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Consumer Products “Either/Or”: California Issues Guidance on Alternatives Analysis for Safer Products

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California’s Green Chemistry Initiative has taken another step forward with the issuance of guidance on the heart of the law, the analysis of safer substitutes for chemicals in consumer products. On September 24, 2015, the California Department of Toxic Substances Control (DTSC) released its Draft Stage 1 Alternatives Analysis Guide (Guide) under its Safer Consumer Products (SCP) Program. This is the first of two stages of the alternative analysis process released in draft for public comment. The second stage is scheduled to be released during the first quarter of 2016. The DTSC also added three new chemicals to its candidate list.

The Guide is not issued as a regulation and does not have the force of law. Rather, it is designed to provide more details from the DTSC about the general process for conducting an alternative analysis for a variety of responsible entities and a diverse set of product types. The Guide also does not provide a single, specific approach for that analysis. Instead, the responsible entity must decide which approaches, assumptions, tools, methodologies, data, and decision frameworks will best suit its particular situation.

In broad overview, the framework for the alternatives analysis is set forth in the statute and previously adopted regulations:

FIRST STAGE ALTERNATIVES ANALYSIS:

- Step 1: Identify product requirements and functions of Chemical of Concern.
- Step 2: Identify alternatives.
- Step 3: Identify factors relevant for comparing alternatives.
- Step 4: Perform initial evaluation and screening of alternative replacement chemicals.
- Step 5: Consider additional information.
- Step 6: Complete preliminary alternatives analysis report.

The Guide identifies “Other Compliance Options” in cases where a responsible entity has already completed an alternatives analysis or a similar comparative analysis. The options include (1) an abridged analysis, (2) an alternate process analysis, or (3) a previously completed analysis. Upon demonstration to the DTSC that the “information and analysis for a different approach are adequate for evaluating the Priority Product and the alternatives” and the information and analysis are sufficiently equivalent to the alternatives analysis process as set forth in the SCP regulations, the responsible entity may commence work under one of these options.

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Some of the key subjects discussed in the Guide include:

Product Requirements and Alternatives

- Product function and performance – A responsible entity must describe a product’s functions and its specific applications to evaluate whether potential alternatives achieve the same or similar functions.” The function may include product characteristics and qualities. The functions of the product and the product’s Chemical of Concern must be considered in the alternatives analysis.
- Legal requirements – The specific requirements, performance standards and labeling requirements that a chemical, product or product packaging is required to meet under California or federal law must be evaluated.
- Identifying Alternatives –
 - Removing a Chemical of Concern from a Priority Product.
 - Reformulating or redesigning a Priority Product to eliminate or reduce the concentration of a Chemical of Concern in a Priority Product.
 - Redesigning a Priority Product to reduce or restrict potential exposures to a Chemical of Concern in a Priority Product.
 - Making any other change to a Priority Product that reduces the potential adverse impacts or potential exposures associated with the Chemical of Concern in a Priority Product.

Relevant Factors

- A potential factor becomes relevant if both of these requirements are met:
 - The factor makes a **material contribution** to adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life impacts, or material and resource consumption. This relates to a factor that is both meaningful and consequential to an observed outcome or impact.
 - There is a **material difference** in the factor’s contribution to the impacts between the Priority Product and one or more of the alternatives under consideration. This relates to a factor’s contribution to an observed impact that is both meaningful and consequential to the comparison of alternatives.
- Identifying relevant factors is an iterative process, part of the scoping process during both stages of the alternatives analysis process.
- The responsible entity uses relevant factors throughout the alternatives analysis process to characterize, evaluate and compare impacts of the Priority Product and its alternatives.

Impact Assessments

- Impact assessments can include the approaches, tools and information sources that a responsible entity may use to conduct its analysis.

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Screening Alternatives

- Approaches a responsible entity may use to narrow the list of alternatives will be evaluated in the second stage of the alternatives analysis.
- Alternatives that would be an improvement over the Priority Product should be retained.

DTSC is accepting comments on the Guide until October 23, 2015, and it will hold two webinars on October 7 and 21, 2015.

SCP Regulations – Proposed CANDIDATE CHEMICAL LIST AMENDMENT

Also on October 2, 2015, the DTSC proposed to add three additional chemicals: **(1) 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, (2) 4-nonylphenol, branched and linear, and 3) 4-nonylphenol, branched and linear, ethoxylated** to its Candidate Chemical List. The DTSC will hold a public hearing on November 16, 2015, and it will accept comments until then. A copy of the Guide, the Proposed Rulemaking materials and additional useful information can be found on the Green Chemistry portal web page at <http://www.mofo.com/green-chemistry>.

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