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ENVIRONMENT

California's Green Chemistry initiative has a long REACH

By Chris M. Amantea

The implications of California's Green Chemistry initiative are far REACHing. Many companies have viewed the initiative in the context of doing business primarily in California, but have not considered the implications presented by the many overlapping and conflicting regulatory schemes that govern the manufacturing, importing, distribution and marketing of consumer products and chemicals. For those companies doing business nationally and internationally, the initiative reach is global.

In September 2008, California's initiative became law. Since then, California EPA's Department of Toxic Substances Control (DTSC), which is charged with implementing the law, has been on a roller coaster in its efforts to adopt regulations that both industry stakeholders and environmental groups find acceptable. DTSC has released several drafts of its proposed Safer Consumer Product (SCP) regulations. On Jan. 29, DTSC released a draft which reportedly was intended to address many of the comments from the July 2012 draft. Then, on April 10, DTSC surprised the regulated community and stakeholders by issuing yet another draft. Comments on this latest version of the SCP regulations are due by April 25. The regulations are expected to be finalized in summer or fall 2013.

One of the most significant factors facing companies today is determining how new regulations will interface with the many state, federal and international laws that have been implemented over the years, many of which have overlapping and conflicting provisions, such as California's Safe Drinking Water & Toxic Enforcement Act (Proposition 65), the federal Toxic Substances Control Act, the federal Consumer Product Safety Improvement Act, the Federal Insecticide, Fungicide & Rodenticide Act, the FTC's Green Guides, and the EU's REACH (an acronym for Registration, Evaluation, Authorization, and Restriction of Chemicals).

The SCP regulations would have a major impact on virtually all companies manufacturing, importing, selling or distributing consumer products in or into California, regardless of where they are manufactured or produced. "Consumer product" is broadly defined to include "a product or part of the product that is used, brought, or leased for use by a person for any purposes." The stated goal of the regulations is to phase out the use of so-called "chemicals of concern," cause the reformulation of products that are designated as "priority products," or to ban their sale, manufacture, import or distribution in California.

Four-step process

The proposed regulations establish "a four-step continuous, science-based, iterative process

to identify safer consumer product alternatives":

1. Development of a list of candidate chemicals

The regulations establish an immediate list of approximately 3,000 candidate chemicals (CCs). The initial CCs include (i) all chemicals listed under California's Prop. 65 as carcinogens or reproductive toxins; (ii) chemicals classified as causing mutagenic effects under regulations of the EU; and (iii) chemicals that the U.S. EPA has determined are persistent in the environment, bioaccumulate and are toxic. Subsequently, additional chemicals will be listed based on a number of factors identified in the proposed regulations.

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2. Prioritization of products

DTSC will then evaluate and prioritize product-CC combinations and develop a list of "priority products." Following this analysis, DTSC will assess whether other laws already provide adequate protection of public health and/or the environment, and decide whether listing the product as a priority product will actually have any meaningful impact. Under the draft regulations, DTSC has the authority to demand product information from responsible entities and chemical manufacturers/importers. Retailers will be required to obtain a certificate of compliance from the manufacturer or supplier for each priority product stating that, as applied to the specific product, the manufacturer is in compliance with (or exempt from) the SCP regulations.

3. Notification by responsible entities and product alternatives analysis

The responsible entities (manufacturers, importers and retailers) are required to notify DTSC when their product(s) are listed on the priority products list. The responsible entities of a product listed as a priority product are then required to perform an alternatives analysis (AA) for the product (and the CCs in the product) to determine how best to limit exposures to, or the level of adverse public health and environmental impacts posed by, the product. A short timeframe is proposed for this process, which could involve significant research and development, and take months or longer. The requirement in the July 2012 draft that the AA must be conducted by a certified assessor has been eliminated. However, in its place, the draft SCP regulations now require a public review and comment process for Preliminary AA Reports, Alternate Process AA Work Plans, and draft Abridged AA Reports. The final report will be required to include a summary of the public comments received and how the comments are addressed in the report.

4. Regulatory responses

The regulations give DTSC broad authority

to implement an array of potentially draconian regulatory responses to protect public health and the environment from the sale or use of priority products, such as prohibiting the sale of the product, requiring detailed product information to be provided to consumers, restricting the use of the product, and establishing and funding an end-of-life product management program, among others.

Common "global" themes

Several "global" common themes and trends have emerged in the regulation of products and chemicals:

First, registration and notification requirements for chemicals and products are increasing, particularly those relating to new chemicals and with products containing those chemicals. However, as with the SCP regulations (which may herald the beginning of a new global trend), regulation of chemicals in existing products also is on the rise.

Second, broader and more frequent reporting of chemical information, including reporting relating to existing products. For example, environmental regulatory agencies nationally and internationally are requiring a wider range of data and imposing lower volume thresholds for triggering a reporting obligation. The data required to be reported often involves information that companies perceive as trade secret or business confidential.

Third, less protection for chemical and product information that is reported. As a corollary to the broader information reporting requirements noted above, regulatory agencies more frequently are providing less protections for trade secret or business confidential information. As a result, companies have increasing concerns about the potential for this type of information to get into the hands of their competitors.

Fourth, the identification of priority chemicals and products for hazard characterization and for risk assessment. As with California's SCP regulations, these requirements often are ultimately intended to encourage reformulation or selection of a safer chemical alternative.

Fifth, increasing national and international cooperation and sharing of information and technical expertise amongst environmental regulatory agencies. For example, in January 2012, US EPA and DTSC entered into a "cooperation agreement" under which DTSC and US EPA agreed to cooperate in reducing toxic chemicals in consumer products. The stated objective of the agreement is to facilitate technical support and collaboration between DTSC and EPA on "advancing the science of alternative assessment," as well as the "development of chemical information databases." The alliance has been touted by DTSC as a way to "minimize duplication of effort and promote consistency in methodology" between the two agencies. However, these types of arrangements may (and often do)

result in more vigorous enforcement activity.

Overlapping schemes

One of the most significant issues is how the proposed SCP regulations will interface other laws that have been implemented over the years to address chemicals in consumer products. Companies doing business nationally and internationally must evaluate for the various regulatory schemes, including the SCP regulations, among other things:

What is the scope of products and/or chemicals covered? For example, some laws apply to "chemicals," others to "substances," or "products," or "consumer products," or "household products." All of these may be defined differently but could include some of the same products.

What are threshold levels are applicable? For example, the SCP regulations adopt certain chemical lists from various state, federal, and international laws, such as Prop. 65 and REACH. Each of these laws and regulations contain, for the most part, different threshold levels for chemicals and/or different processes for analyzing and determining the concentrations of a chemical in a product. Also, some jurisdictions may allow exemptions that are not applicable in other jurisdictions. The draft SCP regulations, for example, provide a *de minimis* exemption for products that contain so-called *de minimis* levels of CCs, but such exemptions may not apply elsewhere.

Which jurisdictions require reformulation? If a jurisdiction requires reformulation of a product, how will that impact the manufacturing, importing and distribution of the product in other jurisdictions? This raises a whole host of issues, such as whether the reformulated product can be sold as is in another jurisdiction or whether the reformulation contravenes another jurisdiction's requirements.

What other statutory or regulatory requirements may be applicable? For example, some statutory and/or regulatory schemes for products and chemicals contain detailed labeling requirements, which may differ in many ways amongst the various jurisdictions where companies do business (size, color, listing of hazards, etc.).

What are competitors doing? Under the SCP regulations, any person (including competitors and private citizens) may petition DTSC to evaluate a chemical or product.



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