

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 and 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 chemicals of concern, 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 COCs, and prioritize consumer products containing COCs.
- Establish a process for evaluating Priority Products, and their potential alternatives, to determine how best to limit exposures to, or to reduce the level of adverse impacts posed by COCs in a product.
- Specify the regulatory responses that DTSC may require following the completion of an alternatives analysis.

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 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 gleaned from 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 statute. However, not all consumer products placed into the stream of commerce in California will have to undergo an Alternatives Analysis. Rather, 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 COCs.
- DTSC evaluates and prioritizes consumer products that contain COCs 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 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

Health and Safety Code section 25252 directs DTSC, in adopting these regulations, to develop criteria by which chemicals of concern 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) was specified pursuant to Health and Safety Code section 25256.1.

The first activity triggered by the regulations is the identification as COCs chemicals that exhibit one or more hazard traits and/or environmental or toxicological endpoints identified by OEHHA in their regulations, and that are listed on one or more of 22 existing chemicals lists that are specified in the regulations. These criteria are set out in the regulations at Section 69502.2(a). DTSC is required by Health and Safety Code Section 25252(b)(1) to use hazard traits and endpoints identified by OEHHA as part of the criteria for identifying COCs .

PRIORITY PRODUCTS

The proposed regulations call for further identification and prioritization of COCs 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 Section 25252(a) (1) through (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 set out a process for an evaluation of the COC(s) in Priority Products and for the evaluation of potential alternatives. 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 (which could be a decision to retain the existing Priority Product) and provide the rationale for the selection decision.

REGULATORY RESPONSES

The regulations specify 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 AA Report, the array of regulatory responses that DTSC may impose consist 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: [State type and section number]
- Statutory Exemptions: [State code section number]
- General Rule [CCR, Sec. 15061(b)(3)]

Exemption Title: With certainty, no possibility of a significant effect on the environment.

Reasons Why Project is Exempt:

- DTSC was authorized and mandated 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”. (Health and Safety Code Section 25253(a)(1), Emphasis added.)The regulatory process outlined above accomplishes this mandate.
- The regulations are designed to reduce the adverse public health and environmental impacts throughout the life cycle of products through product redesign, or reformulations, manufacturing process redesign, phase-out of harmful chemicals and/or products removal of COCs in products, and other mechanisms.
- The task of analyzing whether there could be a significant effect on the environment as a result of requiring an alternatives analysis for any of the approximately 1,200 COCs in any of tens or hundreds of thousands of consumer products is incredibly speculative. Quite simply, at this point, DTSC does not yet know which COC(s) in which consumer product(s) will be identified and listed as Priority Products.
- The initial proposed list of Priority Products will not be compiled and published until 180 days after the effective date of the regulations. As specified in Title 14, California Code of Regulations, Section 15145, “If after thorough investigation, a lead agency finds that a particular impact is too speculative for evaluation, the agency should note its conclusion and terminate discussion of the impact.”

- Evaluating the effects of listing of approximately 1,200 chemicals that could be in an untold number of not yet-identified consumer products and the possible environmental impact of possible alternative formulations is both infeasible and unreasonably speculative. In addition, there will be no physical change in the environment resulting from this action on the part of DTSC to adopt regulations that specify a **process** for identifying and prioritizing COCs in consumer products, since the activities being conducted by DTSC are intellectual evaluation and analysis only.
- As mentioned above, the need for additional CEQA evaluation will be considered, as appropriate, during implementation of the regulatory program. Consequently, it is virtually impossible at this point of adoption of the regulations for DTSC to engage in any meaningful evaluation of the significant environmental impacts, if any, that may result from the implementation of the regulations. Therefore, this Notice of Exemption is appropriate.

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:

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

Signature	Date	
Odette Madriago	Chief Deputy Director	(916) 323-4927
Name	Title	Phone #

TO BE COMPLETED BY OPR ONLY

Date Received For Filing and Posting at OPR: