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1 While this redline of the Straw Proposal is intended to highlight key  
2 areas of concern, it is not an indication of KII's support for the Straw  
3 Proposal as originally prepared or as amended; nor should it be  
4 considered an exhaustive review of all of the KII points of concern.

5  
6 STRAW PROPOSAL  
7 FOR  
8 SAFER ALTERNATIVE REGULATIONS  
9 (10/1/09)

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11  
12  
13 Article X. Identification and Prioritization of Chemicals of Concern in  
14 Consumer Products

15  
16 6xxxx.1 Applicability

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

20 (1) Products designed for use primarily by infants or children 12  
21 years of age or younger, pregnant women, the elderly, and  
22 individuals with chronic or acute illness, including, but not limited  
23 to, personal care products, toys, bedroom furnishings. Products  
24 designed for use by infants or children, including, but not limited  
25 to, personal care products, toys, bedroom furnishings, and  
26 clothing;

27 (2) Products designed for use in K-12 schools spans  
28 (2)(3) considers formaldehyde base products and naturally  
29 containing heavy metals as designated chemicals of concern  
30 that it is inconsistent with Green Chemistry principles and  
31 consequently, is unworkable

32 (3)(4) Clothing, linens and textiles including, but not limited to,  
33 shirts, blouses, socks, dresses, pants, handbags, shoes, pillow  
34 cases, bed covers, blankets, sheets, and mattress covers and  
35 liners;

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

39 (6) Cleaning products for use in the home, school or office  
40 including, but not limited to, kitchen and bathroom cleaning  
41 products, soaps, and laundry detergents, except those already  
42 regulated under the FFCA or the California Safe Cosmetics  
43 Act;

44 (4)(7) Products designed to release fragrances or scents,  
45 including, but not limited to, scented candles, air fresheners and

Comment [A1]: Document as written does not allow for risk/risk tradeoffs, involves no prioritization, and offers no incentives to build better chemistry. It is unworkable for these and many other reasons exposed in the following.

Comment [A2]: Applicability should be narrowed and further described to avoid confusion and focus resources.

Comment [A3]: Language to align with CPSC definition for children's products.

Comment [A4]: Original Number 2 (designed for use by infants...) was deleted because it is redundant with products in category 1, also the category was too broad as defined, need to focus to those things that have greater risk of exposure to those things used by children, indoor air quality standards are already in place to regulate products used in California schools.

Comment [A5]: Deleted as redundant to number 1.

Comment [A6]: Products designed for use in K-12 schools (Deleted). Does this mean building products such as wood, plywood, particleboard, wallboard or insulation? None of these materials would pass the requirements of the law. For example, a 2x4 piece of wood contains formaldehyde and heavy metals by nature, in trace concentrations. In fact, every living thing whether it is algae or humans contains and emits formaldehyde. It appears that the first principle of Green Chemistry requires the use of bio-based materials yet all of these contain formaldehyde and metals absorbed by plants as micronutrients. Consequently, as this regulation considers formaldehyde-base products and naturally containing heavy metals as designated chemicals of concern that it is inconsistent with Green Chemistry principles and consequently, is unworkable. Stringent, yet more workable frameworks such as the "Collaboration for High Performance Schools" or "Greenguard for Children in Schools" recognize protective and safe levels of chemicals of concern.

Comment [A7]: The original category of products designed for application directly in or to the human body was deleted. This category is already regulated by the FDA under the FFCA.

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room deodorizers, except those cosmetics already regulated under the FFDCA;

- ~~(8)~~
- ~~(9) Products designed, or reasonably anticipated, to release any chemicals during intended use by consumers or after disposal except for those already regulated by the FFDCA, e.g. food additives and food-contact articles. (e.g., automobile brake pads, automobile tires, fireplace logs, glues, adhesives, and solvents)~~
- ~~(10) Products known to release chemicals after disposal (e.g., automobile brake pads, automobile tires, fireplace logs, glues, adhesives, and solvents);~~
- ~~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~~
  - ~~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;~~
  - ~~(11) 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;~~
  - ~~(11) Furnishings including, but not limited to, mattresses, sofas, chairs, tables, draperies, household appliances, lighting fixtures, and carpet;~~
  - ~~(11) Cleaning products including, but not limited to, kitchen and bathroom cleaning products, soaps, and laundry detergents;~~
  - ~~(11) Products designed to release fragrances or scents, including, but not limited to, perfumes, colognes, scented candles, air fresheners and room deodorizers;~~
  - ~~(11) 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;~~
  - ~~(11) 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);~~
  - ~~(11) Any products that contain any of the chemicals specified in section 6xxxx.2 of this Article; and~~
  - ~~(13)(11) Any of the chemicals specified in section 6xxxx.2 of this Article.~~

**Comment [A8]:** The original category of food contact and service ware items are already regulated by the FDA and FFDCA.

**Comment [A9]:** Originally proposed categories 10, and 11 are too broad for the original program, may be considered for inclusion after a review period and a number of years of experience with the program. Suggest deletion.

**Comment [A10]:** Originally proposed categories 10, and 11 are too broad for the original program, may be considered for inclusion after a review period and a number of years of experience with the program. Suggest deletion..

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(b) At least every two years following the effective date of these regulations, the Department shall evaluate other categories of consumer products, and

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may initiate a rulemaking to revise the list of product categories in subsection (a) of this section.

**6xxxx.2 Chemicals of Concern List of Chemicals for Consideration**

(a) ~~Notwithstanding section 6xxxx.7 of this Article,~~ The following chemicals or chemical ingredients are designated chemicals for consideration for possible inclusion by the Department in a candidate list which will be developed based on public comments provided at public workshops. The candidate list will undergo a scientific review to determine the final list of "chemicals of concern".<sup>1</sup>

- (1) Arsenic (inorganic arsenic compounds).
- (2) Cadmium and cadmium compounds.<sup>2</sup>
- (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 may be added by the Department, from time to time after proper prioritization, to the list of chemicals of concern in (a). :

<sup>1</sup> This is consistent with other programs in CA like Proposition 65 that allow a safe harbor from warning requirements if risk determinations meet certain requirements

<sup>2</sup> The four Coneg metals, Cd, P b, Cr, and Hg, should not be considered designated chemical of concern if not added intentionally and if their aggregated concentration is less than 100ppm, per Coneg, EU packaging directive, and the CA Toxics in Packaging Prevention Act. If those requirements are met, then they are not designated chemicals of concern.

**Comment [A11]:** As suggested in our comment letter, we encourage DTSC to develop a process first identifying chemicals for consideration with opportunity for public comment, then identifying a candidate list, from which the DTSC will go through a scientific review to determine whether they should be listed as a chemicals of concern. In order to have a workable regulation, the effect and the conditions necessary for the effect must be identified in order to properly identify the hazard that identifies a chemical of concern. Therefore, it is the end point, pathway, dose, time of exposure, relevant age, and other relevant conditions that define a chemical of concern. As written, an endpoint and a single molecule triggers a lengthy process that adds cost to the consumer and limits consumer choice without providing any value to the consumer.

**Comment [A12]:** The compounds below are data rich. It should be an option to perform risk analysis of products rather than having all products containing them as considered harmful or suspect.

**Comment [A13]:** Note: Arsenic is naturally found in drinking water, food, soil, and gypsum used in wall board manufacturing.

**Comment [A14]:** The 4 Coneg metals should enjoy the same exclusion when in products as provided in the regulations of Coneg, EU Packaging directive, and CA Toxics in Packaging Prevention Act

**Comment [A15]:** Note: Both chromium +3 and +6 can be found naturally occurring.

**Comment [A16]:** Note: Cadmium and cadmium compounds can be found naturally occurring.

**Comment [A17]:** Note: Lead and lead compounds naturally occurring.

**Comment [A18]:** Note: Mercury and mercury compounds can be found naturally occurring.

**Comment [A19]:** Note: Uranium can be found naturally occurring.

**Comment [A20]:** Data regarding the risk and hazards associated with these chemicals are conflicting. We encourage DTSC to carefully identify the criteria that should be used to screen chemicals.

**Comment [A21]:** Biocide with data showing sensitization. However, many biocides are sensitizers as a neat solution. Regulation would ban these chemicals if any concentration of solution resulting in sensitization. Regulation ...

**Comment [A22]:** KII encourages DTSC to use the list of lists as a reference from which the Department, after proper review and ...

**Comment [A23]:** It is unworkable to request the CA manufacturers to properly integrate and prioritize this global, catch-all, list of chemicals, for the purposes of this regulation per the str ...

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- 1 (c) (1) California Proposition 65 List of chemicals known to the state to  
2 cause cancer or developmental or reproductive effect.
- 3 (2) International Agency for Research on Cancer, chemicals classified  
4 as Groups 1, 2A and 2B carcinogens.
- 5 (3) National Toxicology Program (NTP) list of chemicals identified as  
6 known or reasonably anticipated to be human carcinogens in the  
7 Report on Carcinogens.
- 8 (4) Carcinogens classified by Europe as Categories 1 and 2, or with  
9 Risk Phrases R45 (may cause cancer) or R49 (may cause cancer  
10 by inhalation).
- 11 (5) NTP Center for Evaluation of Risks to Human Reproduction  
12 (CERHR), chemicals classified as posing "serious concern,"  
13 "concern" or "some concern" with regard to developmental or  
14 reproductive toxicity.
- 15 (6) Chemicals classified by the European Commission as Reproductive  
16 Toxicity Categories 1 and 2, or in the hazard category for lactation  
17 effects (effects on or via lactation) or with Risk Phrases R60 (may  
18 impair fertility), R61 (may cause harm to the unborn child), and R64  
19 (may cause harm to breastfed babies).
- 20 (7) Persistent, bioaccumulative toxicants (PBTs) and very persistent,  
21 very bioaccumulative chemicals (vPvBs).
- 22 (8) Chemicals identified as persistent, bioaccumulative, inherently toxic  
23 (PBiT) by Environment Canada.
- 24 (9) Chemicals identified by the European Commission as PBTs, vPvBs
- 25 (10) Chemicals on the State of Washington PBT list.
- 26 (11) Oslo-Paris Convention Commission (OSPAR) list of substances of  
27 possible concern (includes the subset of chemicals for priority  
28 action).
- 29 (12) U.S. EPA National Waste Minimization Program Priority Chemicals.
- 30 (13) U.S. EPA Priority PBTs.
- 31 (14) U.S. EPA Emergency Planning and Community Right to Know Act  
32 (EPCRA) PBTs.
- 33 (15) U.S. EPA Toxic Release Inventory (TRI) PBT Chemical List.
- 34 (16) Chemicals classified by the European Commission as Category 1  
35 or 2 endocrine disruptors.

**Comment [A24]:** If this is a criteria DTSC should also allow risk determination based on Prop 65 safe harbor numbers without the need for alternatives assessment.

**Comment [A25]:** Products containing inhalation carcinogens should not have to go through alternatives assessment if exposure can not occur by this route.

**Comment [A26]:** "some concern" is the level directly above "no concern" We question the use by DTSC of the "some concern" category. Any data appears to find a chemical in the "some concern" category. We feel data should be based on a weight of the evidence rather than strength of the evidence evaluation.

**Comment [A27]:** DTSC should develop a PBT list. It will be impossible for companies to manage all of these various lists. This could also be said for other effects.

**Comment [A28]:** [We feel your definition of biopersistence is adequate. The review of all these lists is redundant and burdensome.]

**Comment [A29]:** Delete these highlighted lists.

**Comment [A30]:** These lists based on screening tests and chemical prioritization. They are added to and removed from frequently. It is not a listing of hazard, but rather a means to determine if further testing should be conducted. Definitive data in reproductive and developmental studies in mammals should be used to classify a chemical hazard, not data derived from screening tests of a science which is poorly defined and not widely accepted.

Again, there are natural products that effect the endocrine system such as genistein in soy. This is a beneficial chemical. It will not be listed here, however, it will probably be positive in your endocrine related testing in section 6xxx.7. However, it's difficult to know the extent of this endpoint as very little data is available. This would be required for a chemical to be sold in California. Again an example of a disincentive is as follows: a formaldehyde resin alternative uses a soy-based resin. No endocrine disruption testing has been conducted on this resin. This would be required by this regulation. Additionally, the board also emits naturally occurring formaldehyde. Thus, there would be two reasons not to mention heavy metals naturally occurring in wood that would essentially ban the material.

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- 1 (17) Chemicals classified by the European Commission as Category 1
- 2 or 2 germ cell mutagens or with Risk Phrase R46 (may cause
- 3 heritable genetic damage).
- 4 (18) Japan International Center for Occupational Safety and Health list
- 5 of mutagenic chemicals.
- 6 (19) Chemicals classified by Europe as respiratory sensitizers or with
- 7 Risk Phrases R42 (may cause sensitization by inhalation) and
- 8 R42/43 (may cause sensitization by inhalation and skin contact).
- 9 (20) Chemicals identified by the Association of Occupational and
- 10 Environmental Clinics as occupational asthmagens.
- 11 (21) Chemicals classified by Canada as inherently toxic to aquatic
- 12 organisms.
- 13 ~~(22) Chemicals classified by the European Commission as hazardous to~~
- 14 ~~the aquatic environment~~
- 15 (23) Chemicals classified by the European Commission as hazardous to
- 16 the ozone layer or with the Risk Phrase R59 (dangerous to the
- 17 ozone layer).
- 18 (24) California Toxic Air Contaminants Program.
- 19 (25) Potential chemical contaminants of concern at California school
- 20 sites.
- 21 (26) Priority chemicals for biomonitoring under the California
- 22 Environmental Contaminant Biomonitoring Program.
- 23 (27) Chemicals with drinking water maximum contaminant levels.
- 24 (28) Chemicals with water quality standards.
- 25 (29) Additional chemicals classified by Health Canada as high priorities
- 26 for human health.

**Comment [A31]:** These endpoints should be able to be challenged in definitive reproductive and developmental studies. This section shows a lack of prioritization or hierarchy. In general, if a chemical shows mutagenic potential then the manufacturer has the opportunity to conduct a cancer bioassay. If the cancer bioassay is negative the chemical is basically "cleared." This regulation discusses no such hierarchy and is thus illogical and overly burdensome.

**Comment [A32]:** Mutation does not imply hazard. Carcinogenicity should be what determines hazard.

**Comment [A33]:** California needs to develop their own list of aquatic toxins. It will be too difficult for companies to manage these multiple lists.

**Comment [A34]:** Redundant. These chemicals are already banned by U.S. law.

**Comment [A35]:** Biomonitoring only implies exposure. It does not mean hazard or risk. If there is a low level of exposure, i.e. below that which can cause a health effect, then chemical should be considered safe.

**Comment [A36]:** By the very nature of assigning drinking water levels suggests there is a dose issue that is important. By this definition as Cu has a drinking water standard that any product containing Cu (which is an essential nutrient) would be banned. Consequently, copper pots in your kitchen would not be allowed in CA.

**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.

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(3) The characterization of chemicals is performed adhering to basic scientific principles and procedures, accepted internationally and by more than one such type of international body.

(b) Except as expressly stated otherwise, “chemical” means any element, chemical compound organic or inorganic substance of a particular molecular identity including (a) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (b) any element or uncombined radical. Chemical shall not include those elements, chemical compounds, or substances that are naturally occurring, not intentionally added, incidental, or that are present in a consumer product but have no technical or functional effect.

**Comment [A37]:** The regulation should exempt any chemicals found in consumer products that are naturally occurring, found only in trace amounts, incidental, not intentionally added, or which provide no functional purpose.

**Comment [A38]:** Based on 15 U.S.C. 2602(2)(A)

**Comment [A39]:** Please refer to the CA Toxics in Packaging act for definition of incidental use.

(c) Except as expressly stated otherwise, “chemical ingredient” means any chemical used as a functional component in a consumer product, not including incidental chemicals present in a consumer product that have no technical or functional effect.

**Comment [A40]:** The definition as proposed needs to be better defined – examples include catalysts, solvents, intermediates, process chemicals that condition the product but are not present in the product such as bleaching or heat treating?

(d) “Chemical of concern” (CoC) means:

**Comment [A41]:** Based on the FDA Cosmetic Reg. 21 CFR 700.3(e) and 21 CFR §701.3.

- (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 following hazard characteristics: carcinogen, mutagen, reproductive toxicant, or persistent bioaccumulative toxins as 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) “De Minimis” means the concentration of the chemical is less than 0.1% by weight in the consumer product.

~~(f)~~(g) “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)~~(h) “Make available for use in California” means that a person sells, offers to sell, distributes, leases, offers to lease or supplies a consumer product to another person for ultimate use by California consumers, or who transfers ownership of a consumer product within the borders of California directly to a California consumer. 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

**Comment [A42]:** The original proposed definition can not be assured in any situation even with contract terms, label warnings, MSDSs, etc. This pulls too many people in the supply into this regulation and creates redundancy. Should place obligation on person providing product to consumer and let them go back up the supply chain to obtain information to comply.

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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.

**Comment [A43]:** The regulation should not apply to a "California consumer" (resident) that purchases and takes control of a product outside the borders of CA

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

(j) "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]**.

(k) "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.

(l) "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.

**Comment [A44]:** We request that further information is included here. These groups may or may not be more sensitive than the general population. In addition, as there is no dose involved in the DTSC evaluation it is unclear how the law will further protect these sensitive subpopulations over the general population. Finally, the inclusion of the statement "but not limited to" is burdensome to the regulated community. Without deleting this statement or providing further clarity it would give the right to DTSC to determine another subpopulation after an alternatives assessment were completed perhaps making that assessment with all it's costs and time essentially moot.

(m) "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.

(c) This article shall not apply to a consumer product if an existing law or regulation already regulates the use of chemicals in consumer products to promote health, safety or to minimize impacts on the environment.

**Comment [A45]:** The regulation should recognize the existing laws and regulations that currently restrict the use of chemicals in consumer products.

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**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:

**Comment [A46]:** Has the agency evaluated any products that do not contain CoCs to determine if they have the essential data set as recognized in this section? New chemicals that are not listed as a CoC would have to generate the same set of toxicity data as a CoC prior to being sold in the state of CA. It appears that is listed above as "new chemicals." The evaluation of the "new chemical" should be consistent with the criteria that DTSC uses to evaluate chemicals under the scientific review process we suggest above.

**Comment [A47]:** This will not be enough time. EU REACH model is a more reasonable estimate of timing. It's doubtful with the amount of testing that will be necessary to fulfill this requirement that testing will be completed in 1 years time. In our experience with other testing programs 2 years was difficult but doable. Also, from reading the regulation it is difficult to understand what the testing requirements actually are. For example, in the acute, tissue, and repeat dose sections it appears the requirement is for all routes. Is this correct? If so are all of the remaining tests required for all routes? Just gavage? Just the most appropriate exposure? It's unclear how to gauge data availability at this time.

**Comment [A48]:** How does California plan to determine approved uses? For each existing chemical in all consumer products? Do they plan to maintain a listing for industry to be aware of approved uses?

**Comment [A49]:** Volume approach similar to REACH should be considered before requiring testing.

**Comment [A50]:** Does this mean published in a journal from an independent third party or does it mean the data must be generated by an independent third party. What is the definition of a "third party" for this regulation?

**Comment [A51]:** Anywhere or are there specific requirements?

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- (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.

**Comment [A52]:** Would product knowledge or chemical similarity suffice in this section or is QSAR the only method to group chemicals? In the HPV program chemical groups were accomplished. QSAR was not a requirement.

(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.

**Comment [A53]:** How will CBI be handled in California? Is there a process in place?

(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.

**Comment [A54]:** It should be desirable to define or describe the intention be accurate and up-to-date when such terms are applied to quite a broad range and quantity of material.

**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 chemical ingredients and who makes, or will make, that product available for use in California shall take the following actions:

**Comment [A55]:** DTSC should not include this additional step for inclusion under the program. The process described in our letter would allow DTSC to add chemicals to the list of chemicals of concern after scientific review. For new chemicals, manufacturers should only be required to develop a similar set of data that would be considered for inclusion after being put on the candidate list. The same criteria should apply to the chemicals for consideration and new chemicals. We suggestion initially limiting the chemicals included in the program to those displaying the characteristics of CMR or PBT.

(1) evaluate each such chemical ingredient 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 such chemical ingredient may be designated as a chemical of concern. For

**Comment [A56]:** As a general comment, for the below hazard criteria, it seems that the evaluation should be limited to new chemical ingredients, not all chemicals or chemical ingredients? Further clarification is needed to understand the intent of this section.

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example, if a chemical ingredient 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 ingredient 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 subsection (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.~~

**Comment [A57]:** Does this regulation require that all tests be conducted? These tests are outside of similar requirements internationally. Consequently, it is doubtful that companies will have completed these data requirements. Likewise for products that do not contain CoCs but would still need to populate this database it is likely that these companies have no required data on the chemicals in their products. Such a data requirement is a disincentive for doing business in CA.

**Comment [A58]:** Deleted the requirement for manufacturers to input hazard data on all chemicals. This is duplicative of existing requirements under TSCA and REACH. DTSC and OEHHA are required under Section 25257.1(c) to avoid duplication of existing regulations.

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(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.

**Comment [A59]:** For what type of effects? What if effect is reversible?

**Comment [A60]:** What about reacted chemicals and polymers? Hazard provide will be different than parent chemical. Is testing required to show safety of a large molecular weight polymer that contains 50% of reacted ethylene glycol?

**Table 1. Acute Toxicity**

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

**Comment [A61]:** Does DTSC believe there are chemicals that exhibit acute toxicity currently in commerce in CA. If so, are there not other avenues to restrict or ban such products. We believe that most, if not all products would **not** exhibit acute toxicity and that this requirement is burdensome, costly, and a poor use of animals. Does the regulation require these data for all routes?

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(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.

**Comment [A62]:** Do we understand correctly that the hazard criteria evaluations only apply to "new chemicals"?

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

<b>Criteria</b>
<p>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 <u>in consumer products</u> shall be classified on the basis of:</p> <ul style="list-style-type: none"> <li>• evidence from human cases or epidemiological studies; or</li> <li>• 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,</li> <li>• 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.</li> </ul>

**Comment [A63]:** This needs to be clarified further. Certainly many chemicals would be considered toxic to humans if used, for example, for suicide. This is another example where dose is necessary and without dose that the regulation is unworkable

**Comment [A64]:** Needs a definition to be applied consistently.

**Comment [A65]:** Depending on the exposure there is likely an LD50 for any chemical. We don't find these criteria useful in a chemical evaluation.

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

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

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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.

Comment [A66]: Is the required data set for all exposures or is one category sufficient? Concerned about the potential breadth of this requirement.

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**Table 4. Criteria for Specific Organ Toxicity-Repeated Exposure**

Criteria
<p>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:</p> <ul style="list-style-type: none"> <li>evidence from human cases or epidemiological studies; or</li> <li>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,</li> <li>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.</li> </ul>

**Comment [A67]:** The basis of toxicity studies is to show an effect. Consequently, most if not all chemicals would cause a response at some concentration. Has the DTSC reviewed chemicals in products not listed as CoCs that have experimental data showing no effects. If not, then the DTSC has no idea if any chemical in products sold in the state of California can meet the burden of this regulation.

**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

**Comment [A68]:** This section provides another example of where a hazard is not practical. For example, formaldehyde as a 37% solution will cause ocular harm, however, formaldehyde in plywood will not. The exposure dose is inherent in the toxicity.

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

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

7 **Table 6. Criteria For Adverse Eye Effects**

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<b>Criteria</b>
<p>A chemical or chemical ingredient that when applied to the eye of an animal produces:</p> <p>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</p> <p>in at least 2 of 3 tested animals, a positive response of:</p> <ul style="list-style-type: none"> <li>-corneal opacity <math>\geq 3</math>, and/or</li> <li>-iritis <math>&gt; 1,5</math>, or</li> </ul> <p>A chemical or chemical ingredient that when applied to the eye of an animal produces:</p> <p>in at least in 2 of 3 tested animals, a positive response of:</p> <ul style="list-style-type: none"> <li>-corneal opacity <math>\geq 1</math> and/or</li> <li>-iritis <math>\geq 1</math>, and/or</li> <li>-conjunctival redness <math>\geq 2</math> and/or</li> <li>-conjunctival oedema (chemosis) <math>\geq 2</math></li> </ul> <p>calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material.</p>

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

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**Table 7. Criteria For Germ Cell Mutagens**

**Comment [A69]:** This section lacks traditional hierarchy. The lack of prioritization makes the regulation too burdensome. DTSC should include the traditional hierarchy in order to make this section of the regulation workable.

<b>Criteria</b>
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.

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**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 more than one any authoritative body in independent assessment studies 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.

**Comment [A70]:** This example is not defined, however, the use of in vitro assays such as the e-screen have been shown to be irrelevant when tested in traditional mammalian reproductive studies. The use of these methods may be useful in screening but should not be used to direct the determination of a CoC.

**Comment [A71]:** There is not scientific consensus that clearly defines endocrine disruptor. US EPA has not provided adequate guidance or test methodology and the EU recognizes that tests developed are for screening and prioritization or future testing. Recommend that DTSC drop endocrine disruption and rely on reproductive and developmental studies by approved guidelines in mammalian systems.

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(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.

**Comment [A72]:** As mentioned earlier, this would prohibit many biocides. In addition, it would ban the use of western red cedar lumber used for decks, etc. In addition, almost all dusts, of any type, may result in rhinitis. It would be hard to imagine that an alternative "dust" would not have this property.

**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.

**Comment [A73]:** Data quality concerns are included in this section. They seem to have been forgotten in other locations.

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.

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**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  $\geq 500$  shall be considered indicative of the potential to bioconcentrate for classification purposes. Any chemical or chemical ingredient with a log  $K_{ow} \geq 4$  or a BCF  $\geq 500$  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.

**Comment [A74]:** Bioaccumulation does not imply hazard. If a material bioaccumulates but has not been demonstrated to be toxic then bioaccumulation is irrelevant. Exceeding a toxicity threshold is the end point that needs to be examined, therefore the evaluation should look at dose and toxicity.

**Table 12. Hazard Criteria for aquatic toxicants**

Criteria	
Acute (short-term) aquatic hazard	
96 hr LC50 (for fish)	$\leq 1$ mg/l and/or
48 hr EC50 (for crustacea)	$\leq 1$ mg/l and/or
72 or 96 hr ErC50 (for algae or other aquatic plants)	$\leq 1$ mg/l.

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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).	

**Comment [A75]:** Where do these levels come from? The state of CA designates a waste stream as hazardous if the level is < 500 mg/l

**Comment [A76]:** Obviously, metals are not rapidly degradable. Will any metal come into this category?

'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.

**Comment [A77]:** These values seem reversed, shouldn't the chronic number be less than the acute? DTSC should list chronic study time points?

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

**Comment [A78]:** Does this mean only chemicals that affect California's Ozone layer? If a chemical cannot be released to affect ozone then there is no risk.

15 **Table 13. Generic Concentration Limit For Chemicals (In A Mixture)**  
 16 **Classified As Hazardous To The Ozone Layer, That Trigger Classification**  
 17 **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%

**Comment [A79]:** This is a major problem area with the regulation. It will ban the use of natural products. Essentially, any "living" product will contain formaldehyde at some level. Humans have roughly 2 ppm in their blood. Additionally, heavy metals are naturally occurring. For building products, the alternative assessment for wood would include steel, concrete, stone, or plastic, all of which also contain a CoC. Thus, the manufacturer must go through this burdensome process for no useful reason. In addition to dose, route is important. For example, ethanol is a developmental toxicant by the oral route, however, when used as a hand sanitizer it is hygienic.

18  
 19 **6xxx.8 Prioritization of Chemicals of Concern**

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

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

**Comment [A80]:** What is the acceptable threshold for risk of exposure? What if exposure is below any safe harbor value?

8 a. Reasonably anticipated to be released to the environment  
9 during use, reuse, reclamation, or during or after disposal of the  
10 consumer product, or during reasonably foreseeable use of the  
11 consumer product (e.g., children putting toys into their mouths);  
12 showing an unreasonable degree of risk to humans or the  
13 environment or are above a de minimis concentration or,

14 b. to which humans are being or have been exposed based on  
15 data from the California Environmental Contaminant  
16 Biomonitoring Program, or any other biomonitoring studies  
17 conducted by an authoritative body under appropriate scientific  
18 guidelines and procedures. Certain metals listed in this  
19 regulation are required micronutrients and, by definition, would  
20 exist in the body.

**Comment [A81]:** What if biomonitored chemical is without an adverse effect at monitored level?

21 (2) Priority 2 chemicals of concern include any new or existing  
22 chemical identified as a chemical of concern and that does not  
23 otherwise meet the priority 1 criteria described in subsection (a)(1)  
24 of this section, and that is encapsulated in such a manner that it will  
25 not be released to the environment during the normal intended use  
26 of the consumer product containing the chemical or chemical  
27 ingredient, but it may be released to the environment in sufficient  
28 quantities to resulting in unreasonable risk during reclamation or  
29 disposal.

**Comment [A82]:** What does this term mean?

**Comment [A83]:** This is very poorly defined. Encapsulated is an archaic term. As science improves, levels of detection will decrease. California needs to focus on level of exposure versus hazard level and come up with an acceptable margin of exposure for toxic endpoint and robustness of toxicological database.

30 (3) Priority 3 chemicals of concern include any new or existing  
31 chemical identified as a chemical of concern and that does not  
32 otherwise meet the priority 1 or 2 criteria described in subsections  
33 (a)(1) or (2) of this section, respectively, and that is either below a  
34 de minimis level in the product, or, is encapsulated in such a  
35 manner that a complete exposure route can not be recognized in  
36 that it will not be released to the environment during the normal  
37 intended use of the consumer product containing the chemical or  
38 chemical ingredient, or during reclamation or disposal, or is below a  
39 unreasonable risk threshold during normal use or when released to  
40 the environment

**Comment [A84]:** This is a flaw in the regulation. It will ban the use of natural products. Essentially, any "living" product will contain formaldehyde at some level. Humans have roughly 2ppm in their blood. Additionally, heavy metals are naturally occurring. For building products, the alternative products (not functional equivalents) for wood would include steel, concrete, stone, or plastic, all of which also contain CoC. Thus, the manufacturer must go through this burdensome process for no useful reason. In addition to dose, route is important. For example, ethanol is a developmental toxicant by the oral route, however, when used as a hand sanitizer it is hygienic.

**Comment [A85]:** Same as previous comment.

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(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.

**Comment [A86]:** Not enough time. The data requirements will likely make this schedule impossible.

**Comment [A87]:** Who determines new use?

**6xxxx.9 Supply Chain Information Dissemination Requirements**

(a) ~~Unless otherwise prohibited by law, any person in the State of California who 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 that contains one or more priority 1 or 2 chemicals of concern, as defined in section 6xxxx.8 of this article, shall provide its direct consumer, as appropriate, with documentation that does the following~~ ~~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:~~

**Comment [A88]:** DTSC does not appear have the authority under the existing statute to require supply chain dissemination of this information. Much of the information contemplated by this section would require the disclosure of CBI. In addition, disclosing certain information may be limited by non disclosure agreements with suppliers. Finally, requiring manufacturers to disclose this information to other companies raises unfair competition issues.

- (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 6xxxx.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, when applicable, 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.

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1 (b) Notwithstanding subsection (a) of this section, if the person who makes a  
2 consumer products available for use in California determines that the  
3 product does not contain a chemical of concern, they shall provide its  
4 direct consumer, as appropriate, with documentation stating that the  
5 respective product does not contain any chemicals of concern, and  
6 specifying the address and contact information where a copy of  
7 documentation to show compliance with this Article may be requested in  
8 writing by the Department, including information that was relied upon to  
9 make the determination that the product in question does not contain any  
10 chemicals of concern.

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

16 (d) ~~A person~~ A person making a product available for use in California shall  
17 maintain documentation relied upon to show compliance with this Article  
18 during the time that person makes that product available for use in  
19 California, and for at least three years thereafter. A person shall make  
20 documentation relied upon to show compliance with this Article available  
21 to the Department within 30 days of a written request from the  
22 Department. ~~The manufacturer shall maintain all documentation relied~~  
23 ~~upon to achieve compliance with this Article during the time that~~  
24 ~~manufacturer makes that product available for use in California, and for at~~  
25 ~~least three years thereafter. The manufacturer shall make all~~  
26 ~~documentation relied upon to achieve compliance with this Article~~  
27 ~~available to the Department within 30 days of a written request from the~~  
28 ~~Department.~~

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

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

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Comment [A89]: Transferees are covered by "a person" in prior subsections. May not be located in California, so potential for no enforcement authority if outside of California.

41 **Article XX. Alternatives Analysis**  
42 **Section 6xxxx.10. Applicability**  
43

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1 (a) Any consumer product made available for use in California that contains  
2 one or more chemical ingredients that are priority ized-chemicals of concern as  
3 defined in Section 6xxx.8 above de minimis thresholds shall be evaluated in  
4 accordance with the alternatives analysis process contained in this article.

5 (b) A manufacturer of a consumer product to which this article applies shall  
6 prepare a work plan outlined in Section 6xxxx.XX and after approval evaluate the  
7 product using the alternatives analysis process contained in this article.

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

10 (1) Identification of all potential alternatives pursuant to section  
11 6xxxx.12;

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

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

19 (d) The alternatives analysis required by this article shall be completed in the  
20 time period indicated in the work plan approved by the Department ~~or before~~  
21 ~~one the end of the second year from the date of completion of the hazard~~  
22 ~~categorization~~ required in section 6xxxx.17.1.

23 (e) Notwithstanding subsections (b) and (d), the Department may grant a  
24 petition for a variance for any provision in this article pursuant to section  
25 6xxxx.21.

26  
27 **Section 6xxxx.10.1. Standards for Consumer Products.**

28 (a) Except as provided in section 6xxxx.10.2 of this article, no person shall  
29 make available for use in California any consumer product that is subject to this  
30 article, but has not been evaluated pursuant to sections 6xxxx.12 through  
31 6xxxx.18.

32 (b) Except as provided in section 6xxxx.10.2 of this article, no person shall  
33 make available for use in California any consumer product that is subject to this  
34 article, or safer alternative thereto, that has been evaluated pursuant to sections  
35 6xxxx.12 through 6xxxx.18 of this article, but for which the response actions  
36 required by section 6xxxx.20 have not been taken.

37  
38 **6xxxx.10.2. Exemptions.**

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

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

**Comment [A90]:** Would the AA be on the component part or the entire product as a whole? With complex products with multiple components, to have this huge process to undertake would be difficult to undertake for any individual manufacturer. (Article exemption?) Need clarity on applicability.

**Comment [A91]:** We have proposed an environmental impact section using life cycle assessment tools.

**Comment [A92]:** For reasons explained later, economic impacts need to be separated from the more traditional environmental impacts, ecological and resource depletion.

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(c) This article shall not apply to a consumer product if an existing law or regulation already regulates the use of chemicals in consumer products to promote health, safety or to minimize impacts on the environment.

**Comment [A93]:** The regulation should recognize the existing laws and regulations that currently restrict the use of chemicals in consumer products.

**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<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>), ammonia (NH<sub>3</sub>), 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<sub>10</sub> and PM<sub>2.5</sub>), 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~~ the partitioning of the input or output flows of a process or a product system between the product system under study and one or more other product systems.

**Comment [A94]:** We prefer the definition in ISO 14044 which is the reason the term is defined here, specifically the LCA study.

“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.)

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1 | “Emission” means a chemical or physical discharge (e.g., of a substance,  
2 | heat, noise.) into the environment.

3 |  
4 | “End-of-life” means a product at the end of its useful life that will undergo  
5 | waste management or reuse.

6 |  
7 | “Environmental assessment” means a detailed study of the reasonably  
8 | foreseeable significant effects on the environment, beneficial as well as adverse,  
9 | of a product, service or process. Life Cycle Assessment (LCA) and  
10 | Environmental Risk Assessment (ERA) are examples.

11 |  
12 | “Environmental impact” means any change to the environment, whether  
13 | adverse or beneficial, wholly or partially resulting from an activity, product or  
14 | service.

15 |  
16 | “Eutrophication” means excessive enrichment of terrestrial and aquatic  
17 | ecosystems with nutrients such as nitrogen and phosphorus, and the associated  
18 | adverse biological effects, resulting in changed species composition, especially  
19 | displacement of sensitive species. (e.g., the degradation of excess organic  
20 | material in receiving waters consumes oxygen resulting in oxygen deficiency and  
21 | fish kill.)

22 |  
23 | “Functional unit” means ~~the properties of a product used to establish a~~  
24 | ~~standardized frame of reference for comparison~~ ~~The quantified performance of a~~  
25 | ~~product system for use as a reference unit (ISO 14044).~~

26 | Note: A product property is to be included in the functional unit when it is an  
27 | obligatory product property, e.g., a property that the alternative product must  
28 | have in order to be at all considered as a relevant alternative. The functional unit  
29 | describes and quantifies those properties of the product that must be present for  
30 | the studied substitution to take place. These properties (e.g., the functionality,  
31 | appearance, stability, durability, ease of maintenance) are in turn determined by  
32 | the requirements in the market in which the product is to be sold.

Comment [A95]: Use the ISO definition which goes to the point. Use all the rest as a Note, not as the definition.

33 |  
34 | “Functionally equivalent” means an alternative that performs the same  
35 | function as the consumer product. ~~This is determined by the person conducting~~  
36 | ~~the alternatives analysis and is likely to be product- and process-specific.~~

Comment [A96]: Second sentence confuses the definition and does not add value.

37 |  
38 | “Global warming” means changes in the global, average surface-air  
39 | temperature and subsequent change of various climate parameters and their  
40 | effects such as storm frequency and intensity, rainfall intensity and frequency of  
41 | flooding.

42 |  
43 | “Human toxicity” means the degree to which a chemical or chemical  
44 | ingredient elicits a deleterious or adverse effect upon the biological system of

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1 humans exposed to the chemical or chemical ingredient over a designated time  
2 period.

3  
4 “Life cycle impact assessment” (LCIA) means the phase of life cycle  
5 assessment aimed at understanding and evaluating the magnitude and  
6 significance of the potential environmental impacts for a product system  
7 throughout the life cycle of the product [ISO 14044]. ~~the third phase of an LCA.~~  
8 ~~This phase is concerned with understanding and evaluating the magnitude and~~  
9 ~~significance of the potential environmental impacts of the product(s) under study.~~

10  
11 “Input” means a material or energy flow that enters a unit process  
12 including raw materials, intermediate products, co-products, and waste for  
13 treatment.

14  
15 “Land use” means the use of land and/or the change of that use,  
16 considering land occupation as well as transformation impacts related to use and  
17 conversion (transformation) of land area by product-related activities such as  
18 agriculture, roads, housing, mining, etc. Land occupation considers the effects of  
19 the land use, the amount of area involved and the duration of its occupation  
20 (quality-changes multiplied with area and duration). Land transformation  
21 considers the extent of changes in land properties and the area affected (quality  
22 changes multiplied by the area).

23  
24 “Life cycle” means consecutive and interlinked stages of a product system,  
25 including initial design, raw material acquisition, manufacturing, and use to final  
26 disposal.

27  
28 “Life Cycle Assessment (LCA)” means the compilation and evaluation of  
29 the inputs, outputs and the potential environmental impacts of a product system  
30 throughout its life cycle. [\[ISO 14044\]](#).

31  
32 “Make available for use in California” has the meaning given to it in  
33 section 6xxxx.3.

34  
35 “Output” means a product, material or energy flow that leaves a unit  
36 process including raw materials, intermediate products, co-products, wastes and  
37 releases (e.g., emissions to air and discharges to water and soil).

38  
39 “Potential alternative” means a change in chemicals, materials, production  
40 processes or design for a particular product. Potential alternatives may include,  
41 but are not limited to, alternatives resulting in chemical substitution or elimination,  
42 process change, material substitution, product redesign, or a change in systems  
43 or operations.

Comment [A97]: The text of the proposal must acknowledge and indicate that it is derived from the ISO 14044 standard.

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

3  
4 "Process" means a set of interrelated or interacting activities that  
5 transforms inputs into outputs.

6  
7 "Resource depletion" addresses impacts due to the use of natural  
8 resources, either renewable or non-renewable, and either biotic or abiotic.

9  
10 "Safer alternative" means a potential alternative for a product that results  
11 in reduced hazard, exposure ~~and ecological impacts~~ without resulting in  
12 significant environmental life cycle and economic impacts.

Comment [A98]: Note: environmental life cycle impacts includes both ecological and resource depletion.

13  
14 "Secondary data" means data gathered from other than primary  
15 sources,(e.g. data base, industry, literature or governmental sources)

16  
17 "Sensitivity and uncertainty analysis" means a step of the LCA  
18 Interpretation phase to assess the robustness of the overall LCA results with  
19 respect to variations and uncertainties in the system boundaries, methods and  
20 data used. These analyses provide systematic procedures for estimating the  
21 effects of the choices made regarding methods and data on the outcome of a  
22 study.

23  
24 "Societal cost" means the external costs of an activity, product or system  
25 (e.g., not including the value of all the resources used in providing a product or  
26 service), including the value of all resulting impacts to human health and the  
27 environment from production, use and end-of-life. The sum of the costs of  
28 externalities (societal) and the priced resources makes up the total cost.

29  
30 "Substitution" means the replacement or reduction of hazardous  
31 substances in products and processes by less hazardous or non-hazardous  
32 substances.

33  
34 "System boundary" means a set of criteria specifying which unit processes  
35 are part of a product system to identify the interface between that product system  
36 and the environment or other product systems.

37  
38 "Transparency" means an open, comprehensive and understandable  
39 presentation of information.

40  
41 "Terrestrial toxicity" means an attribute that addresses impacts to  
42 terrestrial ecosystems as a result of toxicological mechanisms due to exposure to  
43 substances in the environment. (e.g., the potential for biological, chemical or  
44 physical stressors to affect or to disrupt the natural biochemistry, physiology,  
45 behavior and interactions of the living organisms that comprise the ecosystem.)

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1  
2 “Uncertainty” means the lack of certainty such as in the prediction of a  
3 certain outcome, in a measurement, or in an assessment results. It is a general  
4 term used to cover any distribution of data caused by either random variation,  
5 measurement precision or bias. In LCA, evaluation or measurement of  
6 uncertainty is an on-going process and relates to all the elements of data quality.

7  
8 “Unit process” means the smallest portion of a product system for which  
9 data are analyzed when performing a life cycle assessment.

10  
11 **Section 6xxxx.12. Identification of Potential Alternatives**

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

- 18 (1) the function of the consumer product;
- 19 (2) the function of the chemical of concern in the consumer product;
- 20 (3) the performance factors relevant to the specific function of the

21 consumer product and specific function of the chemical of concern in the  
22 consumer product.

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

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

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

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

37 (4) The alternative analysis process specified in this article shall be  
38 repeated no later than two-four years from the date that the notification required  
39 pursuant to subsection (b)(3) was provided to the Department. Data and testing  
40 previously conducted, if appropriate and valid, can be used in the  
41 analysis.

42  
43 **Section 6xxxx.13. Hazard Categorization Comparison**

44 (a) For each potential alternative identified pursuant to section 6xxxx.12, a  
45 person conducting the alternatives analysis shall perform hazard categorization

**Comment [A99]:** Difficult standard to meet – need to limit potential liability. Commercially available needs to be included. Not just theoretically available. Need to have consumer acceptance. Capacity must also be considered – that it is readily available adequate supply.

**Comment [A100]:** For each component? Formula for complex product will be impacted here. Look at every alternative for every component part for every chemical of concern. There will be multiple potential alternatives for multiple component products. Need to look at exposure, de minimis, etc. If component does not have exposure potential, no need for AA. Identify key chemicals of concern that truly have exposure potential and focus assessment on what will make a difference.

**Comment [A101]:** Please see comments above re complex parts.

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1 in accordance with the process specified in Article X to identify chemicals of  
2 concern in the potential alternative(s).

3  
4 (b) If a potential alternative is found to use or contain a chemical of concern  
5 that is assigned to the same hazard categories as the chemical of concern in the  
6 consumer product, the following shall apply:

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

Comment [A102]: These two elements of the assessments are pertinent at this stage.

14 (2) If all of the potential alternatives identified pursuant to section  
15 6xxx.12 are eliminated from further consideration, the following requirements  
16 shall apply:

17 (A) The consumer product shall be subject to the response action  
18 specified in section 6xxx.20(b)(1)(B), 6xxx.20(b)(1)(D), or  
19 6xxx.20(d)(3), if imposed by the Department;

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

25 (C) The manufacturer shall provide notification to the Department  
26 that all potential alternatives have been eliminated from  
27 consideration, as described in the requirements for the  
28 alternatives analysis findings report in accordance with section  
29 6xxx.17(c) and the date of this notification shall be added to  
30 the supply chain documentation required pursuant to section  
31 6xxx.6;

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

Comment [A103]: This time frame is not reasonable. The repeat of the AA should be triggered due to advances in science and technology, not an arbitrary time line. If a time line is needed, we suggest 10 years.

36  
37 **Section 6xxx.14. General Requirements for Assessment of Hazards,  
38 Exposure and, Life Cycle Environment and Economic Impacts**

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

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

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- 1 (2) Completeness: The assessment includes all inputs and outputs that
- 2 provide a material contribution to the assessment of impacts;
- 3 (3) Consistency: The data and information used provides meaningful
- 4 comparisons of results;
- 5 (4) Accuracy: Bias and uncertainties are minimized;
- 6 (5) Transparency: Sufficient information is disclosed to allow other
- 7 persons to validate results and make associated decisions with confidence.
- 8

- 9 (b) The alternatives assessment shall identify impacts associated with
- 10 implementation of alternatives, including, but not limited to:
- 11 (1) Increased hazard
- 12 (2) Increased exposure
- 13 (3) Increased negative ~~life cycle~~ environmental impacts
- 14 (4) Increased ~~ecological~~ economic impacts
- 15

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

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

Comment [A104]: Collected implies it is available or existing. In some cases, it may need to be estimated.

23 (b) Hazard information shall be collected for the specified criteria, until such  
24 time as the criteria are ~~modified~~ or superseded by criteria published by the Office  
25 of Environmental Health Hazard Assessment and posted on the Toxics  
26 Information Clearinghouse website. These criteria shall be evaluated in  
27 accordance with the procedure contained in section 6xxxx.7 and quantitative  
28 results shall be collected:

- 29 (1) Acute toxicity
- 30 (2) Specific target organ toxicity (single exposure)
- 31 (3) Target organ toxicity (repeated exposure)
- 32 (4) Adverse eye effects
- 33 (5) Mutagenicity and genetic toxicity
- 34 (6) Reproductive toxicity
- 35 (7) Carcinogenicity
- 36 (8) Endocrine disruption
- 37 (9) Respiratory sensitization
- 38 (10) Skin sensitization
- 39 (11) Bioaccumulation
- 40 (12) Aquatic toxicity
- 41 (13) Hazardous to the ozone layer
- 42

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(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

**Comment [A105]:** In an effort to eliminate the use of dose in the regulation, DTSC has basically changed the basic definition of risk. In this section, DTSC has changed the definition of toxicity by eliminating concentration. In this example there is no incentive for new chemistry for a CoC. For example, this exposure criteria examines a 37% monomer solution in the same fashion as formaldehyde naturally occurring in wood. The risks of these two examples vary greatly, however, this is not considered in the regulation. Moreover, this would gut the current CARB rule on particleboard. The CARB rule allows for improved chemistry to reduce the concentration emitted from the board. This regulation provides disincentive to improve chemistry as the use of the chemical precludes its future use exclusive of the process.

**Section 6xxxx.16. Methodological Approach for Assessment of Environmental Impacts using Life Cycle Impacts Assessment Tools**

(a) ~~Life cycle Environmental impacts comprise both ecological and resource depletion impacts.~~ For the product and each potential alternative that has not been eliminated in section 6xxxx.13(b) or 6xxx.16(b), the ~~life cycle environmental~~ impacts shall be determined as described in this section, ~~except as provided in the screening step provided described below in (b).~~

**Comment [A106]:** There is so much uncertainty here that we did not want to comment on everything until we are able to work with DTSC on a new approach. DTSC needs to review and – Work plan should be used to outline the methodology and focus key aspects of the life cycle assessment needs to be focused on to evaluate the consumer product.

(b) Screening Procedure. Prior to the environmental impact component of the assessment, the analyst shall conduct a screening evaluation. If the evaluation of the consumer product with and without each of the identified potential functionally equivalent alternatives indicates that all of the relevant ecological and resource depletion indicators remain the same, then the environmental impact assessment component will not be required.

**Comment [A107]:** Will introduce screening step which will be described below before function and functional unit.

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(c) The following approach shall be taken to determine if significant impacts would result from a [functionally equivalent](#) 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.

(d) Functional equivalence  
The impact assessment specified in this section shall [mean a comparative evaluation of](#) the originally [identified chemical of concern in the consumer product](#) [with identified functionally equivalent alternatives to the chemical\[s\] of concern](#). A general description of the product and its intended and reasonably foreseeable uses shall be provided as supporting information. Comparisons between [chemical alternatives](#) and the originally [identified chemical of concern in the consumer product](#) shall be made on the basis of the same function(s), quantified by the same functional unit(s).

(e) ~~Life Cycle system~~[Environmental Impact 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. [The evaluation shall apply the LCIA tools TRACI or CML. Such-The key environmental impact life cycle phases-impact indicators](#) include:

- (1) Raw materials,
- (2) Energy consumption,
- (3) Manufacturing,
- (4) Transportation,
- (5) Use, and

Comment [A108]: Unclear what this means?

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1 (6) End-of-life.

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

Comment [A109]: Key environmental impact indicators should include: the Materials consumed, Energy Consumed, and EOL (disposability and leachability)?

7  
8 (fe) Information/data collection

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

15  
16 (2) When identifying data for use, preference shall be given as follows:

- 17 (A) For time-related coverage: data that are time-specific to the  
18 product being assessed shall be preferred (e.g., age of data and  
19 the minimum length of time over which data are collected).  
20 Where the data associated with any life cycle phase of a  
21 product vary over time, the data shall be collected over a period  
22 of time sufficient to establish the data needed to characterize  
23 the life cycle of the product and its alternative(s). Where a  
24 product is made available on a continuing basis, the information  
25 used for the assessment of impacts shall cover at least one  
26 year. Where a product or a component part is differentiated by  
27 time (e.g. seasonal products), the information collected shall  
28 cover the particular period associated with the production of the  
29 product or component;
- 30 (B) For geographical specificity: data that are geographically-  
31 specific to the product being assessed shall be preferred (e.g.  
32 district, country, region);
- 33 (C) For technology coverage: data that are technology-specific to  
34 the product being assessed shall be preferred (e.g., whether the  
35 data relates to a specific technology or a mix of technologies);
- 36 (D) For accuracy of the information: data that are most accurate  
37 shall be preferred (e.g. data, models and assumptions);
- 38 (E) For precision: data that are more precise (i.e. has the lowest  
39 statistical variance) shall be preferred (i.e., measure of the  
40 variability of the data);
- 41 (F) For completeness: the data that are primary, and the degree to  
42 which the data represents the population of interest shall be  
43 preferred (i.e., the sample size is large enough, the periodicity of  
44 measurement is sufficient, etc.);

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- (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 or module 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

(4) The economic information shall consist of relevant elements of the following list, allowing when pertinent or only practical, qualitative information in some of these elements.

- (A) 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

**Comment [A110]:** We recommend limiting the environmental information to the following key impact indicators: material consumption, energy consumption, and end of life (disposal and leachability).

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1  
2 | (gf) Impact assessment

3 | (1) The selection of impact categories shall reflect a comprehensive  
4 set of environmental and economic characteristics related to the product system  
5 being studied. The analyst shall use discretion in selecting the relevant,  
6 appropriate impact categories from the following list in a number not less than a  
7 minimum of four(4) of such ecological and resource depletion indicators. A set of  
8 impact categories shall include, but not be limited to:

9 | (A) Ecological impacts

- 10 | (i) Global warming
- 11 | (ii) Acidification
- 12 | (iii) Terrestrial toxicity
- 13 | (iv) Photochemical smog
- 14 | (v) Stratospheric Ozone depletion
- 15 | (vi) Eutrophication
- 16 | (vii) Water quality (e.g. BOD, COD and TSS)
- 17 | (viii) Ecotoxicity (including both aquatic and terrestrial ecosystems)
- 18 | (ix) Radioactivity

19 | (B) Human health impacts

- 20 | (i) Occupational health effects
- 21 | (ii) Human toxicity and Public health effects (excluding work  
22 environment)
- 23 | (iii) Human social disturbance effects

24 | (C) Resource depletion impacts

- 25 | (i) Energy consumption
- 26 | (ii) Natural resource (renewable and non-renewable) consumption
- 27 | (iii) Energy efficiency
- 28 | (iv) Water consumption and conservation
- 29 | (v) Land use
- 30 | (i)

31  
32 | (2) While quantitative results are desired, the practitioner of the study may  
33 choose qualitative or semi qualitative metrics (e.g. low, medium, high level; or 1-5  
34 rating system) based on data quality. The method of calculating results (e.g.,  
35 the characterization model and characterization factors used) shall be identified  
36 and documented, including the value-choices and assumptions used.

37  
38 | (3) The comparative impact assessment shall be conducted by evaluating the  
39 results of the alternatives based on potential benefits and tradeoffs versus the  
40 original product. The processes resulting in significant impacts for the  
41 alternatives versus the original product are then identified. Sensitivity of the  
42 results should be quantified by re-evaluating the results considering the  
43 maximum (worst acceptable) and minimum (best viable) data for the identified  
44 processes.  
45

Comment [A112]: There is a need to make the impact assessment relevant

Comment [A113]: Moved to new section 6xxx.16.1.

Comment [A114]: This impact assessment section should be simplified as suggested in our comment letter.

Comment [A115]: While the above approaches have been used for hazard and exposure estimation, for life cycle impacts they are neither practical nor informative. For the life cycle impacts, the qualitative High, Medium, and Low terms should be used on the level of difference between the consumer product and each alternative for the resulting values/results for each impact category indicator. A "Less" level is added to capture situations in which the alternative's specific impact indicator value is less than the consumer product's being evaluated.

Comment [A116]: This is an important interpretation of the H, M, L terms and one which would bring the life cycle impact assessment into the regime of qualitative predictions used all around the proposal for other components of the safer alternative assessment.

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

7  
8 (5) The economic analysis shall provide a range of projected capital costs and  
9 operating costs, societal costs, cost savings, and revenues for the alternatives  
10 under study in comparison to the original product containing the chemical of  
11 concern. All life cycle phases and processes analyzed in the environmental  
12 analysis shall be included in the economic analysis. Additional processes and  
13 phases may need to be included to adequately assess costs, including, but not  
14 limited to external costs.

15  
16 (6) The environmental mechanism and decision criteria that relate the  
17 information collected in (e) to the impact category in (f) shall be described and  
18 documented. The appropriateness of the decision criteria used for deriving the  
19 category metrics in the context of the goal and scope of the study shall be  
20 described and documented. The results of the impact assessment shall be valid  
21 until there is a change in the design, manufacturing or formulation of the product  
22 which is being assessed.

23  
24 (g) Documentation

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

34  
35 (2) The results of the study shall be made available to the Department  
36 within 30 days of a request from the Department in the form of a report that  
37 contains, at a minimum, the following sections:

38 A. Administrative Information

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

44  
45 B. Product System Description

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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.

**Comment [A117]:** The description should be limited to those key indicators that show a difference between the use of the original chemical and the functional alternatives.

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**New Section:**

**Section 6xxx.16.1 Methodological Approach for Assessment of Economic Impacts**

(a) 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.

(b) The categories or types of costs to be examined will be the following to the extent proper information is available and reliable :

1) Direct Corporate costs,

2) Indirect Corporate costs,

(3) Future and contingent liability costs, and

(4) Societal external costs (due to human health and environmental impact social costs.

**Section 6xxx.17. Comparison of Alternatives**

(a) The properties of the functionally equivalent potential alternatives identified in section 6xxx.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 6xxx.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 6xxx.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 6xxx.13. If all of

**Comment [A118]:** This does not make sense until we understand better what the entire process will look like and what industry will be tasked to do. Need a methodology for comparison. We note that under an LCA, the evaluation will provide information on alternatives but is not a decision making tool. We will be collecting info through an LCA process and the act of and synthesis of information into alternatives does not constitute a decision, just information that may be acted upon in the future.

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- 1 the potential alternatives were eliminated from consideration, the report shall  
2 describe in detail the justification for elimination.  
3
- 4 (d) The third section of the alternatives analysis report shall contain a  
5 comparison of alternatives. The properties of the potential alternatives identified  
6 shall be compared to those of the consumer product as depicted in Table XX -  
7 Alternatives Analysis Summary.
- 8 (1) In the summary table, the hazard, exposure, ~~and~~ life cycle impacts  
9 (ecological impacts, ~~and~~ resource consumption impacts) ~~and~~, economic  
10 impacts) for the consumer product shall be reported using one or a combination  
11 of the following methods:
- 12 (A) reported in quantitative terms with clear units,  
13 (B) reported as high, medium or low impact, as ~~determined~~ determined  
14 by Table XX—Impact Assessment Criteria for Exposure, or  
15 (C) left blank if information cannot be reported for any given attribute.  
16
- 17 (2) For each alternative that was not eliminated from consideration pursuant  
18 to section 6xxxx.13(b), the results of the hazard and exposure assessment and  
19 the results of the life cycle impact assessment shall be reported.  
20
- 21 (3) The attributes of the alternatives shall either be reported in quantitative  
22 terms with the same units used for the consumer product in 6xxxx.17(d)(1) for  
23 the same impact, or tabulated in relation to the consumer product using a  
24 qualitative scale as follows:
- 25 (A) For those attributes in which the potential alternative achieves  
26 approximately the same impact assessment value as the consumer product, the  
27 comparison is depicted by an equal sign (=).  
28 (B) For those attributes for which the impact assessment of the  
29 potential alternative is unknown, the comparison is depicted by a question mark  
30 (?).  
31 (C) For those attributes for which the impact assessment of the  
32 potential alternative is known relative to the consumer product, the comparison  
33 shall be depicted by a qualitative scale with sufficient detail to express the results  
34 of the comparison accurately.

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- 1 (D) An example of a permissible qualitative scale follows:  
2 + the alternative is less impactful / less hazardous than the consumer  
3 product;  
4 ++ the alternative is significantly less impactful / less hazardous than  
5 the consumer product;  
6 - the alternative is more impactful / more hazardous than the  
7 consumer product;  
8 -- the alternative is significantly more impactful / more hazardous than  
9 the consumer product;.
- 10 (E) A different qualitative scale may be used for comparison of  
11 alternative with the consumer product if the replacement scale contains sufficient  
12 detail to determine significant impacts.  
13
- 14 (e) The fifth section of the alternatives analysis report shall describe the  
15 process used to decide among alternatives, and report which alternative was  
16 chosen, or if no alternatives were chosen. This description shall include the  
17 following:
- 18 (1) Identification of any potential alternatives that are clearly superior to  
19 the product with regard to the hazard and exposure impacts;
- 20 (2) Identification of any potential alternatives that are clearly superior to  
21 the product with regard to the life cycle ecological impacts ecological and  
22 resource depletion; ~~(3) Identification of any potential alternatives that are~~  
23 ~~clearly superior to the product with regard to the resource impacts~~
- 24 (4) Identification of any potential alternatives that are clearly superior to  
25 the product with regard to the economic impacts;
- 26 (5) The decision factors used to either select an alternative or retain  
27 the product unchanged;
- 28 (6) Identification of any attributes that will be significantly more  
29 impactful and the dominant life cycle phase where the impact occurs as a result  
30 of the selection as determined by comparison of the product and potential  
31 alternatives;
- 32 (7) Any other factors the analyst deems relevant to the decision.  
33
- 34 (f) The sixth section of the alternatives analysis report shall state:  
35 (1) the person who conducted the study and their affiliation;  
36 (2) date of the report;  
37 (3) a signed statement that the study and findings report have been  
38 conducted in accordance with the requirements in this article.  
39
- 40 (g) The seventh section of the alternatives analysis report shall describe an  
41 implementation plan and schedule for implementing an alternative, if applicable.  
42  
43

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**Table XX – Alternatives Analysis Summary**

	Impacts	Product	Alt A	Alt B	Alt C
<b>Hazard and Exposure Impacts</b>	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				
<b>Ecological Impacts</b>	Global warming				
	Acidification				
	Photochemical smog				
	Stratospheric Ozone depletion				
	Eutrophication				
	Water quality (eg. BOD, COD and TSS)				
	Ecotoxicity (including both aquatic and terrestrial ecosystems)				
Radioactivity					
<b>Resource Depletion Impacts</b>	Energy consumption				
	Natural resource (renewable and non-renewable) consumption				
	Energy efficiency				
	Water consumption and conservation				
	Land use				
<b>Economic Impacts</b>	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)				

**Comment [A119]:** Should be simplified to reflect the environmental impact assessment suggested in our letter and throughout this redline. We also have a concern regarding the comparability and consistency of this type of approach.

**Comment [A120]:** These impact indicators are seldom and equally approached on the existent LCIA approach available (From Gabi to Traci going thru Humberto). They need to be simplified in number with reference to a couple of LCIA approaches to provide guidance and some level of consistency. In this group it is very important to make clear for global warming, that CO2 from biomass combustion is neutral or zero.

**Comment [A121]:** Same as comment above, with respect to the LCIA approaches. Need to clarify the distinction between energy and materials renewable and non-renewable since most of the LCIA approaches (Gabi, CML, Traci) consider renewable as non-impact and focus on non-renewable.

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**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~~ work plan specified in [New Section] and 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.~~

**Comment [A122]:** As we have discussed in our comment letter, we believe a work plan should be submitted to DTSC outlining the proposed AA methodology and time line for expected completion. We are happy to work with the Department on suggested regulatory language.

(b) ~~When~~ the alternative analysis is shall be completed as identified in the submitted work plan, the date of completion shall be added to the supply chain documentation required pursuant to section 6xxxx.9.

(c) After completion of the work plan, if a safer alternative is not selected for implementation, ~~then following requirements apply:~~

~~(1) the alternatives analysis process shall be repeated, and the associated Report shall be revised, every two eight years, with a reasonable effort to identify safer functionally equivalent 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, if applicable. 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 Relevant Information relied upon 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).

**Comment [A123]:** The work plan review and approval process we have discussed should provide the Department with ample opportunity to request information whilst at the same time providing manufacturers with the certainty required to move forward with the AA. We welcome the opportunity to work with the Department on work plan language.

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~~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.~~

(e) 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) Following the completion of one or more alternatives analyses, as described in Section 6.xxx18 above, for a specific Chemical of Concern in a priority consumer product, the Department may proceed, by formal rulemaking, to propose and adopt one of the following response actions, as necessary to protect public health or the environment, as applicable, from exposures to the Chemical of Concern in the priority consumer product that exceed the thresholds specified in Section 6.xxx.XX (De Minimis Criteria).

- (a) No further action.
- (b) Submittal to the Department of additional information needed to assess the Chemical of Concern in the priority consumer product and the potential alternatives, if any, to the Chemical of Concern in that consumer product.
- (c) Labeling of the priority consumer product, or other type of consumer product information, to the extent that such labeling or other information requirement is consistent with any product information requirements applicable to such consumer product that are imposed pursuant to other federal or state laws
- (d) Restrictions on the use of the Chemical of Concern in the consumer product, including product design requirements that would control

**Comment [A124]:** The suggested language below reflects the need for DTSC to undertake a regulatory process for imposing response actions. DTSC has discretion and should chose between the 9 different options listed in the statute (Section 25253(b)(1-9)), including the option to select "no further action" as a response to a completed AA.

**Comment [A125]:** We suggest including de minimis criteria or evaluation in the regulation.

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1 access to or limit exposure to the chemical of concern in the  
2 consumer product.

3 (e) Prohibiting the use of the chemical of concern in the consumer  
4 product.

5 (f) End of life product management requirements, including recycling  
6 or responsible disposal of the consumer product by consumers or  
7 product manufacturers.

8 (g) Funding of challenge grants to identify or develop commercially  
9 feasible alternatives to the Chemical of Concern in a priority  
10 consumer product where no commercially feasible alternative  
11 currently has been identified or exists.

12  
13 (2) The Department shall not propose any of the actions set forth in  
14 sections (A) (1) (b) through (A)(1)(e) above unless it first finds:

15 (a) Such action is necessary to protect public health from known risk of  
16 adverse health effects resulting from exposures to the Chemical of  
17 Concern in such consumer product;

18 (b) Such action is reasonably calculated to significantly reduce  
19 exposure to the Chemical of Concern to users of the product,  
20 including sensitive subpopulations, during normal intended use of  
21 the product and proper disposal;

22 (c) No other action set out in subsection (a) above or otherwise known  
23 to the Department that is less burdensome or less costly to  
24 manufacturers or to consumers would be equally effective as the  
25 requirement proposed by the Department; and

26 (d) Such requirement is reasonably implementable on a current basis  
27 for the majority of existing manufacturers of such consumer product  
28 or, if it is not, that a sufficient time has been allowed for  
29 implementation of the requirement as proposed by the Department.

30  
31 (3) The Department shall not prohibit the use a Chemical of Concern in a  
32 priority consumer product pursuant to subsection (A)(1)(e) above unless it  
33 also first finds that:

34  
35 (a) A feasible substitute chemical for the Chemical of Concern is  
36 commercially available for use in the priority consumer product; or

37 (b) A feasible substitute chemical for the Chemical of Concern that is  
38 commercially available for use in the priority consumer product can  
39 be developed before the effective date of the prohibition proposed  
40 by the Department; or

41 (c) The benefits to users, including sensitive subpopulations, of  
42 availability of the priority consumer product are outweighed by the  
43 risk of adverse health effects from exposure to the Chemical of  
44 Concern during normal.

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(4) The Department shall not impose end-of-life waste management requirements under section (A)(1)(g) above, or require the manufacturers or users of a priority consumer product to separately manage the consumer product at the end of its useful life, unless the Department first finds that:

- (a) Such action is necessary to protect the environment from exposures to a Chemical of Concern in the priority consumer product that result when that product is disposed in compliance with applicable regulations governing disposal household waste;
- (b) The product at end of life is a unique waste that cannot be efficiently managed through existing programs for management of household hazardous waste;
- (c) Alternative waste management options for the product are reasonably calculated to significantly reduce exposure to the Chemical of Concern in the environment; and
- (d) Users of the product reasonably can be expected to participate in the alternative management programs as proposed by the Department.

(5) The Department shall not require a green chemistry challenge grant under subsection (A)(1)(h) above unless it first finds that:

- (a) The risk to public health or the environment from the Chemical of Concern in the priority consumer product is significant;
- (b) No feasible alternative for the Chemical of Concern in the priority consumer product is commercially available on a current basis; and
- (c) A feasible alternative for the Chemical of Concern in the priority consumer product that is commercially available can be identified and developed within a reasonable period, not to exceed (xx) years, and at a reasonable cost.

(6) Any regulatory response proposed by the Department under subsection (A)(1) shall identify with specificity the particular chemical of concern and the particular priority consumer product or products to which it applies. On and after the effective date for that response action set out in the final regulation, no priority consumer product to which that response action applies may be sold or leased in California unless it is in compliance with the requirements of that response action or unless the manufacturer of the priority consumer product has obtained a waiver or variance from the Department pursuant to subsection (A)(8) below or has determined that the consumer product does not result in an exposure to

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1 [the Chemical of Concern above the threshold specified in Section](#)  
2 [6xxxx.XX \(De Minimis Criteria\).](#)

3  
4 [\(7\) Any response action proposed by the Department pursuant to](#)  
5 [subdivision \(a\) shall set forth an effective date that is reasonable in light of](#)  
6 [the actions that will be necessary for manufacturers and retailers of](#)  
7 [products to which the response action applies to produce and market](#)  
8 [products that will comply with the requirements of the response action.](#)  
9 [Any response action adopted by the Department shall apply only to](#)  
10 [products made available for use in California after the effective date of the](#)  
11 [response action.](#)

12  
13 [\[\(8\) The Department shall grant a variance or waiver from any response](#)  
14 [action for any priority consumer product to which such response action](#)  
15 [would otherwise apply where the submitter can show by a preponderance](#)  
16 [of the evidence that use and disposal of the priority consumer product is](#)  
17 [not expected to result in an exposure to the chemical of concern above](#)  
18 [the applicable de minimis threshold specified in Section 6xxxx.XX.](#)  
19 [Upon the completion of the alternatives analysis required by article XX,](#)  
20 [\(A\) the manufacturer shall take response actions pursuant to this](#)  
21 [article, if either a consumer product or the alternative to be](#)  
22 [implemented contains a priority chemical of concern or has a](#)  
23 [significant impact identified pursuant to section 6XXXX.17, provided](#)  
24 [the response action is not otherwise prohibited by law; or](#)  
25 [\(B\) if the manufacturer implements a safer alternative that does not](#)  
26 [contain a priority chemical of concern within one \(1\) year of the](#)  
27 [completion of the alternative analysis, the manufacturer shall](#)  
28 [comply with a notification pursuant to subsection \(a\)\(3\)\(B\)2 within](#)  
29 [90 days of completion of the alternative analysis. The manufacturer](#)  
30 [shall comply with articles X and XX, if applicable.](#)

31  
32 **(9) Response Action Implementation Plan.** When a response action is  
33 required, a manufacturer responsible for taking the action shall prepare a  
34 detailed response action implementation plan. The plan shall be prepared  
35 within ninety (90) days from the date the alternative analysis required by  
36 article XX has been completed. The plan shall address either the  
37 consumer product or the alternative to be implemented. The plan shall  
38 include the following:

- 39 (A) name and physical location of the business;  
40 (B) name of contact person and contact information;  
41 (C) six digit North American Industry Classification System codes  
42 applicable to activities at the business;  
43 (D) number of employees

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- (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 in priority consumer products being made available for use in California per annum for the three prior calendar years;
- (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.

**Comment [A126]:** This is consistent with the REACH requirements.

A manufacturer person 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 person made the consumer product subject to the alternative analysis required by article XX available for use in California. A manufacturer person 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.

**Comment [A127]:** Need to resolve issue of manufacturers/ distributors/ transferees not located in California.

**(103) Notification.**

(a) Within ninety (90) days from the date the alternative analysis required by article XX has been completed, a manufacturer person responsible for completing the alternative analysis shall send an electronic notification to the Department. The notification shall include the following information:

(b) If a regulatory response has been identified pursuant to Section 6.xx20(A)(1), the information specified in subsections 6XXXX.20(A)(a)(2)(A)-(4)(9)(A-I) of the response action implementation plan required by subsection (a)(29) of this section.

(c) The manufacturer submitter shall add the following information to the supply chain documentation pursuant to section 6XXXX.9.

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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.

(dC) Notwithstanding subsection (A)(103)(bB), if the safer alternative has been implemented and the supply chain documentation is no longer required, then only the notification pursuant to subsection (aA) required.

(411) ~~If the Department determines the following:~~  
~~(aA) the a manufacturer responsible for taking response actions has not taken response action pursuant to subsections (Bb) and (Cc) of this section, or~~  
~~(bB) the continued availability in California of the consumer product or implemented alternative selected pursuant to section 6xxx.17, with the implementation of the proscribed response actions, would pose a significant risk to human health or the environment,~~  
~~the Department may impose response actions, as prescribed in subsections (Cc) and (Dd) of this section, provided that the response actions are not otherwise prohibited by law.~~

(125) (a) ~~Prior to initiating a formal rulemaking pursuant to Section A(1), the Department may seek additional information needed to assess the Chemical of Concern in a priority consumer product and the potential alternatives, if any, to the Chemical of Concern in that consumer product by public notice specifying:~~

- ~~(i) The specific type[s] of relevant scientifically defensible information sought;~~
- ~~(ii) The Chemical of Concern and the priority consumer product[s] to which the information request relates;~~
- ~~(iii) That the scientific information is being sought to assess a possible regulatory response action[s] under Section X above; and~~
- ~~(iv) The date by which relevant and scientifically defensible information should be submitted to the Department.~~

~~(b) Any interested party may submit relevant scientifically defensible information to the Department within the time set forth in the notice. Any information submitted in response to an information request issued under this Section XX will be subject to Section 25257 of the Health and Safety Code. The Department may use any data or alternative analysis required by article XX to imposed response actions.~~

**Comment [A128]:** This section was deleted as this is not an appropriate action for the Department. The statute does not provide DTSC with the authority to impose a command and control scheme. DTSC must give manufacturers due process when imposing regulatory response actions.

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1  
2 | **(136) Considerations for Department Authorized Response Actions.**

3 | The Department shall consider the following when determining whether to  
4 | impose a response action:

5 | (aA) Nature of the hazards and potential risk including:

- 6 | 1. hazardous traits, characteristics, and endpoints;  
7 | 2. potential risks to sensitive populations, including but not  
8 | limited to, infants, children, and pregnant women; and  
9 | 3. evaluation of exposure attributes pursuant to section  
10 | 6XXXX.17 that indicate a significant human health or  
11 | environmental impact; or

12 | (bB) Effectiveness of the response action and the appropriateness  
13 | of the time frame for completing the response action ~~identified in~~  
14 | ~~the response action implementation plan submitted to the~~  
15 | ~~Department pursuant to subsection (a)(2) of this section;~~

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

19 | (dD) Duplicative or conflicting requirements: The Department will  
20 | consider existing requirements imposed by other agencies.

21 |  
22 | (714) Not later than sixty (60) days after the Department has provided  
23 | written notification to a manufacturer responsible for taking response  
24 | action that the Department has determined that other or additional  
25 | response actions are required, a manufacturer shall submit a response  
26 | action implementation plan for those response actions.

27 |  
28 | (158) A manufacturer providing information pursuant to this section shall,  
29 | at the time of the submittal, identify all portions of the information claimed  
30 | to be a trade secret or confidential business information.

31 |  
32 | **(B) Response Actions Criteria–Appeal**

33 |  
34 | (1) Within 30 days after the Department adopts a regulatory response  
35 | pursuant to Section X above, any person who filed written comments  
36 | during the public comment period on the proposed regulation may petition  
37 | the Department to review the regulatory response. The petition shall  
38 | include a statement of the reasons supporting the review, including a  
39 | demonstration that any issues being raised either were raised during the  
40 | public comment period (including any public hearing) or arose only after  
41 | the close of the comment period and, when appropriate, a showing that  
42 | the regulatory response as adopted is based in whole or in part on:  
43 |

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- 1 (a) A finding of fact or scientific conclusion that is [clearly erroneous]  
2 [not supported by substantial evidence], or  
3 (b) A finding of fact or scientific conclusion was not based on reliable  
4 studies conducted in accordance with good laboratory practices or  
5 with data from accepted and validated models, or  
6 (c) An alternatives analysis that failed to take into account the factors  
7 listed in Section XX ; or  
8 (d) A failure to make the one or more findings required under Section X  
9 above; or  
10 (e) One or more findings required under Section X above is not  
11 supported by substantial evidence or otherwise not in accordance  
12 with the requirements of Section X above. .

13  
14 (2) Within a reasonable time following the filing of the petition for review,  
15 the Department shall issue an order either granting or denying the petition  
16 for review. Public notice of any grant of review by the Department under  
17 subsection (a) of this section shall be given by the following methods:

- 18  
19 (a) Mailing a copy of the notice to: (i) the petitioner, (ii) members of the  
20 Green Ribbon Science Panel, and (iii) any other agency which the  
21 Department knows have proposed the Chemical of Concern for  
22 listing as a chemical of concern;  
23 (b) Publication of a notice on the Department's website;  
24 (c) Any other method reasonably calculated to give actual notice of the  
25 action in question to the persons potentially affected by it, including  
26 press releases or ay other forum or medium to elicit public  
27 participation.

28  
29 (3) Public notice shall set forth a briefing schedule for the appeal and shall  
30 state that any interested person may file a written argument. Notice of  
31 denial of review shall be sent only to the person(s) requesting review and  
32 the members of the Green Ribbon Science Panel.

33  
34 (4) When a review has been initiated pursuant to subsection (a) of this  
35 section, the order denying review or the decision on the merits shall  
36 constitute the Department's final regulatory response decision, and shall be  
37 effective on the date of mailing of the order denying review or decision on  
38 the merits.

39  
40 (5) A final regulatory response decision on a petition to the Department  
41 under subsection (1) of this section is a prerequisite to seeking judicial  
42 review of the Department's decision.  
43

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1 (6) A notice of appeal filed pursuant to subsection (1) shall stay any  
2 effective date for the regulatory response set forth in the regulation until the  
3 date of issuance of the order denying review or the decision on the merits.  
4 A request for judicial review pursuant to subsection (5) above shall not stay  
5 the effective date of the regulatory response unless and until so ordered by  
6 the court.

7  
8 ~~(1) Upon completion of the alternative analysis required by article XX, if a~~  
9 ~~safer alternative has not been implemented, a manufacturer of a~~  
10 ~~consumer product containing a priority chemical of concern shall be~~  
11 ~~subject to the following requirements:~~

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

13 ~~1. If the chemical of concern is a priority 1 chemical that has~~  
14 ~~been banned by another governmental agency, and there is a~~  
15 ~~potential safer alternative, a manufacturer shall comply~~  
16 ~~with subsections (c)(2), and (c)(3)(A);~~

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

21 ~~3. If the chemical of concern is a priority 2 chemical and~~  
22 ~~there is a potential safer alternative, a manufacturer shall~~  
23 ~~comply with subsections (c)(3)(C); and~~

24 ~~4. If the chemical of concern is a priority 3 chemical and~~  
25 ~~there is a potential safer alternative, a manufacturer shall~~  
26 ~~comply with subsections (c)(3)(D); and~~

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

28 ~~1. If the chemical of concern is a priority 1 chemical that has~~  
29 ~~been banned by another governmental agency, and if there~~  
30 ~~is no potential alternative; a manufacturer shall comply with~~  
31 ~~subsections (c)(2), and (c)(3)(B);~~

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

36 ~~3. If the chemical of concern is a priority 2 chemical and~~  
37 ~~there is no safer potential alternative, a manufacturer shall~~  
38 ~~comply with subsections (c)(3)(D).~~

39 ~~4. If the chemical of concern is a priority 3 chemical and~~  
40 ~~there is no safer potential alternative, a manufacturer shall~~  
41 ~~comply with subsections (c)(3)(E).~~

42  
43 ~~(2) Upon completion of the alternative analysis required by article XX, if~~  
44 ~~the attributes prescribed in subsection 6XXXX.17 of the implemented~~

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1 alternative would have significant impacts in California, the manufacturer  
2 shall be subject to the following requirements when the evaluation  
3 pursuant to section 6XXXX.17 indicates the following:

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

- 7 i. acute toxicity;
- 8 ii. carcinogenicity;
- 9 iii. mutagenicity;
- 10 iv. reproductive; or
- 11 v. endocrine disruption;

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

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

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

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

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

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

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

41  
42 **(j) Response Actions.** The response actions to be taken when required  
43 pursuant to subsection (b) include the following or combination thereof, to the  
44 extent that the response actions are not otherwise prohibited by law:

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~~(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.~~

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~~(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 that meets the following requirements:~~

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- ~~(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 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~~

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- 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~~

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1 ~~strategies for managing and reducing the life cycle impacts of the~~  
2 ~~consumer product, including establishing and maintaining:~~  
3 ~~(A) take-back programs; or~~  
4 ~~(B) statewide or local recycling or collection programs; or~~  
5 ~~(C) statewide or local programs to control priority chemical of~~  
6 ~~concerns or consumer product impacts to the environment.~~

7  
8 **(C5) Additional Notifications** On or before ninety (90) days from the date the  
9 alternative analysis required by article XX has been completed, a ~~manufacturer~~  
10 ~~person making the product available for use in California~~ or, if applicable, a  
11 transferee shall provide the notification as specified in subsection (a)(3) to the  
12 following:

- 13 (A) submit the notification to the Integrated Waste Management  
14 Board;
- 15 (B) submit the notification to the Department of Industrial  
16 Relations;
- 17 (C) submit the notification to the Air Resources Control Board;
- 18 (D) submit the notification to the State Water Resources Control  
19 Board; or
- 20 (E) submit the notification to the Department of Fish and Game; or
- 21 (F) submit the notification to any boards, departments, and  
22 agencies having jurisdiction over a life cycle attribute with  
23 significant impacts.

24  
25 **(6D) Modification** If the response actions specified in subsection (6A) need to  
26 be modified or the dates specified in subsection (Ae) of this section are not  
27 reasonably attainable, a manufacturer may petition the Department for a  
28 modification pursuant to section 6XXXX.21 of this article.

29  
30 **(d) Response Actions.** ~~The following response actions may only be authorized~~  
31 ~~by the Department:~~

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

37  
38 ~~(2) Restrictions. The Department may require a manufacturer or, if~~  
39 ~~applicable, the transferee to impose restrictions or requirements to control~~  
40 ~~access to or limit exposure to the chemical of concern in the consumer~~  
41 ~~product.~~

42  
43 ~~(3) Research and Development. If the manufacturer can demonstrate~~  
44 ~~that research is in progress for the priority chemical of concern, and its~~

**Comment [A129]:** DTSC should be aware that much of the information that will be generated by the AA and other evaluations will rely upon information provided to manufacturers by suppliers. Suppliers may also require manufacturers to sign non-disclosure agreements for information regarding components. We recommend an acknowledgement that some information may need to be shared with other agencies under CBI protections and other information may not be available from the manufacturers for disclosure if the manufacturer is provided the information from suppliers under a NDA.

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1 potential alternatives, through collaboration with other users of the  
2 prioritized chemical of concern or by an independent party, the  
3 Department may authorize a research and development proposal provided  
4 the manufacturer submits to the Department with following documentation:

- 5 (A) To apply for a research and development waiver, a  
6 manufacturer shall provide to the Department a written research  
7 and development notice that identifies the following:  
8 1. The substantive elements of the research and development  
9 program;  
10 2. The expected amount of time required for each substantive  
11 element;  
12 3. The processes, pollution control equipment, and emissions  
13 which are likely to be affected by the program;  
14 4. Potential or expected benefits of the program; and  
15 5. The basis upon which the results of the program will be  
16 evaluated.

- 17 (B) The substantive elements of the research and development  
18 program, which shall include, but are not limited to:  
19 1. Identification and nature of research on a specific product  
20 and/or application of a prioritized chemical of concern;  
21 2. Design of product with substitute chemicals that are not  
22 priority chemicals of concern;  
23 3. Use of chemical ingredients that are restorative of the  
24 environment;  
25 4. Design chemical products to be effective, but reduce toxicity.  
26 5. Use chemicals that readily break down into innocuous  
27 substances in the environment.  
28 6. Other criteria as deemed necessary and appropriate.

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

35  
36 **•(4) Green Chemistry Funding.** If no safer alternative exists, the  
37 Department may authorize a funding proposal for a Green Chemistry  
38 Challenge Grant provided:

- 39 (A) the manufacturer has the ability and intention to comply with the  
40 intent of articles x, xx, and xxx;  
41 (B) the manufacturer is not otherwise legally required to fund this  
42 proposal;

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~~(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**

Comment [A130]: There needs to be a stay of the underlying requirements when a company applies for a variance until a decision has been made. If a variance is denied, the company should have a period of time (12 months) for the products to come into compliance.

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- 1 (a) Any manufacturer or if applicable, a transferee may petition the Department in  
2 writing to modify or waive any provision in article x or article xx, provided efforts  
3 to comply with the requirements can be demonstrated; and a written narrative  
4 demonstrating the good faith efforts undertaken to comply is provided.  
5
- 6 (b) The department shall make one of the following findings:  
7 (1) The chemical of concern is found to be below “no significant risk  
8 levels” for carcinogens or below “maximum allowable daily levels” for  
9 chemicals that cause reproductive toxicity;  
10 (2) The chemical of concern is insignificant or unimportant as a potential  
11 hazard to human health and safety or to the environment;  
12 (3) The consumer product is insignificant or unimportant as a potential  
13 hazard to human health and safety or to the environment, when managed  
14 in accordance with the conditions, limitations, and other requirements  
15 specified in the response action;  
16 (4) The exposure during use of the consumer product is insignificant  
17 potential hazard to human health and safety or the environment;  
18 (5) The consumer product is regulated by another governmental agency in  
19 a manner that ensures it will not pose a substantial present or potential  
20 hazard to human health and safety, and the environment; or  
21 (6) A requirement imposed by another public agency provides protection  
22 of human health and safety or the environment equivalent to the protection  
23 provided by the requirement of this article.  
24
- 25 (c) Upon the completion of the alternatives analysis required by article XX, if a  
26 determination has been made to implement a prohibition as a response action as  
27 prescribed in subsection 6XXXX.20(c)(3), a manufacturer may petition the  
28 Department to allow the continued use of the consumer product, provided there  
29 is no safer alternative that is functionally equivalent or has equivalent  
30 performance; or there is no safer alternative that is economically and technically  
31 viable.  
32
- 33 (d) Each petition must be submitted to the Department by certified mail and must  
34 include:  
35 (1) The name and address of the petitioner;  
36 (2) A statement of the petitioner’s proposed request for modification or  
37 variance and the specific regulatory requirement being modified; and  
38 (3) A statement of the need and justification for the proposed action,  
39 including any supporting tests, studies, or other information.  
40
- 41 (e) The Department shall, within 60 days after receipt of an application for a  
42 variance pursuant to this section, notify the applicant that the application is  
43 complete and accepted for processing by the Department or that the application  
44 is incomplete and what further information is required.

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- 1  
2 (f) The Department shall make a tentative decision to grant or deny a petition and  
3 shall do the following:  
4 (1) publish a 45 day notice of such tentative decision in the California  
5 Regulatory Notice Register or on the internet; and  
6 (2) make the tentative decision and the scientific support for the decision  
7 available on its website;  
8 (3) allow interested parties to submit written comments in support of or in  
9 opposition to the tentative decision during the notice period;  
10 (4) provide responses to the comments submitted within a reasonable  
11 time.  
12  
13 (g) After evaluating all public comments, the Department shall publish its final  
14 decision to grant or deny the petition in the California Regulatory Notice Register  
15 and on the internet and shall notify the applicant in writing that the request for a  
16 variance is granted or denied.  
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