

Brave New World: California Finalizes Safer Consumer Products Regulations

By Lynn L. Bergeson

Products in Commerce in California are Targeted, but the Program Has National and International Implications

It is official. California's Office of Administrative Law (OAL) approved the California Department of Toxic Substances Control (DTSC) Safer Consumer Products regulations, and the program went into effect on October 1, 2013. The regulations mark the much-anticipated regulatory implementation of California's Green Chemistry Initiative. The regulations and final statement of reasons are available at <http://www.dtsc.ca.gov/SCPRegulations.cfm>.

This new program is a true game-changer, and it will have profound national and international business, regulatory, and commercial implications for consumer product manufacturers and others for the reasons noted below. Before discussing the program's implications, however, this article discusses the scope of the regulations, including the four core elements, which are:

- Candidate chemicals,
- Priority products,
- Alternatives analysis, and
- Regulatory responses.

Scope of Persons and Products Subject to the Regulations

The regulations expressly apply to "responsible entities," which include manufacturers, importers, assemblers, and retailers. The requirements for responsible entities are tiered, and the primary responsibility for compliance

lies with the manufacturer. If the manufacturer fails to comply, however, the responsibility for compliance falls to the importer. Only if both the manufacturer and the importer (if any) fail to comply, responsibility for compliance falls to retailers. Pertinent information is posted on the “failure to comply” list on DTSC’s website.

A consumer product is broadly defined as “a product or part of the product that is used, brought, or leased for use by a person for any purposes” (DTSC, 2013a, Section 69501.1(a)(24)(A)).

The regulations also state that a consumer product also means “[w]hen applicable, a component of an assembled ‘consumer product’” (DTSC, 2013a, Section 69501.1(a)(24)(A)).

Products to which the Regulations Apply

The regulations apply only to consumer products placed into the stream of commerce in California. In addition to products not placed into the stream of commerce in California, certain products are expressly exempt from the regulations. These include:

- Dangerous prescription drugs and devices;
- Dental restorative materials;
- Medical devices;
- Pesticides;
- Food;
- Packaging associated with dangerous prescription drugs and devices, dental restorative materials, and medical devices;
- Certain consumer products that DTSC determines are regulated by one or more federal and/or California state regulatory program(s);
- Products that ceased to be manufactured prior to the date the product is listed as a priority product (PP); and

- A product previously owned or leased by someone other than the manufacturer, importer, distributor, assembler, or retailer of the product. (DTSC, 2013a, Sections 69501.1(a)(24)(B)-(C), 69501(b)(2)-(3)).

“Candidate Chemicals” List

DTSC was required to establish by November 1, 2013, a “candidate chemicals list.” DTSC released the List on September 28, 2013 (see <http://www.dtsc.ca.gov/SCP/index.cfm>). DTSC estimates the candidate chemicals list contains approximately 1,200 chemicals of concern (COC). DTSC calls the list it released “informational.”

The candidate chemicals list includes substances that exhibit a hazard trait and/or an environmental or toxicological endpoint, identified through the Office of Environmental Health Hazard Assessment’s (OEHHA) development of a “Toxics Information Clearinghouse,” and that meet one or more of several criteria. These include whether a chemical is included in one or more of 15 different lists already selected by other agencies and organizations, the chemical is identified as belonging to one or more specified types of chemicals, including, but are not limited to, chemicals for which notification levels have been established by the California Department of Public Health, chemicals for which primary maximum contaminant levels have been established in California, and chemicals identified as toxic air contaminants in California (DTSC, 2013a, Section 69502.2(a)).

Initial Candidate Chemicals List

Prior to January 1, 2016, DTSC will consider a limited scope of candidate chemicals when reviewing product-chemical combinations (*i.e.*, a chemical listed on one or more of the authoritative organizations’ hazard-trait-based chemical lists specified in Section 69502.2(a)(1), and that also appears on a chemical list developed based on potential exposure concerns and specified in Section 69502.2(a)(2)) (DTSC, 2013a, Section 69503.6(a)).

The initial candidate chemicals list released on September 28, 2013, (DTSC, 2013b) is significantly smaller than the 1,200 substances listed in the full candidate chemicals list. The initial candidate chemicals list contains 164 substances. However, readers should note that there are

actually more substances than this number suggests because many of the substances on this list belong to groups or classes of chemicals that include other substances that also meet the regulatory criteria for inclusion on the initial candidate chemicals list.

Priority Products

DTSC will evaluate and prioritize products that contain candidate chemicals to develop a list of PPs for which alternatives analysis (AA) must be conducted. To determine products of high priority, DTSC will evaluate the potential adverse health and environmental impacts posed by the candidate chemical(s) in each product based on several factors. These factors include:

- Potential adverse impacts posed by the candidate chemicals and potential exposures during the life cycle of the product;
- Product uses, or discharges or disposals, that have the potential to contribute to or cause adverse waste and end-of-life effects associated with the candidate chemical(s) in the product;
- The “extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects;”
- The extent to which other regulatory programs regulate the product; and
- “Whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible” (DTSC, 2013, Sections 69503.2, 69502.3).

Once a candidate chemical becomes the basis for a product being listed as a PP, DTSC will designate that chemical as a chemical of concern (COC) for that product (DTSC, 2013a, Section 69503.5(b)(1)(B)).

Alternatives Analysis Threshold

DTSC defines the alternative analysis threshold (AAT) as the “practical quantitation limit for a chemical of concern that is present in a priority product solely as a contaminant” or a concentration by weight as specified by DTSC (DTSC, 2013a, Section 69501.1(a)(12)). This means there is no default threshold (e.g., 0.01 percent by weight).

When listing a PP, DTSC also may specify an AAT for any COC that is an intentionally added ingredient. Within 60 days after a product-chemical combination is placed on the PP List, responsible entities will be required to provide a PP notification to DTSC stating that they will conduct an AA unless they submit “alternative notifications.”

Alternative notifications to the PP notification include:

- AAT exemption notification (where the COC is present only as a contaminant and the concentration does not exceed the practical quantitation limit (PQL), or does not exceed the AAT established by DTSC);
- Chemical removal notification (where the only change is the removal of the COC from the PP without use of a replacement chemical or otherwise adding other chemicals to the product);
- Product removal notification (if the PP will cease to be sold or distributed in California); and
- Product-chemical replacement notification (where the COC is removed from the PP and any replacement chemical meets certain criteria) (DTSC, 2013a, Sections 69505.2, 69505.3)).

Initial PP List

Under Section 69503.6, the initial PP list is limited to no more than five products. DTSC must release the initial PP list for public comment and review no later than 180 days after the effective date of the regulations, or by March 30, 2014. There is much speculation regarding which products will be selected, and whether the identification of these products will invite litigation. DTSC also must review the PP list at least once every three years.

Preparing Alternatives Analysis

Responsible entities (generally, manufacturers) must perform an AA for the listed COC-PP combination to determine how best to limit potential exposures or the level of potential adverse public health and environmental impacts posed by the COC in the PP.

Under the regulations, AAs must be conducted in two stages. In the first stage, the responsible entity must identify the PP's functional, performance, and legal requirements that must be met for any potential alternative; the role of the COC in meeting the PP's function, performance, and legal requirements; and if the COC or any alternative replacement chemical is "necessary" to meet the PP's identified requirements. Other conditions apply.

In the second stage, the responsible entity reevaluates the identification of factors under consideration after completion of the first AA stage. Additional factors for consideration include product function and performance and economic impacts. The responsible entity must then evaluate and compare the PP and each of the alternative(s) under consideration with respect to each relevant factor and associated exposure pathways and life cycle segments (if applicable) identified. The responsible entity must select the alternative(s) that will replace the PP, unless the decision is to retain the PP. The responsible entity must prepare a Final AA report.

DTSC and Public Review of AA Reports

Within 60 days of receiving a preliminary AA report, final AA report, or alternative reports, DTSC reviews the report for compliance and issues a

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notice of compliance, notice of deficiency, notice of disapproval, or notice of ongoing review (DTSC, 2013a, Section 69505.9).

To provide a quality assurance mechanism for the AAs, DTSC will provide a public comment period for the final AA report and abridged AA report, review those comments, and then identify, no later than 30 days after the close of the public comment period, any issues that it determines need to be addressed by the responsible entity in an AA report addendum (DTSC, 2013a, Section 69505.8).

Regulatory Responses on COC-PP Combinations

After evaluating the final AA report, DTSC is required to consider the appropriate regulatory response. In selecting regulatory responses, DTSC must seek to “maximize the use of alternatives of least concern when such alternatives are functionally acceptable, technically feasible, and economically feasible” (DTSC, 2013a, Section 69506(a)).

There are several possible regulatory responses triggered by DTSC’s findings and determinations. For example, product information (*e.g.*, brand name, COC, adverse impacts) may be required to be provided to consumers for:

- PPs for which an alternative was not selected;
- PPs that continue to be introduced into commerce in California pending development and distribution of an alternative product for longer than 12 months after DTSC issues a notice of compliance or notice of disapproval for an AA report; and
- Selected alternative products that retain COCs and/or contain any replacement candidate chemical(s).

DTSC can also impose use restrictions (*e.g.*, restrict amount/concentration of a COC) on one or more COCs or replacement candidate chemicals in a selected alternative, or COCs in a PP for which an alternative is not selected, or restrictions on the product itself that the department determines necessary (DTSC, 2013a, Section 69506.4).

Alternatively, if a responsible entity decides in a final AA report to retain an existing PP or select an alternative that still contains a COC or

replacement candidate chemical, DTSC can override a responsible entity's decision based on a determination that a safer alternative exists that does not contain a COC or replacement candidate chemical and is functionally acceptable, technologically feasible, and economically feasible (DTSC, 2013a, Section 69506.5). DTSC "may require a manufacturer to engineer safety measures that integrally contain or control access to, and/or implement administrative controls that limit exposure to, the Chemical(s) of Concern or replacement Candidate Chemical(s) in a selected alternative, or the Chemical(s) of Concern in a Priority Product for which an alternative is not selected, to reduce the potential for adverse impacts" (DTSC, 2013a, Section 69506.6).

In addition, DTSC is authorized to require a responsible entity to establish, maintain, and fund (within one year) an end-of-life product stewardship program (DTSC, 2013a, Section 69506.7). Finally, DTSC can require manufacturers to initiate research and development projects or fund challenge grants to design a safer alternative, improve the performance of a safer alternative, decrease the cost of the safer alternative, or increase the market penetration of a safer alternative (DTSC, 2013a, Section 69506.8).

Analysis

With the release of the Candidate Chemicals List on September 28, 2013, the clock has begun running for DTSC to identify the first set of proposed PPs. Companies with consumer products in the stream of commerce in California that are identified as PPs will need to notify DTSC that its product is a PP; perform an AA and prepare a preliminary AA report and final AA report (or use an approved alternative); and comply with any regulatory responses DTSC applies to its product.

Considering the time frames provided, it will be years from the time the candidate chemicals list is released, the initial priority product list is released and then issued in final, the AA process is completed, and the regulatory responses are issued. Companies also may need to respond to information requests from DTSC, submit notifications to avoid AA responsibilities, substantiate claims when information is submitted as trade secret, and potentially utilize the dispute resolution procedures to dispute certain actions taken by DTSC.

While there are indications that these regulations may be subject to litigation, a prudent initial step for any company doing business in California to consider is to review, when available from DTSC, the initial candidate chemicals list and determine if any of its consumer products contain one or more of those substances. It will also be important for companies with products identified as PPs to identify other entities similarly affected and determine the ability to consolidate efforts (*e.g.*, through a consortium) in conducting an AA.

The best responses to this new game-changing regulatory program is to understand the law, be prepared for its regulatory, commercial, and public image consequences, and recognize and embrace the business opportunities the new program offers.

References

Department of Toxic Substances Control (DTSC), 2013a. Safer Consumer Products (SCP) Web Portal, California Environmental Protection Agency. Accessible at: <http://www.dtsc.ca.gov/SCPRegulations.cfm>.

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