including manufacturing, marketing,
  materials and equipment acquisition, and resource consumption costs.
- (3) Exposure pathways. 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 replacement chemical(s) necessary to manufacture the Priority Product and each alternative under consideration; and
- 2. Estimated volume and/or mass of the Chemical(s) of Concern or alternative replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product and each alternative under consideration.
  - (B) Exposure factors specified in section 69503.3(b).
  - (b) Step 2, Comparison of the Priority Product and Alternatives.

The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to evaluate and compare the Priority Product and each of the alternatives under consideration with respect to each relevant factor and associated exposure pathways and life cycle segments, if applicable, identified under subsection (a) above and section 69505.5(c). The responsible entity shall compare each alternative with the Priority Product and with each of the other alternatives under consideration.

(c) Step 3, Consideration of Additional Information.

As part of the second stage of the AA, the responsible entity may also consider other pertinent information not specifically identified in this section. This may include, but is not limited to, reconsideration of the factors and information identified in section 69505.5.

(d) Step 4, Alternative Selection Decision.

The responsible entity shall select the alternative(s) that will replace 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 under subsections (b) and (c).

(e) Step 5, Final AA Report Preparation.

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

### § 69505.7. Alternatives Analysis Reports.

(a) General Requirements.—All references in this section to "AA Reports" mean the Preliminary and AA Report, Final AA Report, draft Abridged AA Report, and/or final Abridged AA Report, as applicable, unless otherwise specified.

(1) The Preliminary and Final AA Reports; and draft and final Abridged AA Reports; must each include, as applicable, all of the applicable information specified in subsections (b) through (k).

 (2) The responsible entity shall include in the AA Reports sufficient information for the Department to determine compliance with:

 (A) Compliance with the substantive and administrative requirements of this article. ; and

 (3) The responsible entity shall include in the Preliminary AA Report sufficient information for the Department to determine the (B) The appropriate due date for submission of the Final AA Report.

(4) The responsible entity shall include in the Final AA Report sufficient information for the Department to determine or final Abridged AA Report, whichever is applicable, and the appropriate due date for any regulatory response(s), if any, required under article 6.

(53) The responsible entity shall 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. This information shall also be included in a final Abridged AA Report with respect to differences between the draft and final Abridged AA Reports.

(64) The responsible entity shall maximize the scope of information in the AA Report that can be made available to the public, while maintaining protection of legitimate trade secrets.

(A) If the AA Report contains information claimed by the responsible entity to be a trade secret, a separate publicly available AA Report shall be submitted to the Department that <a href="maskeexcludes">maskeexcludes</a> claimed trade secret information only to the extent necessary to protect its confidential nature.

(B) If the Department subsequently rejects a trade secret claim and/or the nature and/or extent of <a href="maskingredaction">maskingredaction</a>, the responsible entity shall, at the Department's request, submit a revised publicly available AA Report and executive summary within thirty (30) days of the request to add any information for which a trade secret claim or <a href="maskingredaction">maskingredaction</a> is rejected.

 (b) Executive Summary. AA Reports must include a publicly available executive summary sufficient to convey a general understanding of the scope and results of the AA and the rationale for the AA selection decision. 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. Information for which trade secret protection is claimed must not be included in the executive summary.
  - (c) Preparer Information. This section of the AA Report must include:
  - (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 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, demonstrating compliance with article 8, for the individual(s) in responsible charge under whose direction the AA was conducted and the AA Report was prepared.; and
  - (4) The method(s) for the public to submit comments on the Preliminary AA Report or draft Abridged AA Report under section 69505.1(d)(2).
  - (d) Responsible Entity and Supply Chain Information. <u>This section of the AA Report must include:</u>
  - (1) The name of, contact information for, and headquarters location of the manufacturer(s) and the importer, (s), 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, any persons person(s) identified on the product Priority Product label as the manufacturer, importer, or distributor;
  - (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 <u>productPriority Product</u> in California, if applicable; and.
  - (5) The proximity of the place(s) of product manufacture to one or more source(s) of virgin or recycled materials that directly or indirectly influences the type and/or amount of Chemical(s) of Concern in the Priority Product.
    - (e) Product Information.
    - (e) Priority Product Information. This section of the AA Report must include:
  - (1) The brand name(s) and product name(s) under which the <u>product Priority Product</u> is placed into the stream of commerce in California;
  - (2) If applicable, the <u>Priority Product is a component of one or more assembled</u> products, a description of the known product(s) and/or homogeneous material(s) and its/their associated in which the component(s) that is/are the focus of the AA; is used;
  - (3) Identification of the Chemical(s) of Concern in the Priority Product that is/are the basis for the product being included on the Priority Product list, and any other Chemical(s) of Concern that is/are known, or reasonably should be known based on available information, to be in the product; and Priority Product;

- (4) <u>Any Material Safety Data Sheets and/or Safety Data Sheets related to the Priority Product; and</u>
  - (5) The information specified in paragraphs (1) and (2) of section 69505.3(b)(15(a).
- (f) Scope and Comparison 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.
- (1)(A) The Preliminary AA Report must include all of the following information for the evaluation and comparison, conducted under section 69505.3(b), 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 under 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 under sections 69505.3(b) and 69505.4:
- (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 under sections 69505.3(b) and 69505.4:
- 1. The relevant exposure pathways and life cycle segments, if applicable, for each relevant comparison factor;
- 2. The information collected for each relevant factor and, where applicable, 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 under 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.
- (3) The responsible entity shall demonstrate in the Final AA Report that all of the requirements of section 69505.4(b) have been met.
- (g) Scope (f) Scope of Relevant Comparison Factors. The Final Each AA Report must identify which factors and, wherewhen applicable, associated exposure pathways and life cycle segments were determined to be relevant, under sections 69505.5(c) and 69505.46(a), for evaluation and comparison of the Priority Product and its alternatives. For each factor, and exposure pathway and life cycle segment, if applicable, determined not to be relevant, the Final AA Report must explain the rationale and identify, and explain the pertinent findings of, the supporting information for this determination.

- (h) Methodology. (g) Scope and Comparison of Alternatives. The AA Report shall Reports must identify and describe the analysisalternatives 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. For any alternative that is screened out because it is determined that its adverse impacts are equal to or greater than those of the Priority Product, the responsible entity shall describe in the AA Report the method used to determine equal or greater adverse impacts, including the method used to compare the multiple factors associated with the impacts, and the rationale for any trade-offs made among the factors.
  - (1) The Each Preliminary AA Report and Abridged AA Report must include the information collected and the comparison conducted under section 69505.5 for the Chemical(s) of Concern and the alternative replacement chemical(s). This must include a matrix, or other summary format, that provides a clear visual comparison that summarizes the information collected regarding the relevant adverse impacts, and their associated relevant exposure pathways and life cycle segments, for the Chemical(s) of Concern and each alternative replacement chemical being considered, and the comparative results of evaluating this information. The information and comparison must be presented in a matrix, or other summary format, that provides a clear visual comparison among the chemicals and their associated adverse impacts.
  - (2) The Final AA Report must include the information collected and the comparison conducted under sections 69505.5 and 69505.6 for the Priority Product and its alternatives, including:
  - (A) A matrix, or other summary format, that provides a clear visual comparison that includes the information collected regarding the relevant comparison factors, and their associated relevant exposure pathways and life cycle segments, for the Priority Product and each alternative considered, and the comparative results of evaluating this information; and
  - (B) Identification and description of how any relevant safeguards provided by other federal and California State regulatory programs were considered in the AA.
  - (3) The responsible entity shall demonstrate in the Final AA Report that all of the requirements of section 69505.6 have been met.
  - (h) Methodology. The AA Report shall identify and describe the analytical tools, models, and software used to conduct the AA, and discuss any of their limitations of these tools, models, and software. The AA Report shall also identify any published methodologies and/or guidelines used, and any deviations taken from the published those methodologies and/or guidelines.
    - (i) 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 must include a brief summary of the information reviewed and considered under section 69505.1(h). d)(1). Final AA Reports and final Abridged AA Reports must include a summary of the public comments submitted under section

1 69505.1(d)(2), and a description as to how the comments are addressed in the report or an explanation as to why the comments are not addressed in the AA Report.

- (2) The Final AA Report must include the identification of identify information that is not currently available but, if it were available, could be used to:
- (A) Validate information used for purposes of sections 69505.3(b)5 and 69505.4; 6; and/or
- (B) Address any uncertainties in the analyses conducted under sections 69505.3(b)5 and 69505.4; and/or
- (C) Ensure that the list of chemical ingredients required to be identified for the product and its alternatives during the conduct of the AA and the preparation of the AA Reports is complete6.
  - (j) Selected Alternative(s).
- (1) The Preliminary AA Report must identify and describe the alternatives selected for further evaluation in the second stage of the AA, and explain the rationale for the selection decision.
- (2) The Final AA Report must identify and describe the alternative, (s), if any, selected to replace or modify the Priority Product. The description of the selection decision must include an analysis that evaluates and compares the selected alternative(s) against the Priority Product and a detailed list and explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable. The Final AA Report must also include all of the following:
- (A) The <u>product function and performance</u> information specified in section 69505.46(a)(2)(B) for the selected alternative.(s). If no alternative is selected, this information must be provided in the Final AA Report or Abridged AA Report, as applicable, for each alternative considered.
- (B) An explanation of the rationale for deciding to retain retaining the Chemical(s) of Concern or to use substitute using the alternative replacement chemical(s), if section 69505.5(a)(3(b)(1)(C)2.)(B) applies, and theone or more selected alternative alternatives retains the Chemical(s) of Concern, that is/are the basis for the product being included on the Priority Products list, or uses substitute chemical(s).one or more replacement chemicals.
- (C) A list of all chemical ingredientschemicals known, based on available information, to be in the selected alternative(s) that are Chemicals of Concern, that differ from the chemical ingredientschemicals in the Priority Product, or that are present in the selected alternative(s) at a higher concentration than in the Priority Product, and all of the relative to other chemicals in the Priority Product other than the Chemical(s) of Concern. The following information-that is, to the extent available, must be provided for those chemicals:
  - 1. Environmental fate;
- 2. Hazard trait(s) and environmental and toxicological endpoint(s) information for any of those chemicals for which such informationthat has not already been provided to the Department under this chapter;

- 1 3. Information onabout the chemical purity, meaning the relative freedom from absence 2 of extraneous matter, of the chemicals and identification of known impurities and additives in 3 the chemical;
  - Physical chemical hazards;
- 5 54. Physicochemical properties; and
- 6 65. Substance identification information, including all of the following that are applicable:
- 7 a. Chemical abstract services number;
- 8 b. Structural formula:
- 9 c. Molecular weight;
- 10 d. Synonyms;

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- 11 e. International Union of Pure and Applied Chemistry name;
- 12 f. European Commission number;
- 13 g. Registry of Toxic Effects of Chemical Substances number;
- 14 h. International Union of Biochemistry and Molecular Biology number;
- i. Japan Ministry of International Trade and Industry number;
- j. Number assigned by the United Nations Experts on the Transport of DangerousGoods:
- 18 k. North America Department of Transportation number;
- 19 I. European Inventory of Existing Commercial Chemical Substances number;
- 20 m. European List of Notified Chemical Substances number;
- 21 n. European Commission Directive 67/548/EEC No Longer Polymers number; and
- o. Other commonly recognized substance identification system numbers.
- 23 (k) Next Steps.
  - (1) <u>Work plan.</u> The Preliminary AA Report must include the work plan and proposed implementation schedule <u>for completion of the second AA stage</u> required to be prepared under section 69505.3(b)(5). (ef)(1). The work plan must include a description of the process that will be used to identify the factors and associated exposure pathways and life cycle segments that are relevant for the comparison of the Priority Product and the alternatives under consideration, as required under section 69505.6(a).
  - (A) The work plan and implementation schedule must specify the proposed submission date for the Final AA Report, and must ensure that the Final AA Report or progress report, if applicable, will be submitted to the Department no later than twelve (12) months after the Department issues a notice of compliance for the Preliminary AA Report. If the Department approves an extended due date under section 69505.\(\frac{89}{2}\)(b)(4)(A), the responsible entity shall provide a yearly progress report until the Final AA Report is submitted. The first yearly progress report shall be submitted no later than twelve (12) months after the Department issues a notice of compliance for the Preliminary AA Report. Each progress report must include:
    - 1. Preparer information specified in subsection (c);
  - 2. Priority Product information specified in subsection (e);
- 41 3. A summary of achievements since the last progress report;
- 42 4. A summary and discussion of issues that have arisen and their resolutions;

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- A summary of work that is pending; and
- An assessment of whether the milestones in the schedule set forth in the Preliminary AA Report or Alternate Process AA Work Plan are anticipated to be completed on time and any contingency plans to ensure timely completion.
- The responsible entity may request an extension extended due date for submittal of (B) the Final AA Report. Any requested extension shall not to exceed twenty-four (24) months from the date the Department issues a notice of compliance for the Preliminary AA Report-The extension request must include a detailed explanation of why additional time is needed. If the Priority Products list identifies more than one component or homogeneous material that must be included in the AA for the product, separate submission dates may be proposed for each component and/or homogeneous material. If the responsible entity chooses to include additional components and/or homogeneous materials in the AA, separate submission dates may be proposed for each of those components and/or homogeneous materials.
- (C) The responsible entity may request an extension for submittal of the Final AA Report, not to exceed thirty-six (36) months from the date the Department issues a notice of compliance for the Preliminary AA Report, if the, unless additional time is needed to conduct regulatory safety and/or performance testing on multiple alternatives prior to making an AA selection decision. The, in which case the requested extension shall not exceed thirty-six (36) months. The extended due date request must include a detailed explanation of why additional time is needed.
- (2) <u>Implementation of selected alternatives.</u> The Final AA Report must include a detailed implementation plan as specified in section 69505.4(efor implementing any selected alternative(s).
- The implementation plan must include key milestones and dates for implementing (A) the selected alternative, (s), if applicable, and identify applicable federal, state, or local laws and-steps that will be taken to ensure compliance with these applicable federal, state, and/or local laws.
- (B) The implementation plan may also include the identification of and implementation plan(s) for 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 or adverse waste and end-of-life effects posed by, any Chemical(s) of Concern or replacement Candidate Chemical(s) that will be in the selected alternative-or-(s) or the Chemical(s) of Concern that is/are in the Priority Product if the decision resulting from the AA is to retain the Priority Product.

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

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#### § 69505.8. Public Comments on AA Reports.

Public Notice of Opportunity for Comment. Upon receipt of a Final AA Report or an 40 Abridged AA Report, the Department shall post on its website, and send to persons on the 41 42 electronic mailing list(s) that the Department establishes related to this chapter, a notice 43

regarding the availability for public review and comment of the Final AA Report or Abridged AA

- 1 Report. The notice shall include the last day for the public to submit written comments to the
- 2 <u>Department, the method(s) for submitting comments, and a link to the location on the</u>
- 3 Department's website where a copy of the Final AA Report or Abridged AA Report may be
- 4 <u>viewed. The last day for submission of public comments shall be no sooner than forty-five (45)</u>
- 5 days from the date the notice of availability of the Final AA Report or Abridged AA Report is
- posted on the Department's website or the date the notice is sent to persons on the electronic
   mailing list(s), whichever is the later date.
  - (b) Department Review of Public Comments. No later than thirty (30) days after the close of the public comment period established under subsection (a), the Department shall review the public comments received and notify the person that submitted the Final AA Report or Abridged AA Report of those issues that the Department determines must be addressed in an AA Report Addendum. The notice shall include the due date by which the person must submit an AA Report Addendum to the Department under subsection (c). In determining the due date for the AA Report Addendum, the Department shall take into consideration the scope and complexity of the issues the Department is requiring the person to address.
  - (c) AA Report Addendum. A person that receives a notice under subsection (b) shall prepare, and submit to the Department by the due date specified under subsection (b), an AA Report Addendum that addresses the issues identified by the Department as requiring further attention. The AA Report Addendum shall also include any revisions to the Final AA Report or Abridged AA Report determined necessary based on consideration of the issues identified by the Department.

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

## § 69505.689. Department Review and Determinations for AA Reports and Work Plans.

- (a)() Review Criteria. In reviewing AA Reports and Alternate Process AA Work Plans for compliance with the substantive and administrative requirements of this article, the Department shall consider:
  - (1) Whether the AA Report or Alternate Process AA Work Plan was submitted timely;
- (2) Whether, and to what extent, the responsible entity considered and addressed all applicable provisions of this article pertaining to the preparation and submittal of an AA Report or Alternate Process AA Work Plan, whichever is applicable;
- (3) Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable; and
- (4) Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA Report were determined using reliable information.
- (b) Preliminary AA Reports, Draft and Final Abridged AA Reports, and Alternate Process AA Work Plans.
- (1) Within sixty (60) days of receiving a Preliminary AA Report, <u>draft or final Abridged</u>

  AA Report, or Alternate Process AA Work Plan, the Department shall review the <u>Preliminary</u>

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AA Report report or work plan for compliance with this article, and issue a notice of compliance, a notice of deficiency, or anotice of disapproval, or notice of ongoing review. (2)((2) Notice of Deficiency.

- (A) The Department shall specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date for submitting the necessary information to complete the Preliminary AA Report. The due date for correcting the areas of deficiency, which 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 report or work plan, whichever is applicable, by the due date specified, and address the areas of deficiency.
- Within thirty (30) days of receipt of the additional information requested in the notice of deficiency, the Department shall issue a notice of compliance, a notice of disapproval, or a notice of ongoing review for 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 under subparagraph (A). A disapproved Preliminary AA Report is not in compliance with section 69505.1(c)(2).report or work plan.
- (3(3) Notice of Disapproval. If the revised report or work plan does not fully address the identified areas of deficiency, the Department shall issue a notice of disapproval. The Department shall also issue a notice of disapproval if a revised report or work plan is not submitted by the due date specified under paragraph (2)(A). If the report or work plan is disapproved, the Department shall explain the basis for the disapproval. A disapproved report or work plan is not in compliance with section 69505.1(b).
- Notice of Compliance. (A)—The Department shall specify in a notice of compliance for a Preliminary AA Report or Alternate Process AA Work Plan the due date for submitting the Final AA Report. 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 an extended due date for submission of the Final AA Report if it determines based on information in the Preliminary AA Report or Alternate Process AA Work Plan that more time is needed. The Department may not establish aalso specify an extended due date for submission of 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 sections responsible entity submits a request under section 69505.<del>1(d) and 69505.57(k)(1)(CB)</del>.
- (b)(B) The Department shall specify in a notice of compliance for a draft Abridged AA Report the due date for submitting the final Abridged AA Report, which shall be no later than ninety (90) days after the end of the public comment period the draft Abridged AA Report.
  - (c) Final AA Reports and Abridged AA Reports.
- Within sixty (60) days of receiving an Final-AA Report Addendum, the Department shall review the Final AA Report or Abridged AA Report, including the AA Report Addendum, for compliance with the requirements of this article, and shall issue a notice of compliance, a notice of deficiency, notice of disapproval, or a notice of ongoing review. If no AA Report Addendum is required under section 69505.8, the Department shall complete its review of the

- Final AA Report or Abridged AA Report within sixty (60) days of whichever of the following
   dates is applicable:
  - (A) The close of the public comment period, if no public comments are received; or
  - (B) Thirty (30) days after the close of the public comment period, if the Department determines after reviewing the public comments that there are no issues that need to be addressed in an AA Report Addendum.
    - (2) Notice of Deficiency.
  - (A) The Department shall specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date for submitting the necessary information to complete the Final AA Report or Abridged AA Report. The due date for correcting the areas of deficiency, which may not exceed sixty (60) days from the date of the notice of deficiency is issued. The responsible entity shall submit a revised Final AA Report or revised Abridged AA Report by the due date specified, and address all areas of deficiency. If requested by Pursuant to section 69505.1(c), the The responsible entity, may request; and the Department may approve, under section 69505.1(c), a one-time extension; of not more than sixty (60ninety (90)) days; for submission of the revised Final AA Report or revised Abridged AA Report to correct the deficiencies.
  - (3<u>B</u>) Within sixty (60) days of receipt of the requested additional information, the Department shall issue a notice of compliance, a second notice of deficiency, or a notice of ongoing review.
  - (A) 1. If the Department issues a second notice of deficiency, the Department may grant no more than thirty (30) days for resubmission of the requested information.
  - (B)2. Within sixty (60) days of receipt of the additional information requested in the second notice of deficiency, the Department shall issue a notice of compliance, a notice of disapproval, or a notice of ongoing review for the Final AA Report or Abridged AA Report.
  - (3) Notice of Disapproval. If the Final AA Report or Abridged AA Report is disapproved does not fully address the areas of deficiency identified in the second notice of deficiency, the Department shall explain the basis for the issue a notice of disapproval in the notice. The Department shall also issue a notice of disapproval if a revised Final AA Report or revised Abridged AA Report is not submitted by the due date specified under paragraph (2)(A) or subparagraph (A), paragraph (2)(B)1., whichever is applicable. If the report or work plan Final AA Report or Abridged AA Report is disapproved, the Department shall explain the basis for the disapproval. A disapproved Final AA Report or Abridged AA Report is not in compliance with section 69505.1(e)(2b).
  - (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, if any, that one or more of the regulatory responses specified in sections 69506.5, 69506.6, 69506.7, 69506.9, and/or 69506.10 is/are required.
  - (2) If the Department requires one or more regulatory responses under sections 69506.5, 69506.6, 69506.7, 69506.9, and/or 69506.10, the Department shall specify in the notice the proposed due date(s) for implementation of the regulatory response(s). In assigning

a due date for completing a regulatory response, the Department shall consider the complexity of implementing the regulatory response.

- (d) Notice of Ongoing Review. The Department shall specify in a notice of ongoing review the estimated date by which the Department expects to issue a notice of compliance or notice of deficiency. The Department, which shall take into account be based on its available resources and the complexity of the AA Report under review in estimating the date for issuance of a notice of compliance or notice of deficiency.
- (e) <u>Issuance of Notices.</u> All notices issued by the Department under this section shall be issued to the person who submitted the <u>AA Reportdocument</u>, and a copy of the notice shall be sent by the Department to all persons identified in the <u>AA Reportdocument</u> under subsections (c)(2) and (c)(3) of section 69505.<del>5</del>7.

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

#### Article 6. Regulatory Responses

#### § 69506. Regulatory Response Selection Principles.

- (a) <u>Need for Regulatory Response.</u> The Department shall identify and require implementation of <u>one or more</u> regulatory responses <u>designed for Priority Products and/or selected alternative products when the Department determines such regulatory responses are necessary to protect public health and/or the environment, and. In selecting regulatory responses, the Department shall seek to maximize the use of alternatives of least concern, where when such alternatives are <u>functionally acceptable</u>, technically <u>feasible</u>, and economically feasible.</u>
- (b) <u>Inherent Protection Preference.</u> In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection. For these purposes, "inherent protection" refers to avoidance or reduction of adverse <u>impact or exposure impacts</u>, <u>exposures</u>, <u>and/or adverse waste and end-of-life effects</u> that is achieved through the redesign of a product or process, rather than through administrative or engineering controls designed to limit exposure to, or the release of, a Chemical of Concern <u>or replacement Candidate Chemical in a product</u>.
- (c) <u>Selection Factors.</u> In selecting regulatory responses, the Department may consider any or all of the following factors:
  - (1) Public health and environmental protection.
- (A) The likely actual effectiveness of degree to which, and speed with which, the regulatory response, including can address the capacity of responsible entities to comply, and the adverse impacts and/or adverse waste and end-of-life effects of the Chemical(s) of Concern or replacement Candidate Chemicals in the selected alternative, or the Chemical(s) of Concern in the Priority Product;

- (B) The ability of end-users to understand and act upon any <u>regulatory response</u>
   involving provision of information and/or directions <del>provided</del> with respect to the <del>product;</del> Priority
   Product; and
  - (2) The relative cost-effectiveness of the regulatory response as compared to other possible responses;
  - (3) The administrative and other burdens that would be placed upon the Department, the responsible entities, the product end-users, and the public;
  - (4) (C) Any adverse ecological impacts of the regulatory response on sensitive resources, or unique or additional burdens that would be imposed by the regulatory response would impose upon sensitive subpopulations; and/or.
  - (5) The ease and efficacy2) Private economic interests of enforcement responsible entities.
  - (A) Existing federal and/or California State regulatory requirements applicable to the Chemical(s) of Concern or replacement Candidate Chemicals in the product;
  - (B) The cost to the responsible entity of the regulatory response-(s) relative to the cost of other possible responses; and
    - (C) The practical capacity of responsible entities to comply with regulatory response(s).
    - (3) Government interest in efficiency and cost containment.
  - (A) The management and clean-up costs imposed on public agencies by the ongoing sale of the Priority Product or a selected alternative;
  - (B) The Department's administrative burden in overseeing implementation of the regulatory response(s); and
    - (C) The ease of enforcing the regulatory response(s).

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

## § 69506.1. Applicability and Determination Process.

- (a) <u>Applicability</u>. <u>Except as specified otherwise</u>, <u>∓this article applies to any product placed into the stream of commerce in California that is:</u>
  - (1) An alternative selected under section 69505.4(c);
  - (2(1) A Priority Product for which an alternative is not selected; or
  - (2) An alternative selected under section 69505.6(d);
- (3) A Priority Product that will remain in commerce in California pending development and distribution of a selected alternative-: or
- (b) Prior to issuing a final regulatory response determination notice under sections 69506.5, 69506.6, 69506.7, 69506.9, and/or 69506.10, the Department, as required(4) A Priority Product for which the Final AA Report or Abridged AA Report is disapproved by the Department under section 69505.689(c)(3).
- (b) Exceptions. This article does not apply to a Priority Product if the manufacturer submits a Removal or Replacement Confirmation Notification that fully meets the applicable content requirements specified in subsections (b) through (e) of section 69505.2 to the

<u>Department prior to the due date for implementing any regulatory response that would</u> otherwise apply to the product.

- (c), shall notify ) Notice of Proposed Determination. After issuing a notice of compliance or a notice of disapproval for a Final AA Report or an final-Abridged AA Report, the Department shall issue a notice of the Department's proposed determination that one or more of the regulatory responses specified in this article is/are required, or that no regulatory response is required. The notice shall be issued no later than ninety (90) days after the Department issues the notice of compliance or a notice of disapproval.
- (d) Public Input. A notice issued pursuant tounder subsection (c) shall be sent to all known responsible entities for the product of the proposed regulatory response(s), and make the proposed regulatory response determination notice, and shall be made available on its the Department's website, for public review and comment. The proposed regulatory response determination notice shall include the Department's rationale for the proposed regulatory response(s). 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 send to individuals persons on the electronic mailing list(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. The 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 no sooner than forty-five (45) days from the date the <u>notice of the</u> availability of the proposed regulatory response determination notice is <u>posted on the Department's website or the date the notice is</u> sent to <u>individualspersons</u> on the electronic mailing list(s) that the Department establishes related to this chapter, and posted on the Department's website; whichever is later.
  - (2) The method(s) for submitting comments to the Department; and.
  - (3) The date, time, and location of anythe public workshop(s).
- (c) (e) Notice of Final Determination. After review and consideration of public comments, the Department shall finalizepost on its website and send to known responsible entities the final regulatory response determination notice. The Department may respond to some or all public comments received.
- (d) <u>f) Contents of Notices.</u> All proposed and final regulatory response determination notices must include all of the following:
  - (1) A description of the required regulatory response(s);
- (2) The Department's basis for requiring the), or a determination that no regulatory response(s); is required, whichever is applicable;
- (32) The rationale, information, and information sources supporting the Department's determination(s); and
  - (43) The implementation due date(s) for the regulatory response(s)., if applicable; and
- (e) (4) The Department's determination as to whether or not the regulatory response(s) apply(ies) to either or both of the following:

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- Priority Products ordered by a retailer prior to the effective date of the Priority Product listing, and still for sale by the retailer as of the date of the final regulatory response determination notice; and/or
- (B) Priority Products manufactured after the effective date of the Priority Product listing, but before the date of the final regulatory response determination notice.
- Implementation Due Date(s). In assigning a due date for aimplementation of one or more regulatory response responses, the Department shall consider the complexity of implementing the regulatory response.(s).
- NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

#### § 69506.2. AA Report Supplemental Information Requirements.

- (a) The Department may at any time require a responsible entity to provide, within a time frame specified by the Department, any information supplementary to the Final AA Report that the Department determines is necessary to select and ensure implementation of one or more regulatory responses that may be imposed under this article.
- (b) The Department may at any time require a responsible entity to obtain or develop, within a time frame specified by the Department, information to fill one or more of the information gaps identified in the Final AA Report, under section 69505.5(i)(2), if the Department determines this information is needed to re-evaluate, under section 69506.10(b), the initial regulatory response(s) imposed for a selected alternative or a Priority Product that remains in commerce.
- (h) Finality of Regulatory Response(s). Once a final regulatory response determination notice has been issued, the Department shall not augment or revise the regulatory responses for the affected product, except as provided otherwise in section 69506.2 and article 7.
- NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

#### § 69506.3. No2. Supplemental Information and Regulatory Response Required. Revisions.

- No(a) Supplemental Information for Selection of Regulatory Response(s). Prior to imposing any regulatory response for a product, the Department may require the responsible entity to obtain or develop, and provide to the Department within a specified time frame, any information supplementary to the AA Report that the Department determines is necessary to select and ensure implementation of one or more regulatory responses.
  - Information-Generation for Revision of Regulatory Response(s). (b)
- When imposing one or more regulatory responses for a product, the Department (1) may include a requirement that the responsible entity provide information to the Department to fill one or more information gaps identified in the AA Report under sections 69506.4 through 69506.10 is required for the selected alternative, section 69505.7(i)(2), if the Department

 determines for the selected alternative that no this information is necessary to re-evaluate one or more of the other initial regulatory responses.

- (2) Following receipt of information required to be provided under paragraph (1), the Department may, based on this new information, revise the initial regulatory response is necessary to prevent or limit adverse(s) imposed for the product in accordance with the procedures set forth in section 69506.1. Any revisions to the initial regulatory responses shall be noticed for public health or environmental impacts review and comment no later than ninety (90) days after receiving the information required to be provided under paragraph (1).
- (c) Regulatory Response Revisions for Revised AA Reports. In addition to the circumstances described in subsection (b), the Department may revise the initial regulatory response(s) imposed for a product in response to a revised AA Report submitted by a responsible entity under section 69505.4(e), within ninety (90) days after issuing the notice of compliance or notice of disapproval for the revised AA Report.

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

#### § 69506.43. Product Information for Consumers.

- (a)(1) Except as provided in paragraph (2), this) Applicability. This section applies to selected alternative products,:
  - (1) Priority Products for which an alternative is not selected, and :
- (2) Priority Products which remain inthat continue to be introduced into commerce in California pending development and distribution of an alternative product for longer than twelve (12) months after the Department issues a notice of compliance or a notice of disapproval for the Final-AA Report.; and
- (3) Selected alternative products that retain the Chemical(s) of Concern, and/or contain any replacement Candidate Chemical(s).
- (b) Required Information. Beginning no later than twelve (12) months after the date specified by the Department issues ain the final regulatory response determination notice of compliance for the Final AA Report for the product, or when the product is first placed into the stream of commerce in California, whichever is later, and for as long thereafter as the product is continues to be placed into the stream of commerce in California, the responsible entity shall ensure that all of the following information is made available to the consumer prior to exposure to any Chemical(s) of Concernproduct purchase:
- (A1) Manufacturer's name and importer's name, and/or the name of any other entity listed on the product label;
  - (B2) Brand name(s) and product name(s), and a description of the product;
- (C3) A list of, and common names for, all Chemicals any Chemical(s) of Concern known to be that remain in the product, and/or any replacement Candidate Chemical(s) and known hazards traits and/or environmental or toxicological endpoints for those chemicals, based on available information;

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- (D(4) A statement informing consumers that the product must be disposed of or otherwise managed as a hazardous waste at the end of its useful life, if applicable;
- Any safe handling and storage procedures and/or other information needed to protect public health or the environment during the useful life of the product, including precautions that consumers may take to prevent or limit exposure to the Chemical(s) of Concern or replacement Candidate Chemical(s), and first aid and accidental release procedures;
- Identification of any end-of-life management requirements specified by law, and any (<del>E</del>6) existing end-of-life management program(s) for the product; and
- The manufacturer's website address and the importer's website address where the consumer can obtain additional information about the product, the adverse public health and/or environmental-impacts associated with the product as identified in the AA Report for the product, and proper end-of-life disposal or management of the product.
- If the product contains no Chemical(s) of Concern above the applicable alternatives analysis threshold, then paragraph (1) does not apply.
- (b) c) Communication to Consumers. The responsible entity shall satisfy subsection (ab) by making the required information 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; and
- Using one or both of the following means of informing consumers at the point of sale of the information specified in subsection (ab):
- Providing the required information on the product packaging or in accompanying written material that is accessible without breaking the product seal; and/or
- Posting the information in a prominent place at the point of retail display. For products offered for sale online, the point of retail display is/are the web page(s) on which the product is offered for sale.

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

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#### § 69506.54. Use Restrictions on Chemical(s) of ConcernChemicals and Consumer Products.

The Department may impose restrictions on the use of one or more Chemicals of Concern or replacement Candidate Chemicals in a selected alternative, or Chemicals of Concern in a Priority Product for which an alternative is not selected, or restrictions on the use of the product itself, that the Department determines are necessary to reduce the ability of potential for the product to contribute to or cause adverse public healthimpacts and/or environmental impacts adverse waste and end-of-life effects. Use restrictions may include one or more of the following:

(a) Restrictions on the amount or concentration of the Chemical(s) of Concern or replacement Candidate Chemical(s) permitted in a product;

- 1 (b) Restrictions on the settings in which a product may be sold or used;
  - (c) Restrictions regarding the form in which a product is sold;
  - (d) Restrictions on who may purchase and/or use a product;
  - (e) Requirements for training of product purchasers and/or users; and/or
  - (f) Any other use restriction that reduces the amount of any Chemical(s) of Concern <u>or replacement Candidate Chemical(s)</u> in the product, or reduces the <u>ability of potential for</u> the product to contribute to or cause an exposure to the Chemical(s) of Concern <u>or replacement</u> Candidate Chemical(s) in the product.

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

#### § 69506.65. Product Sales Prohibition.

- (a) This section does not apply to a product that does not contain any Chemical Existence of Concern above the applicable alternatives analysis threshold.
- (b) Safer Alternative(s). Except as provided in section 69506.3 and subsection (e), the requirements of subsection (c) apply to subsection (c), the Department may require a responsible entity to cease placing into the stream of commerce in California a selected alternative product that contains one or more Chemical(s) of Concern, or replacement Candidate Chemical(s), or a Priority Product for which an alternative is not selected, if the Department determines and notifies provides notice to the responsible entity, under section 69506.1, that there is a safer alternative exists that does not contain the Chemical(s) of Concern or replacement Candidate Chemical(s) and that does not contain a Chemical of Concern and that is both is functionally acceptable and, technically feasible, and economically feasible. In making such athis determination, the Department shall consider the potential adverse impacts and potential exposure pathways that have the ability to contribute to or cause adverse public health and/or environmental impacts associated with the alternative product or Priority Product, as applicable.
- (c) Any responsible entity that is the subject of a notification issued under subsection (b) shall cease to place the noticed product into the stream of commerce in California within one (b) No Existing Safer Alternatives.
- (1)-year after the Department issues the notification, unless the notification specifies a shorter period of time.
- (d)(1) Except as provided in section 69506.3 and subsection (ec), the Department may issue a notificationnotice, under section 69506.1, of its determination that a product containing athe Chemical(s) of Concern or replacement Candidate Chemical(s) may no longer be placed into the stream of commerce in California, notwithstanding the fact that there are no currently identified safer alternatives that are both functionally acceptable and, technically feasible, and economically feasible.
- (2) Prior to issuing a <u>notification</u>notice under paragraph (1), the Department shall request the responsible entity to provide, within sixty (60) days, documentation that demonstrates to the Department's satisfaction both of the following:

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- The overall beneficial public health and/or environmental impacts and/or social utility (A) of the product significantly outweigh the overall adverse public health and environmental impacts of the product; and
- (B) Administrative and/or engineering restrictions on the nature and/or use of the product will adequately protect public health and the environment.
- The Department may issue a notification notice under paragraph (1) if the responsible entity does not provide the requested documentation with sixty (60) days, or if the submitted documentation does not make the required demonstrations to the Department's satisfaction.
- (4) Any responsible entity that is the subject of a notification issued by the Department under paragraph (1) shall cease to place the noticed product into the stream of commerce in California within one (1) year after the Department issues the notification, unless the notification specifies a shorter period of time.
- —(c) Exceptions. A responsible entity that receives a notification notice under subsection ( $\underline{ba}$ ) or ( $\underline{db}$ ) is not subject to the requirements of subsection ( $\underline{ca}$ ) or ( $\underline{d}$ ) if all of the following requirements are met:
- Within sixty (60) days after the notification notice is issued by the Department, the (1) responsible entity notifies the Department in writing of its intent to submit a revised Final-Final AA Report that selects an alternative that does not contain athe Chemical(s) of Concern; or the replacement Candidate Chemical(s);
- Within one (1) year after the notification is issued by the Department, unless the (2) Department specifies a shorter period of time in the notification, the The Department receives, by the date specified by the Department in the final regulatory response determination notice issued under section 69506.1, a timely-revised Final Final AA Report that selects an alternative that does not contain athe Chemical(s) of Concern or the replacement Candidate Chemical(s) and that meets the requirements of complies with section 69505.57; and
- The product containing one or more the Chemical(s) of Concern or the replacement Candidate Chemical(s) is completely removed from no longer placed into the stream of commerce in California by the responsible entity, directly or indirectly, by the date specified by the Department in the notice of compliance or notice of disapproval for the revised Final AA Report submitted under paragraph (2), or in a separatefinal regulatory response determination notice issued under section 69505.6(c). The completion date shall be no longer than three (3) years after the Department issues the notice of compliance or notice of disapproval. 69506.1.

#### (f)((d) Extensions.

- A responsible entity may request a one-time an extension to the due date for the revised Final AA Report to be submitted under subsection (ec), under the procedures specified in section 69505.1(dc) or section 69505.7(k)(1)(B).
- If the Department grants an extension, the responsible entity shall satisfy one of the (2) following requirements by the due date specified in the extension approval:
- A revised Final Final AA Report meeting the requirements of subsection (ec)(2) shall be submitted to the Department; or

(B) The product shall cease to be placed into the stream of commerce in California by the responsible entity, directly or indirectly.

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

#### § 69506.76. Engineered Safety Measures or Administrative Controls

 (a) Requirement for Controls. The Department may, under subsection (b), impose requirements require a manufacturer to engineer safety measures that integrally contain or control access to-or-, and/or implement administrative controls that limit exposure to, the Chemical(s) of Concern or replacement Candidate Chemical(s) in a selected alternative product, or, or the Chemical(s) of Concern in a Priority Product for which an alternative is not selected, to reduce the likelihood of potential for adverse public health and/or environmental impacts.

(b) <u>Criteria.</u> Engineering or administrative controls may be imposed by the Department to either integrally contain the Chemical(s) of Concern within the structure of the product or limit exposure to the Chemical(s) of Concern.required if one or more of the following applies:

 (1) Reliable information indicates the presence of the Chemical(s) of Concern, or replacement Candidate Chemical(s), or its/their degradate, metabolite, or reaction products, in a particular subpopulation that has one or more routes of exposure to the chemical(s);

(2) Reliable information indicates an elevated level of the Chemical(s) of Concern <u>or replacement Candidate Chemical(s)</u> in an indoor building or other enclosed environment; and/or

(3) Improper product handling <u>would increase increases</u> the <u>likelihood of potential for</u> release of, or exposure to, the Chemical(s) of Concern- or replacement Candidate <u>Chemical(s)</u>.

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

## § 69506.87. End-of-Life Management Requirements.

 (a) Except as provided in section 69506.3, a responsible entity for(a) Applicability. A manufacturer of 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 comply with the following requirements are met:of subsection (c) except as otherwise provided under subsections (d) and (e).

(1) The information required by section 69506.4 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.

(2) (b) Manufacturer Collaboration Option. A manufacturer may individually fulfill the requirements of this section, or may join with other manufacturers to form a non-profit third-

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party product stewardship organization, funded by participating manufacturers, to fulfill the requirements of this section on behalf of the participating manufacturers.

- End-of-Life Program Requirements. No later than one (1) year after the date specified by the Department issues ain the final regulatory response determination notice of compliance for the Final AA Report for the product, or no later than the responsible entity shall fund, date the product is first placed into the stream of commerce in California, whichever is later, the manufacturer shall establish, and maintain an end-of-life management program for the product. The program must comply with all of the following requirements:
- (A1) A comprehensive product stewardship plan must be developed and maintained, after beingthe plan is submitted to and approved by the Department. If the Department disapproves the plan, it shall notify the manufacturer in writing, identify what is necessary to correct deficiencies in the plan, and specify a due date for approval. The submission of a revised plan. If the plan is not resubmitted by the due date or does not address all of the deficiencies, the plan will be considered to be non-compliant with this section.
  - (2) Each product stewardship plan must include all of the following:
- 1.(A) A list of, and contact information for, participating manufacturers, importers, and other participating persons.
  - 2. (B) The scope of products and brands to be covered by the plan.
- 3. (C) The roles and responsibilities for manufacturers, importers, assemblers, retailers, consumers, and government throughout the life cycle of the product, and identification of retailers and/or assemblers who have agreed to participate in the program.
  - 4.(D) Identification and description of collection systems that will be used.
- 5.(E) End-of-life management information, that includes describes the steps that will be taken to ensure compliance with all applicable federal and California State and local laws, and that addresses any adverse multimedia impacts.
- 6. Anticipated(F) Identification of anticipated resources needed to implement and sustain the plan, including identification of anywhich must ensure that the end-of-life management program is maintained for sufficient time to be available at the end-of-life for the last covered product, and all previous covered products, that the manufacturer places into the stream of commerce in California. An estimate of the annual and total long-term program costs shall also be identified in the plan, along with the information, assumptions, calculations, and any models used to develop the cost estimate.
- The funding mechanism to cover, but not exceed, the costs identified in subparagraph (F). This requirement shall be satisfied by whichever of the following means is applicable:
- 1. If the end-of-life management program will be administered by a non-profit thirdparty product stewardship organization collecting and pursuant tounder subsection (b), the plan shall describe how the organization will collect operating revenues in an amount necessary to cover, but not exceed, the costs identified in subparagraph (F). This shall include the method and calculations used to determine how much each participant will contribute.
  - If an individual manufacturer is administering a fee to fund the stewardship program.

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7.and funding its own end-of-life management program, the manufacturer shall provide a-A financial guarantee provided by the responsible entity to insure a sustainable end-

with submittal of the plan.

of-life management program for the product.

California.cover the costs identified in subparagraph (F).

b. 2. Increasing recyclability, and recycling rate.

9. (I) A description of how each program goal will be achieved.

10.(J) Public education, outreach, and communications plans.

end-of-life management costs for products placed into the stream of commerce in

"Financial guarantee" means any mechanism, including the mechanisms described

in article 8 of chapter 14, tothat will ensure that adequate funding is available to pay for future

8.(H) Program performance goals, which shall be quantitative to the extent feasible, for:

11.(K) A description of public and stakeholder consultation activities during preparation,

and in periodic of the plan, which shall include, at a minimum, provision of thirty (30) days for

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

the public to comment on the proposed product stewardship plan through the manufacturer's website. The manufacturer shall transmit to the Department all comments received concurrent

(L) A description of public and stakeholder consultation activities for review and

updating, of the plan, which shall occur no less frequently than annually. Reporting and evaluation procedures.

- (B3) The product stewardship program and plan for collecting and, if applicable, recycling the product shall be developed in consultation with California retailers and other owners/operators of prospective collection sites. The collection program must include one or both of the following:
  - 1. (A) Collection mechanisms; and/or
- 2. Compensation(B) If applicable, compensation to retailers and other persons who agree to administer or participate in the collection program.
- (C4) The responsible entitymanufacturer shall provide its product stewardship plan to the Department for review and approval, post a copy of the product stewardship plan on its own website, and provide athat link to the posting to the Department for posting on the Department's website.
- (D5) The responsible entity for manufacturer of a product subject to the requirements of this section shall ensure that aprovide an annual report is provided to the Department annually . The annual report is due one (1) year from the date the end-of-life management program is required to be implemented, and annually thereafter. The report must include, by total tonnage:
- 1. (A) The quantity of products placed into the stream of commerce in California over the previous one-year period; and
  - 2. (B) The quantity of products recovered over the same one-year period.
- (b) 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.

- (c) A responsible entity subject to the requirements of (d) Alternative End-of-Life Programs. A manufacturer subject to 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 A manufacturer may not propose an in-store take-back program as part of an alternative program unless the manufacturer provides in the plan evidence that a sufficient number of retailers have agreed in writing to participate If a manufacturer's alternative end-of-life management program relies on other persons, the manufacturer shall provide written substantiation of their agreement to participate at a level necessary to insure successful implementation of the plan as proposed. A manufacturer may not substitute an alternative end-of-life management program for the program specified in this section unless it receives advanced written approval from the Department.
  - (de) Exemption from End-of-Life Program Requirements.
- (1) A responsible entitymanufacturer 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.
- (2) A manufacturer subject to this section is not exempt from this section until it receives written concurrence from the Department 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.

#### § 69506.98. Advancement of Green Chemistry and Green Engineering.

The Department may require a When a manufacturer concludes that no safer alternative to its Priority Product is functionally acceptable, technically feasible, and economically feasible, or a manufacturer selects an alternative that reduces but does not eliminate the use of Candidate Chemicals in the product, the Department may require the manufacturer to initiate a research and development project or fund a challenge grant pertinent to the Priority Product that uses green chemistry and/or green engineering principles to do one or more of the following:

- (a) Design a safer alternative to the Priority Product;
- (b) Improve the performance of a safer alternative to the Priority Product:
- (c) Decrease the cost of the safer alternative to the Priority Product; and/or
- (d) Increase the market penetration of a safer alternative to the Priority Product.

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

# § 69506.<del>10.</del> <u>9. Exemption from Regulatory Response Selection and Re-Evaluation Regulatory Response Selection Regulatory Response Selection and Re-Evaluation Regulatory Response Selection and Re-Evaluation Regulatory Response Selection Response</u>

- (a) The Department may impose one or more regulatory responses specified in section 69506.2 and sections 69506.4 through 69506.9 to situations other than those specified in those sections.
- (b) The Department may periodically re-evaluate any regulatory response imposed under this section to determine if changes are needed based upon changed circumstances or information identified since a regulatory response was selected, including information that fills one or more of the information gaps identified in the Final AA Report under section 69505.5(i)(2). The Department may accordingly require a new AA to be performed, and Preliminary and Final AA Reports to be submitted to the Department, in a specified time period.

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

#### § 69506.11. Exemption from Regulatory Response Requirements.

- (a) Requests. A product is exempt from the requirements of sections 69506.43 through 69506.408, if the responsible entity requests, and the Department grants, an exemption. A responsible entity seeking an exemption shall submit an exemption request to the Department no later than whichever of the following dates is applicable: sixty (60) days after the Department issues a final regulatory response determination notice for the product.
- (1) Sixty (60) days after the Department issues a notice to the responsible entity under sections 69505.6(c); or
- (2) Sixty (60) days after the Department issues a notice(b) Contents of compliance for a Final AA Report for a product subject to sections 69506.4 or 69506.8.
- (b) Requests. An exemption request submitted under 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(s) and the importer(s) 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 and 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, if the product is a component and/of one or homogeneous material and its/their associated more assembled products, a description of the known product(s) in which the component, if applicable is used; and
- (6) Information that demonstrates to the Department's satisfaction that one or both of the following applies:

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- The required or proposed regulatory response would conflict conflicts with one or (A) more requirements of another California State or federal regulatory program or anapplicable treaties or international trade agreementagreements with the force of domestic law, 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 State or federal regulatory program or anapplicable treaties or international trade agreement agreements with the force of domestic law, without conferring additional public health or environmental protection benefits.
- Departmental Notice. 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) Actions Following Exemption Denial. 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 implementation of a modified regulatory response that resolves the conflict that is the basis for the exemption.
- Rescission of Exemption. The Department shall rescind an exemption granted under 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 notifyprovide notice to the person who submitted the exemption request and known responsible entities for the product.
- Contents of Notices. The Department shall include in all notices granting, denying, or rescinding an exemption under this section a statement of basis for its decision and a new due date for compliance, if applicable.

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

#### § 69506.<del>12</del>10. Regulatory Response Report and Notifications.

- Notification to Supply Chain. A responsible entity subject to a regulatory response other than one imposed under this article, except for the regulatory responses specified in sections 69506.2 and 69506.9,8 shall ensure that a notice notification is sent to all retailers who sellpersons in California, other than the final purchaser or lessee, to whom the responsible entity directly sells the product, and any other person other than the final purchaser or lessee to whom the responsible entity directly sells the product if it is reasonably foreseeable that the product will be placed into the stream of commerce in California, informing the retailers those persons of the applicability of the regulatory response to the product. The noticenotification shall be sent to the retailers, and, with a copy sent to the Department, no later than whichever of the following dates is applicable:
- (1) Thirtythirty (30) days after receiving a final regulatory response determination notice, under section 69506.1; or

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- (2) Thirty (30) days after the Department issues a notice of compliance for a Final AA Report for a product subject to section 69506.4 or 69506.8.
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  - include all of the following:
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- Contents of Notifications. The noticenotification required under subsection (a) shall
  - The name of, and contact information for, the person providing the notification; (1)
- (2) The name of, and contact information for, the responsible entity(ies) on whose behalf the notification is being provided;
- If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer(s) and the importer(s) of the product;
- (2) The responsible entity's name and contact information, if different from the manufacturer or importer;
- (3(4) Information identifying and describing the original Priority Product, and the selected alternative, includingand 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, importer, and/or distributor on the product label; and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used; and
- A description of the required regulatory response(s) and the due date for (45)implementing the regulatory response(s).
- (c) Notifications to the Department. 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-(s). 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).) and/or the development and introduction into the California marketplace of the selected alternative(s). The information provided to the Department under this subsection shall also be posted on the website of the responsible entity.

## (d)(d) Regulatory Response Summary.

- The Department shall prepare and post on its website, and update at least annually, a Regulatory Response Summary that identifies the regulatory response(s) for each selected alternative forto a Priority Product, or for the Priority Product, whichever is applicable. The Regulatory Response Summary must contain all of the following for which information is available:
  - (A) The name of, and contact information for, the manufacturer(s) and the importer:(s):
  - The names of, and contact information for, other known responsible entities: (B)
- (C) Information identifying and describing the original Priority Product, and the selected alternative, (s), if any, including and the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, the name(s) of any persons identified as the manufacturer, importer, and/or distributor on the product label, and, if the product is a component of one or more assembled products, a description of the known product(s) in which the component is used;

- (D) The due date and actual date for completing development and introduction into the California marketplace of the selected alternative, 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 under subsections (a) through (c).
- (2) The Department shall also include in the Regulatory Response Summary the information specified in paragraphs (1)(A) through (1)(D) for each exemption granted by the Department under section 69506.119.

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) <u>Applicability.</u> This article applies to any responsible entity that wishes to dispute a decision made by the Department under this chapter that applies to the responsible entity, except as otherwise provided in subsection (c).
- (b) <u>(b) Exhaustion of Administrative Remedies.</u> 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 waives its right to further contest the disputed issue-administratively.
- (c) AScope. Notwithstanding any other provision of this chapter, a decision made by the Department under article 2, 4, or 109 is not subject to dispute resolution under this article.
- (d) <u>Automatic Stay.</u> A requirement imposed by the Department under this chapter on a responsible entity, and any posting concerning the requirement on the Failure to Comply list <del>under section 69501.2(d),</del> is stayed during the pendency of an administrative 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) Request for Review. For a dispute regarding a decision made by the Department under the provisions of this chapter, other than sections 69506.5, 69506.6, 69506.7, 69506.9, 69506.10, and 69506.11 article 6, a responsible entity may, within thirty (30) days following the mailing of the notice or the website posting of the Department's decision that is the basis of the dispute, whichever is later, 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

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

§ 69507.3.

informal dispute resolution is not received within thirty (30) 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.

Administrative Appeal. 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.

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

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

#### § 69507.2. Appeal to the Director.

- Contents of Appeals. A responsible entity appealing the Department's decision (a) 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 comply with the requirements of this chapter or is otherwise unreasonable. The responsible entity shall also provide all of the following:
  - The original statement of dispute; (1)
  - (2) Supporting documents information; and
  - (3)Copies of responses prepared by the Department.
- The Deadline for Filing an Appeal. A responsible entity appealing a Department (b) decision shall file the appeal with the Department's Director within thirty (30) days after completion of the informal dispute resolution process under section 69507.1.
- Decision on Appeal. The Director or designee shall issue a decision granting or denying the relief sought, in whole or in part, or a notice of ongoing review, within sixty (60) days after receipt of the request under this section. If the relief sought is denied, the decision by the Department must:
- Contain a short and plain description of the basis for denial of the request for further administrative review; and
- Specify the date by which the responsible entity shallmust comply with the (2)requirements of this chapter that were in dispute.
- Finality of Decision. A decision issued under subsection (c) is the Department's final decision and is not subject to additional administrative dispute resolution.
- Notice of Ongoing Review. The Department shall specify in a notice of ongoing review the estimated date by which the Department expects to issue a decision granting or denying the relief sought. The Department shall take into account its available resources and the complexity of the issues raised in the appeal in estimating the date for issuance of the final decision.
- Formal Dispute Resolution Procedures.

For all disputes regarding a decision made by the Department under sections 69506.5, 69506.6, 69506.7, 69506.9, 69506.10, and 69506.11 article 6, the procedures specified in sections 69507.4 through 69507.6 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 <u>final regulatory response</u> determination <u>notice</u> from the Department under <u>section 69506.5</u>, 69506.article 6, 69506.7, 69506.9, 69506.10, or 69506.11, the responsible entity may submit a Request for Review to the Department, requesting review of 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 <u>administrative</u> 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 Requests 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 reconsider.

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) <u>Decision Time Frame.</u> 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, or a notice of ongoing review.
- (b) <u>Finality of Decision.</u> 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. An order denying review must:
- (1) Specify the date by which the responsible entity shallmust comply with the requirements of this chapter that were the subject of the Request for Review; and
- (2) Contain a short and plain description of the basis for the denial of further administrative review.
- (c) <u>Briefing Schedule.</u> An order granting review must specify a schedule for briefing of the issues by the responsible entity and the Department.

- (d) <u>Merits Decision.</u> The Department shall issue an order specifying its decision on the merits of the Request for Review, or a notice of ongoing review, within 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 must specify the date by which the responsible entity shallmust 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) <u>Notice of Ongoing Review.</u> The Department shall specify in a notice of ongoing review the estimated date by which the Department expects to issue an order under subsection (a) or (d), whichever is applicable. The Department shall take into account its available resources and the complexity of the issues raised in the Request for Review in estimating the date for issuance of the order.
- (f) <u>Recusal of Staff.</u> 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.
- (g) Limits on Intra-Departmental Communications. 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. Qualifications and Certification for Assessors.

- (a) An individual in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, shall meet both 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; and
- (2)(A) Have the equivalent of two (2) years of professional experience performing AAs and/or working in a scientific or engineering field.
- (B) 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 experience required under subparagraph (A).

- (b) On and after the date that is two (2) years after the effective date of these regulations, an individual in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, shall successfully complete an assessor training program that is developed and delivered by an accreditation body, successfully complete an exit exam that meets the requirements of section 69508.2(c)(5), and meet all of the following requirements:
- (1) Receive a "Certified Alternatives Assessor" certificate that meets the requirements of section 69508.2(c)(6), and is issued by the accreditation body whose training program the assessor successfully completed.
  - (2) Maintain certification by doing all 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 shall be education and/or training focused on one or more aspects of conducting 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 current certification. If the assessor complies with the requirements of this subparagraph and subparagraph (A), the current certification will remain in effect until the accreditation body makes a determination on the application for renewal; and
- (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 that provided or verified the assessor's continuing education under subparagraph (A).
- (3) Possess, and produce when requested, a current "Certified Alternatives Assessor" certificate meeting the requirements of section 69508.2(c)(6).
- (c) Successful completion of an approved challenge test developed by the accreditation body may be used in lieu of the classroom training requirements specified in section 69508.2(c)(4) and written and practical tests specified in section 69508.2(c)(5) for applicants who meet the competency requirements and/or possess on-the-job training equivalent to that specified in section 69508.2(c)(4)(A) through (E).
- (d) If the Department revokes, under 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 revocation is posted on the Department's website.
- (e) An assessor's certificate shall be subject to reprimand, suspension, probation, or revocation 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 reproved, suspended, placed on

probation, or revoked by the accreditation body, and an explanation of the reasons for the decision.

- (f) Final decisions and a summary regarding actions which result in reprimand, suspension, probation, or revocation shall be posted on the Department's web site for five (5) years after the effective date of the decision.
- (g)(1) A certified assessor may not be in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report, if the certified assessor has an ownership interest in the responsible entity whose product is the subject of the AA. For purposes of this subsection, an ownership interest exists if the certified assessor, or his/her spouse, child, or parent holds a position as an officer or director of the responsible entity or has an equity stake in the responsible entity in the amount of ten thousand dollars (\$10,000) or more.
- (2) Paragraph (1) applies only to third-party certified assessors that are in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report under a contractual agreement with the responsible entity.

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 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 analysis 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 all of the following subject areas:
  - (A) Environmental fate and transport, which shall include all of the following:
- 1. Fundamental processes in natural and engineered systems, including inter-media transport of contaminants between environmental compartments, and chemical and biochemical transformations within these compartments;
- 2. Principles of environmental reactions with emphasis on aquatic chemistry, reaction and phase equilibria, acid-base and carbonate systems, oxidation-reduction, colloids, organic contaminant classes, sources and fates, and groundwater chemistry; and

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- 3. Topics concerning the environment, including ecology, population dynamics, pollution micro-biology, aquatic biology, bio-concentration, limnology, stream sanitation, nutrient cycles, and toxicology atmospheric chemistry. (B) Principles of green chemistry, which shall include both of the following:
- 1. The study of all aspects and types of chemical processes, including synthesis, catalysis, analysis, monitoring, separations and reaction conditions that reduce adverse impacts on public health and the environment through the reduction in, or elimination of, the
- use or generation of hazardous materials; and 2. Pollution prevention and cleaner production methods.
  - (C) Project life cycle management, which shall include both of the following:
- 1. Environmental management of engineering projects from the research through the development, operation, maintenance and ultimate disposal phases; and
- 2. Impacts of exploitation of raw materials and energy resources, and transportation; pollution from use and ultimate disposal of products; economics of environmental resources.
  - (D) Public health, which shall include all of the following:
- Impacts to sensitive populations, including the study of risk and factors that influence the distribution of disease in subpopulations;
- 2. Examination of the basic principles of epidemiology, their application to specific public health situations, and criteria for critically evaluating epidemiology studies; and
- Methods of evaluating the causative factors of disease and the assessment of epidemiological study designs and research activities.
  - (E) Professional ethics, which shall include all of the following:
- Analysis of ethical principles and dilemmas that may arise during the conduct and preparation of the AA and AA Reports;
- 2. Examination of the services provided and approaches to providing impartial, fair, and equitable services dedicated to the protection of public health and the environmental;
  - 3. Fundamental standards that protect the safety, health, and welfare of the public;
- Standards and practices to ensure that services are performed only in areas of competency, statements are made only in an objective and truthful manner, the assessor acts for each employer or client as a faithful agent or trustee, and deceptive acts are avoided; and
  - 5. Rules of practice and professional obligations that support the above.
  - (F) Toxicology and comparative risk assessment, which shall include all of the following:
- 1. The toxic effects that hazardous chemicals have on biological systems, including dose-response curves, mechanisms of toxicity, carcinogenesis, and reproductive hazards;
- 2. The risks associated with exposure to hazardous chemicals and instruction on how risk assessment fits into the risk management processes; and
- Examination of common toxicological effects of chemicals on biological systems through inclusion of relevant case studies.
  - (G) Occupational health and safety, which shall include all of the following:
- The principles, practices, and methods for identifying, evaluating, preventing, and reducing workplace chemical hazards;

- 2. Methods for measuring and evaluating chemical-related hazardous workplace conditions; and
- 3. Federal and State statutory and regulatory requirements regarding occupational health protection.
- (6) The ability to teach, and experience teaching, or have access to subject matter experts with the ability to teach, and experience teaching, in two or more of the following subject areas:
- (A) Economics and financial planning for innovation, which shall include both of the following:
- 1. An introduction to the core principles of economics, finance, and accounting to understand the steps necessary to bring green chemistry innovations to market; and
- 2. Exploration of other relevant topics in business administration and sustainability, including business models, ecological economics, entrepreneurship and service design.
  - (B) Environmental law, which shall include all of the following:
- 1. Federal statutory and regulatory requirements regarding public health and environmental protection;
- 2. State statutory and regulatory requirements regarding public health and environmental protection; and
  - 3. Principles of public policy.
  - (C) Research in emerging technologies, which shall include both of the following:
  - 1. Advances made in materials science; and
- 2. Case studies in lessons learned which must include the principles of design, manufacture, and use of classes of materials such as metals, ceramics, semiconductors, polymers, and biomaterials that addresses fundamental energy, environmental, health, economic, and manufacturing issues relating to those materials.
  - (D) Sustainable practices, which shall include all of the following:
- 1. The examination and fundamental qualities, attributes and competencies to manage resources in a responsible manner, with minimal impact on natural resources and climate;
- 2. Identification of scientific methods for measuring and auditing the effectiveness of eco-friendly practices that make improvements on the amount of resources expended on energy, transportation, water use, recycling, and natural resources through the life cycle of products, technologies, and processes; and
- 3. Identification skills and tools to identify emerging issues and opportunities most pertinent to specific industries, establishing appropriate goals, developing and integrating new strategies, and measuring performance.
- (b) Except as provided in subsection (c), any entity that seeks designation as an accreditation body must be independent of, and may not hold any stock or ownership interest in, any consumer product manufacturing, importation, distribution, or retail business.
- (c) Subsection (b) does not apply to colleges, universities, or their subdivisions, that seek designation as an accreditation body.

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 detailed description of the accreditation program demonstrating that the program meets the requirements specified in subsection (c), including all of the following information:
- (A) The entity's training program for certification of assessors, including for each course the title, content description, hours, and exam plan;
- (B) Demonstrated qualifications and areas of expertise of the individuals responsible for developing the entity's training curriculum, as evidenced by education, experience, professional licenses, registrations, or other relevant credentials; and
- (C) The entity's continuing education curriculum for re-accreditation of assessors, 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 under section 69508(b)(2), 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 analysis tools and methodologies and life cycle thinking, meaning the examination and consideration of public health and environmental impacts over a product's entire life cycle;
  - (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 specified in paragraph (4) and the written and practical tests specified in subparagraph (A), 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 must, at a minimum, include all of the following:
  - The assessor's name;
  - 2. The certificate number;
  - 3. The certificate issuance date and expiration date;

- 1 4. The name of, and contact information for, the accreditation body issuing the certificate;
  - 5. An indication 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 subsections (a) and (b) of section 69508; 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 analysis 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, subject to non-disclosure agreements as needed, to ensure the quality of work and proper application of tools by the assessor.
    - (8) Record Maintenance Program.
  - (A) The accreditation body shall maintain a database of the names of individuals whose applications were accepted or denied, names of and contact information for individuals certified, their certificate numbers, their certificate issuance and expiration dates, and the area(s) of expertise in which each assessor is certified. 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. The accreditation body shall provide the Department with real-time electronic access to the database.
  - (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 under article 9.

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

#### § 69508.3. Accreditation Body Designation Process.

(a) The Department shall review an application submitted under 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.

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- body or a certified assessor. The complaint must include both of the following: (1) The name of, and contact information for, both of the following:

§ 69508.4. Filing a Complaint.

- The accreditation body or certified assessor that is the subject of the complaint; and
- (B) The name of the complainant, unless filing anonymously.

- (b) If the information submitted under 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, under 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 the Department determines an accreditation body is negligently or willfully in violation of this chapter, the Department shall revoke the entity's designation as an accreditation body for a period of at least ten (10) years. After this period, the accreditation body 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 periodically review the performance of an accreditation body to determine whether the accreditation body is in compliance 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 revoke 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 under 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.

(a) A person may file a complaint alleging a violation of this chapter by an accreditation

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

- (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, if not submitted anonymously, 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, unless submitted anonymously, and specify the basis for the determination. Anonymous complaints lacking sufficient information will be dismissed.
- (c) If the complaint substantially complies with the requirements of this section, the Department shall serve a copy to each subject of the complaint, together with an order requiring that the complaint be answered by the subject within thirty (30) days after the date of service.
- (d) The Department shall review the information and documentation in the response from the subject of the complaint 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 of the complaint 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 98. Audits

## § 695098. Audit of Materials Submitted to the Department and Regulatory Responses.

- (a) <u>Audits.</u> The Department may audit any information compiled, and/or submitted to the Department, under this chapter. Information the Department may audit includes, but is not limited to, AAs, AA Reports, information related to notifications submitted under this chapter, and implementation of regulatory responses.
- (b) <u>Scope.</u> The scope of any audit may include, but is not limited to, 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 alternatives, if applicable; and/or
  - (4) Compliance with the regulatory response(s) imposed under article 6, if any.

(c) <u>Notification of Audit Findings.</u> Upon completion of an audit, the Department shall notifyprovide notice to the responsible entity(ies) of the audit findings and the process to dispute audit findings.

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.

#### Article 109. Trade Secret Protection

#### § 6951069509. Assertion of a Claim of Trade Secret Protection.

(a) <u>Substantiation Requirements.</u> 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 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;

 (4) 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;

(5) The measures taken to restrict access to and safeguard the information, and whether or not the person plans to continue utilizing such measures;

 (6) The estimated value of the information to the person and the person's competitors;

 (7) The estimated amount of effort and/or money expended by the person in developing the information;
(8) The estimated ease or difficulty with which the information could can be properly

 acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering;

 (9) Copies of, or references to, any pertinent trade secret or other confidentiality determinations previously made by the Department or other public agencies;

 (10) A description of the nature and extent of harm that would could be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed;

 (11) 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 as required by section 69501.3, and based upon 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
- (12) Contact information for the individual to be contacted if partany of the claimed information is requested to be disclosed under the California Public Records Act- (commencing with Government Code section 6250).
- (b) <u>Streamlining of Submittal.</u> The substantiating information required under subsections (a)(1) through (a)(10) 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)(11) and (a)(12) may be met once for all claims submitted at one time.
- (c) <u>Documentation.</u> 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(1) Except where expressly prohibited by federal law, or by a nondisclosure agreement whose relevant text is provided to the Department, 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) <u>Marking of Documents.</u> 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) Provision of Separate Copies. 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) <u>Hazard Trait Submissions.</u> Except as specified in subsection (g), trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trait submission or <u>for</u> any chemical identity information associated with a hazard trait submission.
- (g)— Trade secret protection may be claimed for the chemical Chemical Identity Masking When a Patent is Pending.
- (1) The precise identity of a chemical that is the subject of a hazard trait submission may be temporarily masked only if the subject of claimthat chemical is a proposed an alternative to a Chemical of Concern in a Priority Product considered or proposed in an

- Alternatives Analysis, and the claimant does all of the following: a patent application is pending for the chemical or its contemplated use in the product. Such masking shall be authorized only until the patent application has been granted or denied information subject to the trade secret claim is made public through any means, including through publication of the patent application, a foreign counterpart, or an issued patent. The person claiming the trade secret shall notify the Department in writing within thirty (30) days after the patent application has been granted or denied information is made public.
  - (1) Demonstrates to the Department's satisfaction that the chemical that is the subject of the claim is a new chemical or a new use of an existing chemical;
  - (2) Provides the Department with sufficient health, safety, and environmental data on the chemical subject to the claim to demonstrate, to the Department's satisfaction, that it is substantially safer than the existing Chemical of Concern in the Priority Product; and
    - (3) Complies with the substantiation requirements of subsections (a)(1) through (a)(12).
  - (h) (2) Any person making a claim of trade secret protection for the temporarily masking the precise identity of a chemical under subsection (gparagraph (1) shall provide the Department with a non-confidential description of the nature of the chemical that is as specific as possible, consistent with the claim of trade secret protection.

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

## § 6951069509.1. Department Review of Claims of Trade Secret Protection.

(a) Review of Support for Trade Secret Designation. Upon receipt of information submitted under 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)((b) Additional Information Requirements.

- (1) If the Department determines that information provided in support of a request for trade secret protection is incomplete or insufficiently responsive to permit a trade secretsecrecy determination, the Department shall:
- (A) NotifyProvide notice to the submitter of the Department's finding of insufficiency; and the basis therefor;
  - (B) Identify the specific area(s) for which additional information is needed; and
- (C) Provide an explanation as to why the Department has determined the information to be insufficient; and
  - (D(C)) Indicate the date by which the submitter must provide the requested information.
- (2) If the submitter fails to provide the information within the timeframe specified, the Department shall notifyprovide notice to the submitter by certified mail that the claim 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 preliminary injunction and/or declaratory relief.

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29 §§ <del>69512</del>69511 -- 69599. [Reserved]

Article 1211. [Reserved]

support of a request for trade secret protection does not meet the substantive criteria for trade secret designation, the Department shall notify provide notice to 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 preliminary injunction and/or declaratory relief.

Notice to Submitter. If the Department determines that information provided in

- Judicial Review. If a person asserting a claim of trade secret protection initiates an (d) action for a preliminary injunction and/or declaratory relief under subsection (b)(2) or (c), the Department may not publicly release or disclose the information that is the subject of the claim of trade secret protection until resolution of any court challenge, including any appeals, if any.
- NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
- Reference: Sections 25252, 25253, and 25257, Health and Safety Code.
- Article 1110. Severability
- § <del>69511</del>69510. 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.
- 25 Reference: Sections 25252 and 25253, Health and Safety Code.