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California Issues New Green Chemistry Requirements for Consumer Products

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In a highly anticipated new development, California's Department of Toxic Substances Control ("DTSC") submitted its Green Chemistry Proposed Regulation for Safer Consumer Products to the state Office of Administrative Law today, triggering the 45-day public comment and formal rulemaking process for the regulations. DTSC must adopt final regulations by January 1, 2011. The Green Chemistry regulation is DTSC's first formal rulemaking process to implement Assembly Bill 1879 and Senate Bill 509 in 2008, which together are known as the Green Chemistry Initiative. The proposed regulations further refine the draft circulated earlier this year and reflect DTSC's landmark approach to reducing or removing potentially toxic chemicals from a wide variety of consumer products.

DTSC's regulations flesh out a process for identifying and prioritizing chemicals in consumer products that that may be subject to additional restrictions, and for conducting an alternatives analysis that will enable California regulators to determine the permissible use of those chemicals in products already in the market as well as in consumer products on the drawing board. 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 manufactured.

I. PRIORITIZATION

The proposed regulations allow DTSC to identify and prioritize the universe of chemicals and consumer products based upon their risk or toxicity. DTSC will create a proposed initial list of Chemicals under Consideration by June 1, 2012, and, from that list, select a shorter proposed initial list of Priority Chemicals by July 1, 2012. Next, DTSC will develop a proposed initial list of Products under Consideration (e.g., the products that contain a Priority Chemical) by March 1, 2013, from which DTSC will create a proposed initial list of Priority Products by September 1, 2013. The final list of Priority Products will be released by December 1, 2013. 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. DTSC has also created a petition process for the public or government agencies seeking to add chemicals or products to the priority lists. Before finalizing the chemical and product lists, DTSC will post the proposed lists on its website for public review and comment. Because the proposed regulations do not include a process to petition for removal of a chemical or product from the priority lists, it will be very important for manufacturers to monitor the proposed lists and participate in the comment period before the lists become final.

II. ALTERNATIVES ASSESSMENTS

The heart of the proposed regulations is the Alternatives Assessments, which are designed to evaluate toxicity and identify alternatives that may make consumer products safer. The proposed regulations require manufacturers to prepare analyses that evaluate the components of their products, the sources of the components' raw ingredients, how the product

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is manufactured and used, what happens to it after its useful life, and what effects it may have on health, the environment, and resources throughout its life cycle. The Alternatives Assessments will identify and evaluate possible alternative chemicals or product redesigns that could lessen the potential health and environmental impacts of Priority Chemicals. The proposed regulations do not set timelines for when manufacturers must submit the Alternatives Assessments, which may be one of the areas on which members of the public can offer comments.

A. Early Chemical Substitutions

After a chemical has been listed as a Chemical under Consideration or Priority Chemical, manufacturers must submit an Alternatives Assessment Notification if they reformulate or redesign products containing the chemical to remove or reduce the concentration of that chemical or replace the original product with an alternative product. The Notification must include either a Tier I Alternatives Assessment or include specific information regarding the rationale for the change, reductions to adverse public health or environmental impacts, and identification of any hazardous traits of any substitute chemicals. This process will enable DTSC to quickly determine whether the new product should be listed as a Priority Product.

B. Tier II Alternatives Assessments

Manufacturers of Priority Products must complete a more extensive Tier II Alternatives Assessment. First, manufacturers must submit an Alternatives Assessment Work Plan for review by DTSC. Once the Work Plan is approved, manufacturers must complete the Alternatives Assessment consisting of a Chemical Hazard Assessment, an Exposure Potential Assessment, and a Multimedia Life Cycle Evaluation. The Alternatives Assessment evaluates the effects of alternative formulations or designs to eliminate or reduce the Priority Chemical 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.

A major concern for regulated parties is the release of trade secrets. Information in the Alternatives Assessments will be made public unless the submitting party makes a substantiated claim of trade secret information. The proposed regulations establish a process whereby DTSC responds to requests for information designated as a "trade secret" by immediately notifying the person who submitted information about the request and making a determination of 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

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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 California 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. DTSC will issue a Notice of Non-Compliance to responsible entities and others in the supply chain for failure to satisfy a requirement. If the non-compliance is not remedied, information about the product and its supply chain will be posted on a Failure to Comply List on DTSC's website. Violations may also result in enforcement actions, including imposition of fines and penalties.

IV. IMPORTANT CHANGES SINCE THE JUNE 2010 DRAFT

DTSC issued a prior draft of the regulations in June 2010 and reviewed comments submitted in response to the draft. Much of the proposed regulation remains the same, but there are several significant differences:

- **Potential for More Regulated Chemicals:** DTSC has widened the scope of the regulations by expanding the list of authoritative bodies that could be consulted in creating the Priority Chemicals list. This means that DTSC will likely have a broader list of chemicals to choose from when determining which chemicals should be considered Priority Chemicals.
- **Stricter Regulatory Deadlines:** The new draft proposes deadlines for creating the priority lists and provides a tiered approach to Alternatives Assessments.
- **Increased Public Participation:** The new draft also increases opportunity for public comment on DTSC actions throughout the process.

V. CONCLUSION

DTSC believes the Green Chemistry Initiative will lead to safer products, fewer exposures to dangerous chemicals, and a healthier environment. The proposed regulations, however, portend 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 throughout 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.

Morrison & Foerster is carefully following DTSC's rulemaking and participating with stakeholders during the notice and comment process. Comments on the proposed regulations are due to DTSC by November 1, 2010. DTSC has set a public hearing on that date. This is a critical time to contribute to the development of a workable and science-based evaluation program with broad implications both for California and for markets worldwide.

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