

Broad Scope and Impact of California “Green Chemistry” Regulations

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New draft “Green Chemistry” regulations released by California’s Department of Toxic Substances Control are expected to impose substantial requirements on manufacturers, importers and retailers nationwide of a number of consumer products distributed in California.

California recently released an updated draft of its “Green Chemistry” regulations, which, if finalized, would apply to approximately 3,000 chemicals and impose new requirements on manufacturers, importers and retailers of a number of consumer products. In addition to affecting the regulation of toxic chemicals in California, these draft regulations could impact reform of the federal Toxic Substances Control Act (TSCA). As previously discussed in [TSCA Reform in the House & Senate: Extending EPA’s REACH](#), bills were introduced in the U.S. Senate and House of Representatives in April 2010 and July 2010, respectively, which proposed to amend TSCA, the statute that authorizes the U.S. Environmental Protection Agency (EPA) to regulate the safety of a broader range of chemicals distributed in commerce.

TSCA is the only major environmental statute that has not been reauthorized since its original enactment in 1976. TSCA reform, as proposed by the 2010 and 2011 bills, would substantially expand chemical testing, reporting and disclosure requirements. If the EPA were to look to California for guidance in promulgating updated regulations under TSCA, the resulting federal regulations could place new burdens on parties involved in the production and distribution of many consumer products.

In 2008 California enacted into law Assembly Bill 1879 (AB 1879) and Senate Bill 509 (SB 509) as the Green Chemistry statute. It requires a life-cycle “alternatives assessment” of hazardous chemicals contained in consumer products, in order to consider potential substitutes for such chemicals based on the risks they pose during the use of such products and after product disposal. The Green Chemistry statute also requires California’s Department of Toxic Substances Control (DTSC) to implement regulations under the statute by January 1, 2011. The DTSC issued draft regulations three times in 2010, withdrawing the drafts each time following public comment. On October 31, 2011, DTSC issued another draft of the regulations.

The draft regulations, as currently proposed, would apply to any consumer product that contains a listed Chemical of Concern (COC) and is sold or otherwise distributed or manufactured in California. The draft regulations, like TSCA, do not apply to certain products, such as medical devices and prescription drugs. They do apply to all “responsible entities,” which include consumer products manufacturers, importers and retailers. However, the draft regulations place the primary duty to comply on manufacturers. Importers are subject to the duties of responsible entities with

respect to a product only if a manufacturer has failed to comply; similarly, retailers are subject to these duties only if the manufacturer and importer, if applicable, have failed to comply and the retailer has been notified of this noncompliance by the DTSC.

Finally, the regulations impose a four-step procedure for identifying substitute chemicals so as to ensure the safety of consumer products.

- Step 1: The DTSC must create and post online a list of COCs within 30 days of the effective date of the regulations. The DTSC estimates this list will include approximately 3,000 chemicals. Listed COCs must be hazardous and must be identified on one or more government lists or by a reliable scientific source as exhibiting a hazard trait or an “environmental or toxicological endpoint.”
- Step 2: Using the COC list, the DTSC must then create a list of Priority Products containing listed COCs. These products will be identified using the following criteria: whether they contain COCs that pose a risk to public health and the environment; whether they are widely distributed and used; whether use of the products may expose individuals to COCs sufficient to have an adverse impact; for assembled products, whether exposure may occur by inhalation or skin contact; and, for formulated products, whether the product is intended to be applied to the body, dispersed as an aerosol or applied to surfaces where there is a likelihood of runoff.
- Step 3: A responsible entity (the manufacturer, importer or retailer) for a consumer product must notify the DTSC within 60 days after the DTSC listing of that product as a Priority Product. The responsible entity must then conduct an alternatives assessment (AA) to identify potential negative effects of the COC in the product. The AA occurs in two stages. First, within 180 days after a consumer product is listed on the Priority Products list, the responsible entity must submit a Preliminary AA Report to the DTSC identifying product criteria, stating whether the COC or a replacement chemical is necessary to the product and identifying and assessing substitute chemicals, and propose a work plan for the second stage of the AA. Second, within 12 months of DTSC’s issuance of a notice of compliance for the Preliminary AA Report, the responsible entity must perform a more detailed evaluation of substitute chemicals, choose a replacement chemical for the product or determine not to modify the product and submit a Final AA Report to DTSC.
- Step 4: The DTSC must respond to both the Preliminary and Final AA Reports within 60 days of their receipt by issuing a preliminary notice of compliance or notice of deficiency. If a notice of deficiency is issued, the responsible entity must address the issues identified in that notice, at which time the DTSC must issue a final notice of compliance or notice of disapproval. In most cases, the DTSC must also develop a Regulatory Response to the Final AA Report, such as by requiring information about the product to be shared with consumers if the product contains a COC above a *de minimis* level or if the manufacturer elects not to modify the product. The DTSC may also respond by prohibiting sale of the product, requiring safety control

measures to be implemented, restricting use of the COC in the product, or requiring more information or additional AAs. The DTSC need not respond to the AA if the chosen substitute product does not contain a COC above the *de minimis* level or does not significantly impact public health or the environment. The draft regulations also require responsible entities to set up and maintain an end-of-life stewardship program for any product that would constitute a hazardous waste in California when discarded.

The draft regulations provide the DTSC with substantial enforcement authority, including the authority to establish a publicly posted Failure to Comply list. The DTSC would also be permitted to issue notices of noncompliance to non-complying parties and to add specific information about the product's noncompliance to the Failure to Comply list if an instance of noncompliance is not abated. In addition, the DTSC would have the authority to conduct compliance audits.

The proposed California regulations, like the TSCA bill now before the Senate, provide a broad grant of authority to the agency administering the program (*i.e.*, the DTSC). It also contains similar provisions with respect to administrative and judicial review of DTSC actions. However, in contrast to the proposed TSCA bill that provides protection for various types of confidential business information, the draft regulations only protect trade secrets.

The public comment period for the draft regulations ends December 30, 2011. At that point, the DTSC is expected to develop formal proposed regulations and seek further public comment on those regulations before they are adopted. If adopted, these regulations will significantly affect many industries in California, as well as products brought into or sold in the state. Consequently, the number and nature of the comments submitted are expected to be quite significant.

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