

CALIFORNIA ENVIRONMENTAL QUALITY ACT
NOTICE OF EXEMPTION

To: Office of Planning and Research
State Clearinghouse
P.O. Box 3044, 1400 Tenth Street, Room 212
Sacramento, CA 95812-3044

From: Department of Toxic Substances Control
P.O. Box 806, 1001 I Street, 11th floor
Sacramento, CA 95812-0806

Project Title: Regulations for Safer Consumer Products

Project Location: Statewide

County: Statewide

Project Description: The project consists of the Department of Toxic Substances Control's (DTSC) approval of regulations (by adoption under the Administrative Procedure Act) adding chapter 55 to Division 4.5 of Title 22, California Code of Regulations (Cal. Code Regs.), that implement the requirements of Division 20, Chapter 6.5, Article 14 of the Health and Safety Code ("Article 14"). These additions pertain to identification of candidate chemicals, prioritization of chemicals of concern (COCs) in consumer products, evaluation of their alternatives, and regulatory responses following completion of the evaluation of the consumer product and potential alternatives. The regulations and the authorizing statutes (Article 14), are intended to implement recommendation #5 of the California Green Chemistry Initiative Final Report (December, 2008) --- Accelerate the Quest for Safer Products and create a systematic, science-based process to evaluate COCs and identify safer alternatives to ensure consumer product safety.

Below is a summary highlighting the major elements and concepts included in the regulations:

REGULATORY OBJECTIVES

The regulations are intended to:

- Establish a process to identify chemicals as candidate chemicals, and prioritize consumer products containing candidate chemicals (a candidate chemical that has been identified as part of a Priority Product is then called a "COC");
- Establish a process for evaluating COCs in Priority Products, and their potential alternatives, to determine how best to limit exposures to, or to reduce the level of adverse impacts posed by the COC(s) in a product; and
- Specify the regulatory responses that DTSC may require following the completion of an alternatives analysis.

Background: Health and Safety Code section 25252 directs DTSC, in adopting these regulations, to develop criteria by which COCs and their alternatives may be evaluated. Section 25252 further requires that these criteria must include, at a minimum, the hazard traits and environmental and toxicological endpoints that the Office of Environmental Health Hazard Assessment (OEHHA) has adopted in its companion regulations, required by Health and Safety Code section 25256.1.

In September 2010, DTSC released its first draft regulations under Health and Safety Code, sections 25252 and 25253. DTSC released revisions to the September 2010 regulations in November 2010. Ultimately, DTSC withdrew those proposed regulations from the Office of Administrative Law. In July 2012, and again in January 2013 and April 2013, DTSC revised its regulations to describe a four-step continuous, science-based, iterative process to identify safer consumer products. As a first step, the regulations identify approximately 1,200 "Candidate Chemicals," already included on one or more of 23 chemicals lists adopted by various authoritative entities. DTSC will select up to five "Priority Products" for the initial Priority Products List. Priority Products must undergo an Alternatives Analysis conducted by the manufacturer or other "Responsible Entity" (as defined in the regulations). The Alternatives Analysis requires manufacturers to determine how best to limit exposures to or reduce the level of adverse public health and environmental impacts posed by the Chemicals of Concern in the product. As noted briefly above, once a "Candidate Chemical" in a product is prioritized as part of a Priority Product, it is then referred to as a "Chemical of Concern." Only at the final stage will DTSC impose a particular regulatory response. These include, but are not limited to, taking no action, imposing a requirement to provide consumer warnings or other product information, restricting use of a Candidate Chemical, banning sale of specific products, imposing administrative or engineered safety controls, or requiring an end-of-life product management program.

Project Activities:

How the Objectives Will Be Accomplished Through the Regulations:

The purpose of these regulations is to eliminate or reduce the adverse public health and environmental impacts of consumer products through product redesign or reformulation, manufacturing process redesign, removal of COCs in products, and other mechanisms. The regulations establish a process for identifying products that contain COCs as Priority Products, and requiring either the product manufacturer, importer, or retailer (individually and collectively referred to as the “responsible entity” in the regulations) to conduct an Alternatives Analysis, and then implement Regulatory Response(s) imposed by DTSC in light of the information provided by the Alternatives Analysis. All steps and phases of the regulations are aimed at the reduction of adverse public health and environmental impacts from the use of products containing COCs.

The regulations apply to all consumer products placed into the stream of commerce in California except for certain products exempted by the authorizing legislation. However, not all consumer products placed into the stream of commerce in California will have to undergo an Alternatives Analysis. Only those consumer products identified and listed by DTSC as Priority Products must undergo an Alternatives Analysis.

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

- DTSC specifies in the regulations a fairly large suite of chemicals that upon adoption of the regulations are identified as Candidate Chemicals.
- DTSC evaluates and prioritizes consumer products that contain Candidate Chemicals to develop a list of “Priority Products.”
- Responsible Entities for the listed Priority Products must conduct an Alternatives Analysis, and submit Preliminary and Final Alternatives Analysis Reports to DTSC. The Alternatives Analysis Reports include a detailed, scientifically-based evaluation of the Priority Product and potential alternatives using evaluation criteria mandated in the regulations. DTSC issues the Responsible Entity either a notice of deficiency or notice of compliance in response to both the Preliminary and Final Alternatives Analysis Reports.
- DTSC may identify and impose one or more regulatory response(s) to effectively limit the adverse public health and/or environmental impacts, if any, posed by the Priority Product due to the COC or the adverse impacts posed by the alternative chemical/product selected to replace the Priority Product, if any.

CHEMICALS OF CONCERN

As stated, Health and Safety Code section 25252 directs DTSC to develop criteria by which chemicals of concern and their alternatives may be evaluated in adopting these regulations. Section 25252(b)(1) requires that these criteria must include, at a minimum, the hazard traits and environmental and toxicological endpoints that OEHHA specified in its companion regulations that OEHHA was required to adopt pursuant to Health and Safety Code section 25256.1.

The first activity triggered by the regulations, which happens automatically upon the effective date of the regulations is the identification of Candidate Chemicals that exhibit one or more hazard traits and/or environmental or toxicological endpoints identified by OEHHA in its regulations, and that are listed on one or more of 23 existing chemicals lists that are specified in the regulations. These criteria are set out in the regulations at Section 69502.2(a).

PRIORITY PRODUCTS

The proposed regulations call for further identification and prioritization of Candidate Chemicals in Priority Products according to specified criteria. These criteria include consideration of the following statutorily mandated criteria: the volume of the chemical in commerce in California; the potential for exposure to the chemical in a consumer product; and potential effects on sensitive subpopulations, including infants and children. (Health & Safety Code § 25252, subs. (a)(1) - (3)). In addition, the regulations set out further prioritization criteria and processes that DTSC must follow in identifying Priority Products. (Note: The regulations require DTSC’s initial list of Priority Products to have no more than five (5) Priority Products.)

ALTERNATIVES ANALYSIS

The regulations establish a process for the evaluation of the COC(s) in Priority Products and for the evaluation of potential alternatives to those COCs. This evaluation is termed the "Alternatives Analysis." A responsible entity for a product that is listed as a Priority Product, or a person acting on behalf of or in lieu of the responsible entity, is required by the regulations to perform an Alternatives Analysis for the Priority Product. The Alternatives Analysis is a two-stage evaluation that includes a step-wise evaluation of the adverse public health and environmental impacts posed by the Priority Product/COC and possible alternatives. A multimedia life cycle evaluation of the product and potential alternatives is required as a part of this evaluation. The defining feature of the prescribed life cycle assessment methodology is that it captures multi-media environmental impacts associated with all upstream and downstream stages of the product's life.

The prescribed Alternatives Analysis uses a multi-stage approach to conduct comparisons among alternatives. Under this approach, alternatives that do not represent an improvement over the Priority Product with the COC with regard to public health and environmental impacts are not considered to be acceptable alternatives.

When the responsible entity submits a Final Alternatives Analysis Report to DTSC pursuant to the regulations, the responsible entity must also identify the selected alternative, if any. That is, this could be a decision to retain the existing Priority Product and provide the rationale for the selection decision.

REGULATORY RESPONSES

The regulations identify regulatory responses that may, under specified conditions, apply to:

- Products manufactured as a selected alternative following completion of an Alternatives Analysis;
- A Priority Product for which an alternative is not selected; and
- A Priority Product that will remain in commerce pending development and distribution of the selected alternative.

The regulatory responses include all of those set out in Health and Safety Code Section 25253(b), which sets out a non-exhaustive list of Regulatory Responses that DTSC may impose following the completion of the Alternatives Analysis.

The regulations further specify the criteria that will be used by DTSC to impose one or more regulatory response(s). In addition to requiring additional information to supplement the Alternatives Analysis Report, the array of regulatory responses that DTSC may impose consists of all of the following: (1) no regulatory response required; (2) requiring product information for consumers; (3) imposing use restrictions on COC(s) and consumer products; (4) specifying a product sales prohibition; (5) requiring engineered safety measures or administrative controls; (6) requiring an end-of-life product management program; and (7) requiring a research and development project or funding of a "challenge grant."

Under specified conditions, the regulations provide a process for a responsible entity to request an exemption from an otherwise applicable regulatory response. The exemption must be based on either or both of the following: (i) the required regulatory response would conflict with a requirement of another California or federal regulatory program or an international trade agreement that has the force of domestic law in such a way that the responsible entity could not reasonably be expected to comply with both requirements; or (ii) the required regulatory response substantially duplicates a requirement of another California or federal regulatory program or an international trade agreement that has the force of domestic law.

PUBLIC INPUT AND MULTI MEDIA LIFE CYCLE EVALUATION

The regulations include requirements at various stages of implementation for public review and comment on proposed DTSC actions: additions to the COC list, listing of Priority Products, and Regulatory Response determinations. Additionally, the regulations specify a comprehensive list of adverse public health and environmental impacts and exposure assessment factors that must be considered during both the prioritization and alternatives analysis processes. These impacts include the factors specified in the statute: product function and 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; environmental impacts; and economic impacts.

The need for additional CEQA evaluation will be considered at the appropriate stage of implementation of these regulations.

Name of Public Agency Approving Project: Department of Toxic Substances Control

Name of Person or Agency Carrying Out Project: Department of Toxic Substances Control

Exemption Status: (check one)

- Ministerial [PRC, Sec. 21080(b)(1); CCR, Sec. 15268]
 Declared Emergency [PRC, Sec. 21080(b)(3); CCR, Sec.15269(a)]
 Emergency Project [PRC, Sec. 21080(b)(4); CCR, Sec.15269(b)(c)]
 Categorical Exemption: CCR, Sec.15308
 Statutory Exemptions: [State code section number]
 General Rule [CCR, Sec. 15061(b)(3)]

Exemption Title: Actions by Regulatory Agencies for Protection of the Environment

Reasons Why Project is Exempt:

Class 8 is a categorical exemption under CEQA that "consists of actions taken by regulatory agencies... to assure the maintenance, restoration, enhancement, or protection of the environment where the regulatory process involves procedures for protection of the environment." [Cal. Code Regs. tit. 14, § 15308]. Because DTSC's regulations will enhance the environment and the regulatory process involves procedures for the protection of the environment, DTSC's action falls under the Class 8 categorical exemption.

Purpose of the Regulations is to Enhance and Protect the Environment and Public Health

First, the regulations' purpose is to reduce the adverse public health and environmental impacts of chemicals in consumer products. To that end, the regulations introduce a framework to carefully and methodically evaluate chemicals in the environment, generate new information about chemical contents in consumer products, and ultimately make regulatory changes in the manufacture of consumer products. The regulations are beneficial to the environment because they will reduce the use of toxic substances in the design of products and industrial processes by fostering safer and sustainable products that do not threaten human health or the environment. The use of fewer hazardous substances will result in healthier air quality, cleaner drinking water, and a safer work environment. The regulations also promote transparency by compelling chemical manufacturers to provide sufficient information for businesses, consumers, and public agencies to choose viable safer alternatives to hazardous chemicals present in consumer products. There will not be any collateral environmental impacts that are not fully analyzed and understood.

Second, the regulations will not cause inadvertent, detrimental impacts to the environment because of a built-in environmental review process. The Alternatives Analysis is a two-stage evaluation that includes a step-wise evaluation of the adverse public health and environmental impacts posed by the Priority Product/COC and possible alternatives. A multimedia life cycle evaluation of the product and potential alternatives is required as a part of this evaluation. The defining feature of the prescribed life cycle assessment methodology is that it captures multi-media environmental impacts associated with all upstream and downstream stages of the product's life. The prescribed Alternatives Analysis uses a multi-stage approach to conduct comparisons among alternatives. Under this approach, alternatives that do not represent an improvement over the Priority Product with the COC with regard to public health and environmental impacts are not considered to be acceptable alternatives. When the responsible entity submits a Final Alternatives Analysis Report to DTSC pursuant to the regulations, the responsible entity must also identify the selected alternative (which could be a decision to retain the existing Priority Product) and provide the rationale for the selection decision. In this way, the Alternatives Analysis is designed to ensure that the regulations will not cause inadvertent detrimental impacts to the environment.

The Environmental Policy Council Determined that the Regulations Will not have Any Significant Adverse Impact on the Environment.

Finally, the Environmental Policy Council (Council) was convened in February 2013, and conclusively determined that "the regulations will not have any significant adverse impact on public health or the environment." Because of this determination by the Council, DTSC is exempt from the Health and Safety Code section 25252.5 requirement to submit a multimedia evaluation to the Council for review prior to adopting the regulations. (See Health & Safety Code section 25252.5(f).) DTSC prepared a report on the need for a multimedia evaluation of the Safer Consumer Products Regulations and determined that the regulations would not result in any significant adverse impact on public health or the

environment. The Council, consisting of the Secretary for Environmental Protection, the Chairman of the California Air Resources Board, the Chairman of the State Water Resources Control Board, the Directors of the Office of Environmental Health Hazard Assessment, DTSC, the Department of Pesticide Regulation, and the Department of Resources Recycling and Recovery on behalf of the California Environmental Protection Agency issued a resolution on February 28, 2013, that conclusively determined that the proposed regulations would not have significant impact on public health or the environment. The pertinent aspects of those findings are briefly summarized below:

-If the Council finds during an initial evaluation of the proposed regulations and conclusively determines that the proposed regulations will not have any significant adverse impact on public health or the environment, a multimedia life cycle evaluation is not required.

-The Council essentially found that the proposed regulations would fulfill the intent of the legislation by its design that includes the processes needed to achieve safer consumer products.

-Multimedia considerations are included throughout the proposed regulations by requiring a comparative life cycle evaluation of an expansive list of potential public health (including worker health) and multimedia environmental impacts, potential waste and end-of-life effects and exposure potential factors during both the prioritization and alternatives analysis processes.

-DTSC's proposed regulations will not affect any specific chemicals or products, and therefore will not result in any direct physical impacts to public health or the environment.

-DTSC's eventual implementation of the proposed regulations may result in potential impacts to public health or the environment; however, because it is impossible for the Council to know at this time what chemicals in which products might be affected by a future action by DTSC in accordance with the regulations, any such potential public health or environmental impacts are speculative and not reasonably foreseeable.

-The proposed regulations include provisions that will assist DTSC in evaluating whether any of its potential chemical-specific or product-specific actions to implement the regulations may have a significant adverse effect on public health or the environment.

-Health and Safety Code section 25252.5, subdivision (g), defines a "multimedia life cycle evaluation" as "the identification and evaluation of a significant adverse impact on public health or the environment, including air, water, or soil, that may result from the production, use, or disposal of a consumer product or consumer product ingredient."

-Requiring DTSC to prepare a multimedia life cycle evaluation, as defined above, of the proposed regulations without identifying any specific consumer products would not result in any meaningful information or analysis for the Council to consider.

-If DTSC, in finalizing its Safer Consumer Products regulations fundamentally alters the regulations in such a manner that the regulations directly affect specific consumer products, DTSC shall re-submit its regulations to the Council.

-The Council conducted a public meeting on February 28, 2013 to receive written and oral comments from interested parties on whether the Council should conclusively determine that the regulation will not have any significant adverse impact on public health or the environment.

Having considered the above, the Council conclusively determined that the regulations will not have any significant adverse impact on public health or the environment.

Conclusion:

The Safer Consumer Products regulations implement one of six policy recommendations in the Final California Green Chemistry Report issued by DTSC in December 2008. The regulations build upon current environmental protection laws to shift the focus from end-of-pipe cleanup or "cradle to grave" regulation to up-front design and prevention of harm, foster innovation, and promote market changes toward a sustainable economy. The six recommendations in the Final Report ensure a comprehensive and collaborative approach to increase accountability and effectiveness of environmental programs across state government for evaluating risk, reducing exposure, encouraging less-toxic industrial processes, and identifying safer alternatives. In general, the regulations' framework is designed to move industries and consumers away from chemicals that pose the greatest risk to human health and the environment and promote their replacement with lower risk chemicals. Because DTSC's regulations will enhance the environment and the regulatory process involves procedures for the protection of the environment, DTSC's action qualifies for the Class 8 categorical exemption to CEQA.

This is to certify that the final environmental document, comments and responses, and the record of project approval are available to the public at the following location:

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