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Manufacturers of Consumer Products Face Extensive California Green Chemistry Requirements

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In a highly-anticipated new development, California's Department of Toxic Substances Control ("DTSC") issued its draft Regulation for Safer Consumer Product Alternatives to implement its innovative Green Chemistry regulatory program. The program reflects a new approach to reduce or remove potentially toxic chemicals from a wide variety of consumer products, by regulating the design of chemical products and processes to reduce or eliminate the use or generation of hazardous substances. To achieve this goal, the state legislature enacted Assembly Bill 1879 and Senate Bill 509 in 2008, which together are known as the Green Chemistry Initiative. The two bills are written in general terms, and direct DTSC to develop detailed regulations.

DTSC's new draft regulation fleshes out a process for identifying and prioritizing chemicals and the consumer products that contain them for potential additional restriction. The process consists of three main parts: Prioritization, Alternatives Assessments, and Regulatory Response. For products already on the market, this will require examining whether safer alternatives exist and, potentially, reformulating the product or having it banned entirely. For new products, this will mean looking at potential impacts and addressing them before the product is produced.

I. PRIORITIZATION

The draft regulation allows DTSC to identify and prioritize the universe of chemicals and consumer products based upon their risk or toxicity. DTSC will create a list of Chemicals Under Consideration and, from that list, select a shorter list of Chemicals of Concern that includes the highest priority chemicals. Next, DTSC will develop a list of Products Under Consideration (*i.e.*, the products that contain a Chemical of Concern), from which DTSC will create a list of Priority Products. In making this determination, DTSC will consider current use, distribution, end-of-product-life issues, and potential use by and exposure to the public, including sensitive subpopulations. The draft regulation also provides a process by which any public or private entity or individual may petition DTSC to evaluate a chemical or a consumer product for inclusion. The draft regulation, however, does not include a process to petition for removal of a chemical or product from the priority lists.

II. ALTERNATIVES ASSESSMENTS

The heart of the draft regulation is the Alternatives Assessments, which are designed to evaluate toxicity and identify alternatives that may make consumer products safer. The draft regulation requires manufacturers to prepare analyses that evaluate the components of their products, the sources of the components' raw ingredients, how the product is manufactured and used, what happens to it after its useful life, and what its effects are on health, the environment, and resources throughout its life cycle.

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The Alternatives Assessments will identify and evaluate possible alternative chemicals or product redesigns that could lessen the potential health and environmental impacts of Chemicals of Concern. Manufacturers of Priority Products must submit an Alternatives Assessment Work Plan for review by DTSC. Once the Work Plan is approved, manufacturers must complete the analysis and submit an Alternatives Assessment Report that evaluates the effects of alternative formulations or designs to eliminate or reduce the Chemical of Concern in the current product and provides information on reductions or mitigations related to health, the environment, and resources that the alternatives would achieve. The manufacturer must select an alternative it intends to implement and provide the rationale for the selection and a proposed timetable for implementation. The Alternatives Assessments must be done by a Lead Assessor, who must be accredited by DTSC or an Accrediting Body designated by DTSC. The Lead Assessor may be an independent third party, manufacturer, or trade association, but if the Assessor works for the manufacturer, the Alternatives Assessments must be verified by an independent third-party Assessor.

The Alternatives Assessments portend to be an expensive and complicated process. The quantity and quality of data to be required and the predictability of the regulatory process are as-yet unknown. DTSC may find itself attempting to manage an enormous amount of detailed and potentially conflicting scientific information. Manufacturers face testing demands with limited degrees of freedom regarding reporting uncertainty or limitations in the requested assessment.

Another concern for many manufacturers is the release of trade secrets. Information in the Alternatives Assessments will be made public unless the submitting party makes a substantiated claim of confidential business information. The statute establishes a process whereby DTSC responds to requests for information designated "trade secret" by immediately notifying the person who submitted information of the request and making a determination whether or not to disclose the information. If DTSC decides to release the information, an appeal is available.

III. REGULATORY RESPONSE

For each Alternatives Assessment Report, DTSC will select the Regulatory Response (its decision on mitigating the product's adverse impacts) that most effectively limits health or environmental threats posed by the product. The possible responses range from taking no further action to requiring a phased-in ban and recall of products already on the market, with numerous other options somewhere in between. Once DTSC notifies a manufacturer that it is subject to a Regulatory Response, the manufacturer must issue a Regulatory Response Notification informing retailers of the applicability of the Response to the product.

DTSC may conduct audits for compliance as resources allow, and the audits may focus on specific industries or products. Violations will result in enforcement actions, and proposed remedies include banning the sale or distribution of the product in California, fines, and penalties.

IV. CONCLUSION

DTSC believes the Green Chemistry Initiative will lead to safer products, fewer exposures to dangerous chemicals, and a healthier environment. The draft regulation, however, portends uncertainty with a complex and expensive program for consumer product manufacturers. Without a process to petition for removal of chemicals or products from the priority lists, the regulated universe could be extremely large. Conducting Alternatives Assessments may be a complicated and time consuming process, and maintaining confidentiality of trade secrets through the process could be challenging. Failure to comply with any of the requirements could have results as extreme as banning a product from sale in California.

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Morrison & Foerster is carefully following DTSC's rulemaking and participating with stakeholders during the notice and comment process. Comments on the draft regulation are due to DTSC by July 15, 2010. This is a critical time to contribute to the development of a workable and science-based evaluation program with broad implications both for the state and for markets worldwide.

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