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## Department of Toxic Substances Control

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**Edmund G. Brown Jr.**  
Governor

**TITLE 22, California Code of Regulations**  
**45-DAY PUBLIC NOTICE AND COMMENT PERIOD**  
**SAFER CONSUMER PRODUCT ALTERNATIVES**

**Department Reference Number: R-2011-02**

**Office of Administrative Law Notice File Number: Z-2012-0717-04**

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**NOTICE IS HEREBY GIVEN** that the Department of Toxic Substances Control (DTSC) proposes to add chapter 55 to division 4.5 of Title 22, California Code of Regulations, and to amend the Table of Contents. These proposed additions pertain to identification and prioritization of chemicals of concern in consumer products, evaluation of their alternatives, and regulatory responses for selected alternatives.

### **PUBLIC HEARING**

DTSC will hold a public hearing on the proposed regulations on September 10, 2012 in the Byron Sher Room, Cal/EPA Building, 2nd Floor, 1001 "I" Street, Sacramento, at which time any person may present statements or arguments orally or in writing relevant to this proposal. The public hearing will convene at 10.00 a.m. and will remain open as long as attendees are presenting testimony. Please submit written comments to the contact person listed at the end of this notice. For written comments to be considered they must be submitted no later than 5:00 p.m. on September 11, 2012.

Representatives of DTSC will preside at the hearing. DTSC requests persons who wish to speak to register before the hearing. Pre-hearing registration is conducted at the location of the hearing from 9.30 a.m. to 12:30 p.m. Registered persons will be heard in the order of their registration. Anyone else wishing to speak at the hearing will have an opportunity after all registered persons have been heard.

All visitors are required to sign in prior to attending any meeting at the Visitor and Environmental Services Center, located just inside and to the left of the building's public

entrance. Please allow adequate time to sign in and receive a visitor badge before the public hearing begins.

**Notice to Hearing Impaired - Accessibility.** If you have special accommodation or language needs, please contact Reasonable Accommodation Coordinator Adrian Recio, at (916) 324-3095 or by e-mail at [ARecio@dtsc.ca.gov](mailto:ARecio@dtsc.ca.gov) as soon as you read this document. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

## **AUTHORITY AND REFERENCE**

### Authority

These regulations are being adopted under the following authorities:

Health and Safety Code section 25252: This section authorizes and requires the Department of Toxic Substances Control (DTSC) to adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern. This section directs DTSC, in adopting these regulations, to develop criteria by which chemicals and their alternatives may be evaluated. This section also directs DTSC to reference and use available information from various sources, but does not limit DTSC to referencing and using only this information.

Health and Safety Code section 25253: This section authorizes and requires DTSC to adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. This section requires that these regulations establish a process that includes: (i) an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives; (ii) an evaluation of critical exposure pathways; and (iii) life cycle assessment tools that take into consideration, at a minimum, thirteen (13) specified factors. This section also requires that the regulations specify the range of regulatory responses that DTSC may make following the completion of an alternatives analysis, including, but not limited to, eight (8) specified responses and “any other outcome the department [DTSC] determines accomplishes the purposes of [article 14 of the statutes]”.

Health and Safety Code section 58012 (added by Gov. Reorg. Plan No. 1, §146, eff. July 17, 1991.) This section grants DTSC authority to adopt regulations to execute its duties.

### Reference

These regulations implement, interpret, or make specific the following statutes:

Health and Safety Code sections 25251, 25252, 25253, 25257, and 25257.1.

## INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

### Policy Statement Overview

#### Background

There are currently more than 80,000 chemicals approved under federal law for use in the United States (U.S.). Each day, a total of 42 billion pounds of chemical substances are produced or imported in the U.S. for commercial and industrial uses. An additional 1,000 new chemicals are introduced into commerce each year. Approximately one new chemical comes to market every 2.6 seconds, and global chemical production is projected to double every 25 years. The average U.S. consumer today comes into contact with 100 chemicals per day. In 2009, the U.S. Centers for Disease Control and Prevention released the Fourth National Report on Human Exposure to Environmental Chemicals, which measured 212 chemicals in the blood and urine of a representative population of the United States. The 2009 Report was updated in February, 2012 to include updated tables for 66 chemicals and tables for 34 new chemicals. California consumers and businesses are becoming increasingly aware and concerned about the abundance of chemicals that they are exposed to in the products that they use on a day-to-day basis in their homes and in the workplace.

For more than a decade, the California Legislature has considered nearly a hundred bills proposing chemical bans and broader chemical policies for California, heard testimony from "battling scientists" and was interested in developing a broader, more comprehensive approach to chemicals policy.

In 2003, the Senate Environmental Quality Committee and the Assembly Committee on Environmental Safety and Toxic Materials commissioned a report from the University of California (U.C.) to investigate the current legal and regulatory structure for chemical substances and to report on how a California chemicals policy could address environmental and health concerns about chemical toxicity, build a long-term capacity to improve the design and use of chemicals, and understand the implications of European policy on the California chemical market.

In 2006, authors from U.C. Berkeley presented the commissioned report, *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation* and made a connection between weaknesses in federal policy, namely the Toxic Substances Control Act (TSCA), and the health and environmental damage happening in California. The report broadly summarized their findings into what they called the "three gaps":

- *Data Gap*: There is a lack of information on which chemicals are safe and which are toxic, and what chemicals are in products. The lack of access to chemical data creates an unequal marketplace. California businesses cannot choose and make safer products and respond to consumer demand without ingredient disclosure and safety testing.
- *Safety Gap*: Government agencies do not have the legal tools or information to prioritize chemical hazards. Under TSCA, only 5 chemicals out of 83,000 have

been banned since 1976. The California Legislature has frequently addressed this problem by approving individual chemical bans. Chemical bans come before the Legislature because there are very few other mechanisms in place at the federal or State level that can remove harmful chemicals from the marketplace.

- *Technology Gap*: There is an absence of regulatory incentive and market motivation which stems from the data gap, and a lack of educational emphasis on green chemistry methodologies and technologies. In order to build a substantial green chemistry infrastructure, a coincident investment and commitment must be made to strengthen industrial and academic research and development.

In 2007, the California Environmental Protection Agency launched California's Green Chemistry Initiative within DTSC. The *California Green Chemistry Initiative Final Report* released in December 2008 included the following six policy recommendations for implementing this comprehensive program in order to foster a new era in the design of a new consumer products economy, which includes inventing, manufacturing and using toxic-free, sustainable products.

1. Expand Pollution Prevention and product stewardship programs to more business sectors to focus on prevention rather than simple source reduction or waste controls.
2. Develop Green Chemistry Workforce Education and Training, Research and Development and Technology Transfer through new and existing educational program and public/private partnerships.
3. Create an Online Product Ingredient Network to disclose chemical ingredients for products sold in California, while protecting trade secrets.
4. Create an Online Toxics Clearinghouse, an online database providing data on chemical, toxicity and hazard traits to the market place and public.
5. Accelerate the Quest for Safer Products, creating a systematic, science-based process to evaluate chemicals of concern and identify safer alternatives to ensure product safety.
6. Move Toward a Cradle-to-Cradle Economy to leverage market forces to produce products that are "benign-by-design", in part, by establishing a California Green Products Registry to develop green metrics and tools for a range of consumer products and encourage their use by businesses.

In 2008, Assembly Bill 1879 (Chapter 559, Feuer) and Senate Bill 509 (Chapter 560, Simitian), were signed into law by Governor Schwarzenegger to implement two key recommendations of the California Green Chemistry Initiative Final Report: acceleration of the quest for safer products, and creation of an online toxics clearinghouse—recommendations #4 and #5 above.

### Broad Objectives

The proposed regulations that are the subject of this notice, and the authorizing statutes (Health and Safety Code sections 25252 and 25253), are intended to implement recommendation #5 of the California Green Chemistry Initiative Final Report --- Accelerate the Quest for Safer Products, and, thus, create a systematic, science-based process to evaluate chemicals of concern, and identify safer alternatives to ensure product safety.

### Specific Objectives

The specific objectives of the proposed regulations are to:

- Establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.
- Establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by chemicals of concern.
- Specify the range of regulatory responses that DTSC may take following the completion of the alternatives analysis.

### Proposed Regulations

The proposed regulations would add a new chapter 55, Safer Consumer Products, to division 4.5 of Title 22, California Code of Regulations. These regulations are necessary to satisfy the mandates of Health and Safety Code sections 25252 and 25253, which require DTSC to adopt regulations to establish a process to identify and evaluate chemicals of concern in consumer products and identify safer alternatives, and to specify regulatory responses that may be imposed upon completion of the alternatives analysis process.

### Benefits

The proposed regulations are among the first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals and are viewed as a potential national model for chemicals policy reform. The rulemaking is a preemptive strategy that reduces the use of toxic substances in the design of products and industrial processes with the aim of creating safer and sustainable products that do not threaten human health or persist in the environment. The use of fewer hazardous substances means healthier air quality, cleaner drinking water and a safer workplace. The rulemaking also promotes transparency by compelling chemical manufacturers to provide sufficient information for businesses, consumers and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products.

## Relation to Existing State Regulations

The proposed regulation is not inconsistent or incompatible with any existing state regulations. An automated search of Title 19 and 22 using the following keywords “consumer products”, “chemicals in consumer products”, and “chemicals in commerce” was conducted via Westlaw and yielded no conflicting state regulations. In addition, DTSC worked with the Office of Environmental Health Hazard Assessment (OEHHA), the California Department of Public Health (CDPH), the California State Water Resources Control Board (SWRCB), and the California Air Resources Board (ARB), among other agencies, to ensure that the proposed regulations do not interfere with or conflict with any regulatory program administered by any of these agencies.

## **I. Summary of Regulations**

### **A. Four-Step Process** *[Section 69501(a)]*

The regulations provide for a four-step continuous, science-based, iterative process to identify safer consumer product alternatives:

- **DTSC** --- The regulations establish an immediate list of Chemicals of Concern (~1,200) based on the work already done by other authoritative organizations, and specify a process for DTSC to identify additional chemicals as Chemicals of Concern (COCs).\* *[Article 2, see section II for further details.]*
  - **DTSC** --- The regulations require DTSC to evaluate and prioritize product/COC combinations to develop a list of “Priority Products” for which an alternatives analysis must be conducted. *[Article 3, see section II for further details.]*
  - **Product Manufacturers** --- The regulations require responsible entities (manufacturers, importers, and retailers) to notify DTSC when their product is listed as a Priority Product. DTSC will post this information on its website. Manufacturers (or other responsible entities) for a product listed as a Priority Product must perform an alternatives analysis (AA) for the product and the Chemicals of Concern in the product to determine how best to limit exposures to, or the level of adverse public health and environmental impacts posed by, the Chemicals of Concern in the product. *[Article 5, see section III for further details.]*
  - **DTSC** --- The regulations require DTSC to identify and impose regulatory responses to effectively prevent or limit adverse public health and/or environmental impacts, if any, posed by the Priority Product/Chemical of Concern (if the manufacturer decides to retain the Priority Product), or the adverse impacts posed by the alternative chemical/product selected to replace the Priority Product. *[Article 6, see section IV for further details.]*
- \* The regulations provide a process for any individual or organization (including federal and other California State agencies) to petition DTSC to add/remove a chemical to/from the Chemicals of Concern list or a product/chemical combination to/from the Priority Products list. Petitions may also be submitted to DTSC requesting that an entire existing list of chemicals be added to the list of Chemicals of Concern. *[Article 4]*

## **B. Applicability** [Section 69501(b)]

Except as noted below, the regulations apply to all consumer products that contain a Chemical of Concern, and are sold, offered for sale, distributed, supplied, or manufactured in California. The regulations do not apply to the following products:

- (1) Products exempted by law (Health and Safety Code section 25251): dangerous prescription drugs and devices; dental restorative materials; medical devices; packaging associated with dangerous prescription drugs and devices, dental restorative materials, and medical devices; food; and pesticides. The regulations also do not apply to products used solely to manufacture a product exempted by law.
- (2) Products manufactured or stored in, or transported through, California solely for use out-of-state.

## **C. Responsibility for Compliance**

- (1) The regulations [Section 69501.1(a)(54)] define “responsible entity” to include:
  - (i) The manufacturer (i.e., the person that makes the product or the person who controls the specifications and design of, or use of materials in, the product).
  - (ii) The US importer of the product.
  - (iii) Retailers who sell the product in California.

However, the principal duty to comply with the requirements of the regulations that apply to responsible entities lies with the manufacturer. If the manufacturer does not comply, the importer, if any, then has a duty to comply. A retailer is required to comply with the regulations only if the manufacturer and importer(s) (if any) fail to comply, and only after this information is posted on the Failure to Comply List on DTSC’s website. [Section 69501.2(a)(1)]

- (2) The regulations [Section 69501.2(a)] require a responsible entity for a product to ensure compliance with the requirements pertaining to:
  - (i) Notifying DTSC that its product is a Priority Product [Section 69503.7], or alternatively submitting an Alternatives Analysis Threshold Exemption Notification [Sections 69503.5 and 69503.6] or a Chemical of Concern Removal Notification [Section 69505.1(g)];
  - (ii) Performing an AA, and submitting AA Reports to DTSC, for its product; and
  - (iii) Complying with regulatory responses applicable to its product.
- (3) A manufacturer or importer may opt out of complying with the above requirements by demonstrating to DTSC that the product is no longer being sold, offered for sale, distributed, supplied, or manufactured in California. [Section 69501.2 (b)]

A retailer who becomes responsible for complying with the above requirements, due to non-compliance by the manufacturer/importer, may opt out by ceasing to order the product and providing a notification to DTSC. [Section 69501.2 (c)]

If the manufacturer or importer subsequently introduces into the California marketplace a product that replaces (in terms of use and customer bases) the removed Priority Product, and that replacement product contains a Chemical of Concern, the manufacturer or importer must provide a notice to DTSC. [Section 69501.2 (b)]

- (4) The regulatory requirements applicable to responsible entities may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, one or more responsible entity(ies). (This does not apply to the Priority Product Notification or Alternatives Analysis Threshold Exemption Notification requirements.) [Section 69501.2(a)(2)]

#### **D. Consequences of Non-Compliance**

- (1) When DTSC determines a requirement has not been fulfilled for a product, DTSC will issue a notice of non-compliance to the manufacturer and importer(s). [Section 69501.2(d)]
- (2) If the non-compliance is not remedied, the product and information concerning the product will be placed on a Failure to Comply List maintained on DTSC's website. The regulations specify the conditions under which a product will be removed from the Failure to Comply List. [Section 69501.2(d)]
- (3) DTSC may conduct audits to determine compliance with the requirements of the regulations pertaining to alternatives analyses, regulatory responses, and various notifications and information submittals. [Article 9, Section 69509]
- (4) In accordance with *article 8 of chapter 6.5 of division 20 of the Health and Safety Code*, DTSC may also initiate enforcement actions, including imposition of fines and penalties, against responsible entities for failure to comply with the regulations.

#### **E. Chemical and Product Information [Section 69501.4]**

DTSC's implementation of the regulations will be informed by a wealth of information that DTSC will obtain from the public domain. In addition, DTSC will request information from responsible entities for products and chemical manufacturers/importers. DTSC will maintain on its website a Response Status List that provides information as to how a responsible entity or a chemical manufacturer/importer has or has not responded to a request for information from DTSC. DTSC will also maintain on its website a Safer Consumer Products Partner Recognition List that identifies persons that have voluntarily provided DTSC with information that advances the quest for safer consumer products.

#### **F. Information on DTSC's Website [Section 69501.5]**

The regulations require DTSC to post on its website a comprehensive list of information pertaining to implementation of the regulations. In some cases, a notice of the availability of the information will be provided to persons on DTSC's electronic mailing list for these regulations. This will be DTSC's main avenue of communication with responsible entities and the public.

#### **G. Disputes [Article 7, commencing with Section 69507]**

The regulations provide a process for a responsible entity to dispute an action taken by DTSC. A requirement imposed on the responsible entity by DTSC, and posting of information in the Failure to Comply list concerning the non-compliance with that requirement, will be stayed while a dispute is pending. (The dispute process does not apply to: actions taken by DTSC with regard to the listing of Chemicals of Concern,

petitions concerning the chemicals and products lists, and trade secret protection claims.)

#### **H. Certified Assessors** [Article 8, commencing with Section 69508]

Beginning two years after the regulations become effective, an AA must be conducted by or under the responsible charge of one or more persons certified as an assessor by a DTSC-designated accreditation body, as well as meeting specified education and experience requirements. The regulations spell out the requirements for certified assessors and accreditation bodies.

#### **I. Trade Secret Protection** [Article 10, commencing with Section 69510]

The regulations set out provisions for: submitting trade secret claims and the treatment of information submitted under the regulations for which a claim of trade secret protection is asserted by the submitter. The regulations are based on the authorities for handling trade secrets found in Health and Safety Code section 25257, the Uniform Trade Secrets Act (See Civil Code Section 3426.1), and the Public Records Act (See Government Code Section 6254.7).

## **II. Chemical and Product Prioritization**

### **A. Chemicals of Concern (COC) Identification**

- (1) Initial List of COCs --- As of the effective date of the regulations, ~1,200 chemicals are identified as COCs because they exhibit a hazard trait or an environmental or toxicological endpoint (listed in OEHHA's regulations), and are listed or identified by one or more authoritative bodies specified in the regulations. [Section 69502.2(a)] NOTE: ~500 additional chemicals currently used only in pesticides and drugs (and, thus, excluded from these regulations under Health and Safety Code section 25251) could be added to the list in the future if they are used in products that are not excluded under Health and Safety Code section 25251.
- (2) Additions to the Initial List of COCs --- DTSC may identify additional chemicals (that exhibit a hazard trait or an environmental or toxicological endpoint) as COCs based on consideration of the following factors [Section 699502.2(b)]:
  - Chemical adverse public health and environmental impacts
  - Adverse impacts of special consideration --- Adverse impact(s) for:
    - (i) Sensitive subpopulations;
    - (ii) Environmentally sensitive habitats;
    - (iii) Endangered and threatened species;
    - (iv) Environments in California designated as impaired; and
    - (v) Adverse impacts associated with the ability of the chemical to contribute to or cause widespread adverse public health and/or environmental impacts.
  - Exposures to the chemical
  - Availability of substantiating reliable information
  - Availability of safer, functionally acceptable, alternative chemicals

Refer to the definitions in the regulations [Section 69501.1] for the list of adverse public health and environmental impacts, physicochemical properties, and environmental fate properties that will be considered during the identification of COCs and the prioritization of COCs/products.

- (3) Listing Process --- An informational list of those chemicals identified as COCs as of the effective date of the regulations will be posted on DTSC's website within 30 days after the regulations become effective. Any subsequent revisions to the list will be made in accordance with the listing process described in II.D. below. [Section 69502.3]

## **B. Chemicals of Concern and Product Prioritization**

- (1) Product Prioritization Criteria [Section 69503.2(a)]: DTSC will evaluate products to determine the adverse impacts for, and exposures associated with the product, to the COCs in each product based on consideration of the factors listed below. Based on this evaluation, DTSC may list as Priority Products those products that are determined to be of high priority.
- (a) Adverse Impacts and Exposures [Section 69503.2(a)(1)]: The adverse public health and environmental impacts posed by the COC(s) in the product due to exposures during the manufacture, useful life, and end-of-life disposal or management of the product, considering:
- Adverse Impacts from the COCs --- The ability of the COC(s) in the product to contribute to or cause adverse public health and/or environmental impacts, considering specified factors. This includes consideration of adverse impact(s) for:
    - (i) Sensitive subpopulations;
    - (ii) Environmentally sensitive habitats;
    - (iii) Endangered and threatened species;
    - (iv) Environments in California designated as impaired; and
    - (v) Adverse impacts associated with the ability of the chemical to contribute to or cause widespread adverse public health and/or environmental impacts.
  - Exposures --- Public health and/or environmental exposures to the COC(s) in the product, considering:
    - (i) Market presence information for the product;
    - (ii) Reliable information regarding public and/or aquatic, avian, or terrestrial animal or plant organism exposures to the COC(s) in the product, and reliable information demonstrating the occurrence of exposures to the COC(s) in the product;
    - (iii) Information concerning the household presence and use of the product, and other products containing the same COC(s);
    - (iv) Public and/or aquatic, avian, or terrestrial animal or plant organism exposures to the COC(s) in the product during the product's life cycle; and
    - (v) Product uses, or discharges or disposals, in any manner that would contribute to or cause adverse waste and end-of-life impacts.

- (b) Availability of Information [Section 69503.2(a)(2)]: The availability of information to substantiate the adverse impacts and exposures.
- (c) Other Regulatory Programs [Section 69503.2(a)(3)]: The scope of federal and/or other California State laws, and any applicable international trade agreements, under which the product or the COC(s) is/are regulated, and the extent to which these other regulatory requirements address, and provide protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product.

(2) Key Prioritization Factors [Section 69503.2(b)]: DTSC will give priority to products meeting both of the following criteria:

- The COCs in the product have a significant ability to contribute to or cause adverse public health and environmental impacts.
- There is a significant ability for the public and/or aquatic, avian, or terrestrial animal or plant organisms to be exposed to the COCs in the product in quantities that would contribute to or cause adverse public health or environmental impacts, which may include consideration of how widely the product is distributed in commerce and how widely the product is used by consumers.

### **C. Process to Evaluate Products [Section 69503.3]**

- (1) Adverse Impacts and Exposures and Availability of Information --- DTSC will begin the product evaluation and identification process by using available information to evaluate the product's adverse impact and exposure factors, along with the extent of available information.
- (2) Other Regulatory Programs --- DTSC will then assess whether, and to what extent, any of these adverse impacts and/or exposures pathways are adequately addressed by other California and federal laws, and international agreements. DTSC will adjust the prioritization of the product based on whether listing the product as a Priority Product would meaningfully enhance protection of public health and/or the environment in light of any protections already provided under other laws.
- (3) Priority Products --- DTSC may list as a Priority Product one or more products determined to be of high priority after completion of the steps (1) and (2) described above.
- (4) Safer Alternatives --- DTSC may consider whether there is a readily available safer alternative, that is functionally acceptable and technically and economically feasible, 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, DTSC will evaluate the list for consistency with the key prioritization factors described in B.(2) above, and make adjustments as needed.

- (6) Priority Product Work Plan --- No later than January 1, 2014, DTSC will issue a Priority Product Work Plan that identifies the product categories that will be evaluated to identify products to be added in the future to the Priority Products list during the next three years. The regulations specify conditions under which DTSC may revise the work plan subsequent to its issuance. Subsequent work plans will be issued no later than one year before the three-year expiration date of the current work plan.
- (7) Initial Priority Products List --- Prior to January 1, 2016, DTSC will list a product as a Priority Product only if the product is being listed on the basis of one or more COCs in the product meeting specified criteria.

**D. Listing Process** [Sections 69502.4 and 69503.7]

- (1) Prior to finalizing each augmentation to the initial COCs list, and the initial and revised Priority Products list, DTSC will make the proposed list available for public review and comment for a minimum 45-day period.
- (2) After consideration of public comments on a proposed list, DTSC will finalize and post the final list on its website.
- (3) DTSC will review, and revise as appropriate, the Priority Products list at least once every 3 years.
- (4) The initial proposed list of Priority Products, which will include no more than five products, will be made available for public review and comment no later than 180 days after the effective date of the regulations.
- (5) For some products, DTSC will specify in the Priority Products list the product component, or the homogenous material within a component, that is the required minimum focus of the alternatives analysis for the product.
- (6) Each responsible entity for a product listed on the Priority Products list must provide to DTSC a Priority Product Notification, an Alternatives Analysis Threshold Exemption Notification, Priority Product Removal Notification, or a COC Removal Notification within 60 days after the product is listed as a Priority Product.

**E. Petition Process** [Sections 69504 and 69504.1]

Subject to one specified exception, any person may petition DTSC to add or remove a chemical to/from the Chemicals of Concern list or a product/chemical combination to/from the Priority Products list. Petitions may also be submitted to DTSC requesting that an entire existing list of chemicals be added to the list of Chemicals of Concern. High priority will be given to petitions by federal and other California State agencies that relate to the petitioning agency's legislative and/or regulatory authorities. After granting a petition, DTSC will evaluate and, if applicable, prioritize the chemical and/or the product in accordance with the prioritization processes described above.

**F. Alternatives Analysis Threshold Exemption**

- (1) A product that is listed as a Priority Product and that meets the criteria for an alternatives analysis exemption will be exempt from the requirement to perform an alternatives analysis, if the responsible entity submits an Alternatives Analysis Threshold Exemption Notification. [Section 69503.5(a)]

- (2) An alternatives analysis exemption applies only to products in which the concentration of the COC(s), that are the basis for the product being listed as a Priority Product, does not exceed the applicable alternatives analysis threshold specified by DTSC. *[Section 69503.5(b)]*
- (3) The regulations specify criteria to be used by DTSC when setting the alternatives analysis threshold for each COC in a Priority Product. This includes: (i) the ease or difficulty of removing the COC from the product if the COC is a contaminant rather than an ingredient; (ii) the detection limit for the COC; and (iii) various public health and environmental protection considerations. In no case, may DTSC specify an alternatives analysis threshold that is lower than the detection limit for the COC. *[Section 69503.5(c)]*
- (4) If multiple COCs that exhibit the same hazard trait and/or environmental or toxicological endpoint(s) are identified as the basis for the product being listed as a Priority Product, DTSC may specify a single alternatives analysis threshold that applies to the total concentration in the Priority Product of all such COCs. *[Section 69503.5(d)]*
- (5) The regulations specify the information that must be included in an Alternatives Analysis Threshold Exemption Notification *[Section 69503.6(a)]*. The responsible entity is required to notify DTSC if the information in the Alternatives Analysis Threshold Exemption Notification significantly changes, or the product no longer meets the criteria for an alternatives analysis exemption *[Section 69503.6 (c) and (d)]*.

### **III. Alternatives Analyses (AAs)**

#### **A. Guidance Materials**

The regulations require DTSC to prepare, and make available on its website, guidance materials to assist persons in performing AAs, and to post on its website AAs that are available in the public domain and are supported by reliable information. *[Section 69505]*

#### **B. Alternatives Analyses --- General Requirements**

- (1) A responsible entity for a Priority Product must conduct an AA for the Priority Product, and submit a Preliminary AA Report and a Final AA Report to DTSC within specified timeframes. *[Section 69505.1(c)]*
  - The Preliminary AA Report must be submitted no later than 180 days after the date the product is listed on the final Priority Products list, unless DTSC specifies a different due date for the product in the Priority Products list.
  - The Final AA Report must be submitted no later than 12 months after the date DTSC issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests, and DTSC approves, a longer period of time not to exceed 24 months (or up to 36 months if regulatory safety and/or performance testing is required for the alternatives being considered).

- (2) The regulations allow for a responsible entity to request a one-time extension, not to exceed 90 days, for submitting the Preliminary and/or Final AA Report, if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. [Section 69505.1(d)]
- (3) Each AA completed two years or later after the effective date of the regulations must be performed, and each Preliminary and Final AA Report submitted two years or later after the effective date of the regulations must be prepared, by or under the responsible charge of an assessor certified by an accreditation body designated by DTSC. [Section 69505.1(e)] (See Article 8, commencing with Section 69508, of the regulations for further details concerning assessor requirements and accreditation bodies.)
- (4) The regulations allow a responsible entity to fulfill the AA requirements by submitting a report for a previously completed AA for the Priority Product --- if DTSC determines that the report is substantially equivalent to the AA Report requirements specified in the regulations, and that the report contains sufficient information to identify regulatory response(s). [Section 69505.1(f)]
- (5) If a responsible entity reformulates the Priority Product to remove the COC(s), that is/are the basis for the Priority Product listing, without adding a substitute chemical, the responsible entity may submit a Chemical of Concern Removal Notification to the Department in lieu of conducting an AA and submitting an AA Report. [Section 69505.1(g)]

### **C. Analysis of Priority Products and Alternatives**

- (1) The regulations require that each AA be conducted in two stages. The Preliminary AA Report is submitted to DTSC after completion of the first AA stage, and the Final AA Report is submitted after completion of the second AA stage. [Section 69505.2(a)]
- (2) *The first stage of the AA includes:*
  - (a) Step 1, Identification of Product Requirements and Function of COCs [Section 69505.3(b)(1)]:
    - The function, performance, and legal requirements associated with the Priority Product that must be met by alternatives being considered.
    - The function of the COC(s) in meeting the Priority Product's function, performance, and legal requirements.
    - A determination as to whether the COC(s) or substitute chemical(s) is/are necessary to meet the Priority Product's function, performance, and legal requirements.
    - If it is determined that neither the COC(s) or substitute chemical(s) is/are necessary to meet the Priority Product requirements, the removal of the COC(s) from the Priority Product without the addition of substitute chemical(s) must be evaluated in the AA as one of the alternatives to the Priority Product.
  - (b) Step 2, Identification of Alternatives [Section 69505.3(b)(2)]:

Identification of alternatives for consideration that meet the requirements for the Priority Product, and eliminate or reduce the concentration of the COC(s) in the Priority Product and/or reduce or restrict for public health and/or environmental exposures to the COC(s) in the Priority Product. The responsible entity is required to include in the AA consideration of any identified existing viable alternatives.

- (c) Step 3, Initial Screening of Alternative Chemicals [*Section 69505.3(b)(3)*]:
- The responsible entity is required to collect and use available relevant information to identify the adverse public health and environmental impacts associated with each chemical being considered as an alternative to the COC(s) in the Priority Product.
  - Using this information, the responsible entity must compare each of the identified alternative chemicals with the COC(s) in the Priority Product.
  - The responsible entity must eliminate from further consideration in the AA any alternative chemical that it determines poses equal or greater adverse public health and/or environmental impacts than the COC(s).
- (d) Step 4, Consideration of Additional Information [*Section 69505.3(b)(4)*]:  
As part of the first stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above.
- (e) Step 5, Identification of Next Steps [*Section 69505.3(b)(5)*]:  
The responsible entity is required to prepare a work plan and proposed implementation schedule for completion of the second AA stage, as described in (3) below, and preparation and submittal of the Final AA Report.

Abridged AA Report [*Section 69505.2(b)*]:

A responsible entity, that determines (after completion of steps 1 through 4 above) that a functionally acceptable alternative is not available or feasible, may prepare and submit an Abridged AA Report, in lieu of Preliminary and Final AA Reports, if the responsible entity meets specified requirements.

(3) *The second stage of the AA includes:*

- (a) Step 1, Identification of Factors Relevant for Comparison of Alternatives [*Section 69505.4(a)*]:
- A factor, in conjunction with an associated exposure pathway and life cycle segment, is relevant if:
    - (i) It makes a demonstrable contribution to the adverse impacts of the Priority Product and/or one or more alternatives under consideration, and
    - (ii) There is a demonstrable difference in the factor's contribution to such impacts between two or more of the alternatives being considered.
  - The responsible entity must use available quantitative information and analysis tools, supplemented by available qualitative information and analysis tools, to identify the factors listed below, and the associated

exposure pathways and life cycle segments, that are relevant for the comparison of the Priority Product and the alternatives under consideration:

(i) Multimedia life cycle impacts and Chemical hazards:

- ✓ Adverse environmental impacts
- ✓ Adverse public health impacts
- ✓ Adverse waste and end-of-life impacts
- ✓ Environmental fate properties
- ✓ Materials and resource consumption impacts
- ✓ Physical chemical hazards
- ✓ Physicochemical properties

(ii) Product function and performance

(iii) Economic impacts

- The identification of relevant exposure pathways must consider:

(i) Chemical quantity information

(ii) Exposure factors

(b) Step 2, Comparison of the Priority Product and Alternatives [*Section 69505.4(b)*]:

The responsible entity must use available quantitative information and analyses, supplemented by available qualitative information and analyses, to evaluate and compare the Priority Product and each alternative with respect to each relevant factor and associated exposure pathways and life cycle segments.

(c) Step 3, Alternative Selection Decision [*Section 69505.4(c)*]:

The responsible entity selects the alternative that will replace or modify the Priority Product, or decides to retain the Priority Product.

(d) Step 4, Consideration of Additional Information [*Section 69505.4(d)*]:

As part of the second stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above, including reconsideration of factors evaluated in the first stage of the AA.

(e) Step 5, Identification of Next Steps [*Section 69505.4(e)*]:

The responsible entity is required to prepare a Final AA Report that includes an implementation schedule for implementing the selected alternative, if any, and/or any proposed regulatory responses.

(4) A responsible entity may use an AA process that differs from the process described above if certain requirements are met, including [*Section 69505.2(c)*]:

- The alternate process will provide the information needed to prepare an AA Report that substantially meets the AA Report requirements specified in the regulations.
- The alternate process will compare the Priority Product and the alternatives using the same factors and associated exposure pathways and life cycle segments that would be used if the process specified in the regulations was followed.

- The responsible entity submits a work plan to DTSC for the alternate process no later than 60 days after the product is included on the Priority Products list.

#### D. Alternatives Analysis Reports

- (1) The Preliminary and Final AA Reports must include the information listed below. All differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report must be identified and explained in the Final AA Report. *[Section 69505.5(a)]*
  - An **executive summary** *[Section 69505.5(b)]*. The executive summary cannot include any information for which trade secret protection is claimed --- this will enable the executive summary to be posted on DTSC's website in its entirety.
  - Information regarding the **preparer** of the AA Report *[Section 69505.5(c)]*
  - Information regarding the **responsible entity** and the **supply chain** for the product *[Section 69505.5(d)]*
  - Information describing the **Priority Product** and the **COCs** *[Section 69505.5(e)]*
  - A description of the **alternatives** chosen to be evaluated and compared, and an explanation of the rationales for selecting and screening out specific alternatives at each stage of the alternatives comparison process. *[Section 69505.5(f)]*
  - Detailed information on the **evaluation and comparison of the Priority Product and its alternatives** for all of the relevant comparison factors, and associated exposure pathways and life cycle segments. *[Section 69505.5(f)]*
  - Identification of **comparison factors**. The AA Reports must identify which factors, and associated exposure pathways and life cycle segments, were determined to be relevant for evaluation and comparison of the Priority Product and its alternatives. The AA Report must explain the rationales for each factor, exposure pathway, and life cycle segment determined not be relevant. *[Section 69505.5(g)]*
  - A description of the **methodology** used to conduct the AA *[Section 69505.5(h)]*
  - Identification of all information used as **supporting information** in performance of the AA and preparation of the AA Reports. This information must be made available to DTSC, upon request. The Final AA Report must also identify any **information gaps**. *[Section 69505.5(i)]*
  - Identification and description of the **alternative selected** to replace or modify the Priority Product (or a decision to retain the Priority Product); the **implementation plan** for the selected alternative, if any; and any **proposed regulatory responses**. *[Section 69505.5 (j) and (k)]*
- (2) The information in the Final AA Report concerning the alternative selection decision must include:
  - A description of the alternative, if any, selected, and the rationales for the selection decision. This includes an analysis that evaluates and compares the selected alternative against the Priority Product, and an explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable. *[Section 69505.5(j)(2)]*

- A discussion of the functional and performance acceptability of the selected alternative as compared to the Priority Product. If no alternative is selected, this information must be provided for each alternative considered. *[Section 69505.5(j)(2)(A)]*
  - The rationales for selecting an alternative that retains one or more COC(s) or uses substitute chemicals, if it is determined during the AA that neither the COC(s) nor substitute chemicals are necessary to satisfy the requirements for the Priority Product (i.e., functional, performance, and legal requirements). *[Section 69505.5(j)(2)(B)]*
  - A list of all chemicals known, based on available information, to be in the selected alternative that differ in type, or are present at a higher concentration, relative to the chemicals contained in the Priority Product; available environmental fate information for the chemicals; available hazard trait and environmental and toxicological endpoint information for those chemicals; and available chemical identification and description information for those chemicals. *[Section 69505.5(j)(2)(C)]*
- (3) After the Final AA Report is submitted, if the alternative selection decision specified in the Final AA Report changes prior to introduction of the new product into the California marketplace, the responsible entity is required to submit a revised Final AA Report with an explanation of the change. A revised Final AA Report is also required if the original alternative selection decision was to retain the Priority Product, and the responsible entity later decides to replace the Priority Product with an alternative product. *[Section 69505.2(d)]*

**E. DTSC Review and Determinations for AA Reports** *[Section 69505.6]*

- (1) Within 60 days of receiving an AA Report, DTSC will review the AA Report for compliance with the regulations, and issue a notice of compliance, a notice of deficiency, or a notice of ongoing review. Notices of deficiency will generally give the responsible entity 60 days to remedy the deficiency. If the submitter of the AA Report fails to adequately and timely respond to 2 notices of deficiency for the Final AA Report (or 1 notice of deficiency for the Preliminary AA Report), the product will be placed on the Failure to Comply List.
- (2) Notices of compliance for Preliminary AA Reports will specify the due date for submitting the Final AA Report, which will range from 12 to 24 months (or up to 36 months if regulatory safety and/or performance testing is required for alternatives being considered) after DTSC issues the notice of compliance. In the notice of compliance for the Final AA Report, or in a separate notice, DTSC will provide notice of its proposed determination as to whether one or more of the regulatory responses that are triggered by a DTSC determination or other action (as described below) are required. The regulatory response determination does not become final until completion of the regulatory response public notice and comment process described below.

## **IV. Regulatory Responses**

### **A. Regulatory Response Selection Principles [Section 69506]**

- (1) DTSC will require implementation of regulatory responses designed to protect public health and the environment, and maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible.
- (2) DTSC will give preference to regulatory responses providing the greatest level of inherent protection (i.e., avoidance or reduction of adverse impact or exposure achieved through product or process redesign, rather than through administrative or engineering controls designed to limit exposure to a COC in a product.
- (3) In selecting regulatory responses, DTSC may consider any or all of the following factors:
  - The likely actual effectiveness of the regulatory response, including the capacity of responsible entities to comply, and the ability of end-users to understand and act upon any information and directions provided with respect to the product;
  - The relative cost-effectiveness of the regulatory response as compared to other possible responses;
  - The administrative and other burdens that would be placed upon DTSC, the responsible entities, the product end-users, and the public;
  - Any unique or additional burdens that would be imposed by the regulatory response upon sensitive subpopulations; and
  - The ease and efficacy of enforcement of the regulatory response.

### **B. Applicability**

- (1) The regulations specify regulatory responses that will, under specified conditions, apply to [Section 69506.1(a)]:
  - Products manufactured as a selected alternative following completion of an AA;
  - Priority Products for which an alternative is not selected; and
  - Priority Products that will remain in commerce pending development and distribution of the selected alternative.
- (2) No regulatory response (other than providing supplemental AA Report information if requested by DTSC) will be required for a selected alternative, if DTSC determines that no regulatory response is necessary to protect prevent or limit adverse public health or environmental impacts [Section 69506.3]

### **C. Regulatory Response Process** [Sections 69506.1 (b)-(d) and 69506.12]

- (1) For regulatory responses triggered by a DTSC determination or other action (including use restrictions, sales prohibitions, engineering or administrative controls, and research and development projects), DTSC will notify affected responsible entities of its proposed regulatory response determination.
- (2) The proposed regulatory response determination will also be made available for public review and comment for a minimum 45-day period.
- (3) After consideration of public comments, DTSC will send a final determination notice to the responsible entity(ies) and post the final notice on its website.
- (4) The responsible entity must notify DTSC, and California retailers of affected consumer products, of the applicability of regulatory responses to the responsible entity's product within 30 days.
- (5) The responsible entity must notify DTSC upon completion of the implementation of the required regulatory response, and (if applicable) upon completion of the implementation of the selected alternative.
- (6) DTSC will post on its website a Regulatory Response Summary that identifies the regulatory response(s) for each selected alternative for a Priority Product (and each Priority Product, as applicable), and the implementation dates for the alternative product, if any, and the regulatory response(s).

### **D. Supplemental AA Report Information** [Section 69506.2]

- (1) If required by DTSC, a responsible entity must provide any information DTSC determines is necessary to select and ensure implementation of regulatory responses.
- (2) If required by DTSC, a responsible entity must obtain/develop and provide to DTSC information to fill one or more information gaps identified during the AA, if DTSC determines this information is needed to re-evaluate the initial regulatory response(s) imposed for the product.

### **E. Self-Implementing Regulatory Responses**

The regulations set forth specific circumstances under which the following regulatory responses will always be required, along with implementation due dates:

- (1) Product Information for Consumers. Product information must be provided to consumers (within 12 months) if the alternative product contains a COC in exceedance of the applicable alternatives analysis threshold, or if the manufacturer chooses to retain the Priority Product (indefinitely or for more than 12 months pending development and distribution of the alternative product). The regulations specify the types of information that must be provided to consumers, and the mechanisms that must be used to provide the information. [Section 69506.4]
- (2) End-of-Life Product Management Program. A responsible entity must establish, maintain, and fund (within 1 year) an end-of-life product stewardship program, and provide product information to consumers, if the alternative product (or the Priority Product, if the manufacturer chooses to retain the Priority Product) is required to

be managed as a hazardous waste in California at end-of-life. The requirements for the product stewardship plan and program are specified in the regulations. [Section 69506.8]

## **F. Regulatory Responses Triggered by a DTSC Determination or Other Action**

- (1) Use Restrictions. DTSC may impose specified restrictions on the use of COCs in a product, or restrictions on the use of the product itself, to reduce the amount of a COC in the product, or reduce the ability of the product to contribute to or cause an exposure to the COC in the product. [Section 69506.5]
- (2) Product Sales Prohibition. If the selected alternative contains a COC above the applicable alternatives analysis threshold (or if an alternative is not selected), and DTSC determines there is a safer alternative that does not contain a COC and that is functionally acceptable and technologically and economically feasible, the responsible entity must do one of the following within 1 year (or sooner if required by DTSC) [Section 69506.6]:
  - Ensure that the Priority Product is no longer sold in California; or
  - Submit to DTSC an AA Report that selects an alternative that does not contain a COC.

DTSC may also impose a product sales prohibition in the absence of a determination that there is a safer, functionally acceptable, and technologically and economically feasible alternative, unless the responsible entity demonstrates to DTSC's satisfaction that: (i) the overall beneficial public health and environmental impacts of the product significantly outweigh the overall adverse public health and environmental impacts of the product; and (ii) administrative and/or engineering restrictions on the nature and use of the product will adequately protect public health and the environment.

- (3) Engineering or Administrative Controls. Under specified conditions, DTSC may impose requirements that control access to or limit exposure to COCs in a product to reduce the likelihood of adverse public health and/or environmental impacts. This may include controls that integrally contain a COC within the structure of a product. [Section 69506.7]
- (4) Advancement of Green Chemistry and Green Engineering. DTSC may require a manufacturer to initiate a research and development project or fund a challenge grant that uses green chemistry and/or green engineering principles to: (i) design a safer alternative; (ii) improve the performance of a safer alternative; (iii) decrease the cost of a safer alternative; and/or (iv) increase the market penetration of a safer alternative. [Section 69506.9]
- (5) Other Regulatory Responses. DTSC may impose one or more regulatory responses described above to situations that may differ from the specific situations described above. DTSC may periodically re-evaluate any regulatory response imposed under this provision. DTSC may also require a new AA to be performed, and new Preliminary and Final AA Reports to be submitted. [Section 69506.10]

## **G. Regulatory Response Exemptions** [Section 69506.11]

The regulations provide a process for a responsible entity to request an exemption from an otherwise applicable regulatory response (other than the requirement to provide to DTSC information supplemental to an AA Report) based on either or both of the following:

- (1) The required regulatory response would conflict with a requirement of another California or federal regulatory program or an international trade agreement, in such a way that the responsible entity could not reasonably be expected to comply with both requirements. In this situation, DTSC may require implementation of a modified regulatory response that resolves the conflict.
- (2) The required regulatory response substantially duplicates a requirement of another California or federal regulatory program or an international trade agreement without conferring additional public health or environmental protection benefits.

## **Existing Laws and Regulations**

### State Law

Existing law establishes the Department of Toxic Substances Control, in the California Environmental Protection Agency, with powers and duties regarding, among other things, hazardous waste disposal, underground storage of hazardous substances and waste, and the handling and release of hazardous materials.

Health and Safety Code section 25252 requires DTSC to adopt regulations to establish a process by which chemicals or chemical ingredients in consumer products may be identified and prioritized for consideration as being chemicals of concern. This process is required to include, at a minimum, consideration of: (i) the volume of a chemical in commerce in California, (ii) the potential for exposure to a chemical in a consumer product, and (iii) potential effects on sensitive subpopulations, including infants and children.

Health and Safety Code section 25252 directs DTSC, in adopting these regulations, to develop criteria by which chemicals and their alternatives may be evaluated. These criteria must include, at a minimum, the hazard traits and environmental and toxicological endpoints that the Office of Environmental Health Hazard Assessment (OEHHA) is required to specify. The requirement imposed on OEHHA is set out in Health and Safety Code section 25256.1. The endpoints developed by OEHHA will also be included in the Toxics Information Clearinghouse that DTSC is required to establish pursuant to Health and Safety Code section 25256.

Health and Safety Code section 25252 also directs DTSC, in adopting these regulations, to reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies. However, the statute provides that DTSC is not limited to referencing and using only this information.

Health and Safety Code section 25253 requires DTSC to adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of

hazard posed by a chemical of concern. This section requires that these regulations establish a process that includes: (i) an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives; (ii) an evaluation of critical exposure pathways; and (iii) life cycle assessment tools that, at a minimum, take into consideration: product function or performance; useful life; materials and resource consumption; water conservation; water quality impacts; air emissions; production, in-use, and transportation energy inputs; energy efficiency; greenhouse gas emissions; waste and end-of-life disposal; public health impacts, including potential impacts to sensitive subpopulations, including infants and children; environmental impacts; and economic impacts.

Health and Safety Code section 25253 also requires that the regulations specify the range of regulatory responses that DTSC may take following the completion of an alternatives analysis, including, but not limited to, requiring: no regulatory response; additional information to be provided to DTSC needed to assess a chemical of concern and its potential alternatives; labeling or other types of product information; a restriction on, or prohibition of, the use of a chemical of concern in a consumer product; controlling access to or limiting exposure to the chemical of concern in a consumer product; managing the product at the end of its useful life; funding green chemistry challenge grants; and any other outcome DTSC determines accomplishes the requirements of the authorizing statute.

Health and Safety Code section 25251 defines “consumer product”, for purposes of the regulations required by Health and Safety Code sections 25252 and 25253, to mean a product or part of a product that is used, bought, or leased for used by a person for any purpose. However, “consumer product” does not include: dangerous prescription drugs and devices; dental restorative materials; medical devices; packaging associated with dangerous prescription drugs and devices, dental restorative materials and medical devices; food; or pesticides. (Mercury containing lights were exempted through December 31, 2011.)

Health and Safety Code section 25257 establishes a procedure for the protection of information submitted to DTSC, for purposes of Health and Safety Code sections 25252 and 25253, that is claimed to be a trade secret.

Health and Safety Code section 25257.1 states that DTSC is not authorized to supersede the regulatory authority of any other department or agency, and that DTSC shall not adopt duplicative or conflicting regulations for product categories already regulated, or subject to pending regulation, consistent with the purposes of Health and Safety Code sections 25252 and 25253.

Article 8 of chapter 6.5 of division 20 of the Health and Safety Code sets forth DTSC’s authority and mechanisms for enforcing the provisions of chapter 6.5 (which includes the above listed statutes) and the regulations adopted pursuant thereto.

Health and Safety Code section 58012 (added by Gov. Reorg. Plan No. 1, §146, eff. July 17, 1991) grants DTSC authority to adopt and enforce regulations for execution of its duties.

## Federal Law

The federal Toxic Substances Control Act of 1976 (TSCA) (Title 15, United States Code, commencing with Section 2601) authorizes the United States Environmental Protection Agency (USEPA) to require reporting, record-keeping and testing requirements, and to set restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides. TSCA addresses the production, importation, use, and disposal of specific chemicals. Among its provisions, TSCA requires USEPA to maintain the TSCA inventory, which currently contains more than 83,000 chemicals. As new chemicals are commercially manufactured or imported, they are placed on the TSCA inventory.

TSCA requires the submission of health and safety studies that are known or available to those who manufacture, process, or distribute in commerce specified chemicals, and allows USEPA to gather information from manufacturers and processors about production/import volumes, chemical uses and methods of disposal, and the extent to which people and the environment are exposed. However, there were 62,000 chemicals in use in 1976 when TSCA was adopted into federal law. TSCA provides a “grandfather” clause for those 62,000 chemicals. Therefore, these 62,000 chemicals are not subject to the information-gathering requirements in TSCA.

TSCA places the responsibility for conducting health and environmental impact testing on USEPA, not the producer of the chemical substance or mixture. To date, USEPA has conducted testing and published data on only 200 chemicals in the inventory of 83,000 chemicals.

In 2009, the United States Government Accountability Office, an investigative arm of the United States Congress found USEPA's implementation of TSCA to be "high-risk" because "EPA has failed to develop sufficient chemical assessment information on the toxicity of many chemicals that may be found in the environment as well as tens of thousands of chemicals used commercially in the United States".

### **Relation to Existing Federal Law**

The proposed regulations by DTSC do not duplicate or conflict with existing federal law. The initiative for safer consumer products was developed, to a great extent, to address structural weaknesses in the federal Toxic Substances Control Act of 1976 (“TSCA”, Title 15, United States Code, section 2601 et seq). TSCA places the cost of obtaining data about chemical safety on the United States Environmental Protection Agency (US EPA) rather than requiring the chemical companies to develop and submit such information. Consequently, information about the 80,000 chemicals in U.S. commerce is severely limited and there is little to no information on the health or environmental effects of many of these chemicals.

### **Relation to Existing Federal and State Regulations**

Some of the chemicals and products that potentially may become subject to these regulations are also regulated to some degree by other existing federal or State regulatory programs. However, consistent with Health and Safety Code section

25257.1(c), these regulations contain provisions (for example, sections 69503.2(a)(3) and 69506.11) that expressly work to ensure that there is no duplication or conflict with other federal or State regulations. More specifically, the regulations require DTSC to take into consideration the nature and extent of existing or pending State or federal regulations of the same entities for the same chemicals and/or products so as to avoid duplicative or conflicting regulation under this program.

In addition, DTSC has worked closely with several sister agencies whose regulatory purview is closest to that of DTSC under these regulations. In particular, DTSC worked with OEHHA, the California Department of Public Health (CDPH), the California State Water Resources Control Board (SWRCB), and the California Air Resources Board (ARB), among other agencies, to ensure that the proposed regulations do not interfere with or conflict with any regulatory program administered by any of these agencies. Finally, DTSC has conducted extensive public outreach, including public workshops, public hearings, and public comment periods. DTSC has not received any comments during any of these opportunities for comment indicating that its regulations conflict with other State or federal regulations.

## **CONSIDERATION OF ALTERNATIVES**

DTSC must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which these regulations are proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this notice.

DTSC considered and rejected the following alternatives. 1. Do Nothing. DTSC rejected this option because Health and Safety Code sections 25252 and 25253 *require* DTSC to adopt regulations that address chemicals of concern in consumer products. So, this is not a lawful option.

2. Products and Chemical Hazard Categories Prioritization Process to Develop Safer Consumer Products. Again, after much consideration and input, DTSC determined that this approach may not fully comport with the authorizing statute. DTSC also became concerned that there was a lack of DTSC oversight during various stages of the proposed process. Many stakeholders were also very skeptical of this approach. For all these reasons, this alternative was rejected.

3. Other Options Considered in Earlier Proposed Drafts of the Regulations. DTSC released two other drafts of these regulations in 2010. During the public comment periods for the two prior formal regulatory proposals, DTSC received thousands of specific comments from hundreds of commenters suggesting other approaches to various provisions in the regulations. DTSC has again considered those comments, as well as input during meetings of the Green Ribbon Science Panel and in other informal meetings. All of this input has led DTSC to revise various provisions that were in prior versions of both formally and informally proposed iterations of the regulations.

## **MANDATES ON LOCAL AGENCIES OR SCHOOL DISTRICTS**

DTSC has made a determination that adoption of this regulation will not impose a local mandate or result in costs subject to reimbursement pursuant to part 7 of division 4, commencing with section 17500, of the Government Code or other nondiscretionary costs or savings to local agencies.

## **COST OR SAVINGS TO STATE OR LOCAL AGENCIES, OR SCHOOL DISTRICTS SUBJECT TO REIMBURSEMENT**

DTSC has made a determination that adoption of these regulations will not: (i) impose a local mandate, (ii) result in costs subject to reimbursement pursuant to part 7 of division 4, commencing with section 17500, of the Government Code, (iii) impose any other non-discretionary costs or savings on local agencies, or (iv) result in any decrease in federal funds to California as a result of these regulations.

These regulations address chemicals in products and any fiscal impact from the regulation on local agencies would likely be in the operating expense and possibly equipment line items. However, generally, DTSC does not expect the regulations to result in cost increases, given the wide variety of competitive safer products readily available at competitive prices. (Please see a more detailed explanation immediately below in the Fiscal Impact section.)

Any costs incurred by local government agencies would not likely be state-reimbursable because any increase in costs would not be unique to local government and would apply generally to all entities purchasing the same products.

## **COST OR SAVINGS TO ANY STATE AGENCY**

### **Cost of Goods**

These regulations address chemicals in products and any fiscal impact from the regulation on State agencies would likely be in the operating expense and possibly equipment line items.

However, generally, DTSC does not expect the regulations to result in cost increases, given the wide variety of comparable safer products readily available at competitive prices. This will provide the incentive for companies that redesign their products to keep prices for the redesigned products competitive. It will also ensure that agencies, and other consumers, have a wide variety of products to choose from at competitive prices (even if the particular brand they are using is replaced with a higher price product).

It is important to note that nothing in the regulations would force an agency to buy a particular product or to replace in-use items (e.g., carpet, furniture, paint). However, these regulations will have the benefit of making more information available for state and local agencies to assist them in making their own discretionary purchasing decisions for their environmentally preferable purchasing programs.

Even if DTSC ends up banning a product, cost impacts are not expected because of the wide variety of comparable safer products readily available at competitive prices.

### **DTSC State Operations Expenditures**

The implementation activities during the first three years will include: preparing Chemicals of Concern and Priority Product lists; developing guidance for businesses and other interested parties; determining data needs; and performing legal review of: trade secret claims, chemical and product lists, various notifications and guidance and information requests.

In future years, as the program is fully implemented through all phases (chemical and product prioritization, alternatives analyses, and regulatory responses), operational and programmatic needs will increase, and DTSC will need additional resources. In these out years, businesses will begin submitting alternatives analyses and the scope of chemicals listed as Chemicals of Concern and products listed as Priority Products will expand. Thus, DTSC's resource needs will grow over time based on the need to research and evaluate additional chemicals and products, review alternatives analysis work plan and reports (including review of trade secret protection claims), develop and monitor regulatory responses, and enforce compliance with the alternatives analysis and regulatory response requirements.

### **DETERMINATION OF ADVERSE STATEWIDE ECONOMIC IMPACT**

DTSC has made a determination that this regulation may have a significant statewide economic impact directly affecting businesses, but that it is not expected to affect the ability of California businesses to compete with businesses in other states. It is important to note that the regulations apply with equal force to businesses in California and those outside of California. This is because the regulations apply to those businesses placing consumer products into the stream of commerce in California—regardless of the place of manufacture of those products. DTSC is unable to quantify the economic impact on businesses but has outlined factors that will increase or decrease the economic impact to businesses. Until DTSC prepares the Priority Products list, there is no way to know which or how many products will be on the list or how many businesses will be required to perform an alternatives analysis. Likewise, it is not possible to estimate how many businesses will be subject to regulatory responses.

### **Types of Businesses Affected**

Businesses impacted will primarily be those that directly or indirectly make a Priority Product available in California's stream of commerce. Businesses involved in the supply chain of Chemicals of Concern contained in Priority Products will also be impacted. To a lesser degree, businesses in the supply chain for a broader range of products (and chemicals contained those products) placed into California's stream of commerce will be impacted, but only with respect to voluntarily providing chemical and product information to DTSC upon request. The regulation impacts both out-of-state and in-state businesses. This includes: chemical and product producers, brand name manufacturers, importers and retailers in the supply chain for a Priority Product.

## Projected Compliance Requirements

Compliance requirements will vary from business to business depending on the products they produce, sell or import, and the arrangements that are made between the various responsible entities in the supply chain for each product. Some businesses will have no compliance requirements. Others will be required to comply with one or more of the following types of requirements: performance of alternatives analyses and submission of alternatives analyses work plans and reports for Priority Products (or submission of various notifications to DTSC in lieu of complying with alternatives analysis requirements); and compliance with regulatory responses imposed on selected products by DTSC after completion of an alternatives analysis. California retailers, in particular, for a product subject to these compliance requirements can “opt out” by ceasing to sell a Priority Product. Manufacturers and importers also have various options for less rigorous compliance than the general compliance rules depending on what actions they take regarding a Chemical of Concern present in a Priority Product.

In developing these regulations, DTSC has sought to minimize the impact on businesses by:

- Making responses to DTSC requests for information on chemicals and products optional instead of mandatory.
- Providing options to extend compliance deadlines.
- Allowing businesses to meet the requirements of the regulations through consortiums, partnerships and similar arrangements.
- Providing guidance documents and sample alternatives analyses.
- Providing exemptions for products containing only threshold amounts of chemicals of concern.
- Providing flexibility in the alternatives analysis process.
- Allowing businesses to submit alternatives analyses that do not have all the required data. Businesses would only be required to fill data gaps if DTSC requires the additional data as a component of a regulatory response.
- Allowing businesses to avoid the alternatives analysis requirement by notifying DTSC that the chemical of concern has been removed from the product.

These regulations do not require all businesses to prepare reports. The regulations also do not impose any annual or other on-going reporting requirements on any businesses.

The regulations do allow DTSC to request businesses to provide information to DTSC (using existing information or by developing new information). There is no mandate for businesses to provide such information requested by DTSC (except as part of the

Alternatives Analysis process or as a regulatory response requirement). Also, responsible entities that have a Priority Product would have to conduct an Alternatives Analysis and submit work plans and preliminary and final Alternative Analysis Reports. For the reasons described under A.2 and B.1/B.2 of this attachment, DTSC cannot estimate the costs to businesses of providing requested information or completing the Alternatives Analysis Reports until implementation is under way.

DTSC finds that it is necessary for the health, safety, or welfare of the people of California that the reporting requirements that are compulsory apply to businesses subject to these regulations.

## **COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES**

These regulations do not impose new responsibilities for private persons. These regulations do impact products made available for sale in California and may have the effect of increasing the costs of products identified as Priority Products or their alternatives. The impacts on consumers will be proportionate to the amount of their budget spent on Priority Products. If the Priority Products represent a small proportion of consumer expenditures, then the impacts to individual consumers should not be significant. It is anticipated that competition will protect consumers from facing higher prices for consumer products. Additionally, it is anticipated that at least some consumers will realize cost savings from the use of safer products that do not present the health threats associated with Priority Products.

As discussed above, DTSC has made a determination that this regulation will have an economic impact on businesses. However, DTSC is unable to quantify the economic impact on businesses. In particular, DTSC is unable to quantify the cost impacts on a “representative” business, as the compliance requirements will vary from business to business depending on: (i) which products are listed as Priority Products, (ii) which products each business produces, sells, distributes or imports, and (iii) the arrangements that are made between the various responsible entities in the supply chain for each Priority Product.

## **RESULTS OF REGULATORY ECONOMIC IMPACT ANALYSIS**

DTSC has made the determination that the regulation may have a possible short term minimal impact on the reduction of jobs, with a much larger potential for creation of new jobs as new materials and processes are developed. DTSC cannot estimate the number of jobs created or eliminated by the regulations.

DTSC has made the determination that the regulation may result in the creation of new businesses as new materials and processes are created, with the potential for expanded export markets for California-made products. Furthermore, current firms have time to adapt prioritized consumer products to meet regulatory requirements. Since DTSC does not know which products will become subject to the requirement to perform an alternatives analysis, it cannot predict the number of businesses that may be created or eliminated.

DTSC has made the determination that the regulation provides opportunities for growth as California businesses have access to a wider range of safer consumer products and can provide services and products for an expanding number of consumers demanding safer and greener products. It is thought that California businesses working to study, develop and promote safer and greener consumer products will benefit from these regulations.

The rulemaking may have a significant statewide economic impact directly affecting some businesses. However, the benefits of this rulemaking outweigh any adverse economic impacts. Not only does the rulemaking aim to protect public health and the environment from harmful toxic substances, it also presents the potential for the creation of new businesses and jobs and for the market expansion of safer and greener products.

### **EFFECT ON HOUSING COSTS**

DTSC has made a determination that there will be no impact on housing costs.

### **EFFECT ON SMALL BUSINESSES (1 CCR 4)**

DTSC has determined that these regulations will have an effect on small businesses. However, DTSC is unable to quantify the economic impact on small businesses for the reasons discussed above. DTSC has considered alternatives for small businesses to ameliorate the impacts of compliance with the regulations for such businesses (e.g., allowing small businesses longer time frames than other businesses to meet the requirements of the regulations). However, based upon prior public comments received on the proposed regulations, and a re-evaluation of alternatives considered, DTSC has determined that the statutes authorizing and mandating these regulations do not provide the authority to apply these regulations in a differential manner based upon the size of a business. Nonetheless, DTSC has determined that the Alternatives Analysis Guidance, that is required to be prepared by DTSC, will disproportionately work to the benefit of small businesses. This is because larger businesses may already possess, or have ready access to, expertise to assist them in complying with the regulations.

### **CALIFORNIA ENVIRONMENTAL QUALITY ACT (CEQA) COMPLIANCE**

DTSC has found this rulemaking to be exempt under the California Environmental Quality Act (Public Resources Code section 21000, et seq.). This rulemaking meets the statutory exemption available under subdivision (b)(8) of Public Resources Code section 21080. A draft Notice of Exemption is available for review with the rulemaking file and will be filed with the State Clearinghouse when the regulations are adopted.

### **PEER REVIEW**

DTSC is having the scientific basis of these regulations peer reviewed pursuant to Health and Safety Code section 57004.

## CALIFORNIA ENVIRONMENTAL POLICY COUNCIL REVIEW

As required by Health and Safety Code section 25252.5, DTSC will be submitting the proposed regulations to the California Environmental Policy Council (CEPC) for review after the close of the public comment period and a determination as to whether the proposed regulations require revisions.

### CONTACT PERSONS

Inquiries regarding technical aspects of the proposed regulations or CEQA documents may be directed to Corey Yep of DTSC at 916-445-3601 or, if unavailable, Odette Madriago of DTSC at (916) 323-4927. However, such oral inquiries are not part of the rulemaking record.

A public comment period has been established commencing on July 27, 2012, and closing on **September 11, 2012** for statements, arguments, or contentions regarding the rulemaking and/or supporting documents that must be submitted in writing or may be presented orally or in writing at the public hearing in order for them to be considered by DTSC before it adopts, amends, or repeals these regulations.

### AVAILABILITY OF TEXT OF REGULATIONS AND STATEMENT OF REASONS

Copies of the Notice, Initial Statement of Reasons, the text of the proposed regulations, all the information upon which its proposal is based, and the express terms of the proposed regulations are posted to DTSC's Internet site at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm> or may be obtained from **Kryisia Von Burg** of DTSC's Regulations Section as specified below.

After the close of the comment period, DTSC may adopt the proposed regulations. If substantial changes are made, the modified full text will be made available for comment for at least 15 days prior to adoption. Only persons who request the specific proposed regulations, attend the hearing, or provide written comments on this specific regulation will be sent a copy of the modified text if substantive changes are made.

Once the regulations have been adopted, DTSC prepares a Final Statement of Reasons which updates the Initial Statement of Reasons, summarizes how DTSC addressed comments and includes other materials, as required by Government Code section 11346.9. Copies of the Final Statement of Reasons may be obtained from **Kryisia Von Burg** at the address listed below. A copy of the Final Statement of Reasons will also be posted on DTSC's Internet site at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm>, along with the date the rulemaking is filed with the Secretary of State and the effective date of the regulations.

To be included in this regulation package's mailing list and to receive updates of this rulemaking, please visit <http://www.dtsc.ca.gov/ContactDTSC/ELists.cfm> and subscribe to the applicable electronic mailing list or e-mail: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov).

Please direct all written comments, procedural inquiries, and requests for documents by mail, e-mail, or fax to:

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

E-mail Address: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Fax Number: (916) 324-1808

Ms. Von Burg's phone number is (916) 324-2810. If Ms. Von Burg is unavailable, please call Mr. Cordova at (916) 324-7193.