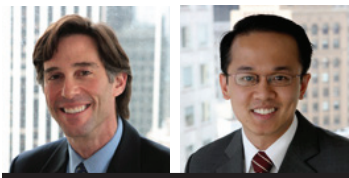


## Green Chemistry Initiative — Once More



**Joshua A. Bloom and John D. Le**

**A**fter numerous attempts, California is once again moving forward with regulations to implement its Green Chemistry Initiative. As directed by the 2008 Green Chemistry law, the California Department of Toxic Substances Control proposed regulations in 2010, only to face vehement opposition each time from either the business community, environmentalists or both. Now, almost a year after its last attempt, DTSC on Oct. 31 issued an “informal” draft regulation, named the “Safer Consumer Products Regulation.” Compared to the last proposal in November 2010, the most recent proposal is in many ways much broader and far-reaching than its predecessor.

Enacted in September 2008 through two companion bills, Assembly Bill 1879 (titled the “Safer Consumer Product Alternatives”) and Senate Bill 509, the Green Chemistry Initiative is designed as a new regulatory approach to pollution prevention, which ultimately requires the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances. Under the

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law, DTSC was to adopt regulations on or before Jan. 1 to establish a process for identifying and evaluating “chemicals of concern in consumer products and their potential alternatives.”

As DTSC’s proposals have evolved, a “four step” process has emerged as the foundation for its regulatory efforts: (1) identify chemicals of concern; (2) develop a list of “priority products”; (3) responsible entities are to perform an “alternatives assessment” on those priority products; and (4) DTSC must identify and impose “regulatory responses.” As proposed, the regulations would apply to all consumer products that contain a COC and are sold, offered for sale, supplied, distributed or manufactured in California, unless otherwise exempted.

### SIGNIFICANT CHANGES FROM PRIOR PROPOSAL

The informal draft regulation makes a number of significant changes to the prior proposal, in most cases expanding the breadth of the regulation. The changes include:

- The universe of COCs will now be “robust,” including approximately 3,000 chemicals, and will be based on a broad array of all hazard traits and environmental and toxicological endpoints specified by the California Office of Environmental Health Hazard Assessment. Chemicals considered carcinogens and reproductive toxins will also be more broadly considered than was previously the case. The initial list of COCs will be established by DTSC as of the effective date of the regulations, and published within 30 days of that time.
- Previous proposals limited DTSC’s consideration of the initial list of priority products during the first five

years to children’s products, personal care products and household cleaning products. That would no longer be the case under the current proposal, which has no limit on the product categories that will be initially considered. The initial priority products list must be published within six months of the regulation’s effective date.

- Worker exposure has been added as a prioritization factor.
- Entities responsible for compliance include a product’s manufacturer, importer and retailer. However, the manufacturer has the principal duty to comply with requirements applicable to a responsible entity. If the manufacturer does not comply, the duty falls to the importer (if there is one). If both the manufacturer and importer (as applicable) fail to comply, the retailer becomes responsible. However, as was the case with earlier drafts, the obligations of a “responsible party” may be fulfilled by a consortium, trade association, public-private entity or any other entity action on behalf of the responsible party.
- The alternatives assessment is more specific and structured than in previous proposals and no longer requires third-party verification, but will require that the assessment be conducted by a certified assessor. The assessor will be certified by a DTSC-designated accreditation body.
- There is an exemption for products with *de minimis* levels. For chemicals exhibiting any of nine specific hazard traits, the default *de minimis* level is a cumulative concentration of all COCs in a product at or below 0.01 percent by weight. For other chemicals, the default is 0.1 percent. DTSC retains the flexibility to set a higher or lower

level if specified in the priority products list.

Significantly, one element of the draft remains unchanged from prior drafts — the absence of a citizen enforcement provision. Unlike Proposition 65, which has generated a cottage industry for private plaintiffs and their attorneys, enforcement of the Green Chemistry Initiative and its regulations would be left to the state.

The draft regulations are very detailed — 68 pages — but the following summarizes the principal elements.

### IDENTIFICATION OF CHEMICALS OF CONCERN

The initial list of COCs, which must be in place as of the effective date of the regulations, will be composed of chemicals that exhibit a hazard trait, or an environmental or toxicological endpoint (as set forth in OEHHA regulations) and is listed by one or more authoritative bodies specified in the regulations. The universe from which the COCs will be drawn is broad and diverse. Approximately 3,000 chemicals are expected to be initially identified as COCs.

After the initial list of COCs is established, DTSC can thereafter add to the list other chemicals that exhibit a hazard trait or an environmental or toxicological endpoint. The decision whether to add such chemicals to the list will be based on: (1) potential chemical adverse impacts, (2) adverse impacts of special consideration, such as to children or pregnant women, or environmentally sensitive habitats, (3) potential exposures, (4) availability of reliable information, and (5) availability of safer alternative chemicals. Before DTSC augments the initial COC list, it will provide a 45-day public review and comment period. It will review the list at least once every three years.

### PRODUCT PRIORITIZATION

From the COC list, DTSC must then evaluate and identify “Priority Products” to determine, in view of the COCs in a product, the potential adverse impacts resulting from those COCs, and potential exposure to the COCs. The potential adverse public health and environmental impacts resulting from COC exposure are considered by looking at the product’s manufacture, product life and end-of-life

disposal and management.

In its prior regulation, DTSC proposed that for the first five years of implementation, it would limit the scope of “Priority Products” to children’s products, personal care products and household cleaning products. DTSC drew substantial criticism for this decision, and the draft regulation no longer limits initial consideration to those product categories. Nonetheless, when assessing the potential adverse impacts caused by COCs in a product, DTSC will take into consideration the type and severity of potential impacts for children, pregnant women and other sensitive subpopulations, environmentally sensitive habitats and widespread adverse public health or environmental impacts. When establishing priority products, DTSC will also consider availability of information, safer alternatives and the extent to which the product or COC in question is regulated under federal or other California regulatory programs and applicable international trade agreements.

Products meeting one or more of the following criteria will be given priority:

- The COCs in the product pose significant potential to cause adverse public health and environmental impacts.
- The products are widely distributed in commerce and used by consumers.
- Potential public and environmental exposures to the COCs may result in significant impacts.
- There is potential for inhalation or dermal exposures with respect to assembled products.
- For formulated products, the product is intended to be applied to the body, dispersed as an aerosol or vapor, or is applied to hard surfaces with the likelihood of runoff or vaporization.

Unless a responsible entity for a product listed as a priority product has submitted a *de minimis* exemption notification, it must, within 60 days after the product is listed, notify DTSC that its product is a priority product. The same 60-day period applies to *de minimis* exemption notifications. If the product is first produced, or placed in the stream of commerce, in California after the product is listed as a priority product, notification must be provided to DTSC within 60 days after the product is first placed into the stream of commerce in California.

### ALTERNATIVES ASSESSMENT

The Alternatives Assessment is the cornerstone of DTSC’s implementing regulations. It forms the basis for choosing the most suitable product alternative and the appropriate regulatory response imposed on a responsible entity.

As proposed, a responsible entity would be required to submit a preliminary AA report within 180 days after a product becomes a listed “priority product.” A final AA report work must be submitted to DTSC within one year after DTSC issues a notice of compliance for the preliminary AA report, although on request of the responsible entity, DTSC can agree to an extension of an additional year. Any AA completed after Jan. 1, 2015, must be performed by a certified assessor, and any preliminary AA report submitted after that date must also be prepared by a certified assessor.

The AA is made up of two stages, preceding the preliminary AA report and the final AA report. The first stage includes identifying product criteria, identifying alternatives that meet the criteria of the priority product, and initial screening of alternative chemicals to replace the COCs in the product. The first stage also includes developing a work plan to complete the second stage and ensure that the final AA report is submitted on schedule.

The second stage includes identification of factors relevant for comparison of alternatives, followed by a comparison of the priority product with its alternatives, and finally an alternative selection decision. Once the final AA report is submitted, DTSC has 60 days to review the report, and either issue a notice of compliance or a notice of deficiency.

### REGULATORY RESPONSE

Following submission of the AA report, DTSC would then select the regulatory response. The regulatory responses can range from requiring additional information, to “no regulatory response required,” to a phased product ban-and-recall regime.

“Self-implementing” regulatory responses require the responsible entity to provide product information to consumers within 12 months if the manufacturer chooses to retain the priority product, or if the alternative product contains COCs above *de minimis* levels. The responsible

entity must also establish, maintain and fund, within two years, an end-of-life product stewardship program.

Of the array of possible regulatory responses, most significant is product prohibition. If the selected alternative contains a COC, or if an alternative is not selected, and DTSC notifies the responsible entity that it has determined that "a safer alternative exists that does not contain a COC and that

is both functionally acceptable and technologically and economically feasible," the "product sales prohibition" requirements will apply. Under those requirements, unless DTSC specifies a shorter time, the responsible entity has one year from DTSC's notification to stop placing the product in the stream of commerce in California, and three years to ensure that an inventory recall program for the product is imple-

mented and completed. In the alternative, the responsible entity can submit to DTSC within one year an AA report that selects an alternative that does not contain a COC.

The public comment period on the informal draft regulation ends Dec. 30. The draft regulation was discussed at DTSC's Green Ribbon Science Panel's Nov. 14-15 meetings, and will be the subject of a DTSC workshop on Dec. 5.

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