Updated Informative Digest

UPDATED INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Authority and Reference

Authority

These regulations are being adopted under the following authorities:

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

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

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

Reference

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

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

Existing Laws and Regulations

State Law

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

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

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

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

Health and Safety Code section 25253 requires DTSC to adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. This section requires that these regulations establish a process that includes: (i) an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives; (ii) an evaluation of critical exposure pathways; and (iii) life cycle assessment tools that, at a minimum, take into consideration: product function or performance; useful life; materials and resource consumption; water conservation; water quality impacts; air emissions; production, in-use, and transportation energy inputs; energy efficiency; greenhouse gas emissions;

waste and end-of-life disposal; public health impacts, including potential impacts to sensitive subpopulations, including infants and children; environmental impacts; and economic impacts.

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

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

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

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

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

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

RELATION TO EXISTING STATE REGULATIONS

The Safer Consumer Products regulation is not inconsistent or incompatible with any existing State regulations. A search of Title 19 and 22 using the following keywords "consumer products", "chemicals in consumer products", and "chemicals in commerce" was conducted via Westlaw and yielded no conflicting State regulations. In addition, DTSC has worked closely with several sister agencies whose regulatory purview is closest to that of DTSC under these regulations. In particular, DTSC worked with OEHHA, the California Department of Public Health (CDPH), the California State Water Resources Control Board (SWRCB), and the California Air Resources Board (ARB), among other agencies, to ensure that the regulations do not interfere with or conflict with any regulatory program administered by any of these agencies.

Some of the chemicals identified as Candidate Chemicals under these regulations, as well as products that potentially may be listed as Priority Products in future rulemakings are also regulated to some degree by other State regulatory programs. However, consistent with Health and Safety Code section 25257.1(c), these regulations contain provisions that expressly work to ensure that there is no duplication or conflict with other State regulations. More specifically, the regulations require DTSC to take into consideration the nature and extent of existing State regulation of the same chemicals and/or products so as to avoid duplicative or conflicting regulation under this program.

Federal Law

The federal Toxic Substances Control Act of 1976 (TSCA) (Title 15, United States Code, commencing with Section 2601) authorizes the United States Environmental Protection Agency (U.S. EPA) 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 U.S. EPA to maintain the TSCA inventory, which currently contains more than 83,000 chemicals. As new chemicals are commercially manufactured or imported, they are placed on the TSCA inventory.

TSCA requires the submission of health and safety studies that are known or available to those who manufacture, process, or distribute in commerce specified chemicals, and allows U.S. EPA to gather information from manufacturers and processors about production/import volumes, chemical uses and methods of disposal, and the extent to which people and the environment are exposed. However, there were 62,000

chemicals in use in 1976 when TSCA was adopted into federal law. TSCA provides a "grandfather" clause for those 62,000 chemicals. Therefore, these 62,000 chemicals are not subject to the information-gathering requirements in TSCA.

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

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

RELATION TO EXISTING FEDERAL LAW

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

Some of the chemicals identified as Candidate Chemicals under these regulations, as well as products that potentially may be listed as Priority Products in future rulemakings are also regulated to some degree by federal regulatory programs. However, consistent with Health and Safety Code section 25257.1(c), these regulations contain provisions that expressly work to ensure that there is no duplication or conflict with federal regulations. More specifically, the regulations require DTSC to take into consideration the nature and extent of existing federal regulation of the same chemicals and/or products so as to avoid duplicative or conflicting regulation under this program.

NOTE: Since these regulations were first proposed in July 2012, there have been no impactful changes in applicable laws relating to these regulations. Furthermore, while DTSC has made post-hearing revisions to the July 2012 proposed regulations, these

revisions do not impact the affects of existing laws on these regulations or the effect of these regulations.

Policy Statement Overview

Background

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

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

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

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

called the "three gaps":

- *Data Gap*: There is a lack of information on which chemicals are safe and which are toxic, and what chemicals are in products. The lack of access to chemical data creates an unequal marketplace. California businesses cannot choose and make safer products and respond to consumer demand without ingredient disclosure and safety testing.

- *Safety Gap*: Government agencies do not have the legal tools or information to prioritize chemical hazards. Under TSCA, only 5 chemicals out of 83,000 have been banned since 1976. The California Legislature has frequently addressed this problem by approving individual chemical bans. Chemical bans come before the Legislature because there are very few other mechanisms in place at the federal or State level that can remove harmful chemicals from the marketplace.

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

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

1. Expand Pollution Prevention and product stewardship programs to more business sectors to focus on prevention rather than simple source reduction or waste controls.

2. Develop Green Chemistry Workforce Education and Training, Research and Development and Technology Transfer through new and existing educational program and public/private partnerships.

3. Create an Online Product Ingredient Network to disclose chemical ingredients for products sold in California, while protecting trade secrets.

4. Create an Online Toxics Clearinghouse, an online database providing data on chemical, toxicity and hazard traits to the market place and public.

5. Accelerate the Quest for Safer Products, creating a systematic, science-based process to evaluate chemicals of concern and identify safer alternatives to ensure product safety.

6. Move Toward a Cradle-to-Cradle Economy to leverage market forces to produce products that are "benign-by-design", in part, by establishing a California Green Products Registry to develop green metrics and tools for a range of consumer products and encourage their use by businesses.

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

Broad Objectives

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

Specific Objectives

The specific objectives of the regulations are to:

- Establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.

- Establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by chemicals of concern.

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

Benefits

The regulations themselves only describe the processes for identificating and prioritizing Priority Products-Chemicals of Concern, conducting Alternatives Assessments for Priority Products, and imposing regulatory responses (as required by Health and Safety

Code sections 25252 and 25253) – as such the immediate benefits of these regulations are minimal. The direct benefits of these regulations are the information that DTSC will collect to help implement the program, the description of the processes DTSC will use in implementing the Safer Consumer Products program, and the guidance DTSC is required to develop.

However, looking into the future, implementation of the processes established by these regulations – which will be triggered by the adoption of future regulations listing Priority Products – will create one of the first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals. As such, these regulations are viewed as a possible national model for chemical reform. These regulations, in effect, will set in motion a preemptive strategy that reduces the use of toxic substances in the design of products and industrial processes with the aim of creating safer and more sustainable products that do not threaten human health or persist in the environment. The use of fewer hazardous substances means healthier air quality, cleaner drinking water, and safer workplaces. Implementation of the processes set forth in these regulations will promote transparency by compelling chemical manufacturers to provide sufficient information for businesses, consumers, and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products. Further relevant details are discussed immediately below.

The Regulations

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

The regulations (summarized below) reflect post-hearing revisions to the regulations originally proposed in July 2012. These revisions were noticed for public review and comment in January 2013, April 2013, and August 2013. Following is a summary of key revisions:

- The list of chemicals is now called the “Candidate Chemicals” list. A “Candidate Chemical” that is the basis for a product-chemical combination being listed as a Priority Product is designated as a “Chemical of Concern” with respect to that product. NOTE: This change in terminology does not affect the application of the regulations to the chemicals on the chemicals list.

- Language has been added to make it clear that the Priority Products list will be established and updated through the Administrative Procedure Act rulemaking process.
- Persons who assemble consumer products using components that are Priority Products will not be classifed as “manufacturers”. Instead, assemblers will have compliance duties and options similiar to retailers.
- The requirement for Alternatives Analyses (AAs) to be performed by certified assessors has been eliminated, along with all of the ancillary provisions relating to certified assessors and accreditation bodies. To address the underlying purpose of these prior provisions – provide a quality assurance mechanism – the regulations now provide a public review and comment process for Final AA Reports and Abridged AA Reports. DTSC will review the comments and identify any issues that DTSC determines need to be addressed by the responsible entity in an AA Report Addendum.
- The Alternatives Analysis Threshold (AAT) is now defined as the Practical Quantitation Limit (PQL); and, typically, the exemption applies only if the Priority Product contains the Chemical of Concern solely as a contaminant chemical. If during the product prioritization process DTSC determines that an AAT is needed for a particular intentionally added chemical in a particular product – or an AAT above the PQL if needed for a contaminant – this can be addressed in the rulemaking for that Priority Product listing.
- The basis for, and application of, regulatory responses has in general been limited to the Chemicals of Concern for the product and any replacement Candidate Chemicals.
- The provision allowing DTSC to impose regulatory responses to situations other than those specifically spelled out in the regulations has been eliminated; and the circumstances under wich DTSC can impose revised regulatory responses have been restricted.
- The provision allowing DTSC to require that a new AA be performed based on receipt of new information has been eliminated.
- Only manufacturers will be required to comply with regulatory responses imposed by DTSC for: (i) engineered safety measures / administrative controls; (ii) end-of-life management requirements; and (iii) advancement of Green Chemistry and Green Engineering.
- A provision has been added to require that documents submitted to DTSC under the regulations be in English and be provided in an electronic format accessible to DTSC.
- DTSC will be required to review a trade secret claim for information submitted under the regulations before disclosing the information that is the subject of the trade secrecy claim.

- If DTSC determines that information submitted in support of a trade secrecy claim does not establish that the information claimed to be trade secret meets the definition of "trade secret", DTSC must notify the submitting party of its determination, and inform the submitting party that thirty (30) days from the date of the notice, the information will be regarded as a public record subject to disclosure. During the 30-day period the submitting party may seek judicial intervention to prevent disclosure of the information claimed as trade secret.

Summary of Regulations

A. Four-Step Process *[Section 69501(a)]*
The regulations provide for a four-step continuous, science-based, iterative process to identify safer consumer product alternatives:

- *DTSC* --- The regulations establish an immediate list of Candidate Chemicals (~1,200) based on the work already done by other authoritative organizations, and specify a process for DTSC to identify additional chemicals as Candidate Chemicals (CCs).*****
  [Article 2, see section II for further details.]

- *DTSC* --- The regulations require DTSC to evaluate and prioritize product/Candidate Chemical combinations to develop a list of "Priority Products" for which Alternatives Analyses must be conducted.* A Candidate Chemical that is the basis for a product being listed as a Priority Product is designated as a Chemical of Concern (COC) for that product and any alternative considered or selected to replace that product.
  [Article 3, see section II for further details.]

- *Product Manufacturers* --- The regulations require responsible entities (manufacturers, importers, assemblers, and retailers) to notify DTSC when their product is listed as a Priority Product. DTSC will post this information on its website. Manufacturers (or other responsible entities) of a product listed as a Priority Product must perform an Alternatives Analysis (AA) for the product and the COCs in the product to determine how best to limit exposures to, or the level of adverse public health and environmental impacts posed by, the COCs in the product. *[Article 5, see section III for further details.]*

- *DTSC* --- The regulations require DTSC to identify and require implementation of regulatory responses designed to protect public health and/or the environment, and maximize the use of acceptable and feasible alternatives of least concern. DTSC may require regulatory responses for a Priority Product (if the manufacturer

decides to retain the Priority Product), or for an alternative product selected to replace the Priority Product. *[Article 6, see section IV for further details.]*

* The regulations provide a process for any individual or organization (including federal and other California State agencies) to petition DTSC to add/remove a chemical to/from the Candidate Chemicals list or a product/chemical combination to/from the Priority Products list. Petitions may also be submitted to DTSC requesting that an entire existing list of chemicals be added to or removed from the list of Candidate Chemicals. *[Article 4]*

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

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

(1) Products exempted by law (Health and Safety Code section 25251): dangerous prescription drugs and devices; dental restorative materials; medical devices; packaging associated with dangerous prescription drugs and devices, dental restorative materials, and medical devices; food; and pesticides.

(2) A product that DTSC determines is regulated by other federal or California State regulatory programs, or treaties or international trade agreements, for the same adverse public health and/or environmental impacts, exposure pathways, and adverse waste and end-of-life effects that would otherwise be the basis for listing the product as a Priority Product. This exemption only applies if DTSC determines that these other program(s) provide a level of public health and environmental protection equivalent to or greater than the protection that would potentially be provided if the product were listed as a Priority Product.

C. Responsibility for Compliance

(1) The regulations *[Section 69501.1(a)(60)]* define "responsible entity" to include:
  (i) The manufacturer (i.e., the person who manufactures a product that is subject to the requirements of this chapter, or any person that controls the manufacturing process for, or specifies the use of chemicals to be included in, the product).
  (ii) The U.S. importer of a product that is subject to the regulations.
  (iii) Assemblers (i.e., persons who assemble a product containing a component that is a product subject to the regulations; this includes creating, repairing, refurbishing, maintaining, or making non-material alterations to a consumer product).

(iv) Retailers (i.e., persons to whom a product that is subject to the regulations is delivered or sold for purposes of sale or distribution by that person to a consumer).

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

(2) The regulations *[Section 69501.2(a)]* require a responsible entity for a product to ensure compliance with the requirements pertaining to:

(i) Notifying DTSC that its product is a Priority Product;
(ii) Performing an AA, and submitting AA Reports to DTSC, for its product; and
(iii) Complying with regulatory responses applicable to its product.

(3) Under specified conditions, a manufacturer may opt out of complying with the AA and regulatory response requirements by submitting a chemical removal, product removal, product-chemical replacement, or alternatives analysis threshold exemption notification to DTSC. *[Sections 69505.2, 69505.3, and 69506.1(b) – see section III.C. and D. for further details.]*

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

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

D. Consequences of Non-Compliance

(1) When DTSC determines a requirement has not been fulfilled for a product that is a Priority Product, DTSC will issue a notice of non-compliance to the manufacturer and importers. *[Section 69501.2(c)]*

(2) If the non-compliance is not remedied, the product and information concerning the product will be placed on a Failure to Comply List maintained on DTSC's website.

The regulations specify the conditions under which a product will be removed from the Failure to Comply List. *[Section 69501.2(c)]*

(3) DTSC may conduct audits to determine compliance with the requirements of the regulations pertaining to Alternatives Analyses, regulatory responses, and various notification and information submittals. *[Article 8, Section 69508]*

(4) In accordance with *article 8 of chapter 6.5 of division 20 of the Health and Safety Code*, DTSC may also initiate enforcement actions, including imposition of fines and penalties, against responsible entities for failure to comply with the regulations.

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

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

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

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

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

The regulations provide a process for a responsible entity to dispute an action taken by DTSC. A requirement imposed on the responsible entity by DTSC, and posting of information on the Failure to Comply List concerning the non-compliance with that requirement, will be stayed while a dispute is pending. (The dispute process does not apply to actions taken by DTSC with regard to the listing of Candidate Chemicals, petitions concerning the chemicals and products lists, and trade secret protection claims.)

H. Trade Secret Protection *[Article 9, commencing with Section 69509]*

The regulations set out provisions for the treatment of information submitted under the regulations for which a claim of trade secret protection is asserted by the submitter.

The regulations are based on the authorities for handling trade secrets found in Health and Safety Code section 25257 and the California Public Records Act.

Chemical and Product Prioritization

A. Candidate Chemicals (CC) Identification

(1) Initial List of Candidate Chemicals --- The regulations, as of their effective date, establish an immediate list of ~1,200 Candidate Chemicals (that exhibit one or more hazard traits and/or environmental or toxicological endpoints specified in Chapter 54, California Code Regulations, Title 22 (Chapter 54)). The sources used to identify the chemicals for inclusion on the initial Candidate Chemicals list are 23 existing authoritative body lists that: (i) list chemicals on the basis of exhibiting at least one of eight hazard traits (carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, respiratory sensitivity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity); or (ii) list chemicals on exposure indicator lists for water quality, air quality, or biomonitoring. *[Section 69502.2(a)]*
NOTE: ~500 chemicals currently used only in pesticides or drugs (and, thus, excluded from these regulations under Health and Safety Code section 25251) could be added to this list in the future if they are used in products that are not excluded under Health and Safety Code section 25251.

(2) Additions to the Initial Candidate Chemicals List --- DTSC may identify additional chemicals (that exhibit a Chapter 54 hazard trait or environmental or toxicological endpoint) as CCs based on consideration of the following factors for which reliable information is available *[Section 69502.2(b)]*:

- *Chemical adverse public health and/or environmental impacts*
- *Adverse impacts of special consideration*
  - (i) Sensitive subpopulations
  - (ii) Environmentally sensitive habitats
  - (iii) Endangered and threatened species
  - (iv) Environments in California designated as impaired
- *Adverse impacts associated with the potential for the chemical to contribute to or cause widespread adverse public health and/or environmental impacts*
- *Structurally or mechanistically similar chemicals with a known toxicity profile*
- *Exposures to the chemical*

- *Extent and quality of information available to substantiate the existence or absence of potential adverse public health and environmental impacts and exposures*

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

(3) Chemicals Listing Process --- An informational list of those chemicals identified as Candidate Chemicals as of the effective date of the regulations will be posted on DTSC's website within 30 days after the regulations become effective. Any subsequent additions/deletions of chemicals to/from the Candidate Chemicals list made based on the Section 69502.2(b) critieria summarized above will be made through the Administrative Procedure Act rulemaking process.

B. Candidate Chemicals and Product Prioritization

(1) Key Prioritization Factors *[Section 69503.2(a)]*: Any product-chemical combination identified and listed as a Priority Product must meet both of the following criteria:

- There must be potential exposure to the Candidate Chemical(s) in the product; and
- There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse public health and/or environmental impacts.

(2) Product Prioritization Criteria *[Section 69503.2(b) and 69503.3]*: DTSC may list as Priority Products those products that are determined to be of high priority. DTSC's decision to list a product-CC combination as a Priority Product will be based on an evaluation of the potential adverse impacts, exposures, and waste and end-of-life effects associated with the product based on consideration of the factors listed below.

(a) Adverse Impacts and Exposures: DTSC will begin the product-CC evaluation process by evaluating the potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures during the life cycle of the product. The listing of a product-chemical combination as a Priority Product will be based on one or more potential adverse public health and/or environmental impact factors and one or more exposure potential factors in addition to other factors indicated below.

- *Adverse Impacts from the CCs* --- The potential for the CC(s) in the product to contribute to or cause adverse public health and/or environmental impacts, considering one or more specified factors, including:

  - The Candidate Chemical's Chapter 54 hazard traits, environmental and/or toxicological endpoints, aggregate effects, cumulative effects, physicochemical properties, and environmental fate

  - The human populations, and/or aquatic, avian, or terrestrial animal or plant organisms for which the Candidate Chemical(s) has/have the potential to contribute to or cause adverse impacts

  - The potential for the Candidate Chemical(s) to degrade, form reaction products, or metabolize into another Candidate Chemical or a chemical that exhibits one or more Chapter 54 hazard traits and/or environmental or toxicological endpoints

  - Adverse impact(s) for:
    (i) Sensitive subpopulations
    (ii) Environmentally sensitive habitats
    (iii) Endangered and threatened species
    (iv) Environments in California designated as impaired

  - The adverse impacts associated with structurally or mechanistically similar chemicals for which there is a known toxicity profile

- *Exposures* --- Potential public health and/or environmental exposures to the CC(s) in the product, considering one or more of the following for which information is reasonably available:

  (i) Market presence for the product
  (ii) Occurrence or potential occurrence of exposures to the CC(s) in the product
  (iii) Household and workplace presence of the product, and other products containing the same CC(s)
  (iv) Potential exposures to the CC(s) in the product during the product's life cycle

(b) Adverse Waste and End-of-Life Effects. DTSC may also consider product uses, or discharges or disposals, that have the potential to contribute to or cause adverse waste and end-of-life effects associated with the Candidate Chemical(s) in the product.

(c) Availability of Information: DTSC will consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse public health and environmental impacts, exposures, and adverse waste and end-of-life effects. The regulations list factors that DTSC will consider in evaluating the quality of available information.

(d) Other Regulatory Programs: DTSC will consider the scope of other California State and federal laws, and treaties and international agreements, under which the product or the Candidate Chemical(s) in the product is/are regulated and the extent to which these other regulatory requirements address, and provide adequate protections with respect to the same potential adverse public health and environmental impacts, exposure pathways, and adverse waste and end-of-life effects, that are under consideration as a basis for the product-chemical combination being listed as a Priority Product. If a product is regulated by another entity with respect to the same adverse impacts and exposure pathways, DTSC may only list the product as a Priority Product if DTSC determines that the listing would meaningfully enhance protection of public health and/or the environment.

(e) Safer Alternatives: When deciding whether to list a product-chemical combination as a Priority Product, DTSC may also consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible.

C. Products Listing Process *[Sections 69503.4, 69503.5, and 69503.7]*

(1) Rulemaking Process --- The Priority Products list will be established and updated through the Administrative Procedure Act's rulemaking process.

(2) Priority Product Work Plan --- Within one year after the effective date of the regulations, DTSC will issue a Priority Product Work Plan that identifies the product categories that will be evaluated to identify products to be added to the Priority Products list during the next three years. Subsequent work plans will be issued no later than one year before the three-year expiration date of the current work plan. The regulations specify conditions under which DTSC may revise the work plan subsequent to its issuance.

(3) Priority Product List Revisions --- DTSC will review, and revise as appropriate, the Priority Products list at least once every 3 years.

(4) Components --- If the Priority Product is a component of one or more assembled products, the Priority Product listing will include a description of the known assembled product(s) in which the component is used.

(5) Complex Durable Products --- For a complex durable product, DTSC will not list as Priority Products, in a 3-year period, more than 10 components contained in that product.

(6) Due Dates --- The Priority Products list will include the due dates for the Priority Product Notification (default is 60 days) and the Preliminary AA Report (default is 180 days).

(7) Priority Product Notifications --- A responsible entity for a product listed on the Priority Products list must provide to DTSC a Priority Product Notification within 60 days after the product is listed as a Priority Product (unless DTSC specifies a later notification date in the Priority Products list).

D. Initial Priority Products List *[Sections 69503.6]*

(1) Prior to January 1, 2016, DTSC will list a product as a Priority Product only if the product is being listed on the basis of one or more Candidate Chemicals in the product that have both listed hazard trait and listed exposure concerns.

(2) The initial list of Priority Products will include no more than five products.

(3) The initial proposed list of Priority Products will be made available for public review and comment no later than 180 days after the effective date of the regulations.

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

Subject to specified limitations, a person may petition DTSC to add to or remove from the Candidate Chemicals list one or more chemicals, or to add to or remove from the Candidate Chemicals list the entirety of an existing chemicals list. A person may also petition DTSC to add to or remove from the Priority Products list a product-chemical combination. High priority will be given to petitions by federal and other California State agencies that relate to the petitioning agency's statutory and/or regulatory authorities. After granting a petition, DTSC will evaluate and, if applicable, prioritize the chemical and/or the product in accordance with the prioritization processes described above.

Alternatives Analyses (AAs)

A. Guidance Materials

The regulations require DTSC to prepare, and make available on its website, guidance materials to assist persons in performing AAs, and to post on its website AAs that are available in the public domain at no cost. *[Section 69505]*

B. Alternatives Analysis --- General Provisions

(1) A responsible entity for a Priority Product must conduct an AA for the Priority Product and submit a Preliminary AA Report and a Final AA Report to DTSC within specified timeframes. *[Section 69505.1(b)]*

- The Preliminary AA Report must be submitted no later than 180 days after the date the product is listed on the final Priority Products listing, unless DTSC specifies a different due date for the product in the Priority Products list.

- The Final AA Report must be submitted no later than 12 months after the date DTSC issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests, and DTSC approves, a longer period of time not to exceed 24 months (or up to 36 months if regulatory safety and/or performance testing is required for the alternatives being considered), or if DTSC specifies a longer time frame.
  [Sections 69505.7(k)(1)(B) & 69505.9(b)(4)]

(2) The regulations allow for a responsible entity to request a one-time extension, not to exceed 90 days, for submitting the Preliminary and/or Final AA Report, if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. *[Section 69505.1(c)]*

C. Chemical/Product Removal/Replacement Notifications *[Section 69505.2]*

(1) An AA is not required for a Priority Product if the manufacturer submits one of the following notifications by the due date for the Preliminary AA Report (or by the due date for the Final AA Report if a Preliminary AA Report has already been submitted):

- A Chemical Removal Intent and/or Confirmation Notification, certifying that the COC(s) will be / have been removed from the product without the use of any replacement chemical(s);

- A Product Removal Intent and/or Confirmation Notification, certifying that the manufacturer will or has ceased fulfilling orders for the product from persons selling or distributing the Priority Product in California.

- A Product-Chemical Replacement Intent and/or Confirmation Notification, certifying that the COC(s) will be or have been removed from the product and any replacement chemical meets one of the following criteria:
  - The replacement chemical is not on the list of Candidate Chemicals; or
  - The replacement chemical is a Candidate Chemical that is already in use, in lieu of the Chemical(s) of Concern, to manufacture the same product by the same or a different manufacturer.

(2) An Intent Notification must be followed by submission of a Confirmation Notification within 90 days or by the due date for the Preliminary AA Report (or Final AA Report), whichever is later.

D. Alternatives Analysis Threshold Exemption *[Section 69505.3]*

(1) A product that is listed as a Priority Product and that meets the criteria for an alternatives analysis threshold exemption will be exempt from the requirement to perform an alternatives analysis if the manufacturer of the product submits an Alternatives Analysis Threshold Exemption Notification to DTSC.

(2) A manufacturer may submit an Alternatives Analysis Threshold Exemption Notification for its Priority Product if the COC(s) are present in the product solely as contaminants, and the concentration of the COC(s) does not exceed the Practical Quantitation Limit (PQL) for the chemical(s). Additionally, DTSC may specify in a proposed/final Priority Products list an Alternatives Analysis Threshold concentration for any COC that is an intentionally added ingredient. DTSC could also specify in a proposed/final Priority Products list an Alternatives Analysis Threshold concentration greater than the PQL for any COC that is a contaminant.

(3) The regulations specify the information that must be included in an Alternatives Analysis Threshold Exemption Notification, including the source of the COC(s). The notification must identify the PQL(s) for contaminant COC(s) and the methods used to determine the PQL(s). The manufacturer is required to notify DTSC if the information in the Alternatives Analysis Threshold Exemption Notification significantly changes, or the product no longer meets the criteria for an alternatives analysis threshold exemption.

E. Alternatives Analysis Process and Options

(1) Two-Stage AA: The regulations require that each AA be conducted and reported in two stages. The Preliminary AA Report is submitted to DTSC after completion of the first AA stage, and the Final AA Report is submitted after completion of the second AA stage. *[Section 69505.4(a)]*

(2) Abridged AA Report: A responsible entity that determines (after completion of steps 1 through 5 of the first AA stage as described below) that a functionally acceptable and technically feasible alternative is not available may prepare and submit an Abridged AA Report, in lieu of Preliminary and Final AA Reports, if the responsible entity meets specified requirements. *[Section 69505.4(b)]*

(3) Alternate Process AA: A responsible entity may use an AA process that differs from the process described in the regulations if certain requirements are met, including
[Section 69505.4(c)]:

- The alternate process will provide the information needed to prepare an AA Report that substantially meets the AA Report requirements specified in the regulations.
- The alternate process will compare the Priority Product and the alternatives using at a minimum the same factors, and associated exposure pathways and life cycle segments, that would be used if the process in the regulations was followed.
- The responsible entity submits an Alternate Process AA Work Plan to DTSC no later than the due date for the Priority Product Notification.

(4) Previously Completed AAs: The regulations allow a responsible entity to fulfill the AA requirements by submitting a report for a previously completed AA for the Priority Product – if DTSC determines that the report is substantially equivalent to the AA Report requirements specified in the regulations, and that the report contains sufficient information to identify regulatory response(s). *[Section 69505.4(d)]*

(5) Revised Alternative Selection Decision: After the Final AA Report is submitted, if the alternative selection decision specified in the Final AA Report changes the responsible entity is required to submit a revised Final AA Report with an explanation of the change. A revised Final AA Report is also required if the original alternative selection decision was to retain the Priority Product and the responsible entity later decides to replace the Priority Product with an alternative product, or visa versa. This requirement only applies for 3 years after DTSC approves the original Final AA Report. *[Section 69505.4(e)]*

(6) Reformulations: If prior to submitting the Final AA Report for a Priority Product the responsible entity removes, or reduces the concentration of, the COC(s) and uses one or more replacement Candidate Chemical(s), the AA evaluation and comparison must address both the original Priority Product and the reformulated product. *[Section 69505.4(f)]*

F. First Stage of the AA

(1) Step 1, Identification of Product Requirements and Function(s) of COCs *[Section 69505.5(a)]*:

- The function, performance, and legal requirements associated with the Priority Product that must be met by alternatives being considered.
- The function(s) of the COC(s) in meeting the Priority Product's function, performance, and legal requirements.
- A determination as to whether the COC(s) or alternative replacement chemical(s) is/are necessary to meet the Priority Product's function, performance, and legal requirements.
- If it is determined that neither the COC(s) or alternative replacement chemical(s) is/are necessary to meet the Priority Product's requirements, the removal of the COC(s) from the Priority Product without the addition of alternative replacement chemical(s) must be evaluated in the AA as one of the alternatives to the Priority Product.

(2) Step 2, Identification of Alternatives *[Section 69505.5(b)]*:
Identification of alternatives for consideration that meet the requirements for the Priority Product, and eliminate or reduce the concentration of the COC(s) in the Priority Product and/or reduce or restrict public health and/or environmental exposures to the COC(s) in the Priority Product. The responsible entity is required to include in the AA consideration of any identified existing viable alternatives.

(3) Step 3, Identification of Factors Relevant for Comparison of Alternatives *[Section 69505.5(c)]*:

- A factor, in conjunction with an associated exposure pathway and life cycle segment, is relevant if:
  (i) It makes a material contribution to the adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, and/or materials and resource consumption impacts associated with the Priority Product and/or one or more alternatives under consideration; and

(ii) There is a material difference in the factor's contribution to such impacts between the Priority Product and one or more of the alternatives being considered, and/or between two or more alternatives.

- The responsible entity must use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors listed below, and the associated exposure pathways and life cycle segments, that are relevant for the comparison of the Priority Product and the alternatives under consideration.
  - ✓ Adverse environmental impacts
  - ✓ Adverse public health impacts
  - ✓ Adverse waste and end-of-life impacts
  - ✓ Environmental fate
  - ✓ Materials and resource consumption impacts
  - ✓ Physical chemical hazards
  - ✓ Physicochemical properties

- The identification of relevant exposure pathways must consider:
  (i) Chemical quantity information; and
  (ii) Exposure factors

(4) Step 4, Initial Evaluation and Screening of Alternative Replacement Chemicals *[Section 69505.5(d)]*:

- The responsible entity is required to use available information and analytical tools to evaluate and compare each of the alternative replacement chemicals under consideration with the COC(s) in the Priority Product with respect to relevant factors related to adverse public health and environmental impacts, environmental fate, physical chemical hazards, and physicochemical properties.

- The responsible entity may eliminate from further consideration in the AA any alternative replacement chemical that it determines has the potential to pose equal or greater adverse public health and/or environmental impacts as compared to the COC(s).

(5) Step 5, Consideration of Additional Information *[Section 69505.5(e)]*:
As part of the first stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above, including the factors and information for the second AA stage (described below). A responsible entity may eliminate an alternative from further consideration based on the additional factors and information as long as the reason for its

elimination is explained in the Preliminary AA Report and there are alternatives remaining to be evaluated in the second AA stage.

(6) Step 6, Preliminary AA Report Preparation *[Section 69505.5(f)]*:
The responsible entity is required to prepare, and include in the Preliminary AA Report, a work plan and proposed implementation schedule for completion of the second AA stage (as described in G. below) and preparation and submittal of the Final AA Report.

G. Second Stage of the AA

(1) Step 1, Identification of Factors Relevant for Comparison of Alternatives *[Section 69505.6(a)]*:
The responsible entity may use available information and analytical tools to re-evaluate the identification of adverse impact and multimedia life cycle impact factors (and the associated exposure pathways and life cycle segments) determined to be relevant during the first AA stage for the comparison of the Priority Product and the alternatives still under consideration after completion of the first AA stage. In addition, product function / performance / legal requirements and economic impacts are relevant factors for all comparisons of the Priority Product and the alternatives.

(2) Step 2, Comparison of the Priority Product and Alternatives *[Section 69505.6(b)]*:
The responsible entity must use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to evaluate and compare the Priority Product and each alternative with respect to each relevant factor and associated exposure pathways and life cycle segments.

(3) Step 3, Consideration of Additional Information *[Section 69505.6(c)]*:
As part of the second stage of the AA the responsible entity may also consider other relevant information not specifically identified above, including reconsideration of factors evaluated in the first AA stage.

(4) Step 4, Alternative Selection Decision *[Section 69505.6(d)]*:
The responsible entity selects the alternative(s) that will replace the Priority Product, or decides to retain the Priority Product.

(5) Step 5, Identification of Next Steps *[Section 69505.6(e)]*:
The responsible entity is required to prepare a Final AA Report.

H. Alternatives Analysis Reports

(1) Preliminary and Final AA Reports and Abridged AA Reports must include the information listed below, as applicable. All differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report must be identified and explained in the final report. *[Section 69505.7(a)]*

- An **executive summary** *[Section 69505.7(b)]*. The executive summary cannot include any information for which trade secret protection is claimed --- this will enable the executive summary to be posted on DTSC's website in its entirety.
- Information regarding the **preparer** of the AA Report *[Section 69505.7(c)]*
- Information regarding the **responsible entity** and the **supply chain** for the Priority Product. *[Section 69505.7(d)]*
- Information describing the **Priority Product** and the **COCs** *[Section 69505.7(e)]*
- Identification of **comparison factors**. The AA Reports must identify which factors, and associated exposure pathways and life cycle segments, were determined to be relevant for evaluation and comparison of the Priority Product and its alternatives. The AA Report must explain the rationale for each factor, exposure pathway, and life cycle segment determined not to be relevant. *[Section 69505.7(f)]*
- A description of the **alternatives** chosen to be evaluated and compared, and an explanation of the rationale for selecting and screening out specific alternatives at each stage of the alternatives comparison process. *[Section 69505.7(g)]*
- Detailed information on the **evaluation and comparison of the Priority Product and its alternatives** for all of the relevant comparison factors and associated exposure pathways and life cycle segments. *[Section 69505.7(g)]*
- A description of the **methodology** used to conduct the *AA*. *[Section 69505.7(h)]*
- Identification of all information used as **supporting information** in performance of the AA and preparation of the AA Reports. The information itself must be made available to DTSC upon request. The Final AA Report must also identify any **information gaps**. *[Section 69505.7(i)]*
- The Preliminary AA Report must identify and describe the alternatives selected for further evaluation in the second stage of the AA, and explain the rationale for the selection decision. The Final AA Report must include an identification and description of the **alternative(s) selected** to replace the Priority Product (or a decision to retain the Priority Product); the **implementation plan** for the selected alternative(s), if any; and any **proposed regulatory responses**. *[Section 69505.7 (j) and (k)]*

(2) The information in the Final AA Report concerning the alternative selection decision must include *[Section 69505.7(j)]*:

- A description of the alternative(s), if any, selected and the rationale for the selection decision. This includes an analysis that evaluates and compares the selected alternative(s) against the Priority Product, and an explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable.

- A discussion of the acceptability of the selected alternative, as compared to the Priority Product, with respect to functional, performance, and legal requirements. If no alternative is selected, this information must be provided for each alternative considered.

- The rationale for selecting an alternative that retains one or more COC(s) or uses replacement chemicals, if it is determined during the AA that neither the COC(s) nor replacement chemicals are necessary to satisfy the requirements for the Priority Product (i.e., functional, performance, and legal requirements).

- A list of, and information for, all chemicals known based on available information to be in the selected alternative(s) that are COCs, that differ from the chemicals in the Priority Product, or that are present in the selected alternative(s) at a higher concentration than in the Priority Product (relative to other chemicals in the Priority Product other than the COC(s)). The required information includes: available environmental fate information for the chemicals; available hazard trait and environmental and toxicological endpoint information for those chemicals; and available chemical identification and description information for those chemicals.

I. DTSC Review and Determinations for AA Reports *[Sections 69505.8 & 69505.9]*

(1) A public comment period (of at least 45 days) will be provided for each Final AA Report and Abridged AA Report. Within 30 days after the close of the public comment period, DTSC will review the comments and notify the responsible entity of any issues that DTSC determines need to be addressed in an AA Report Addendum. The notice will specify the due date for the AA Report Addendum.

(2) Within 60 days after receiving an AA Report or Alternate Process AA Work Plan (or 60 days after receiving the AA Report Addendum, if applicable), DTSC will review the AA Report for compliance with the regulations, and issue a notice of compliance, a notice of deficiency, a notice of disapproval, or a notice of ongoing

review. Notices of deficiency will give the responsible entity 60 days to remedy the deficiency (or 30 days if it is a second notice of deficiency). If the submitter of the AA Report fails to adequately and timely respond to 2 notices of deficiency for the Final AA Report (or 1 notice of deficiency for the Preliminary AA Report), DTSC will issue a notice of disapproval and the product will be placed on the Failure to Comply List (following notice to the submitter of the report). A notice of disapproval will also be issued if a revised report or work plan is not submitted by the due date.

(3) Notices of compliance for Preliminary AA Reports and Alternate Process AA Work Plans will specify the due date for submitting the Final AA Report, which will range from 12 to 24 months (or up to 36 months if regulatory safety and/or performance testing is required for alternatives being considered) after DTSC issues the notice of compliance. DTSC may specify an extended due date for submission of the Final AA Report if it determines based on information in the Preliminary AA Report or Alternate Process AA Work Plan that more time is needed.

Regulatory Responses

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

(1) DTSC will require implementation of regulatory responses designed to protect public health and the environment, and maximize the use of alternatives of least concern, when such alternatives are functionally acceptable and technically and economically feasible.

(2) DTSC will give preference to regulatory responses providing the greatest level of inherent protection. More specifically, preference will be given to alternatives that avoid or reduce adverse public health and/or environmental impacts, exposures, and/or waste and end-of-life effects through product or process redesign as opposed to alternatives that use administrative or engineering controls to limit exposures to, or releases of, a COC or a replacement Candidate Chemical in a product.

(3) In selecting regulatory responses, DTSC may consider the following factors:
- The degree to which, and speed with which, the regulatory response can address the adverse public health and/or environmental impacts and/or adverse waste and end-of-life effects of the COC(s) or replacement Candidate Chemical(s);
- The ability of end-users to understand and act upon any regulatory response involving provision of information with respect to the Priority Product;

- Any adverse ecological impacts of the regulatory response on sensitive resources, or unique or additional burdens that the regulatory response would impose upon sensitive subpopulations;
- Existing federal and/or California State regulatory requirements applicable to the COC(s) or replacement Candidate Chemical(s);
- The cost to the responsible entity of the regulatory response(s) relative to the cost of other possible responses;
- The practical capacity of responsible entities to comply with the regulatory response(s);
- The management and clean-up costs imposed on public agencies by the ongoing sale of the Priority Product or a selected alternative;
- DTSC's administrative burden in overseeing implementation of the regulatory response(s); and
- The ease of enforcing the regulatory response(s).

B. Applicability

(1) The regulations specify regulatory responses that will, under specified conditions, apply to *[Section 69506.1(a)]*:
- Products manufactured as a selected alternative following completion of an AA;
- Priority Products for which an alternative is not selected;
- Priority Products that will remain in commerce pending development and distribution of the selected alternative; and
- Products for which the AA Report is disapproved by DTSC.

(2) A regulatory response is not required for a Priority Product if the manufacturer submits a compliant Removal or Replacement Confirmation Notification (see section III.C. above) to DTSC prior to the due date for implementing any regulatory response that would otherwise apply to the product.

C. Regulatory Response Process *[Sections 69506.1 and 69506.10]*

(1) Within 90 days after issuing a notice of compliance or a notice of disapproval for a Final AA Report or an Abridged AA Report, DTSC will issue a notice of its proposed determination that one or more of the regulatory responses described below are required, or that no regulatory response is required.

(2) The proposed regulatory response determination will be sent to all known affected responsible entities and made available for public review and comment for a minimum 45-day period.

(3) After consideration of public comments, DTSC will send a final regulatory response determination notice to known responsible entities and post the final notice on its website. The notice will include the due date for implementing the regulatory response(s). In assigning an implementation due date, DTSC will consider the complexity of implementing the regulatory response(s).

(4) Each proposed and final regulatory response determination notice will include DTSC's determination as to whether or not the regulatory response applies to either or both of the following:

- Priority Products ordered by a retailer prior to the effective date of the Priority Product listing, and still for sale by the retailer as of the date of the final regulatory response determination notice; and/or
- Priority Products manufactured after the effective date of the Priority Product listing, but before the date of the final regulatory response determination notice.

(5) Once a final regulatory response determination notice has been issued, DTSC will not augment or revise the regulatory responses for the affected product, except as discussed in section D. (1) below or in the event of a relevant dispute.

(6) The responsible entity must notify DTSC of the applicability of regulatory responses to the responsible entity's product within 30 days. The responsible entity must send the same notice within 30 days to all persons in California (other than the final purchaser or lessee) to whom the responsible entity directly sells the product. The responsible entity must also send the notice to any other person (other than the final purchaser or lessee) to whom the responsible entity directly sells the product if it is reasonably foreseeable that the product will be placed into the California marketplace.

(7) The responsible entity must notify DTSC upon completion of the implementation of the required regulatory response(s), and (if applicable) upon completion of the implementation of the selected alternative(s). If requested by DTSC, the responsible entity must provide periodic implementation status reports regarding the selected regulatory response(s) and/or the development and introduction into the California marketplace of the selected alternative(s).

(8) DTSC will post on its website a Regulatory Response Summary that identifies the regulatory response(s) for each selected alternative for a Priority Product (and each Priority Product, as applicable), and the implementation dates for the alternative product(s), if any, and the regulatory response(s).

D. Regulatory Responses

(1) *Supplemental AA Report Information and Regulatory Response Revisions [Section 69506.2]*:

- Prior to imposing any regulatory response for a product, DTSC may require the responsible entity to provide to DTSC any information supplementary to the AA Report that DTSC determines is necessary to select and ensure implementation of one or more regulatory responses.

- When imposing one or more regulatory responses for a product, DTSC may include a requirement that the responsible entity provide information to DTSC to fill one or more information gaps identified in the AA Report, if DTSC determines this information is necessary to re-evaluate the initial regulatory responses. Following receipt of the requested information DTSC may, based on this new information, revise the initial regulatory response(s) imposed for the product. Any revisions to the initial regulatory responses will be noticed for public review and comment no later than 90 days after receiving the requested information.

- In addition to the circumstances described above, DTSC may revise the initial regulatory response(s) imposed for a product in response to a revised AA Report submitted by a responsible entity when there is a revision to the alternative selection decision.

(2) *Product Information for Consumers*: Product information must be provided to consumers if the alternative product contains a COC or any replacement Candidate Chemicals, or if the manufacturer chooses to retain the Priority Product (indefinitely or for more than 12 months pending development and distribution of the alternative product). The regulations specify the types of information that must be provided to consumers, and the mechanisms that must be used to provide the information. [Section 69506.3]

(3) *Use Restrictions*: DTSC may impose restrictions on the use of COCs or replacement Candidate Chemicals in a product, or specified restrictions on the product, to reduce the amount of a COC or replacement Candidate Chemical in the product, or reduce the potential for the product to contribute to or cause an exposure to the COC or replacement Candidate Chemicals in the product. *[Section 69506.4]*

(4) *Product Sales Prohibition*: If the selected alternative contains a COC or replacement Candidate Chemical (or if an alternative is not selected), and DTSC determines there is a safer alternative that does not contain a COC or

replacement Candidate Chemical and that is functionally acceptable and technologically and economically feasible, the responsible entity must do one of the following *[Section 69506.5]*:

- Cease placing the product into the California marketplace, directly or indirectly; or
- Submit to DTSC an AA Report that selects an alternative that does not contain a COC or replacement Candidate Chemical.

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

(5) *Engineering or Administrative Controls*: Under specified conditions, DTSC may require a manufacturer to engineer safety measures that integrally contain or control access to, and/or implement administrative controls that limit exposure to, the COC(s) or replacement Candidate Chemical(s) in a selected alternative, or the COC(s) in a Priority Product for which an alternative is not selected, to reduce the potential for adverse public health and/or environmental impacts. *[Section 69506.6]*

(6) *End-of-Life Product Management Program [Section 69506.7]*:

- A manufacturer must establish, maintain, and fund an end-of-life product stewardship program, and provide product information to consumers, if the alternative product (or a Priority Product that the manufacturer chooses to retain) is required to be managed as a hazardous waste in California at end-of-life. The requirements for the product stewardship plan and program are specified in the regulations.
- A manufacturer may individually fulfill these requirements, or may join with other manufacturers to form a non-profit third-party product stewardship organization, funded by participating manufacturers, to fulfill the requirements.
- A manufacturer may request DTSC's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program specified in the regulations.

- A manufacturer may request an exemption from the requirement to provide an end-of-life management program by demonstrating to DTSC's satisfaction that an end-of-life management program cannot feasibly be implemented for the product.

(7) *Advancement of Green Chemistry and Green Engineering*: When a manufacturer concludes that no safer alternative to its Priority Product is functionally acceptable and technically and economically feasible, or a manufacturer selects an alternative that reduces but does not eliminate the use of Candidate Chemicals in the product, DTSC may require the manufacturer to initiate a research and development project or fund a challenge grant pertinent to the Priority Product that uses green chemistry and/or green engineering principles to: (i) design a safer alternative; (ii) improve the performance of a safer alternative; (iii) decrease the cost of a safer alternative; and/or (iv) increase the market penetration of a safer alternative. [*Section 69506.8]*

E. Regulatory Response Exemptions *[Section 69506.9]*

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

(1) The required regulatory response would conflict with a requirement of another California State or federal regulatory program, or a treaty or international trade agreement, in such a way that the responsible entity could not reasonably be expected to comply with both requirements. In this situation, DTSC may require implementation of a modified regulatory response that resolves the conflict.

(2) The required regulatory response substantially duplicates a requirement of another California State or federal regulatory program, or a treaty or international trade agreement, without conferring additional public health or environmental protection benefits.

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 to be exempt under the California Environmental Quality Act (Public Resources Code section 21000, et seq.). Specifically, this rulemaking falls under the Class 8 categorical exemption available under section 15308, California Code of Regulations, Title 14. A Notice of Exemption will be filed with the State Clearinghouse when the regulations are adopted.

Peer Review

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

California Environmental Policy Council Review

As required by Health and Safety Code section 25252.5, DTSC submitted the proposed regulations to the California Environmental Policy Council (CEPC) for review. At the conclusion of a public hearing held on February 28, 2013 concerning the proposed regulations, the CEPC unanimously adopted by resolution a determination that, "the 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". (In the absence of such a determination by the CEPC, DTSC would have been required to prepare a multimedia life cycle evaluation for the regulations.) NOTE: The CEPC's determination was based on the revised proposed regulations issued for public comment on January 29, 2013. However, none of the subsequent revisions to the regulations affect the fundamental bases for the CEPC's determination.

COST IMPACTS BACKGROUND INFORMATION

The SCP regulations establish a process for identifying and prioritizing chemicals and product-chemical combinations and a process by which chemicals of concern in products and their potential alternatives are evaluated to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. The SCP regulations do not require the private sector to take any actions specific to any chemicals or products and these process regulations do not have any physical impacts to public health or the environment.

Using the process and prioritization factors set forth in these SCP regulations, DTSC will adopt a list of Priority Products for which manufacturers or other responsible entities

must perform an alternatives analysis or take an alternate course of action. Whenever it lists Priority Products, DTSC will go through the rulemaking process pursuant to the Administrative Procedure Act (APA) (commencing with Government Code section 11340), including completion of an Economic and Fiscal Impact Statement (Std. Form 399) for those product-chemical combinations proposed to be listed as Priority Products. At the time that DTSC proposes specific Priority Products it will have sufficient information to provide much more specific cost impact information (e.g., private sector impacts and benefits of the regulations) than is possible for these SCP process regulations.

Under the SCP regulations, the only impacts to the private sector are that DTSC may request businesses to provide existing information or generate new information necessary to implement the regulations. DTSC is required to maintain and post on its website a "Response Status List" that identifies businesses that have been requested to provide information to DTSC and whether those businesses have provided the information, failed to make the information available, or have demonstrated to DTSC's satisfaction that the information is unavailable or cannot be produced.

Additional information is provided below concerning the cost impacts of these process regulations, as well as the factors that will affect private and public sector impacts when Priority Products are listed in subsequent rulemakings as discussed above.

IMPACTS ON LOCAL AGENCIES OR SCHOOL DISTRICTS

As discussed above, these are process regulations; and DTSC thus has made a determination that adoption of these regulations will have no impact on local agencies or school districts.

Mandates on Local Agencies and School Districts: DTSC has made a 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 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.

Impacts that can/will be more specifically identified and evaluated as part of future APA rulemaking processes for the proposed listing of product-chemical combinations as Priority Products

The future priority product regulations address chemicals in products. Any fiscal impact from these future regulations to local agencies would likely be in the operating expense and possibly the equipment and capital outlay line items. (That is, there would be no direct costs imposed on local governments because the regulations only apply to manufacturers, importers, assemblers, and retailers of consumer products.) However, generally, DTSC does not expect the future priority product regulations to result in cost increases given the wide variety of products readily available at competitive prices. (A more detailed explanation is provided below under "Cost or Savings to Any State Agency".)

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

Local governments could also be impacted if manufacturers are required to implement end-of-life management strategies for priority products. For certain products, the SCP regulations allow DTSC to require for products listed in future priority product regulations that the manufacturers of those products identify the roles and responsibilities of various parties, including government, throughout the life cycle of the product. Further, the regulations require that the manufacturer of a listed priority product provide a financial guarantee mechanism for a sustainable end-of-life management program for the product. The SCP regulations allow multiple manufacturers to form a third-party product stewardship organization, funded by participating manufacturers, to provide local services to collect, recycle, or otherwise appropriately manage the product types that they manufacturer in common.

The goal is to transfer the costs of end-of-life product management programs to the manufacturers, with the understanding that manufacturers will likely pass these costs on to consumers. Local governments implementing such programs in the future would not be required to incur any additional costs for which they are not reimbursed.

FISCAL IMPACT

Cost or Savings to Any State Agency: As discussed above, these are process regulations; and DTSC thus has made a determination that adoption of these regulations will have no impact on State agencies.

Impacts that can/will be more specifically identified and evaluated as part of future APA rulemaking processes for the proposed listing of product-chemical combinations as Priority Products

COST OF GOODS

The future priority product regulations address chemicals in products. Any fiscal impact from these future priority product regulations to State agencies in general would likely be in the operating expense and possibly equipment and capital outlay line items.

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

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

Even if DTSC ends up banning a product as a regulatory response for a product listed in its future priority product regulations, significant cost impacts are not expected because comparable safer products should be readily available at competitive prices, and because economic feasibility is one of the key findings DTSC must make before imposing a ban on a priority product for which an alternative is not selected. In this use, economic feasibility means that there are safer alternatives to the product or product component that do not contain the chemical of concern that the manufacturer could choose without significantly impacting the manufacturer's operating margin.

Even if costs of some products do increase, products do not make up a significant proportion of most State agencies' operating budgets. Further, the benefits of using a safer product would outweigh any increase in price.

DTSC STATE OPERATIONS

DTSC has been redirecting staff and operating expenses for the past four fiscal years to develop these regulations and implement the Green Chemistry Initiative. For fiscal year 2012/2013 and ongoing, DTSC increased the amount of redirected resources so that sufficient resources are available to implement these SCP regulations. DTSC has redirected a total of 39 positions as follows: 23 positions within the Safer Products and Workplaces Program, 3 positions within the Environmental Chemical Laboratory, 3 positions within the Office of Legal Affairs, 4 positions within the Enforcement Program, and 6 positions within Information Technology. Total annual staff costs are $4.8 million. DTSC also cut several vacant positions to supplement existing contract funds to budget

a total of $1.4 million for contracts and laboratory equipment required to implement the regulations. DTSC estimates its annual cost to implement these regulations will be $6.2 million.

The fiscal impact is a conservative estimate based on a limited initial Priority Products list. As DTSC gains experience in implementing the regulations, resource needs could change as the Priority Product list expands and as DTSC identifies improvements and efficiencies.

Cost or Savings in Federal Funding to the State: As discussed above, these are process regulations; and DTSC thus has made a determination that adoption of these regulations will not result in any cost or savings in federal funding to California.

Impacts that can/will be more specifically identified and evaluated as part of future APA rulemaking processes for the proposed listing of product-chemical combinations as Priority Products

Federal funds provide full or partial support for a wide range of programs administered by California State government. DTSC does not expect any decrease in federal funds to California as a result of implementing the future priority product regulations.

Even if federal funds provided to State government agencies are used to pay for Priority Products, the future priority product regulations pose no risk/jeopardy to the receipt of federal funds. As discussed above (in "Cost or Savings to Any State Agency"), the implementation of the priority product regulations are not expected to increase costs or add a cost pressure since government agencies can switch to safer products of similar cost. Thus, the future priority product regulations also would not result in a redirection of federal funds from direct services to operating equipment and expenses.

HOUSING COSTS

As discussed above, these are process regulations; and DTSC thus has made a determination that adoption of these regulations will not directly impact housing costs.

Impacts that can/will be more specifically identified and evaluated as part of future APA rulemaking processes for the proposed listing of product-chemical combinations as Priority Products

It is possible that a product used in housing construction would be listed as a Priority Product. However, at this time, DTSC is unable to estimate what, if any, impact the future priority product regulations could have on housing costs. If a proposed priority product rulemaking has the potential to impact housing costs, the Economic and Fiscal

Impact Statement for that rulemaking would identify the potential impact to housing costs.

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

As discussed above, these are process regulations; and DTSC has made a determination that adoption of these regulations will not have a significant statewide economic impact directly affecting businesses or affecting the ability of California businesses to compete with businesses in other states. The bases for this determination are discussed below under *Statement of the Results of the Economic Impact Assessment*, *Cost Impacts on Representative Person or Business*, *Business Report*, and *Small Business*.

NOTE: These regulations, and the subsequent rulemakings for the listing of Priority Products, are *not* expected to affect the ability of California businesses to compete with businesses in other states. It is important to note that these regulations (and any future Priority Product listing regulations) will apply with equal force to businesses in California and those outside of California. This is because the regulations apply to those businesses placing consumer products into the stream of commerce in California — regardless of the place of manufacture of those products.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

Creation or elimination of jobs within California

Creation of new businesses or elimination of existing businesses within California

Expansion of businesses currently doing business in California

As discussed above, these are process regulations; and DTSC thus has made a determination that adoption of these regulations will not create or eliminate any businesses or jobs.

Impacts that can/will be more specifically identified and evaluated as part of future APA rulemaking processes for the proposed listing of product-chemical combinations as Priority Products

The principal duty to comply with the requirements of the Priority Product regulations lies with the manufacturer. If the manufacturer does not comply the importer, if any, then has the duty to comply. A retailer or assembler is required to comply with the

regulations only if the manufacturer and importers (if any) fail to comply, and only after this information is posted on the Failure to Comply List on DTSC's website.

The duty to comply applies to responsible entities located outside of California and outside of the United States.

Businesses will incur significant costs to comply with the future Priority Product regulations. Responsible entities will be required to perform and will incur associated costs to:

- Notify DTSC if their product is a Priority Product;
- Perform an AA, unless a publically available AA is available or the responsible entity opts out of the requirement to perform an AA by removing the chemical of concern from the product, removing the product from the market, replacing the chemical of concern with another chemical, or submitting an alternatives analysis threshold exemption demonstrating that the concentration of the chemical of concern in the product meets certain criteria;
- Implement the alternative selected in the AA or implement the chemical of concern removal, product removal, or product-chemical replacement; and
- Comply with regulatory response applicable to product, if any.

In order to determine the economic and fiscal impacts of the future Priority Product regulations, DTSC will need to know at a minimum:

- The number of businesses producing the priority product;
- The number of responsible entities located inside and outside of California;
- The number of responsible entities located inside and outside of California that comply with the regulations;
- The availability of substitutes for the priority product, e.g., the same or similar product performing the same functions that do not contain the chemical of concern;
- The availability of, the number of, and the location of existing businesses selling safer substitutes for the priority product;
- The number of businesses expected to submit chemical removal, product removal, or product chemical replacements, or alternative analysis threshold exemptions;
- Estimates of businesses cost to remove the chemical, remove the product from the market, or substitute a chemical for a chemical of concern in the priority product, or cost to conduct testing to support an AA threshold (costs to businesses to implement one of these alternatives will vary depending on numerous factors including the role of the chemical of concern in the product, availability of a substitute chemical that will perform the same functions in the

product as the chemical of concern, the cost to business to revamp production lines and equipment to manufacture the product without the chemical of concern or with a substitute chemical, testing of the revised product to ensure that it meets manufacturer and any regulatory agency specifications, availability of existing data or cost of new data to show that the chemical of concern is only in the product at the alternative analysis threshold level, etc.);

- The availability of public domain AAs or supporting data for an AA for the priority product;
- The number of businesses inside and outside of California that will need to prepare an AA;
- The estimated complexity (the more complex the more costs businesses will incur) of the AA;
- The availability of consortia, trade associations, or public-private partnerships to assist with or fulfill AA and other regulatory requirements;
- The availability of, the potential for and the location of new businesses that may be willing to bring a substitute product without the chemical of concern into the market;
- The number of functionally acceptable and technically and economically feasible alternatives to the AA and the cost to implement those alternatives;
- The number and location of businesses that will be required to implement a regulatory response; and
- The cost of implementing the regulatory responses.

The primary responsibility for implementing the Priority Product regulations is with the manufacturer of the Priority Product, regardless of the place of manufacture, and many manufacturers are located outside of California. Thus, the adoption of these regulations and the implementation of them will not just impact businesses in California; they will impact manufacturers in other states and countries. Therefore the Priority Product regulations will have the potential to create businesses/jobs and eliminate businesses/jobs. DTSC will be in a better position to evaluate the potential impacts to California's businesses once the Priority Products are known.

Benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment ---

The SCP regulations themselves only describe the processes for identification and prioritize Priority Products-Chemicals of Concern, conductions Alternatives Assessments for Priority Products, and imposing regulatory responses (as required by Health and Safety Code sections 25252 and 25253) – as such the immediate benefits of these regulations are minimal. The direct benefits of these regulations are the

information that DTSC will collect to help implement the program, the description of the processes DTSC will use in implementing the Safer Consumer Products program, and the guidance DTSC is required to develop.

However, looking into the future, implementation of the processes established by these regulations – which will be triggered by the adoption of future regulations listing Priority Products – will create one of the first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals. As such, these regulations are viewed as a possible national model for chemical reform. These regulations, in effect, will set in motion a preemptive strategy that reduces the use of toxic substances in the design of products and industrial processes with the aim of creating safer and more sustainable products that do not threaten human health or persist in the environment. The use of fewer hazardous substances means healthier air quality, cleaner drinking water, and safer workplaces. Implementation of the processes set forth in these regulations will promote transparency by compelling chemical manufacturers to provide sufficient information for businesses, consumers, and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products. Further relevant details are discussed immediately below.

Impacts that can/will be more specifically identified and evaluated as part of future APA rulemaking processes for the proposed listing of product-chemical combinations as Priority Products

Implementation of the Priority Product regulations should accomplish several goals of the Green Chemistry Initiative as outlined in the August 30, 2008, Assembly Floor Analysis of AB 1879: …" reducing exposure, encouraging less-toxic industrial processes, and identifying safer, non-chemical alternatives" for consumer products.

In selecting the Priority Products, the product-chemical combination must have a potential exposure to the candidate chemical in the product and there must be the potential for one or more exposures to contribute to or cause significant or widespread adverse public health and/or environmental impacts. Thus, when the Priority Product regulations are noticed, DTSC will be able to identify the specific adverse impacts and exposures of the candidate chemical in the product due to exposures during the life cycle of the product.

The initial up to five (5) Priority Products must include a candidate chemical meeting one or more of the criteria in both:

- Section 69502.2 (a)(1) which includes 15 different lists of chemicals of which two are:

  - Chemicals known to cause cancer and/or reproductive toxicity that are listed under Health and Safety Code section 256249.8 of the California Safe Drinking Water and Toxic Enforcement Act of 1986, and
  - Chemicals that are identified as Persistent Bioaccumulative and Toxic Priority Chemicals that are identified by the United States Environmental Protection Agency's National Waste Minimization Program.

- Section 69502.2(a)(2) which includes 8 different types of chemicals two of which are:
  - Chemicals for which Notification Levels, as defined in Health and Safety Code section 116455, have been established by the California Department of Public Health, and,
  - Chemicals for which primary Maximum Contaminant Levels have been established and adopted under section 64431 or 64444 of chapter 15 of title 22 of the California Code of Regulations.

The Priority Products listed could have adverse waste and end-of-life effects which means the waste materials and byproducts generated during the life cycle of a product, and the associated adverse effects including special handling needed to mitigate adverse impacts, effects on solid waste and wastewater disposal and treatment, including operation of solid waste and wasterwater handling or treatment facilities, and the ability to reuse or recycle materials resulting from the treatment of solid waste and/or wastewater.

Depending upon the Priority Products selected examples of public health or environmental benefits that could be achieved by identifying safer alternatives are the reduction of disease or the reduction of local governments' cost to treat wastewater.

In certain situations, DTSC has the authority to impose regulatory responses on the priority product. Examples of benefits from regulatory responses include additional product information for consumers, use restrictions on a product to reduce exposures, end-of-life product management practices, and advancement of green chemistry and green chemistry engineering.

It is also possible that businesses having a Priority Product will also incur some benefits. For example, gain in market share, improvements in the supply chain process, improvements in the supply base, and right-sizing of product lines.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

As discussed above, these are process regulations; and thus DTSC has determined that these regulations will have no cost impacts or impose any responsibilities on private persons.

Adoption of the SCP regulations only impacts those businesses from which DTSC requests information. DTSC may request a business to provide existing information or generate new information. A business is not required to comply with the request. If a business already has the information that DTSC is requesting, then the costs to respond to the request are expected to be insignificant and would only include the costs of collecting the information and sending it to DTSC. If businesses are able to generate new data in response to information requested by DTSC, the cost to generate the data is expected to be minimal because businesses are not required to provide the information and would not do so if the costs were too high. Businesses may decide to generate the new data based on a request from DTSC if they believe there is a positive impact on their business from being listed as business responding to DTSC's request for information on DTSC's "Response Status List".

Impacts that can/will be more specifically identified and evaluated as part of future APA rulemaking processes for the proposed listing of product-chemical combinations as Priority Products

The Priority Product regulations will not impose any direct responsibilities on private persons. However, there is a potential for private individuals to pay more for priority products. Whether a consumer will see the cost of priority products increase will depend on numerous factors such as the current availability on the market of safer alternatives to the priority product and the ability of businesses to pass on the costs to consumers.

Businesses whose products are listed as Priority Products will incur significant costs to comply with the SCP process regulations. As noted above, the primary responsibility for implementing the Priority Product regulations is with the manufacturer of the Priority Product, regardless of the place of manufacture, and many manufacturers are located outside of California.

There are many factors that will impact costs businesses will incur, many of which are identified above. DTSC believes that despite the potentially significant costs that businesses will likely incur, the benefits will outweigh the costs.

BUSINESS REPORT

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

The SCP regulations do allow DTSC to request businesses to provide information to DTSC (using existing information or by developing new information); however, there is no mandate for businesses to provide such information requested by DTSC.

Impacts that can/will be more specifically identified and evaluated as part of future APA rulemaking processes for the proposed listing of product-chemical combinations as Priority Products

Upon adoption of future priority product regulations, there will be significant reporting requirements for those responsible entities that have a Priority Product. NOTE: With the exception of manufacturers subject to an end-of-life management regulatory response, the reporting requirements are not annual or otherwise ongoing reporting requirements. A responsible entity for a priority product will be required to notify DTSC that they have a priority product and provide the requested information outlined in the SCP regulations. Depending upon the course of action a responsible entity chooses to follow, the reporting requirements will vary. If a responsible entity decides to remove the chemical of concern from the priority product, cease producing the product or replace the chemical of concern with another chemical, then the responsible entity would be required to send one or more notifications including the required data and information to DTSC. If the responsible entity chooses to perform an alternative analysis there are several options that the responsible entity could choose. If DTSC determines that a regulatory response is required of the responsible entity there are additional reporting requirements depending upon the regulatory action DTSC requires. Finally, a responsible party would have information and reporting requirements to comply with in the event DTSC audits their activities or if the responsible entity disputes an action by DTSC or files a trade secret claim. DTSC cannot estimate the costs to businesses of providing requested information or reports until implementation is under way. When the proposed priority product listing regulations are released, DTSC will be required to provide an estimate of the costs to businesses of these reporting requirements.

SMALL BUSINESS

Small businesses as with larger businesses may receive a request for chemical or product information from DTSC. Businesses do not have a mandatory requirement to provide the chemical or product information to DTSC, although DTSC will indicate that

the business did not respond to DTSC's request for the information on its "Response Status List". DTSC believes that small businesses as with larger businesses would incur only minimal cost to provide existing information to DTSC. However, if DTSC requested a small business to generate new chemical or product information, fulfilling that request might be more expensive for a small business than a larger business. DTSC anticipates that in this case, a small business would be able to provide data demonstrating that the information was not available and costs to generate new data would be prohibitive. DTSC would note on the "Response Status List" that the business demonstrated to DTSC's satisfaction that the business didn't have the information and was unable to produce the information.

Impacts that can/will be more specifically identified and evaluated as part of future APA rulemaking processes for the proposed listing of product-chemical combinations as Priority Products

Creating exemptions for small to medium sized businesses is not authorized under Health and Safety Code sections 25251 through 25257.1, the authorizing legislation. The regulations have options that any business, including small and medium businesses, may avail themselves of that may help to reduce cost. A group of manufacturers or other "responsible entities," whether large, medium or small, may work together to offset the costs of performing an AA on their own and achieve a common goal. Businesses are allowed to use an already prepared AA, if it meets their needs. Businesses that are not manufacturers will not be required to comply with Regulatory Responses imposed by DTSC for engineered safety measures/administrative controls, end-of-life management requirements, and the advancement of Green Chemistry and Green Engineering.

Furthermore, when deciding whether to list a product-chemical combination as a Priority Product, DTSC may also consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible. Proposed section 69501.1(a)(29) of the regulations defines "economically feasible" to mean "an alternative product or replacement chemical does not significantly reduce the manufacturer's operating margin." By including the "economic feasibility" of a readily available safer alternative as potential criteria for listing a product-chemical combination, DTSC has the ability to consider whether the negative economic impacts would outweigh the public health and environmental benefits of listing a product-chemical combination.

A business may decide during the AA to retain the Priority Product based in whole or in part on internal cost impacts; however, this decision must be explained in the Final AA Report. The Final AA Report must include a quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing,

materials and equipment acquisition, and resource consumption costs. If a business does decide to retain the Priority Product, DTSC must consider economic feasibility among other factors, in determining a regulatory response it may impose, if any on the business.

Having both the business entity and DTSC to look at the economic feasibility of proposed actions should help balance cost impacts on businesses with the public health and environmental benefits of the actions.

ALTERNATIVES DETERMINATION

DTSC has determined that no reasonable alternative considered by DTSC or that has otherwise been identified and brought to DTSC's attention would be: (i) more effective in carrying out the purpose for which this regulation is proposed; (ii) as effective as and less burdensome to affected private persons than this regulation; or (iii) more cost-effective to affected private persons and equally effective in implementing the statutory policy of other provision of law implemented by this regulation.

Alternatives considered are described in the Final Statement of Reasons for these regulations.

AVAILABILITY STATEMENTS

Copies of the Final Statement of Reasons, the text of the regulations, and the information upon which the regulations are based are posted to DTSC's Internet site at http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm
or may be obtained from ***Manpreet Singh*** of DTSC's Regulations Section as specified below.

Please direct all requests for documents by mail, e-mail, or fax to:

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