

Green Ribbon Science Panel
November 14 and 15, 2011 Meeting

SAFER CONSUMER PRODUCTS --- INFORMAL DRAFT REGULATIONS

QUESTIONS for DISCUSSION

(1) Chemicals of Concern (COCs) List

The decision was made to start with a rather large list of chemicals of concern that incorporates 22 lists of chemicals developed by a range of other authoritative bodies (refer to ***Attachment 1***). This approach was chosen to: (i) send signals to manufacturers and consumers; (ii) enable DTSC to immediately begin work on developing the list of Priority Products for which AAs will be required; and (iii) reduce the motivation for manufacturers to implement early (potentially regrettable) substitutes.

- Are these the right lists? Should there be fewer or more lists included?
- Are there unforeseen consequences to this approach?

(2) Prioritization of Products

The decision was made to use a narrative standard for prioritizing products and selecting those products that will be placed on the Priority Products list. The narrative standard includes consideration of: (i) potential adverse impacts from the COC(s) in the product; (ii) potential exposures; (iii) availability of reliable information to substantiate potential adverse impacts and exposures; (iv) protections already provided by other regulatory programs; and (v) the existence of available viable safer alternatives. (Refer to ***Attachment 2***.)

- What steps might be included to structure the prioritization process so that manufacturers are better able to predict the likelihood of their products being listed as Priority Products?

(3) Quality Assurance for Alternatives Assessments (AAs)

The decision was made to ensure quality for the AAs through: (i) DTSC audits; (ii) creating a certification program for assessors; and (iii) posting non-redacted portions of the AAs on DTSC's website for public review.

- Given DTSC's limited resources, is this approach sufficient to provide meaningful quality assurance?
- What steps could we take to restructure or supplement this approach?

Section 69502.2. Chemicals of Concern Identification.

- (a) Initial Chemicals of Concern List. As of the effective date of these regulations, a chemical is identified as a Chemical of Concern, if it exhibits a hazard trait or an environmental or toxicological endpoint, and meets one or more of the following criteria:
- (1) The chemical is identified as exhibiting a hazard trait on one or more of the following lists:
 - (A) California Safe Cosmetics Program's Chemicals Known or Suspected to Cause Cancer or Reproductive Toxicity;
 - (B) California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65);
 - (C) Canadian Environmental Protection Act Environmental Registry's Persistent, Bioaccumulative, and Inherently Toxic to the Environment (CEPA PBiT);
 - (D) Category A and B Carcinogens, Report on Carcinogens, US Department of Health and Human Services, Public Health Service, National Toxicology Program;
 - (E) Chemicals for which primary Maximum Contaminant Levels (MCLs) have been established under the federal Safe Drinking Water Act;
 - (F) European Chemical Substances Information System Persistent Bioaccumulating Toxins (ESIS PBT);
 - (G) European Commission Category 1 and Category 2 endocrine disruptors;
 - (H) European Union Directive on Dangerous Substances (Directive 67/548/EEC), Category 1 Carcinogens and Category 1 Reproductive toxins;
 - (I) European Union EC 1272/2008 Annex VI, Category 1A and 1B carcinogens, Category 1A and 1B reproductive toxins, and Category 1A and 1B mutagens;
 - (J) International Agency for Research on Cancer (IARC), Groups 1, 2A, and 2B carcinogens;
 - (K) Pollutants listed by California or the US EPA for one or more water bodies in California pursuant to section 303(d) of the federal Clean Water Act;
 - (L) Pollutants requiring monitoring and reporting in waste discharges to land that have Notification Levels (NLs) specified under the Waste Discharge and Water Reuse Requirements (WDRs/WRRs) of the Porter-Cologne Water Quality Control Act;
 - (M) Priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act;
 - (N) US EPA Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals; and/or
 - (O) Washington Department of Ecology Persistent, Bioaccumulative, Toxic Chemicals.

- (2) The chemical is identified by one or more of the following lists based on exposures or environmental or toxicological endpoints:
 - (A) National Report on Human Exposure to Environmental Chemicals, Center for Disease Control;
 - (B) OSPAR List of Chemicals for Priority Action;
 - (C) OSPAR List of Substances of Possible Concern; and/or
 - (D) US EPA National Waste Minimization Program list of Persistent Bioaccumulative and Toxic Priority Chemicals.

- (3) The chemical is identified by one or more of the following sources of reliable information:
 - (A) Grandjean & Landrigan identification of neurotoxicants;
 - (B) National Toxicology Program, Office of Health Assessment and Translation (formerly the Center for the Evaluation of Risks to Human Reproduction (CERHR)) reports; and/or
 - (C) US EPA Integrated Risk Information System (IRIS) identification of carcinogens.

Section 69503.2. Priority Products Prioritization.

(a) Product Prioritization Criteria. The Department will evaluate products to determine the potential adverse impacts and potential exposures by considering the factors listed in paragraphs (1) through (3) for which information is available. Based on that evaluation the Department may identify and list as Priority Products, consistent with the provisions of subsections (b) and (c) and the procedures specified in section 69503.3, products that it determines to be of high priority.

(1) Potential Adverse Impacts and Exposures. The Department shall consider the potential adverse public health and environmental impacts posed by the Chemical(s) of Concern in a product due to potential exposures during the manufacture, useful life, and end-of-life disposal or management of the product. The evaluation of the potential adverse impacts and exposures shall consider both of the following:

(A) POTENTIAL ADVERSE IMPACTS FROM CHEMICALS OF CONCERN.

1. The potential for the Chemical(s) of Concern in a product to cause adverse public health and/or environmental impacts, considering:
 - a. The Chemical(s) of Concern's hazard trait(s) and environmental and toxicological endpoint(s), and mode(s) of action;
 - b. The Chemical(s) of Concern's aggregate effects;
 - c. The Chemical(s) of Concern's cumulative effects with other Chemicals of Concern with similar modes of action;
 - d. The Chemical(s) of Concern's physicochemical properties;
 - e. The Chemical(s) of Concern's environmental fate properties; and
 - f. The populations and/or environmental receptors that are potentially adversely impacted.

2. The Department shall give special consideration to the type and severity of potential adverse impact(s), and the potency of the chemical(s) associated with the adverse impact(s), for all of the following:
 - a. Children, pregnant women, and other sensitive subpopulations;
 - b. Environmentally sensitive habitats, endangered and threatened species, and environments in California that have been designated as impaired by a State or federal regulatory agency; and
 - c. Widespread adverse public health and/or environmental impacts.

(B) POTENTIAL EXPOSURES. The potential for public and/or environmental exposures to the Chemical(s) of Concern in the product in quantities that could result in adverse impacts, considering:

1. Market presence information for the product;
2. Relevant reliable information that indicates the possibility for public or environmental exposures to the Chemical(s) of Concern in the product, and reliable information demonstrating the occurrence, or potential occurrence, of exposures to the Chemical(s) of Concern in the product;
3. Information concerning the household presence of the product, and other products containing the same Chemical(s) of Concern that is/are the basis for the Priority Product listing, including the number of such of products, how common their household presence is, the frequency of use, and the concentration of the chemical in those products; and
4. The potential for public or environmental exposures to the Chemical(s) of Concern in the product, during the useful life of the product and end-of-life disposal or management of the product, considering:
 - a. Manufacturing, use, storage, transportation, and end-of-life management practices and the locations of these practices;
 - b. The types of uses that could result in public exposure to the Chemical(s) of Concern in the product, considering:
 - i. Household and recreational use;
 - ii. Sensitive subpopulation potential use or exposure at locations frequented by members of sensitive subpopulations; and
 - iii. Workers, customers, clients, and members of the general public who use, or otherwise come in contact with, the product or releases from the product in the home, workplace, or other location;
 - c. Frequency and duration of exposure for each use scenario and end-of-life scenario;
 - d. Containment of the Chemical(s) of Concern within the product, and engineering and administrative controls; and
 - e. Potential for release into, migration from, or distribution across environmental media, and potential for accumulation and persistence in biological and/or environmental components or systems of the Chemical(s) of Concern or its/their degradation products, considering the environmental fate properties of the Chemical(s) of Concern and its/their degradation products.

- (2) Availability of Information. The Department shall consider the availability of reliable information to substantiate the potential adverse impacts and exposures.
 - (3) Other Regulatory Programs. The Department shall consider the scope of federal and/or other California State regulatory programs, and any applicable international trade agreements ratified by the United States Senate, under which the product or the Chemical(s) of Concern in the product is/are regulated, and the extent to which these other regulatory requirements address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a potential basis for the product being listed as a Priority Product.
- (b) Key Prioritization Criteria. In using the factors specified in subsection (a) to prioritize products, the Department shall give priority to products meeting one or more of the following criteria:
- (1) The Chemical(s) of Concern in the product have a significant potential to cause adverse public health and environmental impacts;
 - (2) The product is widely distributed in commerce, and widely used by consumers;
 - (3) There is a significant potential for public and environmental exposures to the Chemical(s) of Concern in the product in quantities that can result in adverse public health or environmental impacts;
 - (4) For assembled products, the product contains one or more Chemical(s) of Concern that may present potential exposure(s) through inhalation or dermal contact in quantities that can result in adverse public health or environmental impacts; and/or
 - (5) For formulated products, the product is intended to be:
 - (A) Applied directly to the body;
 - (B) Dispersed as an aerosol or a vapor; or
 - (C) Applied to hard surfaces with the likelihood of runoff or volatilization.

(c) Process for Consideration of the Prioritization Factors.

- (1) Potential Adverse Impacts and Exposures and Availability of Information. The Department shall begin the product prioritization process by evaluating products based on the factors specified in subsection (a)(1) in conjunction with subsection (a)(2).
- (2) Other Regulatory Programs. Having considered the potential adverse impacts and the potential exposures for the product and its Chemical(s) of Concern, the Department shall then determine which of these potential adverse impacts and exposures are addressed by consideration of subsection (a)(3), and adjust the prioritization accordingly.
- (3) Priority Products. Products determined to be of high priority after completion of the steps specified in paragraphs (1) and (2) may be listed as Priority Products.
- (4) Safer Alternative. The Department may, at its discretion, consider whether there is a readily available safer alternative, that is functionally acceptable and technologically and economically viable, to further adjust the prioritization prior to listing a product as a Priority Product.
- (5) Key Prioritization Factors. Prior to issuing the proposed and final Priority Products lists, the Department shall review the list for consistency with subsection (b), and make adjustments as needed.