Washington: California Is Setting Precedent

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The California Department of Toxic Substances Control (DTSC) released on June 23, 2010, draft regulations implementing California's precedent-setting and game-changing Green Chemistry Initiative.

Manufacturers need to understand how this controversial regulatory program may operate, and why it will alter forever the way consumer products are designed and manufactured.

Overview of Draft Regulations

Driven by a relentless quest to ensure that consumer products are designed and manufactured in a way that diminishes the toxic chemicals in them, Gov. Arnold Schwarzenegger signed the Green Chemistry Initiative into law in 2008. This requires DTSC to identify, review and prioritize "chemicals of concern" used in consumer products. A goal of the law also is to stimulate innovation in the product development sector.

Since 2008, DTSC has been balancing the need to implement the law and addressing the concerns of a very engaged consumer product community. An earlier straw proposal was met with intense criticism by industry stakeholders.

DTSC states the draft regulations "would prioritize toxic chemicals and products, require manufacturers to seek safer alternatives to toxic chemicals in their products and create tough governmental responses for lack of compliance."

Under the draft regulations, DTSC would create a list of chemicals that it deems toxic and believes could harm people or the environment. Products containing those chemicals would be prioritized based on such factors as the volume in commerce, the extent of exposure and how the product is eventually managed end of life. Manufacturers would be required to perform an alternatives assessment to determine if a safer alternative is available.

DTSC says the draft regulations call for three phases: Phase 1, the prioritization process, during which DTSC will identify and prioritize chemicals of concern and products that contain them for those priority products identified in Phase 1; Phase 2 is an alternatives assessment, conducted by the product manufacturers, to identify safer alternatives; and Phase 3, when DTSC will impose various regulatory response actions to address any concerns raised by the alternatives selected by manufacturers for implementation and to move manufacturers to design safer products.

DTSC states that draft regulations will first identify chemicals that pose public health and environmental threats, and are most prevalent in consumer products. DTSC will narrow the list of chemicals under consideration to a list of chemicals of concern. Once DTSC establishes the final chemicals of concern list, DTSC will create two product lists.

The first – the Products under Consideration list – will include products that pose public health and environmental threats because they contain chemicals of concern. From that list, DTSC will identify and list Priority Products – those products that are of the highest priority based on the relative degree of public health and environmental threats posed by the product due to the chemical of concern contained in the product. According to DTSC, it will use a number of factors to make this determination, including the chemical in the product, current use, distribution, end-of-product-life issues and potential use by and exposure to the public, including sensitive subpopulations.

DTSC will require manufacturers to submit information describing the types, categories and classes of products containing chemicals of concern and will post information on its website. DTSC will create an online database providing data on chemical toxicity and hazard traits, and will publish on its website "a list of manufacturers and their product types that are out of compliance with the regulation." The draft regulations would require manufacturers to notify retailers if DTSC has determined that their product cannot be sold in California.

Once DTSC identifies a product as a priority product, the manufacturer must perform an alternatives assessment – a process that evaluates toxicity and other information concerning the chemicals of concern in the product, and compares those data to alternative chemicals or product redesigns that may make that product safer. After the alternatives assessment is complete, if the product alternative selected by the manufacturer still contains a chemical of concern, and DTSC determines there is a safer alternative "that is functionally equivalent, and technologically and economically feasible," DTSC will impose a sales ban on that product within two years.

Manufacturers would be able to sell products that contain chemicals of concern while the chemical and product are going through the prioritization and alternatives assessment phases of the regulation, "as long as the manufacturer remains in compliance with the regulatory requirements that apply to the product." The manufacturer would have a one-year opportunity to submit a revised alternatives assessment.

Unlike DTSC's straw proposal, the draft regulations do not designate any chemicals for inclusion on the lists of chemicals under consideration or chemicals of concern. Under the draft regulations, DTSC would be required to review and revise the lists of chemicals under consideration and chemicals of concern at least every three years.

Concerns with the Proposal

There are many concerns with the proposal. First, on an administrative level, the deadline for submitting comments was very short, although the DTSC says there may be another opportunity to comment. According to its website, DTSC "may revise the draft regulation based on comments received and will release the revised draft following the July 15 comment deadline. The formal Administrative Procedures Act (APA) rulemaking process will begin with the release of that draft." The APA process calls for public hearings and a 45-day comment period. DTSC states that it will announce specific information about the APA process "when the final draft regulation is available for review."

Second, the breadth of the criteria for identifying chemicals and products of concern virtually ensure that few chemicals will be excluded from the process. Third, the prioritization process includes factors to be considered that are inherently open-ended and subject to broad interpretation. For example, factors in making the determination of what is a "priority product" include the chemical, its current uses, distribution, end-of-product life issues and potential use by and exposure to the public, including sensitive subpopulations.

Fourth, the "alternatives assessment process" is equally open-ended. For example, an alternatives assessment report must include a product lifecycle analysis that takes into account product function and performance, human health and environmental impacts, materials and resource consumption, economic impacts and "other information as needed." None of these criterion is well-defined, and the application of each in an alternatives assessment analysis could lead to materially different results depending upon how each criterion is calibrated and applied.

Fifth, "trade secret" status will be difficult to achieve. The information submitted under the regulation is presumptively public unless proven otherwise. Sixth, "nanoscale" is de fined to mean one or more dimensions of the order of 1,000 nanometers or less, a definition un like virtually all other definitions of nanoscale propounded by regulatory or standard-setting organizations.

Finally, the regulation authorizes the imposition of a sales ban. The terms and conditions under which a ban may be imposed are particularly disturbing to product manufacturers given the draconian consequences that would flow from application of such a ban.

There are many important issues raised by the draft regulations. Because this is a precedent-setting initiative, it will have significant national and international product marking implications. Stakeholders are urged to review the proposal carefully and provide comment.

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