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CALIFORNIA**GREEN CHEMISTRY**

Following a period of redrafting, California's Department of Toxic Substances Control recently issued its revised Safer Consumer Products Proposed Regulations (making changes to the October 2011 Informal Draft regulations). The proposed regulations are part of DTSC's Green Chemistry Initiative, which seeks to reduce the use of toxic chemicals in manufacturing. The proposed regulations contain numerous substantive revisions responding to input provided by the Green Ribbon Science Panel which met at Cal-EPA Headquarters last November.

California Pares Back Green Chemistry Initiative in Latest Draft Regulation

By **KEITH B. WALKER**

Most notable among the changes made to the Green Chemistry proposal, the number Chemicals of Concern (COCs) to be regulated in Priority Products, to be designated by DTSC, has been re-

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duced from over 3,000 chemicals (as previously anticipated) to approximately 1,200. Also, possibly in response to comments from the Panel, the lists of hazardous materials and toxic substances from which the COCs are drawn has been narrowed by imposing more stringent criteria.

DTSC has not yet indicated the Priority Products that will be regulated for concentrations of COCs, however, which is the multimillion-dollar question. Another key question is how the costs of implementing the initiative will be funded—a topic that underlies nearly all discussions regarding the regulations.

Background

The Green Chemistry Initiative, a front-end pollution regulation established through two companion bills (Assembly Bill 1879 and Senate Bill 509), reflects Cal-EPA's desire to reduce pollution at the point of origin by reducing the use of toxic chemicals in manufacturing. More specifically, the Green Chemistry Initiative focuses on the use of COCs in products to be sold in California. If adopted, the regulation would require manufacturers to review the COCs to be included in designated Priority Products and then determine whether less-toxic chemicals could be substituted in their place.

The Four Steps to Identifying Safer Consumer Product Alternatives

DTSC described its approach to identifying safer consumer product alternatives as a continuous, four-step, science-based iterative process. First, DTSC will establish its list of COCs. Then, it will evaluate and prioritize product/COC combinations to develop a list of Priority Products for which an Alternatives Assessment must be prepared. The purpose of the Alternatives Assessment is to require that manufacturers evaluate ways to reduce or eliminate COC concentrations. Third, DTSC will require that manufacturers perform an Alternatives Assessment for their Priority Products to determine how best to reduce the use of—and exposure to—COCs and to limit environmental impacts. Fourth, DTSC will evaluate the manufacturer's Alternatives Assessment, with responses that range from requiring additional information and/or submittal of another assessment, to potentially prohibiting the sale of the Priority Product within California.

The List of COCs

Although the number of potential COCs to be regulated in Priority Products has significantly decreased, the goal has remained the same: to identify chemicals that (1) exhibit a hazard trait or an environmental or toxicological endpoint (specified in regulations enacted by the Office of Environmental Health Hazard Assessment (OEHHA)) and (2) are listed or identified by one or more authoritative bodies specified by the regulations. In addition, DTSC may designate additional COCs based on potential adverse impacts, especially in the context of special considerations that include (i) children, pregnant women, and other sensitive sub-populations; (ii) environmentally sensitive habitats, endangered and threatened species, and environments in California designated as impaired; and (iii) widespread adverse public health and/or environmental impacts.

DTSC has also expressed that a main objective in composing its list of COCs is to send a signal to the marketplace regarding the substances designated as potential concerns, and to enable DTSC to move ahead expeditiously with respect to identifying Priority Products that contain one or more COCs. Another of DTSC's key objectives is to prevent manufacturers from being able to make a "regrettable substitution" by swapping out a COC with a chemical that is no better—or potentially worse—than the COC, merely because the alternative chemical had not been listed. Ultimately, the initial list of COCs seems less significant than the list of the Priority Products to be regulated. This Priority Product list will set the initial parameters of DTSC's initiative and kick-start industry's response to the pending requirements.

Prioritization of Products

The Priority Product list will set the initial parameters of DTSC's initiative. The factors to be considered by DTSC in composing its Priority Product list include (1) potential adverse impacts posed by the COCs; (2) potential exposures resulting from the presence of the COCs in the Priority Products; and (3) the availability of information indicating the potential adverse impacts and exposures posed by the COCs. DTSC has further expressed that singling out specific products would not be legally defensible, as opposed to identifying particu-

lar Priority Product/COC combinations that focus not on the nature of the product but on the COCs within the products.

Narrowing the initial focus of its regulations, DTSC has expressed that its initial list of Priority Products will include no more than five product-chemical combinations. Part of the professed benefit of the conservative scope is to enable DTSC to experiment with the implementation of its initiative on a small scale, as it prepares to expand the list of Priority Products. In addition, this pilot program approach seems to reflect DTSC's pragmatic budget considerations.

At this point, it remains unclear when DTSC will issue its list of Priority Products.

Alternatives Assessments

There are two stages to the Alternatives Assessment (AA) process. In the first stage, the responsible entity must identify the function, performance, technical feasibility, and legal requirements associated with the Priority Product, and evaluate the feasibility of excluding COCs. Next, the responsible entity must identify chemical alternatives to the COCs in the Priority Product, collect and evaluate information identifying adverse public health and environmental impacts associated with each alternative chemical, and develop a work plan for implementation of Alternatives Assessment's second stage. This information must then be submitted to DTSC in the form of a "Preliminary AA Report." In Stage 2, responsible entities must identify relevant factors for comparing alternative product formulations, compare the Priority Product with the alternatives, select the alternative that will replace or modify the Priority Product, and then submit these analyses to DTSC in a detailed "Final AA Report."

Enforcement

In the November 2010 draft regulations, the primary responsibility for compliance was limited to the manufacturer. Expanding the scope of DTSC's authority, however, the current draft regulations impose requirements on (1) the person who controls the design of the product, (2) the U.S. importer and, potentially, (3) the retailer. The principal compliance duty remains with the manufacturer. If the manufacturer does not comply, however, then the duty applies next to the importer, if there is one. If there is no importer, or if both the manufacturer and importer fail to comply, then DTSC may shift the responsibility for compliance to the retailer. DTSC anticipates that manufacturers will retain the principal duty for compliance, and that the burden shift to the retailer will most commonly occur when DTSC lacks authority over an overseas manufacturer or importer.

If these parties fail to comply, or if an otherwise-complying party submits an Alternatives Assessment that fails to select a safer alternative for a COC (and DTSC determines that a safer alternative exists), the responsible party has one year to ensure that the Priority Product is no longer sold in California. In addition, the responsible party must complete an inventory recall program within three years. To avoid these requirements, the responsible party must submit to DTSC an Alternatives Assessment selecting an alternative that does not contain a COC.

What Has Changed

The proposed 2012 regulations differ from the October 2011 Informal Draft regulations in several important ways:

Chemical-Product Prioritization

- The COC list has been reduced to approximately 1,200 chemicals, down from 3,000.
- DTSC has announced that it will list only five Priority Products—containing one or more COCs that (a) exhibit one or more hazard traits and (b) are listed on one of the exposure indicator lists pertaining to water quality, air quality, or biomonitoring.
- Parties may now petition for (1) the removal of chemicals from the COC list (with certain exceptions); (2) removal of products from the Priority Products list; (3) adding an entire list of chemicals to the COC list; and (4) the establishment or revision of an alternatives analysis threshold, for COCs in Priority Products.
- The proposed regulations eliminate the up-front exemption for products regulated by other laws. This factor will, however, be considered during the product prioritization process.

Alternatives Analysis Threshold Exemption

- The regulations no longer distinguish between “assembled” and “formulated” products.
- Manufacturers may have an abridged Alternatives Assessment option, provided that they can show that no viable alternative currently exists to the current formulation of COCs in their Priority Products.
- Manufacturers working within a consortium, for preparation of the preliminary and final reports, may protect their trade secrets by preparing certain portions of those reports by themselves.
- The deadline for completing an Alternatives Assessment is extended to three years—up from one year with a one-year extension—so long as the manufacturer can demonstrate that this amount of time is necessary for complying with regulatory safety and/or performance testing requirements for multiple alternatives (prior to choosing an alternative).
- There is no deadline for submitting the Alternatives Assessment Reports, and no due date for implementing the Alternatives Assessment decision and introducing the new product into the marketplace. Instead, manufacturers must submit an implementation plan, with key milestones and dates, to DTSC and must notify DTSC when introducing the new product. This lack of deadlines, however, seems to have no effect on DTSC enforcement options.
- Economic impact analysis requirements have been reduced, lessening the burden to analyze externalized cost impacts.
- Manufacturers are no longer required to identify their manufacturing facility location.

- Certified assessors engaged to perform the Alternatives Assessment need only have two years of related experience (half of the previous four-year requirement).
- The conflict-of-interest standard for Accreditation Bodies, for the certified assessors, has been revised to avoid unnecessarily excluding organizations with the requisite qualifications.

Regulatory Responses

- The regulations now flesh out the circumstances under which specified regulatory responses (for example, use restrictions, sales prohibitions, engineering or administrative controls, and research and development projects) are required, along with the principles and factors to be considered by DTSC when choosing its regulatory response.
- Manufacturers are no longer required to post product information at the point of sale.
- DTSC is no longer required to implement an inventory recall for products subject to a sales ban.

Additional Changes

- The definition of “functionally acceptable” has been modified to ensure that alternatives not only meet all applicable legal requirements but also will be accepted by consumers.
- The definitions of “adverse public health impacts” and “sensitive subpopulations” have been revised to clearly include occupational health impacts.
- Exceedance of enforceable California or federal public health or environmental standards has been added to the definitions of adverse public health and environmental impacts.
- The regulations now incorporate the consideration of a chemical’s ability to degrade, form reaction products, or metabolize into another chemical.
- The administrative dispute procedure will be unavailable with respect to DTSC’s actions to list chemicals, act on petitions, or respond to claims of trade secret protection.
- The exclusion for “bulk chemicals” has been eliminated.
- If a manufacturer/importer of a Priority Product fails to comply with Alternatives Assessment requirements or respond to regulatory requirements, retailers have 90 days (up from 60) to comply with the requirements or notify DTSC they have stopped ordering the Priority Product.
- DTSC’s “Failure to Respond” list, for manufacturers who fail to provide required information, will be renamed as the “Response Status List”—and will also list manufacturers that have provided the required information, manufacturers that have not provided the required information but have explained why the information is unavailable, and manufacturers that have neither provided the required information nor explained its unavailability.

Funding Issues

Although the Governor’s budget proposed redirecting 39 staff positions and more than \$6 million to cover

the first phase of implementing the Green Chemistry Initiative, several Democratic legislators signed a joint letter (known as the *Perea Letter*) asking that the fee proposal be excised from the budget trailer bill. Ulti-

mately, the question as to whether the existing funds will be sufficient to implement the initiative, without the benefit of the additional fees, is a question that remains to be answered.