UNOFFICIAL

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 originally proposed test, as modified by the January 2013 post-hearing changes, is shown with no underlines. 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.

NOTE: This "unofficial" version of the revised proposed regulations shows only the April 2013 changes to the text. This is provided as a courtesy copy only. It is not the official version of the April 2013 revised proposed regulations. The official version is provided separately, and shows both the January 2013 and April 2013 text insertions and deletions.

DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS

CHAPTER 55. SAFER CONSUMER PRODUCTS

Amend the Table of Contents by adding chapter 55, articles 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and 11, and sections 69501, 69501.1, 69501.2, 69501.3, 69501.4, 69501.5, 69502, 69502.1, 69502.2, 69502.3, 69503, 69503.1, 69503.2, 69503.3, 69503.4, 69503.5, 69503.6, 69503.7, 69504, 69504.1, 69505, 69505.1, 69505.2, 69505.3, 69505.4, 69505.5, 69505.6, 69505.7, 69505.8, 69505.9, 69506, 69506.1, 69506.2, 69506.3, 69506.4, 69506.5, 69506.6, 69506.7, 69506.8, 69506.9, 69506.10, 69507, 69507.1, 69507.2, 69507.3, 69507.4, 69507.5, 69507.6, 69508, 69509, 69509.1, 69510, and 69511 through 69599 to division 4.5 of title 22 of the California Code of Regulations, to read:

Table of Contents

***

Chapter 55. Safer Consumer Products

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

Chapter 55. Safer Consumer Products

Article 1. General

§ 69501. Purpose and Applicability.

(a) Safer Consumer Products Regulations. This chapter specifies the process for identifying and prioritizing Priority Products and their Chemicals of Concern, and identifying and analyzing alternatives to determine how best to eliminate or reduce potential exposures to, or the level of potential adverse impacts posed by, the Chemical(s) of Concern in Priority Products. This chapter also specifies the regulatory responses that will be imposed by operation of article 6 or that may be required by the Department following completion of an alternatives analysis.

(b) Applicability and Non-Duplication.

(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.

(3)(A) This chapter does not apply to a consumer product that the Department determines is regulated by one or more federal and/or California 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 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. Reference: Sections 25251, 25252, 25253, and 25257.1, Health and Safety Code.

§ 69501.1. Definitions.

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

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

(2) "Adverse air quality impacts" means indoor or outdoor air emissions of any of the air contaminants listed below that have the potential to result in adverse public health, ecological, soil quality, or water quality impacts:

(A) California Toxic Air Contaminants as specified in title 17, California Code of Regulations, sections 93000 through 93001;

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

1. Carbon dioxide;
2. Hydrofluorocarbons;
3. Methane;
4. Nitrogen trifluoride;
5. Nitrous oxide;
6. Perfluorocarbons;
7. Sulfur hexafluoride; or
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.

(3) "Adverse ecological impacts" means any of the following direct or indirect effects on living organisms and/or their environments:

(A) Adverse effects to aquatic, avian, or terrestrial animal or plant organisms or microbes, including:

1. Acute or chronic toxicity;
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 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 effects 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.

(4) “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 article 2 or article 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 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 covering surface soil with a layer of impervious material or changing the nature of the soil so that it behaves as an impermeable medium.

(8) "Adverse waste and end-of-life effects" means the waste materials and byproducts generated during the life cycle of a product, and the associated adverse effects due to one or more of the following:
(A) The volume or mass generated;
(B) Any special handling needed to mitigate adverse impacts;
(C) Effects on solid waste and wastewater disposal and treatment, including operation of solid waste and wastewater handling or treatment facilities, and the ability to reuse or recycle materials resulting from the treatment of solid waste and/or wastewater;
(D) Discharge(s) or disposal(s) to storm drains or sewers 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 chemicals contained in the product.

(9) "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:

(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 pollutants identified for California under section 303(c) of the federal Clean Water Act;

2. Pollutants listed by California or the United States 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 have been established and adopted under section 64431 or section 64444 of chapter 15 of title 22 of the California Code of Regulations;

4. Chemicals for which Notification Levels 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).

(10) "Alternative" means any of the following:

(A) Removal of Chemical(s) of Concern from a Priority Product, with or without the use of one or more replacement chemicals;

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

(C) Redesign of a Priority Product and/or manufacturing process 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 potential adverse impacts and/or potential 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.

(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) ~~t~~The Practical Quantitation Limit for a Chemical of Concern that is present in a Priority Product solely as a contaminant; or

(B) The applicable concentration, if any, specified by the Department under section 69503.5(c).

(13) "Alternatives Analysis Threshold Notification" means a notification submitted to the Department under section 69505.3.

(14) "Aqueous hydrolysis half-life" means the time required for the concentration of a chemical to be reduced by one-half after being introduced into water.

(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.

(18) "Bioaccumulation" means bioaccumulation, as specified in section 69405.2.

(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.

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

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; or

2. A chemical ingredient, which means a substance comprising one or more substances described in subparagraph 1.

(B) "Molecular identity" means the substance's properties listed below:

1. Agglomeration state;
2. Bulk density;
3. Chemical composition, including surface coating;
4. Crystal structure;
5. Dispersability;
6. Molecular structure;
7. Particle density;
8. Particle size, size distribution, and surface area;
9. Physical form and shape, at room temperature and pressure;
10. Physicochemical properties;

11. Porosity;
12. Solubility in water and biologically relevant fluids;
13. Surface charge; and
14. Surface reactivity.

(21) "Chemical of Concern" means a Candidate Chemical that has been designated as a Chemical of Concern under section 69503.5(b)(2)(B).

(22) "Chemical Removal Intent Notification" and "Chemical Removal Confirmation Notification" mean the notifications submitted to the Department under section 69505.2(a)(1)(A)1.

(23)(A) "Component" means a uniquely identifiable homogeneous material, part, piece, assembly, or subassembly that is a necessary or intended element of a consumer product.
(B) "Homogeneous material" means either of the following:
1. One material of uniform composition throughout; or
2. A material, consisting of a combination of materials, that cannot be readily disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding, or abrasive processes.

(24)(A) "Consumer product" or "Product" means any of the following:
1. A "consumer product" as defined in Health and Safety Code section 25251; or
2. When applicable, a component of an assembled "consumer product."
(B) "Consumer product" or "Product" does not mean a product that ceased to be manufactured prior to the date the product is listed as a Priority Product.
(C) "Consumer product" or "Product" does not mean a product previously owned or leased by someone other than the manufacturer, importer, distributor, assembler, or retailer of the product.

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

(26)(A) "Contaminant" means a chemical that is not an intentionally added ingredient in a product and the source(s) of the chemical in the product is/are one or more of the following:
1. A naturally occurring contaminant commonly found in raw materials that are frequently used to manufacture the product;
2. Air or water frequently used as a processing agent or an ingredient to manufacture the product;
3. A contaminant commonly found in recycled materials that are frequently used to manufacture the product; and/or

4. 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.

(B) “Intentionally added ingredient” means a chemical that is deliberately used in the 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.

(D) "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.

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

(29) “Economically feasible” means that an alternative product or replacement chemical does not significantly reduce the manufacturer’s operating margin.

(30) “End-of-life” means the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs first.

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

(32) “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.

(33) “Environmental or toxicological endpoint” means any environmental or toxicological endpoint specified in chapter 54.

(34) “Failure to Comply List” means the list prepared by the Department under section 69501.2(c).

(35) “Functionally acceptable” means that an alternative product meets both of the following requirements:

(A) The product complies with all applicable legal requirements; and

(B) The product performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace.

(36) "Hazard trait" means any hazard trait specified or defined in chapter 54.

(37) “Hazard trait submission” means any health, safety, or environmental study of, or health, safety, or environmental information regarding, a chemical submitted to the Department under this chapter or article 14 of chapter 6.5 of division 20 of the Health and Safety Code. Precise chemical identity is part of any hazard trait submission, except as otherwise provided in section 69509(g).

(38) “Import” means to bring, or arrange to bring, a product into the United States for purposes of placing the product into the stream of commerce in California. “Import” includes reimporting a 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.

(39) “Importer” means a person who imports a product 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.

(40) “Information” means data, documentation, records, graphs, reports, or any other depiction of specific pieces of knowledge.

(41) “Legal requirements” means specifications, performance standards, and/or labeling requirements that a chemical, product, or product packaging is required to meet under federal or California law.

(42) “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.

(43) “Manufacture” means to make or produce. “Manufacture” does not include acts that meet the definition of “assemble.”

(44) "Manufacturer" means any person who manufactures a product that is subject to the requirements of this chapter, or any person that controls the manufacturing process for, or ~~has the capacity to specify~~specifies the use of chemicals to be included in, ~~such a~~the product.

(45)(A) "Materials and resource consumption" means the consumption of renewable and nonrenewable resources that are used for a consumer product throughout its life cycle.

(B) Except as specified in subparagraph (C)2., a renewable resource is a resource that is capable of being replaced by natural processes at a rate equal to or faster than its consumption rate. Renewable resources include solar and wind energy, timber, agriculture, and water.

(C) Both of the following are nonrenewable resources:

1. An inherently finite resource that is formed over long periods of geologic time, including petroleum, coal, 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 will drive the resource to exhaustion.

(46) "Persistence" means environmental persistence, as specified in section 69405.3.

(47) "Person" has the same meaning as in Health and Safety Code section 25118.

(48) "Physical chemical hazards" means physical hazard traits specified in article 6 of chapter 54.

(49) "Physicochemical properties" means the physicochemical properties specified in section 69407.2.

(50)(A) "Placed into the stream of commerce in California" means that a consumer product has been sold, offered for sale, distributed, supplied, or manufactured in or for use in California as a finished product or as a component in an assembled product.

(B) "Sold or offered for sale" means any transfer or offer to transfer for consideration of title or the right to use, by lease or sales contract, including, but not limited to, transactions conducted and offers made through sales outlets, catalogs, or the Internet or other similar electronic means.

(51)(A) "Potential" means that the phenomenon described is reasonably foreseeable based on reliable information.

(B) Subparagraph (A) does not apply to the use of the term "potential' in paragraph (2) above or section 69502.2(a)(1)(M).

(52) "Practical Quantitation Limit" or "PQL" means the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.

(53) "Priority Product" means a product-chemical combination identified and listed as a Priority Product by the Department under section 69503.5.

(54) "Product-Chemical Replacement Intent Notification" and "Product-Chemical Replacement Confirmation Notification" mean the notifications submitted to the Department under section 69505.2(a)(1)(A)3.

(55) "Product Removal Intent Notification" and "Product Removal Confirmation Notification" mean the notifications submitted to the Department under section 69505.2(a)(1)(A)2.

(56) "Release" means an intentional or unintentional liberation, emission, or discharge of a chemical into the environment.

(57) "Reliable information" means a scientific study or other scientific information that ~~is trustworthy based on the following:~~

~~(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, corroborated, 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:

~~a.~~1. Published in a scientifically peer reviewed report or other literature;

~~b.~~2. Published in a report of the United States National Academies;

~~c.~~3. Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or

~~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.

~~2.~~(B) With respect to a scientific study, ~~T~~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.

(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 homes, 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 from one or both of the following sources that show the chemical to be present in human organs, tissues, or fluids:
1. California Environmental Contaminant Biomonitoring Program; and/or
2. United States Centers for Disease 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:
1. Bioaccumulation;
2. Persistence; or
3. Lactational or transplacental transfer, as specified in section 69405.5.
(D) Exposure or environmental modeling that indicates ~~either~~one or both of the following:
1. Exposure point concentration(s) associated with adverse impacts; or
2. Environmental accumulation of a chemical.
(E) Monitoring data indicating the presence of a chemical or its degradation products in California solid waste, wastewater, biosolids, or storm water streams collected or managed by California State or local agencies in concentrations or volumes that:
1. Potentially contribute to or cause adverse impacts;
2. Require the expenditure of public funds to mitigate potential adverse 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;
4. 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.

(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) A chemical that is not present in the Priority Product; or
(B) A chemical that is or would be present ~~at a lower~~in the alternative at a higher 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:
(A) Manufacturer;
(B) Importer;
(C) Assembler; or
(D) Retailer.

(61) “Retailer” means a person to whom a product that is subject to the requirements of this chapter is delivered or sold for purposes of sale or distribution by that person to a consumer.

(62) “Safer alternative” means an alternative that, in comparison with another product or product manufacturing process, has reduced potential adverse impacts and/or potential exposures associated with one or more Candidate Chemical(s), Chemical(s) of Concern, and/or replacement chemicals, whichever is/are applicable.

(63) “Sales outlet” means any place at which consumer products are sold, supplied, or offered for sale directly to consumers in California.

(64) “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.

(65) "Technically feasible" means that the technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement an alternative product or replacement chemical.

(66) "Trade secret" means “Trade secret” as defined in Civil Code section 3426.1(d).

(~~7~~67) “Useful life” means the period of time during which a product can be used as intended, expressed in terms of a single use, number of applications, or days, months, or years 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.

(a) Duty to Comply.

(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 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 provides notice to the retailer or assembler of such non-compliance by posting the information on the Failure to Comply List.

(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 69503.7, 69505.2, or 69505.3, 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 the stead of, the responsible entity.

(b) Retailer and Assembler Options.

A retailer or assembler who has received a notice from the Department under subsection (a)(1)(A) is not 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 within ninety (90) days after the Department issues the notice; or

(2) The retailer or assembler complies 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 or assembler submits a Product Cease Ordering Notification informing the Department that the retailer or assembler 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 or assembler, as applicable, in the supply chain for the product;

5. Information describing the product, and the brand name(s) and product name(s) under which the retailer's or assembler's 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;

6. The length of time the retailer or assembler estimates will be needed to exhaust the remaining inventory of the Priority Product; and

7. A statement certifying that the retailer or assembler 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.

(c) 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 importer(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.

(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. The Department shall post this information on the Failure to Comply List not later than ninety (90) days after issuing the notice of non-compliance.

(3) Paragraph (2) does not apply if there is a 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 the following information for each product covered by a notice of non-compliance:

(A) Information identifying and describing the product, 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 and, if applicable, assemblers on notice under subsection (a)(1)(A) of the failure to comply by the manufacturer(s) and importer(s), including identification of the requirement with which the retailer and, if applicable, assembler shall comply and the timeframe for compliance, which shall be no less than ninety (90) days after the notice is posted on the Department's website;

(D) The Chemical(s) of Concern and any other Candidate Chemical(s) known to the Department to be present in the product;

(E) The name of and, if known, the contact information for any person(s) listed on the product label as the manufacturer, importer, or distributor;

(F) The name of, and contact information for, any manufacturer or importer that has been noticed by the Department, under paragraph (1);

(G) The name of, and contact information for, retailers and, if applicable, assemblers known to the Department who have not fully complied with the requirements of subsection (b); and

(H) The date the product is first listed on the Failure to Comply List.

(5) The Department shall remove a product and the associated information from the Failure to Comply List if the Department determines that the condition of non-compliance has been fully remedied.

(6) 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 (b).

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

§ 69501.3. Information Submission and Retention Requirements.

(a) Signatures. All documents required to be submitted to the Department under this 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.

(b) Format. All 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) 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 document~~s listed in this paragraph~~, and by the responsible individual in charge of preparing, or overseeing the preparation of, the information:

"I certify 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 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) Document Retention. 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 the information to the Department, shall retain the information for a

period of three (3) years following the date the person was required to obtain or prepare the information.

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

§ 69501.4. Chemical and Product Information.

(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:

(A) Obtain and/or review information in the public domain that is readily available in a usable format, without a subscription or other charge;

(B) 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;

(C) Request one or more product or chemical manufacturers, importers, assemblers, and/or retailers to make existing information available to the Department, in accordance with a schedule specified by the Department; and/or

(D) Request one or more product or chemical manufacturers, importers, assemblers, and/or retailers 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) Information Requests. 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 person electronically or by United States mail; and/or

(2) Information call-ins that, unless otherwise specified, apply to all manufacturers, importers, assemblers, and retailers, as applicable, of a specific chemical or product or group of chemicals or products. The Department shall post information call-ins on its website, and provide notice to ~~individuals~~persons on the electronic mailing list(s) established by the Department related to this chapter.

(c) 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 person, who has been requested to provide information to the Department under this section, or someone acting on behalf of or in the stead of that person, 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 by the due 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 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 a person has taken action to change its status under paragraph (1).

(d) Safer Consumer Products Partner Recognition List. The Department may 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 may include, but are not limited to, persons that have done the following:

(1) Voluntarily completed an 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) Website Postings Requiring Noticing. The Department shall post on its website, and update as appropriate, all of the information listed below. The Department shall also provide notice of the availability of the information, including the availability of updates to the information, to ~~individuals~~persons on the electronic mailing list(s) that the Department establishes related to this chapter.

(1) The Failure to Comply List.

(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) Priority Product Work Plans, ~~P~~proposed and final Candidate Chemicals and Priority Products lists and revisions to the lists, supporting rationale and documentation, copies of all written comments received during the public comment periods for the proposed lists, and copies of 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 due date extension requests approved for submission of AA Reports.

~~(6)~~(7) AA Report notices of public review periods, notices of compliance, notices of deficiency, notices of disapproval, and notices of ongoing review.

~~(7)~~(8) Proposed and final regulatory response determination notices issued by the Department, copies of all written comments received during the public comment period for a proposed regulatory response determination, and copies of written responses the Department provides to the comments.

~~(8)~~(9) A list of regulatory response exemption requests submitted to the Department, and copies of all 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.

(b) Additional Website Postings. The Department shall also post on its website, and update as appropriate, all of the following information:

(1) The Response Status List prepared under section 69501.4(c).

(2) 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, post~~ed 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 that have submitted a timely and compliant Confirmation Notification under section 69505.2;

(C) Other responsible entities for the product, except for the responsible entities that have complied with the requirements of section 69501.2(b);

(D) The identity of the person 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 applicable AA Report and each Alternate Process AA Work Plan; 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 Notifications, and notifications submitted to the Department under subsections (c) and (d) of section 69505.3, and notices issued by the Department under section 69505.3(e);
3. Chemical Removal Intent and Confirmation Notifications;
4. Product Removal Intent and Confirmation Notifications;
5. Product-Chemical Replacement Intent and Confirmation Notifications; and
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 AA Reports, ~~and~~ Alternate Process AA Work Plans, and AA progress reports 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 notices issued by the Department and all documents submitted to the Department under section 69506.5.

~~(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) 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 69506.10(d).

~~(10)~~(11) Findings of audits conducted by the Department under section 69508.

(c) Website Posting Date. All 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.

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

Article 2. Process for Identifying Candidate Chemicals

§ 69502. General.

This article identifies Candidate Chemicals that can be considered under article 3 for designation as a Chemical of Concern, and specifies the process by which the Department may identify additional Candidate Chemicals. 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 and 58012, Health and Safety Code. Reference: Section 25252, Health and Safety Code.

§ 69502.1. Applicability.

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

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

§ 69502.2. Candidate Chemicals Identification.

(a) Candidate Chemicals List. As of the effective date of these regulations, a chemical is identified as a Candidate Chemical 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 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) Chemicals classified by the European Commission as carcinogens, mutagens, and/or reproductive toxicants Categories 1A and 1B in Annex VI to Regulation (~~European Commission~~EC) 1272/2008;

(C) Chemicals included as Category 1 endocrine disruptors 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;

(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 Groups 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 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;

(J) Groups 1, 2A, and 2B carcinogens identified by the International Agency for Research on Cancer;

(K) 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;

(L) Persistent Bioaccumulative and Toxic Priority Chemicals that are identified by the United States Environmental Protection Agency's National Waste Minimization Program;

(M) Reproductive or developmental toxicants identified in Monographs on the Potential Human Reproductive and Developmental Effects, National Toxicology Program, Office of Health Assessment and Translation;

(N) 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

(O) 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 section 64431 or section 64444 of chapter 15 of title 22 of the California Code of Regulations;

(C) Chemicals identified as Toxic Air Contaminants under sections 93000 and 93001 of title 17 of the California Code of Regulations;

(D) Chemicals that are identified as priority pollutants in California Water Quality Control Plans under section 303(c) of the federal Clean Water Act and in section 131.38 of title 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 to~~under 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 Candidate Chemicals List. In addition to the chemicals identified as Candidate Chemicals under subsection (a), the Department may identify as Candidate Chemicals those chemicals that exhibit one or more hazard traits and/or environmental or toxicological endpoints by considering the following factors for which reliable information is available:

(1) Adverse Impacts.

(A) The Department shall evaluate the potential for the chemical to contribute to or cause adverse impacts, considering one or more of the following factors:

1. The chemical's hazard trait(s) and/or environmental or toxicological endpoint(s);

2. The chemical's aggregate effects;
3. The chemical's cumulative effects with other chemicals with the same or similar hazard trait(s) and/or environmental or toxicological endpoint(s);
4. The chemical's physicochemical properties;
5. The chemical's environmental fate;
6. The human populations, and/or aquatic, avian, or terrestrial animal or plant organisms for which the Candidate Chemical(s) has/have the potential to contribute to or cause adverse impacts; and/or
7. The potential for the chemical to degrade, form reaction products, or metabolize into another Candidate Chemical or a chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints.

(B) The Department shall give special consideration to the potential for the chemical to contribute to or cause adverse impacts for:
1. Sensitive subpopulations;
2. Environmentally sensitive habitats;
3. Endangered and threatened species 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) The Department shall also give special consideration to the potential for the chemical to contribute to or cause widespread adverse impacts.

(D) The Department may also evaluate and consider, based on reliable information, structurally or mechanistically similar chemicals for which there is a known toxicity profile.

(2) Exposures. The Department shall consider potential exposures to the chemical, based on both of the following:
(A) Reliable information regarding potential exposures to the chemical; and
(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).

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

§ 69502.3. Candidate Chemicals List.

(a) Informational List. The Department shall post an informational list of the chemicals identified as Candidate Chemicals 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 list using the factors specified in section 69502.2(b) and the procedures specified in subsections (c) and (d).

(c) Public Notice of Proposed List Revisions. The Department shall make proposed revisions to the Candidate Chemicals 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 Candidate Chemicals list. The Department shall hold one or more public workshop(s) to provide an opportunity for comment on the proposed revisions to the list. 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 revisions to the list and supporting documentation. The notice must include:

(1) The last day for the public to submit written comments on the proposed revisions to the Candidate Chemicals list. The last day for submission of public comments shall be no sooner than forty-five (45) days from the date the notice of availability of the proposed revisions is posted on the Department's website or the date the notice is sent to ~~individuals~~persons on the electronic mailing list(s) that the Department establishes related to this chapter, whichever is the later date.

(2) The method(s) for submitting comments to the Department.

(3) The date, time, and location of the public workshop(s).

(d) Website Posting of Final List Revisions. The Department shall post the final revisions to the Candidate Chemicals 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. Process for Identifying and Prioritizing Product-Chemical Combinations

§ 69503. General.

This article specifies the process by which the Department shall identify and prioritize products containing Candidate Chemicals. 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. 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 Candidate Chemicals and that are placed into the stream of commerce in California.

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

§ 69503.2. Product-Chemical Identification and Prioritization Factors.

(a) Key Prioritization 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 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 its associated potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects by considering the factors described in paragraphs (1) and (2) for which information is reasonably available. The Department may additionally, in its discretion, consider paragraph (3).

(1)(A) Adverse Impacts and Exposures. The Department shall begin the product-chemical combination evaluation process by evaluating the potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures during the life cycle of the product. The Department's evaluation of potential adverse impacts and potential exposures shall include consideration of 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). 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 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 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.

(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.

(3) Safer Alternatives. When deciding whether to list a product-chemical combination as a Priority Product, the Department may also consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible.

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. 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 or toxicological endpoint(s);

(B) The Candidate Chemical(s)' aggregate effects;

(C) The Candidate Chemical(s)' cumulative effects with other chemicals with the same or similar hazard trait(s) and/or environmental or toxicological endpoint(s);

(D) The Candidate Chemical(s)' physicochemical properties;

(E) The Candidate Chemical(s)' environmental fate;

(F) The human populations, and/or aquatic, avian, or terrestrial animal or plant organisms for which the Candidate Chemical(s) has/have the potential to contribute to or cause adverse impacts; and/or

(G) The potential for the Candidate Chemical(s) to degrade, form reaction products, or metabolize into another Candidate Chemical or a chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints.

(2) The Department shall give special consideration to the potential for the Candidate Chemical(s) in the product to contribute to or cause adverse impacts for:

(A) Sensitive subpopulations;

(B) Environmentally sensitive habitats;

(C) Endangered and threatened species listed by the California Department of Fish and Wildlife; and

(D) Environments in California that have been designated as impaired by a California State or federal regulatory agency.

(3) The Department may also evaluate and consider, based on reliable information, the adverse impacts associated with structurally or mechanistically similar chemicals for which there is a known toxicity profile.

(b) 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) in the product, by considering one or more of the following factors for which information is reasonably available:

(1) Market presence of the product, including:

(A) Statewide sales by volume;

(B) Statewide sales by number of units; and/or

(C) Intended product use(s), and types and age groups of targeted customer base(s).

(2) The occurrence, or potential occurrence, of exposures to the Candidate Chemical(s) in the product.

(3) The household and workplace presence of the product, and other products containing the same Candidate Chemical(s) that is/are the basis for considering the listing of the product-chemical combination as a Priority Product.

(4) Potential exposures to the Candidate Chemical(s) in the product during the product's life cycle, considering:

(A) Manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices;

(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;

2. Sensitive subpopulation potential use of, or exposure to, the product; and/or

3. 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 homes, schools, workplaces, or other locations;

(E) Frequency, extent, level, and duration of potential exposure for each use scenario and end-of-life scenario;

(F) Containment of the Candidate Chemical(s) within the product, including potential accessibility to the Candidate Chemical(s) during the useful life of the product and the potential for releases of the Candidate Chemical(s) during the useful life and at the end-of-life;

(G) Engineering and administrative controls that reduce exposure concerns associated with the product; and/or

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

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

§ 69503.4. Priority Product Work Plan.

(a) Initial Work Plan. Within one (1) year after the effective date of these regulations, 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 product-chemical combinations to be added to the Priority Products list during the 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.

(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.

(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 comment.

(e) Public Notice. 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 of the availability of each work plan and each revised work plan.

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

§ 69503.5. Priority Products List.

(a) Listing Process.

(1) The Department shall use the procedures specified in this section and the identification and prioritization criteria and process specified in sections 69503.2 and 69503.3 to identify and list product-chemical combinations as Priority Products.

(2) The Priority Products list shall be established and updated through rulemaking ~~pursuant to~~under 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) List Contents. The Department shall specify in the proposed and final Priority Products lists the following for each listed product-chemical combination:

(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) 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 Report shall be 180 days after the date the product is listed on 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.

~~(c)~~(d) Complex Durable Products.

(1) For a complex durable product, the Department may not list as Priority Products more than ten (10) components contained in that product in a three-year period.

(2) For purposes of paragraph (1), “complex durable product” means a product that meets the following criteria:

(A) The product is assembled from 100 or more manufactured components;

(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

(C) The product is typically not consumed, destroyed, or discarded after a single use.

(3) Paragraph (1) does not apply to either of the following types of products:

(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) Products intended to be worn or placed on the human body.

~~(d)~~(e) Revisions to the 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.

~~(e)~~(f) Priority Product Notifications to the Department. ~~Each~~As specified in section 69503.7(a), the responsible entity for a product-chemical combination listed on the Priority Products list shall provide a Priority Product Notification to the 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, unless the Department specifies a later due date in the Priority Products list. If applicable, 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 69505.2 or section 69505.3.

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

§ 69503.6. Initial Priority Products List.

The following provisions apply only to the initial list of Priority Products:

(a) Scope of Candidate Chemicals. In the initial list of Priority Products, the Department may list a product as a Priority Product only if one or more Candidate Chemical(s) that is/are the basis for listing the product meet one or more of the criteria specified in subsection (a)(1) of section 69502.2 and one or more of the criteria specified in subsection (a)(2) of section 69502.2. This subsection also applies to any revisions to Priority Products list adopted prior to January 1, 2016.

(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 a Priority Product shall notify the Department that its product-chemical combination is a Priority Product. For a Priority Product that is first manufactured or first placed into the stream of commerce in California after the date of the Priority Product listing, the responsible entity shall provide the Priority Product Notification within sixty (60) days after the product is first placed into the stream of commerce in California. The notification must include:

(1) The responsible entity's name and contact information, and a statement indicating whether the responsible entity is the product manufacturer, importer, assembler, or retailer;

(2) The type, brand name(s) and product name(s) of the Priority 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;

(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 the stead of the responsible entity; and

(4) If 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 responsible entity fails to fully and timely meet the requirements specified in subsection (a).

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) Petition Process. Except as provided in subsection (b), a person may petition the Department to add to or remove from the Candidate Chemicals list one or more chemicals, or to add to or remove from the lists specified in section 69502.2(a) the entirety of an existing chemicals list. A person may also petition the Department to add to or remove from the Priority Products list a product-chemical combination. A petition must include:

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

(A) The petitioner; and

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

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

(3) A description of the uses of the chemical and/or product-chemical combination;

(4) The basis for the petition, including an analysis of the basis for the existence or absence of potential adverse impacts, potential exposures, and/or potential adverse waste and end-of-life effects associated with the chemical and/or product-chemical combination;

(5) Information supporting the petition; and

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

(b) Limitations on Petitions.

(1) A person may not petition the Department to delist any chemical identified as a Candidate Chemical under section 69502.2(a), unless that chemical is no longer listed on any of the lists specified 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.

(3) 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 product-chemical 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 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 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.

(a) Process and Timing. The Department shall determine whether to grant or deny a petition in accordance with the criteria and processes specified in 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 list or Priority Products list, as applicable. The Department shall give high priority to reviewing petitions by federal and other California State agencies that relate to the petitioning agency's statutory and/or regulatory authorities.

(b) Substantive Review. The Department's merits review of each complete petition shall, to the extent applicable, be based on:

(1) The comprehensiveness of the information submitted that pertains to the factors specified in section 69502.2(b) and/or section 69503.2.

(2) The quality of the information submitted.

(3) The availability of information, other than that submitted with the petition, that supports the petitioner's claims that:

(A) The chemical does or does not exhibit one or more hazard traits and/or environmental or toxicological endpoints; and

(B) An evaluation of the chemical and/or the product, based on the factors specified in section 69502.2(b) and/or section 69503.2, as applicable, does or does not indicate potential adverse impacts and potential exposures, and, if applicable, adverse waste and end-of-life effects.

(4) 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) Supplemental Information Requests. The Department may request that the petitioner provide, within a specified timeframe, additional information to assist the merits review.

(d) Notice of Decision. After completing the merits review, the Department shall provide a notice to the petitioner of its decision to grant or deny the petition that includes a statement explaining the basis for 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) Guidance Materials. Before finalizing the initial list of Priority Products, the Department shall make available on its website guidance materials to assist persons in

performing AAs ~~in accordance with~~under this article. The Department shall periodically revise and update the guidance materials.

(b) Sample Alternatives Analyses. The Department shall also post on its website examples of AAs that are available in the public domain at no cost. 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) 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.

(1) Except as otherwise provided in subsection (a) above and subsections (b), (c) and (d) of section 69505.4, a responsible entity for a Priority Product shall conduct an AA for the Priority Product and shall comply with all applicable requirements of this article.

(2) A responsible entity subject to the requirements of paragraph (1) shall prepare, sign, and submit to the Department AA Reports as follows:

(A) Except as provided in subsection (c), 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 in the Priority Products list.

(B) Except as provided in subsection (c), 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 and the Department approves 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.

(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 the AA Report 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:

(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 importer(s) of the product;

(D) Information identifying and describing the responsible entity's Priority Product, and the brand name(s) and product name(s) 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;

(E) The due date for the AA Report;

(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 the extension request in whole or in part and provide 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.

(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 Final AA Report or final Abridged AA Report, whichever is applicable.

~~(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 an AA Report or Alternate Process AA Work Plan within the applicable timeframe specified in section 69505.~~8~~9, or failure of the Director or the Department to respond to an appeal or Request for Review submitted under article 7 within sixty (60) days, shall not cause an 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.

§ 69505.2. Removal/Replacement Notifications in Lieu of Alternatives Analysis.

(a) Applicability.

(1)(A) The requirements of this article do not apply to a responsible entity's Priority 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 Report:

1. A Chemical Removal Intent and/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, ~~draft~~ 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 Abridged 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~~ or final Abridged 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

2. The due date for the Final AA Report~~ or final 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 and assurance 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 is/are already in use 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 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; and fulfills the functional, performance, and legal requirements of the Priority Product.

(10) The certification statement specified in subsection (c), (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 ~~on~~in 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 ~~on~~in 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.

§ 69505.3. Alternatives Analysis Threshold Notification in Lieu of Alternatives 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 Threshold~~PQL 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) If applicable, ~~i~~identification of the PQL for each Chemical of Concern in the Priority Product, and the information and method used to determine the PQL;

(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.

(2) The responsible entity shall initially complete the first stage of the AA, and submit a Preliminary AA Report that complies with sections 69505.1(b)(2)(A) and 69505.7.

(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(b)(2)(B) and 69505.7.

(b) Abridged AA Reports. After completing the first ~~four (4)~~five (5) steps of the first stage of the AA ~~pursuant to~~under subsections (a) through (~~d~~e) of section 69505.5, a responsible entity that determines a functionally acceptable and technically feasible alternative

is not available may prepare and submit ~~draft and final~~an Abridged AA Report~~s~~, in lieu of the Preliminary and Final AA Reports, if:

(1) The responsible entity summarizes in the Abridged AA Report the first stage AA findings in compliance with the applicable requirements of section 69505.7;

(2) The responsible entity ~~identifies the factors relevant for comparison of the Priority Product and the alternatives under consideration as specified in section 69505.6(a), and~~ summarizes in the Abridged AA Report its findings with respect to section 69505.6(a) in compliance with the applicable requirements of section 69505.7;

~~(3)~~(2) The responsible entity submits an ~~draft~~ Abridged AA Report to the Department by the due date specified in section 69505.1(b)(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 69506.3 and 69506.8.

(c) Alternate Process AA.

(1) A responsible entity may use an AA process that differs from the process specified in sections 69505.5 and 69505.6, if:

(A) The responsible entity's alternate process provides the information needed to prepare a Final AA Report that substantially complies with section 69505.7.

(B) The responsible entity's alternate process compares the Priority Product and the alternatives under consideration using, at a minimum, the same relevant factors and, when applicable, associated exposure pathways and life cycle segments specified in sections 69505.5 and 69505.6.

(C) The responsible entity submits an Alternate Process AA Work Plan to the Department with sufficient information to demonstrate that the alternate process complies with subparagraphs (A) and (B), and sufficient information for the Department to specify an appropriate due date for submittal of the Final AA Report.

1. The Alternate Process AA Work Plan shall include the information specified in subsections (c), (d), and (e) of section 69505.7.

2. If the Alternate Process AA Work Plan includes information for which trade secret protection is claimed, the responsible entity shall also submit a redacted copy of the work plan that ~~masks~~excludes that information.

3. The 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, and that ~~masks~~excludes any information for which trade secret protection is claimed. 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 specifies must be included in the executive summary.

(D) The 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. 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 Alternate Process AA Work Plan shall be due sixty (60) days after the Priority Product is first placed into the stream of commerce in California~~the due date for the Priority Product Notification for the product.

(E)1. The responsible entity timely submits a Final AA Report to the Department that substantially complies with section 69505.7.

2. The due date for the Final AA Report is eighteen (18) months after the date the Department issues a notice of compliance for the Alternate 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.~~8~~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).

(2) If the Alternate Process AA Work Plan is disapproved by the Department under section 69505.~~8~~9(b)(3), the responsible entity shall submit a Preliminary AA Report to the Department within 180 days after the Department issues the notice of disapproval.

(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.

(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 alternative(s) identified as the selected alternative(s) in the Final AA Report, the responsible entity shall submit a revised Final AA Report 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 from the original Final AA Report, identify the information used to support the revisions to the Final AA Report, 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 in accordance with the procedures and criteria set forth in section 69505.~~8~~9.

(2) Paragraph (1) also applies if:

(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

(B) The responsible entity later decides to retain the Priority Product in lieu of a previously selected alternative product.

(3) The requirements of this subsection only apply for three (3) years after the date the original Final AA Report is approved by the Department.

(f) Reformulation. Except as provided in section 69505.2, if prior to 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.

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

§ 69505.5. Alternatives Analysis: 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.

(1) The responsible entity shall identify the functional, performance, and legal 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).

(B) If the responsible entity determines that neither the Chemical(s) of Concern nor 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 Reports.

(b) Step 2, Identification of Alternatives.

(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).

~~(c)~~(d) Step ~~3~~4, 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;

~~2.~~(B) 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 ~~4~~5, 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 ~~5~~6, 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.

§ 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 ~~shall~~may 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 ~~sub~~paragraphs ~~(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:~~

~~1. Adverse environmental impacts;~~

~~2. Adverse public health impacts;~~

~~3. Adverse waste and end-of-life effects;~~

~~4. Environmental fate;~~

~~5. 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

3. Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.

~~(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.

The responsible entity shall prepare and submit to the Department a Final AA Report as specified under section 69505.7.

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 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 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:

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

(B) The appropriate due date for submission of the Final AA Report ~~or final Abridged AA Report, whichever is applicable~~, and the appropriate due date for any regulatory response(s) required under article 6.

(3) 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.~~

(4) 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 ~~masks~~excludes 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 ~~masking~~redaction, 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 ~~masking~~redaction 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

(3) The names of the parties that were involved in funding, directing, overseeing, preparing, and/or reviewing the AA~~; 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. This section of the AA Report must include:

(1) The name of, contact information for, and headquarters location of the manufacturer(s) and 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 contact information;

(2) The name of, and contact information for, any person(s) identified on the 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 Priority Product in California, if applicable.

(e) Priority Product Information. This section of the AA Report must include:

(1) The brand name(s) and product name(s) under which the Priority Product is placed into the stream of commerce in California;

(2) 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;

(3) Identification of the Chemical(s) of Concern for the Priority Product;

(4) Any Material Safety Data Sheets and/or Safety Data Sheets related to the Priority Product; and

(5) The information specified in paragraphs (1) and (2) of section 69505.5(a).

(f) Scope of Relevant Comparison Factors. ~~The Final~~Each AA Report must identify which factors and, when applicable, associated exposure pathways and life cycle segments were determined to be relevant, under sections 69505.5(c) and 69505.6(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.

(g) 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. 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~~summarizes 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. The AA Report shall also identify any published methodologies and/or guidelines used, and any deviations from 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(d)~~(1). Final AA Reports and final Abridged AA Reports must include a summary of the public comments submitted under section 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 identify information that is not currently available but, if it were available, could be used to:

(A) Validate information used for purposes of sections 69505.5 and 69505.6; and/or

(B) Address any uncertainties in the analyses conducted under sections 69505.5 and 69505.6.

(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 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. The Final AA Report must also include:

(A) The product function and performance information specified in section 69505.6(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 retaining the Chemical(s) of Concern or using the alternative replacement chemical(s), if section 69505.5(a)(3)(B) applies, and one or more selected alternatives retains the Chemical(s) of Concern or uses one or more replacement chemicals.

(C) A list of all chemicals known, based on available information, to be in the selected alternative(s) that are Chemicals of Concern, that differ from the chemicals in the Priority Product, or that are present in the selected alternative(s) at a higher concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern. The following information, to the extent available, must be provided for those chemicals:

1. Environmental fate;
2. Hazard trait and environmental and toxicological endpoint information that has not already been provided to the Department under this chapter;
3. Information about the chemical purity, meaning the relative absence of extraneous matter, and identification of known impurities and additives in the chemical;
4. Physicochemical properties; and
5. Substance identification information, including all of the following that are applicable:

a. Chemical abstract services number;
b. Structural formula;
c. Molecular weight;
d. Synonyms;
e. International Union of Pure and Applied Chemistry name;
f. European Commission number;
g. Registry of Toxic Effects of Chemical Substances number;
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 Dangerous Goods;
k. North America Department of Transportation number;

l. European Inventory of Existing Commercial Chemical Substances number;
m. European List of Notified Chemical Substances number;
n. European Commission Directive 67/548/EEC No Longer Polymers number; and
o. Other commonly recognized substance identification system numbers.

(k) Next Steps.

(1) Work plan. The Preliminary AA Report must include the work plan and proposed implementation schedule for completion of the second AA stage required to be prepared under section 69505.5(~~e~~f)(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.~~8~~9(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);
3. A summary of achievements since the last progress report;
4. A summary and discussion of issues that have arisen and their resolutions;
5. A summary of work that is pending; and
6. 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.

(B) The responsible entity may request an extended due date for submittal of the Final AA Report. Any requested extension shall not exceed twenty-four (24) months from the date the Department issues a notice of compliance for the Preliminary AA Report, unless additional time is needed to conduct regulatory safety and/or performance testing on multiple alternatives prior to making an AA selection decision, 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) Implementation of selected alternatives. The Final AA Report must include a detailed plan for implementing any selected alternative(s).

(A) The implementation plan must include key milestones and dates for implementing the selected alternative(s), if applicable, and identify steps that will be taken to ensure compliance with 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 exposure to, or reduce the level of adverse 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(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.

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

§ 69505.8. Public Comments on AA Reports.

(a) Public Notice of Opportunity for Comment. Upon receipt of a Final AA Report or an Abridged AA Report, the Department shall post on its website, and send to persons on the electronic mailing list(s) that the Department establishes related to this chapter, a notice regarding the availability for public review and comment of the Final AA Report or Abridged AA Report. The notice shall include the last day for the public to submit written comments to the Department, the method(s) for submitting comments, and a link to the location on the Department's website where a copy of the Final AA Report or Abridged AA Report may be viewed. The last day for submission of public comments shall be no sooner than forty-five (45) 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.~~8~~9. 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~~, draft or final Abridged AA Report,~~ or Alternate Process AA Work Plan, the Department shall review the report or work plan for compliance with this article, and issue a notice of compliance, notice of deficiency, notice of disapproval, or notice of ongoing review.

(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, which may not exceed sixty (60) days from the date the notice of deficiency is issued. The responsible entity shall submit a revised report or work plan, whichever is applicable, by the due date specified, and address the areas of deficiency.

(B) 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 report or work plan.

(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).

(4) 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 twelve (12) months from the date the Department issues the notice of compliance, except that the Department may specify 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 also specify an extended due date for submission of the Final AA Report if the responsible entity submits a request under section 69505.7(k)(1)(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.

(1) 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 this article, and shall issue a notice of compliance, notice of deficiency, notice of disapproval, or 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, which may not exceed sixty (60) days from the date of the notice of deficiency. 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. ~~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 ninety (90) days for submission of the revised Final AA Report or revised Abridged AA Report to correct the deficiencies.

(B) 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.

1. If the Department issues a second notice of deficiency, the Department may grant no more than thirty (30) days for submission of the requested information.

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 does not fully address the areas of deficiency identified in the second notice of deficiency, the Department shall issue a notice of disapproval. 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 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(b).

(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, which shall be based on its available resources and the complexity of the ~~AA Report~~document under review.

(e) Issuance of Notices. All notices issued by the Department under this section shall be issued to the person who submitted the ~~AA Report~~document, and a copy of the notice shall

be sent by the Department to all persons identified in the ~~AA Report~~document under subsections (c)(2) and (c)(3) of section 69505.7.

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) Need for Regulatory Response. The Department shall identify and require implementation of one or more regulatory responses 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. In selecting regulatory responses, the Department shall seek to maximize the use of alternatives of least concern when such alternatives are functionally acceptable, technically feasible, and economically feasible.

(b) Inherent Protection Preference. 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 impacts, exposures, and/or adverse waste and end-of-life effects 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 or replacement Candidate Chemical in a product.

(c) Selection Factors. In selecting regulatory responses, the Department may consider the following factors:

(1) Public health and environmental protection.

(A) The degree to which, and speed with which, the regulatory response can address 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 regulatory response involving provision of information and/or directions with respect to the Priority Product; and

(C) Any adverse ecological impacts of the regulatory response on sensitive resources, or unique or additional burdens that the regulatory response would impose upon sensitive subpopulations.

(2) Private economic interests of 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) Applicability. Except as specified otherwise, ~~T~~this article applies to any product placed into the stream of commerce in California that is:
(1) A Priority Product for which an alternative is not selected;
(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
(4) A Priority Product for which the Final AA Report or Abridged AA Report is disapproved by the Department under section 69505.~~8~~9(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 Department prior to the due date for implementing any regulatory response that would otherwise apply to the product.

(c) 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 to~~under subsection (c) shall be sent to all known responsible entities for the product, and shall be made available on 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 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:
(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 notice of the availability of the proposed regulatory response determination notice is posted on the Department's website or the date the notice is

sent to ~~individuals~~persons on the electronic mailing list(s) that the Department establishes related to this chapter, whichever is later.

(2) The method(s) for submitting comments to the Department.

(3) The date, time, and location of ~~any~~the public workshop(s).

(e) Notice of Final Determination. After review and consideration of public comments, the Department shall post 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.

(f) Contents of Notices. All proposed and final regulatory response determination notices must include:

(1) A description of the required regulatory response(s), or a determination that no regulatory response is required, whichever is applicable;

(2) The rationale, information, and information sources supporting the Department's determination(s);

(3) The implementation due date(s) for the regulatory response(s), if applicable; and

(4) The Department's determination as to whether or not the regulatory response(s) apply(ies) to either or both of the following:

(A) 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.

(g) Implementation Due Date(s). In assigning a due date for implementation of one or more regulatory responses, the Department shall consider the complexity of implementing the regulatory response(s).

(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.

§ 69506.2. Supplemental Information and Regulatory Response Revisions.

(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.

(b) Information-Generation for Revision of Regulatory Response(s).

(1) When imposing one or more regulatory responses for a product, the Department 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 section 69505.7(i)(2), if the

Department determines 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(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 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.

§ 69506.3. Product Information for Consumers.

(a) Applicability. This section applies to:

(1) Priority Products for which an alternative is not selected;

(2) Priority Products that 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 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 the date specified by the Department in the final regulatory response determination notice 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 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 product purchase:

(1) Manufacturer’s name and importer’s name, and/or the name of any other entity listed on the product label;

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

(3) A list of, and common names for, any Chemical(s) of Concern 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;

(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;

(5) 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;

(6) Identification of any end-of-life management requirements specified by law, and any existing end-of-life management program(s) for the product; and

(7) The manufacturer's website address and the importer's website address where the consumer can obtain additional information about the product, the adverse 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.

(c) Communication to Consumers. The responsible entity shall satisfy subsection (b) by making the required information available to consumers, in easily seen, legible, and understandable formats, by both:

(1) Posting the information in a prominent place on the manufacturer's website and the importer's website; and

(2) Using one or both of the following means of informing consumers at the point of sale of the information specified in subsection (b):

(A) Providing the required information on the product packaging or in accompanying written material that is accessible without breaking the product seal; and/or

(B) 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.

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

§ 69506.4. Use Restrictions on Chemicals 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 potential for the product to contribute to or cause adverse impacts and/or 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;

(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 or replacement Candidate Chemical(s) in the product, or reduces the potential for the product to contribute to or cause an exposure to the Chemical(s) of Concern or replacement Candidate Chemical(s) in the product.

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

§ 69506.5. Product Sales Prohibition.

(a) Existence of Safer Alternative(s). Except as provided in 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 provides notice to the responsible entity under section 69506.1 that a safer alternative exists that does not contain the Chemical(s) of Concern or replacement Candidate Chemical(s) and that is functionally acceptable, technically feasible, and economically feasible. In making this determination, the Department shall consider the potential adverse impacts and potential exposure pathways associated with the alternative product or Priority Product, as applicable.

(b) No Existing Safer Alternatives.

(1) Except as provided in subsection (c), the Department may issue a notice, under section 69506.1, that a product containing the 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 functionally acceptable, technically feasible, and economically feasible.

(2) Prior to issuing a 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:

(A) The overall beneficial public health and/or environmental impacts and/or social utility of the product significantly outweigh the overall adverse 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.

(3) The Department may issue a 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.

(c) Exceptions. A responsible entity that receives a notice under subsection (a) or (b) is not subject to the requirements of subsection (a) or (b) if all of the following requirements are met:

(1) Within sixty (60) days after the notice is issued by the Department, the responsible entity notifies the Department in writing of its intent to submit a revised Final AA Report that selects an alternative that does not contain the Chemical(s) of Concern or the replacement Candidate Chemical(s);

(2) 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 AA Report that selects an alternative that does not contain the Chemical(s) of Concern or the replacement Candidate Chemical(s) and that complies with section 69505.7; and

(3) The product containing the Chemical(s) of Concern or the replacement Candidate Chemical(s) is 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 final regulatory response determination notice issued under section 69506.1.

(d) Extensions.

(1) A responsible entity may request an extension to the due date for the revised AA Report to be submitted under subsection (c), under the procedures specified in section 69505.1(c) or section 69505.7(k)(1)(B).

(2) If the Department grants an extension, the responsible entity shall satisfy one of the following requirements by the due date specified in the extension approval:

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

(B) The 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.

§ 69506.6. Engineered Safety Measures or Administrative Controls

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

(b) Criteria. Engineering or administrative controls may be 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 or replacement Candidate Chemical(s) in an indoor building or other enclosed environment; and/or

(3) Improper product handling increases the potential for release of, or exposure to, the Chemical(s) of Concern or replacement Candidate Chemical(s).

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

§ 69506.7. End-of-Life Management Requirements.

(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 comply with the requirements of subsection (c) except as otherwise provided under subsections (d) and (e).

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

(c) End-of-Life Program Requirements. No later than the date specified by the Department in the final regulatory response determination notice for the product, or no later than the 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:

(1) A comprehensive product stewardship plan must be developed and maintained, after the 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 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:

(A) A list of, and contact information for, participating manufacturers, importers, and other participating persons.

(B) The scope of products and brands to be covered by the plan.

(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.

(D) Identification and description of collection systems that will be used.

(E) End-of-life management information that 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.

(F) Identification of anticipated resources needed to implement and sustain the plan, which 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.

(G) 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 third-party product stewardship organization ~~pursuant to~~under 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.

2. If an individual manufacturer is administering and funding its own end-of-life management program, the manufacturer shall provide a financial guarantee that will ensure that adequate funding is available to cover the costs identified in subparagraph (F).

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

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

2. Increasing recyclability, and recycling rate.

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

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

(K) A description of public and stakeholder consultation activities during preparation of the plan, which shall include, at a minimum, provision of thirty (30) days for 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 with submittal of the plan.

(L) A description of public and stakeholder consultation activities for review and updating of the plan, which shall occur no less frequently than annually.

(M) Reporting and evaluation procedures.

(3) 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:~~

~~(A) Collection mechanisms; and/or~~

~~(B) If applicable, compensation to retailers and other persons who agree to administer or participate in the collection program.~~

(4) The manufacturer 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 that link to the Department for posting on the Department's website.

(5) The manufacturer of a product subject to this section shall provide an annual report to the Department. 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:

(A) The quantity of products placed into the stream of commerce in California over the previous one-year period; and

(B) The quantity of products recovered over the same one-year period.

(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 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.

(e) Exemption from End-of-Life Program Requirements.

(1) A manufacturer subject to 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 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.

§ 69506.8. Advancement of Green Chemistry and Green Engineering.

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.

§ 69506.9. Exemption from Regulatory Response Requirements.

(a) Exemption Requests. A product is exempt from sections 69506.3 through 69506.8, 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 sixty (60) days after the Department issues a final regulatory response determination notice for the product.

(b) Contents of Requests. An exemption request submitted under subsection (a) must include:

(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 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, 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; and

(6) Information that demonstrates to the Department's satisfaction that one or both of the following applies:

(A) The required or proposed regulatory response conflicts with one or more requirements of another California State or federal regulatory program or applicable treaties or international agreements 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 applicable treaties or international agreements with the force of domestic law~~,~~ without conferring additional public health or environmental protection benefits.

(c) 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.

(e) 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 provide notice to the person who submitted the exemption request and known responsible entities for the product.

(f) 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.

§ 69506.10. Regulatory Response Report and Notifications.

(a) Notification to Supply Chain. A responsible entity subject to a regulatory response other than one imposed under sections 69506.2 and 69506.8 shall ensure that a notification is sent to all persons 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 those persons of the applicability of the regulatory response to the product. The notification shall be sent, with a copy sent to the Department, no later than thirty (30) days after receiving a final regulatory response determination notice~~,~~ under section 69506.1.

(b) Contents of Notifications. The notification required under subsection (a) shall include:

(1) The name of, and contact information for, the person providing the notification;

(2) The name of, and contact information for, the responsible entity(ies) on whose behalf the notification is being provided;

(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) Information identifying and describing the original Priority Product~~,~~ and the selected alternative, ~~and~~ 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

(5) A description of the required regulatory response(s) and the due date for 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) Regulatory Response Summary.

(1) 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 to 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 importer(s);

(B) The names of, and contact information for, other known responsible entities;

(C) Information identifying and describing the original Priority Product~~,~~ and the selected alternative(s), if any, ~~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(s), 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 69506.9.

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) Applicability. 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) Exhaustion of Administrative Remedies. 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.
(c) Scope. Notwithstanding any other provision of this chapter, a decision made by the Department under article 2, 4, or 9 is not subject to dispute resolution under this article.
(d) Automatic Stay. 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, 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 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 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.

(b) 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.

(a) Contents of Appeals. A responsible entity appealing the Department's decision following completion of the informal dispute resolution process shall submit information stating the basis for seeking further review, and the reasons why the decision does not comply with this chapter or is otherwise unreasonable. The responsible entity shall also provide:

(1) The original statement of dispute;

(2) Supporting information; and

(3) Copies of responses prepared by the Department.

(b) Deadline for Filing an Appeal. A responsible entity appealing a Department 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.

(c) 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:

(1) Contain a short and plain description of the basis for denial of the request for further administrative review; and

(2) Specify the date by which the responsible entity must comply with the requirements of this chapter that were in dispute.

(d) Finality of Decision. A decision issued under subsection (c) is the Department's final decision and is not subject to additional administrative dispute resolution.

(e) 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.

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. Formal Dispute Resolution Procedures.

For all disputes regarding a decision made by the Department under 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 final regulatory response determination notice from the Department under article 6, 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 administrative 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, 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) Decision Time Frame. 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) Finality of Decision. 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 must 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) Briefing Schedule. An order granting review must specify a schedule for briefing of the issues by the responsible entity and the Department.

(d) Merits Decision. 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 must 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) Notice of Ongoing Review. 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) Recusal of Staff. 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. Audits

§ 69508. Audit of Materials Submitted to the Department and Regulatory Responses.

(a) Audits. 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) Scope. 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 selected alternatives, if applicable; and/or

(4) Compliance with the regulatory response(s) imposed under article 6, if any.

(c) Notification of Audit Findings. Upon completion of an audit, the Department shall provide 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 9. Trade Secret Protection

§ 69509. Assertion of a Claim of Trade Secret Protection.

(a) Substantiation Requirements. A person who asserts a claim of trade secret protection with respect to 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 non-disclosure 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 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 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 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 any of the claimed information is requested to be disclosed under the California Public Records Act (commencing with Government Code section 6250).

(b) Streamlining of Submittal. 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) Documentation. 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) 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.

(d) Marking of Documents. 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) Hazard Trait Submissions. Except as specified in subsection (g), trade secret protection may not be claimed for any hazard trait submission or for any chemical identity information associated with a hazard trait submission.

(g) 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 that chemical is an alternative considered or proposed in an Alternatives Analysis, and 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.

(2) Any person temporarily masking the precise identity of a chemical under paragraph (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.

§ 69509.1. 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) 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 secrecy determination, the Department shall:

(A) Provide 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) 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 provide 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.

(c) Notice to Submitter. If the Department determines that information provided in support of a request for trade secret protection does not meet the substantive criteria for trade secret designation, the Department shall 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.

(d) Judicial Review. If a person asserting a claim of trade secret protection initiates an 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.

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

Article 10. Severability

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

Article 11. [Reserved]

§§ 69511 -- 69599. [Reserved]