



California Environmental Protection Agency

**Department of Toxic Substances Control**

**Recommendation on Need for a  
Multimedia Evaluation of the  
Safer Consumer Product Alternatives  
Regulations**

**REPORT TO THE CALIFORNIA ENVIRONMENTAL POLICY COUNCIL**

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## I. BACKGROUND AND REPORT OVERVIEW

In 2008, the enactment of Assembly Bill 1879 (Stats. 2008, Ch. 559) established Health and Safety Code sections 25252 and 25253, requiring the Department of Toxic Substances Control (DTSC) to adopt regulations, on or before January 1, 2011, to:

- 1) Establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being chemicals of concern.
- 2) 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 the chemical of concern. This process must include an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, and an evaluation of critical exposure pathways.
- 3) Specify the range of regulatory responses that DTSC may take following the completion of the alternatives analysis.

DTSC is proposing to adopt the Safer Consumer Product Alternatives regulations to implement Health and Safety Code sections 25252 and 25253. As required by the statute, in developing these regulations, DTSC has consulted with other appropriate State agencies, and has conducted two half-day public workshops.

With one important exception, Health and Safety Code section 25252.5 requires DTSC to prepare for the regulations, and submit to the Environmental Policy Council, a multimedia life cycle evaluation. When an evaluation is required, it must identify and evaluate any significant adverse public health or environmental impacts that may result from the production, use or disposal of a consumer product or consumer product ingredient. The evaluation must, at a minimum, address impacts associated with: air pollutant emissions; surface water, groundwater, and soil contamination; disposal or use of byproducts and waste materials; worker safety and impacts to public health; and other anticipated impacts to the environment.

Subdivision (f) of Health and Safety Code section 25252.5 provides that a multimedia life cycle evaluation is *not* required if the Environmental Policy Council, following an initial evaluation of the proposed regulations, conclusively determines that the regulations will not have any significant adverse impact on public health or the environment.

Chapter II of this report presents the analysis that demonstrates that the proposed Safer Consumer Product Alternatives regulations will not have any significant adverse impact on public health or the environment. Chapter III provides DTSC's recommendation to the Environmental Policy Council that is based on this analysis. Chapter IV presents a summary of the proposed regulation.

## II. ANALYSIS

This chapter addresses the question that is before the Environmental Policy Council: Can the Council conclusively determine, following an initial evaluation of DTSC's proposed Safer Consumer Product Alternatives regulations, that the regulations will not have any significant adverse impact on public health or the environment?

As directed by the enabling statute, DTSC's proposed regulations have been specifically designed to ensure that multimedia considerations are factored in at many steps of the process so that no significant adverse impacts will occur to public health or the environment as a consequence of the implementation of the regulations. California's Green Chemistry Initiative called for a systematic scientific and engineering approach that seeks to reduce the use of hazardous chemicals in the manufacturing of consumer products and the generation of toxic wastes by changing how society designs, manufactures, and uses chemicals in products. The proposed DTSC regulations shift our focus to designing chemicals and products that have less or no adverse effects – throughout their life cycle – on California's people and our environment. The proposed regulation is a landmark effort that uses a science-based prioritization and alternatives analysis framework that will lead to safer chemicals in consumer products.

Prior Environmental Policy Council reviews of multimedia life cycle evaluations, as well as findings that such an evaluation is not required, have focused on regulations pertaining to specific chemicals, such as fuel additives. These prior reviews and findings were, therefore, based on the adverse impacts posed by the specific chemicals and how those impacts were mitigated by the regulatory requirements being proposed. DTSC's proposed Safer Consumer Product Alternatives regulations, in contrast, do not focus on any specific chemical. Rather, these regulations implement the statutory directive to establish a multi-step process for chemical and product prioritization, alternatives assessment, and imposition of safeguarding regulatory responses. The regulations build into this process: 1) multimedia life cycle evaluation; 2) avoidance of regrettable substitutes; 3) a focus on identifying and *reducing* adverse public health and environmental impacts; and 4) a focus on ensuring that no increase in significant adverse impacts will result from the implementation of the regulations.

Additionally, the regulations include features that build on the public health and environmental protections already provided by existing federal and California state regulatory programs, and that ensure that the implementation of these regulations will not impede businesses' ability to comply with these other regulatory requirements. These features include:

- The factors that will be considered in the prioritization of chemicals and products will take into account the extent to which other federal and/or California State regulatory programs already address any public health and environmental threats posed by each chemical or product. This is intended to ensure that in making a decision to list a chemical or product as a Priority Chemical or Priority Product,

that decision will be based solely on the potential public health and/environmental exposures and resulting harm that are not already addressed by other federal and/or California State regulatory programs.

- The alternative assessment process, which will lead to a manufacturer's selection of an alternative to replace a Priority Product (or a decision to retain a Priority Product), will include consideration of product function and performance, including the functional equivalency of each alternative relative to the Priority Product. To be considered "functionally equivalent", an alternative must substantially satisfy the intended performance and function of the original Priority Product, including safety and environmental standards required by federal or California law.
- An exemption may be requested from any regulatory response imposed under the regulations if the regulatory response would conflict with a requirement of another California or federal regulatory program in such a way that compliance with both requirements could not reasonably be expected.

Chapter IV of this report provides a detailed summary of the proposed regulations. The analysis presented in this chapter discusses the key components of the regulations that support the recommendation set forth in Chapter III. Specifically, Section A below explains in further detail the key design features of the proposed regulations that will ensure that their implementation will not lead to significant adverse public health and environmental impacts. Section B provides the comprehensive list of multimedia impacts that will be considered as part of both the prioritization and alternatives assessment processes. Section C describes those provisions of the regulations that will motivate, encourage and facilitate the actual reduction of existing adverse impacts.

#### **A. No Significant Adverse Impact on Public Health or the Environment**

DTSC finds that the Safer Consumer Product Alternatives draft regulations will, by design, have no significant adverse impact on public health or the environment. This stems from the fact that changes to the status quo, and their resulting impacts, that could result from the processes set forth in the regulations are limited as described below.

##### **1) Product Reformulation or Redesign Following an Alternatives Assessment**

The listing of a product as a Priority Product requires a responsible entity or manufacturer to complete an alternatives assessment (referred to as a Tier II Alternatives Assessment) in accordance with the process set forth in the regulations, and as a result the responsible entity or manufacturer may select and introduce into the California marketplace a new alternative product to replace the Priority Product. (Responsible entities include: (i) the owner of the product brand name or trademark, (ii) California importers of the product, (iii) California distributors of the product, (iv) retailers who sell the product in California, and (v)

any other person who has a contractual agreement with one of these entities concerning the product.)

The Tier II Alternatives Assessment includes a chemical hazard assessment, exposure potential assessment, and multimedia life cycle evaluation. The factors that are required to be considered in a Tier II Alternatives Assessment (AA) are listed in section II.B. below. The results of the chemical hazard assessment, exposure potential assessment, and multimedia life cycle evaluation are required to be included in the AA Report submitted to DTSC.

The Tier II Alternatives Assessment Report that is required to be submitted to DTSC must include a demonstration that the production, use and disposal of the selected alternative (in conjunction with any regulatory response(s) proposed by the responsible entity or manufacturer) will have no greater significant adverse impacts on public health or the environment than the current impacts associated with the Priority Product.

The Tier II Alternatives Assessment, along with the required demonstration of no greater significant adverse impacts, will ensure that any potential significant adverse impacts to public health and the environment associated with potential alternatives are identified and avoided, and will lead to the selection of alternatives that are more favorable to public health and the environment than the original chemical and/or product --- either by selection of a different alternative or by imposition of one or more regulatory responses.

It is possible that, at the conclusion of the Tier II Alternatives Assessment, the responsible entity or manufacturer may opt to retain the Priority Product in lieu of selecting and implementing an alternative. For example, there may not be an available alternative that is functionally equivalent and technologically and economically feasible. In this case, the Priority Product will be subject to one or more regulatory responses. (At a minimum, this will include the requirement to provide product information to consumers.) The regulatory response(s) imposed pursuant the regulations will reduce the adverse impacts on public health and the environment associated with the Priority Product.

Therefore, in all cases, the end result of the combined prioritization / alternatives assessment / regulatory response processes set forth in the regulations will be either no change, or in most cases, a reduction (if not an elimination) of significant adverse impacts on public health and the environment.

## 2) Early Product Reformulation or Redesign

The listing by DTSC of a chemical as a Chemical under Consideration or Priority Chemical will prompt some responsible entities and manufacturers to voluntarily reformulate or redesign products containing such chemicals well before the product is listed as a Priority Product. This may also be prompted by the call-in of data to support the chemical and product prioritization processes, which will better



inform DTSC and the marketplace. In some cases the reformulation or redesign will include replacing the listed chemical with another chemical without first going through the type of alternatives assessment process set forth in the regulations.

When a responsible entity or manufacturer chooses to embark on such an early product reformulation or redesign, it will be required to provide an AA Notification to DTSC, which must be accompanied by a Tier I AA report, or other information describing the rationale for the redesign or reformulation and hazard trait information for the original chemical and any replacement chemical contained in the product.

This will enable DTSC to quickly determine if the replacement chemical should be listed as a Priority Chemical and if the new product should be listed as a Priority Product --- with the consequent requirement for a rigorous Tier II Alternatives Assessment that complies with the regulations.

As explained in 1. above, this will ensure an end result that will be either no change, or in most cases, a reduction (if not an elimination) of adverse impacts on public health and the environment.

## **B. Multimedia Considerations Embodied in the Regulations**

The regulations specify an expansive list of public health and environmental impacts and exposure potential assessment factors that must be considered during both the prioritization and alternatives assessment processes. These impacts include the factors specified in Health and Safety Code section 25252.5 for the multimedia life cycle evaluation: air pollutant emissions; surface water, groundwater, and soil contamination; disposal or use of byproducts and waste materials; worker safety and impacts to public health; and other anticipated impacts to the environment. The list of factors that will be considered during the prioritization and alternatives assessment processes specified in the regulations is set out below. Additionally, as noted above (see section II.A.1), the Tier II Alternatives Assessment Report must include a demonstration that the production, use and disposal of the selected alternative (in conjunction with any regulatory response(s) proposed by the responsible entity or manufacturer) will have no greater significant adverse impacts on public health or the environment than the current impacts associated with the Priority Product.

### 1) Chemical and Physical Properties

- Density
- Dissociation constant
- Explosiveness
- Flammability
- Flash point
- Granularity

- Melting/boiling point
- Oxidizing properties
- Partition coefficient
- Stability in organic solvents and identity of relevant degradation byproducts
- Surface tension
- Vapor pressure
- Viscosity
- Water solubility
- Other physical, chemical, or quantum properties specific to nanomaterials

## 2) Adverse Public Health Impacts

Includes impacts that may result from single, intermittent or frequent use of or contact with the chemical or product, including dermal, oral and inhalation exposures:

- Acute or chronic toxicity
- Bioaccumulation in humans
- Carcinogenicity
- Cardiovascular toxicity
- Dermatotoxicity
- Developmental toxicity
- Effects of electromagnetic radiation that includes ionizing radiation and non-ionizing radiation
- Endocrine toxicity
- Epigenetic toxicity
- Genotoxicity
- Hematotoxicity
- Hepatotoxicity
- Immunotoxicity
- Musculoskeletal toxicity
- Nephrotoxicity and other toxicity to the urinary system
- Neurotoxicity
- Ocular toxicity
- Organ or tissue system toxicity,
- Ototoxicity
- Persistence
- Reactivity in biological systems
- Reproductive toxicity
- Respiratory effects
- Toxicokinetics
- Any hazard traits not listed above that relate to adverse impacts on human health
- Adverse health impacts on sensitive subpopulations

### 3) Adverse Ecological Impacts

- Acute or chronic toxicity in aquatic, avian or terrestrial organisms
- Adverse impacts on aquatic ecosystems, including, but not limited to, aquatic sediments
- Adverse impacts on terrestrial ecosystems
- Adverse impacts on environmentally sensitive habitats, including, but not limited to, habitat loss or deterioration
- Adverse impacts on habitats essential to the continued existence of an endangered or threatened species, and other factors affecting the ability of an endangered or threatened species to survive or reproduce
- Adverse impacts associated with population loss, decline in population diversity, or changes in historical communities
- Adverse impacts that can cause vegetation contamination or damage, including phytotoxicity

### 4) Adverse Environmental Impacts

- *Chemical traits.* Includes intrinsic traits of a chemical or its degradation products that relate to adverse impacts on the environment:
  - Stability and persistence in biological and environmental compartments
  - Fate and transport among environmental compartments
  - Bioaccumulation in biological and environmental compartments
  - Biodegradation
  - Photodegradation
  - Production of transformation products in environmental settings
  - Hydrolysis half-life
  - Aerobic and anaerobic soil half-lives
  - Aerobic and anaerobic sediment half-lives
- *Air quality impacts.* Includes adverse impacts associated with air emissions, including air contaminants:
  - Nitrogen oxides
  - Sulfur oxides
  - Toxic air contaminants
  - Greenhouse gases
  - Secondary organic aerosols
  - Stratospheric ozone-depleting compounds
  - Other ozone forming compounds
  - Particulate matter
- *Water quality impacts.* Includes adverse impacts associated with degradation of the beneficial uses of the waters of California and any of the following:
  - Biological oxygen demand
  - Chemical oxygen demand

- Total dissolved solids
  - Chronic and acute toxicity in the water column and sediments
  - Chemicals identified as priority toxic pollutants for California pursuant to the federal Clean Water Act
  - Pollutants listed by California or US EPA for one or more water bodies in California pursuant to the federal Clean Water Act
  - Chemicals identified as contaminants that have primary Maximum Contaminant Levels (MCLs) under the federal Safe Drinking Water Act
  - 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
  - Thermal pollution
  - Other impacts affecting the quality of surface waters and groundwaters
- *Soil quality impacts.* Includes adverse impacts associated with the following:
    - Chemical contamination
    - Biological contamination
    - Loss of biodiversity
    - Loss of organic matter
    - Erosion
    - Compaction or other structural changes
    - Soil sealing
    - Other impacts that affect or alter soil function or soil chemical, physical or biological characteristics or properties.
  - Any other factors that relate to adverse impacts on the environment, including, but not limited to, the release of heat, odor or radiation.

#### 5) Materials and Resource Consumption Impacts

- Water consumption and conservation
- Production, in-use, and transportation energy inputs
- Energy consumption and efficiency
- Reusability and recyclability

#### 6) Waste and End-of-Life Impacts

- Amount of waste and byproducts generated
- Special handling required for the waste and byproducts
- Disposal, treatment or use of waste and byproducts, including solid waste, wastewater and storm water discharge streams

## 7) Exposure Potential Evaluation

- Potential for the public or the environment to be exposed to the Priority Chemical that is contained in the product, during the useful life of the product and end-of-life disposal or management of the product
- Types and extent of consumer uses that could result in public exposure to the Priority Chemical that is contained in the product, which in turn could result in adverse public health impacts
- Product uses or management or disposal practices that could result in releases to the environment of the Priority Chemical that is contained in the product, which in turn could result in adverse ecological or other environmental impacts
- Existence of data and other information relating to actual or potential public or environmental exposures to the chemical

## **C. Features that Will Lead to Reduced Significant Adverse Impacts**

The features of the draft regulations highlighted below will result in reductions in significant adverse impacts on public health and the environment from chemicals contained in products used and purchased by California consumers.

- 1) The chemical and product prioritization processes to be performed by DTSC, and the alternatives assessment process to be performed by manufacturers and others, are based on consideration of a comprehensive list of multimedia impacts. (See section B above.) This will ensure that the chemicals and products that pose the greatest level of hazard are addressed first. It will also ensure that significant adverse impacts of those chemicals and their alternatives are fully assessed so that they can be addressed by selection of safer alternatives and/or safeguarding regulatory responses.

The alternatives assessment process set out in the regulations ensures that all alternatives assessments will comply with Health and Safety Code section 25253(a) which requires, at a minimum, consideration of all of the following multimedia impacts:

- 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;
  - Environmental impacts; and
  - Economic impacts.
- 2) The comprehensiveness of the chemical and product information that DTSC will obtain and review will ensure that DTSC has the information necessary to identify and evaluate the hazards posed by chemicals and the products that contain them.
  - 3) The requirement for responsible entities to notify DTSC when one of their products is listed as a Priority Product by DTSC, and the requirement for DTSC to post this information on its website, will assist DTSC in ensuring compliance with the regulations. This will also provide useful information to other persons in the product's supply chain and to consumers. DTSC will also post on its website a list of products that contain Priority Chemicals, as this information becomes known to DTSC.
  - 4) The requirement for alternatives assessments to be performed by trained and accredited lead assessors employed by qualified assessment entities will ensure the quality of the assessments and the information reported to DTSC which will lead to the selection of the necessary regulatory responses. Additionally, if the alternatives assessment is performed by a qualified *in-house* assessment entity, then it must be verified by a second lead assessor employed by a qualified *third-party* assessment entity. This will further ensure the quality and integrity of the alternatives assessment process by requiring the involvement of an independent trained individual that does not have a vested interest in the outcome.
  - 5) The regulatory responses that may be imposed will ensure the limitation of exposures and reduction of hazards associated with selected alternative products or Priority Products that remain in the California marketplace.

### **III. RECOMMENDATION**

DTSC staff recommends that the Environmental Policy Council concur with DTSC's finding and conclusively determine that the proposed Safer Consumer Product Alternatives regulations will not have any significant adverse impact on public health or the environment.

## **IV. SUMMARY OF SAFER CONSUMER PRODUCTS ALTERNATIVES REGULATIONS**

This section provides an overview of the key components of DTSC's proposed regulations.

### **A. Applicability**

The regulations apply to all consumer products placed into the stream of commerce in California, and all chemicals that exhibit a hazard trait and are reasonably expected to be contained in these consumer products; EXCEPT for those products exempted by the statute. The statutorily-exempted products are: prescription drugs and devices; dental restorative materials; medical devices; the packaging associated with prescription drugs and devices, dental restorative materials and medical devices; food; pesticides; and mercury-containing lights. (Mercury-containing lights are exempted only through December 31, 2011.) The regulations by their own terms do not apply to products used solely to manufacture a product exempted by the statute, or to products manufactured, stored or transported through California solely for use out-of-state. The regulations also do not apply to unintentionally-added chemicals that the producer does not know to be present in a product after exercising due diligence.

If a responsible entity or manufacturer notifies DTSC that: (i) a Chemical under Consideration or a Priority Chemical has been (or will be) removed from a product, or (ii) a product is no longer (or will no longer be) placed into commerce in California, the product that is the subject of the notice will no longer being subject to the regulations.

### **B. Guiding Principles**

The regulations provide guiding principles for DTSC, manufacturers, and responsible entities to follow in implementing their respective responsibilities under the regulations. Those guiding principles are:

- Green chemistry principles and life cycle thinking should be considered throughout implementation of the regulations.
- Adverse public health and environmental impacts that may result from the production, use or end-of-life management of consumer products and their ingredients should be significantly reduced or eliminated.
- Adverse public health and environmental impacts of chemicals used in commerce should be significantly reduced by encouraging redesign of consumer products and manufacturing processes.
- Chemical and product prioritization processes should seek to give priority to chemicals and consumer products that pose the greatest public health and environmental threats, are most prevalently used by consumers, and pose the greatest potential for harmful public health or environmental exposures.



### C. Three-Step Process

The regulations provide for a three-step continuous, science-based, iterative process to identify safer consumer product alternatives. Those three steps are:

- 1) DTSC --- Evaluation and prioritization of chemicals and consumer products to develop a list of “Priority Products” that contain “Priority Chemicals”. This will be accomplished as follows:
  - Identifying chemicals that exhibit one or more hazard traits and that are reasonably expected to be present in consumer products.
  - Using chemical prioritization factors specified in the regulations to determine which of these chemicals will be identified as Chemicals of Concern, and then prioritized by being placed on either the list of Chemicals under Consideration or the list of Priority Chemicals.
  - Identifying consumer products that are reasonably expected to contain one or more Priority Chemicals.
  - Using product prioritization factors specified in the regulations to determine which of these products will be identified and prioritized as either Products under Consideration or Priority Products.
- 2) Consumer Product Responsible Entities & Manufacturers --- Assessment of alternatives, which must be performed for the Priority Chemical used in each product that is a listed Priority Product, with the objective of identifying and selecting a viable safer alternative (if one exists). A responsible entity must notify DTSC when its product is listed as a Priority Product, and DTSC posts this information on its website. The assessment of alternatives includes: (i) chemical hazard assessment, (ii) exposure potential assessment, and (iii) multimedia life cycle evaluation. Each phase of the alternatives assessment may be used to narrow the range of alternatives being considered and to make adjustments to the work plan for the next phase.
- 3) DTSC --- Identification and imposition of regulatory responses to effectively limit the public health and/or environmental threats, if any, posed by the Priority Product (due to the Priority Chemical) or the lesser threats posed by the alternative chemical/product selected to replace the Priority Product.

## **D. Responsibility for Compliance**

- The responsible entity for a consumer product has primary responsibility for ensuring compliance with the requirements pertaining to: (i) providing chemical and product information to DTSC needed for the prioritization process, (ii) notifying DTSC that its product is a Priority Product, (iii) performing an alternatives assessment (AA) and submitting an AA Work Plan and AA Report to DTSC for their Priority Product, and (iv) complying with regulatory responses applicable to their product.
- The regulations define “responsible entity” to include: (i) the owner of the product brand name or trademark, (ii) California importers of the product, (iii) California distributors of the product, (iv) retailers who sell the product in California, and (v) any other person who has a contractual agreement with one of these entities concerning the product (unless the agreement states that the product will not be placed into California’s stream of commerce).
- There will be multiple responsible entities for each consumer product. The requirements will be deemed to be satisfied as long as at least one responsible entity, or another person, fulfills the requirement for the product. It is anticipated that in many cases the requirements will be fulfilled on behalf of the responsible entity(ies) by the product manufacturer, a trade association or consortium, or a public-private partnership.
- Responsible entities may opt out of complying with the requirements of the regulations, avoid being identified on the Failure to Comply List, and avoid DTSC enforcement actions by ceasing their involvement in placing the product into California’s stream of commerce and providing a notice with basic product and supply chain information to DTSC. This will motivate manufacturers, who are typically in the best position to provide chemical and product information and perform alternatives assessments, to proactively assume responsibility for fulfilling these requirements. It will also ensure that products containing harmful chemicals are removed from the California marketplace when their manufacturers choose not to comply with these requirements.

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

- When DTSC determines a requirement has not been fulfilled for a product, DTSC will issue a notice of non-compliance to known responsible entities and others in the supply chain.
- If the non-compliance is not remedied, the product name and information concerning the product and its supply chain will be placed on a Failure to Comply List maintained on DTSC’s website.
- DTSC may conduct audits to determine compliance with the requirements of the regulations pertaining to alternatives assessments and regulatory responses.

- DTSC may also initiate enforcement actions, including imposition of fines and penalties, against responsible entities for failure to comply with the regulations.

## **F. Information on DTSC's Website**

The regulations require DTSC to post on its website a comprehensive list of documents and information pertaining to implementation of the regulations. In some cases, a notice of the availability of the information will be provided in the California Regulatory Notice Register (CRNR) and to persons on DTSC's listserv for these regulations. These will be DTSC's main avenue of communication with responsible entities, others in the supply chain, and the public.

## **G. Chemical and Product Prioritization**

This chapter describes in detail the process that DTSC will use to identify and prioritize chemical and consumer products containing those chemicals. The chemical prioritization process will evaluate chemicals that exhibit one or more hazard traits, and will generate a list of Chemicals under Consideration and a list of Priority Chemicals. The product prioritization process will examine consumer products that contain Priority Chemicals, and will generate a list Products under Consideration and a list of Priority Products. Priority Products will be subject to the Alternatives Assessment and Regulatory Response requirements described below in chapters VI and VII.

### **1) Chemical and Product Information**

The prioritization process will be informed by a wealth of information that DTSC will obtain from the public domain. This will include seeking public health and environmental data and information from other governmental agencies, including: the California Environmental Protection Agency boards, departments and offices; other California State agencies; other states; federal agencies; and other nations. Responsible entities will be required to provide any necessary information DTSC is unable to obtain from the public domain. Arguably, this placement of organized data before DTSC and the marketplace will allow for more prudent and protective decisions throughout implementation of the regulations. The type of data and other information that DTSC will seek, to the extent it determines there is a need for the information, include:

- Chemical and product data and information pertinent to the public health, environmental and other factors used to prioritize chemicals and products.
- Information describing the types, categories and classes of products that contain Priority Chemicals.
- Identification of intentionally-added chemicals and chemical ingredients in products, including quantity information.

- Chemical and product market data.
- Standard analytical chemistry protocols for the detection and measurement of a chemical in products and in environmental and biological media.

## 2) Applicability

DTSC will *not* include in the chemical or product prioritization a chemical/product for which DTSC makes one of the following determinations:

- The chemical is regulated by one or more federal and/or other California State regulatory program(s) that, in combination, address, for each life cycle segment, the same public health and environmental threats addressed by these regulations and the authorizing/mandating statute.
- There is no exposure pathway by which the chemical might pose a threat to public health or the environment in California during the useful life or the end-of-life management of the chemical or any product containing the chemical.

## 3) Chemical Prioritization

Chemicals of Concern are identified and prioritized using a three-step screening process:

(a) Only chemicals that exhibit a hazard trait, as identified by OEHHA for purposes of the Toxics Information Clearinghouse, will be considered in the prioritization process. In the event that OEHHA's hazard traits are not identified by the time DTSC starts the first prioritization process, the hazard traits that will be used for the first chemicals lists are:

- Carcinogens and reproductive toxins listed on specified lists by other regulatory bodies, including: OEHHA, National Toxicology Program, US EPA's Integrated Risk Information System, International Agency Research on Cancer, and European Union's Globally Harmonized System of Classification and Labeling;
- Mutagens listed by the European Union; and
- US EPA listed persistent bioaccumulative toxins.

NOTE: The current draft OEHHA regulations propose a much more extensive list of hazard traits, and so it is anticipated that future chemicals lists will encompass a much broader range of chemicals.

(b) Using the following prioritization factors, DTSC will develop a list of "Chemicals under Consideration":

- Chemical and physical properties.

- Adverse public health impacts.
  - Adverse ecological impacts.
  - Adverse environmental impacts.
  - Volume of the chemical in the stream of commerce in California.
  - Potential for public or environmental exposure to the chemical during the useful life and end-of-life management of consumer products that contain the chemical.
  - Existence of data and other information relating to actual and potential public or environmental exposures to the chemical.
  - The degree to which federal and/or other California State regulatory programs address the public health and environmental threats posed by the chemical throughout the life cycle of the chemical and consumer products that contain the chemical.
- (c) From the Chemicals of Concern that are on the Chemicals under Consideration list, DTSC will develop a list of "Priority Chemicals". Priority Chemicals will be identified based on the following factors:
- The relative degree of threat posed by each chemical to public health and the environment,
  - Availability of reliable information to substantiate the threat(s) posed by the chemical, and
  - Availability of DTSC resources.

In evaluating the relative degree of threat DTSC will give priority to those chemicals that pose the greatest public health and environmental threats, are most prevalently distributed in commerce and contained in products used by consumers, and for which there is the greatest potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in public health or environmental harm. DTSC will consider both the potential for exposure to the chemical and the potential harm resulting from potential exposures.

In evaluating the potential for exposure, DTSC will, at a minimum, consider all of the following:

- Market data for the chemical and products containing the chemical;
- Reliable information demonstrating the occurrence of public health and environmental exposures;

- Information concerning the presence of the chemical in products commonly found in households, including the number of such of products, the frequency of use, and the concentration of the chemical in those products; and
- Information showing how widely used the chemical is in products placed into the stream of commerce in California.

In evaluating the potential for harm resulting from potential exposures, DTSC will, at a minimum, consider chemical potency and resulting harm for all of the following:

- Children, pregnant women and other sensitive subpopulations; and
- Environmental receptors, in particular, environmentally sensitive habitats and endangered and threatened species.

#### 4) Product Prioritization

Products are also identified and prioritized using a three-step screening process:

- (a) Only consumer products that contain a Priority Chemical will be considered in the prioritization process.
- (b) Using the following prioritization factors, DTSC will develop a list of “Products under Consideration”:
  - Volume of the product in the stream of commerce in California, and the product’s contribution to the volume of the Priority Chemical in the stream of commerce in California.
  - Potential for public or environmental exposure to the Priority Chemical in the product during the useful life and end-of-life management of the product.
  - Types and extent of consumer uses that could result in public exposure to the Priority Chemical in the product, which in turn could result in adverse public health impacts.
  - Product uses or management or disposal practices that could result in releases to the environment of the Priority Chemical in the product, which in turn could result in adverse ecological or other environmental impacts.
  - Existence of data and other information relating to actual and potential public or environmental exposures to the Priority Chemical in the product.
  - Whether the product is required to be managed as a hazardous waste in California at the end of its useful life.
  - Whether the Priority Chemical is required to be used in or contained in the product pursuant to a federal or California State law.

- The degree to which federal and/or other California State regulatory programs address the public health and environmental threats posed by the Priority Chemical in the product throughout the life cycle of the product.
- (c) From the consumer products that are on the Products under Consideration list, DTSC will develop a list of “Priority Products”. Priority Products will be identified based on the following factors:
- The relative degree of threat posed by each product, due to the Priority Chemical in the product, to public health and the environment,
  - Availability of reliable information to substantiate the threat(s) posed by the product,
  - Availability of an existing alternatives assessment that is relevant to the product or the Priority Chemical in the product, and
  - Availability of DTSC resources.

In evaluating the relative degree of threat, DTSC will give priority to those chemicals, and the products that contain them, that pose the greatest public health and environmental threats, are most prevalently distributed in commerce and used by consumers, and for which there is the greatest potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in public health or environmental harm. DTSC will consider both the potential for exposure to the chemical in the product and the potential harm resulting from potential exposures.

In evaluating the potential for exposure, DTSC will, at a minimum, consider all of the following:

- Market data for the products containing the chemical;
- Reliable information demonstrating the occurrence of public health and environmental exposures;
- Information concerning the household presence of the product, and other products containing the same chemical, including the number of such of products, how common their household presence is, the frequency of use, and the concentration of the chemical in those products; and
- Information showing how widely the product is placed into the stream of commerce in California.

In evaluating the potential for harm resulting from potential exposures to the chemical contained in the product, DTSC will, at a minimum, consider chemical potency and resulting harm for all of the following:

- Children, pregnant women and other sensitive subpopulations; and

- Environmental receptors, in particular, environmentally sensitive habitats and endangered and threatened species.

#### 5) Listing Process

- Prior to finalizing the chemical and product lists, DTSC will make the proposed lists available on its website, for public review and comment, along with supporting documentation, including DTSC's rationale, data and data sources.
- DTSC will publish in the CRNR, send to persons on any listserv(s) that DTSC establishes related to these regulations, and post on its website a notice regarding the availability of the proposed lists and supporting documentation. The notice will include the deadline for submitting public comments, and notification of any workshops that DTSC may, at its discretion, hold for the proposed lists.
- After review and consideration of public comments on the proposed lists, DTSC will finalize and post the final lists on its website.
- Using the same procedures, DTSC will update the chemical and product lists as needed. Revisions may include additions and deletions to the prior lists.
- The initial lists will be issued according to the following schedule:
  - Proposed initial list of Chemicals under Consideration --- June 1, 2011
  - Final initial list of Chemicals under Consideration --- March 1, 2012
  - Proposed initial list of Priority Chemicals --- July 1, 2012
  - Proposed initial list of Products under Consideration --- March 1, 2013
  - Proposed initial list of Priority Products --- September 1, 2013
  - Final initial list of Priority Products --- December 1, 2013

While the four initial lists will be developed separately, subsequent lists may be issued simultaneously or sequentially.

#### 6) Petition Process

- Any person may petition DTSC to evaluate a chemical or a product using the chemical prioritization and/or product prioritization processes described above.
- DTSC will prioritize the technical review of petitions determined to be complete based on the comprehensiveness of the petitions and the availability of resources. Highest priority will be given to petitions from federal and other California State regulatory programs that relate to the petitioning agency's legislative and/or regulatory mandates.
- DTSC will conduct a technical review of each petition determined to be complete to determine whether to grant or deny the petition based on: (i) the



comprehensiveness of the data and information supporting the petition that pertains to the prioritization factors identified above; (ii) the quality of supporting data and information; and (iii) the availability of data and information, other than the data and information submitted with the petition, for DTSC to determine hazard traits exhibited by the chemical and evaluate the chemical and/or the product based on the prioritization factors identified above.

- After completing the technical review, DTSC will either grant or deny the petition. 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.

## **H. Alternatives Assessments**

This chapter details the requirements for the alternatives assessments that must be performed by responsible entities or manufacturers of Priority Products. Additionally, section A describes the requirements applicable to products that have not yet been listed as Priority Products but are reformulated or redesigned to remove Chemicals under Consideration or Priority Chemicals.

### **1) AA Notifications & Tier I AA Reports for Early Chemical Substitutions**

After a chemical has been listed as a Chemical under Consideration or Priority Chemical, if any product containing that chemical is reformulated or redesigned to remove or reduce the concentration of that chemical, or the original product is replaced with an alternative product, the responsible entity must provide an AA Notification to DTSC before placing the reformulated, redesigned or replacement product into the stream of commerce in California.

The AA Notification must include specified information identifying and describing the product, including brand name, the chemical removed from or reduced in the product, and intended uses and customer base. Additionally, the notice must include either: (i) a report for a Tier I alternatives assessment (defined as an assessment substantially equivalent to the Green Screen for Safer Chemicals, published by Clean Production Action, or any other AA tool acceptable to DTSC); or (ii) the following additional information:

- Information explaining the rationale for and the factors considered in selecting the reformulation, redesign or substitution alternative;
- Identification, and a qualitative or quantitative description, of any reduction(s) to adverse public health or environmental impacts achieved by the reformulation, redesign or substitution; and

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

This will enable DTSC to quickly determine if the replacement chemical should be listed as a Priority Chemical and if the new product should be listed as a Priority Product --- with the consequent requirement for a more rigorous Tier II Alternatives Assessment that conforms to the regulations (as described below). This will ensure an end result that will be either no change, or preferably, a reduction (if not an elimination) of adverse impacts on public health and the environment.

## 2) Tier II Alternatives Assessments (AA)

### Tier II AA Evaluation and Comparison Process and Factors

The regulations define the term Tier II alternatives assessment (AA) to include a Chemical Hazard Assessment and an Exposure Potential Assessment (which together are referred to as a Tier II-A AA), and a Multimedia Life Cycle Evaluation (referred to as a Tier II-B AA).

The Chemical Hazard Assessment is performed first to evaluate and compare a Priority Product and all alternatives initially identified for consideration. Following completion of the Chemical Hazard Assessment, an Exposure Potential Assessment is performed to further evaluate and compare the Priority Product and any alternative being considered that contains a chemical that exhibits one or more hazard traits. An Exposure Potential Assessment is not required if none of the alternatives being considered contain a chemical that exhibits a hazard trait. The results of the Chemical Hazard Assessment and/or, if applicable, the Exposure Potential Assessment, may be used to screen out alternatives before proceeding with the Multimedia Life Cycle Evaluation.

The Priority Product and all alternatives being considered must be evaluated and compared for the same set of life cycle segments, using the same methodologies and a consistent set of factors. In identifying the list of factors that will be used for the AA evaluation and comparison, the person performing the Tier II AA is required to review the list of factors specified in the regulations to determine which factors are pertinent to, and will be used for, the evaluation and comparison. The AA evaluation and comparison factors listed in the regulations include:

**Chemical Hazard Assessment** --- chemical information, public health impacts, ecological impacts, and chemical traits related to environmental impacts.

**Exposure Potential Assessment** --- exposure limitations, chemical quantity information, consumer uses, and environmental releases.

**Multimedia Life Cycle Evaluation** --- product function and performance, materials and resource consumption impacts, environmental impacts, and economic impacts.

The regulations list a number of detailed factors for each of the broad categories identified above.

### Requirements for Performing a Tier II AA

A responsible entity for a product that is listed as a Priority Product, or a person acting on behalf of or in lieu of the responsible entity, is required to perform a Tier II AA for the Priority Product.

A Work Plan for the AA must be submitted to DTSC no later than one hundred and eighty (180) days following the date that the product is listed as a Priority Product on DTSC's website. The regulations specify the content requirements for the AA Work Plan, which include: preparer information, product information, supply chain information, AA goal and scope of alternatives, scope of life cycle segments to be evaluated, approach and methodology, and schedule and deliverables.

In lieu of an AA Work Plan, a report for a previously completed AA for the Priority Product may be submitted to DTSC, if DTSC determines that the report is substantially equivalent to the requirements of the regulations.

All alternatives assessments must be performed by a qualified in-house assessment entity or qualified third-party assessment entity, both of which must be designated by DTSC. The designation process requires the entity to demonstrate its capability and methods for performing alternatives assessment, compliance with ISO 14040 standards, and recordkeeping practices. Each alternatives assessment must be performed under the responsible charge of a lead assessor. An alternatives assessment performed by a qualified in-house assessment entity must also be verified by a second lead assessor employed by a qualified third-party assessment entity. Lead assessors must be trained and accredited by an accrediting body designated by DTSC. The regulations include detailed requirements for accreditation programs, and detailed qualification requirements for lead assessors.

### 3) De Minimis Exemptions

A responsible entity is exempt from the Tier II AA requirements if the manufacturer of the responsible entity's product requests, and DTSC grants, a de minimis exemption.

By default, "de minimis" level is defined as the lower of 0.1% by weight or the lowest applicable federal or California State public health or environmental regulatory threshold. However, in the Priority Products list, DTSC has the option to specify that an exemption is not available for a specific product/chemical combination if: (i) The chemical has been shown to be harmful in concentrations below the de minimis level; or (ii) The chemical is found below the de minimis level in numerous consumer products that are commonly used on a frequent basis, and these aggregate exposures to de minimis concentrations of the chemical have been shown to be harmful.

When the chemical has been shown to be harmful or potentially harmful in concentrations below the de minimis level, DTSC may, at its discretion, specify a lower de minimis level for the product if reliable information identifies a specific lower de minimis threshold for the chemical that is based on a scientific evaluation of public health and environmental adverse impacts. The de minimis exemption will not be allowed, in any situation, for chemicals, materials, or substances manufactured or engineered at the nanoscale, or which contain nanostructures, or are considered to be a nanomaterial. Arguably, this approach is more protective than the current 0.1% default de minimis level used in other regulatory programs, such as TSCA and REACH.

A request for a de minimis exemption must be submitted to DTSC no later than sixty (60) days after the product has been listed as a Priority Product. Within sixty (60) days of receiving a de minimis exemption request DTSC will issue a notice granting or denying the exemption or requesting more information. The regulations specify the criteria for DTSC to use in making a decision to grant or deny a de minimis exemption. De minimis exemptions will be rescinded if DTSC determines that the data or other information that DTSC relied upon in granting the exemption was not, or is no longer, valid. All notices granting, denying or rescinding de minimis exemption must include a statement of basis for DTSC's decision.

#### 4) Tier II AA Reports

The Tier II-A and Tier II-B AA Reports must be submitted simultaneously to DTSC and the verifying lead assessor (if verification is required) by the respective due dates specified by DTSC in the notice of completeness for the AA Work Plan. Both Reports must include: information on the preparer, the manufacturer, the facility, the product, the supply chain, and supporting information used in the AA; an executive summary; and information concerning the lead assessor that will be verifying the AA (if required). The verification statement must be submitted to DTSC within ninety (90) days following submission of the AA Report.

The Tier II-A AA Report must also include: information on the AA goal and scope of alternatives, scope of life cycle segments evaluated, and approach and methodology; detailed information on Chemical Hazard Assessment and Exposure Potential Assessment evaluations and comparisons; and any adjustments to the AA Work Plan.

The Tier II-B AA Report must also include: identification and explanation of any changes to the Tier II-A AA Report information; information on the AA goal and scope of alternatives, scope of life cycle segments evaluated, and approach and methodology; detailed information on the Multimedia Life Cycle Evaluation comparison and evaluation; identification and description of the alternative selected to replace, reformulate or redesign the current Priority Product; an implementation plan for the selected alternative; and any proposed regulatory responses.

The information in the Tier II-B AA Report concerning the alternative selection decision must include:

- A description of the alternative selected, if any, and the rationale for the selection decision. This includes an assessment that evaluates and compares the selected alternative against the Priority Product, and a detailed list and explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable.
- A discussion of the functional equivalency of the selected alternative as compared to the Priority Product, and an assessment of the technological and economic feasibility for the selected alternative. If no alternative is selected, this information must be provided for each alternative considered in the Tier II-B AA.
- A demonstration that the production, use and disposal of the selected alternative, in conjunction with any proposed regulatory response(s), will have no greater significant adverse impacts on public health or the environment than the impacts associated with the Priority Product.
- A list of all chemical ingredients contained in the selected alternative and hazard trait information for those chemicals.

Once DTSC determines an AA Report to be complete, it will issue a completeness determination notice to the submitter of the AA Report, as well as the product manufacturer and responsible entities. In the completeness determination notice, or a subsequent notice sent to the manufacturer and responsible entities, DTSC will provide notice of its proposed determination as to whether one or more of the regulatory responses that are triggered by a DTSC finding (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.

## **I. Regulatory Responses**

This chapter describes the regulatory responses that will or may be imposed on Priority Products and certain selected alternative products, and the conditions under which the different regulatory responses will apply. This portion of the regulations implements Health and Safety Code section 25253(b) which requires the range of possible regulatory responses to include, as a minimum, all of the following:

- No action;
- Submission of additional information to DTSC;
- Labeling or other consumer product information;
- Restrictions on the use of the chemical of concern in the consumer product;
- Prohibitions on the use of the chemical of concern in the consumer product;
- Measures that control access to or limit exposure to the chemical of concern in the consumer product;
- Management of the product at the end of its useful life;
- Funding green chemistry challenge grants, where no feasible safer alternative exists; and

- Any other outcome DTSC determines accomplishes the requirements of the Green Chemistry statutes.

## 1) Applicability

The regulations specify regulatory responses that will, under specified conditions, apply to: (i) products manufactured as a selected alternative following completion of an AA; (ii) a Priority Product for which an alternative is not selected; and (iii) a Priority Product that will remain in commerce pending development and distribution of the selected alternative. The regulatory responses include: self-implementing regulatory responses; regulatory responses triggered by specified DTSC findings; and other regulatory responses to be determined by DTSC.

Regulatory responses will not be required for a selected alternative product, if it is demonstrated to DTSC's satisfaction that:

- The selected alternative contains no Priority Chemical above the applicable de minimis level;
- The selected alternative does not pose a significant public health or environmental threat; and
- The Priority Product being replaced by the alternative will be completely phased out from sale in California within three (3) years.

## 2) Self-Implementing Regulatory Responses

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

- Product Information for Consumers. Product information must be provided to consumers (within 12 months) if the alternative product contains a Priority Chemical (or if the manufacturer chooses to retain the Priority Product).

Product information can be provided by including an information sheet in the product packaging, printing the required information on the product packaging, printing the information in a prominent place in the product manual if a hard copy manual is packaged with the product, or posting the information in a prominent place at the point of sale for products that are not packaged. Unless precluded by the type or size of the product, the product must also be permanently marked or labeled with certain product information.

- End-of-Life Product Stewardship Program. The responsible entity and/or manufacturer must establish, maintain and fund (within 2 years) 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 at

end-of-life. The requirements for the product stewardship plan and program are specified in the regulations.

### 3) Regulatory Responses Triggered by Specified DTSC Findings

For each of the following regulatory responses, the regulations set forth specific DTSC findings that would trigger the regulatory response, along with implementation due dates:

- *Additional Information.* The responsible entity must provide to DTSC any information DTSC determines is necessary to determine and ensure implementation of regulatory responses.
- *Product Information for Consumers.* In addition to the self-implementing requirement described above, product information must be provided to consumers, if DTSC determines any of the following:
  - Information for the consumer will promote significantly safer uses, and significantly reduce the threats posed by the product/chemical,
  - Product stewardship is needed to address end-of-life impacts, or
  - End-of-life reclamation is needed to conserve resources and mitigate damages resulting from extraction of raw materials.
- *End-of-Life Product Stewardship Program.* In addition to the self-implementing requirement described above, the responsible entity and/or manufacturer must establish, maintain and fund an end-of-life product stewardship program and provide product information, if DTSC determines any of the following:
  - There is a significant potential for end-of-life mismanagement that would pose significant adverse impacts,
  - End-of-life reclamation is needed to conserve resources and mitigate damages resulting from extraction of raw materials, or
  - Without a product stewardship program there would be significant waste management costs borne by local governments, ratepayers or taxpayers.
- *Product Sales Prohibition.* If the selected alternative contains a Priority Chemical (or if an alternative is not selected), and DTSC determines there is a safer alternative that does not contain a Priority Chemical and that is functionally equivalent and technologically and economically feasible, the responsible entity (or manufacturer) must do one of the following:
  - Within one (1) year, ensure that the Priority Product is no longer placed into the stream of commerce in California, and ensure that an inventory recall

program for the Priority Product is implemented and completed within two years; or

- Submit to DTSC, within 1 year, an AA Report that selects an alternative that does not contain a Priority Chemical. A responsible entity choosing this option, must notify DTSC within 60 days of its intent to submit a revised AA Report.

#### 4) Other Regulatory Responses

The regulations also specify that DTSC may require any of the following as regulatory responses that it determines are necessary to limit exposure to, and reduce the level of public health or environmental hazards posed by, a selected alternative, or a Priority Product for which an alternative is not selected:

- Product information for consumers
- End-of-life product stewardship program
- Product sales prohibition
- Engineered safety measures to control access or limit exposure to the Priority Chemical in a product
- Restrictions on the use of the Priority Chemical
- Green Chemistry research and development project, or Green Chemistry challenge grant
- New AA (but no sooner than 3 years after prior AA) if: (i) the prior AA did not identify or select an alternative, or (ii) DTSC becomes aware of a safer alternative that is functionally equivalent and technologically and economically feasible
- Any other regulatory response determined necessary by DTSC

#### 5) Regulatory Response Exemptions

The regulations provide a process for a responsible entity or manufacturer to request an exemption from an otherwise applicable regulatory response based on either or both of the following:

- 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 or manufacturer could not reasonably be expected to comply with both requirements. In this situation, DTSC may, at its



discretion, require implementation of a modified regulatory response that resolves the conflict.

- The required regulatory response substantially duplicates a requirement of another federal or California State regulatory program or an international trade agreement.

#### 6) Regulatory Response Determination Process

- For the non-self-implementing regulatory responses (i.e., the responses triggered by a DTSC determination), DTSC will notify affected responsible entities and manufacturers of its proposed regulatory response determination.
- The proposed regulatory response determination will also be made available for public review and comment. DTSC will publish in the CRNR, send to persons on any listserv(s) that DTSC establishes related to the regulations, and post on its website a notice regarding the availability of the proposed determination. The notice will include the deadline and methods for submitting public comments, and notification of any workshops that DTSC may, at its discretion, hold for the proposed lists.
- After review and consideration of public comments on the proposed lists, DTSC will send a final determination notice to the responsible entity(ies) and manufacturer(s) and post the final notice on its website.
- Within thirty (30) days, 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.
- The responsible entity or manufacturer must notify DTSC upon completion of implementation of the required regulatory response, and, if applicable, upon completion of implementation of the selected alternative. This information must also be posted on the website(s) of the manufacturer and responsible entity(ies).
- DTSC will post on its website, and update quarterly, a Regulatory Response Report that identifies the regulatory response(s) for each selected alternative for a Priority Product, and the implementation dates for the alternative and the regulatory response. The Regulatory Response Report will also include information on any regulatory response exemptions granted by DTSC.

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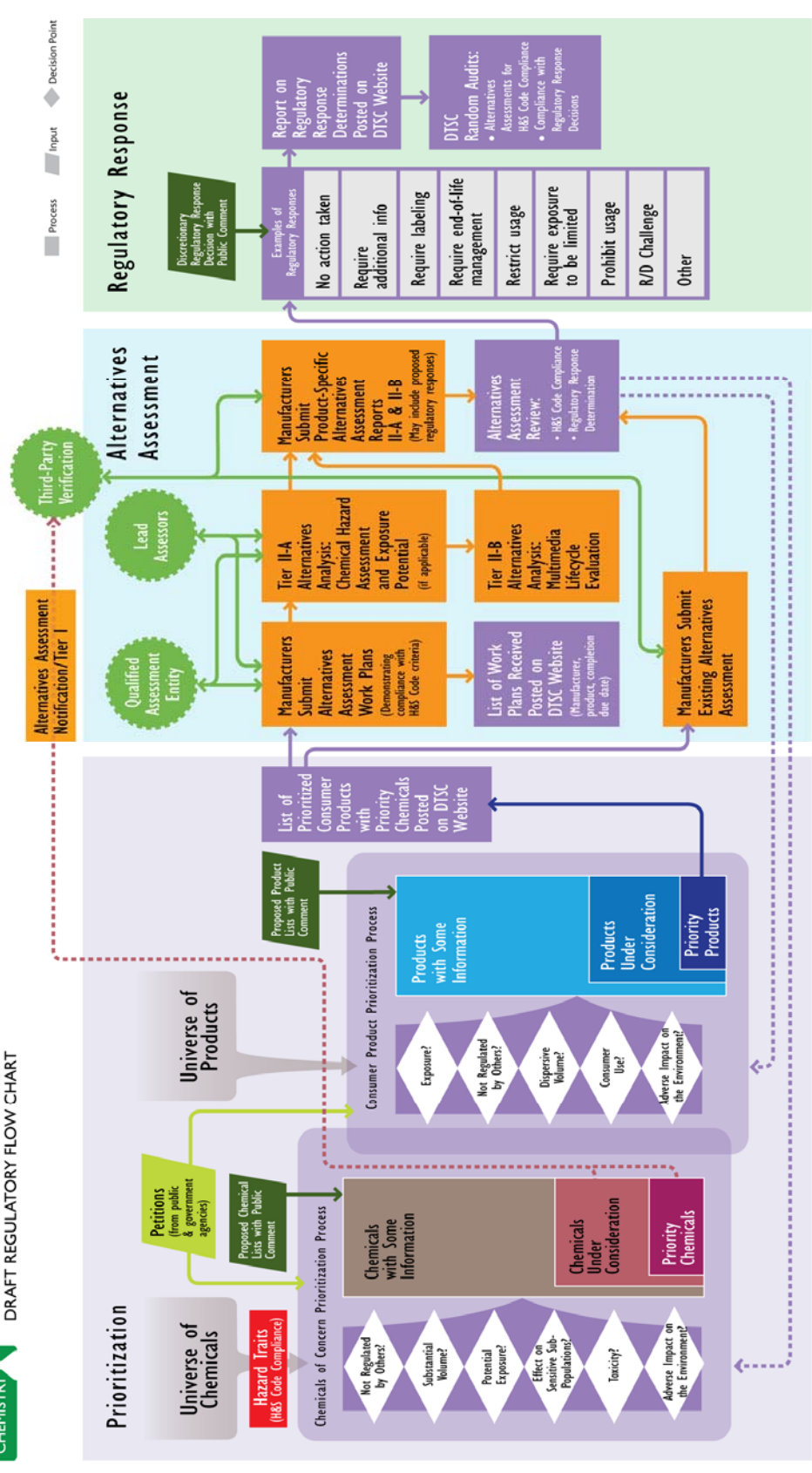
## APPENDIX A

Regulatory Flowchart  
September 14, 2010



# Regulation for Safer Consumer Products

ARTICLE 14, CHAPTER 6.5, DIVISION 20 OF THE HEALTH & SAFETY CODE  
 CHAPTER 53, DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS  
 DRAFT REGULATORY FLOW CHART



SEPTEMBER 14, 2010

## APPENDIX B

Health and Safety Code, Division 20, Article 14. Green Chemistry

Article 14. Green Chemistry  
Division 20, Health and Safety Code

**25251.** For purposes of this article, the following definitions shall apply:

(a) "Clearinghouse" means the Toxics Information Clearinghouse established pursuant to Section 25256.

(b) "Council" means the California Environmental Policy Council established pursuant to subdivision (b) of Section 71017 of the Public Resources Code.

(c) "Office" means Office of Environmental Health Hazard Assessment.

(d) "Panel" means the Green Ribbon Science Panel established pursuant to Section 25254.

(e) "Consumer product" means a product or part of the product that is used, brought, or leased for use by a person for any purposes. "Consumer product" does not include any of the following:

(1) A dangerous drug or dangerous device as defined in Section 4022 of the Business of Professions Code.

(2) Dental restorative materials as defined in subdivision (b) of Section 1648.20 of the Business and Professions Code.

(3) A device as defined in Section 4023 of the Business of Professions Code.

(4) A food as defined in subdivision (a) of Section 109935.

(5) The packaging associated with any of the items specified in paragraph (1), (2), or (3).

(6) A pesticide as defined in Section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. Sec. 136 and following).

(7) Mercury-containing lights defined as mercury-containing lamps, bulbs, tubes, or other electric devices that provide functional illumination.

(f) This section shall remain in effect only until December 31, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before December 31, 2011, deletes or extends that date.

**25251.** For purposes of this article, the following definitions shall apply:

(a) "Clearinghouse" means the Toxics Information Clearinghouse established pursuant to Section 25256.

(b) "Council" means the California Environmental Policy Council established pursuant to subdivision (b) of Section 71017 of the Public Resources Code.

(c) "Office" means Office of Environmental Health Hazard Assessment.

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(1) A dangerous drug or dangerous device as defined in Section 4022 of the Business of Professions Code.

(2) Dental restorative materials as defined in subdivision (b) of Section 1648.20 of the Business and Professions Code.

(3) A device as defined in Section 4023 of the Business of Professions Code.

- (4) A food as defined in subdivision (a) of Section 109935.
- (5) The packaging associated with any of the items specified in paragraph (1), (2), or (3).
- (6) A pesticide as defined in Section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide (7 United States Code Sections 136 and following).
- (f) This section shall become effective on January 1, 2012.

**25252.** (a) On or before January 1, 2011, the department shall 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, in accordance with the review process specified in Section 25252.5. The department shall adopt these regulations in consultation with the office and all appropriate state agencies and after conducting one or more public workshops for which the department provides public notice and provides an opportunity for all interested parties to comment. The regulations adopted pursuant to this section shall establish an identification and prioritization process that includes, but is not limited to, all of the following considerations:

- (1) The volume of the chemical in commerce in this state.
  - (2) The potential for exposure to the chemical in a consumer product.
  - (3) Potential effects on sensitive subpopulations, including infants and children.
- (b) (1) In adopting regulations pursuant to this section, the department shall develop criteria by which chemicals and their alternatives may be evaluated. These criteria shall include, but not be limited to, the traits, characteristics, and endpoints that are included in the clearinghouse data pursuant to Section 25256.1.
- (2) In adopting regulations pursuant to this section, the department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy.
- (3) Paragraph (2) does not require the department, when adopting regulations pursuant to this section, to reference and use only the available information specified in paragraph (2).

**25252.5.** (a) Except as provided in subdivision (f), the department, in adopting the regulations pursuant to Sections 25252 and 25253, shall prepare a multimedia life cycle evaluation conducted by affected agencies and coordinated by the department, and shall submit the regulations and the multimedia life cycle evaluation to the council for review.

- (b) The multimedia evaluation shall be based on the best available scientific data, written comments submitted by interested persons, and information collected by the department in preparation for adopting the regulations, and shall address, but is not limited to, the impacts associated with all the following:
- (1) Emissions of air pollutants, including ozone forming compounds, particulate matter, toxic air contaminants, and greenhouse gases.
  - (2) Contamination of surface water, groundwater, and soil.

- (3) Disposal or use of the byproducts and waste materials.
- (4) Worker safety and impacts to public health.
- (5) Other anticipated impacts to the environment.

(c) The council shall complete its review of the multimedia evaluation within 90 calendar days following notice from the department that it intends to adopt regulations. If the council determines that the proposed regulations will cause a significant adverse impact on the public health or the environment, or that alternatives exist that would be less adverse, the council shall recommend alternative measures that the department or other state agencies may take to reduce the adverse impact on public health or the environment. The council shall make all information relating to its review available to the public.

(d) Within 60 days of receiving notification from the council of a determination of significant adverse impact, the department shall adopt revisions to the proposed regulation to avoid or reduce the adverse impact, or the affected agencies shall take appropriate action that will, to the extent feasible, mitigate the adverse impact so that, on balance, there is no significant adverse impact on public health or the environment.

(e) In coordinating a multimedia evaluation pursuant to subdivision (a), the department shall consult with other boards and departments within the California Environmental Protection Agency, the State Department of Public Health, the State and Consumer Services Agency, the Department of Homeland Security, the Department of Industrial Relations, and other state agencies with responsibility for, or expertise regarding, impacts that could result from the production, use, or disposal of consumer products and the ingredients they may contain.

(f) Notwithstanding subdivision (a), the department may adopt regulations pursuant to Sections 25252 and 25253 without subjecting the proposed regulation to a multimedia evaluation if the council, following an initial evaluation of the proposed regulation, conclusively determines that the regulation will not have any significant adverse impact on public health or the environment.

(g) For the purposes of this section, "multimedia life cycle evaluation" means the identification and evaluation of a significant adverse impact on public health or the environment, including air, water, or soil, that may result from the production, use, or disposal of a consumer product or consumer product ingredient.

**25253.** (a) (1) On or before January 1, 2011, the department shall adopt regulations pursuant to this section 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, in accordance with the review process specified in Section 25252.5. The department shall adopt these regulations in consultation with all appropriate state agencies and after conducting one or more public workshops for which the department provides public notice and provides an opportunity for all interested parties to comment.

(2) The regulations adopted pursuant to this section shall establish a process that includes an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives, as well as an evaluation of critical exposure pathways. This process shall include life cycle assessment tools that take into consideration, but shall not be limited to, all of the following:



- (A) Product function or performance.
- (B) Useful life.
- (C) Materials and resource consumption.
- (D) Water conservation.
- (E) Water quality impacts.
- (F) Air emissions.
- (G) Production, in-use, and transportation energy inputs.
- (H) Energy efficiency.
- (I) Greenhouse gas emissions.
- (J) Waste and end-of-life disposal.
- (K) Public health impacts, including potential impacts to sensitive subpopulations, including infants and children.
- (L) Environmental impacts.
- (M) Economic impacts.

(b) The regulations adopted pursuant to this section shall specify the range of regulatory responses that the department may take following the completion of the alternatives analysis, including, but not limited to, any of the following actions:

- (1) Not requiring any action.
- (2) Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives.
- (3) Imposing requirements on the labeling or other type of consumer product information.
- (4) Imposing a restriction on the use of the chemical of concern in the consumer product.
- (5) Prohibiting the use of the chemical of concern in the consumer product.
- (6) Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product.
- (7) Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product.
- (8) Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists.
- (9) Any other outcome the department determines accomplishes the requirements of this article.

(c) The department, in developing the processes and regulations pursuant to this section, shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

**25254.** (a) In implementing this article, the department shall establish a Green Ribbon Science Panel. The panel shall be composed of members whose expertise shall encompass all of the following disciplines:

- (1) Chemistry.
- (2) Chemical engineering.
- (3) Environmental law.

- (4) Toxicology.
- (5) Public policy.
- (6) Pollution prevention.
- (7) Cleaner production methods.
- (8) Environmental health.
- (9) Public health.
- (10) Risk analysis.
- (11) Materials science.
- (12) Nanotechnology.
- (13) Chemical synthesis.
- (14) Research.
- (15) Maternal and child health.

(b) The department shall appoint all members to the panel on or before July 1, 2009. The department shall appoint the members for staggered three-year terms, and may reappoint a member for additional terms, without limitation.

(c) The panel shall meet as often as the department deems necessary, with consideration of available resources, but not less than twice each year. The department shall provide for staff and administrative support to the panel.

(d) The panel meetings shall be open to the public and are subject to the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code).

**25255.** The panel may take any of the following actions:

(a) Advise the department and the council on scientific and technical matters in support of the goals of this article of significantly reducing adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of those impacts to the state's society, by encouraging the redesign of consumer products, manufacturing processes, and approaches.

(b) Assist the department in developing green chemistry and chemicals policy recommendations and implementation strategies and details, and ensure these recommendations are based on a strong scientific foundation.

(c) Advise the department and make recommendations for chemicals the panel views as priorities for which hazard traits and toxicological end-point data should be collected.

(d) Advise the department in the adoption of regulations required by this article.

(e) Advise the department on any other pertinent matter in implementing this article, as determined by the department.

**25256.** The department shall establish the Toxics Information Clearinghouse, which shall provide a decentralized, Web-based system for the collection, maintenance, and distribution of specific chemical hazard trait and environmental and toxicological end-point data. The department shall make the clearinghouse accessible to the public through a single Internet Web portal, and, shall, to the maximum extent possible, operate the clearinghouse at the least possible cost to the state.

**25256.1.** On or before January 1, 2011, the office shall evaluate and specify the hazard traits and environmental and toxicological end-points and any other relevant

data that are to be included in the clearinghouse. The office shall conduct this evaluation in consultation with the department and all appropriate state agencies, after one or more public workshops, and an opportunity for all interested parties to comment. The office may seek information from other states, the federal government, and other nations in implementing this section.

**25256.2.** (a) The department shall develop requirements and standards related to the design of the clearinghouse and data quality and test methods that govern the data that is eligible to be available through the clearinghouse.

(b) The department may phase in the access to eligible information and data in the clearinghouse as that information and data become available.

(c) The department shall ensure the clearinghouse is capable of displaying updated information as new data becomes available.

**25256.3.** The department shall consult with other states, the federal government, and other nations to identify available data related to hazard traits and environmental and toxicological end-points, and to facilitate the development of regional, national, and international data sharing arrangements to be included in the clearinghouse.

**25257.** (a) A person providing information pursuant to this article may, at the time of submission, identify a portion of the information submitted to the department as a trade secret and, upon the written request of the department, shall provide support for the claim that the information is a trade secret. Except as provided in subdivision (d), a state agency shall not release to the public, subject information supplied pursuant to this article that is a trade secret, and that is so identified at the time of submission, in accordance with Section 6254.7 of the Government Code and Section 1060 of the Evidence Code.

(b) This section does not prohibit the exchange of a properly designated trade secret between public agencies, if the trade secret is relevant and necessary to the exercise of the agency's jurisdiction and the public agency exchanging the trade secrets complies with this section. An employee of the department that has access to a properly designated trade secret shall maintain the confidentiality of that trade secret by complying with this section.

(c) Information not identified as a trade secret pursuant to subdivision (a) shall be available to the public unless exempted from disclosure by other provisions of law. The fact that information is claimed to be a trade secret is public information.

(d) (1) Upon receipt of a request for the release of information that has been claimed to be a trade secret, the department shall immediately notify the person who submitted the information. Based on the request, the department shall determine whether or not the information claimed to be a trade secret is to be released to the public.

(2) The department shall make the determination specified in paragraph (1), no later than 60 days after the date the department receives the request for disclosure, but not before 30 days following the notification of the person who submitted the information.

(3) If the department decides that the information requested pursuant to this subdivision should be made public, the department shall provide the person who submitted the information 30 days' notice prior to public disclosure of the information,

unless, prior to the expiration of the 30-day period, the person who submitted the information obtains an action in an appropriate court for a declaratory judgment that the information is subject to protection under this section or for a preliminary injunction prohibiting disclosure of the information to the public and promptly notifies the department of that action.

(e) This section does not authorize a person to refuse to disclose to the department information required to be submitted to the department pursuant to this article.

(f) This section does not apply to hazardous trait submissions for chemicals and chemical ingredients pursuant to this article.

**25257.1.** (a) This article does not limit and shall not be construed to limit the department's or any other department's or agency's existing authority over hazardous materials.

(b) This article does not authorize the department to supersede the regulatory authority of any other department or agency.

(c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.

## APPENDIX C

California Environmental Protection Agency, Department of Toxic Substances Control.  
Safer Consumer Product Alternatives Draft Regulations. September, 2010.

## APPENDIX D

California Environmental Protection Agency, Department of Toxic Substances Control.  
Initial Statement of Reasons for the Safer Consumer Product Alternatives  
Draft Regulations. September, 2010.

These appendices are available as separate documents. Copies may be obtained in electronic form from DTSC's Internet site at:  
<http://www.dtsc.ca.gov/LawsRegsPolicies/SCPA.cfm> or printed copies may be requested from Jeff Woled of DTSC's Regulations Section, by telephone at (916) 322-5225 or by email at [jwoled@dtsc.ca.gov](mailto:jwoled@dtsc.ca.gov) or [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)