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DTSC Releases Proposed Green Chemistry Regulations

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The California Department of Toxic Substances Control (“DTSC”) has released its proposed Safer Consumer Products Regulation, commonly known as the Green Chemistry Initiative, requiring manufacturers to seek alternative ingredients in widely-used products. A 45-day comment period closes on September 11, 2012[1]. The regulations include a list of “chemicals of concern” (“COCs”), and establish a process (discussed in greater detail below) designed to identify safer consumer product alternatives[2].

- DTSC is to evaluate and prioritize product/COC combinations, and then prepare a list of “Priority Products” for which Alternatives Analyses will be conducted. This Alternatives Analysis is aimed at determining how best to limit exposures to, and address public health and environmental impacts posed by, the COCs in the product.
- Product manufacturers, importers or retailers must notify the DTSC when their product is listed as a Priority Product and must then perform an Alternatives Analysis for the product and the COCs.
- DTSC will then identify and require implementation of feasible alternatives.

The proposed regulations will apply to all consumer products that contain a COC and are sold, offered for sale or distributed, and supplied or manufactured in California. Exceptions include certain medical products and products not intended for use in California, among others. The manufacturer is primarily responsible for compliance, with the importer and then the

retailer becoming responsible where the manufacturer (or the importer) fails to comply. Consequences for non-compliance include listing of the product on the Failure to Comply List on the DTSC's website, and possible DTSC enforcement action, including the imposition of fines and penalties.

The List of COCs

The list of approximately 1,200 COCs is actually comprised of the combined lists of chemicals from 22 other authoritative bodies[3]. Each COC on the list has been deemed to exhibit at least one of seven hazard traits (including carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity). There are approximately another 500 chemicals currently used only in pesticides or drugs that are excluded under the proposed regulations, but that could be added to the list in the future if the COCs are used in products that are not otherwise excluded. There are also provisions for the DTSC to add to the COC list based on a chemical's adverse impact on public health, the environment, sensitive subpopulations, and the availability of safer alternatives.

DTSC's Listing of Products

The proposed regulations require the DTSC to evaluate products to determine the adverse impacts and exposures associated with the product and its COCs, and to then publish a list of Priority Products. Specifically, the DTSC is to:

- Evaluate available information on the product's adverse impact and exposure factors;
- Assess whether, and to what extent, any of the adverse impacts and/or exposure pathways are adequately addressed by other California and federal laws and international agreements;
- List as a Priority Product one or more products determined to be of high priority;
- Consider whether there are readily-available, safer alternatives that are functionally acceptable and technically and economically feasible, and adjust the prioritization list accordingly;
- Evaluate the final Priority Products list for consistency with its set of prioritization factors and make adjustments as needed;
- Issue, no later than January 1, 2014, a Priority Product Work Plan that identifies the product categories that will be evaluated which will be aimed at identifying products to be added to the Priority Products list during the next three years;
- Publish the Priority Product list prior to January 1, 2016.

Alternatives Analyses

The manufacturer, or other entity responsible for a Priority Product, must conduct an Alternatives Analysis ("AA") for the Priority Product and submit a Preliminary AA Report and a Final AA Report to DTSC within specified timeframes. The Preliminary AA Report must be submitted no later than

180 days after the date the product is included on the final Priority Products list, unless DTSC specifies a different due date. The Final AA Report must be submitted no later than 12 months after the date the 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).

The regulations allow for a responsible entity to request a one-time extension of up to 90 days for submitting the Preliminary and/or Final AA Report, based on unanticipated circumstances. Where the Priority Product is reformulated to remove the COC that is the basis for the Priority Product listing, without adding a substitute chemical, the responsible entity may submit a Chemical of Concern Removal Notification to DTSC in lieu of conducting an AA and submitting an AA Report.

There are also education and experience requirements for those conducting the AA.

The proposed regulations include various exemptions from the AA process, including one based on a demonstration that the concentration of each COC does not exceed the applicable alternatives analysis threshold specified by the DTSC. The proposed regulations should be reviewed for other potentially-applicable exemptions.

The first stage of the AA process includes the steps listed below.

- Product requirements and function(s) of the COCs will be identified to ensure that any alternatives being considered will meet these requirements and functions. This includes a determination of whether the COC or any substitute chemical is necessary to meet the Priority Product's function, performance, and legal requirements.
- Alternatives will then be identified.
- Once the alternatives are identified, the responsible entity is to compare the various alternatives and eliminate those that pose equal or greater adverse effects.
- The responsible entity may also consider other relevant information and data not specifically identified in the regulations.
- A work plan and proposed implementation schedule is to be prepared by the responsible entity for completion of the second AA stage, as described below.

The second stage of the AA process includes the following steps.

- Identification of factors relevant for comparison of alternatives must be established by the responsible entity.
- A comparison of the Priority Product and alternatives will be conducted by the responsible entity.
- Next, an Alternative selection decision is to be made.
- The responsible entity will then conduct a consideration of additional information.

- The identification of next steps is the final step in the process. The responsible entity is required to prepare a Final AA Report that includes an implementation schedule for employing the use of the selected alternative, if any, or any proposed regulatory responses.

DTSC Review of the AA Report

Within 60 days of receipt, the DTSC will review the AA Report for compliance with the regulations and issue a notice of compliance, a notice of deficiency, or a notice of ongoing review. Notices of deficiency will generally give the responsible entity 60 days to remedy the deficiency. If the submitter of the AA Report fails to adequately and timely respond to two notices of deficiency for the Final AA Report (or one notice of deficiency for the Preliminary AA Report), the product will be placed on the Failure to Comply List.

Notices of compliance issued by the DTSC for Preliminary AA Reports 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.

Next Action by DTSC

The initial proposed list of Priority Products, which will include no more than five products, will be made available for public review and comment no later than 180 days after the effective date of the regulations.

DTSC will issue a Priority Product Work Plan by January 2014 that identifies the product categories that will be evaluated in order 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. Additionally, prior to issuing the proposed Priority Products list, DTSC will hold one or more public workshops to discuss candidate products to allow for further public review and comment.

[1]Written comments may be submitted to Kryisia Von Burg, Regulations Coordinator, Regulations Section, Department of Toxic Substances Control, P.O. Box 806, Sacramento, CA 95812-0806; e-mail address: gcregs@dtsc.ca.gov; fax number: (916) 324-1808.

[2]The complete set of proposed regulations and other information can be found at <http://www.dtsc.ca.gov/SCPRegulations.cfm>.

[3] Links to the websites containing the lists can be found at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/COC-lists-weblinks2.pdf>.