



JONES DAY
COMMENTARY

REGULATION OF CHEMICALS IN CONSUMER PRODUCTS

Environmental agencies are taking more aggressive steps to regulate the content of consumer products. On the national level, EPA has released draft guidance expanding on how it conducts “alternatives assessments,” which EPA uses to identify safer alternatives to targeted chemicals found in consumer products. The assessments often are included in Chemical Action Plans implemented under the federal Toxic Substances Control Act (“TSCA”). At the state level, California’s Department of Toxic Substances Control (“DTSC”) has proposed regulations under its Green Chemistry program that, if adopted, will require certain manufacturers to review their products in order to identify safer alternatives to chemicals of concern. DTSC’s proposed regulations, and the underlying statute, give the agency substantial authority over consumer products, including the authority to prohibit the sale of products in California that do not contain safer alternative chemicals.

EPA’S EXPANDED USE OF TSCA

EPA has been criticized by environmental groups for not paying enough attention to the potential risks associated with chemicals in products. To address this concern, EPA has been taking steps to enhance the Agency’s chemical management program pursuant to its existing authorities under TSCA.

For example, EPA has broadened the use of Chemical Action Plans, which are prepared by EPA to identify and review chemicals that may pose a potential threat to public health. In selecting chemicals for development of Chemical Action Plans, EPA considers a variety of factors, including whether the chemicals (1) are persistent, bioaccumulative, and toxic (known as “PBT” chemicals); (2) are used in high volumes; (3) potentially threaten children’s health; or (4) actually are absorbed by the human body through environmental exposures. EPA has established criteria to identify PBT chemicals based upon persistence in the environment, ability to accumulate in biological organisms, and toxicity.¹

¹ EPA’s TSCA Policy for PBT Chemicals, 64 Fed. Reg. 60194 (November 4, 1999). See also EPA’s “TSCA New Chemicals Program (NCP) Chemical Categories,” August 2010, which can be found at www.epa.gov/oppt/newchemicals/pubs/cat02.pdf.

Generally speaking, Chemical Action Plans prepared by EPA identify chemicals that are candidates for enhanced risk management. The plans summarize the available chemical hazard, exposure, and use information; suggest steps to further evaluate the chemical; outline the risks the chemical may present; and identify specific steps to address the risks. EPA has posted several Chemical Action Plans on its web site, including plans for bisphenol, phthalates, perfluorinated chemicals, and polybrominated diphenyl ethers.² EPA plans to prepare additional Chemical Action Plans at four-month intervals. Chemical Action Plans can result in further action by EPA under the authorities granted to it by TSCA, including requiring the submission of additional data, and a decision by EPA to conduct an alternatives assessment for the chemical. EPA also may initiate regulatory action under TSCA to require labeling, or to restrict or ban the chemical, as it has done for asbestos and PCBs.

EPA “alternatives assessments” are a component of the Agency’s Design for the Environment program and often are required by EPA’s Chemical Action Plans. EPA uses alternatives assessments to identify safer alternatives to targeted chemicals found in consumer products. EPA released draft guidance on how to conduct alternatives assessments in November 2010 and accepted comments on the draft until January 31, 2011.³ The primary steps in conducting an alternatives assessment include (1) determining whether alternatives are commercially available, cost effective, and likely to result in lasting change; (2) collecting information on the chemical of concern and potential alternatives; (3) convening stakeholders to discuss the chemical under review and potential alternative chemicals; (4) identifying viable alternatives; (5) conducting a hazard assessment of each alternative; (6) applying economic and life cycle considerations; and (7) deciding if there are commercially viable safer chemical substitutes.

To date, EPA has applied the alternatives assessment methodology to flame retardants in furniture and printed circuit boards. In both cases, the assessments were undertaken in conjunction with major stakeholders (including the chemical manufacturers), and they resulted in reports identifying potential alternative chemicals and their characteristics. EPA currently is applying the alternatives assessment approach to another flame retardant and a chemical found in thermal paper. EPA plans to conduct additional alternatives assessments in the future, including assessment of plasticizers and chemicals used in polystyrene foam.

While ongoing EPA action under the enhanced chemical management program likely will lead to additional restrictions on use of certain chemicals in consumer products, environmental groups have expressed concern that the regulatory structure of TSCA is insufficient to successfully manage all the chemicals currently in the market and that will be introduced in the future. This concern led to several proposed amendments to TSCA in 2010, most notably Senate Bill 3209 (“Safe Chemicals Act of 2010”) introduced by Senator Lautenberg, and House Bill 5820 (“Toxic Chemicals Safety Act of 2010”) introduced by Representatives Waxman and Rush. Both bills would have prohibited the manufacture, import, processing, and distribution of a chemical substance or mixture if the safety of the product had not been demonstrated to the satisfaction of EPA. Neither bill was enacted.

CALIFORNIA’S GREEN CHEMISTRY PROGRAM

Concern over the perceived inadequacy of TSCA has prompted states to take independent action. In 2008, the California legislature passed, and Governor Schwarzenegger signed into law, Senate Bill 509 and Assembly Bill 1879, which together constitute the state’s “Green Chemistry” program.⁴ The law directs DTSC to identify and prioritize chemical ingredients in consumer products that may be chemicals of concern,⁵ and to determine how best to limit or

² www.epa.gov/oppt/existingchemicals/pubs/ecactionpln.html.

³ “Design for the Environment Program, Alternatives Assessment Criteria for Hazard Evaluation”; November 2010, http://epa.gov/dfe/alternatives_assessment_criteria_hazard_eval_nov2010_final_draft2.pdf.

⁴ California Health & Safety Code sections 25251–25257.1.

⁵ California Health & Safety Code section 25252.

reduce the hazards posed by such chemicals.⁶ The law also directs DTSC to establish a process for evaluating potential alternatives to chemicals of concern.⁷ Significantly, the law requires DTSC to specify in the regulations how it will respond to an alternatives assessment, including prohibiting use of a chemical in a consumer product.⁸

DTSC proposed regulations to implement the statute on September 7, 2010, and accepted comments until the close of its public hearing on November 1, 2010. DTSC subsequently revised its proposal to reflect post-hearing changes.⁹ DTSC issued a notice opening up an additional public comment period until December 3, 2010. The date for additional comments has closed.

Under the proposed regulations, DTSC will identify and prioritize chemicals of concern.¹⁰ The process will include public notice and opportunity for comment, and at least one public workshop. Factors that DTSC will consider in selecting chemicals of concern will include the degree of threat posed by the chemical, the potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in adverse impacts, the availability of reliable information, the scope of existing federal and/or California regulatory programs, and the availability of DTSC resources. DTSC will finalize the initial list of chemicals of concern no later than December 31, 2011, when it will post the list on the DTSC web site.

In a subsequent step, DTSC will prepare a list of products that are "priority products" due to the presence of chemicals of concern in them. The list will take into account the relative degree of threat posed by the product due to the chemical of concern, the availability of reliable information to substantiate the threats, the scope of other existing federal and/or

California programs, the availability of a relevant alternatives assessment, and the availability of DTSC resources.¹¹ The process of listing priority products will include public notice and opportunity for comments. DTSC will finalize the initial priority product list no later than December 31, 2012, when it will post the list on the DTSC website.

After DTSC identifies chemicals of concern and priority products, the burden under the proposed regulations will shift to the party responsible for the product. The responsible party typically will be the manufacturer of the product, although it also could be a retailer if the manufacturer fails to comply with the regulations. The proposed regulations will require the responsible party to notify DTSC if its product is a priority product¹² and thereafter will require the responsible party to conduct an alternatives assessment.¹³ The alternatives assessment must include a chemical hazard assessment, a potential exposure assessment, a multimedia life cycle evaluation, a product function and performance analysis, and an economic impact analysis, each of which is described in the regulations. The alternatives assessment also must identify and describe the alternative, if any, selected to replace the chemical of concern, or the rationale for not selecting an alternative, substitute chemical.

The proposed regulations will not require further action by the responsible party (usually the manufacturer) if (1) the responsible party implements the alternatives assessment and substitutes the alternative chemical, if any is identified, for the original chemical of concern; (2) the selected alternative does not contain a chemical of concern above a *de minimis* level and does not pose a significant threat to public health or the environment; and (3) the product containing the original chemical of concern is completely removed from commerce in California within three years after DTSC

6 California Health & Safety Code section 25253(a)(1).

7 California Health & Safety Code section 25253(a)(2).

8 California Health & Safety Code section 25253(b).

9 The revised proposal may be found at www.dtsc.ca.gov/LawsRegsPolicies/Regs/SCPA.cfm.

10 Proposed Sections 69302–69302.3.

11 Proposed Sections 69303–69303.4.

12 Proposed Section 69303.4.

13 Proposed Sections 69305–69395.5.

determines that the report was complete.¹⁴ The proposed regulations will require further action by the responsible party if the selected alternative contains a chemical of concern above *de minimis* levels or if no alternative is selected. In this event, the responsible party must make specified information available to the consumer, including providing a list of the chemicals of concern in the product and describing safe handling procedures needed to protect health or the environment.¹⁵ In addition, if the product is required to be managed as a hazardous waste at the end of its useful life, the responsible party must fund, establish, and maintain an end-of-life management program that satisfies numerous requirements, including collection mechanisms, and programs to recycle or otherwise appropriately manage the waste.¹⁶

The most significant regulatory response to an alternatives assessment will occur if the responsible party selects an alternative that contains a chemical of concern above *de minimis* levels, or does not select any alternative to the chemical of concern. In this case, if DTSC determines a safer alternative exists that does not contain a chemical of concern, and notifies the responsible party of this finding, then the responsible party must cease selling the product in California within one year and must complete a recall program within three years.¹⁷ Under the proposed regulations, DTSC will provide public notice and an opportunity for public comment, and hold at least one public workshop, before issuing a final notice of its determination that a safer alternative chemical exists.¹⁸ Other regulatory responses available to

DTSC will include (1) requiring engineered safety measures to control access to or limit exposure to the chemical of concern; (2) placing restrictions on the use of the chemical of concern; (3) requiring the responsible party to initiate a research and development project if the alternatives assessment report did not identify any alternatives; and (4) requiring preparation of a new alternatives assessment report.¹⁹

Responsible parties who receive a notice of determination by DTSC that a safer alternative chemical exists, or who receive from DTSC certain other regulatory responses (except for responses requiring research and development or requiring preparation of a new alternatives assessment report), must send a notice to retailers that sell the product in California, including a description of DTSC's notice of determination or other regulatory response.²⁰ The proposed regulations give DTSC the authority to grant exemptions from the regulatory response requirements described above if DTSC concludes that the response would conflict with and/or duplicate a requirement of another California or federal program or international trade agreement.²¹

CONCLUSION

The era of regulatory agencies specifying which chemicals can be used in which products, and which products are safe, is here. Manufacturers, distributors, and retailers of consumer products should become familiar with these new regulatory programs, as they will directly affect their businesses.

14 Proposed Section 69306.2.

15 Proposed Section 69306.3.

16 Proposed Section 69306.4.

17 Proposed Section 69306.5.

18 Proposed Section 69306.8.

19 Proposed Section 69306.6.

20 Proposed Section 69306.9.

21 Proposed Section 69306.7.

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