

CLIENT ALERT

California Finalizes Green Chemistry Regulations

September 19, 2013

California's Department of Toxic Substances Control (DTSC) has now approved the state's final Safer Consumer Products Regulations (the "Regulations"), commonly known as the "Green Chemistry" regulations.

After more than four years of public comments and revisions, the Regulations will take effect on October 1, 2013. The final version of the Regulations is nearly identical to the draft released for public comment in April 2013, but adds additional trade secret protection processes for information submitted to the DTSC.

The stated purpose of the Regulations is to "require manufacturers to seek alternative ingredients in widely used products, offering California industry the opportunity to lead the way in producing safer versions of goods in demand around the world." The Regulations will apply across the life cycle of affected products, including their design, manufacture, use, and disposal, and create a process by which manufacturers will be required to identify and use safer alternatives. Given that California is the largest market for consumer products in the U.S., and one of the ten largest economies in the world, this new regulatory regime will have substantial ripple effects on manufacturers and retailers worldwide.

The Regulations themselves have caused no small amount of controversy. Critics contend they will give California too much power over how consumer goods are made and sold, make goods too costly to manufacture, stifle innovation, fail to protect trade secrets, and discourage the use of recycled materials. Environmental groups have argued that the Regulations will not remove toxic products from shelves and will create "paralysis by analysis" as industries litigate against DTSC over unfavorable department decisions.

An immediate priority for companies in the distribution chain for consumer products is to determine their compliance obligations under the Regulations. The Regulations apply to "responsible entities," including manufacturers, importers, assemblers, and retailers, which sell products in the state. Exempted from the Regulations are products covered by the Health and Safety Code section 25251 (such as prescription drugs, medical devices, food, and pesticides) and products that DTSC determines are regulated by other federal or California state programs for the same public health and/or environmental impacts that the Regulations are intended to address. Before the requirements under the Regulations begin to phase in over the next several months, the participants in the distribution chain for likely priority products ought to establish how they will coordinate their regulatory response.

The Regulations introduce a four-step "science-based, iterative process" to identify safer consumer product alternatives:

1. DTSC establishes an immediate list of "Candidate Chemicals" exhibiting one or more of the following traits: carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, respiratory sensitivity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity. The Candidate Chemicals list will be derived, in part, from already-existing lists of regulated chemicals in the U.S. and abroad, and is expected to eventually number approximately 1,200 substances.

2. DTSC must next prioritize Product/Candidate Chemical combinations to develop a list of "Priority Products" for which "Alternative Analyses" must be conducted by the manufacturers. DTSC has indicated that the initial list will be limited to five priority products. Prioritization is to be based on an assessment of hazard and exposure potential over the product lifecycle. DTSC has also indicated that the initial list of products will be fairly specific, but has not elaborated further on that determination. However, even if the Product/Candidate Chemical combination is somewhat specific (e.g. phthalates/vinyl), such a prioritization could have ramifications across a wide swath of industries as compared to something much more specific (e.g. lead/lipstick). In order to aid its hazard and exposure assessment for prioritization, DTSC may request information from product manufacturers, importers and retailers. The Regulations allow for stakeholders to petition DTSC to add or remove a product/chemical combination from the Priority Products List.
3. "Responsible entities" must notify DTSC if one of their products has been listed as a Priority Product. The Responsible Entity must then perform an Alternative Analysis (AA) for the product and the Chemical(s) of Concern to determine how best to limit potential exposures. In general, the Responsible Entity must provide DTSC with a preliminary AA report within 180 days of listing on the Priority Products List. The final AA report must be submitted within 12 months of DTSC's determination that the preliminary report is satisfactory. The Regulations require a public review and comment process for each Alternative Analysis. In lieu of an AA report, a Responsible Entity can opt out of the process by notifying DTSC that the product is no longer being sold or that the Chemical of Concern is not present, has been removed, has been replaced with an existing alternative, or meets a certain threshold exemption.
4. Finally, based on its evaluation of the final AA report, DTSC issues a "regulatory response" designed to protect public health and/or the environment and to maximize the use of "acceptable and feasible alternatives of least concern." The Regulatory Response will be subject to public notice and comment and a public workshop, and may include requesting supplemental information from the Responsible Entity, mandating additional labeling, imposing use restrictions or other controls, banning the product, or requiring further research into alternatives.

The Regulations will be implemented on the following schedule:

- October 31, 2013 – deadline for DTSC to post list of Candidate Chemicals.
- March 31, 2014 – deadline for DTSC to release initial proposed Priority Products list for public review and comment. The initial list will include no more than five products.
- October 1, 2014 – deadline for DTSC to issue Priority Product Work Plan that "identifies and describes the product categories that the DTSC will evaluate to identify product-chemical combinations to be added to the Priority Products list during the three (3) years following the issuance of the work plan."

The text of the final Regulations can be found at [DTSC's website](#).

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