

**CALIFORNIA REGULATORY HEARING ON PROPOSED "SAFER CONSUMER PRODUCTS REGULATIONS"
WE NEED YOUR SUPPORT!**

On Monday, September 10 in Sacramento, the Department of Toxic Substance Control (DTSC) conducted a public hearing on its newly proposed Safer Consumer Products Regulations. You can find more information on these proposed regulations on the following webpage: <http://beautyisourbusiness.org/issues/california-green-chemistry-initiative>.

Please read further to supply written comments. Representatives from the beauty industry were on-site to assist speakers.

ICMAD will provide extensive written comments and will have information to assist members with their written comments. If you did not attend but would like to, the DTSC requires all written comments to be submitted no later than Thursday, October 11th at 5pm.

All written comments must be submitted to:

Krycia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
E-mail Address: gcregs@dtsc.ca.gov
Fax Number: (916) 324-1808
Phone number: (916) 324-2810
If Ms. Von Burg is unavailable, please call Mr. Cordova at (916) 324-7193.

Please email ssebor@icmad.org or yseaton@icmad.org or call 800-334-2623, ext. 102 or ext. 107 to let us know if you plan to submit written comments. Don't hesitate to call or email at any time with questions.

Links to Copies of the Proposed Regulations and Summary explanation are:

Information on the regulation: www.dtsc.ca.gov/SCPRegulations.cfm

For information on DTSC's nail polish report:
<http://www.dtsc.ca.gov/PollutionPrevention/SaferNailProducts.cfm>

On July 27, 2012, the California Department of Toxic Substances Control (DTSC) issued newly revised Proposed Regulations under its legislative mandate to provide for Safer Consumer Products, which state that specified Chemicals of Concern in consumer products be replaced with safer chemicals (i.e., “green chemistry”).

The list of Chemicals of Concern (COC) will be published by DTSC and will be based on and include lists prepared by numerous domestic and international bodies that identify both existing and possible COCs. Final comments are due on these Regulations, which will have far-reaching effects on the cosmetic and personal care industry, by October 11, 2012 (DTSC announced that it is extending the comment deadline from September 11, 2012, to October 11, 2012).

Covered Products and Entities

Cosmetic and prescription drug products will be covered by these regulations and apply to “Responsible Entities,” including manufacturers, marketers, importers, and, in some instances, retailers of products that contain COCs. The thrust of these new regulations will be to require reformulation of COC-containing products with green chemical alternatives or to otherwise justify continued marketing of the COC-containing product in California by demonstrating through detailed analysis that human and environmental health and safety concerns can be addressed through limitations on use, concentrations of the COCs, or other means. If reformulation or demonstration of safety cannot be achieved, the product would have to be removed from sale in California.

New Requirements

If finalized as proposed, these regulations will require the DTSC to issue an immediate list of COCs. It is estimated that the DTSC will initially identify at least 1,200 COCs. Based upon the COCs and information the DTSC has developed from prior product studies, including the recently conducted nail polish study along with consideration of relative product risks, the DTSC is expected to identify a list of Priority Products of Concern. Responsible Entities that manufacture or import Priority Products of Concern are then required to identify those products to the DTSC and engage in an extensive process of evaluation and assessment by qualified assessors to determine how best to limit exposure to, or the level of, adverse public health and environmental impact posed by these COCs, removal and/or substitution of the COC ingredient using green chemistry.

If the Product of Concern cannot or is not reformulated, the DTSC will identify and impose regulatory responses to prevent or limit adverse public health and/or environmental impacts posed by the Priority Product/COCs. The DTSC can then require consumer disclosures; establish requirements that the Responsible Entity maintain and fund end-of-life product programs; restrict the use of COCs in the product or use of the product itself; and/or prohibit sales of the product in California.

Specific Areas of Concern

While it is difficult to assess the full impact these proposed regulations will have on the cosmetic and personal care industry, it is clear that if the regulations are finalized in their current form, the ingredients as well as existing product formulations will be reviewed for hazards beyond human exposures. As proposed, these regulations authorize DTSC to identify COCs from an incredibly broad range of domestic and international authoritative lists, which cover environmental and other hazards that go far beyond those of human exposure risks. These lists typically contain chemicals that have been found to present stated risks, chemicals under study, or chemicals suspected of containing possible exposure risks.

What this means for you

This proposed regulatory initiative is very different from California’s prior regulatory initiatives, Proposition 65 and the California Safe Cosmetics Act. Proposition 65 is inherently a labeling statute that requires products containing listed chemicals to bear a prescribed warning statement on the labels. California’s Safe Cosmetic Act

is inherently a registration statute which requires registration of products that contain listed ingredients. Neither of these statutes authorizes the state to require product reformulation or failing reformulation to ban product distribution.

The regulatory scheme proposed by these “green chemistry” regulations empower the state to develop lists of ingredients that are considered to be COCs and then identify Priority Products containing these COCs. Once a Priority Product is identified, the manufacturer will be forced to perform a broad study refuting and or ameliorating the exposures failing this test. The Priority Products either have to be reformulated with chemicals perceived to be “safer” or withdrawn from the California market.

The regulations as proposed do not recognize de minimus concentrations and no consideration is given to whether the listed COC is an intentional ingredient or an inadvertent ingredient that may be present in an ingredient in very low levels. The process of determining the presence or concentrations of these inadvertent ingredients can be costly.

Lastly and perhaps most troublesome is that a listed COC may only be “suspected” of being a hazard. This could result in either banning or reformulation only to find that the COC after study turns out not to present the suspected hazard. A good example is what might have happened if these regulations went into effect while benzoyl peroxide, a well-known active used in acne products, was under study by the FDA for possible health hazards. Benzoyl peroxide was for many years suspected of being a possible health hazard. The FDA permitted continued use of this ingredient until definitive studies were completed. After years of testing it was determined that the ingredient did not present the suspected health hazard and the ingredient was permanently listed in the acne monograph.

Under DTSC’s proposed regulations it could well have listed this ingredient as a COC and forced marketers to discontinue sale of products containing this ingredient in California. This would have resulted not only in extraordinary and unnecessary costs but it also would more importantly have denied consumers access to an important medication. This is but one example of the myriad of issues that these regulations may create both from the perspective of product access for California residents but also from the clear burden that this will create on national marketers especially if other states decide to follow California’s example and identify their own COCs which could well be different from those identified by California.

From a procedural perspective the regulations establish a complex series of reviews and submissions once a COC and a Priority Product have been identified with timelines for submissions and compliance. While these timelines have been extended from what was previously proposed, there has been no separate consideration or accommodations made for the impact of compliance on small- to mid-sized companies. Nor do the regulations clearly address duplicative regulatory reviews by other state or federal governmental regulatory bodies, which have concurrent regulatory oversight of product safety. For your information links to the proposed regulations and a summary of the proposed regulations are located below.

Based upon recent studies conducted by the DTSC on nail polish products there is concern that when these regulations are finalized nail polish may be one of their initial Products of Concern.

Further Action

In the next several weeks, we will be calling on our members to send comments .