



October 2010

PRODUCT LIABILITY UPDATE

Proposed California Green Chemistry Regulations to Impose New Requirements*Companies Have Until November 1 to Provide Comments*

California's Department of Toxic Substances Control (DTSC) recently proposed groundbreaking Green Chemistry Initiative regulations ("the regulations"). The regulations, which will affect a broad array of consumer products, establish a process for the identification and prioritization of "Chemicals of Concern" contained in consumer products and require "Responsible Entities" to conduct performance evaluations of alternatives to such chemicals.

Responsible Entities are any and all businesses in the chain of consumer product distribution, including manufacturers, brand name owners, importers, distributors, or retailers. Products that contain a "Priority Chemical" can be banned or the Responsible Entities can be required to:

- Provide certain information to the customer in the form of a product insert or labeling on the product itself;
- Institute a take-back program under which the consumer can return the used consumer product to the Responsible Entity for proper disposal; or
- Engineer safety measures.

Responsible Entities have the burden to identify and report to the DTSC the identity of chemicals contained in their consumer products and to analyze safer alternatives to chemicals identified by the DTSC as Priority Chemicals.

BACKGROUND OF THE REGULATIONS

In 2008, California's legislature passed legislation requiring the DTSC to have these regulations in place by January 1, 2011. Previously, an increasing number of chemical-specific bills were introduced to ban particular chemicals or restrict their use in certain products. The Green Chemistry Initiative regulations are an attempt to create a systematic regulatory process that potentially addresses all chemicals. The current draft of the regulations is the product of two years of stakeholder and public involvement. Comments on these proposed final regulations must be submitted to the DTSC no later than November 1, 2010.



THE REGULATIONS' REACH EXTENDS BEYOND CALIFORNIA

The regulations apply to any product that is placed “into the stream of commerce in California.” This is defined as when a person sells, offers for sale, distributes, supplies, or otherwise transfers control over the disposition of a consumer product directly to a California consumer, or to another person without maintaining sufficient control over the distribution, sale, supply, or other transfer of the consumer product by that person to prevent the use of the consumer product by a California consumer. Thus, even where a Responsible Entity itself does not sell or distribute its products to a California consumer, the Responsible Entity must still abide by the regulations unless it takes affirmative steps to insure that its products are not used by a California consumer.

FOUR-STAGE PROCESS REQUIRED TO IDENTIFY PRIORITY CHEMICALS AND PRODUCTS

The regulations specify the process by which the DTSC will prepare a list of Priority Chemicals that will be used to prepare a list of “Priority Products” that will be regulated. After the DTSC exhausts all publicly available information regarding the chemicals used in consumer products, it can require Responsible Entities to submit a host of product information, including identification of the chemicals contained in the product, sales volumes and locations, and target customer bases.

The DTSC will then prepare a list of “Chemicals Under Consideration,” considering factors including each chemical’s:

- Physical and chemical properties;
- Potential for adverse public health impact;
- Adverse ecological impacts;
- Adverse environmental impact;
- Dispersive volume information;
- Potential for the public or environment to be exposed in commonly used products;
- Existence of data and other information relating to actual or potential public or environmental exposure; and
- Extent of regulation by other California state or federal regulatory programs.

DTSC will identify Priority Chemicals from the list of Chemicals Under Consideration. Next, by cross-referencing its list of Priority Chemicals with information from the Responsible Entities, the DTSC will then identify what products contain Priority Chemicals and place those products on the list of “Products Under Consideration.” From that list, DTSC will prepare a list of Priority Products.



There are three regulatory exemptions: if the product is already regulated by another governmental entity to address environmental and public health impacts; if there is no exposure pathway for the Priority Chemical contained in the product to threaten the environment or public health; or if the product only contains a *de minimis* concentration of the Priority Chemical.

PRIORITY PRODUCTS SUBJECT TO ALTERNATIVE ASSESSMENT REQUIREMENT

The regulations place the potentially onerous burden on a Responsible Entity to submit an “Alternative Assessment” for each Priority Product. The Assessment includes a chemical hazard assessment, exposure potential assessment and multimedia life cycle evaluation. The multimedia life cycle evaluation is a comparison of a possible alternative to the Priority Chemical it would replace and must include an assessment of the following factors:

- Product function and performance;
- Materials and resource consumption impacts;
- Environmental impacts; and
- Economic impacts of each possible alternative.

Ultimately, the Alternative Assessment must address whether a safer substitute for the Priority Chemical is available and then demonstrate that the alternative would have no adverse impacts on public health or the environment.

Upon receipt of the Alternative Assessment, the DTSC has authority to take a range of actions regarding a product that contains a Priority Chemical. The DTSC may ban the product upon a showing that there is a functionally equivalent alternative that is safer, available, and affordable. Additionally, as explained above, DTSC can restrict the use of the product and/or require the Responsible Entity to provide a product insert or labeling on the product itself, institute a take-back program, or engineer safety measures.

A Responsible Entity, other than a manufacturer, may avoid the requirement to submit an Alternative Assessment or provide other product information to the DTSC if the Responsible Entity ceases to place the product into the stream of commerce in California and notifies the DTSC that it has done so. That notification also must provide the DTSC with the location of all known product sales outlets; name and contact of the person immediately upstream in the product chain of supply; name and contact information for all individuals known to be in the chain of supply; brand names under which the Responsible Entity placed the product into commerce; a copy of all information contained on the product label, package and insert; and documentation demonstrating that the Responsible Entity had a contractual agreement with its product supplier requiring the supplier to comply with the Green Chemistry Initiative regulations.



NANOMATERIALS

Consumer products containing “Nanomaterials” are also subject to the new regulations. Nanomaterials are included in the definition of “Chemical.” Further, one of the physical properties of a chemical to be considered by DTSC in compiling the list of Chemicals Under Consideration is its physical, chemical, or quantum properties specific to Nanomaterials. Nanomaterials also are specifically excluded from any *de minimis* exemption. Thus, Nanomaterials in and of themselves, separate from their chemical composition, will be considered and can be listed as Priority Chemicals.

DTSC ENFORCEMENT AUTHORITY

The DTSC will post and maintain on its website a list of all Responsible Entities that fail to comply with the regulations. The listed information will include for each product in non-compliance the brand name of the product, Priority Chemicals contained in the product, and the name and contact information of the Responsible Entities. A non-complying Responsible Entity is also subject to various enforcement actions, fines, and penalties.

TIMELINE FOR IMPLEMENTATION OF REGULATIONS

The regulations require the proposed list of Chemicals Under Consideration to be issued for public comment by June 1, 2011, with the final list to be issued by March 1, 2012. The proposed initial list of Priority Chemicals must be issued by July 1, 2012. The proposed initial list of Products Under Consideration must be issued by March 1, 2013. The proposed list of Priority Products must be issued by September 1, 2013, and the final list of Priority Products must be issued by December 1, 2013.

PLAN AHEAD FOR COMPLIANCE

Businesses, trade associations, and other stakeholders interested in this regulation should consider submitting comments by the November 1, 2010 deadline. At the same time, Responsible Entities should anticipate that the DTSC will require the submission of information well in advance of issuing its list of Priority Products in September 2013, which will be finalized by December 2013. Indeed, since the process of identifying Priority Chemicals will begin much earlier with the identification of Chemicals Under Consideration, which will be issued in the first half of 2011, the DTSC may require consumer product information from Responsible Entities in early 2011. Responsible Entities should consider the following actions in order to best prepare for the Green Chemistry regulations:

- Conduct an audit of consumer products to determine whether any chemicals the DTSC is seeking to regulate or ban are contained in such products, which may require significant planning and resources;
- Request product information from suppliers if such information is not already on hand;



- Review and, if necessary, amend supplier agreements to require that suppliers agree to comply with the regulations and ensure the risks of non-compliance with the regulations are properly allocated;
- Review Material Safety Data Sheets provided to customers and those received from suppliers in light of the new regulations;
- Monitor the DTSC's process to gain an understanding of the chemicals that are being considered so that the Responsible Entity can plan accordingly;
- Consider challenging the DTSC's determinations regarding Priority Chemicals and Products; and
- Consider alternative ingredients for affected consumer products.

These issues should be considered in the next few months and continuously as the DTSC prepares its lists of Priority Chemicals and Products so that the Responsible Entity has adequate time to prepare for and comply with the regulations.

FOR MORE INFORMATION

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