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# Consumer Product Alert: California Revives Green Chemistry Initiative with Draft Regulations that Impact Manufacturers, Importers, and Retailers

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After a failed attempt last year that sent state regulators back to the drawing board, California is pushing forward with its own regulation of chemicals in consumer products. On October 31, 2011, the California Department of Toxic Substances Control (DTSC) issued a new "informal" draft of its Green Chemistry regulation, titled the "Safer Consumer Products Regulation." Already 11 months late, the current iteration makes substantial changes to draft regulations that have come under intense criticism at each step.

Notably, the list of "Chemicals of Concern" will be much broader than initially anticipated and is expected to include nearly 3,000 chemicals (beating the Proposition 65 list by at least 2,200). Like its predecessor regulation, this version imposes compliance obligations on manufacturers, distributors, and retailers alike, introducing yet another California-specific burden for the consumer product industry. While children's products, personal care products, and household cleaning products are no longer called out as the specific targets for immediate prioritization, the product prioritization criteria suggest that this regulation will likely impact them early on and affect many other everyday consumer products over time.

As drafted, the regulations require extensive risk and life cycle analyses for prioritized products. The analyses may lead to limitations on the use of certain chemicals, reformulation requirements to eliminate targeted chemicals, or the outright ban on sales of certain products in California.

## BACKGROUND

California's Green Chemistry statute, known as Assembly Bill 1879 (2008), provides the broad outline of an ambitious regulatory program to evaluate and regulate hazardous chemicals in consumer products. However, many important details were left to DTSC to develop through regulations, which were to be issued by January 1, 2011. DTSC was tasked with establishing "a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern."

DTSC issued draft versions of the regulation for public comment in June, September, and November 2010. See September 2010 MoFo Update. Following intense criticism of the regulations by both environmental and industry stakeholders, DTSC withdrew the draft regulations. The current draft is designated by DTSC as an "informal" draft, issued outside the normal administrative process, which is intended to provide the opportunity for additional comments by stakeholders and DTSC's own Green Ribbon Science Panel (GRSP).

## SUMMARY OF THE INFORMAL DRAFT

**Process**

The draft regulations establish a four-step process to identify safer consumer product alternatives.

**1. Chemicals:** DTSC will publish an initial list of Chemicals of Concern (COCs), based on chemicals identified by other authoritative organizations and on the regulations currently being adopted by the Office of Environmental Health Hazard Assessment (OEHHA) on a broad range of hazard traits and environmental and toxicological endpoints. DTSC estimates the initial list will include approximately 3,000 chemicals.

**2. Priority Products:** Next, DTSC will develop a list of Priority Products based on its evaluation of products that contain the identified COCs, as well as the distribution, use, and disposal patterns of the products.

**3. Business Duty to Notify and Evaluate:** Responsible entities (which include manufacturers, importers, *and* retailers) must notify DTSC when their product is listed as a Priority Product. DTSC will post this information on its website. The responsible entity will be required to perform an Alternatives Assessment (AA) for its product and the COCs in the product to determine how to best limit potential exposures or potential adverse impacts. The regulation imposes the "principal duty to comply" on the manufacturer.

**4. Product/Chemical Limits/Regulations:** DTSC will identify and impose a Regulatory Response to limit potential adverse public health and environmental impacts, if any, from the Priority Product or its COCs or from the alternative chemical or product selected to replace the Priority Product.

**Applicability**

The regulations apply to all consumer products containing a COC that are sold, offered for sale, supplied, distributed, or manufactured in California. There are limited exemptions for:

- Products exempted by law (specified medical and dental devices, "dangerous" prescription drugs, food, and pesticides) and products used solely to manufacture a product exempted by law;
- Products manufactured, stored in, or transported through, California, solely for out-of-state use; and
- Products regulated by other federal or California state regulatory programs or international trade agreements, where the program or agreement provides an equivalent or greater level of protection of public health and the environment than would be provided if the product were listed as a Priority Product (no examples are specified, but EU programs seem likely candidates).

The regulations apply to any "responsible entity," which includes the manufacturer, or, if the manufacturer does not comply, the importer or retailer. The responsible entity must notify DTSC of Priority Products and perform the AA. A responsible entity may opt out of the program by deciding not to offer Priority Products in California. Responsible entities may also use a consortium, trade association, public-private partnership, or other cooperating entity to assist in fulfilling their obligations.

**Chemical and Product Prioritization**

DTSC must establish the initial list of COCs within 30 days after the effective date of the regulations. The initial list is

derived from chemicals that (1) exhibit a hazard trait or an environmental or toxicological endpoint set forth in OEHHA regulations and (2) are identified based on one or more of the following:

- Fifteen "authoritative body" lists based on hazard traits;
- Four authoritative body lists based on exposures or environmental or toxicological endpoints; or
- Three specified sources of "reliable information."

DTSC may add chemicals to the initial list of COCs based on factors set forth in the regulations.

The regulations contemplate identification of Priority Products for purposes of AA preparation based on the following criteria:

- The COCs in the product pose a significant potential to cause adverse public health and environmental impacts;
- The product is widely distributed in commerce and used by consumers;
- There is a significant potential for public and environmental exposures to the COC(s) in quantities that can result in adverse public health or environmental impacts; and
- For assembled products, the product contains COC(s) that may present potential exposures through inhalation or dermal contact.
- For formulated products, the product is intended to be:
    - Applied directly to the body;
    - Dispersed as an aerosol or a vapor; or
    - Applied to hard surfaces with the likelihood of runoff or volatilization.

There are *de minimis* exemptions for products with COCs at concentrations equal to:

- 0.01% by weight for chemicals exhibiting one of nine specified hazard traits (carcinogenicity, developmental toxicity, reproductive toxicity, endocrine toxicity, genotoxicity, immunotoxicity, neurotoxicity, bioaccumulation, or environmental persistence);
- 0.1% by weight for chemicals that do not exhibit any of the nine specified hazard traits and environmental and toxicological endpoints; or
- A lower or higher concentration if specified by DTSC in the Priority Products list.

**Alternatives Assessment**

This assessment remains at the heart of the Green Chemistry regulations. Each AA must be conducted in two stages, with a report sent to DTSC at the end of each stage.

**Necessity/Identification of Alternatives:** In the first stage, product criteria are identified (e.g., by function, performance, technical, and legal requirements). A statement must be provided on whether the COC or a substitute chemical is necessary to meet the product's requirements. Next, alternatives to the usage of the COC must be identified and screened, and a work plan proposed for the second stage. This information is reported to DTSC in a Preliminary AA

Report, which is due 180 days after the product is listed on the final Priority Products list.

**Detailed Assessment of Alternatives:** The second stage requires a more detailed assessment of alternatives. The product and each alternative must be evaluated with respect to relevant factors and associated exposure pathways and life cycle segments. At this stage, the responsible entity selects an alternative that will replace or modify the Priority Product or decides not to modify the Priority Product (or discontinue the distribution of the product in California). A Final AA Report is due to DTSC within a year after the date DTSC issues a notice of compliance for the Preliminary AA Report, unless an extension of up to one additional year is approved.

**Regulatory Responses**

After evaluating the AA Report, DTSC is required to consider the appropriate regulatory response. In general, product information must be provided to consumers if the alternative product contains a COC above the *de mimimis* level or the manufacturer decides not to modify the original Priority Product. Other possible regulatory responses include:

- Requiring additional information to be provided to DTSC;
- Prohibition on sale—
    - Ensures the Priority Product is no longer sold in California (including implementing an inventory recall program) where DTSC determines there is a safer alternative that is functionally acceptable and technologically and economically feasible, or
    - Submits to DTSC an AA Report that selects an alternative that does not contain a COC;
- Other responses DTSC may require include—
    - Engineered safety measures to control access or limit exposure to the COC in a product;
    - Restrictions on the use of the COC;
    - Research and development projects or challenge grants; and
    - New alternative assessments.

Regulatory responses are not required for selected alternatives that do not contain a COC above the *de minimis* level, or for selected alternatives that do not pose a potentially significant adverse public health or environmental impact.

Another very important feature of the draft—one that could easily be overlooked by businesses, would require responsible entities to establish, maintain, and fund an end-of-life product stewardship program for any product that is required to be managed as a hazardous waste in California.

## SIGNIFICANT CHANGES FROM THE DTSC'S NOVEMBER 2010 DRAFT REGULATIONS

With this new draft, DTSC extensively revised its November 2010 regulation. Many timeframes were shortened or made more specific. In some cases, deadlines are now linked to the effective date of the regulations. The regulations call for an immediate, robust list of COCs. The list of hazard traits has been significantly expanded to include all hazard traits and environmental and toxicological endpoints specified by OEHHA (whose regulations are not yet finalized). The universe of chemicals considered to be carcinogens and reproductive toxins is far broader than earlier envisioned. The regulations no longer limit the product categories DTSC can consider when listing Priority Products during the first five years; earlier

drafts targeted toys, personal care, and household products. Worker exposure has been added as a prioritization factor.

Regarding the AA, the provisions expand the primary responsibility for compliance beyond the manufacturer to the importer and retailer. The AA process is more specific and structured. The requirement to fill information gaps during the AA is eliminated, but DTSC may require this as a regulatory response. The third party verification requirement for the AA has been replaced by a requirement that AAs must be conducted by a certified assessor, and DTSC's role in auditing AAs is expanded.

Another major change in response to criticisms from both environmental groups and industry is to redefine the exemptions from the regulations. While the default *de minimis* level remains at 0.01% for chemicals with one of nine specified hazard traits, DTSC has the option to set a higher or lower level for all other chemicals. The exemption for unintentionally added chemicals has been eliminated, but these chemicals may be considered in setting a higher *de minimis* level. The "no exposure pathway" exemption has been eliminated, but will still be considered during the prioritization process.

In addition, a manufacturer may no longer avoid doing an AA by simply removing the COC once the product is listed as a Priority Product. Removing the product from the California marketplace and introducing another similar product containing a COC will require a notice to DTSC.

## CONCLUSION

The current informal draft will be discussed by DTSC's GRSP at its November 14-15 meetings. On December 5, DTSC will hold a workshop on the informal draft. Following the informal public comment period, which ends on December 30, 2011, DTSC will develop formal proposed regulations and solicit further comment before adopting the final version. With reform of the Toxic Substances Control Act stalled in Congress, California appears determined to take the lead in product stewardship and chemical regulation through this initiative. The consumer product industry can only hope that California proceeds with caution, and recognizes the value of harmonizing its program with work previously done in the European Union and other states and countries on chemical use regulation.

Morrison & Foerster's lawyers have worked on product stewardship and chemical use issues since the 1980s, including in agency rulemaking, litigation, and requirements imposed by the U.S. Consumer Product Safety Act, California's Proposition 65, EU's REACH, RoHS and WEEE Directives, as well as China RoHS. We represent global manufacturers, distributors, retailers, and trade associations in addressing product design, content, disposal, as well as warning and labeling requirements. We have followed the scientific debate on the Green Chemistry Initiative throughout its history and understand how the new regulations may affect a wide variety of clients and their interests.

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