STRAW PROPOSAL
FOR
SAFER ALTERNATIVE REGULATIONS
(10/1/09)

Article X. Identification and Prioritization of Chemicals of Concern in Consumer Products

6xxxx.1 Applicability

(a) This Article applies to all consumer products that are made available for use in California and that are properly categorized as one or more of the following:

(1) Products designed for use by infants or children, including, but not limited to, personal care products, toys, bedroom furnishings, and clothing;

(2) Products designed for use in K-12 schools;

(3) Products designed for application directly in or to the human body, including, but not limited to, personal care products, cosmetics, lipstick, nail polish, toothpaste, shampoos, perfumes and colognes;

(4) Clothing, linens and textiles including, but not limited to, shirts, blouses, socks, dresses, pants, handbags, shoes, pillow cases, bed covers, blankets, sheets, and mattress covers and liners;

(5) Furnishings including, but not limited to, mattresses, sofas, chairs, tables, draperies, household appliances. lighting fixtures, and carpet;

(6) Cleaning products including, but not limited to, kitchen and bathroom cleaning products, soaps, and laundry detergents;

(7) Products designed to release fragrances or scents, including, but not limited to, perfumes, colognes, scented candles, air fresheners and room deodorizers;

(8) Products designed to store or dispense food products or designed for food preparation including, but not limited to, bags or containers, flatware, eating and cooking utensils, and pots and pans;

(9) Products designed, or reasonably anticipated, to release any chemicals during intended use by consumers or after disposal (e.g., automobile brake pads, automobile tires, fireplace logs, glues, adhesives, and solvents);

(10) Any products that contain any of the chemicals specified in section 6xxxx.2 of this Article; and

(11) Any of the chemicals specified in section 6xxxx.2 of this Article.

(b) At least every two years following the effective date of these regulations, the Department shall evaluate other categories of consumer products, and may initiate a rulemaking to revise the list of product categories in subsection (a) of this section.

6xxxx.2 Designated Chemicals of Concern

(a) Notwithstanding section 6xxxx.7 of this Article, the following chemicals or chemical ingredients are "chemicals of concern".

(1) Arsenic (inorganic arsenic compounds)

(2) Cadmium and cadmium compounds

(3) Chromium (VI) [CASRN 18540-29-9]

(4) Lead and lead compounds

(5) Mercury and mercury compounds

(6) Uranium [CASRN 7440-61-4]

(7) Bisphenol A [CASRN 80-05-7]

(8) Diethylhexyl phthalate [CASRN 117-81-7]

(9) Diisodecyl phthalate [CASRN 26761-40-0]

(10) Diacetyl [CASRN 431-03-8]

(11) Triclosan [CASRN 3380-34-5]

(12) Sulfur Dioxide [CASRN 7446-09-5]

(13) Nitrogen Dioxide [CASRN 10102-44-0]

(14) Methyl Isocyanate [CASRN 624-83-9]

(15) Perfluorooctanoic Acid

(16) Perflourooctane Sulfonate

(b) Any chemicals or chemical ingredients identified in any of the following references:

(1) California Proposition 65 List of chemicals known to the state to cause cancer or developmental or reproductive effect.

(2) International Agency for Research on Cancer, chemicals classified as Groups 1, 2A and 2B carcinogens.

(3) National Toxicology Program (NTP) list of chemicals identified as known or reasonably anticipated to be human carcinogens in the Report on Carcinogens.

(4.) Carcinogens classified by Europe as Categories 1 and 2, or with Risk Phrases R45 (may cause cancer) or R49 (may cause cancer by inhalation).

(5) NTP Center for Evaluation of Risks to Human Reproduction (CERHR), chemicals classified as posing "serious concern," "concern" or "some concern" with regard to developmental or reproductive toxicity

(6) Chemicals classified by the European Commission as Reproductive Toxicity Categories 1 and 2, or in the hazard category for lactation effects (effects on or via lactation) or with Risk Phrases R60 (may impair fertility), R61 (may cause harm to the unborn child), and R64 (may cause harm to breastfed babies).

(7) Persistent, bioaccumulative toxicants (PBTs) and very persistent, very bioaccumulative chemicals (vPvBs)

(8) Chemicals identified as persistent, bioaccumulative, inherently toxic (PBiT) by Environment Canada.

(9) Chemicals identified by the European Commission as PBTs, vPvBs

(10) Chemicals on the State of Washington PBT list.

(11) Oslo-Paris Convention Commission (OSPAR) list of substances of possible concern (includes the subset of chemicals for priority action).

(12) U.S. EPA National Waste Minimization Program Priority Chemicals.

(13) U.S. EPA Priority PBTs.

(14) U.S. EPA Emergency Planning and Community Right to Know Act (EPCRA) PBTs.

(15) U.S. EPA Toxic Release Inventory (TRI) PBT Chemical List.

(16) Chemicals classified by the European Commission as Category 1 or 2 endocrine disruptors.

(17) Chemicals classified by the European Commission as Category 1 or 2 germ cell mutagens or with Risk Phrase R46 (may cause heritable genetic damage).

(18) Japan International Center for Occupational Safety and Health list of mutagenic chemicals.

(19) Chemicals classified by Europe as respiratory sensitizers or with Risk Phrases R42 (may cause sensitization by inhalation) and R42/43 (may cause sensitization by inhalation and skin contact) .

(20) Chemicals identified by the Association of Occupational and Environmental Clinics as occupational asthmagens.

(21) Chemicals classified by Canada as inherently toxic to aquatic organisms.

(22) Chemicals classified by the European Commission as hazardous to the aquatic environment.

(23) Chemicals classified by the European Commission as hazardous to the ozone layer or with the Risk Phrase R59 (dangerous to the ozone layer).

(24) California Toxic Air Contaminants Program.

(25) Potential chemical contaminants of concern at California school sites.

(26) Priority chemicals for biomonitoring under the California Environmental Contaminant Biomonitoring Program.

(27) Chemicals with drinking water maximum contaminant levels.

(28) Chemicals with water quality standards.

(29) Additional chemicals classified by Health Canada as high priorities for human health.

6xxxx.3 Definitions

For the purposes of this article, the following terms have the meanings indicated:

(a) ”Authoritative body” means any government agency, foreign or domestic, that meets the following requirements:

(1) It characterizes chemicals pursuant to a process in which stakeholders are able to participate and communicate through written and oral comments.

(2) It publishes its characterization of chemicals via web postings, press releases, government regulations, periodic reports, monographs, or similar publications.

(b) Except as expressly stated otherwise, “chemical” means any chemical in a consumer product other than a "chemical ingredient", as defined in subsection (c) of this section .

(c) Except as expressly stated otherwise, "chemical ingredient" means any chemical in a consumer product that is necessary for the manufacturing process to produce a product that will function as intended.

(d) **"**Chemical of concern" (CoC) means:

(1) any chemical or chemical ingredient identified in section 6xxxx.2 of this Article; and,

(2) any chemical or chemical ingredient that has any of the hazard characteristics listed in section 6xxxx.7 of this Article, and is contained in a category of consumer product that is subject to this Article pursuant to Section 6xxxx.1.

(e) "Consumer product" has the meaning given to it by Health and Safety Code section 25251, subdivision (e).

(f) "Existing chemical" means any chemical or chemical ingredient contained in a consumer product, where that chemical or chemical ingredient was being used in that product, and that product was being made available for use in California before **[insert effective date of this article].**

(g) Make available for use in California" means that a person sells, offers to sell, distributes, leases, offers to lease, 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, lease, supply, or other transfer of the consumer product by that person to prevent the use of the consumer product by a California consumer.

(h) Manufacturer" means any person who imports, manufactures, assembles, produces, or that packages, repackages, or re-labels under their own brand name, a consumer product.

(i) "New chemical" means any chemical or chemical ingredient that was not contained in a consumer product that was made available for use in California before **[insert effective date of this article].**

(j) "New use" refers to any use or application of any existing or new chemical chemical ingredient in a consumer product that first occurs after **[insert effective date of this article]**, in either a new or existing consumer product that is or will be made available for use in California.

(k) "Sensitive subpopulations" means subgroups of the general population, including, but not limited to, born and unborn infants, children, pregnant women, the elderly, and individuals with chronic or acute illness, that may be more susceptible than the general population to adverse impact from exposure to certain chemicals or chemical ingredients.

(l) "Transferee" means: (1) a distributor, seller, supplier, lessor, or other person who receives a right to use the product or to transfer an ownership

or other legal interest to use the product to another person, except that manufacturers and consumers are not transferees.

6xxxx.4 Standards for Consumer Products.

(a) Except as provided in section 6xxxx.5 of this article, no person shall make available for use in California any consumer product that is subject to this article and has not been evaluated pursuant to sections 6xxxx.6, 6xxxx.7 and 6xxxx.8 of this article, or that lacks the documentation required by section 6xxxx.9.

6xxxx.5 Exemptions.

(a) This article shall not apply to a consumer product that is made available for use in California for the sole purpose of redistribution, sale, supply or lease for use outside of California.

(b) This article shall not apply to a consumer product if any of the activities prescribed in sections 6xxxx.6, 6xxxx.7, 6.xxxx.8 or 6.xxxx.9 are otherwise prohibited by law.

6xxxx.6 Data Requirements

(a) Unless otherwise prohibited by law, a manufacturer of a consumer product which does, or will, contain one or more existing or new chemicals shall obtain all of the information and data necessary to evaluate those chemicals pursuant to section 6xxxx.7 of this Article.

(b) The information required pursuant to subsection (a) of this section shall be obtained by the following dates:

(1) For an “existing” chemical all information needed to evaluate that chemical pursuant to section 6xxxx.7 of this Article shall be generated no later than one year from the effective date of these regulations.

(2) For new use of an “existing” chemical in a consumer product, all information needed to evaluate that chemical or chemical ingredient pursuant to section 6xxxx.7 of this Article shall be generated before making that consumer product available for use in California.

(3) For a “new” chemical, all information needed to evaluate that chemical pursuant to section 6xxxx.7 of this Article shall be generated before making the new chemical available for use in California.

(c) In complying with subsection (a) of this section, a person may:

(1) rely on published, peer-reviewed, scientific literature, published by an independent third party; and/or,

(2) rely on evaluations and categorizations that have already been performed by authoritative bodies (e.g., if an authoritative body has

already identified a chemical as a carcinogen, additional testing of that chemical for carcinogenicity is not required); and/or

(3) conduct laboratory and analytical testing.

(d) Any data required to evaluate and categorize chemicals or chemical ingredients pursuant to section 6xxxx.7 of this Article may be generated by any applicable, standardized test method that is reasonably within the capability of private sector laboratories to generate, or, by any test method that it can be shown would be accepted as a valid test method by any authoritative body for the respective categorization.

(e) Notwithstanding subsections (c) and (d) of this section, the use of qualitative or quantitative structure-activity relationship ((QSAR) results obtained from valid qualitative or quantitative structure-activity relationship models QSARs) to categorize chemicals or chemical ingredients pursuant to section 6xxxx.7 of this Article is acceptable in lieu of laboratory testing if, and only if, the following conditions are met:

(1) results are derived from a QSAR model whose scientific validity has been established by an authoritative body,

(2) the substance falls within the applicability domain of the QSAR model,

(3) results are adequate for the purpose of risk assessment, and

(4) adequate and reliable documentation of the applied method is submitted to the Department within 30 days of a written request by the Department.

(f) Any test data and/or documentation that a person relies upon to comply with the requirements of this Article shall be maintained by that person while that person continues to make a product available for use in California, and for a period of at least three years after that the last date the person makes a product available for use in California. A copy of all test data and/or documentation that person relied upon to achieve compliance with this Article shall be made available to the Department within 30 days of a written request from the Department.

(g) Individuals, members of industry trade associations, and/or any other interested persons or stakeholders, may collaborate to collect the data and documentation needed to achieve compliance with this article. However, it is the responsibility of each manufacturer of a consumer product that relies upon such data and documentation to ensure its accuracy.

(h) Any person who is responsible for evaluating chemicals or chemical ingredients pursuant to section 6xxxx.7 of this Article shall take all reasonable steps, including, at a minimum, an annual review of available

information, to ensure that any data and/or documentation relied upon to comply with section 6xxxx.7 of this Article is accurate and up-to-date.

Section 6xxxx.7 Hazard Categories

(a) Unless otherwise prohibited by law, a manufacturer of a consumer product that contains one or more existing or new chemicals and who makes, or will make, that product available for use in California shall take the following actions:

(1) evaluate each chemical with respect to each of the hazard criteria listed in subsection (b) of this section, until such time as the criteria are modified or superseded by criteria published by the Office of Environmental Health Hazard Assessment and posted on the Toxics Information Clearinghouse website pursuant to Health and Safety Code section 26256.1;

(2) determine and document all applicable hazard criteria from subsection (b) of this section for which each specific chemical may be designated as a chemical of concern. For example, if a chemical may be categorized as a chemical of concern for endocrine disruption, toxicity, carcinogenicity, and so on, those results shall all be documented. If it is determined that a given chemical is not a chemical of concern, that result shall also be documented along with the basis for that determination;

(3) maintain all documentation relied upon to arrive at the determinations specified in subsubsection (a) (2) of this section during the time that the person makes that product using those chemicals available for use in California, and for at least three years thereafter. The manufacturer shall make the documentation available to the Department within 30 days of a written request, and shall also make the information generally available to any interested parties by posting the information on the internet; and,

(4) enter the Chemical Abstracts Service (CAS) number, the name as recognized by the International Union of Pure and Applied Chemistry (IUPAC), and all hazard categorization information, as determined pursuant to subsection (b) of this section, for each chemical, into the Toxics Information Clearinghouse established by the Department pursuant to section 25256 of the Health and Safety Code within one year of the effective date of these regulations.

(b) Hazard criteria

(1) Toxicity

i. Acute toxicity (other than aquatic toxicity): Any chemicals or chemical ingredients in consumer products with acute toxicity values less than or equal to those shown in

Table 1, as measured by the oral, dermal or inhalation route, shall be designated as chemicals of concern based on acute toxicity.

Table 1. Acute Toxicity

Exposure Route	Values
Oral (mg/kg body weight)	≤ 50
Dermal (mg/kg bodyweight)	≤ 200
Gases (ppmV)[1]	≤ 500
Vapors (mg/L)	≤ 2.0
Dusts and Mists (mg/L)	≤ 0.5

(1) Gas concentrations are expressed in parts per million per volume (ppmV)

ii. Chemicals or chemical ingredients with specific target organ toxicity-single exposure: Specific target organ toxicity (single exposure) is defined as specific non-lethal organ toxicity arising from a single exposure to a chemical or chemical ingredient. Those chemicals or chemical ingredients exhibiting any of the criteria listed in Table 2 at, or below, the concentration values listed in Table 3, shall be designated as a chemical of concern for specific target organ toxicity-single exposure.

Table 2. Characteristics for specific target organ toxicity-single exposure

Criteria
Chemicals or chemical ingredients that have produced significant toxicity in humans, or, that on the basis of evidence from studies in experimental animals, can be presumed to have the potential to produce significant toxicity in humans following single exposure. Chemicals or chemical ingredients shall be classified on the basis of: • evidence from human cases or epidemiological studies; or • observations from appropriate studies in experimental animals in

which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations; or,

- evidence from studies in experimental animals suggesting that the chemical or chemical ingredient can be presumed to have the potential to be harmful to human health following single exposure.

Table 3. Guidance Value Concentrations For Single-dose Exposures Which Have Produced A Significant Non-lethal Toxic Effect

Route of Exposure	Units	Concentration (C)
Oral (rat)	mg/kg body weight	C ≤ 2000
Dermal (rat or rabbit)	mg/kg body weight	C ≤ 2000
Inhalation (rat) gas	ppV/4h	C ≤ 20000
Inhalation (rat) vapor	Mg/L4h	C ≤ 20
Inhalation (rat) dust/mist/vapor	Mg/L4h	C ≤ 5

iii. Chemical or chemical ingredients with target organ toxicity-repeated exposure: Target organ toxicity (repeated exposure) is defined as specific, target organ toxicity arising from a repeated exposure to a chemical or chemical ingredient. Those chemicals or chemical ingredients exhibiting any of the criteria listed in Table 4 at, or below, any concentration values listed in Table 5, shall be designated as a chemical of concern for target organ toxicity-repeated exposure.

Table 4. Criteria for Specific Organ Toxicity-Repeated Exposure

Criteria
Chemicals or chemical ingredients that have produced significant toxicity in humans or that, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to produce significant toxicity in humans, following repeated exposure. Chemicals or chemical ingredients shall be classified on the basis of: • evidence from human cases or epidemiological studies; or • observations from appropriate studies in experimental animals in which significant and/or severe toxic effects, of relevance to human health, were produced at generally low exposure concentrations; or, • evidence from studies in experimental animals suggesting that the chemical or chemical ingredient can be presumed to have the potential to be harmful to human health following repeated exposure.

Table 5. Guidance Values To Assist In Classification

Route of Exposure	Units	Guidance Values (Dose Concentration)
Oral (rat)	mg/kg body weight/day	C ≤ 100
Dermal (rat or rabbit)	mg/kg body weight/day	C ≤ 200
Inhalation (rat) gas	ppmV/6h/day	C ≤ 250
Inhalation (rat) vapor	mg/liter/6h/day	C ≤ 1
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	C ≤ 0.2

(2) Chemicals or chemical ingredients which cause serious eye damage: Serious eye damage means the production of tissue

damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, and which is not fully reversible within 21 days of application. Any chemicals or chemical ingredients exhibiting any of the criteria in Table 6 shall be designated as a chemical or chemical ingredient of concern for serious eye damage.

Table 6. Criteria For Adverse Eye Effects

Criteria
A chemical or chemical ingredient that when applied to the eye of an animal produces: effects in at least one animal on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or in at least 2 of 3 tested animals, a positive response of: -corneal opacity ≥ 3, and/or -iritis > 1,5, or A chemical or chemical ingredient that when applied to the eye of an animal produces: in at least in 2 of 3 tested animals, a positive response of: -corneal opacity ≥ 1 and/or -iritis ≥ 1, and/or -conjunctival redness ≥ 2 and/or -conjunctival oedema (chemosis) ≥ 2 calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material.

(3) Germ cell mutagenicity and genetic toxicity: Chemicals or chemical ingredients shall be designated chemicals of concern for germ cell mutagenicity if they exhibit any of the criteria shown in Table 7.

Table 7. Criteria For Germ Cell Mutagens

Criteria
A. Any chemicals or chemical ingredients known to induce heritable mutations or that are regarded as if they induce heritable mutations in the germ cells of humans based on evidence from epidemiological studies, positive result(s) from in vivo heritable germ cell mutagenicity tests in mammals. or positive result(s) from in vivo somatic cell mutagenicity tests in mammals; or B. Chemicals or chemical ingredients which may induce heritable mutations in the germ cells of humans, based on: -positive evidence obtained from experiments in mammals and/or from in vitro experiments, obtained from: -somatic cell mutagenicity tests in vivo, in mammals; or -other in vivo somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays

(4) Reproductive Toxicity: Reproductive toxicity includes adverse effects on sexual function and fertility in males and females, as well as developmental toxicity in offspring. For the purpose of categorization for reproductive toxicity, any chemical or chemical ingredient meeting the criteria listed in Table 8 shall be designated as a chemical of concern for reproductive toxicity.

Table 8. Criteria For Reproductive Toxicants

Criteria
Known or presumed human reproductive toxicant-Chemicals or chemical ingredients that are known to have produced an adverse effect on sexual function and fertility, or on development, in humans, or, where there is evidence from animal studies to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans; or Suspected human reproductive toxicant-Chemicals or chemical ingredients for which there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development.

(5) Carcinogenicity: A chemical or chemical ingredient that has not been tested for carcinogenicity may be classified based on tumor data from a structural analogue, together with consideration of other important factors such as formation of common significant metabolites; e.g. for benzidine congener dyes. Any chemical or chemical ingredient meeting the hazard criteria shown in Table 9 shall be designated as a chemical of concern for carcinogenicity.

Table 9. Criteria For Carcinogens

Criteria
Any known or presumed human carcinogens, or suspected human carcinogens, as designated by any authoritative body.

(6) Endocrine disruptors: Any chemical or chemical ingredient that has been characterized by any authoritative body as showing evidence of endocrine disrupting activity in at least one species using intact animals; or, showing at least some *in vitro* evidence of biological activity related to endocrine disruption, shall be designated as a chemical of concern for endocrine disruption.

(7) Respiratory sensitizers: Chemicals or chemical ingredients shall be evaluated in accordance with the criteria presented in Table 10.

Evidence that a chemical or chemical ingredient can induce specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis shall also be considered. Any chemical or chemical ingredient that exhibits the criteria listed in Table 10 shall be designated as a chemical of concern for respiratory sensitization.

Table 10. Criteria For Respiratory Sensitizers

Criteria
Chemicals or chemical ingredients shall be classified as respiratory sensitizers in accordance with the following criteria: (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity; and/or, (b) if there are positive results from an appropriate animal test.

(8) Skin sensitizers: Chemicals or chemical ingredients shall be evaluated in accordance with the criteria in Table 11. For classification as a skin sensitizer, evidence may include, but is not limited to, any or all of the following:

1. positive data from patch testing, normally obtained in more than one dermatology clinic;
2. epidemiological studies showing allergic contact dermatitis caused by the substance; positive data from appropriate animal studies;
3. positive data from experimental studies on humans;
4. well-documented episodes of allergic contact dermatitis, normally obtained in more than one dermatology clinic.

Any chemical or chemical ingredient categorized as a skin sensitizer pursuant to these criteria, or those shown in Table 11, shall be designated as a chemical of concern for skin sensitization.

Table 11. Hazard Criteria For Skin Sensitizers

Criteria
A chemical or chemical ingredient shall be classified as a skin sensitizer in accordance with the following criteria: (i) if there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons; or, (ii) if there are positive results from an appropriate animal test.

(9) Bioaccumulation; The potential for bioaccumulation shall be determined by using either the octanol/water partition coefficient, reported as a log K_{ow}, or its equivalent, or the "bioconcentration factor". The relationship between the log K_{ow} of an organic substance and its bioconcentration as measured by its bioconcentration factor (BCF) in fish is well documented. The experimentally determined BCF provides a better measure and shall be used in preference to the log K_{ow} if available. A BCF in fish of ≥ 500 shall be considered indicative of the potential to bioconcentrate for classification purposes. Any chemical or chemical ingredient with a log K_{ow} ≥ 4 or a BCF ≥ 500 shall be considered as having a real potential to bioaccumulate, and shall be designated as a chemical of concern for bioaccumulation.

(10) Acute aquatic toxicity: Criteria are summarized in Table 12 The system consists of acute and chronic classification categories. The acute and chronic classification categories shall be applied independently. Any chemical or chemical ingredient exhibiting acute or chronic toxicity at or below the concentration ranges given in Table 12, shall be designated as an aquatic toxicant and a chemical of concern for aquatic toxicity.

Table 12. Hazard Criteria for aquatic toxicants

Criteria	
Acute (short-term) aquatic hazard	
96 hr LC50 (for fish)	≤ 1 mg/l and/or

48 hr EC50 (for crustacea)	≤ 1 mg/l and/or
72 or 96 hr ErC50 (for algae or other aquatic plants)	≤ 1 mg/l.
Chronic (long-term) aquatic hazard	
96 hr LC50 (for fish)	≤ 10 mg/l and/or
48 hr EC50 (for crustacea)	≤ 10 mg/l and/or
72 or 96 hr ErC50 (for algae or other aquatic plants)	≤ 10 mg/l
and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log Kow ≥ 4).	
'Safety net' classification	
This applies in cases when data do not allow classification under the above criteria but there are nevertheless grounds for concern. This includes, for example, poorly soluble chemicals or chemical ingredients for which no acute toxicity is recorded at levels up to the water solubility, and which are not rapidly degradable, and have an experimentally determined BCF ≥ 500 (or, if absent, a log Kow ≥ 4), indicating a potential to Bioaccumulate. Such chemicals or chemical ingredients shall be classified as chemicals or chemical ingredients of concern.	

(11) Substances hazardous to the ozone layer: A chemical or chemical ingredient shall be classified as hazardous to the ozone layer, and thus as a chemical of concern, if available evidence concerning its properties, and/or its predicted or observed environmental fate and behavior, indicate that it may present a danger to the structure and/or the functioning of the stratospheric ozone layer. Mixtures shall be classified as hazardous to the ozone layer on the basis of the individual concentration of the chemicals or chemical ingredients contained in the mixture that are classified as Hazardous to the Ozone Layer, in accordance with Table 13. In addition, any chemical or chemical ingredient that has been designated as hazardous to the ozone layer by any authoritative body shall be designated as a chemical of concern for hazardous to the ozone layer.

Table 13. Generic Concentration Limit For Chemicals (In A Mixture) Classified As Hazardous To The Ozone Layer, That Trigger Classification Of The Mixture As Hazardous To The Ozone Layer

Classification Of The Substance	Classification Of The Mixture
Hazardous To The Ozone Layer	Concentration > 0.1%

6xxxx.8 Prioritization of Chemicals of Concern

(a) Unless otherwise prohibited by law, a manufacturer of a consumer product that contains one or more chemicals of concern who makes or will make that product available for use in California, shall determine the appropriate priority for each chemical of concern contained in that product based on the following:

(1) Priority 1 chemicals of concern include any new or existing chemical that is identified as a chemical of concern and that is:

a. Reasonably anticipated to be released to the environment during use, reuse, reclamation, or during or after disposal of the consumer product, or during reasonably foreseeable use of the consumer product (e.g., children putting toys into their mouths); or,

b. to which humans are being or have been exposed based on data from the California Environmental Contaminant Biomonitoring Program, or any other biomonitoring studies conducted by an authoritative body under appropriate scientific guidelines and procedures.

(2) Priority 2 chemicals of concern include any new or existing chemical identified as a chemical of concern and that does not otherwise meet the priority 1 criteria described in subsection (a)(1) of this section, and that is encapsulated in such a manner that it will not be released to the environment during the normal intended use of the consumer product containing the chemical or chemical ingredient, but it may be released to the environment during reclamation or disposal.

(3) Priority 3 chemicals of concern include any new or existing chemical identified as a chemical of concern and that does not otherwise meet the priority 1 or 2 criteria described in subsections (a)(1) or (2) of this section, respectively, and that is encapsulated in such a manner that it will not be released to the environment during the normal intended use of the consumer product containing the chemical or chemical ingredient, or during reclamation or disposal.

(b) The prioritization required pursuant to subsection (a) of this section shall be obtained by the following dates:

(1) For an "existing" chemical, no later than one year from the effective date of these regulations.

(2) For an "existing" chemical in a "new use" application, before making any consumer product containing the new use application of that chemical available for use in California.

(3) For a "new" chemical, before making the consumer product containing the new chemical available for use in California.

6xxxx.9 Supply Chain Information Dissemination Requirements

(a) Unless otherwise prohibited by law, a manufacturer of a consumer product that contains one or more priority 1, 2, or 3 chemicals of concern, as described in section 6xxxx.8 of this article, who makes that product available for use in California, either through one or more transferees or directly to a consumer, shall provide each of its transferees, or its direct consumer, as appropriate, with documentation that does the following:

(1) identifies the respective hazard categories for the chemicals of concern contained in the product (e.g., acute toxicity, carcinogenicity, reproductive toxicity, etc.) and their respective priority, as determined pursuant to sections 6xxxx.7 and 6.xxxx.8 of this Article, respectively;

(2) identifies possible routes of exposure to the chemicals of concern contained it the product;

(3) provides notice that the product is subject to the alternatives analysis requirement pursuant to Article XX, and specifies the date by which the alternatives analysis shall be completed pursuant to Article XX;

(4) identifies the date on which the alternatives analysis was completed, as applicable; and,

(5) specifies the address and contact information where a copy of all documentation required to show compliance with this Article, and Article XX, may be obtained upon written request by the Department.

(b) Notwithstanding subsection (a) of this section, if the manufacturer of a consumer product who makes that product available for use in California, either through one or more transferees or directly to a consumer, determines that the product does not contain a chemical of concern, the manufacturer shall provide each of its transferees, or its direct consumer, as appropriate, with documentation stating that the respective product

does not contain any chemicals of concern, and specifying the address and contact information where a copy of all documentation required to show compliance with this Article may be requested in writing by the Department, including all documentation that was relied upon to make the determination that the product in question does not contain any chemicals of concern.

(c) A manufacturer is prohibited from making a consumer product available for use in California unless the manufacturer provides the documentation required by subsections (a) or (b) of this section, as applicable, to each of its transferees, or to its direct California consumers, as appropriate.

(d) The manufacturer shall maintain all documentation relied upon to achieve compliance with this Article during the time that manufacturer makes that product available for use in California, and for at least three years thereafter. The manufacturer shall make all documentation relied upon to achieve compliance with this Article available to the Department within 30 days of a written request from the Department.

(e) A transferee in a distribution system for a product made available for use in California shall not transfer a consumer product to the next person in the distribution system, or directly sell, lease or supply a consumer product to a California consumer, without also concurrently providing that person with the documentation required by subsection (a) of this section.

(f) Each transferee shall keep a copy of the documentation required by subsections (a) or (b) of this section for a period of three years following the last date the consumer product was transferred to the next person in the distribution system, or directly to a California consumer, as appropriate, and for at least three years thereafter. Each person in the distribution system shall make that documentation available to the Department within 30 days of a written request from the Department.

Article XX. Alternatives Analysis

Section 6xxxx.10. Applicability

(a) Any consumer product made available for use in California that contains one or more prioritized chemicals of concern, as determined pursuant to Article X, shall be evaluated in accordance with the alternatives analysis process contained in this article.

(b) A manufacturer of a consumer product to which this article applies shall evaluate the product using the alternatives analysis process contained in this article.

(c) The alternatives analysis required by this article shall include the following components:

(1) Identification of all potential alternatives pursuant to section 6xxxx.12;

(2) Comparison of each potential alternative with the consumer product based on the hazard categories specified in Article X for the chemicals of concern in the consumer product pursuant to section 6xxxx.13;

(3) Identification and evaluation of the potential hazards, critical exposure pathways and life cycle impacts associated with the subject consumer product and with the identified potential alternatives pursuant to sections 6xxxx.14 through 6xxxx.17.

(d) The alternatives analysis required by this article shall be completed on or before one year from the date of completion of the hazard categorization required in section 6xxxx.7.

(e) Notwithstanding subsections (b) and (d), the Department may grant a petition for a variance for any provision in this article pursuant to section 6xxxx.21.

Section 6xxxx.10.1. Standards for Consumer Products.

(a) Except as provided in section 6xxxx.10.2 of this article, no person shall make available for use in California any consumer product that is subject to this article, but has not been evaluated pursuant to sections 6xxxx.12 through 6xxxx.18.

(b) Except as provided in section 6xxxx.10.2 of this article, no person shall make available for use in California any consumer product that is subject to this article, or safer alternative thereto, that has been evaluated pursuant to sections 6xxxx.12 through 6xxxx.18 of this article, but for which the response actions required by section 6xxxx.20 have not been taken.

6xxxx.10.2. Exemptions.

(a) This article shall not apply to a consumer product that is made available for use in California for the sole purpose of redistribution, sale or lease for use outside of California.

(b) This article shall not apply to a consumer product, or any safer alternative thereto, if any of the applicable requirements prescribed in sections 6xxxx.12 through 6xxxx.20 are otherwise prohibited by law.

Section 6xxxx.11. Definitions

When used in this article, the following terms have the meanings given below:

"Acidification" means the potential of emissions such as sulfur dioxide (SO_2), nitrogen oxides (NO_x), ammonia (NH_3), hydrochloric acid (HCl), etc. to directly or after conversion to other substances lower the pH of soil and water bodies.

"Air emissions" means air pollutants including ozone precursors, particulate matter (both PM_{10} and $PM_{2.5}$), and secondary organic aerosols; air toxics; stratospheric ozone depleting compounds, and greenhouse gases/materials.

"Allocation" means the partitioning and attribution of input or output flows of a process or a product system.

"Chemical of concern" (CoC) has the meaning given to it in section 6xxxx.3.

"Climate change" means the condition caused by the greenhouse effect which is induced by greenhouse gas emissions. Global Warming Potential means the value as specified in the Intergovernmental Panel on Climate Change (IPCC) 1995 Second Assessment Report (SAR), as reported in Table 2.14, in Climate Change 2007: The Physical Sciences Basis. Contribution of Working Group I to the Fourth Assessment Report (FAR) of the Intergovernmental Panel on Climate Change.

"Data quality" means a method for evaluating the quality of data that includes technological, geographical and time-related representativeness, as well as completeness and precision.

"Ecotoxicity" means an attribute that addresses impacts to ecosystems as a result of toxicological mechanisms due to exposure to substances in the environment. (e.g.,the potential for biological, chemical or physical stressors to affect or to disrupt the natural biochemistry, physiology, behavior and interactions of the living organisms that comprise the ecosystem.)

"Emission" means a chemical or physical discharge (e.g.,of a substance, heat, noise.) into the environment.

"End-of-life" means a product at the end of its useful life that will undergo waste management or reuse.

"Environmental assessment" means a detailed study of the reasonably foreseeable significant effects on the environment, beneficial as well as adverse, of a product, service or process. Life Cycle Assessment (LCA) and Environmental Risk Assessment (ERA) are examples.

"Environmental impact" means any change to the environment, whether adverse or beneficial, wholly or partially resulting from an activity, product or service.

"Eutrophication" means excessive enrichment of terrestrial and aquatic ecosystems with nutrients such as nitrogen and phosphorus, and the associated adverse biological effects, resulting in changed species composition, especially displacement of sensitive species. (e.g., the degradation of excess organic

material in receiving waters consumes oxygen resulting in oxygen deficiency and fish kill.)

"Functional unit" means the properties of a product used to establish a standardized frame of reference for comparison. A product property is to be included in the functional unit when it is an obligatory product property, e.g.,. a property that the alternative product must have in order to be at all considered as a relevant alternative. The functional unit describes and quantifies those properties of the product that must be present for the studied substitution to take place. These properties (e.g., the functionality, appearance, stability, durability, ease of maintenance) are in turn determined by the requirements in the market in which the product is to be sold.

"Functionally equivalent" means an alternative that performs the same function as the consumer product. This is determined by the person conducting the alternatives analysis and is likely to be product- and process-specific.

"Global warming" means changes in the global, average surface-air temperature and subsequent change of various climate parameters and their effects such as storm frequency and intensity, rainfall intensity and frequency of flooding.

"Human toxicity" means the degree to which a chemical or chemical ingredient elicits a deleterious or adverse effect upon the biological system of humans exposed to the chemical or chemical ingredient over a designated time period.

"Impact assessment" means the third phase of an LCA. This phase is concerned with understanding and evaluating the magnitude and significance of the potential environmental impacts of the product(s) under study.

"Input" means a material or energy flow that enters a unit process including raw materials, intermediate products, co-products, and waste for treatment.

"Land use" means the use of land and/or the change of that use, considering land occupation as well as transformation impacts related to use and conversion (transformation) of land area by product-related activities such as agriculture, roads, housing, mining, etc. Land occupation considers the effects of the land use, the amount of area involved and the duration of its occupation (quality-changes multiplied with area and duration). Land transformation considers the extent of changes in land properties and the area affected (quality changes multiplied by the area).

"Life cycle" means consecutive and interlinked stages of a product system, including initial design, raw material acquisition, manufacturing, and use to final disposal.

"Life Cycle Assessment (LCA)" means the compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle.

"Make available for use in California" has the meaning given to it in section 6xxxx.3.

"Output" means a product, material or energy flow that leaves a unit process including raw materials, intermediate products, co-products, wastes and releases (e.g., emissions to air and discharges to water and soil).

"Potential alternative" means a change in chemicals, materials, production processes or design for a particular product. Potential alternatives may include, but are not limited to, alternatives resulting in chemical substitution or elimination, process change, material substitution, product redesign, or a change in systems or operations.

"Primary data" means data that are collected, measured or estimated specifically for a product system.

"Process" means a set of interrelated or interacting activities that transforms inputs into outputs.

"Resource depletion" addresses impacts due to the use of natural resources, either renewable or non-renewable, and either biotic or abiotic.

"Safer alternative" means a potential alternative for a product that results in reduced hazard, exposure and ecological impacts without resulting in significant life cycle impacts.

"Secondary data" means data gathered from other than primary sources,(e.g. data base, industry, literature or governmental sources)

"Sensitivity and uncertainty analysis" means a step of the LCA Interpretation phase to assess the robustness of the overall LCA results with respect to variations and uncertainties in the system boundaries, methods and data used. These analyses provide systematic procedures for estimating the effects of the choices made regarding methods and data on the outcome of a study.

"Societal cost" means the external costs of an activity, product or system (e.g., not including the value of all the resources used in providing a product or service), including the value of all resulting impacts to human health and the environment from production, use and end-of-life. The sum of the costs of externalities (societal) and the priced resources makes up the total cost.

"Substitution" means the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances.

"System boundary" means a set of criteria specifying which unit processes are part of a product system to identify the interface between that product system and the environment or other product systems.

"Transparency" means an open, comprehensive and understandable presentation of information.

"Terrestrial toxicity" means an attribute that addresses impacts to terrestrial ecosystems as a result of toxicological mechanisms due to exposure to substances in the environment. (e.g.., the potential for biological, chemical or physical stressors to affect or to disrupt the natural biochemistry, physiology, behavior and interactions of the living organisms that comprise the ecosystem.)

"Uncertainty" means the lack of certainty such as in the prediction of a certain outcome, in a measurement, or in an assessment results. It is a general term used to cover any distribution of data caused by either random variation, measurement precision or bias. In LCA, evaluation or measurement of uncertainty is an on-going process and relates to all the elements of data quality.

"Unit process" means the smallest portion of a product system for which data are analyzed when performing a life cycle assessment.

Section 6xxxx.12. Identification of Potential Alternatives

(a) A manufacturer shall identify all functionally equivalent potential alternatives using information regarding the production, use and disposal of the chemical of concern and the consumer product containing the chemical of concern throughout the life cycle and any other information the person conducting the analysis deems to be relevant. To identify potential alternatives the manufacturer shall consider all of the following factors:

(1) the function of the consumer product;

(2) the function of the chemical of concern in the consumer product;

(3) the performance factors relevant to the specific function of the consumer product and specific function of the chemical of concern in the consumer product.

(b) If no potential alternative is identified for the consumer product, all of the following requirements shall apply:

(1) The consumer product shall be subject to the response action specified in section 6xxxx.20(b)(1)(B), 6xxxx.20(b)(1)(D), or 6xxxx.20(d)(3), if authorized by the Department;

(2) The manufacturer shall document the identification of alternatives, including all of the information compiled to complete subsections (a) and (b) of this section, and retain this documentation until a new alternatives analysis is completed;

(3) The manufacturer shall provide notification to the Department that no potential alternative was identified, as described in the requirements for the alternatives analysis findings report in accordance with section 6xxxx.17(b) and the date of this notification shall be added to the supply chain documentation required pursuant to section 6xxxx.9;

(4) The alternative analysis process specified in this article shall be repeated no later than two years from the date that the notification required pursuant to subsection (b)(3) was provided to the Department.

Section 6xxxx.13. Hazard Categorization Comparison

(a) For each potential alternative identified pursuant to section 6xxxx.12, a person conducting the alternatives analysis shall perform hazard categorization in accordance with the process specified in Article X to identify chemicals of concern in the potential alternative(s).

(b) If a potential alternative is found to use or contain a chemical of concern that is assigned to the same hazard categories as the chemical of concern in the consumer product, the following shall apply:

(1) If the chemical of concern in the potential alternative has been assigned to any additional hazard categories, the alternative shall be eliminated from further consideration as a potential alternative, unless the analyst demonstrates through the assessment of hazards, exposure and life cycle impacts outlined in this article that use of the chemical of concern in the potential alternative results in no relevant risk of exposure during reasonably foreseeable use of the product.

(2) If all of the potential alternatives identified pursuant to section 6xxxx.12 are eliminated from further consideration, the following requirements shall apply:

(A) The consumer product shall be subject to the response action specified in section 6xxxx.20(b)(1)(B), 6xxxx.20(b)(1)(D), or 6xxxx.20(d)(3), if imposed by the Department**;**

(B) The manufacturer shall document the hazard categorization comparison of the potential alternatives, including all of the information compiled to complete subsections (a) and (b) of this section, and retain this documentation in accordance with section 6xxxx.xx;

(C) The manufacturer shall provide notification to the Department that all potential alternatives have been eliminated from consideration, as described in the requirements for the alternatives analysis findings report in accordance with section 6xxxx.17(c) and the date of this notification shall be added to the supply chain documentation required pursuant to section 6xxxx.6;

(D) The alternative analysis process specified in this article shall be repeated no later than two years from the date that the most recent hazard categorization comparison required by this section was completed.

Section 6xxxx.14. General Requirements for Assessment of Hazards, Exposure and Life Cycle Impacts

(a) A person conducting the alternatives assessment shall ensure that the assessment of the hazards, exposure and life cycle impacts of a product and potential alternatives meets the following general requirements:

(1) Relevance: The information sources, data and methods used to conduct the analysis are appropriate to the assessment of the impacts arising from the product and alternative(s) under study;

(2) Completeness: The assessment includes all inputs and outputs that provide a material contribution to the assessment of impacts;

(3) Consistency: The data and information used provides meaningful comparisons of results;

(4) Accuracy: Bias and uncertainties are minimized;

(5) Transparency: Sufficient information is disclosed to allow other persons to validate results and make associated decisions with confidence.

(b) The alternatives assessment shall identify impacts associated with implementation of alternatives, including, but not limited to:

(1) Increased hazard

(2) Increased exposure

(3) Increased negative life cycle impacts

(4) Increased ecological impacts

Section 6xxxx.15. Methodological Approach for Assessment of Hazards and Exposure

(a) For the product and any alternatives that have not been eliminated in section 6xxxx.13(b), hazard and exposure information shall be collected for each chemical of concern identified in the consumer product and alternatives as specified below:

(b) Hazard information shall be collected for the specified criteria, until such time as the criteria are modified or superseded by criteria published by the Office of Environmental Health Hazard Assessment and posted on the Toxics

Information Clearinghouse website. These criteria shall be evaluated in accordance with the procedure contained in section 6xxxx.7 and quantitative results shall be collected:

(1) Acute toxicity
(2) Specific target organ toxicity (single exposure)
(3) Target organ toxicity (repeated exposure)
(4) Adverse eye effects
(5) Mutagenicity and genetic toxicity
(6) Reproductive toxicity
(7) Carcinogenicity
(8) Endocrine disruption
(9) Respiratory sensitization
(10) Skin sensitization
(11) Bioaccumulation
(12) Aquatic toxicity
(13) Hazardous to the ozone layer

(c) Exposure information shall be collected for the following properties and evaluated by assigning a high, medium or low impact assessment in accordance with the criteria depicted in Table XX – Impact Assessment Criteria:

(1) Potential dermal contact with the chemical of concern during intended product use
(2) Potential ingestion of the chemical of concern during intended product use
(3) Potential inhalation of the chemical of concern during intended product use.

Table XX – Impact Assessment Criteria for Exposure

Potential dermal contact with COC during product use	Dermal contact > 8 hours/day	Dermal contact < 8 hours/day	No known or suspected dermal contact
Potential ingestion of COC during product use	Known ingestion potential	Suspected ingestion potential	No known or suspected ingestion potential
Potential inhalation of COC during product use	Inhalation contact > 8 hours/day	Inhalation contact < 8 hours/day	No known or suspected inhalation potential

Section 6xxxx.16. Methodological Approach for Assessment of Life Cycle Impacts

(a) For the product and each potential alternative that has not been eliminated in section 6xxxx.13(b), the life cycle impacts shall be determined as described in this section.

(b) The following approach shall be taken to determine if significant impacts would result from a potential alternative:

(1) Review any differences in the functionality or use phase lifetime of the product and the alternatives and find equivalence so that comparison can be made.

(2) Assess any significant differences in inputs and outputs from raw materials acquisition to end-of-life phases of the product and alternative lifecycles.

(3) For those phases with significant differences, find relevant and most representative data to assess the impacts associated with the product and the alternatives,

(4) Assign data to impact categories, assess the impacts, and quantify differences between the product and the alternatives,

(5) Identify improvements that can be made to reduce any significant trade-offs identified between each alternative and the product, and refine the impact results noting if the modifications result in functionality differences or in significant changes in any excluded life cycle phases.

(c) Functional equivalence

The impact assessment specified in this section shall apply to the original product and functionally equivalent alternatives. A general description of the product and its intended and reasonably foreseeable uses shall be provided as supporting information. Comparisons between alternatives and the original product shall be made on the basis of the same function(s), quantified by the same functional unit(s).

(d) Life Cycle system boundary and initial review

The system boundary and all underlying processes shall be clearly defined for each product and alternative(s) as well as underlying processes. Comparable life cycle phases may be identified. The boundary can be reduced based on equivalence for comparative evaluations. The specific life cycle phases, processes, inputs and outputs that shall be included at a minimum are those that exhibit or may exhibit a significant difference between the original product and the given alternatives under study. Such phases include:

(1) Raw materials,

(2) Energy consumption,

(3) Manufacturing,
(4) Transportation,
(5) Use, and
(6) End-of-life.

Each life cycle phase shall be reviewed to determine if significant differences in the inputs or outputs, costs and energy use for each step or process is found. The entire life cycle shall be considered unless specific life cycle phases or processes have been deemed equivalent and excluded from further study.

(e) Information/data collection

(1) The qualitative information and quantitative data collected for the analysis shall be relevant to all impacts occurring within the system boundary of the product and alternatives under comparison. When information and data, whether measured, calculated or estimated, have been collected from public sources, the source shall be referenced. Qualitative information may be gathered when quantitative data are not available or accessible.

(2) When identifying data for use, preference shall be given as follows:

(A) For time-related coverage: data that are time-specific to the product being assessed shall be preferred (e.g., age of data and the minimum length of time over which data are collected). Where the data associated with any life cycle phase of a product vary over time, the data shall be collected over a period of time sufficient to establish the data needed to characterize the life cycle of the product and its alternative(s). Where a product is made available on a continuing basis, the information used for the assessment of impacts shall cover at least one year. Where a product or a component part is differentiated by time (e.g. seasonal products), the information collected shall cover the particular period associated with the production of the product or component;

(B) For geographical specificity: data that are geographically-specific to the product being assessed shall be preferred (e.g. district, country, region);

(C) For technology coverage: data that are technology-specific to the product being assessed shall be preferred (e.g., whether the data relates to a specific technology or a mix of technologies);

(D) For accuracy of the information: data that are most accurate shall be preferred (e.g. data, models and assumptions);

(E) For precision: data that are more precise (i.e. has the lowest statistical variance) shall be preferred (i.e., measure of the variability of the data);

(F) For completeness: the data that are primary, and the degree to which the data represents the population of interest shall be

preferred (i.e., the sample size is large enough, the periodicity of measurement is sufficient, etc.);

(G) For consistency: data selection that is carried out uniformly in the various components of the analysis shall be preferred; and

(H) For reproducibility: methods and data values that would allow an independent practitioner to reproduce the results reported in the study shall be preferred.

(I) The uncertainties of the information and the assumptions made when collecting data shall be stated relevant to the criteria above.

(3) The economic and environmental information shall be collected for each process included in the system boundary under study as specified below:

(A) Environmental Information:

(i) materials consumption
(ii) ancillary materials consumption including recyclable material content
(iii) energy consumption and demand
(iv) water consumption
(v) air emissions
(vi) solid waste raw
(vii) wastewater releases
(viii) liquid waste
(ix) end of life options
(x) reusability and recyclability
(xi) land use change

(B) Economic Information:

(i) capital investment
(ii) operations and maintenance cost
(iii) cost for resources
(iv) energy costs
(v) insurance and other internal costs
(vi) byproduct value
(vii) waste disposal and treatment cost
(viii) outsourced service cost
(ix) corporate image and brand value
(x) consumer acceptance
(xi) worker wellness and morale
(xii) external costs, such as societal health costs and environmental damage costs
(xiii) non-compliance liability

(f) Impact assessment

(1) The selection of impact categories shall reflect a comprehensive set of environmental and economic characteristics related to the product system being studied. A set of impact categories shall include, but not be limited to:

- (A) Ecological impacts
  - (i) Global warming
  - (ii) Acidification
  - (iii) Terrestrial toxicity
  - (iv) Photochemical smog
  - (v) Stratospheric Ozone depletion
  - (vi) Eutrophication
  - (vii) Water quality (e.g. BOD, COD and TSS)
  - (viii) Ecotoxicity (including both aquatic and terrestrial ecosystems)
  - (ix) Radioactivity
- (B) Human health impacts
  - (i) Occupational health effects
  - (ii) Human toxicity and Public health effects (excluding work environment)
  - (iii) Human social disturbance effects
- (C) Resource depletion impacts
  - (i) Energy consumption
  - (ii) Natural resource (renewable and non-renewable) consumption
  - (iii) Energy efficiency
  - (iv) Water consumption and conservation
  - (v) Land use
- (D) Economic impacts
  - (i) Direct corporate cost
  - (ii) Indirect corporate cost
  - (iii) Future and contingent liability cost
  - (iv) Corporate intangible cost
  - (v) Societal/External cost (due to human health and environment impact social costs)

(2) While quantitative results are desired, the practitioner of the study may choose qualitative or semi qualitative metrics (e.g. low, medium, high level; or 1-5 rating system) based on data quality. The method of calculating results (e.g., the characterization model and characterization factors used) shall be identified and documented, including the value-choices and assumptions used.

(3) The comparative impact assessment shall be conducted by evaluating the results of the alternatives based on potential benefits and tradeoffs versus the original product. The processes resulting in significant impacts for the alternatives versus the original product are then identified. Sensitivity of the results should be quantified by re-evaluating the results considering the maximum (worst acceptable) and minimum (best viable) data for the identified processes.

(4) Further improvement shall be considered to mitigate the significant impacts identified. Improvements include changes such as reformulation, process improvements and end-of-life management options. A subsequent iteration of the assessment steps starting with (e) with improvements identified shall be conducted, checking to assure that the system boundary and functional unit are not modified.

(5) The economic analysis shall provide a range of projected capital costs and operating costs, societal costs, cost savings, and revenues for the alternatives under study in comparison to the original product containing the chemical of concern. All life cycle phases and processes analyzed in the environmental analysis shall be included in the economic analysis. Additional processes and phases may need to be included to adequately assess costs, including, but not limited to external costs.

(6) The environmental mechanism and decision criteria that relate the information collected in (e) to the impact category in (f) shall be described and documented. The appropriateness of the decision criteria used for deriving the category metrics in the context of the goal and scope of the study shall be described and documented. The results of the impact assessment shall be valid until there is a change in the design, manufacturing or formulation of the product which is being assessed.

(g) Documentation

(1) The results and conclusions of the study shall be completely and accurately documented. The results, data/information, methods and assumptions shall be transparent and presented in sufficient detail to allow the reader to comprehend the assumptions inherent in the study and trade-offs found. For information and data that proves to be significant for the conclusions of the comparison, details about the relevant information collection process and the time when information has been collected shall be documented and disclosed. The document shall also allow the results and interpretation to be used in a manner consistent with the purposes of this section.

(2) The results of the study shall be made available to the Department within 30 days of a request from the Department in the form of a report that contains, at a minimum, the following sections:

A. Administrative Information

1. the name, title, and affiliation of the person who conducted the study ;
2. date of report;
3. statement that the study has been conducted in accordance with the requirements of this article.

B. Product System Description
1. statement of functional characteristics of the product;
2. functional unit for the product and equivalence for the alternative(s) studied;
3. a list of and justification for any equivalent life cycle stages and processes omitted if any;
4. a description of the system boundary studied.

C. Data Sources and Data Quality
1. sources of data;
2. data/information collection procedures;
3. calculation procedures;
4. validation of data and data quality assessment.

D. Operational Assumptions
1. assumptions about electricity production;
2. cut-off criteria for initial inclusion of inputs and outputs in any given process;
3. full transparency in terms of value-choices, rationales and expert judgments.

E. Inventory Analysis
1. identification of energy and material inputs and outputs;
2. qualitative or quantitative description of processes.

F. Impact Assessment
1. impact categories and category indicators considered, including a rationale for their selection;
2. descriptions of or reference to all characterization models or scoring criteria, characterization factors or rating methods used, including all assumptions;
3. descriptions of or reference to all value-choices used in relation to impact categories, characterization models, characterization factors, and scoring criteria, if applicable, including justification for their use and their influence on the results;
4. the impact evaluation procedures, calculations and results of the comparative study.

G. Interpretation
1. iteration and improvement methodology description considering data ranges for significant processes identified;
2. evaluation of the significance of the impact differences found;

3. description of the refinements considered to mitigate the impacts of alternatives.

Section 6xxxx.17. Comparison of Alternatives

(a) The properties of the potential alternatives identified in section 6xxxx.12 shall be compared to those of the consumer product in an Alternatives Analysis Findings Report (Report). The Report shall contain, at a minimum, the following sections:

(b) The first section of the Report shall contain a concise description of the consumer product being evaluated and a description of each potential alternative that was considered pursuant to section 6xxxx.12(a). For each potential alternative that was excluded from consideration, the report shall describe in detail the justification for excluding the potential alternative. The description of the product and alternatives shall be consistent with the requirements of section 6xxxx.12(a) and shall include all the factors identified in that section, including:

(1) the function of the consumer product;

(2) the function of the chemical of concern in the consumer product;

(3) performance factors relevant to the specific function of the consumer product and specific function of the chemical of concern in the consumer product.

(c) The second section of the alternatives analysis report shall contain a report of the results of hazard categorization comparison for all chemicals of concern found in the potential alternatives, pursuant to section 6xxxx.13. If all of the potential alternatives were eliminated from consideration, the report shall describe in detail the justification for elimination.

(d) The third section of the alternatives analysis report shall contain a comparison of alternatives. The properties of the potential alternatives identified shall be compared to those of the consumer product as depicted in Table XX - Alternatives Analysis Summary.

(1) In the summary table, the hazard, exposure and life cycle impacts (ecological impacts, resource consumption impacts, economic impacts) for the consumer product shall be reported using one or a combination of the following methods:

(A) reported in quantitative terms with clear units,

(B) reported as high, medium or low impact, as detemined by Table XX—Impact Assessment Criteria for Exposure, or

(C) left blank if information cannot be reported for any given attribute.

(2) For each alternative that was not eliminated from consideration pursuant to section 6xxxx.13(b), the results of the hazard and exposure assessment and the results of the life cycle impact assessment shall be reported.

(3) The attributes of the alternatives shall either be reported in quantitative terms with the same units used for the consumer product in 6xxxx.17(d)(1) for the same impact, or tabulated in relation to the consumer product using a qualitative scale as follows:

(A) For those attributes in which the potential alternative achieves approximately the same impact assessment value as the consumer product, the comparison is depicted by an equal sign (=).

(B) For those attributes for which the impact assessment of the potential alternative is unknown, the comparison is depicted by a question mark (?).

(C) For those attributes for which the impact assessment of the potential alternative is known relative to the consumer product, the comparison shall be depicted by a qualitative scale with sufficient detail to express the results of the comparison accurately.

(D) An example of a permissible qualitative scale follows:

\+ the alternative is less impactful / less hazardous than the consumer product;

++ the alternative is significantly less impactful / less hazardous than the consumer product;

\- the alternative is more impactful / more hazardous than the consumer product;

-- the alternative is significantly more impactful / more hazardous than the consumer product;.

(E) A different qualitative scale may be used for comparison of alternative with the consumer product if the replacement scale contains sufficient detail to determine significant impacts.

(e) The fifth section of the alternatives analysis report shall describe the process used to decide among alternatives, and report which alternative was chosen, or if no alternatives were chosen. This description shall include the following:

(1) Identification of any potential alternatives that are clearly superior to the product with regard to the hazard and exposure impacts;

(2) Identification of any potential alternatives that are clearly superior to the product with regard to the ecological impacts;

(3) Identification of any potential alternatives that are clearly superior to the product with regard to the resource impacts;

(4) Identification of any potential alternatives that are clearly superior to the product with regard to the economic impacts;

(5) The decision factors used to either select an alternative or retain the product unchanged;

(6) Identification of any attributes that will be significantly more impactful and the dominant life cycle phase where the impact occurs as a result

of the selection as determined by comparison of the product and potential alternatives;

(7) Any other factors the analyst deems relevant to the decision.

(f) The sixth section of the alternatives analysis report shall state:

(1) the person who conducted the study and their affiliation;

(2) date of the report;

(3) a signed statement that the study and findings report have been conducted in accordance with the requirements in this article.

(g) The seventh section of the alternatives analysis report shall describe an implementation plan and schedule for implementing an alternative, if applicable.

1 **Table XX – Alternatives Analysis Summary**

Impacts		Product	Alt A	Alt B	Alt C
Hazard and Exposure Impacts	Acute toxicity				
	Specific target organ toxicity (single exposure)				
	Target organ toxicity (repeated exposure)				
	Adverse eye effects				
	Mutagenicity and genetic toxicity				
	Reproductive toxicity				
	Carcinogenicity				
	Endocrine disruption				
	Respiratory sensitization				
	Skin sensitization				
	Bioaccumulation				
	Aquatic toxicity				
	Hazardous to the ozone layer				
	Occupational Health Effects				
	Other human health and public health effects				
	Human social disturbance effects				
	Dermal contact with COC during product use				
	Potential ingestion of COC during product use				
	Potential inhalation of COC during product use				
Ecological Impacts	Global warming				
	Acidification				
	Photochemical smog				
	Stratospheric Ozone depletion				
	Eutrophication				
	Water quality (eg. BOD, COD and TSS)				
	Ecotoxicity (including both aquatic and terrestrial ecosystems)				
	Radioactivity				
Resource Depletion Impacts	Energy consumption				
	Natural resource (renewable and non-renewable) consumption				
	Energy efficiency				
	Water consumption and conservation				
	Land use				
Economic Impacts	Direct corporate cost				
	Indirect corporate cost				
	Future and contingent liability cost				
	Corporate intangible cost				
	External cost (due to human health and environment impact social costs)				

Section 6xxxx.18. Compliance

(a) On or before one year from the date the chemicals of concern in a consumer product subject to article X are prioritized pursuant to section 6xxxx.8, the alternative analysis findings report specified in section 6xxxx.17 shall be completed and made publicly available through an electronic submittal process and posting to a publicly available Internet website. The alternative analysis findings report shall also be submitted to the Department upon request within 30 days.

(b) When the alternative analysis is completed, the date of completion shall be added to the supply chain documentation required pursuant to section 6xxxx.9.

(c) If a safer alternative is not selected for implementation, the following requirements apply:

(1) the alternatives analysis process shall be repeated, and the associated Report shall be revised, every two years, with a reasonable effort to identify safer alternatives that do not require a statement of over-riding socio-economic benefit from the continued use of the consumer product. Whenever the alternative analysis is repeated, the most recent date of completion shall be added to the supply chain documentation required pursuant to section 6xxxx.9; and

(2) the description of the decision process required by section 6xxxx.17(e) shall include a justification for continuing to use the consumer product, which shall include a statement of over-riding socio-economic benefit. The justification shall include the following at a minimum:

(A) a description of how the benefit to society from the continued use of the consumer product outweighs the impacts associated with the chemical of concern in the product

(B) a description of any associated costs from continued use of the consumer product

(C) a description of why no alternatives are economically or technologically viable as substitutes for the consumer product.

(d) All information used to conduct the evaluations and studies pursuant to this article shall be made available to the Department upon request within 30 days. When making information available, information claimed to be trade secret or confidential business information shall be identified but shall not include chemical hazard information pursuant Health and Safety Code Section 25257(f).

(e) The Department may require revision of any part of an alternatives analysis at any time, including submittal of additional information regarding the properties of chemicals, or any of the hazard, exposure or lifecycle impacts.

(f) The process specified in this article represents the minimum level of analysis required. In the alternative analysis, a person may conduct a more comprehensive and/or quantitative analysis. Any person may:

(1) use an independent third party to prepare or validate any or all parts of the analysis.

(2) collaborate with related associates to prepare any or all parts of the analysis.

(3) use any established model or alternatives assessment process that includes all of the factors and attributes for alternatives analysis specified in this article.

Article XXX Response Actions

6XXXXX.20 Regulatory Response Actions

(a) General Response Actions

(1) Upon the completion of the alternatives analysis required by article XX,

(A) the manufacturer shall take response actions pursuant to this article, if either a consumer product or the alternative to be implemented contains a priority chemical of concern or has a significant impact identified pursuant to section 6XXXX.17, provided the response action is not otherwise prohibited by law; or

(B) if the manufacturer implements a safer alternative that does not contain a priority chemical of concern within one (1) year of the completion of the alternative analysis, the manufacturer shall comply with a notification pursuant to subsection (a)(3)(B)2 within 90 days of completion of the alternative analysis. The manufacturer shall comply with articles X and XX, if applicable.

(2) **Response Action Implementation Plan**. When a response action is required, a manufacturer responsible for taking the action shall prepare a detailed response action implementation plan. The plan shall be prepared within ninety (90) days from the date the alternative analysis required by article XX has been completed. The plan shall address either the consumer product or the alternative to be implemented. The plan shall include the following:

(A) name and physical location of the business;

(B) name of contact person and contact information;

(C) six digit North American Industry Classification System codes applicable to activities at the business;

(D) number of employees
(E) identification of the chemicals of concern, and the respective priority for each;
(F) identification of the consumer product, any associated brands, and the applicable article X, section 6XXXX.1(a) product categories;
(G) volume(s) of the chemicals of concern being used;
(H) date the most recent alternative analysis required by article XX was completed;
(I) identification of specific response actions to be taken;
(J) if applicable, the results of the impact assessment required by section 6XXXX.17, including, but not limited to identification of significant impacts, the specific product life phase required by subsection 6XXXX.16(d) in which the impacts occur, and a description of how significant impacts will be mitigated;
(K) identification of laws prohibiting a required response action or required a modification of a response action, if applicable;
(L) timeline for the implementation of the required response action; and
(M) a description of how each response action will be monitored.

A manufacturer responsible for taking the response action shall keep a copy of this plan onsite for a period of three (3) years after the last date that the manufacturer made the consumer product subject to the alternative analysis required by article XX available for use in California. A manufacturer shall make the plan available to the Department within thirty (30) days of a written request; and shall make the information generally available to any interested parties by posting the information on the internet.

(3) **Notification.**

(A)Within ninety (90) days from the date the alternative analysis required by article XX has been completed, a manufacturer shall send an electronic notification to the Department. The notification shall include the information specified in subsections 6XXXX.20(a)(2)(A)-(I) of the response action implementation plan required by subsection (a)(2) of this section. (B) The manufacturer shall add the following information to the supply chain documentation pursuant to section 6XXXX.9.

1. the implementation date for the response actions if a response action is implemented, or
2. the date the determination for no further action if a safer alternative is implemented.

(C) Notwithstanding subsection (3)(B), if the safer alternative has been implemented and the supply chain documentation is no longer required, then only the notification pursuant to subsection (A) is required.

(4) If the Department determines the following:

(A) the A manufacturer responsible for taking response actions has not taken response action pursuant to subsections (b) and (c) of this section, or

(B) the continued availability in California of the consumer product or implemented alternative selected pursuant to section 6xxxx.17, with the implementation of the prescribed response actions, would pose a significant risk to human health or the environment,

the Department may impose response actions, as prescribed in subsections (c) and (d) of this section, provided that the response actions are not otherwise prohibited by law.

(5) The Department may use any data or alternative analysis required by article XX to imposed response actions.

(6) **Considerations for Department Authorized Response Actions.** The Department shall consider the following when determining whether to impose a response action:

(A) Nature of the hazards and potential risk including:

1. hazardous traits, characteristics, and endpoints;
2. potential risks to sensitive populations, including but not limited to, infants, children, and pregnant women; and
3. evaluation of exposure attributes pursuant to section 6XXXX.17 that indicate a significant human health or environmental impact; or

(B) Effectiveness of the response action and the appropriateness of the time frame for completing the response action identified in the response action implementation plan submitted to the Department pursuant to subsection (a)(2) of this section;

(C) Consistency in response actions: The Department will consider how similar situations have been handled in determining the measures to be taken to enforce the regulation; and

(D) Duplicative or conflicting requirements: The Department will consider existing requirements imposed by other agencies.

(7) Not later than sixty (60) days after the Department has provided written notification to a manufacturer responsible for taking response action that the Department has determined that other or additional response actions

are required, a manufacturer shall submit a response action implementation plan for those response actions.

(8) A manufacturer providing information pursuant to this section shall, at the time of the submittal, identify all portions of the information claimed to be a trade secret or confidential business information.

(b) **Response Actions Criteria**

(1) Upon completion of the alternative analysis required by article XX, if a safer alternative has not been implemented, a manufacturer of a consumer product containing a priority chemical of concern shall be subject to the following requirements:

(A) **A potential safer alternative exists but is not implemented**

1. If the chemical of concern is a priority 1 chemical that has been banned by another governmental agency, and there is a potential safer alternative, a manufacturer shall comply with subsections (c)(2), and (c)(3)(A);
2. If the chemical of concern is a priority 1 chemical that has not been banned by another governmental agency, and there is a potential safer alternative, a manufacturer shall comply with subsections (c)(2), and (c)(3)(B); and
3. If the chemical of concern is a priority 2 chemical and there is a potential safer alternative, a manufacturer shall comply with subsections (c)(3)(C); and
4. If the chemical of concern is a priority 3 chemical and there is a potential safer alternative, a manufacturer shall comply with subsections (c)(3)(D); and

(B) **There is no potential safer alternative to be implemented**

1. If the chemical of concern is a priority 1 chemical that has been banned by another governmental agency, and If there is no potential alternative; a manufacturer shall comply with subsections (c)(2), and (c)(3)(B);
2. If the chemical of concern is a priority 1 chemical that has not been banned by another governmental agency, and there is no potential safer alternative, a manufacturer shall comply with subsections (c)(2), and (c)(3)(C); and
3. If the chemical of concern is a priority 2 chemical and there is no safer potential alternative, a manufacturer shall comply with subsections (c)(3)(D).
4. If the chemical of concern is a priority 3 chemical and there is no safer potential alternative, a manufacturer shall comply with subsections (c)(3)(E).

(2) Upon completion of the alternative analysis required by article XX, if the attributes prescribed in subsection 6XXXX.17 of the implemented alternative would have significant impacts in California, the manufacturer shall be subject to the following requirements when the evaluation pursuant to section 6XXXX.17 indicates the following:

(A) if exposure impacts (for ingestion or inhalation which cannot be mitigated to less than significant) and hazard impacts are significant for:

i. acute toxicity;
ii. carcinogenicity;
iii. mutagenicity;
iv. reproductive; or
v. endocrine disruption;

the manufacturer shall be subject to the requirements in subsections (c)(3)(B) of this section when there is a potential safer alternative; and shall be subject to the requirements in subsections (c)(3)(C) of this section when there is no potential safer alternative; and

(B) if exposure risks are significant but can be mitigated to less than significant by use or disposal practices which control access or limit exposure associated with the consumer product, the manufacturer shall comply with subsection (c)(2). The labeling requirement pursuant to subsection (c)(2)(A)1 is applicable; and

(C) if any attribute impacts are significant at the end of life phase, the manufacturer shall be subject to the requirements in subsections (c)(2), (c)(4), (c)(5)(A), and if applicable (c)(5)(F). The labeling requirement pursuant to subsection (c)(2)(A)2 is applicable; and

(D) if exposure risks to workers who are reasonably expected to use the consumer product on a daily or frequent basis are significant, the manufacturer shall be subject to the requirements in subsections (c)(2), (c)(5)(B), and if applicable (c)(5)(F). The labeling requirement pursuant to subsection (c)(2)(A)3 is applicable; and

(E) if greenhouse gas emissions or air qualify impacts are significant, the manufacturer shall be subject to the requirement in subsection (c)(5)(C), and if applicable (c)(5)(F); of this section; and

(F) if water quality impacts, or eutrophication are significant, the manufacturer shall be subject to the requirement in subsection (c)(5)(D), and if applicable (c)(5)(F) of this section; and

(G) if ecotoxicity risk is significant, the manufacturer shall be subject to the requirement in subsection (c)(5)(E), and if applicable (c)(5)(F) of this section.

(c) Response Actions. The response actions to be taken when required pursuant to subsection (b) include the following or combination thereof, to the extent that the response actions are not otherwise prohibited by law:

(1) **No further action**. On or before ninety (90) days from the date the alternative analysis required by article XX has been completed as specified in subsection (a) of section 6XXXX.18, no further action is required if a determination based on alternative analysis has been made that the risk of exposure from continued use of the consumer product is not significant.

(2) **User Notification/Hazard Communication (Labeling)**. On or before one (1) year from the date the alternative analysis required by article XX has been completed, a manufacturer shall provide a label the meets the following requirements:

(A) The label shall include the following information, if applicable:

1. Restricted Use Statement - a description of the specific conditions for use or disposal which mitigate the hazardous traits, hazardous characteristics, and toxic endpoints of the priority chemical of concern to avoid potential significant adverse effects on the environment unless the these impacts have been mitigated by engineered or passive controls which control access or limit exposure of the priority chemical of concern; or
2. Disposal and end of life management requirements - a description of the "regulatory response restrictions" as specified in subsection (c)(4) of this section, if applicable. This description provides instructions for disposing of any unused product, the product packaging, the product container and product stewardship requirements; or
3. Worker Protection Warnings - warnings related to the hazards of the priority chemical of concern and the use of the consumer product by workers that may be reasonably expected to use the consumer product on a daily or frequent basis resulting in significant exposures to the priority chemical of concern.

(B) The information specified in subsection (2)(A) shall be included on one of the following:

1. Packaging Label
   i. The label shall be clearly shown on the packaging. If the consumer product is inside one or more layers of packaging, the label shall be shown on any such layer

which is likely to be the outermost layer during the distribution or use of the product; and

ii. The label shall be placed so that it can be read when the package is set down normally; and

iii. The dimensions of the label shall be not less than 2 inches by 3 inches; and

iv. The font on the label must be printed in legible and indelible characters; or

2. The information shall be clearly printed on the normal packaging label; or

3. The information shall be affixed in some other appropriate manner on packaging too small to allow labeling; or

4. The information shall be included in a packaging insert; or

5. The information shall be posted on a manufacturer's website.

(3) Prohibition. On or before one (1) year from the date the alternative analysis required by article XX has been completed, a manufacturer of a consumer product shall implement any of the following

(A) On and after January 1, 2013 or 2 years after the initial determination of a new priority chemical of concern, whichever date occurs later, consumer products containing a priority chemical of concern shall be prohibited from being made available for use in California.

(B) On and after January 1, 2017 or 5 years after the initial determination of a new priority chemical of concern, whichever date occurs later, consumer products containing a priority chemical of concern shall be prohibited from being made available for use in California.

(C) On and after January 1, 2022 or 10 years after the initial determination of a new priority chemical of concern, whichever date occurs later, consumer products containing a priority chemical of concern shall be prohibited from being made available for use in California.

(D) On and after January 1, 2027 or 15 years after the initial determination of a new priority chemical of concern, whichever date occurs later, consumer products containing a priority chemical of concern shall be prohibited from being made available for use in California.

(E) On and after January 1, 2032 or 20 years after the initial determination of a new priority chemical of concern, whichever date occurs later, consumer products containing a priority chemical of concern shall be prohibited from being made available for use in California.

(4) End-of-Life Management. On or before one (1) year from the date the alternative analysis required by article XX has been completed, a manufacturer of a consumer product shall implement any of the following strategies for managing and reducing the life cycle impacts of the consumer product, including establishing and maintaining:

(A) take-back programs; or

(B) statewide or local recycling or collection programs; or

(C) statewide or local programs to control priority chemical of concerns or consumer product impacts to the environment.

(5) Additional Notifications On or before ninety (90) days from the date the alternative analysis required by article XX has been completed, a manufacturer or, if applicable, a transferee shall provide the notification as specified in subsection (a)(3) to the following:

(A) submit the notification to the Integrated Waste Management Board;

(B) submit the notification to the Department of Industrial Relations:

(C) submit the notification to the Air Resources Control Board;

(D) submit the notification to the State Water Resources Control Board; or

(E) submit the notification to the Department of Fish and Game; or

(F) submit the notification to any boards, departments, and agencies having jurisdiction over a life cycle attribute with significant impacts.

(6) If the response actions specified in subsection (c) need to be modified or the dates specified in subsection (c) of this section are not reasonably attainable, a manufacturer may petition the Department for a modification pursuant to section 6XXXX.21 of this article.

(d) Response Actions. The following response actions may only be authorized by the Department:

(1) Additional Data. The Department may require a manufacturer or, if applicable, the transferee to furnish and transmit to the Department any information related to the consumer product that contains a priority chemical of concern; or a revised alternative analysis required by article XX;

(2) Restrictions. The Department may require a manufacturer or, if applicable, the transferee to impose restrictions or requirements to control access to or limit exposure to the chemical of concern in the consumer product.

(3) Research and Development. If the manufacturer can demonstrate that research is in progress for the priority chemical of concern, and its potential alternatives, through collaboration with other users of the prioritized chemical of concern or by an independent party, the Department may authorize a research and development proposal provided the manufacturer submits to the Department with following documentation:

(A) To apply for a research and development waiver, a manufacturer shall provide to the Department a written research and development notice that identifies the following:

1. The substantive elements of the research and development program;
2. The expected amount of time required for each substantive element;
3. The processes, pollution control equipment, and emissions which are likely to be affected by the program;
4. Potential or expected benefits of the program; and
5. The basis upon which the results of the program will be evaluated.

(B) The substantive elements of the research and development program, which shall include, but are not limited to:

1. Identification and nature of research on a specific product and/or application of a prioritized chemical of concern,
2. Design of product with substitute chemicals that are not priority chemicals of concern,
3. Use of chemical ingredients that are restorative of the environment,
4. Design chemical products to be effective, but reduce toxicity.
5. Use chemicals that readily break down into innocuous substances in the environment.
6. Other criteria as deemed necessary and appropriate.

(C) The research and development program being undertaken shall include a provision for the employment of qualified independent firm(s) to prepare written reports at least annually which evaluate each completed significant stage of the research and development program, including all relevant information and data generated by the program.

(4) Green Chemistry Funding. If no safer alternative exists, the Department may authorize a funding proposal for a Green Chemistry Challenge Grant provided:

(A) the manufacturer has the ability and intention to comply with the intent of articles x, xx, and xxx;

(B) the manufacturer is not otherwise legally required to fund this proposal;

(C) the amount of the funding shall exceed by at least 20% the economic benefit of noncompliance during the affected time period;

(D) the Department may not play any role in managing or controlling funds that may be set aside or escrowed for funding a green chemistry proposal, but may perform oversight to ensure the proposal is implemented pursuant to the approved provisions;

(E) The grant shall primarily support fundamental and applied research in green chemistry in order to provide industry with the chemically viable tools and methods necessary to develop products and processes that are more environmentally benign; and

(F) The grant may include research proposals for reformulation or redesign of products, substitution of raw materials, technology modifications, process or procedure modifications, improvements in housekeeping and maintenance, training, inventory control, or other operational and maintenance procedures. Funding may also include any proposal which accomplish any of the following:

1. extending useful life of commercial products.
2. reducing materials and resource consumption.
3. improving water conservation.
4. reducing water quality impacts.
5. reducing air emissions.
6. improved energy efficiency.
7. reducing production, in-use, and transportation energy inputs.
8. reducing greenhouse gas emissions.
9. reducing waste and end-of-life disposal impacts.
10. reducing public health impacts, including potential impacts to sensitive subpopulations, including infants and children;
11. reducing environmental impacts; or
12 . any that proposal the Department determines to have environmental merit which do not fit within the above categories but are otherwise fully consistent with the intent of this article.

(5) Other response actions. The Department may determine other response actions that accomplish the requirements of this article.

6XXXX.21 Petition for a Variance for Article X, Article XX, and Article XXX Requirements

(a) Any manufacturer or if applicable, a transferee may petition the Department in writing to modify or waive any provision in article x or article xx, provided efforts to comply with the requirements can be demonstrated; and a written narrative demonstrating the good faith efforts undertaken to comply is provided.

(b) The department shall make one of the following findings:

(1) The chemical of concern is found to be below "no significant risk levels" for carcinogens or below "maximum allowable daily levels" for chemicals that cause reproductive toxicity;

(2) The chemical of concern is insignificant or unimportant as a potential hazard to human health and safety or to the environment;

(3) The consumer product is insignificant or unimportant as a potential hazard to human health and safety or to the environment, when managed in accordance with the conditions, limitations, and other requirements specified in the response action;

(4) The exposure during use of the consumer product is insignificant potential hazard to human health and safety or the environment;

(5) The consumer product is regulated by another governmental agency in a manner that ensures it will not pose a substantial present or potential hazard to human health and safety, and the environment; or

(6) A requirement imposed by another public agency provides protection of human health and safety or the environment equivalent to the protection provided by the requirement of this article.

(c) Upon the completion of the alternatives analysis required by article XX, if a determination has been made to implement a prohibition as a response action as prescribed in subsection 6XXXX.20(c)(3), a manufacturer may petition the Department to allow the continued use of the consumer product, provided there is no safer alternative that is functionally equivalent or has equivalent performance; or there is no safer alternative that is economically and technically viable.

(d) Each petition must be submitted to the Department by certified mail and must include:

(1) The name and address of the petitioner;

(2) A statement of the petitioner's proposed request for modification or variance and the specific regulatory requirement being modified; and

(3) A statement of the need and justification for the proposed action, including any supporting tests, studies, or other information.

(e) The Department shall, within 60 days after receipt of an application for a variance pursuant to this section, notify the applicant that the application is

complete and accepted for processing by the Department or that the application is incomplete and what further information is required.

(f) The Department shall make a tentative decision to grant or deny a petition and shall do the following:

(1) publish a 45 day notice of such tentative decision in the California Regulatory Notice Register or on the internet; and

(2) make the tentative decision and the scientific support for the decision available on its website;

(3) allow interested parties to submit written comments in support of or in opposition to the tentative decision during the notice period;

(4) provide responses to the comments submitted within a reasonable time.

(g) After evaluating all public comments, the Department shall publish its final decision to grant or deny the petition in the California Regulatory Notice Register and on the internet and shall notify the applicant in writing that the request for a variance is granted or denied.