TEXT OF PROPOSED REGULATIONS
September 2010

DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS
CHAPTER 53. SAFER CONSUMER PRODUCT ALTERNATIVES

Amend the Table of Contents by adding chapter 53 to division 4.5 of California Code of Regulations, title 22, to read:

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Add California Code of Regulations, title 22, division 4.5, chapter 53 to read:

Chapter 53. Safer Consumer Product Alternatives

Article 1. General

§ 69301. Purpose and Applicability.

(a) This chapter describes the process by which chemicals and chemical ingredients that are contained in consumer products and that may be considered Chemicals of Concern will be identified and prioritized, and the process for evaluating Chemicals of Concern in consumer products and their potential alternatives to determine how best to limit exposure or the level of hazard posed by the Chemical of Concern. This chapter also specifies the regulatory responses that will be or may be taken following completion of such an alternatives assessment.

(b)(1) Except as provided in paragraphs (2) and (3) of this subsection, this chapter applies to all consumer products placed into the stream of commerce in California.

(2) This chapter does not apply to any product that is exempted from the definition of consumer product specified in Health and Safety Code section 25251, or any product that is placed into the stream of commerce in California solely for the manufacture of one or more of the products exempted under Health and Safety Code section 25251.

(3) This chapter does not apply to any consumer product manufactured or stored in, or transported through, California solely for use outside of California. In establishing whether or not a product is manufactured, stored or transported solely for use outside of California, the burden of proof shall be on the manufacturer.

(c) The requirements of this chapter that pertain to consumer products or to chemicals or chemical ingredients contained in consumer products do not apply to an unintentionally-added chemical or chemical ingredient that is not known by the producer to be present in the product, if all of the following conditions are met:

(1) The producer of the consumer product has exercised due diligence to obtain knowledge of any chemical or chemical ingredient that might reasonably be expected to be present, intentionally or unintentionally, in the consumer product by taking reasonable steps to obtain and apply knowledge of the following factors, to the extent applicable:

(A) Source, composition and chemicals and chemical ingredients contained in all raw material and recycled feedstocks, components and processing agents used in the formulation or assembly of the consumer product, and

(B) The manufacturing process(es) used to produce the consumer product, including chemical reactions likely to occur during the manufacturing process(es);

(2) The producer cannot reasonably be expected to know of the presence of the unintentionally-added chemical or chemical ingredient in the product under all the facts and circumstances;

(3) If requested by the Department, the producer demonstrates to the Department's satisfaction that the conditions specified in paragraphs (1) and (2) have been satisfied; and

(4) If the producer does have knowledge of the presence of one or more unintentionally-added chemicals or chemical ingredients in the consumer product, the producer provides the information, upon request, to the Department and any known responsible entity for the product.

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

§ 69301.1. Guiding Principles.

In fulfilling their respective requirements and responsibilities under this chapter, the Department, manufacturers, and responsible entities, and persons acting on behalf of one or more of the aforementioned, shall base their analyses and determinations on the best scientific principles and practices, and shall be guided by the following principles:

(a) Green chemistry principles and life cycle thinking should be considered throughout implementation of the regulations in this chapter.

(b) Adverse impacts on public health and the environment that may result from the production, use or end-of-life management of consumer products and consumer product chemical ingredients should be significantly reduced or eliminated, to the extent technologically and economically feasible.

(c) Adverse public health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts on the people of California, should be significantly reduced, by encouraging the redesign of consumer products and manufacturing processes and approaches, while maintaining or enhancing product function and performance.

(d) Chemical and consumer product prioritization processes should seek to identify and give priority to those chemicals, and the consumer products that contain them, that pose the greatest public health and environmental threats, are most prevalently distributed in commerce and used by consumers, and for which there is the greatest potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in public health or environmental harm.

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

§ 69301.2. Definitions.

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

(1) "AA Notification" means the notification required to be provided to the Department pursuant to section 69305.1.

(2)(A) "AA Report" means a report that is required to be prepared for a Tier II AA pursuant to section 69305.2(a)(2), and that meets the requirements of sections 69305.6 through 69305.8.

(B) "AA Report" means any of the following, depending on the context of its use:

1. The report prepared for a Tier II-A AA,

2. The report prepared for a Tier II-B AA, or

3. The collective reports prepared for the Tier II-A AA and Tier II-B AA for a product or component.

(3) "AA verification statement" means the statement required to be prepared for a Tier II AA pursuant to section 69305.2(c)(3)(C).

(4) "AA Work Plan" means a work plan that is required to be prepared for a Tier II AA pursuant to section 69305.2(a)(2), and that meets the requirements of section 69305.4.

(5) "Alternatives assessment" or "AA" means any activity or process that leads to either:

(A) A decision to redesign or reformulate a consumer product, or substitute a different consumer product for an existing product; or

(B) A decision not to alter or replace an existing consumer product.

(6) "Bioaccumulation" means the net accumulation of a chemical substance in an organism or part of an organism, or an environmental compartment, that absorbs the chemical at a rate greater than that at which the chemical is lost.

(7) "California distributor" means any person, other than a manufacturer or retailer, who takes title to a consumer product for purposes of directly or indirectly placing the product into the stream of commerce in California.

(8) "California importer" means a person who brings, or arranges to bring, a consumer product into California for purposes of directly or indirectly placing the product into the stream of commerce in California.

(9) "Carcinogen or reproductive toxin" means a chemical listed as a carcinogen or a reproductive toxin, or both, pursuant to one or more of the following:

(A) Health and Safety Code section 25249.8,

(B) The National Toxicology Program Report on Carcinogens that lists chemicals known and reasonably anticipated to be human carcinogens;

(C) United States Environmental Protection Agency chemicals classified as Known or Likely (Group A, B1 or B2), as maintained on its Integrated Risk Information System, or equivalent weight-of-evidence classifications that result from subsequent revisions to its "Guidelines for Carcinogen Risk Assessment";

(D) The International Agency for Research on Cancer Group I and 2A chemicals;

(E) The International Agency for Research on Cancer Group 2B chemicals where there exists sufficient evidence of carcinogenicity in animals, even if evidence of carcinogenicity in humans is inadequate; and

(F) The European Union Classification and Labeling (Globally Harmonized System) Category 1A and 1B chemicals.

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

(A) A chemical substance;

(B) A chemical mixture;

(C) Nanomaterial.

(11) "Chemical ingredient" means a chemical contained in a consumer product or component.

(12) "Chemical Hazard Assessment" means the evaluation and comparison of a product or component, and the alternatives selected for consideration, using pertinent factors listed in section 69305.5(b).

(13) "Chemical mixture" means a mixture or solution of two or more chemical substances.

(14) "Chemical of Concern" means a chemical that is listed by the Department on either the Chemicals Under Consideration List or the Priority Chemicals List.

(15) "Chemical Removal Confirmation Notification" means a notification submitted to the Department by a manufacturer of a product or component that contained one or more Chemical under Consideration and/or Priority Chemicals notifying the Department that the manufacturer has removed all Chemicals under Consideration and/or Priority Chemicals from the product or component, without replacing the removed Chemicals under Consideration and/or Priority Chemicals with another chemical, or otherwise adding another chemical to the product or component. The Chemical Removal Confirmation Notification must include all of the following:

(A) The manufacturer's name and contact information;

(B) The name of and contact information for any responsible entities known to the manufacturer;

(C) Information describing the product or component, including the brand name(s) and labeling information;

(D) Identification of all Chemicals under Consideration and/or Priority Chemicals that were removed from the product or component;

(E) A statement certifying both of the following:

1. Any and all Chemicals under Consideration and/or Product under Consideration have been removed from the product or component, and

2. The manufacturer has completed all actions necessary to ensure the version of the product or component that contained the Chemicals under Consideration and/or Priority Chemicals is no longer placed into the stream of commerce in California.

(F) A signed certification statement as required by section 69301.5(b).

(16) "Chemical Removal Intent Notification" means a notification submitted to the Department by a manufacturer of a product or component that contains one or more Chemicals under Consideration and/or Priority Chemicals notifying the Department of the manufacturer's intent to remove all Chemicals under Consideration and/or Priority Chemicals from the product or component, without replacing the removed Chemicals under Consideration and/or Priority Chemicals with another chemical, or otherwise adding another chemical to the product or component. The Chemical Removal Intent Notification must include all of the following:

(A) The manufacturer's name and contact information;

(B) The name of and contact information for any responsible entities known to the manufacturer;

(C) Information describing the product or component, including the brand name(s) and labeling information;

(D) Identification of all Chemicals under Consideration and/or Priority Chemicals intended to be removed from the product or component;

(E) A statement certifying that the manufacturer intends to do all of the following within ninety (90) days of the date the Chemical Removal Intent Notification is submitted to the Department:

1. Complete all actions necessary to remove from the product or component any and all Chemicals under Consideration and/or Priority Chemicals,

2. Complete all actions necessary to ensure the version of the product or component that contained the Chemicals under Consideration and/or Priority Chemicals is no longer placed into the stream of commerce in California, and

3. Submit a Chemical Removal Confirmation Notification to the Department for the product or component.

(F) A signed certification statement as required by section 69301.5(b).

(17) "Chemical substance" means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

(18) "Chemical Under Consideration" means a chemical listed by the Department pursuant to section 69302.2(a)(1).

(19)(A) "Component" means a uniquely identifiable part, piece, assembly or subassembly, system or subsystem of a consumer product that:

1. Is required to complete or finish an item; or
2. Performs a distinctive and necessary function in the operation of a system; or
3. Is intended to be included as a part of a finished item.

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

(20)(A) "Consumer product" or "Product" means any of the following:
1. A "consumer product" as defined in Health and Safety Code section 25251;
2. A component that meets the definition of a "consumer product" as defined in Health and Safety Code section 25251;
3. A chemical that meets the definition of a "consumer product", as defined in Health and Safety Code section 25251, and that is packaged, and placed into the stream of commerce in California, as an individual chemical.

(B) "Consumer product" does not include a product that is no longer being placed into the stream of commerce by any person in California as of the date that it would otherwise become subject to one or more requirements of this chapter.

(21) "Contact information" means mailing and electronic address, headquarters location, phone number(s), and website address.

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

(23) "De minimis exemption" means an exemption requested and granted pursuant to section 69305.3.

(24)(A) "De minimis level" means a concentration less than or equal to the lower of:
1. 0.1% by weight; or
2. The lowest federal or California State public health or environmental regulatory threshold that applies to the chemical or the chemical/product combination.

(B) For purposes of the definition of "de minimis level", federal and California State public health and environmental regulatory thresholds include, but are not limited to:
1. Maximum Contaminant Levels (MCLs) and MCL goals developed by the United States Environmental Protection Agency under the federal Safe Drinking Water Act,
2. MCLs developed by the California Department of Public Health pursuant to Health and Safety Code section 116365(a),
3. Public Health Goals (PHGs) developed by the California Office of Environmental Health Hazard Assessment pursuant to Health and Safety Code section 116365(c),
4. Maximum Allowable Dose Levels (MADLs) for chemicals that cause reproductive toxicity developed by the California Office of Environmental Health Hazard Assessment pursuant to the Safe Drinking Water and Toxic Enforcement Act of 1986,

5. No Significant Risk Levels (NSRLs) for chemicals that cause cancer developed by the California Office of Environmental Health Hazard Assessment pursuant to the Safe Drinking Water and Toxic Enforcement Act of 1986,

6. Regional Screening Levels developed by the United States Environmental Protection Agency pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended by the 1986 Superfund Amendments and Reauthorization Act, and

7. The criteria for the identification of hazardous waste pursuant to Health and Safety Code section 25141.

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

(26) “Distributor” means any person, other than a manufacturer or retailer, who takes title to a consumer product for purposes of placing the product into the stream of commerce in the United States.

(27) “Economic impacts” means an increase or decrease in any of the following:

(A) Jobs or businesses,

(B) The costs of doing business,

(C) The cost of goods to consumers, or

(D) Other economic impacts including, but not limited to, those specified in section 69305.5(d)(4).

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

(29) “Energy efficiency” means the reduction of energy usage while maintaining a comparable level of service during the manufacturing process or the use of the consumer product.

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

(31) “Environmental impact” means any change to the environment, whether adverse or beneficial, wholly or partially resulting from an activity, product or service.

(32) “Exposure Potential Assessment” means the evaluation and comparison of a product or component, and the alternatives selected for consideration, using pertinent factors listed in section 69305.5(c).

(33) “Failure to Comply List” means the list prepared by the Department pursuant to section 69301.4(f)(3).

(34) "Failure to Respond List" means the list prepared by the Department pursuant to section 69301.6(d)(3).

(35) "Financial guarantee" means a mechanism or mechanisms to ensure that adequate funding is available to pay for future end-of-life management costs for the producer's or manufacturer's products placed into the stream of commerce in California.

(36) "Functionally equivalent" means that a product that has been altered by a chemical or component substitution, or that has replaced another product, substantially satisfies the intended performance and functionality of the original product.

(37) "Greenhouse gas" means any of the following gases:
(A) Carbon dioxide.
(B) Methane.
(C) Nitrous oxide.
(D) Hydrofluorocarbons.
(E) Perfluorocarbons.
(F) Sulfur hexafluoride.
(G) Nitrogen trifluoride.

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

(39) "Hazard trait" means one of the following:
(A) Hazard traits as identified by the Office of Environmental Health Hazard Assessment ("OEHHA") pursuant to Health and Safety Code section 25256.1;
(B) Until OEHHA promulgates its initial list of hazard traits, "hazard trait" is limited to all of the following:
1. Carcinogenicity or reproductive toxicity. Chemicals with these traits are those meeting the definition of carcinogen or reproductive toxin as defined in this section.
2. Mutagenicity. Chemicals with this trait are those listed as having mutagenic properties in the European Union Category 1A or 1B under Annex VI, part 3 of the Regulation.
3. Chemicals that have been determined by the United States Environmental Protection Agency to be Persistent Bioaccumulative Toxic chemicals.

(40) "Importer" means a person who brings, or arranges to bring, a consumer product into the United States for purposes of placing the product into the stream of commerce.

(41) "Intentionally-added chemical or chemical ingredient" means a chemical or chemical ingredient that is deliberately used in the formulation or assembly of product where the

continued presence is desired in the final consumer product to provide a specific characteristic, appearance, or quality.

(42) "Intermediate manufacturing process" means:
(A) The primary processing of raw materials into industrial materials, and
(B) The secondary processing of industrial raw materials including, formulating, casting and molding, forming, separating, conditioning, further refining, assembling and finishing processes to manufacture consumer products.

(43) "Inventory recall" means to cause the return, directly or indirectly, of a consumer product that has not been sold at retail back to the responsible entity or the manufacturer of the consumer product.

(44) "Life cycle" means the activities in the course of a consumer product's life span, including its design, raw materials, resource inputs, manufacture, transportation for distribution, use, operation, resource consumption, waste generation, maintenance, and ultimate disposition.

(45) "Life cycle thinking" means examining environmental sustainability over a product's entire life cycle; including, but not limited to, raw material selection, manufacturing, transportation, use and end-of-life disposal or reuse and waste management.

(46) "Listserv" means an electronic mailing list that persons may subscribe to on the Department's website in order to automatically receive electronic notification concerning the posting of documents and other information on the Department's website, including documents and information posted pursuant to section 69301.7(a).

(47) "Manufacturer" means any of the following:
(A) The producer of a consumer product;
(B) The person who is the owner or licensee of the brand name or trademark, whether or not the brand name or trademark is registered, under which a consumer product is placed into the stream of commerce in California.

(48)(A) "Materials and resource consumption" means renewable and nonrenewable resources that are used for a consumer product during its life.
(B) A renewable resource is a resource that is replaced by natural processes at a rate that is equal to or faster than its consumption rate and includes solar, wind, timber, agricultural and water. A renewable resource may become a nonrenewable resource if the rate at which it is consumed exceeds the rate at which it is produced such that its continued use may drive the resource to exhaustion.

(C) A nonrenewable resource is a resource that is formed over long periods of geologic time and includes petroleum, coal, metals (mined and recycled), minerals, and exhausted renewable resources.

(49) "Multimedia Life Cycle Evaluation" means the evaluation and comparison of a product or component, and the alternatives selected for consideration, using pertinent factors listed in section 69305.5(d).

(50)(A) "Nanomaterial" means any form of an intentionally engineered chemical, substance or material that is intended to be composed of a discrete nanostructure that meets either of the following criteria:

1. At least one spatial dimension of the nanostructure is at the nanoscale, or

2. The nanostructure is larger than nanoscale in any spatial dimension, but is 1000 nanometers or less in at least one spatial dimension, and the nanostructure exhibits one or more nanoscale phenomena.

(B) "Nanoscale" means of the order of no less than one (1) nanometer and no more than 100 nanometers.

(C) "Nanoscale phenomena" means properties of a nanomaterial that are attributable to its size and distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material.

(D) "Nanostructure" means any intentionally manufactured structure or feature that is composed of discrete functional parts, either internally or at the surface, at the nanoscale.

(51) "Persistence" means the ability of a chemical substance or its degradation products to remain in an environment.

(52) "Person" shall have the same meaning as in Health and Safety Code section 25118.

(53)(A) "Place into the stream of commerce in California" means that a person sells, offers for sale, distributes, supplies, or otherwise transfers control over the disposition of a consumer product directly to a California consumer, or to another person without maintaining sufficient control over the distribution, sale, supply, or other transfer of the consumer product by that person to prevent the use of the consumer product by a California consumer.

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

(54) "Priority Chemical" means a chemical listed by the Department pursuant to section 69302.2(a)(2).

(55) "Priority Product" means a product listed by the Department pursuant to section 69303.2(a)(2).

(56)(A) "Produce" means to make a product.

(B) "Produce" does not include any of the following actions, unless the action results in the addition of a Chemical of Concern to, or replacement of a Chemical of Concern in, a product:

1. Repair or refurbishment of an existing consumer product,
2. Installation of standardized components to an existing consumer product, or
3. Making non-material alterations to an existing consumer product.

(57) "Producer" means the entity that produces a product that is placed into the stream of commerce in California.

(58) "Product function and performance" means the principal use(s) or application(s) of a product by a consumer, as intended by the manufacturer, including function and performance attributes, and safety and environmental standards required by federal or California law.

(59) "Product Removal Confirmation Notification" means a notification submitted to the Department by a manufacturer of a product or component that contained one or more Chemicals under Consideration and/or Priority Chemicals notifying the Department that the product or component is no longer being placed into the stream of commerce in California. The Product Removal Confirmation Notification must include all of the following:

(A) The manufacturer's name and contact information;

(B) The name of and contact information for any responsible entities known to the manufacturer;

(C) Information describing the product or component, including the brand name(s) and labeling information;

(D) Identification of all Chemicals under Consideration and/or Priority Chemicals that were contained in the product or component;

(E) A statement certifying that the manufacturer has completed all actions necessary to ensure the product or component is no longer placed into the stream of commerce in California.

(F) A signed certification statement as required by section 69301.5(b).

(60) "Product Removal Intent Notification" means a notification submitted to the Department by a manufacturer of a product or component that contains one or more Chemicals under Consideration and/or Priority Chemicals notifying the Department of the manufacturer's intent to discontinue placing the product into the stream of commerce in California. The Product Removal Intent Notification must include all of the following:

(A) The manufacturer's name and contact information;

(B) The name of and contact information for any responsible entities known to the manufacturer;
(C) Information describing the product or component, including the brand name(s) and labeling information;
(D) Identification of all Chemicals under Consideration and/or Priority Chemicals contained in the product or component;
(E) A statement certifying that the manufacturer intends to do both of the following within ninety (90) days after the date the Chemical Removal Intent Notification is submitted to the Department:
1. Complete all actions necessary to ensure the product or component is no longer placed into the stream of commerce in California, and
2. Submit a Product Removal Confirmation Notification to the Department for the product or component.
(F) A signed certification statement as required by section 69301.5(b).

(61) “Product stewardship” means the shared responsibility of product producers, manufacturers and responsible entities, for end-of-life product management. The primary responsibility lies with the product producer, or manufacturer, who makes the product design and marketing decisions.

(62) “Product Under Consideration” means a product listed by the Department pursuant to section 69303.2(a)(1).

(63) “Public health impacts” means effects on the health of the general population or sensitive subpopulations.

(64) "Recycled material" means a material that has been separated from a waste stream for the purpose of recycling the material as feedstock including paper, plastic, wood, glass, ceramics, metals, and other materials.

(65) “Release” means an intentional or unintentional process that liberates or discharges a chemical that is contained in a consumer product into the environment and includes, but is not limited to any release which results in exposure to persons during any phase of the product’s life cycle. This includes releases of chemicals, heat, and ionizing and non-ionizing radiation.

(66) “Reliable information” means data, studies and other information that have been:
(A) Scientifically peer-reviewed; or
(B) Generated using established federal guidelines, including, but not limited to, any of the following:
1. United States Food and Drug Administration Good Laboratory Practices (Part 58 of Title 21 of the Code of Federal Regulations),

2. United States Environmental Protection Agency's Office of Chemical Safety and Pollution Prevention Harmonized Test Guidelines,
3. Federal Toxic Substances Control Act (TSCA) (Chapter 1 of Title 40 of the Code of Federal Regulations), and
4. TSCA Testing Guidelines (Parts 798 and 799 of Title 40 of the Code of Federal Regulations); or

(C) Published in scientifically peer reviewed literature; or

(D) Published in final state or federal scientific reports; or

(E) Published in a final report of the National Academy of Sciences, National Academy of Engineering, Institute of Medicine, or National Research Council; or

(F) Published in final reports from the agencies that implement the laws and programs described in section 69301.6(c)(2); or

(G) Developed, or reviewed and accepted, by a federal agency or a California State or local agency for compliance or other regulatory purposes; or

(H) Generated according to valid accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method, such as:

1. Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals,
2. REACH/ECHA Guidance on Information Requirements and Chemical Safety Assessment, and
3. Canadian Environmental Protection Act (CEPA) Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers.

(67) "Responsible entity" means any of the following:

(A) The person who is the owner or licensee of the brand name or trademark, whether or not the brand name or trademark is registered, under which a consumer product is placed into the stream of commerce in California. If the product is labeled or marked with more than one brand name or trademark, the responsible entity is the person which the product was "manufactured for" or "distributed by", as noted on the label.

(B) A California importer;

(C) A California distributor;

(D) A retailer;

(E) Any other person who is party to a contractual agreement with a California importer, California distributor, or retailer concerning a consumer product that is placed into the stream of commerce in California, unless that contractual agreement specifically states that the consumer product shall not be placed into the stream of commerce in California.

(68) "Retailer" means a person who sells, supplies, or offers for sale, directly to a consumer in California, a consumer product not produced by that person.

(69) "Safer" means a demonstrated net reduction of projected public health and environmental adverse impacts.

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

(71) "Selected alternative" means the alternative that is selected to replace a Priority Product or component, and is identified pursuant to section 69305.8(f).

(72) "Sensitive subpopulations" means subgroups that comprise a meaningful portion of the general population that are identifiable as being at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait, including, but not limited to, infants, children, pregnant women, elderly individuals, and individuals with a history of serious illness.

(73) "Soil sealing" means the covering of the soil surface with a layer of impervious material or changing the nature of the soil so that it behaves as an impermeable medium.

(74) "State or local agency" means a California State agency or a California local agency.

(75) "Supply chain" means every entity, other than the final purchaser or leaser of a finished consumer product, which comes in contact with the product, including, but not limited to the product producer, manufacturer, importer, distributor, California importer, California distributor, and retailer.

(76)(A) "Technologically and economically feasible alternative" means an alternative for which:

1. The current technological knowledge, equipment, materials and other resources available to the manufacturer are sufficient to develop and implement the alternative;
2. The manufacturer may earn at least a comparable rate of return on the alternative product, as compared to the rate of return earned on the Priority Product or component, over a reasonable period of time after the alternative has been implemented; and
3. The manufacturer and the product impose no significant increase in externalized aggregate costs to the consumer and to public health and the environment.

(B) As part of a determination of whether a "technologically and economically feasible alternative" exists, consideration shall be given to all of the following to the extent applicable:

1. The extent to which a functionally equivalent alternative is currently available in the marketplace;
2. The affordability of any currently available functionally equivalent alternative; and
3. The purchase price differential between the Priority Product and the alternative.

(77) "Threat" means a potential to cause an adverse impact.

(78) "Tier I Alternatives Assessment" or "Tier I AA" means an assessment that the Department concurs is substantially equivalent to the Green Screen For Safer Chemicals, as published and amended by Clean Production Action, or any other AA tool and/or methodology that the Department concurs is acceptable for purposes of section 69305.1(a)(5).

(79) "Tier I AA Report" means a report prepared to describe the conduct, findings and conclusions of a Tier I AA.

(80) "Tier II Alternatives Assessment" or "Tier II AA" means an alternatives assessment that conforms to the applicable requirements of section 69305.5.

(81) "Trade secret" means information including a formula, pattern, compilation, program, device, method, technique, or process that:
(A) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
(B) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

(82) "Unintentionally-added chemical or chemical ingredient" means a chemical or chemical ingredient that is present in a consumer product but is not an intentionally-added chemical or chemical ingredient.

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

(84) "Water conservation" means reducing water usage throughout the life cycle of a product.

(85) "Water quality impacts" means any effect upon beneficial uses as specified in Water Code section 13050(f) or adopted in a Water Quality Control Plan pursuant to article 3 of chapter 3 and article 3 of chapter 4 of division 7 of the Water Code, and includes impacts that may occur in waters of the State as defined in Water Code section 13050(e), including, but not limited to, groundwater, fresh water, brackish water, marsh lands, wetlands, or coastal bodies or systems.

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.

§ 69301.3. Acronyms.

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

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

§ 69301.4. Duty to Comply and Consequences of Non-Compliance.

(a) Submission of Chemical and Product Information.

(1) When information is requested by the Department pursuant to section 69301.6, a responsible entity for a product that is the subject of the request shall make the information available to the Department by the date requested. If a chemical is the subject of the request for information, a responsible entity for any product containing that chemical shall make the information available to the Department. In either case, the responsible entity may fulfill this obligation by ensuring that the requested information is made available to the Department by another person by the date requested. If requested by the responsible entity, or a person acting on behalf of the responsible entity, the Department may, at its discretion, approve no more than one 60-day extension to the due date for making the requested information available to the Department.

(2) Notwithstanding paragraph (1), a responsible entity will not be held responsible for making available the requested information if any of the following occurs:

(A) The Department notifies the responsible entity that the requested information has been made available to the Department by another person.

(B) The requested information is made available to the Department by another person, the responsible entity receives a notice from that person identifying the information made available and the date the information was made available to the Department, and a copy of this notice is provided to the Department.

(C) The responsible entity complies with the requirements of subsection (e).

(b) Priority Product Notification.

The responsible entity shall be responsible for complying with the notification requirements of section 69303.5, unless one of the following occurs:

(1) The notification is provided to the Department by the product manufacturer or another person in the product supply chain; or

(2) The responsible entity complies with the requirements of subsection (e).

(c) Alternatives Assessments.

(1) The responsible entity shall be responsible for complying with any requirement(s) of article 5 that apply to one or more of the products that entity places into the stream of commerce in California. The responsible entity may fulfill this obligation by ensuring that the applicable requirements of article 5 are fulfilled for that particular product within the required time line(s) by another person.

(2) Notwithstanding paragraph (1), a responsible entity will not be held responsible for complying with one or more applicable requirements of article 5 if any of the following occur:

(A) The requirement has been fulfilled to the Department's satisfaction by another person;

(B) The Department has granted a de minimis exemption for the product, pursuant to section 69305.3; or

(C) The responsible entity complies with the requirements of subsection (e).

(d) Regulatory Responses.

(1) The responsible entity shall be responsible for complying with any requirement(s) of article 6 that apply to one or more of the products that entity places into the stream of commerce in California. The responsible entity may fulfill this obligation by ensuring that the applicable requirements of article 6 are fulfilled for that particular product within the required time line(s) by another person.

(2) Notwithstanding paragraph (1), a responsible entity will not be held responsible for complying with one or more applicable requirements of article 6 if one of the following occurs:

(A) The requirement has been fulfilled to the Department's satisfaction by another person; or

(B) The responsible entity complies with the requirements of subsection (e).

(e) Options for Responsible Entities.

(1) A responsible entity will not be held responsible for complying with requirements of section 69301.6, section 69303.5, article 5, or article 6 that are applicable to a product, or to a chemical contained in a product, placed into the stream of commerce in California by that responsible entity, if the responsible entity is not the manufacturer of the product and has complied with all of the following requirements:

(A) The responsible entity has ceased to place the product into the stream of commerce in California, notifies the Department of this action no later than thirty (30) days after the original or extended due date for the applicable requirement, and provides any additional related information subsequently requested by the Department within the time specified.

(B) The notification required pursuant to subparagraph (A), must include all of the following information:

1. The responsible entity's name and contact information;

2. Identification and location of all known sales outlets where the product is sold, supplied or offered for sale in California;

3. Name of and contact information for the person immediately upstream from the responsible entity in the supply chain for the product;

4. Name of and contact information for all other persons, known to the responsible entity, in the supply chain for the product, including, but not limited to, other responsible entities, chemical and product manufacturer(s), California importer(s), California distributor(s), person(s) who import the product into the United States, and person(s) who distribute the product in the United States;

5. Brand name(s) under which the responsible entity placed the product into the stream of commerce in California, along with a copy of, or reproduction of all information contained on the product label, package, and packaging insert, as applicable; and

6. Documentation demonstrating that the responsible entity had a contractual agreement with the person(s) who supplied the product to the responsible entity that requires the supplier(s) to ensure that all applicable requirements of this chapter have been and will be complied with for any product(s) supplied under the agreement.

(C) The responsible entity has signed up for any listservs established by the Department related to this chapter.

(2) A responsible entity that is the manufacturer of a product will not be held responsible for complying with requirements of section 69301.6, section 69303.5, article 5, or article 6 that are applicable to that product, or to a chemical contained in that product, if the responsible entity provides documentation to the Department demonstrating to the Department's satisfaction that the product is no longer placed into the stream of commerce in California by any person.

(f) Failure to Comply List.

(1)(A) When the Department determines that one or more requirements of this chapter have not been complied with for a specific chemical or product, the Department shall issue a notice of non-compliance to all responsible entities for the product known to the Department. A copy of the notice shall also be sent to all other persons in the supply chain for the product or chemical known to the Department.

(B) A notice of non-compliance issued pursuant to subparagraph (A) shall describe the nature of the non-compliance and the Department's intent to place information concerning the determination of non-compliance on the Failure to Comply List on its website pursuant to paragraph (3).

(2) No sooner than forty-five (45) days and no later than ninety (90) days after issuing a notice of non-compliance pursuant to paragraph (1), if the non-compliance has not been remedied to the satisfaction of the Department, and there is no pending dispute under article 7 concerning 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 pursuant to paragraph (3). The non-compliance shall be deemed to be remedied if the Department determines that the requirements of subsection (e)(2) have been fulfilled.

(3) The Department shall post and maintain on its website a Failure to Comply List that includes all of the following information for each product covered by a notice of non-compliance:

(A) Information identifying and describing the product, including the brand name(s) under which the product is placed into the stream of commerce in California;

(B) The requirement(s) of this chapter, and any applicable due date(s), that are the basis for the notice of non-compliance;

(C) Any Priority Chemical(s) know to be contained in the product;

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

(E) The name of and contact information for any responsible entity that has been notified by the Department, pursuant to paragraph (1), except that the Department shall not include any responsible entity that the Department has determined has fully complied with the requirements of subsection (e)(1);

(F) The name of and contact information for any other person that has been notified by the Department, pursuant to paragraph (1);

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

(4) The Department shall remove a product, and the associated information, from the Failure to Comply List upon a determination by the Department that the condition of non-compliance has been fully remedied, or that the requirements of subsection (e)(2) have been fulfilled. A product, and its associated information, shall also be removed from the Failure to Comply List if a Chemical Removal Confirmation Notification or a Product Removal Confirmation Notification has been submitted to the Department for the product, and the condition of non-compliance was not related to the requirements of section 69301.6.

(5) The Department shall remove information concerning a responsible entity from the Failure to Comply List upon a determination by the Department that the responsible entity has complied with the applicable requirements of subsection (e).

(g) Violations. The following consequences for non-compliance with the requirements of this chapter are in addition to subsection (f):

(1) A person who fails to comply with any of the requirements of this chapter shall be subject to all applicable provisions of article 8 of chapter 6.5 of division 20 of the Health and Safety Code, including, but not limited to, those provisions pertaining to enforcement actions and fines and penalties.

(2) Any person who intentionally or negligently makes a false statement or false representation in any information or document made available to the Department or any other entity pursuant to this chapter shall be subject to the fines and penalties, and other provisions, of article 8 of chapter 6.5 of division 20 of the Health and Safety Code applicable to persons who make false statements or representations.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Article 8 of Chapter 6.5 of Division 20 and Sections 25252 and 25253, Health and Safety Code.

§ 69301.5. Information Submission and Retention Requirements.

(a) All documents and other information submitted to the Department pursuant to this chapter shall be signed by the owner or an officer of the company and by the person(s) in charge of preparing or overseeing the preparation of the document or information. All

documents, data and information shall be submitted in English, and shall be generated and submitted in a manner and in an electronic format specified or approved by the Department. Unless specified otherwise by the Department, the electronic documents or electronic media shall be submitted via certified mail or electronically to either:

Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
Attention: Green Chemistry

or

Email at: safer.alternatives@dtsc.ca.gov

(b) All Chemical Removal Confirmation Notifications, Chemical Removal Intent Notifications, Product Removal Confirmation Notifications, Product Removal Intent Notifications, de minimis exemption requests, AA Notifications, AA Work Plans, AA Reports, Tier I AA Reports, AA verification statements, documentation for designation pursuant to section 69308 or 69308.1 as a qualified third-party assessment entity or a qualified in-house assessment entity, and documentation for designation as an accrediting body pursuant to section 69308.2 shall include the following certification statement, signed by an officer of the entity submitting the document and by the responsible individual in charge of preparing the information:

"I certify under penalty of perjury that this document and all attachments were prepared or compiled under my direction or supervision to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons directly responsible for gathering the information, the information submitted is, to be the best of my knowledge and belief, true, accurate, and complete. I also certify that in carrying out the duties above, life cycle thinking and green chemistry principles were considered. I am aware that submitting false information or statements is punishable under all applicable provisions of law."

(c) Any information or documentation required to be obtained or prepared, but that is not required to be submitted to the Department or has not yet been requested to be submitted to the Department, shall be retained by the person to whom the requirement applies for a period of three (3) years following the date the person was required to obtain or prepare the information or documentation.

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

§ 69301.6. Chemical and Product Information.

(a)(1) This section specifies a process for the Department to review and/or obtain data and other information, concerning chemicals and products, that the Department determines is necessary to implement article 14 of chapter 6.5 of division 20 of the Health and Safety Code and/or this chapter.

(2) Notwithstanding paragraph (1), nothing in this section precludes the Department from reviewing and/or obtaining data and other information through any other means available to the Department.

(3) The provisions of this section requiring a person to provide or make available data or other information to the Department may be complied with by either:

(A) Submitting the requested data or information to the Department in a format specified by, or acceptable to, the Department, or

(B) Providing the Department with electronic access to the data or information in a format specified by, or acceptable to, the Department, unless the Department specifically requests that the data or information be submitted to the Department.

(b) In seeking to review and/or obtain data and other information that the Department determines is necessary to implement article 14 of chapter 6.5 of division 20 of the Health and Safety Code and/or this chapter, the Department shall use the following sequential steps, with each subsequent step being used only to review and/or obtain data and information that could not be reviewed and/or obtained by use of the preceding step(s):

(1) Review and/or obtain needed data and other information readily available, without a subscription or other charge, in a usable format in the public domain;

(2) Review and/or obtain needed data and other information readily available, with a subscription or other charge, in a usable format in the public domain, to the extent resources are available to the Department to pay the required costs;

(3) Request and require a responsible entity to make available to the Department to review and/or obtain existing data and other information that is needed by the Department, in accordance with a schedule specified by the Department and pursuant to section 69301.4(a); and

(4) Request and require a responsible entity to generate and make available to the Department to review and/or obtain data and other information that is needed by the Department, in accordance with a schedule specified by the Department and pursuant to section 69301.4(a).

(c)(1) The types of data and other information that may be requested and required to be made available to the Department to review and/or obtain pursuant to this section include, but are not limited to:

(A) Chemical and product data and information specified in sections 69302.3 and 69303.3.

(B) Information describing the types, categories and classes of products that contain Priority Chemicals.

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

(D) Chemical and product market data, including:
1. Volume or units sold in California;
2. Description of sales locations;
3. The intended uses of the product;
4. Targeted customer base(s); and
5. Description of end-of-life management program, if any.

(E) Standard analytical chemistry protocols for the detection and measurement of a chemical in products and in environmental and biological media.

(F) Information concerning a product that has been reformulated or redesigned to remove, or reduce the concentration of, a Priority Chemical, or a product containing a chemical that has been substituted for a product that contained a Priority Chemical, if the reformulation, redesign or replacement occurred subsequent to the listing of the chemical.

(2) Requests and requirements for making available the data and information described in paragraph (1) may, to the extent applicable, be fulfilled by making available to the Department data and information that has been provided under the REACH, TSCA, or CEPA programs.

(d)(1) Data and other information requested and required to be made available to the Department, pursuant to subsections (b)(3) and (b)(4), shall be limited to data and information that is pertinent to either products placed into the stream of commerce in California or chemicals contained in such products.

(2) When requesting and requiring the availability to the Department of data and other information pursuant to subsections (b)(3) and (b)(4), the Department shall make reasonable efforts to avoid requesting the same information from multiple parties, unless the Department determines there is reason to do so.

(3) In addition to subsections (b)(3) and (b)(4), the Department may also request any needed data and information directly from the manufacturer of the chemical or product. If the manufacturer does not make the requested information available to the Department by the date specified by the Department, the Department shall include the request, and a notice that the manufacturer has not made the requested information available to the Department, along with information identifying the manufacturer and the chemical and/or product that are the subject of the request, on a Failure to Respond List posted on its website. The Department shall remove this information from its website upon determining that the manufacturer or another person has fulfilled the request for data or other information.

(e) The Department may request and require that data and other information be made available to it pursuant to this section by either or both of the following methods:

(1) Correspondence sent to an individual responsible entity or other person electronically or by United States mail.

(2) Data and information call-ins that, unless otherwise specified, apply to all responsible entities, or manufacturers, of a specific chemical or product or group of chemicals or products. Data and information call-ins shall be posted on the Department's website, noticed to persons on any listservs established by the Department related to this chapter, and noticed in the CRNR.

(f) Any responsible entity or other person may at any time make reliable information regarding a chemical or product available to the Department for consideration in the chemical prioritization or product prioritization process. Such information may be made available in support of comments calling for a chemical or product to be included in, or excluded or removed from, the chemical lists or product lists. The Department shall give good faith consideration to the data or other information made available pursuant this subsection.

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

§ 69301.7. Availability of Information on the Department's Website.

(a) The Department shall post on its website, and update as needed, all of the information and documents listed in paragraphs (1) through (16), subject to article 10. The availability of these documents and information, including the availability of updates to the information and documents, shall be noticed in the CRNR and to persons on any listserv(s) that the Department establishes related to this chapter.

(1) A Failure to Comply List prepared pursuant to section 69301.4(f);

(2) A Failure to Respond List prepared pursuant to section 69301.6(d)(3);

(3) Requests for data and information made pursuant to section 69301.6(e);

(4)(A) Exemption determinations made pursuant to sections 69302.1 and 69303.1, and the rationale supporting those determinations;

(B) Determinations, made pursuant to sections 69302.1(d) and 69303.1(d), rescinding previously-made exemption determinations;

(5) The proposed and final chemical lists, and supporting rationale and documentation, prepared pursuant to section 69302.2, copies of all written comments received during the public comment period for the proposed lists, and copies of any written responses the Department chooses to provide to the comments;

(6) The proposed and final product lists, and supporting rationale and documentation, prepared pursuant to section 69303.2, copies of all written comments received during the public comment period for the proposed lists, and copies of any written responses the Department chooses to provide to the comments;

(7) Petitions designated as complete pursuant to section 69304(b), and notices of decision and statements of basis prepared by the Department pursuant to section 69304.1(d);

(8) Chemical Removal Confirmation Notifications, Chemical Removal Intent Notifications submitted to the Department, Product Removal Confirmation Notifications, and Product Removal Intent Notifications;

(9) For each AA Work Plan, the due dates for the Tier II-A and Tier II-B AA Reports;

(10) A list of extension requests approved, pursuant to section 69305.2(b), for submission of AA Work Plans and AA Reports;

(11) A list of de minimis exemption requests submitted to the Department pursuant to section 69305.3(a), and copies of all notifications issued by the Department granting, denying or rescinding a de minimis exemption pursuant to sections 69305.3(c) and 69305.3(e);

(12) AA Report notices of completeness issued pursuant to sections 69305.10;
(13) Proposed and final regulatory response determination notices issued by the Department pursuant to article 6, copies of all written comments received during the public comment period for a proposed notice, and copies of any written responses the Department chooses to provide to the comments;
(14) A list of regulatory response exemption requests submitted to the Department pursuant to section 69306.7(a), and copies of all notifications issued by the Department granting, denying or rescinding an exemption pursuant to sections 69306.7(c) and 69306.7(f);
(15) Copies of all disputes and petitions for review filed with the Department pursuant to article 7, and copies of all Department decisions issued in response to such disputes and petitions; and
(16) A list of accrediting bodies whose designation has been rescinded by the Department pursuant to section 69308.2(g), and list of lead assessors whose accreditation has been rescinded pursuant to section 69308.3(c).
(b) The Department shall also post on its website, and update as needed but not less frequently than quarterly, all of the following information and documents, subject to article 10:
(1) A list of products determined by the Department to contain a Chemical under Consideration or Priority Chemical pursuant to section 69302.5;
(2) Guidance documents prepared by the Department pursuant to section 69305(a);
(3) AAs available in the public domain pursuant to section 69305(b);
(4) AA Notifications submitted to the Department pursuant to section 69305.1;
(5) A list of Tier I AAs performed by a qualified third-party assessment entity or verified by a third-party lead assessor and submitted to the Department pursuant to section 69305.1(e);
(6) A list of all AA Work Plans that have been submitted to the Department pursuant to article 5, a full or redacted copy of each AA Work Plan, in accordance with the provisions of article 10, including both the originally submitted AA Work Plan and the AA Work Plan approved by the Department, if different;
(7) A list of all AA Reports that have been submitted to the Department pursuant to article 5, the executive summary for each AA Report, the AA verification statement, if applicable, and a full or redacted copy of each AA Report, including both the originally submitted AA Report and the AA Report approved by the Department, if different;
(8) The Regulatory Response Report prepared and updated pursuant to section 69306.9(d);
(9) Links to product stewardship plans provided to the Department pursuant to section 69306.4(d);
(10) A list of entities that have been designated as qualified third-party assessment entities pursuant to section 69308, and a list of entities that have been designated as qualified in-house assessment entities pursuant to section 69308.1;
(11) A list of persons designated as accrediting bodies, and the product types and/or industry sectors for which they are designated, pursuant to section 69308.2; and
(12) Findings of audits conducted by the Department pursuant to section 69309.

(c) All documents and information posted on the Department's website pursuant to this chapter shall include the date the document or information is first posted and the date(s) of any revised postings.

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

§ 69301.8. Chemicals and Products Lists: Timelines and Sequencing.

(a) This initial lists of Chemicals under Consideration, Priority Chemicals, Products under Consideration and Priority Products shall be issued, using the procedures specified in sections 69302.2 and 69303.2, in accordance with the following schedule:

(1) The proposed initial list of Chemicals under Consideration shall be issued for public review and comment no later than June 1, 2011.

(2) The final initial list of Chemicals under Consideration shall be issued no later than March 1, 2012.

(3) The proposed initial list of Priority Chemicals shall be issued for public review and comment no later than July 1, 2012.

(4) The proposed initial list of Products under Consideration shall be issued for public review and comment no later than March 1, 2013.

(5) The proposed initial list of Priority Products shall be issued for public review and comment no later than September 1, 2013.

(6) The final initial list of Priority Products shall be issued no later than December 1, 2013.

(b) In updating and revising previously issued lists of Chemicals under Consideration, Priority Chemicals, Products under Consideration and Priority Products, using the procedures specified in sections 69302.2 and 69303.2, the Department may, at its discretion:

(1) Simultaneously or sequentially issue the updated and/or revised Chemical under Consideration list and Priority Chemical list; and

(2) Simultaneously or sequentially issue the updated and/or revised Product under Consideration list and Priority Product list.

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

Article 2. Chemical Prioritization Process

§ 69302. General.

(a) This article specifies the process by which the Department shall identify and prioritize Chemicals of Concern.

(b) The Department may use information reviewed and/or obtained pursuant to section 69301.6 to perform its duties under this article.

(c) The Department is not limited to using the information reviewed and/or obtained pursuant to subsection (b) in performing its duties under this article.

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

§ 69302.1. Applicability.

(a) This article applies to all chemicals that exhibit a hazard trait and are reasonably expected to be contained in products placed into the stream of commerce in California, unless the Department determines that the chemical meets either or both of the following criteria:

(1) The chemical is regulated by one or more federal and/or other California State regulatory program(s) that, in combination, address, for each life cycle segment, the same public health and environmental threats addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter. This exemption shall not apply if, after taking into consideration the combined effect of all applicable federal and/or other California State regulatory programs, the Department determines that there are significant gaps, for one or more life cycle segments, between the combined public health and environmental threats that are addressed by these programs and the public health and environmental threats addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter. In making this determination, the Department shall identify and compare the life cycle segments for which public health and environmental threats are addressed by the combined effects of the federal and/or other California State regulatory programs and the life cycle segments addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter.

(2) There is no exposure pathway by which the chemical might pose a threat to public health or the environment in California during the useful life or the end-of-life management of the chemical or any product containing the chemical.

(b) In the absence of a determination by the Department to the contrary, it shall be presumed that subsections (a)(1) and (a)(2) do not apply to any chemical that exhibits a hazard trait and is reasonably expected to be, or to be contained in, products placed into the stream of commerce in California. This presumption shall affect the burden of proof specified pursuant to subsection (c).

(c) Any person requesting the Department to make a determination specified in subsection (a)(1) and/or (a)(2) shall bear the burden to prove by clear and convincing evidence to the Department's satisfaction that subsection (a)(1) and/or (a)(2) applies to the chemical in question. For a subsection (a)(2) exemption determination request, the evidence must include, to the extent applicable, the results of any use and abuse tests, including the assumptions and testing methodologies, conducted for purposes of and pursuant to a federal and/or California State regulatory program.

(d) The Department may, at its discretion, re-evaluate an exemption determination previously made pursuant to this section and rescind that exemption determination if the

Department finds that the facts and/or assumptions upon which the exemption determination was based were not, or are no longer, valid.

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

§ 69302.2. Chemicals Lists.

(a) The Department shall prepare two lists based on consideration of prioritization factors that relate to the threat(s) to public health and/or the environment posed by a chemical:

(1) A list of Chemicals under Consideration, using factors specified in section 69302.3, and

(2) A list of Priority Chemicals, using the factors specified in section 69302.4.

(b) Prior to finalizing the Chemical under Consideration and/or Priority Chemical list(s), the Department shall make the proposed list(s) available on its website, for public review and comment, along with supporting documentation, including, but not limited to, the Department's rationale, data and data sources, subject to article 10. The supporting information shall include an identification of the hazard trait(s) exhibited by, and potential exposure pathways for, each listed chemical. The Department shall publish in the CRNR, send to persons on any listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed list(s) and supporting documentation. The notice shall include:

(1) The time period during which the public may submit comments, which may include comments in support of adding or removing a chemical from the Chemical under Consideration list and/or Priority Chemical list;

(2) The method(s) for submitting comments to the Department on the proposed list(s); and

(3) Notification of any workshops, if the Department determines one or more workshops are necessary.

(c) After review and consideration of public comments on the proposed list(s), the Department shall finalize and post on its website the final Chemical under Consideration list and/or final Priority Chemical list. The Department may, at its discretion, respond to some or all public comments received.

(d) Using the procedures specified in this section, the Department shall update the Chemical under Consideration list and/or Priority Chemical list as needed. Revisions may include additions and deletions to the prior list(s).

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

§ 69302.3. Chemicals Under Consideration.

The prioritization factors that the Department may use to place chemicals on the list of Chemicals under Consideration, pursuant to section 69302.2, include:

(a) Chemical and physical properties, including, but not limited to:
(1) Density,
(2) Dissociation constant,
(3) Explosiveness,
(4) Flammability,
(5) Flash point,
(6) Granularity,
(7) Melting/boiling point,
(8) Oxidizing properties,
(9) Partition coefficient,
(10) Stability in organic solvents and identity of relevant degradation byproducts,
(11) Surface tension,
(12) Vapor pressure,
(13) Viscosity,
(14) Water solubility, and
(15) Other physical, chemical, or quantum properties specific to nanomaterials.

(b) Adverse public health impacts. Evaluation and comparison of public health impacts shall include consideration of impacts that may result from single, intermittent or frequent use of or contact with the chemical, including dermal, oral and inhalation exposures. Factors to be considered include, but are not limited to:
(1) Acute or chronic toxicity,
(2) Bioaccumulation in humans,
(3) Carcinogenicity,
(4) Cardiovascular toxicity,
(5) Dermatotoxicity,
(6) Developmental toxicity,
(7) Effects of electromagnetic radiation that includes ionizing radiation and non-ionizing radiation,
(8) Endocrine toxicity,
(9) Epigenetic toxicity,
(10) Genotoxicity,
(11) Hematotoxicity,
(12) Hepatotoxicity,
(13) Immunotoxicity,
(14) Musculoskeletal toxicity,
(15) Nephrotoxicity and other toxicity to the urinary system,
(16) Neurotoxicity,
(17) Ocular toxicity,
(18) Organ or tissue system toxicity,
(19) Ototoxicity,
(20) Persistence,
(21) Reactivity in biological systems,

(22) Reproductive toxicity,
(23) Respiratory effects,
(24) Toxicokinetics,
(25) Any hazard traits not listed above that relate to adverse impacts on human health, and
(26) Adverse health impacts on sensitive subpopulations.
(c) Adverse ecological impacts. Factors to be considered include, but are not limited to:
(1) Acute or chronic toxicity in aquatic, avian or terrestrial organisms,
(2) Adverse impacts on aquatic ecosystems, including, but not limited to, aquatic sediments,
(3) Adverse impacts on terrestrial ecosystems,
(4) Adverse impacts on environmentally sensitive habitats, including, but not limited to, habitat loss or deterioration,
(5) Adverse impacts on habitats essential to the continued existence of an endangered or threatened species, and other factors affecting the ability of an endangered or threatened species to survive or reproduce,
(6) Adverse impacts associated with population loss, decline in population diversity, or changes in historical communities, and
(7) Adverse impacts that can cause vegetation contamination or damage, including phytotoxicity.
(d) Adverse environmental impacts. Factors to be considered include, but are not limited to:
(1) Chemical traits. This includes any intrinsic trait of the chemical or its degradation products that relates to adverse impacts on the environment, including, but not limited to:
(A) Stability and persistence in biological and environmental compartments,
(B) Fate and transport among environmental compartments,
(C) Bioaccumulation in biological and environmental compartments,
(D) Biodegradation,
(E) Photodegradation,
(F) Production of transformation products in environmental settings,
(G) Hydrolysis half-life,
(H) Aerobic and anaerobic soil half-lives, and
(I) Aerobic and anaerobic sediment half-lives
(2) Air quality impacts. This includes any adverse impacts associated with air emissions, including the air contaminants listed below:
(A) Nitrogen oxides,
(B) Sulfur oxides,
(C) Toxic air contaminants,
(D) Greenhouse gases,
(E) Secondary organic aerosols,
(F) Stratospheric ozone-depleting compounds,
(G) Other ozone forming compounds, and

(H) Particulate matter.

(3) Water quality impacts. This includes, but is not limited to, adverse impacts associated with degradation of the beneficial uses of the waters of California and any of the following:

(A) Biological oxygen demand,

(B) Chemical oxygen demand,

(C) Total dissolved solids,

(D) Chronic and acute toxicity in the water column and sediments,

(E) Chemicals identified as priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act and listed in section 131.38 of Title 40 of the Code of Federal Regulations published in the Federal Register May 18, 2000,

(F) Pollutants listed by California or the United States Environmental Protection Agency for one or more water bodies in California pursuant to section 303 (d) of the federal Clean Water Act,

(G) Chemicals identified as contaminants that have primary Maximum Contaminant Levels (MCLs) under the federal Safe Drinking Water Act,

(H) Pollutants requiring monitoring and reporting in waste discharges to land that have Notification Levels (NLs) specified under the Waste Discharge and Water Reuse Requirements (WDRs/WRRs) of the Porter-Cologne Water Quality Control Act,

(I) Thermal pollution, and

(J) Other impacts affecting the quality of surface waters and groundwaters.

(4) Soil quality impacts. This includes adverse impacts associated with any of the following:

(A) Chemical contamination,

(B) Biological contamination,

(C) Loss of biodiversity,

(D) Loss of organic matter,

(E) Erosion,

(F) Compaction or other structural changes,

(G) Soil sealing, and

(H) Other impacts the affect or alter soil function or soil chemical, physical or biological characteristics or properties.

(5) Any other factors that relate to adverse impacts on the environment, including, but not limited to, the release of heat, odor or radiation.

(e) Dispersive volume information, as it relates to the volume of a chemical placed into the stream of commerce in California. This may include, but is not limited to:

(1) Projected annual sales by volume and/or mass,

(2) Annual regional distributions by volume and/or mass,

(3) Marketing and customer targeted volumes and/or mass,

(4) Volume and/or mass of the chemical in current use,

(5) Annual estimated volume and/or mass of the chemical used in products and components, and

(6) Controlled distribution systems, if any.

(f) Potential for the public or the environment to be exposed to the chemical in commonly used products that contain the chemical, during the useful life of those products and end-of-life disposal or management of the products. Factors to be considered include, but are not limited to, the factors listed in section 69303.3(b).

(g) Existence of data and other information relating to actual or potential public or environmental exposures to the chemical, including but not limited to:

(1) California Environmental Contaminant Biomonitoring Program data, or other biomonitoring data meeting the definition of reliable information, that show the chemical to be present in human bodily tissues or fluids;

(2) Data that meets the definition of reliable information and that show the chemical to be present in household dust, indoor air, drinking water, or elsewhere in the indoor household environment;

(3) Monitoring data that meet the definition of reliable information, or that have been produced or reviewed and accepted by a California State or local agency for compliance and regulatory purposes, and that show the chemical to be present in the environment, including aquatic, avian or terrestrial organisms;

(4) Data that meet the definition of reliable information and that indicate that the chemical or its degradation products are showing up in California solid waste, wastewater or storm water streams collected or managed by California State or local agencies in concentrations or volumes that present public health or environmental threats, or that require the significant expenditure of public funds to mitigate public health or environmental threats, or that significantly increase the costs of reusing or recycling materials containing the chemical;

(5) Estimates of potential fate and transport of the chemical or its degradation products based on one or more of the following:

(A) Fugacity modeling,

(B) Field studies,

(C) Measurements and observations,

(D) Microcosm studies,

(E) Environmental or biological presence estimated by using either a point source or market-wide source term calculation, modeling or measurement, and/or environmental presence estimated by a combination of these methodologies, and

(F) Any other relevant data or studies;

(6) Data showing that one or more other chemicals are formed during breakdown of the chemical, including transformation in an environmental setting, or when the chemical is combined with other chemicals, and that the newly formed chemical(s) exhibit one or more hazard traits;

(7) Results of computational modeling for structural activity relationships or short term in vitro bioassays; and

(8) Computational modeling data that informs any element of this section.

(h)(1) Scope of federal and/or California State regulatory programs under which the chemical is regulated, and the extent to which these other programs address the public health

and environmental threats specified in this section posed by the chemical throughout the life cycle of the chemical and any consumer product that contains the chemical. In evaluating this factor, the Department shall identify and compare the life cycle segments for which public health and environmental threats are addressed by the combined effects of the federal and/or other California State regulatory programs and the life cycle segments addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter.

(2) A chemical is not a Chemical of Concern, and may not be listed as a Chemical under Consideration or Priority Chemical, if the Department determines that the chemical is regulated by one or more federal and/or other California State regulatory program(s) that, in combination, address, for each life cycle segment, the same public health and environmental threats addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter. This paragraph does not apply if, after taking into consideration the combined effect of all applicable federal and/or other California State regulatory programs, the Department determines that there are significant gaps, for one or more life cycle segments, between the combined public health and environmental threats that are addressed by these programs and the public health and environmental threats addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter.

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

§ 69302.4. Priority Chemicals.

(a) From the list of Chemicals under Consideration, the Department shall prepare a list of Priority Chemicals that are determined to be of highest priority based on consideration of the following factors:

(1) The relative degree of threat posed by each chemical to public health or the environment based on consideration of pertinent factors specified in section 69302.3.

(2) Availability of reliable information to substantiate the threat(s) posed by the chemical.

(3) Availability of Department resources.

(b)(1) In evaluating the relative degree of threat, pursuant to subsection (a)(1), the Department shall seek to identify and give priority to those chemicals that pose the greatest public health and environmental threats, are most prevalently distributed in commerce and contained in products used by consumers, and for which there is the greatest potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in public health or environmental harm. The Department shall consider both the potential for exposure to the chemical and the potential harm resulting from potential exposures.

(2) In evaluating the potential for exposure, the Department shall, at a minimum, consider all of the following:

(A) Market data for the chemical and products containing the chemical;

(B) Reliable information demonstrating the occurrence of public health and environmental exposures;

(C) Information concerning the presence of the chemical in products commonly found in households, including the number of such of products, the frequency of use, and the concentration of the chemical in those products; and

(D) Information showing how widely used the chemical is in products placed into the stream of commerce in California.

(3) In evaluating the potential for harm resulting from potential exposures, the Department shall, at a minimum, consider chemical potency and resulting harm for all of the following:

(A) Children, pregnant women and other sensitive subpopulations;

(B) Environmental receptors, in particular, environmentally sensitive habitats and endangered and threatened species.

(c) A chemical that exhibits no hazard trait other than causing carcinogenicity or reproductive toxicity, or both, shall not be placed on the list of Priority Chemicals unless the chemical is a carcinogen or reproductive toxin, or both, as defined in section 69301.2(a)(9).

(d) In preparing the initial list of Priority Chemicals, pursuant to subsection (a), the Department shall only consider chemicals that are one or more of the following:

(1) Chemicals that are carcinogens or reproductive toxins, or both, as defined in section 69301.2(a)(9).

(2) Chemicals that are listed as having mutagenic properties in the European Union Category 1A or 1B under Annex VI, part 3 of the Regulation.

(3) Chemicals that have been determined by the United States Environmental Protection Agency to be persistent bioaccumulative toxic chemicals.

(e) Subsection (d) does not apply to any list of Priority Chemicals issued after the initial list.

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

§ 69302.5. Products Containing a Priority Chemical.

(a) When the Department determines that a product contains a Priority Chemical, or contained a Priority Chemical as of the date the applicable chemical list was finalized, the Department shall post information identifying and describing the product and the chemical on its website. Such a product will not be listed on, or will be removed from, the Department's website if any of the following applies:

(1) A Chemical Removal Confirmation Notification or a Product Removal Confirmation Notification has been submitted to the Department for the product;

(2) An AA Notification has been submitted to the Department for the product pursuant to section 69305.1; or

(3) The product was subsequently reformulated, redesigned or replaced as the result of a Tier II AA, and the information required pursuant to article 5 of this chapter has been provided to the Department.

(b) A determination made by the Department pursuant to subsection (a) shall be based on one or more of the following:

(1) Reliable information;

(2) Information made available by a responsible entity or the manufacturer of the product; or

(3) Information on the product label or packaging or a product information sheet.

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

Article 3. Product Prioritization Process

§ 69303. General.

(a) This article identifies the process by which the Department shall identify and prioritize products containing Priority Chemicals.

(b) The Department may use information reviewed and/or obtained pursuant to section 69301.6 to perform its duties under this article.

(c) The Department is not limited to using the information reviewed and/or obtained pursuant to subsection (b) in performing 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.

§ 69303.1. Applicability.

(a) This article applies to all products that contain a Priority Chemical, and that are reasonably expected to be placed into the stream of commerce as a product in California, unless the Department determines that either or both of the following criteria apply to the product:

(1) The product is regulated by one or more federal and/or other California State regulatory program(s) that, in combination, address, for each life cycle segment, the same public health and environmental threats addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter. This exemption shall not apply if, after taking into consideration the combined effect of all applicable federal and/or other California State regulatory programs, the Department determines that there are significant gaps, for one or more life cycle segments, between the combined public health and environmental threats that are addressed by these programs and the public health and environmental threats addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter. In making this determination, the Department shall identify and compare the life cycle segments for which public health and environmental threats are addressed by the combined effects of

the federal and/or other California State regulatory programs and the life cycle segments addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter.

(2) There is no exposure pathway by which the Priority Chemical that is contained in the product might pose a threat to public health or the environment in California during the useful life or the end-of-life management of the product.

(b) In the absence of a determination by the Department to the contrary, it shall be presumed that subsections (a)(1) and (a)(2) do not apply to any product that contains a Priority Chemical. This presumption shall affect the burden of proof required pursuant to subsection (c).

(c) Any person requesting the Department to make a determination specified in subsection (a)(1) and/or (a)(2) shall bear the burden to prove by clear and convincing evidence to the Department's satisfaction that subsection (a)(1) and/or (a)(2) applies to the product in question. For a subsection (a)(2) exemption determination request, the evidence must include, to the extent applicable, the results of any use and abuse tests, including the assumptions and testing methodologies, conducted for purposes of and pursuant to a federal and/or California State regulatory program.

(d) The Department may, at its discretion, re-evaluate an exemption determination previously made pursuant to this section and rescind that exemption determination if the Department finds that the facts and/or assumptions upon which the exemption determination was based were not, or are no longer, valid.

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

§ 69303.2. Products Lists.

(a) The Department shall prepare two lists based on consideration of prioritization factors that relate to the threat(s) to public health and/or the environment posed by the product or component, due to the Priority Chemical contained in the product or component:

(1) A list of products that, when they contain a Priority Chemical, will be designated as Products under Consideration, using factors specified in section 69303.3; and

(2) A list of products that, when they contain a Priority Chemical, will be designated as Priority Products, using the factors specified in section 69303.4.

(3) For each listed Product under Consideration or Priority Product, the Department shall indicate in the listing the Priority Chemical(s) that is the basis for the product being listed as a Product under Consideration or Priority Product.

(b) Prior to finalizing the Product under Consideration and/or Priority Product list(s), the Department shall make the proposed list(s) available on its website, for public review and comment, along with supporting documentation, including but not limited to, the Department's rationale, data and data sources subject to article 10. The supporting information shall include an identification of the hazard trait(s) exhibited by and the potential exposure pathways for each Priority Chemical that is the basis for a product being listed as a Product under

Consideration or Priority Product. The Department shall publish in the CRNR, send to persons on any listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed list(s) and supporting documentation. The notice shall include:

(1) The time period during which the public may submit comments, which may include comments in support of adding or removing a product from the Product under Consideration list and/or Priority Product list;

(2) The method(s) for submitting comments to the Department on the proposed list(s); and

(3) Notification of any workshops, if the Department determines one or more workshop is necessary.

(c) After review and consideration of public comments on the proposed list(s), the Department shall finalize and post on its website the final Product under Consideration list and/or final Priority Product list. The Department may, at its discretion, respond to some or all public comments received.

(d)(1) The proposed and final list of Priority Products shall include for each listed product both of the following, if applicable:

(A) The Department's determination that a de minimis exemption, pursuant to section 69305.3, shall not be allowed for the product. Subject to article 10, the Department shall include the supporting rationale, data, and data sources for this determination.

(B) The component(s) of the Priority Product to which the de minimis concentration applies, and which is the required minimum focus of the Tier II AA.

(2) A determination by the Department that a de minimis exemption may not be considered for a product shall include an explanation of the basis(es) for this determination, which may include, but are not limited to, the following factors:

(A)1. Reliable information shows the Priority Chemical to be harmful or potentially harmful in concentrations below the de minimis level.

2. When the Department has reliable information showing the Priority Chemical to be harmful or potentially harmful in concentrations below the de minimis level, the Department may, at its discretion, specify a lower de minimis level for the product if reliable information identifies a specific lower de minimis threshold for the chemical that is based on a scientific evaluation of public health and environmental adverse impacts;

(B) The Priority Chemical is found at or below the de minimis level in numerous products that are commonly used on a frequent basis, and reliable information shows these aggregate exposures to the Priority Chemical to be harmful or potentially harmful even when individual product concentrations of the Priority Chemical are below the de minimis level.

(3) In no case, shall the de minimis exemption be allowed for chemicals, materials, or substances manufactured or engineered at the nanoscale, or which contain nanostructures, or are considered to be a nanomaterial.

(e) An individual manufacturer's product that is of a product type listed by the Department on the products lists prepared pursuant to this section shall not be considered to be a Product under Consideration or a Priority Product, and a Tier II AA shall not be required

for that product, if the product does not contain any known or detectable amount of the Priority Chemical which is the basis for that product type being placed on the product lists.

(f) Using the procedures specified in this section, the Department shall update the Product under Consideration list and/or Priority Product list as needed. Revisions may include additions and deletions to the prior list(s), and revisions to prior de minimis determinations.

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

§ 69303.3. Products Under Consideration.

The prioritization factors that the Department may use to place products that contain a Priority Chemical on the list of Products under Consideration, pursuant to section 69303.2, include:

(a) Dispersive volume information for each product as it relates to the volume of the product placed into the stream of commerce in California and the product's contribution to the volume of the Priority Chemical placed into the stream of commerce in California. This may include, but is not limited to:

(1) Projected annual sales by number of units or volume,

(2) Annual regional distribution by number of units or volume,

(3) Marketing and customer targeted volumes,

(4) Volume or units of the product in current use,

(5) Percentage of products estimated to contain the Priority Chemical,

(6) Extrapolation of the data identified in paragraphs (1) through (5) to estimate the volume of the product's Priority Chemical in commerce in California as a result of the product or component, and

(7) Controlled distribution systems, if any.

(b) Potential for the public or the environment to be exposed to the Priority Chemical that is contained in the product, during the useful life of the product and end-of-life disposal or management of the product. Factors to be considered include, but are not limited to:

(1) Containment of the chemical within the product, including the long-term integrity of the containment mechanism or system,

(2) Engineering and administrative controls,

(3) Federal and California State regulatory restrictions that reduce the potential for exposure, and

(4) Frequency and duration of exposure for each use scenario and end-of-life scenario.

(c) Types and extent of consumer uses that could result in public exposure to the Priority Chemical that is contained in the product, which in turn could result in adverse public health impacts as specified in section 69302.3 (b). Factors to be considered include, but are not limited to:

(1) Household use.

(2) Sensitive subpopulation potential use or exposure at:

(A) Home,

(B) Schools, child day care facilities, and other areas frequented by children on a regular basis,

(C) Health care facilities, and

(D) Recreational areas and facilities.

(3) Consumers who purchase, use or otherwise come in contact with the product.

(4) Persons who come in contact with the product while providing or receiving a service.

(5) Workers, customers, clients and members of the general public who come in contact with the product or releases from the product in the workplace, including:

(A) Retail sector locations;

(B) Service sector locations; and

(C) Other non-industrial business sector locations.

(6) The availability of the product to consumers as a finished material or product or part of a product that does not require further processing or assembly. Lower priority will be given to materials, products and parts of products that are solely or primarily marketed for use in, or used in, an intermediate manufacturing process or a research and development program.

(d) Product uses or management or disposal practices that could result in releases to the environment of the Priority Chemical that is contained in the product, which in turn could result in adverse ecological or other environmental impacts as specified in subsections (c) and (d) of section 69302.3. Factors to be considered include, but are not limited to:

(1) Use, storage, transportation and end-of-life management practices and locations.

(2) Potential for release into, migration from or distribution across environmental media, and potential for accumulation or persistence in biological or environmental compartments or systems of the Priority Chemical or its degradation products.

(e) Existence of data and other information relating to actual or potential public or environmental exposures to the Priority Chemical contained in the product, including, but not limited to, the data and other information listed in section 69302.3(g).

(f) Whether the product is required to be managed as a hazardous waste in California at the end of its useful life.

(g) Whether the specific Priority Chemical is required to be used in or contained in the specific product pursuant to a federal or California State law.

(h) (1) Scope of federal and/or other California State regulatory programs under which the product is regulated, and the extent to which these other programs address the public health and environmental threats specified in this section posed by the Priority Chemical that is contained in the product throughout the life cycle of the product. In evaluating this factor, the Department shall identify and compare the life cycle segments for which public health and environmental threats are addressed by the combined effects of the federal and/or other California State regulatory programs and the life cycle segments addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter.

(2) A product shall not be listed as a Product under Consideration or a Priority Product if the Department determines that the product is regulated by one or more federal and/or other California State regulatory program(s) that, in combination, address, for each life cycle segment, the same public health and environmental threats addressed by article 14 of chapter

6.5 of division 20 of the Health and Safety Code and this chapter. This paragraph does not apply if, after taking into consideration the combined effect of all applicable federal and/or other California State regulatory programs, the Department determines that there are significant gaps, for one or more life cycle segments, between the combined public health and environmental threats that are addressed by these programs and the public health and environmental threats addressed by article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter.

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

§ 69303.4. Priority Products.

(a) From the list of Products under Consideration, the Department shall prepare a list of Priority Products that are determined to be of highest priority based on consideration of the following factors:

(1) The relative degree of threat posed by each product, due to the Priority Chemical that is contained in the product, to public health or the environment based on consideration of pertinent factors specified in section 69303.3,

(2) Availability of reliable information to substantiate the threat(s) posed by the product.

(3) The availability of an AA posted on the Department's website pursuant to section 69305(b) that is relevant for the product or the Priority Chemical in the product that substantially meets the requirements of article 5 pertaining to Tier II AAs, and

(4) The availability of Department resources.

(b)(1) In evaluating the relative degree of threat, pursuant to subsection (a)(1), the Department shall seek to identify and give priority to those chemicals, and the products that contain them, that pose the greatest public health and environmental threats, are most prevalently distributed in commerce and used by consumers, and for which there is the greatest potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in public health or environmental harm. The Department shall consider both the potential for exposure to the chemical in the product and the potential harm resulting from potential exposures.

(2) In evaluating the potential for exposure, the Department shall, at a minimum, consider all of the following:

(A) Market data for the products containing the chemical;

(B) Reliable information demonstrating the occurrence of public health and environmental exposures;

(C) Information concerning the household presence of the product, and other products containing the same chemical, including the number of such of products, how common their household presence is, the frequency of use, and the concentration of the chemical in those products; and

(D) Information showing how widely the product is placed into the stream of commerce in California.

(3) In evaluating the potential for harm resulting from potential exposures to the chemical contained in the product, the Department shall, at a minimum, consider chemical potency and resulting harm for all of the following:

(A) Children, pregnant women and other sensitive subpopulations;

(B) Environmental receptors, in particular, environmentally sensitive habitats and endangered and threatened species.

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

§ 69303.5. Priority Product Notification.

(a)(1) Within sixty (60) days after a product is listed as a Priority Product, each responsible entity for such a Priority Product shall notify the Department that its product is a Priority Product. For Priority Products that are first manufactured, or first placed into the stream of commerce in California, subsequent to the date the product is listed as a Priority Product, the responsible entity shall provide this notice within thirty (30) days after the product is first placed into the stream of commerce in California. The notification shall include all of the following:

(A) The name of, and contact information and applicable NAICS code(s) for, the responsible entity and all persons involved in the product supply chain that are known to the responsible entity;

(B) The type and brand name of the Priority Product, and information specifically identifying the pertinent component, if applicable;

(C) The name of, and contact information for, the person that will be complying with the requirements of article 5 on behalf of the responsible entity, if that person is someone other than the responsible entity; and

(D) Whether the responsible entity, or the person identified pursuant to paragraph (3), will seek the Department's approval for a de minimis exemption pursuant to section 69305.3, if applicable.

(2) Paragraph (1) does not apply if a Chemical Removal Confirmation Notification or a Product Removal Confirmation Notification has been submitted to the Department for the product.

(b) If the Department determines that the notice requirements specified in subsection (a) have not been fulfilled for a particular product that is a Priority Product, the Department shall post this information on the Failure to Comply List pursuant to section 69301.4(f).

(c) As the following information becomes available to the Department, the Department shall add this information to the Priority Products list posted on its website for each product that is a Priority Product and shall maintain and update this information for as long as the Priority Product continues to be placed into the stream of commerce in California:

(1) Product brand names;

(2) Product producer and, if different, the manufacturer;

(3) Responsible entities for each product, except for those responsible entities that have complied with the requirements of section 69301.4(e);

(4) Information on any de minimis exemptions that have been granted by the Department pursuant to section 69305.3;
(5) Information concerning any Chemical Removal Confirmation Notifications or Product Removal Confirmation Notifications that have been submitted to the Department for products listed on Priority Product list;
(6) The identity of the person that has been identified as being the person that will fulfill the requirements of article 5;
(7) The due date for, and the date of receipt of, the AA Work Plan; and
(8) The due dates for, and the dates of receipt of, the Tier II-A and Tier II-B AA Reports.

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

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

§ 69304. Applicability and Petition Contents.

(a) Any person, hereafter known as the petitioner, may petition the Department to evaluate a chemical or a product that contains a chemical using the chemical prioritization and/or product prioritization processes specified in articles 2 and 3 of this chapter. The petition shall be submitted to the Department in accordance with section 69301.5, and shall include all of the following:
(1) Name of and contact information for both of the following persons:
(A) The petitioner, and
(B) The person responsible for the contents of the petition, if different from the person identified in subparagraph (A), and the affiliation of this person with the petitioner,
(2) Description of the chemical and/or product which is the subject of the petition,
(3) Uses and applications of the chemical and/or product which is the subject of the petition,
(4) Basis for the petition,
(5) Information supporting the basis for the petition, including, but not limited to, reliable information, and
(6) Identity of any known manufacturers of the chemical or product.
(b) Within sixty (60) days after receiving a petition, the Department shall review the petition and shall designate the petition complete if it contains the items specified in paragraphs (1) through (6) of subsection (a). If the Department determines that a petition is complete, the Department shall notify the petitioner that the petition will undergo a technical review to determine whether to grant or deny the petition. If the Department determines that the petition is incomplete, it shall notify the petitioner of this determination and shall specify the basis for the determination.
(c) The fact that the Department designates a petition complete pursuant to this section does not prohibit the Department from requesting additional information during the technical review conducted pursuant to section 69304.1.

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

§ 69304.1. Technical Review of Petitions.

(a) The Department shall prioritize the technical review of petitions determined to be complete based on the comprehensiveness of the petitions and the availability of resources. Highest priority shall be given to petitions by federal and other California State regulatory programs that relate to the petitioning agency's statutory and/or regulatory mandates.

(b) The Department shall conduct a technical review of each petition determined to be complete to determine whether to grant or deny the petition based on:

(1) The comprehensiveness of the data and information submitted in support of the petition that pertains to the prioritization factors specified in sections 69302.3 and 69303.3;

(2) The quality of the data and information submitted in support of the petition, including, but not limited to, reliable information, or data that has been produced or reviewed and accepted by a California State or local agency for compliance and regulatory purposes; and

(3) The availability of data and information, other than the data and information submitted with the petition, for the Department to:

(A) Determine hazard traits exhibited by the chemical, and

(B) Evaluate the chemical or the product, based on the prioritization factors specified in sections 69302.3 and 69303.3.

(c) The Department may request the petitioner to provide additional information to complete the technical review. The petitioner shall provide, to the extent available, such additional requested information within the timeframe specified by the Department.

(d) After completing the technical review, the Department shall do both of the following:

(1) Prepare a notice of decision to grant or deny the petition and a statement of basis explaining the basis for the decision,

(2) Notify the petitioner of the decision.

(e) After granting a petition, the Department will evaluate and, if applicable, prioritize the chemical and/or the product in accordance with the prioritization processes specified in articles 2 and/or 3.

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

Article 5. Alternatives Assessments

§ 69305. Guidance Materials.

(a) Before finalizing the initial list of Priority Chemicals pursuant to section 69302.2, the Department shall prepare, and make available on its website, guidance materials to assist persons in performing Tier II AAs in accordance with the requirements of this chapter. The Department shall periodically revise and update the guidance materials.

(b) The Department shall also post on its website AAs that are available in the public domain, at no cost, and are supported by reliable information. The posting shall indicate, for each AA, the name of the entity that prepared the AA, and if the AA was prepared or verified by a lead assessor meeting the requirements of section 69308.3.

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

§ 69305.1. Alternatives Assessment Notifications and Tier I AA Reports.

(a) After a chemical has been listed as a Chemical under Consideration or Priority Chemical on the final lists prepared pursuant to section 69302.2, if any product containing that chemical is reformulated or redesigned to remove or reduce the concentration of that chemical, or the original product has been replaced with an alternative product, the responsible entity shall provide an AA Notification to the Department before placing the reformulated, redesigned or replacement product into the stream of commerce in California. The AA Notification shall include all of the following:

(1) The responsible entity's name and contact information;

(2) Information identifying and describing the original product and the reformulated, redesigned or substituted product, including the brand name(s) and labeling information for both products;

(3) The intended uses, and targeted customer base(s), for the product;

(4) The Chemical under Consideration or Priority Chemical removed from, or reduced in, the product; and

(5) A Tier I AA Report comparing the two products, or all of the following information:

(A) Information explaining the rationale for and the factors considered in selecting the reformulation, redesign or substitution alternative;

(B) Identification, and a qualitative or quantitative description, of any reduction(s) to adverse public health or environmental impacts achieved by the reformulation, redesign or substitution; and

(C) Identification of any hazard traits exhibited by the substitute chemical, if another chemical was substituted for the Chemical under Consideration or Priority Chemical.

1. Identification of hazard traits shall be based on criteria developed by the Department or OEHHA, to the extent such criteria are made available by the Department or OEHHA.

2. If relevant criteria have not yet been provided by the Department or OEHHA, reliable information shall be used to determine if the chemical exhibits a hazard trait.

(b) The requirements of subsection (a) do not apply to a product that was reformulated, redesigned, or substituted as the result of the implementation of a selected alternative identified in an AA Report submitted to the Department pursuant to this article.

(c) The requirements of subsection (a) do not apply if the manufacturer of the product has submitted a Chemical Removal Confirmation Notification or a Product Removal Confirmation Notification to the Department.

(d) The information submitted pursuant to subsection (a) shall be taken into consideration by the Department during subsequent chemical and product prioritization processes conducted pursuant to articles 2 and 3 in the evaluation of any prioritization factors that the Department determines this information is pertinent to.

(e) If the AA Notification is accompanied by a Tier I AA Report prepared by a qualified third-party assessment entity, or verified by a lead assessor meeting the requirements of section 69305.2(c)(3)(B), the Department shall, if requested by the person submitting the AA Notification, list the product that is the subject of the Tier I AA Report on the Department's website, along with any identifying and descriptive information that the person submitting the AA Notification requests to be posted on the Department's website.

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

§ 69305.2. Tier II Alternatives Assessments: General Provisions.

(a)(1) Except as otherwise provided in subsections (d) and (f) and sections 69301.4(c), 69303.2(e) and 69305.3, a responsible entity for a product that is listed as a Priority Product, or a person acting on behalf of or in lieu of the responsible entity, shall perform a Tier II AA for the Priority Product, and comply with all applicable requirements of this article.

(2) A responsible entity subject to the requirements of paragraph (1), or a person fulfilling these requirements on behalf of or in lieu of the responsible entity, shall prepare, sign and submit to the Department an AA Work Plan meeting the requirements of section 69305.4 and an AA Report meeting the requirements of sections 69305.6 through 69305.8, as follows:

(A) The AA Work Plan shall be submitted no later than one hundred and eighty (180) days following the date that the applicable final Priority Product listing is posted on the Department's website, except as provided in subsection (b).

(B) The AA Reports for the Tier II-A and Tier II-B AAs, as defined in section 69305.5(a)(1), shall be submitted by the dates specified by the Department pursuant to section 69305.4(b)(4), except as provided pursuant to subsection (b).

(b)(1) A responsible entity, or a person fulfilling the requirements of this article on behalf of or in lieu of the responsible entity, may request a one-time extension to the submission deadline for the AA Work Plan and/or the AA Report. The extension request must be received by the Department no later than sixty (60) days before the due date for the AA Work Plan or AA Report, as applicable.

(2) The extension request shall include:

(A) Name of and contact information for the person filing the extension request,

(B) The name of and contact information for the person(s) on whose behalf the AA Work Plan and AA Report will be submitted,

(C) If different from (A) and (B), the name of and contact information for the manufacturer of the product,

(D) Information identifying and describing the Priority Product, including the brand name(s) under which the Priority Product is placed into the stream of commerce in California,

(E) The due date for AA Work Plan or AA Report, as applicable,

(F) The amount of time requested, not to exceed the maximum extension timeframes specified in paragraph (3), and

(G) The reason the extension is needed.

(3) The Department shall approve or deny in whole or in part the extension request, and notify the person submitting the extension request of the decision, within thirty (30) days of receipt of the extension request. The one-time extension for an AA Work Plan shall not exceed ninety (90) days, and the one-time extension for an AA Report shall not exceed twelve (12) months.

(c)(1) Each Tier II AA shall be performed by, and the AA Work Plan and AA Report prepared by, one of the following:

(A) A qualified third-party assessment entity designated pursuant to section 69308, or

(B) A qualified in-house assessment entity designated pursuant to section 69308.1.

(2) The responsible individual in charge of preparation of the AA Work Plan and AA Report, and performance of the Tier II AA, shall be a lead assessor who meets the requirements of section 69308.3 and is accredited for a product type and/or industry sector appropriate for the Tier II AA being performed. The lead assessor shall be employed by the qualified third-party assessment entity or qualified in-house assessment entity, whichever is applicable.

(3)(A) Each Tier II AA performed by, and AA Report prepared by, a qualified in-house assessment entity shall be reviewed and verified by a second lead assessor. The verifying lead assessor must:

1. Meet the requirements of section 69308.3,

2. Be accredited for a product type and/or industry sector appropriate for the Tier II AA being verified,

3. Be employed by a qualified third-party assessment entity,

4. Not have participated in any way in the design or formulation of the AA Work Plan, data gathering, analysis or other aspects of the Tier II AA, or preparation of the AA Report, and

5. Have no economic interest in any entity that manufactures, or places into the stream of commerce in California, any Chemical of Concern, Product under Consideration, or Priority Product.

(B) The verifying lead assessor shall do all of the following:

1. Verify compliance with the requirements of this article, and indicate the extent to which the guidance document(s) posted by the Department pursuant to subsection (a) were used in conducting the Tier II AA;

2. Verify the proper analysis of the product's or component's life cycle;

3. Verify the appropriate use of life cycle assessment tools and methodologies;

4. Attest to the accuracy of the reported data; and

5. Perform a final quality assurance review of the Tier II AA and AA Report, and of the data on which the Tier II AA is based.

(C) The verifying lead assessor shall prepare an AA verification statement documenting the verification process and findings.

(D) The verifying lead assessor shall base the AA verification statement solely on the factors listed in subparagraphs (B)1. through (B)5. The selected alternative, or the decision not to select an alternative to the Priority Product or component, as identified in the AA Report pursuant to section 69305.8(f), shall not be a consideration factor in verifying the Tier II AA or preparing the AA verification statement.

(d) The requirements of subsection (a) of this section may be fulfilled by submitting to the Department a report for a previously completed AA for the Priority Product or component, if the Department determines that the report is substantially equivalent to the requirements of sections 69305.6 through 69305.8 and that the report contains sufficient information to identify the most appropriate regulatory response pursuant to article 6 of this chapter.

(1) The report submitted pursuant to this subsection shall be submitted no later than one hundred and eighty (180) days following the date that the applicable final Priority Product listing is posted on the Department's website, except that a one-time extension may be requested pursuant to subsection (b).

(2) An existing report submitted pursuant to this subsection may be supplemented with additional information to render the report substantially equivalent to the requirements of sections 69305.6 through 69305.8.

(3) If the existing report submitted pursuant to this subsection is not available in the public domain, the report shall be accompanied by documentation demonstrating that the AA and the report were verified pursuant to subsection (c)(3).

(e) Any person performing a Tier II AA, pursuant to subsection (a), shall consider all relevant information made available on the Department's website and any additional information or technical assistance the Department may provide regarding alternatives assessments. These efforts shall be briefly summarized in the AA Report.

(f)(1) The requirements of subsection (a) pertaining to submission of an AA Work Plan and performance of a Tier II AA do not apply if a Chemical Removal Intent Notification and/or Chemical Removal Confirmation Notification, or a Product Removal Intent Notification and/or Product Removal Confirmation Notification, is submitted to the Department for the product prior to the due date for submitting the AA Work Plan. If only a Chemical Removal Intent Notification or Product Removal Intent Notification is submitted to the Department by that date, one of the following shall be submitted to the Department by the date specified below:

(A) A Chemical Removal Confirmation Notification shall be submitted no later than ninety (90) days after the date the Chemical Removal Intent Notification or Product Removal Intent Notification was submitted;

(B) A Product Removal Confirmation Notification shall be submitted no later than ninety (90) days after the date the Chemical Removal Intent Notification or Product Removal Intent Notification was submitted; or

(C) An AA Work Plan shall be submitted by the due date for the AA Work Plan or no later than ninety (90) days after the date the Chemical Removal Intent Notification or Product Removal Intent Notification was submitted, whichever is later.

(2)(A) If an AA Work Plan has been submitted to the Department, the requirements of subsection (a) pertaining to performance of a Tier II AA and submission of an AA Report do

not apply if a Chemical Removal Intent Notification and/or Chemical Removal Confirmation Notification, or a Product Removal Intent Notification and/or Product Removal Confirmation Notification, is submitted to the Department for the product prior to the due date for submitting the AA Report. If only a Chemical Removal Intent Notification or Product Removal Intent Notification is submitted to the Department by that date, one of the following shall be submitted to the Department by the date specified below:

1. A Chemical Removal Confirmation Notification shall be submitted no later than ninety (90) days after the date the Chemical Removal Intent Notification or Product Removal Intent Notification was submitted;

2. A Product Removal Confirmation Notification shall be submitted no later than ninety (90) days after the date the Chemical Removal Intent Notification or Product Removal Intent Notification was submitted; or

3. An AA Report shall be submitted by the due date for the AA Report or no later than ninety (90) days after the date the Chemical Removal Intent Notification or Product Removal Intent Notification was submitted, whichever is later.

(B) A Chemical Removal Confirmation Notification submitted pursuant to subparagraph (A) shall be accompanied by all of the following additional information:

1. The intended uses, and targeted customer base(s), for the product;

2. Information explaining the rationale for and the factors considered in the decision to remove the Chemicals under Consideration and/or Priority Chemicals from the product, without adding any other chemicals to the product; and

3. Identification, and a qualitative or quantitative description, of any reduction(s) to adverse public health or environmental impacts achieved by removing the Chemicals under Consideration and/or Priority Chemicals from the product.

(g) Notwithstanding any other provision of this chapter, failure of the Department to make a completeness determination within sixty (60) days from receipt of the applicable document, or failure of the Director to respond to a request for further review under section 69307.2 within sixty (60) days, shall not cause an AA Work Plan or AA Report to be deemed complete.

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

§ 69305.3. De Minimis Exemption.

(a) A responsible entity shall be exempt from the requirements of this article pertaining to Tier II AAs, if the manufacturer of the responsible entity's product requests, and the Department grants, a de minimis exemption. The de minimis exemption request must be submitted to the Department no later than sixty (60) days after the product has been listed as a Priority Product, and must include all of the following:

(1) Manufacturer name and contact information;

(2) The name of and contact information for any responsible entity for the product, to the extent known to the manufacturer;

(3) Information identifying and describing the product, including the brand name(s) under which the product is placed into the stream of commerce in California, and information specifically identifying the component, if applicable;

(4) The source and purpose of the Priority Chemical in the product;

(5) Information concerning any attempts taken by the manufacturer to eliminate or reduce the amount of the Priority Chemical in the product;

(6) The maximum concentration at which the Priority Chemical is present in the product, and a listing and description of all data and other information used by the manufacturer to determine and substantiate this concentration; and

(7) A list of all federal and California State regulatory thresholds, intended to protect public health or the environment, which are applicable to the chemical or the chemical/product combination.

(b) Subsection (a) does not apply if the Department has determined, pursuant to section 69303.2(d), that a de minimis exemption may not be considered for the product.

(c)(1) Within sixty (60) days of receiving a de minimis exemption request, the Department shall issue a notice to the manufacturer that:

(A) Grants the de minimis exemption request,

(B) Denies the de minimis exemption request, or

(C) Requests additional information, including, but limited to, information concerning:

1. The source(s) of the Priority Chemical in the product; and

2. Laboratory analytical testing protocols and results used to determine and substantiate the concentration of the Priority Chemical in the product, including quality control and quality assurance protocols and data and information concerning the testing laboratory.

(2) The manufacturer shall provide any additional information requested by the Department within thirty (30) days of receiving the request, unless prior to the due date for submission the manufacturer requests and the Department grants a one-time extension not to exceed an additional thirty (30) days. If a request for additional information is not completely and timely fulfilled, the de minimis exemption request shall be denied. Within sixty (60) days of receiving the requested additional information, the Department shall issue a notice to the manufacturer either granting or denying the de minimis exemption request.

(3) A notice granting or denying a de minimis exemption request shall include the basis for the Department's decision.

(4) A copy of any notice sent to the manufacturer shall also be sent to any responsible entity for the affected product, known to the Department.

(d) A decision by the Department to grant or deny a de minimis exemption request shall be governed by the following:

(1) A de minimis exemption request shall be denied if the manufacturer fails to demonstrate to the Department's satisfaction that the concentration of the Priority Chemical in the product does not exceed the applicable de minimis threshold.

(2)(A) Except as provided in subparagraph (B), a de minimis exemption request shall be denied if the Department has reliable information that shows the Priority Chemical to be harmful or potentially harmful in concentrations below the de minimis level.

(B) When the Department has reliable information showing the Priority Chemical to be harmful or potentially harmful in concentrations below the de minimis level, the Department may, at its discretion, grant a modified de minimis exemption if both of the following apply:

1. Reliable information identifies a specific lower de minimis threshold for the Priority Chemical that is based on a scientific evaluation of adverse public health and environmental impacts; and

2. The information provided by the manufacturer demonstrates to the satisfaction of the Department that the concentration of the Priority Chemical in the product does not exceed the de minimis threshold identified pursuant to subparagraph (B)1.

(3) The Department may also deny a de minimis exemption request, if the Department determines that the Priority Chemical is found at or below the de minimis level in numerous products that are commonly used on a frequent basis, and reliable information shows these aggregate exposures to the Priority Chemical to be harmful or potentially harmful even when individual product concentrations of the Priority Chemical are below the de minimis level.

(e) A de minimis exemption granted pursuant to this section shall be rescinded if the Department determines that the data or other information that the Department relied upon in granting the exemption was not, or is no longer, valid. If the Department rescinds an exemption, the Department shall notify the manufacturer and any responsible entity for the affected product, known to the Department.

(f) All notices issued under this section granting, denying or rescinding a de minimis exemption shall include a statement of basis for the Department's decision.

(g) If the Department denies or rescinds a de minimis exemption provided pursuant to this section, an AA Work Plan shall be submitted for the affected product within one hundred and eighty (180) days after the Department posts the notice of denial or rescission on its website.

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

§ 69305.4. Tier II Alternatives Assessment Work Plan.

(a) The AA Work Plan submitted to the Department pursuant to section 69305.2(a)(2) shall be adequate to ensure that the Tier II AA and the AA Report will provide sufficient detail to support the selection of an alternative, or a decision to retain the existing Priority Product in lieu of an alternative, and selection of appropriate regulatory response(s), if any, upon completion of the Tier II AA. The AA Work Plan shall include all of the following information:

(1) Preparer Information.

(A) Name of and contact information for the person submitting the AA Work Plan,

(B) If applicable, name of and contact information for all persons on whose behalf the AA Work Plan is being submitted, and their relationship to the person identified in subparagraph (A),

(C) The names of the parties that will be involved in funding, directing, overseeing, preparing or reviewing the Tier II AA, and

(D) Any organizations and individuals that it is anticipated will provide expert guidance or review for the Tier II AA, including the name of, and qualifications and accreditation information for, the person(s) in charge under whose direction the AA Work Plan was prepared and the Tier II AA will be conducted.

(2) Product Information. Information identifying and describing the Priority Product and/or component that is the subject of the AA Work Plan, including all of the following:

(A) The brand name(s) under which the product is placed into the stream of commerce in California;

(B) If applicable, the component(s) that will be the focus of the Tier II AA. The Tier II AA must, at a minimum, focus on the component(s) specified for the product in the Priority Products List, but may be expanded to include additional components or the entire product; and

(C) Identification of the Priority Chemical(s) that are the basis for the product being listed as a Priority Product, and any other Priority Chemical(s) that are, or reasonably should be, known to be in the Priority Product.

(3) Supply Chain Information. All of the following information applicable to the product that is, or should reasonably be, known to the preparer of the AA Work Plan:

(A) The name of, and contact information for, the person identified on the product label as the manufacturer, and the person, if any, identified as the distributor;

(B) The name of, and contact information for, the producer of the product;

(C) The name of, and contact information for, all responsible entities for the product; and

(D) The name of, and contact information for, any other person in the supply chain for the product.

(4) AA Goal and Scope of Alternatives. The AA Work Plan shall identify the goal of the Tier II AA and specify which one or more of the following types of alternatives it is anticipated will be assessed during the Tier II AA:

(A) Substitution of a different chemical for the Priority Chemical in the Priority Product or component;

(B) Redesign of the product or component and/or manufacturing process to reduce the concentration of the Priority Chemical in the Priority Product or component;

(C) Redesign of the product or component and/or manufacturing process, using different materials (e.g., plastic, glass, ceramic, or stainless steel) to reduce the potential for the public or the environment to be exposed to the Priority Chemical in the Priority Product or component;

(D) Other AA approach that is proposed to meet the intent and objectives of this article and Health and Safety Code section 25253(a).

(5) Scope of Life Cycle Segments.

(A) The AA Work Plan shall identify which life cycle segments it is anticipated will be evaluated and compared for the product and all alternatives, which may include:

1. Raw materials mining,
2. Intermediary material processes,
3. Manufacturing and packaging,

4. Distribution, transportation and marketing,
5. Use,
6. Product end-of-life, and
7. Reuse and recycling.

(B) If it anticipated that not all life cycle segments will be evaluated and compared for the product and all alternatives, the AA Work Plan shall explain the rationale for the omissions, including an explanation of why an evaluation of the omitted life cycle segments is not necessary to comply with the requirements of Health and Safety Code section 25253(a).

(6) Approach and Methodology. The AA Work Plan shall identify and describe any assessment tools, models, or software that is anticipated will be used to conduct the Tier II AA. The AA Work Plan shall also identify and briefly describe the approach and methodology that is anticipated to be used for each major Tier II AA task, including, but not limited to:

(A) Identifying alternatives to be evaluated,

(B) Determining which of the Chemical Hazard Assessment, Exposure Potential Assessment, and Multimedia Life Cycle Evaluation factors listed in section 69305.5 are pertinent to, and are anticipated to be used to evaluate and compare, the product or component and the alternatives,

(C) Gathering and analyzing data and other information,

(D) Using the data and information to evaluate and compare the product or component and all alternatives being considered,

(E) Making the decision to select an alternative or retain the Priority Product or component, and

(F) Preparing the AA Report.

(7) Schedule and Deliverables. The AA Work Plan shall include a proposed schedule for completion of each major Tier II AA task identified in the AA Work Plan. The schedule shall specify proposed dates for submitting information relating to any interim milestones, and the proposed completion dates for the Tier II-A and Tier II-B AA Reports pursuant to section 69305.6.

(b)(1) Within sixty (60) days of receiving an AA Work Plan, the Department shall review the AA Work Plan for completeness and compliance with the requirements of this section, and issue a notice of its findings with either a:

(A) Notice of deficiency, or

(B) Notice of completeness.

(2) The Department shall specify in the notice of deficiency the areas of deficiency and a date, not to exceed sixty (60) days from the date of the notice of deficiency, for submitting the necessary information to complete the AA Work Plan. The person who submitted the original AA Work Plan shall submit a revised AA Work Plan within the time specified and address the areas of deficiency.

(3) Within sixty (60) days of receipt of the requested additional information, the Department shall issue either a notice of completeness or a notice disapproving the AA Work Plan. If the AA Work Plan is disapproved, the Department shall explain the basis for the

disapproval in the notice. A disapproved AA Work Plan shall be considered non-compliant with the requirements of 69305.2(a)(2).

(4)(A) If the AA Work Plan is determined to be complete, the Department shall specify in the notice of completeness the dates for submitting the Tier II-A and Tier II-B AA Reports. In assigning these due dates, the Department shall consider the following factors:

1. The complexity of the planned Tier II AA, including, but not limited to, the scope of alternatives to be considered; and

2. The existence of any applicable AAs available in the public domain and posted on the Department's website that identify one or more safer functionally equivalent and technologically and economically feasible alternative(s).

(B) Except as provided in section 69305.2(b), the Tier II-A and Tier II-B AA Reports shall be submitted by the due dates specified in subparagraph (A) simultaneously to the Department and the verifying lead assessor, if verification is required pursuant to section 69305.2(c)(3).

(5) All notices issued by the Department pursuant to this subsection shall be issued to the person who submitted the AA Work Plan, and a copy of the notice shall be sent by the Department to all persons identified in the AA Work Plan pursuant to subsections (a)(1)(B) and (a)(3).

(c) If there is a significant change to the information contained in an approved AA Work Plan, a notification shall be provided to the Department by the person who submitted the AA Work Plan, or by the person on whose behalf the AA Work Plan was submitted, that identifies the change(s) and briefly explains the rationale for the change(s).

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

§ 69305.5. Tier II AA Evaluation and Comparison Process and Factors.

(a)(1) Each Tier II AA, required pursuant to section 69305.2(a), shall include both of the following:

(A) A Chemical Hazard Assessment and, except as provided otherwise in paragraph (2)(B), an Exposure Potential Assessment, which together shall be referred to as a Tier II-A AA, and

(B) A Multimedia Life Cycle Evaluation, which shall be referred to as a Tier II-B AA.

(2)(A) A Chemical Hazard Assessment shall be performed to evaluate and compare the Priority Product and all alternatives initially identified for consideration.

(B) Following completion of a Chemical Hazard Assessment evaluation and comparison, an Exposure Potential Assessment shall be performed to evaluate and compare the Priority Product and any alternative being considered that contains a chemical that exhibits one or more hazard traits. An Exposure Potential Assessment is not required if none of the alternatives being considered contain a chemical that exhibits a hazard trait.

1. Identification of hazard traits shall be based on the criteria developed by the Department or OEHHA for determining when a chemical exhibits a hazard trait, to the extent such criteria are made available by the Department or OEHHA.

2. If relevant criteria have not yet been provided by the Department or OEHHA, reliable information shall be used to determine if the chemical exhibits a hazard trait.

(C) The results of the Chemical Hazard Assessment or, if applicable, the Exposure Potential Assessment, or both, may be used to screen out alternatives before proceeding with the Multimedia Life Cycle Evaluation. At a minimum, an alternative shall be eliminated from further consideration if the person conducting the Tier II AA determines that both of the following apply:

1. Based on the Chemical Hazard Assessment, potential exposures to the chemical in the alternative would pose a greater threat of harm to public health or the environment than is posed by the Priority Chemical in the Priority Product, and

2. Based on the Exposure Potential Assessment, if one is performed, there is the same or greater potential for the public or the environment to be exposed to the chemical in the alternative, as compared to the potential to be exposed to the Priority Chemical in the Priority Product, during the product's useful life or end-of-life disposal or management.

(3) The Priority Product, or component, and all alternatives being considered shall be evaluated and compared for the same set of life cycle segments, identified pursuant to section 69305.4(a)(5). The same methodologies, and a consistent set of factors, shall be used to evaluate and compare the Priority Product, or component, and all alternatives being considered. In identifying the list of factors that will be used for this evaluation and comparison, the person performing the Tier II AA shall review the list of factors specified in subsections (b) through (d) to determine which factors are pertinent to, and will be used for, the evaluation and comparison.

(b) Chemical Hazard Assessment. The minimum set of factors that shall be reviewed to determine if they are pertinent for inclusion in the Chemical Hazard Assessment evaluation and comparison of the Priority Product or component and all alternatives being considered include all of the following:

(1) Chemical Information. Chemical and physical properties to be considered, to the extent pertinent, for the Priority Chemical contained in the Priority Product or component, and for any chemical that is being considered as an alternative to the Priority Chemical, include, but are not limited to, those properties listed in section 69302.3(a).

(2) Public Health Impacts. Evaluation and comparison of public health impacts must include, to the extent pertinent, consideration of impacts that may result from single, intermittent or frequent use of, or exposure to, the product, considering opportunities for dermal, oral and inhalation exposures during product use or other stages in the life cycle of the product. Factors to be considered, to the extent pertinent, include, but are not limited to, those factors listed in section 69302.3(b).

(3) Ecological Impacts. Factors to be considered, to the extent pertinent, include, but are not limited to, those factors listed in section 69302.3(c).

(4) Chemical Traits Related to Environmental Impacts. Chemical traits to be considered, to the extent pertinent, include, but are not limited to, those traits listed in section 69302.3(d)(1).

(c) Exposure Potential Assessment. The minimum set of factors that shall be reviewed to determine if they are pertinent for inclusion in the Exposure Potential Assessment evaluation and comparison of the Priority Product or component and all alternatives that are still under consideration following completion of the Chemical Hazard Assessment include all of the following:

(1) Exposure Limitations. Factors to be considered, to the extent pertinent, in evaluating the potential for the public or the environment to be exposed to the chemical that is contained in the product during the product's useful life and end-of-life disposal or management include, but are not limited to, those factors listed in section 69303.3(b).

(2) Chemical Quantity Information.

(A) Quantities of the Priority Chemical or alternative chemical necessary to manufacture the Priority Product or component, or alternative,

(B) Concentration of the Priority Chemical in the Priority Product or component and the corresponding concentration of any chemical substitution being considered,

(C) Volume and/or mass of the Priority Chemical in the Priority Product or component and the corresponding volume and/or mass of any potential chemical substitution,

(D) Extrapolation of the data identified in subparagraphs (A) through (C) to estimate the volume and/or mass of the Priority Chemical or substitute chemical in commerce in California as a result of the product or component, and

(E) Dispersive volume information, as it relates to the volume and/or of the chemical made available in commerce in California, which may include, but is not limited to:

1. Projected annual sales,

2. Annual regional distribution volumes, and

3. Marketing and customer targeted volumes.

(3) Consumer Uses. Factors to be considered, to the extent pertinent, in evaluating the types and extent of consumer uses that could result in public exposure to the chemical that is contained in the product, and could result in adverse public health impacts include, but are not limited to those factors listed in section 69303.3(c).

(4) Environmental Releases. Factors to be considered, to the extent pertinent, in evaluating product uses or management or disposal practices that could lead to releases to the environment of the chemical that is contained in the product, and result in adverse environmental impacts, include, but are not limited to, those factors listed in section 69303.3(d).

(d) Multimedia Life Cycle Evaluation. The minimum set of factors that shall be reviewed to determine if they are pertinent for inclusion in the Multimedia Life Cycle Evaluation and comparison of the Priority Product or component and all alternatives that are still under consideration following completion of the Chemical Hazard Assessment and, if applicable, the Exposure Potential Assessment, include all of the following:

(1) Product Function and Performance.

(A) Function and performance factors attributed to the Priority Chemical in the Priority Product or component, and any essential function and performance attributes that must be met by any potential alternatives,

(B) Useful life, expressed in single use or number of applications, days, months or years, of the Priority Product or component, and that of the potential alternatives,

(C) Functional equivalency of each alternative relative to the Priority Product or component, and

(D) Technological and economic feasibility of each alternative.

(2) Materials and Resource Consumption Impacts.

(A) Water consumption and conservation,

(B) Production, in-use, and transportation energy inputs,

(C) Energy consumption and efficiency, and

(D) Reusability and recyclability.

(3) Environmental Impacts.

(A) Air quality impacts. This includes, to the extent pertinent, adverse impacts associated with air emissions, including the air contaminants listed in section 69302.3(d)(2).

(B) Water quality impacts. This includes, to the extent pertinent, adverse impacts associated with degradation of beneficial uses of waters and any of the factors listed in section 69302.3(d)(3).

(C) Soil quality impacts. This includes, to the extent pertinent, adverse impacts associated with any of the factors listed in section 69302.3(d)(4).

(D) Waste and end-of-life impacts. This includes adverse impacts associated with the amount of waste and byproducts generated, and any special handling required for the waste and byproducts, during the life cycle of the Priority Product or component and each alternative being considered. This also includes an assessment of disposal, treatment or use of waste and byproducts, including solid waste, wastewater and storm water discharge streams.

(E) Other factors that relate to adverse impacts on the environment, including, but not limited to, the release of heat, odor or radiation.

(4) Economic Impacts. This includes any expected increase or decrease in jobs or businesses, costs of doing business, and the costs of goods to consumers. Evaluation and comparison of economic impacts shall take into account both internalized and externalized costs during the life cycle of the Priority Product or component and all alternatives being considered, and shall include an evaluation of the range of projected costs. Evaluation and comparison of externalized costs shall include costs to government agencies, the public, businesses, and consumers. Economic impacts include all of the following:

(A) Capital investment,

(B) Cost for resources,

(C) Energy costs,

(D) Non-compliance liability,

(E) Operations and maintenance costs,

(F) Waste disposal and treatment costs, and

(G) Other relevant financial investments or liabilities not listed above.

(e) The requirement to evaluate the Priority Product, or component, and all alternatives for the factors listed in subsections (d)(1) through (d)(3) may be fulfilled by completing an ISO 14040, or equivalent, life cycle assessment.

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

§ 69305.6. Tier II Alternatives Assessment Reports.

(a) The Tier II-A and Tier II-B AAs shall be completed and the AA Report for each submitted to the Department by the dates specified in section 69305.4(b)(4), unless an extension has been requested and approved pursuant to section 69305.2(b).

(b) The Tier II-A and Tier II-B AA Reports shall each include all of the following:

(1) Preparer Information.

(A) The name of and contact information for the person submitting the AA Report;

(B) If applicable, the name of and contact information for all persons on whose behalf the AA Report is being submitted, and their relationship to the person identified in subparagraph (A); and

(C) The names of the parties that were involved in funding, directing, overseeing, preparing or reviewing the Tier II AA. Any organizations and individuals that provided expert guidance or review for the Tier II AA, including the name of, and qualifications and accreditation information for, the person(s) in charge under whose direction the Tier II AA was conducted and the AA Report was prepared.

(2) Acronyms. An acronym list for the AA Report shall be included to clarify the meanings of abbreviated words.

(3) Manufacturer Information. Name and physical headquarters location of the manufacturer(s) shall be provided. If the AA Report is prepared on behalf of a consortium of manufacturers or other persons in the product's supply chain, a list of the participants shall be provided along with their corresponding contact information.

(4) Facility Description and Location. A description and location of the facility(ies) where the Priority Product or component is produced shall be included. This description shall also indicate the proximity to raw or recycled materials that directly or indirectly influences the type and amount of Priority Chemical contained in the Priority Product or component.

(5) Product Information. Information identifying and describing the Priority Product or component that is the subject of the AA Report, including all of the following:

(A) The brand name(s) under which the product is placed into the stream of commerce in California;

(B) If applicable, the component(s) that is the focus of the Tier II AA. The Tier II AA must, at a minimum, focus on the component(s) specified for the product in the Priority Products List, but may be expanded to include additional components or the entire product; and

(C) Identification of the Priority Chemical(s) that are the basis for the product being listed as a Priority Product, and any other Chemical of Concern(s) that are, or reasonably should be, known to be in the Priority Product.

(6) Supply Chain Information. All of the following information applicable to the product that is, or should reasonably be, known to the preparer of the AA Report:

(A) The name of, and contact information for, the person identified on the product label as the manufacturer, and the person, if any, identified as the distributor;

(B) The name of, and contact information for, the producer of the product;

(C) The name of, and contact information for, all responsible entities for the product; and

(D) The name of, and contact information for, any other person in the supply chain for the product.

(7) Supporting Information. All reference materials, studies, data and other information used as supporting information in performance of the Tier II AA and preparation of the AA Report shall be cited in the AA Report and made available to the Department. The AA Report shall include a brief summary of the information reviewed and considered pursuant to section 69305.2(e).

(8) Executive Summary. The AA Report shall include an executive summary meeting the requirements of section 69305.9.

(9) Verification Information. If an AA verification statement is required pursuant to section 69305.2(c)(3), the AA Report shall include all of the following information:

(A) Identification and qualification information for the verifying lead assessor and the qualified third-party assessment entity that employs the verifying lead assessor,

(B) A copy of the contractual agreement between the preparer of the AA Report and the verifying lead assessor, and

(C) The date by which the lead assessor's AA verification statement will be provided to the Department, which shall be not later than ninety (90) days after submittal of the Tier II-A or Tier II-B AA Report, whichever is applicable.

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

§ 69305.7. Tier II-A Alternatives Assessment Reports.

In addition to the information specified in subsection (b) of section 69305.6, the Tier II-A AA Report shall also include all of the following information:

(a) AA Goal and Scope of Alternatives. The AA Report shall identify the goal of the Tier II AA, identify and briefly describe the alternatives chosen to be evaluated and compared in the Tier II-A AA, and explain the rationale for selecting these alternatives. If the scope of alternative types considered differs from the anticipated scope identified in the AA Work Plan, the AA Report shall note and explain the reason for the change.

(b) Scope of Life Cycle Segments. The AA Report shall identify which life cycle segments were chosen for evaluation and comparison in Tier II-A AA for the product and all alternatives. If not all life cycle segments listed in section 69305.4(a)(5) have been or will be evaluated and compared, the AA Report shall explain the rationale for the omissions, including an explanation of why an evaluation of the omitted life cycle segments is not necessary to comply with the requirements of Health and Safety Code section 25253(a).

(c) Approach and Methodology for the Chemical Hazard Assessment and Exposure Potential Assessment (Tier II-A AA). The AA Report shall identify and describe the

assessment tools, models, or software used to conduct the Chemical Hazard Assessment and, if applicable, the Exposure Potential Assessment, and discuss any limitations of these tools, models and software. The AA Report shall also identify any published methodologies or guidelines used, and any deviations taken from the published methodologies or guidelines. The AA Report shall also identify, and briefly describe the approach and methodology used for each major Tier II-A AA task, including as applicable, but not limited to, the tasks listed in section 69305.4(a)(6).

(d) Chemical Hazard Assessment. The AA Report shall include all of the following information for the Chemical Hazard Assessment:

(1) Identification of the factors listed in section 69305.5(b) that were used to evaluate and compare the Priority Product, or component, and all alternatives considered, and the rationale for the selection of the evaluation and comparison factors.

(2) A comparative matrix, or other format, that provides the reviewer with an easily understood visual comparison, organized in conformance with section 69305.5(b), that presents both of the following:

(A) The data collected for each factor evaluated and compared in the Chemical Hazard Assessment, and

(B) The comparative results of evaluating the data presented pursuant to subparagraph (A).

(3) Data relied on for any determination that one or more alternatives being considered do not exhibit a hazard trait. This information is not required for any alternative that will be evaluated using an Exposure Potential Assessment.

(e) Exposure Potential Assessment. If an Exposure Potential Assessment is required pursuant to section 69305.5(a)(2)(B), the AA Report shall include both of the following information for the Exposure Potential Assessment:

(1) Identification of the factors listed in section 69305.5(c) that were used to evaluate and compare the Priority Product, or component, and all alternatives considered, and the rationale for the selection of the evaluation and comparison factors.

(2) A comparative matrix, or other format, that provides the reviewer with an easily understood visual comparison, organized in conformance with section 69305.5(c), that presents both of the following:

(A) The data collected for each factor evaluated and compared in the Exposure Potential Assessment, and

(B) The comparative results of evaluating the data presented pursuant to subparagraph (A).

(f) Adjustments to the Tier II-B AA Work Plan. The AA Report shall include all of the following information that is applicable:

(1) Any adjustments to the scope of alternatives that will be evaluated and compared in the Multimedia Life Cycle Evaluation (Tier II-B AA), based on the results of the Chemical Hazard Assessment and, if applicable, the Exposure Potential Assessment, and the rationale for any adjustments.

(2) Any adjustments to the scope of the life cycle segments that will be considered in the Multimedia Life Cycle Evaluation, based on the results of the Chemical Hazard Assessment and, if applicable, the Exposure Potential Assessment, and the rationale for any adjustments.

(3) Any other changes to the AA Work Plan for the Multimedia Life Cycle Evaluation, and the rationale for any changes.

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

§ 69305.8. Tier II-B Alternatives Assessment Reports.

In addition to the information specified in subsection (b) of section 69305.6, the Tier II-B AA Report shall also include all of the following information:

(a) Identification and explanation for any changes made to the information submitted in the Tier II-A AA Report.

(b) AA Goal and Scope of Alternatives. The AA Report shall identify the goal of the Tier II AA, identify and briefly describe the alternatives chosen to be evaluated and compared in the Tier II AA-B, and explain the rationale for selecting these alternatives. If the scope of alternative types considered differs from the anticipated scope identified in the AA Work Plan, or if different alternatives were considered in the Tier II-B AA than were considered in the Tier II-A AA, the AA Report shall note and explain the reason for any changes.

(c) Scope of Life Cycle Segments. The AA Report shall identify which life cycle segments were chosen for evaluation and comparison in the Tier II-B AA for the product and all alternatives. If not all life cycle segments listed in section 69305.4(a)(5) were evaluated and compared, the AA Report shall explain the rationale for the omissions, including an explanation of why an evaluation of the omitted life cycle segments is not necessary to comply with the requirements of Health and Safety Code section 25253(a). If the scope of life cycle segments considered differs from the anticipated scope identified in the AA Work Plan, or differs from the life cycle segments considered in the Tier II-A AA, the AA Report shall note and explain the reason for any changes.

(d) Approach and Methodology for the Multimedia Life Cycle Evaluation (Tier II-B AA). The AA Report shall identify and describe the assessment tools, models, or software used to conduct the Multimedia Life Cycle Assessment, and discuss any limitations of these tools, models and software. The AA Report shall also identify any published methodologies or guidelines used, and any deviations taken from the published methodologies or guidelines. The AA Report shall also identify, and briefly describe the approach and methodology used for each major Tier II-B AA task, including as applicable, but not limited to, the tasks listed in section 69305.4(a)(6).

(e) Multimedia Life Cycle Evaluation. The AA Report shall include both of the following information for the Multimedia Life Cycle Evaluation:

(1) Identification of the factors listed in section 69305.5(d) that were used to evaluate and compare the Priority Product, or component, and all alternatives considered, and the rationale for the selection of those factors.

(2) A comparative matrix, or other format, that provides the reviewer with an easily understood visual comparison, organized in conformance with section 69305.5(d), that presents both of the following:

(A) The data collected for each factor evaluated and compared in the Multimedia Life Cycle Evaluation, and

(B) The comparative results of evaluating the data presented pursuant to subparagraph (A).

(f) Selected Alternative. The AA Report shall identify and describe the alternative, if any, selected, and the rationale for the selection decision. This shall include an assessment that evaluates and compares the selected alternative against the Priority Product or component 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 or component, whichever is applicable. The AA Report shall also include all of the following:

(1) The information specified in subparagraphs (C) and (D) of section 69305.5(d)(1) for the selected alternative. If no alternative is selected, this information shall be provided for each alternative considered in the Tier II-B AA.

(2) A demonstration that the production, use and disposal of the selected alternative, in conjunction with any regulatory response(s) proposed pursuant to subsection (h), will have no greater significant adverse impacts on public health or the environment than the impacts associated with the Priority Product. For purposes of this paragraph, “environment”, as it pertains to California’s environment, shall mean “environment” as defined in section 21060.5 of the Public Resources Code.

(3) A list of all chemical ingredients contained in the selected alternative and hazard trait information for any of those chemicals for which hazard trait information has not already been provided to the Department pursuant to this chapter.

(g) Implementation Plan. A detailed plan, including key milestones and dates, for implementing the selected alternative, if applicable, shall be presented in the AA Report. The implementation plan shall include any steps necessary to ensure compliance with applicable federal, state or local laws.

(h) Proposed Regulatory Responses. Identification of any regulatory response(s), that the person submitting the AA Report wishes to propose, that would best limit the exposure to, or reduce the level of hazards posed by, any Priority Chemical that will be contained in the selected alternative or that is contained in the Priority Product, if the decision resulting from the Tier II AA is to retain the Priority Product.

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

§ 69305.9. Tier II AA Report Executive Summary Required Contents.

(a) Each Tier II-A and Tier II-B AA Report shall be accompanied by an executive summary. The executive summary shall be sufficient to convey to the public a general understanding of the scope, goals and results of the Tier II-A AA or Tier II-B AA, whichever is applicable, and allow a technically qualified person to make an independent assessment of the findings presented in the AA Report.

(b) The executive summary shall be organized in conformance with the organization of the AA Report and shall include, for each section of the AA Report, a reiteration or detailed summary of the information presented in the AA Report, but the preparer shall not include in the executive summary any information claimed as confidential pursuant to article 10.

(c) If the Department subsequently rejects a claim of confidentiality, the preparer 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 confidentiality claim is rejected and which the Department determines, and specifies in its request, must be included in the executive summary.

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

§ 69305.10. Department Review and Determination for Tier II AA Reports.

(a) Within sixty (60) days of receiving a Tier II-A or Tier II-B AA Report and, if applicable, the AA verification statement for the AA Report, the Department shall review the AA Report for completeness and compliance with the requirements of Health and Safety Code section 25253(a) and this article, and shall notify the person submitting the AA Report of the Department's finding with either a:

(1) Notice of completeness, or

(2) Notice of deficiency.

(b) The Department shall specify in any notice of deficiency the areas of deficiency and the due date for submitting the necessary information to complete the AA Report, which shall be no later than ninety (90) days after the notice of deficiency is issued.

(1) The revised AA Report shall be submitted within the time specified and shall address all areas of deficiency. If requested, the Department may, at its discretion, approve a one-time extension not to exceed sixty (60) days for submission of the revised AA Report to correct the deficiencies.

(2) Within sixty (60) days of receipt of the requested additional information, the Department shall notify the submitter of the information if the information submitted brings the AA Report into compliance with the requirements of Health and Safety Code section 25253(a) and this article, and either approve or disapprove the AA Report for implementation.

(3) If the Department again disapproves the AA Report, the Department shall issue a second notice of deficiency and grant no more than thirty (30) days for resubmission of the requested information.

(4) If the submitter of the AA Report fails to adequately and timely respond to two (2) notices of deficiency, the product shall be placed on the Failure to Comply List pursuant to section 69301.4(f).

(c) If the AA Report is determined to be complete, the Department shall notify the person who submitted the AA Report of its determination. A copy of the notice shall be sent to the manufacturer and all responsible entities known to the Department.

(1) In the completeness determination notice, or a subsequent notice sent to the manufacturer and all responsible entities known to the Department, the Department shall provide notice of the Department's proposed determination whether one or more of the regulatory responses specified in sections 69306.3(e), 69306.4(b), 69306.5 or 69306.6 is required.

(2) If a regulatory response is required under section 69306.6, the Department shall specify the proposed due date for implementation of the regulatory response.

(3) In assigning a deadline for completing a regulatory response required by the Department under section 69306.6, the Department shall consider the complexity of implementing the regulatory response.

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

Article 6. Regulatory Responses

§ 69306. Applicability.

(a) Except as provided otherwise in subsection (b), the requirements of this article shall apply to any alternative selected pursuant to section 69305.8(h) that is placed into the stream of commerce in California. These requirements shall also apply, as applicable, to the Priority Product or component if an alternative is not selected, or if the Priority Product or component will remain in commerce pending development and distribution of the selected alternative.

(b)(1) The requirements of this article do not apply to a product if the manufacturer submits to the Department, prior to the due date for implementing any regulatory response that would otherwise apply to the product, a Chemical Removal Confirmation Notification or a Product Removal Confirmation Notification.

(2) A Chemical Removal Confirmation Notification submitted pursuant to paragraph (1) shall be accompanied by all of the following additional information:

(A) The intended uses, and targeted customer base(s), for the product;

(B) Information explaining the rationale for and the factors considered in the decision to remove the Chemicals under Consideration and/or Priority Chemicals from the product, without adding any other chemicals to the product; and

(C) Identification, and a qualitative or quantitative description, of any reduction(s) to adverse public health or environmental impacts achieved by removing the Chemicals under Consideration and/or Priority Chemicals from the product.

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

§ 69306.1. AA Report Supplemental Information Requirements.

The Department may at any time request any information supplementary to the AA Report that the Department determines is necessary to determine and ensure implementation of one or more regulatory responses imposed pursuant to this article. This information shall be provided, within the time period specified by the Department, by the person who is the responsible entity for the Priority Product or component that is the subject of the AA Report.

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

§ 69306.2. No Regulatory Response Required.

No regulatory response will be required for a selected alternative, if all of the following are demonstrated to the satisfaction of the Department in the AA Report:

(a) The selected alternative does not contain a Priority Chemical in a concentration exceeding the de minimis level specified in section 69301.2(a)(24) or specified by the Department pursuant to section 69303.2(d), whichever is applicable. For a product or component that the Department has determined the de minimis exemption does not apply, it must be in the AA Report that the selected alternative does not contain a Priority Chemical at or above detectable levels.

(b) The selected alternative does not present a significant threat to public health or the environment.

(c) The Priority Product, which was the subject of the Tier II AA, will be completely removed from commerce in California, and an inventory recall in California will be completed, within three (3) years after the date the Tier II-B AA Report is submitted to the Department.

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

§ 69306.3. Product Information for Consumers.

(a) For a selected alternative that contains a Priority Chemical at a level that exceeds the de minimis level specified in section 69301.2(a)(24) or specified by the Department pursuant to section 69303.2(d), whichever is applicable, or for a Priority Product or component for which an alternative is not selected, the responsible entity shall ensure that all of the following information is made available to the consumer:

(1) Manufacturer's name;

(2) Brand name and description of the product;

(3) A list of the Priority Chemicals contained in the product;

(4) Identification of any sensitive subpopulations that should avoid contact with or other exposure to the product;

(5) Any safe handling procedures needed to protect public health or the environment during the useful life of the product and proper end-of-life disposal or management; and

(6) The manufacturer's website address where the consumer can obtain additional information about the product, the public health and environmental threats posed by the product, and proper end-of-life disposal or management of the product.

(b) The requirements of subsection (a) may be met by including an information sheet in the product packaging, printing the required information on the product packaging, printing the information in a prominent place in the product manual if a hard copy manual is packaged with the product, or posting the information in a prominent place at the point of sale for products that are not packaged.

(c)(1) In addition to the requirements of subsections (a) and (b), unless precluded by the type or size of the product, a product subject to the requirements of subsection (a) shall be permanently marked or labeled with all of the following information, in a manner that is easily seen, legible, and understandable to the consumer:

(A) The manufacturer's name;

(B) Brand name of the product;

(C) A statement that the product contains a Priority Chemical;

(D) Any safe handling procedures needed to protect public health or the environment during the useful life of the product and proper end-of-life disposal or management;

(E) Identification of any end-of-life take back program for this product; and

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

(2) If the size of the product precludes marking or labeling the product with all of the information listed in paragraph (1), the product shall be marked or labeled with as much of this information as the size of the product permits.

(d) A responsible entity that has a product or component subject to the requirements of subsections (a) through (c), shall ensure that these requirements are fully implemented for that product or component no later than twelve (12) months after the Tier II-B AA Report for the product or component is submitted to the Department.

(e)(1) Except as provided in section 69306.2, the requirements specified in subsections (a) through (c) shall also apply to a selected alternative for which the Department makes one or more of the following determinations, and notifies the responsible entity and the manufacturer of that determination pursuant to section 69306.8:

(A) The information will promote significantly safer use, and the public health and environmental threats posed by use of the product can be significantly mitigated by providing information to the consumer; or

(B) Product stewardship is necessary to mitigate adverse end-of-life impacts; or

(C) End-of-life reclamation of the product is necessary to conserve resources and mitigate long term environmental damage as a result of ongoing virgin material extraction.

(2) A responsible entity for a product or component subject to the requirements of this subsection shall ensure these requirements are fully implemented for that product or

component no later than twelve (12) months after being notified by the Department pursuant to section 69306.8(b) of its determination that the responsible entity's product or component is subject to the requirements of this subsection.

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

§ 69306.4. End-of-Life Management Requirements.

(a) Except as provided in section 69306.2, a responsible entity of a selected alternative, or a Priority Product or component for which the an alternative is not selected, which is required to be managed as a hazardous waste at the end of its useful life, shall ensure that both of the following requirements are met:

(1) Consumer product information, as required by section 69306.3, must be provided for the product or component. Additionally, the product information must state that the product or component must be disposed of or otherwise managed as a hazardous waste at the end of its useful life.

(2) No later than two (2) years after the Tier II-B AA Report for the product or component is submitted to the Department, an end-of-life management program for the product or component shall be funded, established and maintained. The program shall comply with all of the following requirements:

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

1. List of participating manufacturers and, if applicable, participating responsible entities;

2. The scope of products to be covered by the plan, which shall include:

a. Brand name and description of the selected alternative, or Priority Product or component, which is being managed under the product stewardship plan,

b. Identification of similar existing products on the market, marketed under other brand names that may be inadvertently recovered by implementation of the product stewardship plan,

c. Identification of legacy products, including brand names if available, that are no longer actively marketed at the time the product stewardship plan is implemented, and

d. Identification of the product stewardship plan's fair share of orphan products, and their brand names if available, whose manufacturer is non-existent at the end of the product's useful life.

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

a. The manufacturer or responsible entity shall finance their stewardship programs as a general cost of doing business, through cost internalization or by recovering costs through arrangements with their distributors and retailers.

b. The manufacturer or responsible entity shall identify any third-party product stewardship organization collecting and administering a fee to fund the stewardship program.

4. Identification of collection system information, which shall include:
a. Existing infrastructure, both regionally and statewide,
b. Needed infrastructure, not currently in place, both regionally and statewide, and
c. Minimum collection services required.
5. End-of-life management information, including what steps will be taken to ensure environmentally-sound management that complies with all applicable federal and California State and local laws;
6. Anticipated resources and a financing mechanism to implement and sustain the plan;
7. Program performance measures for:
a. Increasing the capture rate of the products covered at the end-of-life,
b. Increasing recyclability,
c. Increasing product longevity for consumer use, and
d. Decreasing use and volume of packaging;
8. Public outreach and communications plan;
9. Public and stakeholder consultation activities in preparation, and periodic review and updating, of the plan; and
10. Reporting and evaluation procedures.

(B) The product stewardship program shall include development and maintenance of a public education program geared towards the market for the product.

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

1. Collection mechanisms, including, but not limited to, placement of collection bins at collection centers in visible and accessible locations for consumers, and
2. Compensation to retailers and other persons who agree to administer or participate in the collection program.

(D) The manufacturer or responsible entity of the product shall provide a financial guarantee mechanism for a sustainable end-of-life management program for the product. Multiple manufacturers and/or responsible entities may form a third-party product stewardship organization, funded by participating manufacturers and responsible entities, to provide local services to collect, recycle, or otherwise appropriately manage the designated products.

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

1. The amount of products placed into the stream of commerce in California over the previous 2-year period, by total tonnage, and
2. The amount of products recovered for recycling over the same two-year period, by total tonnage.

(b)(1) Except as provided in section 69306.2, the requirements specified in subsection (a) shall also apply to a selected alternative product or component that contains a Priority

Chemical, or for a Priority Product for which an alternative is not selected, if the Department determines, and notifies the responsible entity and the manufacturer of the determination pursuant to section 69306.8, that one or more of the following applies:

(A) There is significant potential for improper end-of-life handling or disposal practices that pose significant adverse public health or environmental impacts,

(B) End-of-life reclamation of the product is needed to conserve resources and mitigate long term environmental damage as a result of continual virgin material extraction, or

(C) There would be significant waste management costs for local governments, ratepayers or taxpayers in the absence of a product stewardship program.

(2) An end-of-life management program shall be funded, established and maintained for a product or component no later than two (2) years after the Department issues a notification pursuant to section 69306.8(b) of its determination that the product or component is subject to the requirements of this subsection.

(c) Upon request, the product stewardship plan required under this section shall be submitted for review by the Department to ensure compliance with the requirements of this section.

(d) A copy of the product stewardship plan required under this section shall be posted on the websites of the responsible entity and the manufacturer. A link to these postings shall be provided to the Department for posting on the Department's website.

(e) A person subject to the requirements of this section may request the Department's approval to substitute an alternative end-of-life management program that achieves the same results as the program required by this section.

(f) A person subject to the requirements of this section may request an exemption 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 that is subject to the requirements of this section.

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

§ 69306.5. Product Sales Prohibition.

(a) Except as provided in section 69306.2 and subsection (c), the requirements of subsection (b) shall apply to a selected alternative that contains a Priority Chemical, or a Priority Product or component for which the an alternative is not selected, if the Department determines, and notifies the responsible entity and the manufacturer pursuant to section 69306.8, that a safer alternative exists that does not contain a Priority Chemical and is both functionally equivalent and technologically and economically feasible.

(b) Effective one (1) year after the Department issues a notification pursuant to subsection (a), the product or component that is the subject of the notification shall cease to be placed into the stream of commerce in California, and the responsible entity or the manufacturer shall ensure that an inventory recall program for the product or component is

implemented and completed within two (2) years after the notification is issued by the Department.

(c) A product or component that is the subject of a notification issued by the Department pursuant to subsection (a) shall not be subject to the requirements of subsection (b) if both of the following requirements are met:

(1) Within sixty (60) days after the notification is issued by the Department, the responsible entity or the manufacturer notifies the Department of its intent to submit a revised AA Report that selects an alternative that does not contain a Priority Chemical, and

(2) Within one (1) year after the notification is issued by the Department, the Department receives an AA Report that selects an alternative that does not contain a Priority Chemical and that fully meets the requirements of sections 69305.6 through 69305.8.

(d)(1) A request may be submitted to the Department for a one-time extension of the due date for submitting the revised AA Report pursuant to subsection (c)(2). The extension request shall be received by the Department no later than sixty (60) days before the due date for the revised AA Report, and shall include all of the following:

(A) Name of and contact information for the person filing the extension request,

(B) The name of and contact information for the person(s) on whose behalf the revised AA Report will be submitted,

(C) If different from (A) and (B), the name of and contact information for the manufacturer of the product,

(D) The amount of time requested, not to exceed ninety (90) days,

(E) The reason the extension is needed, and

(F) A copy of the notice issued by the Department pursuant to subsection (a), and a copy of the notice of intent submitted to the Department pursuant to subsection (c)(1).

(2) Within thirty (30) days of receipt of the extension request, the Department shall approve or deny the extension request, and notify the person submitting the extension request of its decision. The one-time extension for the revised AA Report shall not exceed ninety (90) days.

(3) If an extension is approved by the Department, one of the following requirements shall be met by the due date specified by the Department in the extension approval:

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

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

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

§ 69306.6. Other Regulatory Responses.

(a) In addition to the regulatory responses specified in sections 69306.1 and 69306.3 through 69306.5, and except as provided in section 69306.2, the Department may impose any of the following regulatory responses that the Department determines are necessary to limit

exposure to, and reduce the level of public health or environmental hazards posed by, a selected alternative, or a Priority Product or component for which an alternative is not selected:

(1) The Department may apply any of the regulatory responses described in sections 69306.3 through 69306.5 to scenarios other than those already identified in sections 69306.3 through 69306.5;

(2) The Department may apply any of the following regulatory responses to any scenario, including those scenarios listed in sections 69306.3 through 69306.5:

(A) Requiring engineered safety measures to control access to or limit exposure to the Priority Chemical in the product;

(B) Placing restrictions on the use of the Priority Chemical that is contained in the product;

(C) Requiring the responsible entity or manufacturer to initiate a green chemistry research and development project or fund a green chemistry challenge grant using green chemistry principles;

(D) Requiring a new Tier II AA to be performed, and an AA Report to be submitted to the Department in a time period specified by the Department, which shall be no less than three (3) years after the date the prior Tier II-B AA Report for the product or component was submitted to the Department, if either of the following applies:

1. The prior AA Report did not identify or select an alternative product or component, or

2. The Department becomes aware of a safer alternative that is both functionally equivalent and technologically and economically feasible; and

(E) Any other regulatory response that the Department determines is necessary to limit exposure to or otherwise reduce the level of public health or environmental hazards posed by the product.

(b) In accordance with the process specified in section 69306.8, the Department shall notify affected manufacturers and responsible entities, known to the Department, of regulatory response determinations made pursuant to this section, along with the implementation due date for the regulatory response and the rationale for the regulatory response determination.

(c) The Department will periodically re-evaluate each regulatory response imposed under this section to determine if any changes are needed based on any significant changes in science, technology or other relevant information or facts that have occurred since the regulatory response was selected.

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

§ 69306.7. Exemption from Regulatory Response Requirements.

(a) A selected alternative, or a Priority Product or component for which an alternative is not selected, shall be exempt from the requirements of this article, if the responsible entity or the manufacturer requests, and the Department grants, an exemption. The exemption request must be submitted to the Department no later than whichever of the following dates is applicable:

(1) Sixty (60) days after the responsible entity is notified by the Department that a selected alternative, or a Priority Product or component, is subject to a regulatory response pursuant to section 69306.6 or a determination under section 69306.3(e), 69306.4(b) or 69306.5, or

(2) Sixty (60) days after a Tier II-B AA Report is submitted to the Department for a product or component subject to subsections (a) through (c) of section 69306.3 or section 69306.4(a).

(b) An exemption request submitted pursuant to subsection (a) must include all of the following:

(1) Name of and contact information for the person filing the exemption request,

(2) The name of and contact information for the person(s) 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 of the product,

(4) The name of and contact information for any responsible entity for the product, to the extent known to the person submitting the exemption request,

(5) Information identifying and describing the product, including the brand name(s) under which the product is placed into the stream of commerce in California, and information specifically identifying the component, if applicable, and

(6) Clear and convincing evidence that demonstrates to the Department's satisfaction that either or both of the following apply:

(A) The required regulatory response would conflict with a requirement of another California or federal regulatory program or an international trade agreement ratified by the United States Senate, in such a way that the responsible entity or manufacturer cannot reasonably be expected to comply with both requirements.

(B) The required regulatory response substantially duplicates a requirement of another California or federal regulatory program or an international trade agreement ratified by the United States Senate.

(c) Within sixty (60) days of receiving an exemption request, the Department shall issue a notice to the person who submitted the request granting or denying the exemption request. A notice granting or denying an exemption request shall include the basis for the Department decision. A copy of the notice shall also be sent to the product manufacturer and any responsible entity, known to the Department.

(d) An exemption request submitted pursuant to subsection (a) shall be denied if the request fails to demonstrate to the satisfaction of the Department that one or both of the criteria specified in subsection (a)(6) apply to the product or component.

(e) If the exemption request or the Department's granting of the exemption is based solely on the criteria specified in subsection (a)(6)(A), the Department may, at its discretion, require implementation of a modified regulatory response that resolves the conflict that is the basis for the exemption.

(f) An exemption granted pursuant to this section shall be rescinded if the Department determines that the facts and/or assumptions that the Department relied upon in granting the

exemption were not, or are no longer, valid. If the Department rescinds an exemption, the Department shall notify the person who submitted the exemption request and, if different, the manufacturer and any responsible entity for the affected product, known to the Department.

(g) All notices issued under this section granting, denying or rescinding an exemption shall include a statement of basis for the Department's decision.

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

§ 69306.8. Regulatory Response Determination Process.

(a) Prior to issuing a final regulatory response determination notice pursuant to sections 69306.3(e), 69306.4(b), 69306.5(a) or 69306.6(b), the Department shall notify the manufacturer and all responsible entities known to the Department of the proposed regulatory response(s) pursuant to paragraphs (1) through (3) of section 69305.10(c), and make the proposed regulatory response determination notice available on its website, for public review and comment. The Department shall publish in the CRNR, send to persons on any listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed regulatory response determination notice. This notice shall include:

(1) The time period during which the public may submit comments,

(2) The method(s) for submitting comments to the Department on the proposed regulatory response determination notice, and

(3) Notification of any workshops, if the Department determines one or more workshops are necessary.

(b) After review and consideration of public comments on the proposed regulatory response determination notice, the Department shall finalize and send to the product manufacturer and responsible entities known to the Department the final regulatory response determination notice. The Department may, at its discretion, respond to some or all public comments received.

(c) All proposed and final regulatory response determination notices shall include all of the following:

(1) A description of the required regulatory response,

(2) The Department's determination(s) that is the basis for the required regulatory response,

(3) Subject to article 10, the rationale, data and data sources, supporting the Department's determination(s), and

(4) The implementation due date for any regulatory response imposed pursuant to section 69306.6.

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

§ 69306.9. Regulatory Response Report and Notifications.

(a) A responsible entity of a product or component subject to a regulatory response pursuant to this article shall ensure that a notice is sent to retailers who sell the product or component in California, informing the retailers of the applicability of the regulatory response to the product or component. The notice shall be sent to the retailers, and a copy sent to the Department, no later than whichever of the following dates is applicable:

(1) Thirty (30) days after receiving a final regulatory response determination notice, pursuant to section 69306.8(b), for a product or component subject to section 69306.3(e), 69306.4(b), 69306.5(a) or 69306.6(b), or

(2) Thirty (30) days after a Tier II-B AA Report is submitted to the Department for a product or component subject to subsections (a) through (c) of section 69306.3 or section 69306.4(a).

(b) The notice required pursuant to subdivision (a) shall include all of the following:

(1) The manufacturer's name and contact information,

(2) The responsible entity's name and contact information,

(3) The names of, and contact information for, any other persons in the supply chain for the product known to the responsible entity,

(4) Information identifying and describing the original Priority Product or component, and the selected alternative, including the brand name(s) under which the product or component is placed into the stream of commerce in California,

(5) A description of the required regulatory response and the due date for implementing the regulatory response.

(c) The responsible entity or the manufacturer shall notify the Department upon completing implementation of the required regulatory response(s) and, if applicable, upon completing development and introduction into the California market of the selected alternative. The notification shall include information describing how the regulatory response(s) was implemented. If requested by the Department, the responsible entity or the manufacturer shall provide periodic implementation status reports regarding the selected regulatory response(s). The information provided to the Department pursuant to this subsection shall also be posted on the websites of the manufacturer and responsible entity.

(d)(1) The Department shall prepare and post on its website, and update at least quarterly, a Regulatory Response Report that identifies the regulatory response or responses for each selected alternative for a Priority Product. The Regulatory Response Report shall contain all of the following information, subject to article 10:

(A) The manufacturer's name and contact information,

(B) The names of, and contact information for, any persons in the supply chain for the product known to the Department,

(C) Information identifying and describing the original Priority Product or component, and the selected alternative, including the brand name(s) under which the product or component is placed into the stream of commerce in California,

(D) The due date and actual date for completing development and introduction into the California market of the selected alternative, if any,

(E) The regulatory response(s), if any,

(F) The applicable section in this article specifying the regulatory responses, and, in the case of regulatory responses imposed based on a determination pursuant to section 69306.3(e), 69306.4(b), 69306.5(a) or 69306.6(a), the rationale for the Department's determination,

(G) The implementation due date, and the actual implementation date, for the regulatory response, and

(H) Any other information provided to the Department pursuant to subsection (b).

(2) The Department shall also include in the Regulatory Response Report the information specified in subparagraphs (A) through (D) of paragraph (1) for each exemption granted by the Department pursuant to section 69306.7.

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

Article 7. Dispute Resolution Processes

§ 69307. Dispute Resolution.

(a) This article applies to any responsible entity or manufacturer that wishes to dispute an action taken by the Department pursuant to this chapter that applies to the responsible entity or manufacturer or the responsible entity's or manufacturer's chemical or product.

(b) The Department and responsible entities and manufacturers shall use their best efforts to resolve all disputes informally. The procedures set out in this article are the required administrative procedures for resolving disputes arising under this chapter. If the responsible entity or manufacturer fails to follow the procedures contained in this article for disputes subject to this article, it shall have waived its right to further contest the disputed issue administratively.

(c) Any requirement imposed by the Department pursuant to this chapter on a responsible entity or manufacturer, and any posting on the Failure to Comply list pursuant to section 69301.4(f) concerning that requirement, shall be stayed during the pendency of a dispute or petition for review filed, pursuant to this article, concerning that requirement.

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

§ 69307.1. Informal Dispute Resolution Procedures.

(a) For any dispute arising from a decision made by the Department pursuant to the provisions of this chapter, other than sections 69306.3(e), 69306.4(b), 69306.5, 69306.6, and 69306.7, the responsible entity or manufacturer may, within fifteen (15) days following the notice or website posting of the Department's decision, request that the Department informally resolve the dispute. The Department shall provide the responsible entity or manufacturer 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 the specified time limit, the Department's decision is final and shall not be subject to additional dispute resolution.

(b) If the responsible entity or manufacturer disagrees with the Department's decision following completion of the informal dispute resolution process pursuant to subsection (a), the responsible entity or manufacturer may appeal to the Department's Director as specified in section 69307.2.

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

§ 69307.2. Request for Further Review by the Director.

(a) A responsible entity or manufacturer wishing to seek review of the Department's decision following completion of the informal dispute resolution process, pursuant to section 69307.1, shall submit information stating the basis for seeking further review and the reasons why the decision does not comport with the requirements of this chapter, or is otherwise unreasonable. The responsible entity or manufacturer shall also provide:

(1) The original statement of dispute;

(2) Supporting documents; and

(3) Copies of any responses prepared by the Department's employees involved with the dispute.

(b) The request for further review shall be made to the Director of the Department within thirty (30) days after completion of the informal dispute resolution process under section 69307.1.

(c) The Director or the Director's designee shall issue a decision granting or denying the relief sought in whole or in part within sixty (60) days after receipt of the request under this section. If the relief sought is denied, the decision shall specify the date by which the responsible entity or manufacturer shall comply with the requirements of this chapter that were the subject of the dispute. A decision issued pursuant to this subsection is the Department's final decision and is not subject to additional dispute resolution.

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

§ 69307.3. Formal Petition for Review Procedures.

For all disputes arising under sections 69306.3(e), 69306.4(b), 69306.5, 69306.6, or 69306.7, the procedures specified in sections 69307.4 through 69307.7 shall apply in lieu of the procedures set forth in sections 69307.1 and 60307.2.

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

§ 69307.4. Time Lines for Petitions for Review.

Within thirty (30) days of a responsible entity or manufacturer receiving a determination from the Department that section 69306.3(e), 69306.4(b), 69306.5, 69306.6, or 69306.7 applies to one or more of its products or selected alternative, the responsible entity or manufacturer may submit a petition for review to the Department to review such determination. If a petition of review is not filed within this time period, the Department's determination is final and shall not be subject to additional dispute resolution.

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

§ 69307.5. Contents of Petition for Review.

A petition for review filed pursuant to section 69307.4 shall include a statement of the reasons supporting that review, and as applicable, a showing that the determination is based on:

(a) Facts, assumptions, or other information or approaches or conclusion of law that is clearly erroneous, or

(b) An exercise of discretion or an important policy consideration which the Department should, in its discretion, review.

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

§ 69307.6. Department Review of Petitions.

(a) Within sixty (60) days following the filing of the petition for review pursuant to section 69307.4, the Department shall issue an order either granting or denying the petition for review.

(b) An order granting review shall specify a schedule for briefing of the issues by the responsible entity or manufacturer and the Department.

(c) An order denying review shall constitute the Department's final decision and shall not be subject to additional dispute resolution. The decision shall be effective on the date of the order. The order denying review shall specify the date by which the responsible entity or manufacturer shall comply with the requirements of this chapter that were the subject of the petition for review.

(d) Following consideration of the information provided during the briefing period, the Department shall issue an order specifying its decision on the merits of the petition. This order shall be issued within one hundred and eighty (180) days from the date the Department issues the order granting the petition for review.

(1) If the final order upholds the Department's action under this chapter the order shall be the Department's final decision and shall not be subject to additional dispute resolution. An order upholding the Department's original action shall specify the date by which the responsible entity or manufacturer shall comply with the applicable requirements of this chapter.

(2) If the final order grants the relief sought by the responsible entity or the manufacturer, in whole or in part, the order shall remand the action that is the subject of the petition for review back to the responsible program for re-evaluation and shall specify the date by which the re-evaluation must be completed, which shall 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) A final decision on the petition for review is a prerequisite to seeking judicial review of the Department's decision.

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

§ 69307.7. Procedures for Department Review of Petitions.

(a) In addition to the procedures specified in section 69307.6, in reviewing a petition for review filed pursuant to section 69307.4, the Department shall also comply with this section.

(b) No Departmental staff that participated in the action or decision that is the subject of the petition for review filed under section 69307.4 may participate in decision-making or review of decisions made under section 69307.6.

(c) No Departmental staff participating in decision-making or review of decisions made under section 69307.6 may have communications about the petition for review with any Department staff that participated in the action or decision that is the subject of the petition for review filed under section 69307.4, unless the Department staff simultaneously communicates with the responsible entity or manufacturer or its representative regarding the issues under discussion with Department staff.

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

Article 8. Accreditation and Qualification Requirements for Performance of Alternatives Assessments

§ 69308. Requirements for Qualified Third-Party Assessment Entities.

(a) An entity wishing to be designated as a qualified third-party assessment entity, shall submit an application to the Department that includes all of the following:

(1) The applicant's name and contact information.

(2) Identification of the combined qualifications of the individuals, including lead assessors meeting the requirements of section 69308.3, available within, or to, the entity for performing or verifying Tier II AAs, including education and experience, and areas of subject matter competency and expertise.

(3) Documentation of the AA elements, inputs, assumptions, methodologies and approaches employed by the entity.

(4) Demonstration of all of the following:

(A) Independence and lack of affiliation with any responsible entity, manufacturer, consortium of manufacturers, or trade association;
(B) No economic interest in any entity that produces, sells or distributes any Chemical of Concern or product containing a Chemical of Concern;
(C) Compliance with the standards of ISO 14040, or equivalent, as certified to in writing by an unaffiliated competent third-party;
(D) Compliance with, and maintenance by regular external audits, ISO/IEC Guide 65 accreditation; and
(E) Record keeping and document retention and retrieval practices and capabilities sufficient to facilitate audits by the Department pursuant to article 9 of this chapter.
(b) The Department shall review the application submitted pursuant to subsection (a) and, based on this review, approve or deny the request for designation as a qualified third-party assessment entity, within sixty (60) days of receiving the information. The Department shall notify the entity submitting the request of its determination. A notice of denial shall state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be designated, or re-designated, as a qualified third-party assessment entity.
(c) If any of the information submitted pursuant to subsection (a) of this section changes, the entity shall provide updated information to the Department within thirty (30) days of the change.
(d) A designation as a qualified third-party assessment entity shall expire after a period of five (5) years, except that it may be renewed upon application by the entity, pursuant to subsection (a) not later than ninety (90) days before expiration of the existing designation.
(e) If an entity is found to be negligently or willfully in violation of this chapter, the entity shall lose its designation as a qualified third-party assessment entity for a period of at least ten (10) years. After this period the entity may reapply to be designated as a qualified third-party assessment entity.

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

§ 69308.1. Requirements for Qualified In-House Assessment Entities.
(a) A manufacturer, consortium of manufacturers, trade association or public-private partnership wishing to be designated as a qualified in-house assessment entity, shall submit an application to the Department that includes all of the following:
(1) The applicant's name and contact information.
(2) The names of and contact information for all members of the applicant's organization, if the applicant is a consortium, trade association or similar organization.
(3) Identification of the combined qualifications of the individuals, including lead assessors meeting the requirements of section 69308.3, available within, or to, the entity for performing Tier II AAs, including education and experience, and areas of subject matter competency and expertise.

(4) Documentation of the AA elements, inputs, assumptions, methodologies and approaches employed by the entity.

(5) Demonstration of both of the following:

(A) Compliance with the standards of ISO 14040, or equivalent, as certified to in writing by an unaffiliated competent third-party;

(B) Compliance with, and maintenance by regular external audits, ISO/IEC Guide 65 accreditation; and

(C) Record keeping and document retention and retrieval practices and capabilities sufficient to facilitate audits by the Department pursuant to article 9 of this chapter.

(b) The Department shall review the information submitted pursuant to subsection (a) of this section, and, based on this review, approve or deny the request for designation as a qualified in-house assessment entity, within sixty (60) days of receiving the information. The Department shall notify the entity submitting the request of its determination. A notice of denial shall state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be designated, or re-designated, as a qualified in-house assessment entity.

(c) If any of the information submitted pursuant to subsection (a) of this section changes, the entity shall provide updated information to the Department within thirty (30) days of the change.

(d) A designation as a qualified in-house assessment entity shall expire after a period of five (5) years, except that it may be renewed upon application by the entity, pursuant to subsection (a) not later than ninety (90) days before expiration of the existing designation.

(e) If an entity is found to be negligently or willfully in violation of this chapter, the entity shall lose its designation as a qualified in-house assessment entity for a period of at least ten (10) years. After this period the entity may reapply to be designated as a qualified in-house assessment entity. During this period of disqualification, any Tier II AAs, including AA Work Plan and AA Report preparation, that the entity is required to perform must be performed by an entity that is unaffiliated with the responsible entity or manufacturer or any consortium, trade association or other partnership of which the responsible entity or manufacturer is a member.

(f) As used in this section, the term “manufacturer” includes “manufacturers” as defined in section 69301.2(a)(47), and other entities that perform AAs on behalf of manufacturers with which the entity is affiliated, including, but not limited to, manufacturer consortiums, trade associations, and manufacturer parent corporations and subsidiaries.

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

§ 69308.2. Requirements for Designated Accrediting Bodies.

(a) Any person wishing to be designated, or to renew designation, by the Department as an accrediting body to accredit lead assessors, who meet the requirements of section 69308.3, shall submit an application to the Department that includes all of the following:

(1) The applicant’s name and contact information;

(2) The applicant’s institutional history;

(3) The products type(s) and/or industry sector(s) for which the applicant is proposing to accredit lead assessors;

(4) A description of the accrediting body's lead assessor accreditation program that meets all of the requirements of subsection (c);

(5) The accrediting body's training curriculum, meeting the requirements of subsection (c)(3), for initial accreditation applicants, including for each course the course title, content description, hours, and exam plan;

(6) The accrediting body's continuing education curriculum, if any, for re-accreditation applicants, including for each course the course title, content description, hours, and exam plan;

(7) Demonstrated qualifications and areas of expertise of those individuals responsible for developing the accrediting body's training curriculum, as evidenced by education and experience, professional licenses, registrations, or other relevant credentials;

(8) A copy of the accrediting body's lead assessor application form, meeting the requirements of subsection (c)(1);

(9) A copy of the accrediting body's lead assessor accreditation certification form, meeting the requirements of subsection (c)(4);

(10) Information demonstrating all of the following:

(A) Ability to teach, and history of teaching, the principles and practices of Chemical Hazard Assessment, Exposure Potential Assessment, and Multimedia Life Cycle Evaluation,

(B) Ability to teach, and history of teaching, the application of life cycle thinking as it applies to products, and

(C) Ability to teach, and history of teaching, the appropriate use of life cycle assessment tools and methodologies as they apply to products;

(11) Disclosure of apparent or existing conflicts of interest; and

(12) A certification statement as required by section 69301.5(b).

(b) Within sixty (60) days after receiving an application for designation, or renewal of designation, as an accrediting body, the Department shall notify the applicant of its decision to approve or deny the application for designation. A notice of denial shall state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be designated, or re-designated, as an accrediting body.

(c) Each lead assessor accreditation program must include, at a minimum, all of the following elements:

(1) Written application and admission procedures for both initial accreditation and biennial renewal of accreditation. These procedures must include a requirement for the applicant, for initial or renewed accreditation, to submit to the accrediting body an application that, at a minimum, includes all of the following:

(A) The applicant's name and contact information,

(B) The products type(s) and/or industry sector(s) for which the applicant is applying for accreditation as a lead assessor;

(C) The applicant's educational experience, which must meet the requirements of section 69308.3(a)(1) and must be substantiated by submittal of transcripts or other equivalent records,

(D) The applicant's employment and other experience history, which must meet the requirements of section 69308.3(a)(2) and for which references must be provided,

(E) Any professional licenses, registrations or other relevant credentials that the applicant possesses,

(F) Documentation of completion of continuing education required pursuant to section 69308.3(a)(5), if the application is for accreditation renewal, and

(G) A signed and dated certification statement: "I certify under penalty of perjury that the information I have entered on this application is true and complete to the best of my knowledge. I further understand that any false, incomplete, or incorrect statements may result in my disqualification as a lead assessor. I authorize the employers and educational institutions identified on this application to release any information they may have concerning my employment or education to the accrediting body with which this application is filed and to the State of California."

(2) Written procedures for verifying an applicant's qualifying education and experience, including verification of fulfillment of continuing education requirements.

(3) An initial accreditation training program that is pertinent to the product type(s) and/or industry sector(s) for which lead assessor accreditation will be offered by the accrediting body, and that includes, at a minimum, all of the following:

(A) The requirements of this chapter, with an emphasis on the requirements of articles 5, 6 and 10,

(B) Training and case studies on principles and practices of Chemical Hazard Assessment, Exposure Potential Assessment, and Multimedia Life Cycle Evaluation, using life cycle thinking and life cycle assessment tools,

(C) Training and case studies on identification of alternatives for consideration in a Tier II AA,

(D) Training and case studies on identification of the life cycle segments for chemicals and products, and

(E) Training needed for the attainment of expertise in specific fields necessary to the performance of Tier II AAs.

(4) Issuance of a written certificate for initial accreditation and re-accreditation that is entitled "Certification of Accreditation as a Lead Assessor" and includes, at a minimum, all of the following:

(A) Lead assessor's name,

(B) The product type(s) and/or industry sector(s) for which the lead assessor is accredited,

(C) Date of issuance and date of expiration of the certification,

(D) Name and contact information for the accrediting body issuing the certification,

(E) An indication as to whether the certification is for initial accreditation or a renewal of accreditation,

(F) A statement that the lead assessor meets the requirements of section 69308.3(a), and

(G) The signature of the owner or an officer of the accrediting body issuing the certification.

(5) Criteria and procedures for denying an application for initial or renewed accreditation. Denial decisions must be provided to the applicant in writing and must state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be accredited or re-accredited as a lead assessor.

(6) A program to audit completed work by lead assessors accredited by the accrediting body to ensure the quality of work and proper application of tools by the lead assessor.

(7) Written procedures for records retention, including, but not limited to, applications, verification information, certifications, training records, and audit records. All records shall be maintained for a minimum of three (3) years.

(d) Each accrediting body shall provide to the Department the name and contact information for each lead assessor accredited by the accrediting body, along with the product type(s) and/or industry sector(s) for which each lead assessor is accredited. Updated information shall be provided to the Department on at least a quarterly basis.

(e) The duration of the designation of an accrediting body shall not exceed 5 years, except that it may be renewed upon application by the accrediting body not later than ninety (90) days before expiration of the designation. Applications for renewal of designation shall extend the expiring designation until the Department makes a determination on the renewal application.

(f) An accrediting body shall not claim trade secret or proprietary restrictions on their admission process, general curriculum and educational approach. An accrediting body applicant may request the Department to treat specific course information or life cycle assessment tools as licensed or proprietary and not available for free distribution in the public domain, or as a trade secret or confidential pursuant to article 10.

(g) The Department shall rescind its designation of an accrediting body if any of the following occurs:

(1) The designation period has lapsed,

(2) A substantial number of individuals accredited by the accrediting body as lead assessors are found to be in violation of this chapter,

(3) The Department finds that the accrediting body has significantly deviated from the documentation submitted to the Department pursuant to subsection (a), or is out of compliance with the requirements of this section, or

(4) The Department finds the accrediting body to be negligent, fraudulent, misrepresentative, or unethical in connection with their accreditation of lead assessors.

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

§ 69308.3. Lead Assessor Accreditation.

(a) A responsible person in charge of performing or verifying a Tier II AA, or preparing an AA Work Plan or AA Report, must be accredited by a designated accrediting body for a product type and/or industry sector appropriate for the Tier II AA being performed or verified, and must meet all of the following requirements:

(1) Possess a Bachelor's degree with a major in a scientific or engineering field from an accredited college or university.

(2)(A) Have the equivalent of three (3) years of professional experience performing AAs and/or working in a scientific or engineering field.

(B) Post-graduate work in the performance of AAs and/or in a scientific or engineering field, while attending an accredited college or university, may be substituted on a year-for-year basis for the experience required pursuant to paragraph (A).

(3) For initial accreditation, successfully complete a lead assessor accreditation training program and exam that meets the requirements of section 69308.2(c)(3) and that is developed and delivered by a designated accrediting body.

(4) Receive an initial "Certification of Accreditation as a Lead Assessor" meeting the requirements of section 69308.2(c)(4) and issued by the accrediting body whose accreditation training program the lead assessor successfully completed pursuant to paragraph (3).

(5) Maintain lead assessor accreditation status by doing all of the following:

(A) Completing continuing education during each two-year accreditation period, as required and provided, or verified, by the designated accrediting body from which the lead assessor will seek re-accreditation upon expiration of their current accreditation. Continuing education may be education and/or training focused on one or more aspects of alternatives assessment relevant to the performance of Tier II AAs or closely related topics.

(B) Submitting an application for re-accreditation to a designated accrediting body at least thirty (30) days prior to the expiration of the lead assessor's current accreditation. If the lead assessor complies with the requirements of this subparagraph and subparagraph (A), their accreditation will remain in effect unless and until the accrediting body denies their application for re-accreditation.

(C) Receiving a renewed "Certification of Accreditation as a Lead Assessor" meeting the requirements of section 69308.2(c)(4) and issued by the accrediting body who provided or verified the lead assessor's continuing education pursuant to subparagraph (A).

(6) Possess, and produce when requested, a current "Certification of Accreditation as a Lead Assessor" meeting the requirements of section 69308.2(c)(4).

(b) If the Department rescinds, pursuant to subsection (g)(2), (g)(3) or (g)(4) of section 69308.2, the designation of the accrediting body from which the lead assessor obtained accreditation, the lead assessor shall apply for reaccreditation from another accrediting body, designated pursuant to section 69308.2, no later than sixty (60) days after information concerning the rescission is posted on the Department's website.

(c) A lead assessor's accreditation shall be subject to rescission by the accrediting body or the Department for failure to comply with the applicable requirements of this chapter, or if the Department or the accrediting body finds the lead assessor to be negligent, fraudulent,

misrepresentative, or unethical in connection with their duties and responsibilities as a lead assessor. The accrediting body shall provide to the Department the name and contact information for any lead assessor whose accreditation is rescinded by the accrediting body, and an explanation of the reasons for the rescission.

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

Article 9. Audits

§ 69309. Audit of Alternatives Assessments and Regulatory Responses.

(a) The Department may audit Tier I and Tier II AAs as resources permit.

(b) The scope of the audit shall include, but not be limited to, an examination of:

(1) Compliance with article 5 requirements;

(2) Compliance with the scope and objective of the AA Work Plan during the conduct of the Tier II AA;

(3) Data quality and adequacy of analysis;

(4) Implementation of the selected alternative, if applicable; and

(5) Compliance with the applicable regulatory response(s) imposed pursuant to article 6;

(c) Upon completion of an audit, the Department shall:

(1) Notify the manufacturer and/or responsible entity(ies) of the audit findings, and

(2) Inform the manufacturer and/or responsible entity(ies) of 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 10. Confidentiality of Information

§ 69310. Confidentiality of Information.

(a) Notwithstanding any other provision of this chapter, any information provided to the Department pursuant to article 14 of chapter 6.5 of division 20 of the Health and Safety Code or this chapter will be made available to the public only to the extent and in the manner authorized by Health and Safety Code section 25257, any other applicable California statute, this chapter, and the California Public Records Act (Government Code section 6250, et seq.) as applicable.

(b) For purposes of this article, the term “confidential information” shall mean all information for which trade secret protection, confidentiality, privilege or other form of exemption from public disclosure is provided under Health and Safety Code section 25257, any other applicable California statute, this chapter or the California Public Records Act.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code, Section 1060, Evidence Code, and Sections 6250 through 6270, inclusive, Government Code.

§ 69310.1. Assertion of a Claim of Confidential Information.

(a) Any person who wishes to claim information as confidential information shall, at the time of submission, do one of the following:

(1) Assert a claim that certain information is a trade secret by identifying the portion of the information subject to the trade secret claim, and making specific reference to Health and Safety Code section 25257 and any other relevant code section(s) in both the appropriate claims index entry required by section 69310.2(b) and any supporting information required by section 69310.4;

(2) Assert a claim that information, while not a trade secret is otherwise confidential and exempt from disclosure under the California Public Records Act by identifying the portion of the information subject to the claim, and making specific reference in both the appropriate index entry required by section 69310.2(b) and any supporting information required by section 69310.4 to the factual or legal authority, privilege, or California Public Records Act provision relied upon.

(b) Any person who asserts a claim of confidential information shall also, at the time of submission, provide the Department with both of the following:

(1) A complete copy of the documentation being submitted, which shall include the claimed confidential information, and

(2) A redacted copy of the documentation being submitted, which shall exclude the claimed confidential information, and which the Department may make available in full to the public.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code, and Sections 6250 through 6270, inclusive, Government Code.

§ 69310.2. Marking and Indexing of Documents.

(a) Any person who asserts a claim of confidential information shall make such assertion at the time of submission by marking the words "Trade Secret" and/or “Confidential”, as appropriate, conspicuously on each page containing the information claimed to be confidential. If no claim of confidential information is made at the time of submission, the Department may make the submitted information available in full to the public without further notice.

(b) Any person who asserts a claim of confidential information shall provide to the Department, at the time of submission, a separate claims index summarizing the kind of confidential information for which confidentiality is claimed, the factual or legal basis authority, privilege, or California Public Records Act provision relied upon, and the place in the submitted

document where the confidential information was originally located. Such claims index shall not contain confidential information, and may be made available in full to the public.

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

§ 69310.3. Safeguarding of Confidential Information.

(a) No employee of the Department shall disclose, or use for his or her private gain or advantage, any confidential information which came into his or her possession, or to which he or she gained access by virtue of his or her official position or employment, except as authorized by Government Code section 6254.5 and this chapter.

(b) Each employee of the Department who has custody, access, or possession of confidential information shall take appropriate measures to properly safeguard such information and protect it against improper disclosure.

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

§ 69310.4. Support of a Claim of Trade Secret Protection.

(a) Any person who wishes to assert a claim of trade secret protection and receives a request from the Department to support trade secret claims shall, at the time of submission, or within ten (10) days of receipt of a request for support, whichever is later, provide the Department with all of the following substantiating information:

(1) The identity of the person making the claim;

(2) A brief description of the information for which trade secret protection is being claimed;

(3) The period of time for which trade secret protection is claimed and a justification for the period selected;

(4) The extent to which the information is known by employees or others involved with the facility or business, and whether or not those individuals with knowledge are bound by non-disclosure agreements;

(5) The extent to which the information is known outside of the facility or business of the person, and whether or not individuals with such knowledge are bound by non-disclosure agreements;

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

(7) The estimated value of the information to you and to your competitors;

(8) The estimated amount of effort or money expended by you in developing the information;

(9) The estimated ease or difficulty with which the information could be properly acquired or duplicated by others;

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

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

(12) The signature of the person's general counsel or other executive with knowledge of the preparation of the substantiating information certifying under penalty of perjury and subject to the provisions of section 69301.4(g), and also 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

(13) Contact information for the individual to be contacted if any part of the claimed information is requested to be disclosed under the California Public Records Act.

(b) The substantiating information required in subsections (a)(1) though (a)(11) shall be provided for each individual trade secret claim, although such information may be incorporated by reference to apply to multiple claims, as appropriate. The requirements contained in subsections (a)(12) and (a)(13) may be supplied once for all claims submitted at one time.

(c) If the substantiating information contains information that is itself subject to a claim of trade secret protection, such substantiating information shall also be separately supplied in both complete and redacted form as required by section 69310.1(b), and marked as required by section 69310.2(a), but shall not itself require indexing under section 69310.2(b) or further support under section 69310.4 in order to comply with this section. Such substantiating information shall be separate from any documentation used to comply with the other provisions of this chapter.

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

§ 69310.5. Departmental Review of Trade Secret Claims.

(a) Upon receipt of a document submitted pursuant to this chapter that contains information labeled or otherwise claimed to be subject to trade secret protection, or at any time thereafter, the Department may, at its discretion, review the trade secret claim and substantiating information for proper justification and compliance with the requirements of this article.

(1) If the Department determines that the substantiating information is incomplete or insufficiently responsive, the Department shall notify the submitter of the information of the Department's deficiency finding, the specific area(s) of deficiency, and the date by which the submitter must provide the necessary information to correct the deficiency. If the submitter fails to provide the necessary information within the time frame set forth by the Department, the

Department shall notify the submitter by certified mail that the claim remains procedurally deficient and out of compliance, and that the information claimed to be a trade secret will be considered a public record subject to disclosure by the Department within thirty (30) days after such notice is mailed. During the 30-day period, the submitter may elect to correct the deficiency, or seek appropriate judicial relief by filing a legal action for a writ of mandate, injunction, protective order, or other appropriate relief. During this 30-day period, and for any extended period ordered by a court of law, the Department shall not publicly release the claimed trade secret information or otherwise disclose such information publicly.

(2) At any time, the Department may also undertake a substantive review of a claim to determine if protection from public disclosure as a trade secret is justified. In the event the Department's review determines that there is insufficient justification for trade secret protection, it shall notify the submitter by certified mail of its determination. The notice shall also provide the submitter with thirty (30) days to seek appropriate judicial relief in response to the Department's determination. During this 30-day period, and for any extended period ordered by a court of law, the Department shall not publicly release the claimed trade secret information or otherwise disclose such information publicly.

(3) After the above procedural requirements have been satisfied, including any judicial review of the Department's determination, any information found to be procedurally deficient or that lacks sufficient justification for trade secret protection shall be treated as if no claim was made and shall be made available to the public by the Department.

(b) In the event the Department receives a request under the California Public Records Act (California Government Code section 6250 *et seq.*) for disclosure of information designated as a trade secret, the following procedure shall apply:

(1) The Department shall immediately notify the submitter of the information that a Public Records Act request has been made. The Department shall then determine whether or not trade secret protection for the information is justified, unless the Department has already considered the justification for trade secret protection after having completed the review and determination in subdivision (a) or subdivision (b) of this section, and also concluded that there is no reasonable justification to conduct a further review.

(2) The Department shall make the determination specified in paragraph 1 no later than sixty (60) days after the date the Department receives the request for disclosure, but not before thirty (30) days following the notification to the submitter.

(3) If the Department decides that the information submitted pursuant to this chapter lacks sufficient justification for trade secret protection, the Department shall provide the submitter 30 days' written notice prior to public disclosure of the information. The Department may publicly release the information after the expiration of the 30-day period, unless, prior thereto, the submitter files a legal action seeking a declaratory judgment, injunction, or other appropriate relief to protect the information from public disclosure, and the submitter promptly notifies the Department that such an action has been filed.

(4) If the Department decides that the claim for trade secret protection for information submitted pursuant to this chapter is justified and such information is not disclosed to the public, it shall so inform the person requesting the information in writing within ten (10) days

after such decision. If the person requesting such information files a petition for writ of mandate seeking disclosure of such information, the Department shall immediately notify the submitter that such an action has been filed. In response to the petition, the Department shall indicate that the information is not being publicly disclosed because it has been designated by the submitter to be a trade secret. It shall be the sole responsibility of the submitter to defend the claim of trade secret before the court. The Department shall not disclose the information to the public during the time the court is deciding the matter.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code, and Sections 6250 through 6270, inclusive, Government Code.

§ 69310.6. Hazard Trait Submissions.

(a) In accordance with Health and Safety Code section 25257(f), no hazard trait submissions, which term is synonymous with "hazardous trait submissions" as used in that section, made pursuant to article 14 of chapter 6.5 of division 20 of the Health and Safety Code and/or this chapter may be claimed as a trade secret.

(b) For purposes of this section, a "hazard trait submission" means information submitted to the Department pertaining to a hazard trait of any chemical or chemical ingredient. The term "hazard trait submission" includes hazard trait information identifying the manufacturer of a product containing a Chemical of Concern or a chosen alternative. The term also includes hazard trait information indicating that a particular Chemical of Concern or a chosen alternative is present in a product, however broadly or narrowly the product is described. The term does not include hazard trait information uniquely identifying a chosen alternative, if such identifying information is claimed as a trade secret and non-confidential identifying information sufficient to permit a consumer to identify the particular alternative is provided in its place. The term also does not include hazard trait information that discloses processes used in the manufacturing or processing of a chemical substance or chemical mixture.

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

Article 11. Small Businesses

§ 69311. Applicability.

(a) For purposes of this article, "small business" means an independently owned and operated business which, together with affiliates, has twenty-five (25) or fewer employees, and average annual gross receipts of one million dollars ($1,000,000) or less over the life of the business or the previous three (3) years, whichever is shorter.

(b) The provisions of this article apply only to a manufacturer or a responsible entity that has demonstrated to the satisfaction of the Department that it meets the definition of a "small business", specified in subsection (a). A manufacturer or responsible entity seeking to qualify

as a small business shall submit all of the following to the Department no more than sixty (60) days after the manufacturer's or responsible entity's product is listed as a Priority Product:

(1) Copies of official government records that verify that the manufacturer or responsible entity employs twenty-five (25) or fewer people, or a declaration or affidavit, signed by the manufacturer or responsible entity under penalty of perjury, that the manufacturer or responsible entity employs twenty-five (25) or fewer people; and

(2) Tax returns that document that the average annual gross receipts of the manufacturer or responsible entity did not exceed one million dollars ($1,000,000) over the life of the business or the prior three (3) years, whichever is shorter.

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

§ 69311.1. Timelines.

For any of the time requirements specified in this chapter, or for those time requirements specified by the Department pursuant to this chapter, the Department may, at its discretion, grant a business that qualifies as a small business, pursuant to section 69311, a longer period of time to comply.

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

§ 69311.2. Consultation Services for Small Businesses.

A manufacturer or responsible entity subject to the requirements of article 5 that qualifies as a small business, pursuant to section 69311, may request, and the Department shall provide, consultative services to assist the manufacturer or responsible entity in complying with article 5 requirements. The manufacturer or responsible entity shall reimburse the Department for any associated costs pursuant to Health and Safety Code section 25201.9.

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

Article 12. Severability

§ 69312. 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.