



Alerts

California Proposes Green Chemistry Regulations for Public Comment

July 9, 2010

Hinshaw Environmental Bulletin

On June 23, 2010, California's Department of Toxic Substances Control (DTSC) issued the initial draft set of regulations implementing California's Green Chemistry Initiative, Cal. Health & Safety Code Section 25251, et seq., which is intended to provide Californians with safer "consumer products" and to shift the burden of proving potential for toxicity to manufacturers. Similar to the European Union's REACH provisions, these new regulations set forth a detailed system for the evaluation of potential toxic exposures in consumer products, and how they can be minimized or alleviated. The regulations would also establish a "Product Stewardship" program, which requires manufacturers to consider not only the use of the product, but also the potential for exposure in the manufacturing process and disposal. Consumer product companies should take active interest in these proposals, as they will have a profound influence in California, and elsewhere, if adopted as proposed.

All "Consumer Products" Are Subject to the Regulations

As noted in Cal. Health & Safety Code Section 25251, all "consumer products," as defined in that statute, are subject to the regulatory scheme set forth in the new draft regulations. According to the DTSC, the following are fundamental precepts for the regulations themselves and for their implementation.

- a. The adverse impacts on public health and the environment from the production, use and disposal of products should be reduced or eliminated.
- b. The means by which this can be accomplished is by either banning substances or redesigning current consumer products.
- c. Those products which have the greatest potential for harm should be the ones that receive the highest priority for eliminating their use or limiting their availability. 22 C.C.R. Section 69301.1 (draft).

The DTSC intends to meet these goals by focusing on two types of chemical products. The first, known as a "Chemical of Concern" ("COC"), is a chemical contained in consumer products which has known health effects, including the potential for causing cancer, reproductive toxicity, endocrine disruption, and a host of other adverse health effects. A "Chemical Under Consideration" ("CUC") falls into the second category of chemical substances which may have the same type of acute or chronic health effects as those listed in the COC category. The DTSC is responsible for issuing lists of these chemicals, and one would anticipate that those products and/or chemicals already listed under Cal.

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Health & Safety Code Section 25249, et seq. (Proposition 65) would be the leading candidates to be put into the CUC category.

Manufacturers' Responsibilities

The draft regulations establish a complicated framework for compliance with the statute and the responsibility for reducing the potential for exposure to "toxic substances" identified as either COC or CUC. Manufacturers are responsible for identifying all products containing COC or CUC available for use by consumers, or which might possibly result in environmental exposures through the production and/or disposal of the product. Once having identified those products, manufacturers are required to disclose the concentrations, and potentials for exposure. There are safe harbors for "*de minimis*" exposures. The default established by the regulations is that any potential exposure is harmful. The burden of proof is on the manufacturer to prove that the potential for exposure, based upon current medical and scientific knowledge, does not result in a potential for causing harm, either to an individual or the environment.

In a new twist, the regulations also focus attention upon information available in the medical and scientific area concerning health affects generally, and require manufacturers to produce information concerning "susceptible populations." Those populations include the elderly, children and those particularly "susceptible" to exposure. The implementation of these regulations calls into question the ability to use population-based epidemiologic data, which usually focuses on effects on populations as a whole and not on "susceptible" populations as defined in the regulations.

Once the products have been identified with a COC, a prioritization process exists for eliminating or substantially reducing the potential for exposure. The regulations require manufacturers whose products contain a COC to provide the DTSC with an Alternatives Assessment (AA) plan. These AA plans require manufacturers to identify potential reengineering, redesign or substitution of COCs in existing consumer products in order to reduce the potential for exposure. The regulations also provide for a regulatory appeal process from the individual originally responsible for reviewing the AA, through a second-level supervisor, to the DTSC as a whole.

If a manufacturer fails to comply with the requirements of the regulations, the product or products that are deemed by the DTSC to have failed to comply can be banned. The regulations provide the DTSC with the ability to ban a product within 60 days of a notice of failure to comply being sent to a manufacturer. This short timeframe not only bars the manufacturer from delivering or selling the product in the state of California, but bans the product from being sold by retailers, distributors, etc. In order to assist the implementation of this short timeframe, the DTSC will maintain a website, which will be updated continuously. The website will provide information to the public concerning products that have been banned for use, which are limited in their ability to be sold, and/or contain a COC and at what concentrations. This "web-focused" enforcement mechanism is also unique to these regulations.

There are limitations. The regulations are not applicable to products which are subject to federal and/or other state oversight which would "pre-empt" their enforcement. Exactly what these statutes and/or regulations are is not made clear by the regulations, and will be subject to some dispute. Likewise, manufacturers do not need to disclose trade secret information. However, the burden is on the manufacturer to establish that trade secret protection is necessary.

Conclusion

The regulations propounded by the DTSC provide a complicated and detailed regulatory scheme for enforcement of the Green Chemistry Initiative. Manufacturers and distributors should consult counsel and their product, science and engineering staffs to determine whether they can suggest improvements and alterations in the draft rules. Informal comments are due by July 15, 2010. The DTSC will then amend the proposed regulations and formally publish them for 45 days of public comment pursuant to the California Administrative Procedures Act. The California offices of Hinshaw & Culbertson LLP include attorneys familiar with consumer product regulation in California.

For further information, please contact [Frederick J. Ufkes](#), [Harvey M. Sheldon](#) or your regular [Hinshaw attorney](#).



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