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TITLE 22, California Code of Regulations

45-DAY PUBLIC NOTICE AND COMMENT PERIOD For Proposed Rulemaking

SAFER CONSUMER PRODUCT ALTERNATIVES

Department Reference Number: R-2010-05

Office of Administrative Law Notice File Number: Z-2010-0908-01

NOTICE IS HEREBY GIVEN that the Department of Toxic Substances Control (DTSC) proposes to add chapter 53 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 AND WRITTEN COMMENT PERIOD

A written comment period has been established commencing on September 17, 2010, and closing on November 1, 2010. DTSC will hold a public hearing on the proposed regulations at 1:00 p.m. on November 1, 2010 in the Byron Sher Auditorium, 2nd Floor, 1001 "I" Street, Sacramento, at which time any person may present statements or arguments orally or in writing, relevant to this proposal. Please submit written comments to the contact person listed at the end of this notice. Written comments on the rulemaking submitted no later than 5:00 p.m. on November 1, 2010 will be considered.

Representatives of DTSC will preside at the hearing. Persons who wish to speak are requested to register before the hearing. Pre-hearing registration will be conducted at the location of the hearing from 10:00 a.m. to 1:00 p.m. Registered persons will be heard in the order of their registration. Any other person wishing to speak at the hearing will be afforded an opportunity after the registered persons have been heard.

Due to enhanced security precautions at the Cal/EPA Headquarters Building located at 1001 "I" Street, Sacramento, all visitors are required to sign in prior to attending any

meeting. Sign-in and badge issuance occur in the Visitor and Environmental Services Center. This Center is located just inside and to the left of the building's public entrance. Depending on their destination and the building security level, visitors may be asked to show valid picture identification. Valid picture identification can take the form of a current driver's license, military identification card, or state or federal identification cards. Depending on the size and number of meetings scheduled on any given day, the security check-in could take from three to fifteen minutes. Please allow adequate time to sign in before being directed to your meeting.

If you have special accommodation or language needs, please contact Jeff Woled, Regulations Coordinator, Regulations Section, at (916) 322-5225 or by e-mail at gcregs@dtsc.ca.gov by October 18, 2010. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

In accordance with the California Government Code and Americans with Disabilities Act requirements, this publication can be made available in Braille, large print, computer disk, or tape cassette, etc. as a disability-related reasonable accommodation for an individual with a disability. To discuss how to receive a copy of this publication in an alternative format, please contact Adrian Recio at (916) 324-3095 or by e-mail at arecio@dtsc.ca.gov.

AUTHORITY AND REFERENCE

Authority: These regulations are being adopted under the following authorities:

Health and Safety Code section 25252: This section authorizes and requires 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 take following

the completion of an alternatives analysis, including, but not limited to, nine (9) specified responses.

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, and article 8 of chapter 6.5 of division 20.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Existing Law

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, by January 1, 2011, 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 by January 1, 2011, pursuant to Health and Safety Code section 25256.1, for purposes of the Toxic 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, by January 1, 2011, 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; 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 this 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; pesticides; and mercury-containing lights. (Mercury-containing lights are exempted only 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) 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 list.

TSCA requires the submission of health and safety studies which 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 for a grandfather clause for those 62,000 chemicals.

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 Government Accountability Office 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".

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 conducted the Fourth National Report on Human Exposure to Environmental Chemicals, which measured 212 chemicals in the blood and urine of a representative population of California. 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, the U.C. Berkeley authors 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 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 incentives, market motivation which stems from the data gap, and 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 the Department of Toxic Substances Control (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.

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

- 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 priority chemicals.

- Specify the range of regulatory responses that DTSC may take following the completion of the alternatives analysis.

Proposed Regulations

The proposed regulation would add a new chapter 53, Safer Consumer Products Alternatives, to division 4.5 of Title 22, California Code of Regulations. These regulations are necessary to fulfill the requirements 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.

Summary of 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: 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; pesticides; and mercury-containing lights. (Mercury-containing lights are exempted only through December 31, 2011.) The regulations 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 be subject to the regulations.

B. Guiding Principles

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

- 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:

- DTSC --- Evaluation and prioritization of chemicals and consumer products to develop a list of “Priority Products” that contain “Priority Chemicals”.
- 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). Responsible entities must notify DTSC when their product is listed as a Priority Product, and DTSC posts this information on its website.
- DTSC --- Identification and imposition of regulatory responses to effectively limit the public health and/or environmental threats, if any, posed by the consumer product (due to the Priority Chemical) or the 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 their 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.
- 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.

- If a regulatory requirement has not been fulfilled, a responsible entity is given the option to fulfill the requirement or cease placing the product into the stream of commerce in California.

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 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. Disputes

The regulations provide a process for a responsible entity or manufacturer to dispute an action taken by DTSC that applies to the responsible entity's or manufacturer's chemical or product. Any requirement imposed by DTSC under the regulations, and posting of information in the Failure to Comply list concerning that requirement, will be stayed while a dispute is pending.

H. Confidentiality of Information

The regulations set out provisions for the treatment of information submitted under the regulations and claimed to be confidential by the submitter. The regulations also specify procedures for DTSC to follow in handling trade secrets. These provisions address the statutory and regulatory authorities that apply to a claim of confidentiality, the procedural requirements for making a claim, and how DTSC may review such a claim.

The regulations are based on the authorities for handling confidential information found in Health and Safety Code section 25257 and the California Public Records Act (PRA). The regulations include provisions that promote faster and more efficient disclosure of information, such as the marking and indexing of all confidential claims and up-front substantiation of trade secret claims. DTSC intends to rely on the PRA statute and substantive criteria already established in case law for determining trade secret justification, including that set forth in Government Code 6255.

I. Small Businesses

The regulations establish special provisions for small businesses that are independently owned and operated and have twenty-five (25) or fewer employees and average annual gross receipts of no more than one million dollars (\$1,000,000). A manufacturer that qualifies as a small business may request, and DTSC shall provide, consultative services to assist the manufacturer in complying with requirements pertaining to alternatives assessments. In addition, for any of the time frames specified in the regulations, or that DTSC specifies pursuant to the regulations, DTSC may, at its discretion, allow a business that qualifies as a small business a longer period of time to comply.

Chemical and Product Prioritization

A. Chemical and Product Information

The prioritization process will be informed by a wealth of information that DTSC will obtain from the public domain. Responsible entities will be required to provide any necessary information DTSC is unable to obtain from the public domain. 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 specified products, including quantities in the entire product or component.
- 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.

Responsible entities required to provide data and information to DTSC may fulfill information requests by making available to DTSC data and information that has been provided under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Toxic Substance Control Act (TSCA), or Canadian Environmental Protection Act (CEPA) programs.

B. Applicability

DTSC will not include in the chemical or product prioritization a chemical or 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 article 14 of chapter 6.5 of division 20 of the Health and Safety Code and this chapter.
- 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.

C. Chemical Prioritization

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

- 1) Only chemicals that exhibit a hazard trait, as identified by the OEHHA for purposes of the Toxic 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 included on specified lists by various other regulatory bodies,
 - Mutagens listed by the European Union, and
 - USEPA-listed persistent bioaccumulative toxins.
- 2) 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.
- 3) 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.

D. Product Prioritization

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

- 1) Only consumer products that contain a Priority Chemical will be considered in the prioritization process.
- 2) 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 related 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.
- 3) 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.

E. 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 this chapter, 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 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.

F. 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. Within sixty (60) days of receiving a petition, DTSC will review the petition and determine if it is complete.
- 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 by 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.

Alternatives Assessments

A. Guidance Materials

The regulations require DTSC to prepare and make available on its website, guidance materials to assist persons in performing alternatives assessments, and to post on its website alternatives assessments (AA) that are available in the public domain and are supported by reliable information.

B. 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 has been replaced with an alternative product, the responsible entity shall 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 being substantially equivalent to the Green Screen For Safer Chemicals, as published and amended by Clean Production Action); or (ii) the following additional information:

- (A) Information explaining the rationale for and the factors considered in selecting the reformulation, redesign or substitution alternative;
- (B) 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
- (C) Identification of any hazard traits exhibited by the substitute chemical, if another chemical was substituted for the Chemical under Consideration or Priority Chemical.

C. 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 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 AA the evaluation and comparison, the person performing the Tier II AA is required 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, 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 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. DTSC will review the work plan within sixty (60) days and issue a notice of completeness or notice of deficiency. Notices of completeness will include due dates for submitting reports for the Tier II-A AA and Tier II-B AA, which are submitted separately.

A one-time extension may be requested for the AA work plan and/or AA reports. A one-time extension for an AA Work Plan cannot exceed ninety (90) days, and a one-time extension for an AA Report cannot exceed twelve (12) months.

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.

D. 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 to 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 cumulative 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.

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.

E. 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: explanation of any changes to the Tier II-A AA Report information; information on 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; 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, if any, selected, 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.

Within sixty (60) days of receiving a Tier II-A or Tier II-B AA Report and, if applicable, the AA verification statement for the AA Report, DTSC will review the AA Report for completeness and for compliance with the regulations, and issue a notice of

completeness or a notice of deficiency. If the submitter of the AA Report fails to adequately and timely respond to two (2) notices of deficiency, the product will be placed on the Failure to Comply List.

The completeness determination notice will be sent 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.

Regulatory Responses

A. 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 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 phased out in 3 years.

B. 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 may 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.

C. 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 government, 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:

- Ensure that the Priority Product is removed from the stream of commerce in California within one year, 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.

D. 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 R&D 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

E. 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 California or federal regulatory program or an international trade agreement.

F. Regulatory Response 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 this chapter, and post on its website a notice regarding the availability of the proposed determination. 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 send a final determination notice to the responsible entity(ies) and manufacturer(s) and post the final notice on its website.
- 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.
- 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 manufacturer's website.
- 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.

Public Health and Environmental Impacts

The regulations specify a comprehensive 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 the statute 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 factors specified in the regulations are listed below.

A. 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

B. 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

C. 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

D. 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 section 303(c) of the federal Clean Water Act and listed in section 131.38 of Title 40 of the Code of Federal Regulations published in the Federal Register May 18, 2000
 - Pollutants listed by California or the United States Environmental Protection Agency for one or more water bodies in California pursuant to section 303 (d) of 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

E. Materials and Resource Consumption Impacts

- Water consumption and conservation
- Production, in-use, and transportation energy inputs

- Energy consumption and efficiency
- Reusability and recyclability

F. 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

G. 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

H. Tier II AA Required Finding of No Adverse Impact

The Tier II AA 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 manufacturer) will have no greater significant adverse impacts on public health or the environment than the current impacts associated with the Priority Product.

I. Early Chemical Substitutions

Once a chemical has been listed by DTSC as a Chemical under Consideration or a Priority Chemical, if a manufacturer reformulates or redesigns a consumer product to remove or reduce the chemical, or substitutes the original product with another product, the manufacturer must notify DTSC of the change, and provide information on the product and the new chemical, including hazard trait information. This will enable DTSC to quickly determine if this new product should be listed as a Priority Product with the consequent requirement for an alternatives assessment that conforms to the regulations. 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.

FEDERAL LAWS OR REGULATIONS

- There is no federal law or regulation mandating the adoption of these regulations.
- There is no existing comparable federal regulation or statute.

OTHER STATUTORY REQUIREMENTS

California Environmental Quality Act (CEQA) Compliance

DTSC has found this rulemaking project to be exempt under CEQA. A Notice of Exemption will be filed with the State Clearinghouse when the regulations are adopted.

Peer Review

DTSC is proceeding with a peer review of the scientific basis of these regulations pursuant to Health and Safety Code section 57004.

Environmental Policy Council Review

DTSC is proceeding with a review of the regulations by the Environmental Policy Council pursuant to Health and Safety Code section 25252.5.

IMPACTS ON LOCAL AGENCIES OR SCHOOL DISTRICTS

Mandates on Local Agencies and School Districts: DTSC has made a preliminary determination that adoption of these regulations will create no new local mandates.

Estimate of Potential Cost or Savings to Local Agencies Subject to Reimbursement: DTSC has made a preliminary 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, or (iii) impose any other non-discretionary costs or savings on local agencies.

FISCAL IMPACT

Cost or Savings to Any State Agency: Adoption of these regulations will impose new duties on DTSC. DTSC estimates that it will need an augmentation in its budget of \$10 million to \$13 million in the fiscal year beginning July 1, 2011. Funding will cover additional staff as well as contracts, grants, and laboratory equipment. Additional funding will be needed in future years to implement an enforcement program. This preliminary estimate does not include estimates for information technology systems that may be required or revenue collection costs if new fees are levied to fund these regulations.

In future years, after the release and updates of the Priority Products list, State agencies that purchase products that are Priority Products may incur increased costs for operating expenses attributed to any price increases for Priority Products resulting from these regulations.

Additionally, the California Prison Industry Authority may be impacted if it uses any listed Priority Chemicals in manufacturing its products. Further discussion with California Prison Industry Authority is needed to determine if it would be considered a manufacturer or retailer or both under this regulation. Until the chemicals and products lists are completed, DTSC is unable to estimate the impact on the California Prison Industry Authority.

Cost or Savings in Federal Funding to the State: DTSC has made a preliminary determination that the proposed regulations will have no impact on federal revenues or costs to California.

HOUSING COSTS

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

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

Determination

DTSC has made an initial 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. 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 assessment. 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 Priority Chemicals 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 providing chemical and product information to DTSC upon request and a limited notification requirement in certain circumstances. The regulation impacts both out-of-state and in-state businesses. This includes chemical and product producers, brand name manufacturers, retailers, importers, distributors and other businesses in the supply chain.

Projected Compliance Requirements

Compliance requirements will vary from business to business depending on the products they produce, sell, distribute or import, and the arrangements that are made

between the various responsible entities in the supply chain for each product. Some business will have no compliance requirements. Others will be required to comply with one or more of the following types of requirements: submission of chemical and/or product information to DTSC; submission of various notifications to DTSC; performance of alternatives assessments and submission of alternatives assessments work plans and reports for Priority Products; and compliance with regulatory responses determined imposed on selected products by DTSC after completion of an alternatives assessment. Most businesses in the supply chain for a product subject to these compliance requirements can “opt out” by ceasing their involvement in placing the product into the stream of commerce in California.

Solicitation of Proposed Alternatives

This regulation impacts in-state and out-of-state businesses similarly as it applies to consumer products placed into the California stream of commerce, regardless of where the product is produced. DTSC has considered alternatives that would lessen any adverse economic impact on business, and has tried to minimize the impact on businesses by providing a tiered approach to alternatives assessments, providing options to extend compliance deadlines, and allowing business to meet the requirements of the regulations through consortia, partnerships and similar arrangements. DTSC invites you to submit proposals that would lessen any adverse economic impact on business. Submissions may include the following considerations:

1. Establishment of differing compliance or reporting requirements or timetables that take into account the resources available to businesses.
2. Consolidation or simplification of compliance and reporting requirements for businesses.
3. The use of performance standards rather than prescriptive standards.
4. Exemption or partial exemption from the regulatory requirements for businesses.

ASSESSMENT STATEMENTS

Creation or elimination of jobs within California --- DTSC has made the preliminary determination that the proposed regulation can 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.

Creation of new businesses or elimination of existing businesses within California --- DTSC has made the preliminary determination that the proposed regulation can 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.

Expansion of businesses currently doing business in California --- DTSC has made the preliminary determination that the proposed regulation provides opportunities for growth as California businesses have access to wider range of safer consumer products and can provide services and products for an expanding number of consumers demanding safer and greener products.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

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 at least some consumers will realize cost savings from the use of safer products that do not present the potential 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.

BUSINESS REPORT

This regulation does not require all businesses to prepare reports. These regulations will require some in-state and out-of-state businesses to prepare and submit alternatives assessment reports for Priority Products. Additionally, some businesses will be required to provide chemical and/or product data and information to DTSC, upon request, which in some cases could be in the form of a report.

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

SMALL BUSINESS

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 included provisions to ameliorate the impacts for small businesses meeting specified requirements, including flexibility to allow such businesses longer time frames to meet the compliance requirements of the regulations.

CONSIDERATION OF ALTERNATIVES STATEMENT

DTSC must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of DTSC would be more effective in carrying out the purpose for which this action is proposed, or would be as effective as and less burdensome to affected private persons than the proposed action. DTSC invites interested persons to present arguments, with respect to the various options, at the scheduled hearing, or during the written comment period.

AVAILABILITY OF TEXT OF REGULATIONS AND STATEMENT OF REASONS

Copies of the Notice, Initial Statement of Reasons and the text of the proposed regulations are available from the Laws, Regulations and Policies page of the DTSC Internet site at <http://www.dtsc.ca.gov/LawsRegsPolicies/index.cfm> or may be obtained from Jeff Woled of DTSC's Regulations Section as specified below. The information upon which DTSC relied is also available at the address listed below.

POST-HEARING CHANGES

After the close of the comment period, DTSC may adopt the proposed regulations. If substantial changes are made, the modified 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 these specific regulations will be sent a copy of the modified text, if substantive changes are made.

FINAL STATEMENT OF REASONS

Once 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 Jeff Woled at the address listed below. A copy of the Final Statement of Reasons will also be available from the Laws, Regulations and Policies page of the DTSC Internet site at <http://www.dtsc.ca.gov/LawsRegsPolicies/index.cfm>, along with the date the rulemaking is filed with the Secretary of State and the effective date of the regulations.

CONTACT PERSONS

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

Statements, arguments or contentions regarding the rulemaking and/or supporting documents 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 these regulations. To be included in this regulation package's mailing list, and to receive updates of this rulemaking, please visit <http://www.calepa.ca.gov/Listservs/dtsc/> and

subscribe to the applicable Listserv. You may also leave a message on the DTSC mailing list phone line at (916) 324-9933 or e-mail: gcregs@dtsc.ca.gov.

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

Jeff Woled, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control

Mailing Address: P.O. Box 806
Sacramento, CA 95812-0806

E-mail Address: gcregs@dtsc.ca.gov

Fax Number: (916) 324-1808

Jeff Woled's phone number is (916) 322-5225. If Mr. Woled is unavailable, please call Jon Cordova at (916) 324-7193.

While not required, we encourage those wishing to submit comments on these proposed regulations to utilize our online comment form, which can be found at:

http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/gc_draft_regs_comment_form.cfm