

Client Alert

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CPSC's Proposed Rule Would Expand Phthalate Ban

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The Consumer Product Safety Commission (CPSC) recently published a long-awaited proposed rule that, if finalized in its current form, would permanently ban certain additional phthalates from children's toys and child care products. 79 Fed. Reg. 78324 (Dec. 30, 2014). The proposed additional phthalate ban covers DIBP, DPENP, DHEXP, and DCHP, and applies to these two categories of products, while leaving in place the CPSC's original ban of DEHP, BBP, and DBP for the same types of items. If the proposed rule is adopted as expected, the CPSC's interim ban of DNOP and DIDP, which applied only to child care products and mouthable toys, will also sunset, so there could be some major changes in store for those that make, source, and sell children's and baby care products.

BACKGROUND

Phthalates are a group of chemicals used to soften plastics and make them pliable and easier to be gripped. They are found in numerous household products, including plastic toys, tote bags for cosmetics and other uses made with vinyl or imitation leather, and some types of home furnishings that utilize the same types of PVC-based materials. Due to concerns that they can act as endocrine disruptors, as part of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Congress enacted requirements regarding phthalate levels in children's products. Specifically, Section 108 (15 U.S.C. § 2057(c)) permanently banned three phthalates (DEHP, DBP, and BBP) in children's toys or child care products at levels greater than 0.1% (> 1,000 parts per million). CPSIA Section 108 placed an interim ban on three additional phthalates (DINP, DIDP, and DNOP) in mouthable child care articles like teething rings until promulgation of a final rule by CPSC.

CPSIA Section 108 also required CPSC to convene a Chronic Hazard Advisory Panel (CHAP) to assess the risks of phthalates and phthalate alternatives. The CHAP was to make recommendations based on its findings, regarding whether to make permanent the interim ban and whether any additional phthalates should be banned. CPSC was then instructed to promulgate a final rule continuing or lifting the interim ban as needed to ensure the safety of "children, pregnant women, or other susceptible individuals"; and to evaluate whether any other children's products containing phthalates should be banned "to protect the health of children." CPSIA § 108(b)(3).

The CHAP issued its report in July 2014. It based its findings on evidence of effects on male reproductive development, and essentially concluded that those phthalates associated with harmful effects on male reproductive organs (i.e., antiandrogenic effects) should be banned, while those that exhibited no such effects should not. Part of its reasoning stemmed from evidence that the antiandrogenic effects of phthalates are cumulative over time. On December 30, 2014, CPSC published a Notice of Proposed Rulemaking, adopting all but one of the CHAP's recommendations.

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1. No Change to Phthalates Permanently Banned by the CPSIA

The CHAP did not make any recommendations regarding DEHP, DBP, or BBP, as these three phthalates were already permanently banned by the CPSIA as enacted by Congress in 2008.

2. DINP Ban Made Permanent; DNOP and DIDP Bans Lifted

With regard to the phthalates that were subject to the CPSIA's interim ban, CPSC adopted the CHAP's recommendation to make permanent the ban on DINP. CPSC noted that "[a]lthough DINP is less potent than DEHP, or other active phthalates, the CHAP reasoned that DINP is antiandrogenic and contributes to the cumulative risk from phthalates." 79 Fed. Reg. at 78329 (citing CHAP report at 95-99).

On the other hand, according to the CPSC's rulemaking, DNOP and DIDP did "not appear to possess antiandrogenic potential," and therefore their risks were not considered cumulative. The CHAP determined that the level of exposure would not be high enough to raise other potential toxicity concerns, and recommended that CPSC lift the ban on these two phthalates. The proposed rule reflects this recommendation.

3. Four Additional Phthalates Face Permanent Bans

Perhaps most significantly, the CHAP recommended **a permanent ban on four additional phthalates with antiandrogenic effects: DIBP, DPENP DHEXP, and DCHP**. CPSC's proposed rule adopts this recommendation.

4. DIOP Has Uncertain Regulatory Future

The CHAP also evaluated DIOP and recommended an interim ban until more data is available. However, CPSC did not take any action with regard to the recommended interim ban on DIOP, noting that "the CPSIA did not provide for an interim prohibition as an option for" CPSC rulemaking. 79 Fed. Reg. at 78337.

5. No Action Recommended for Three Phthalates

Finally, the CHAP assessed DPHP, DMP, and DEP, which were not regulated by the CPSIA. The CHAP did not recommend that CPSC take any action with respect to these phthalates; however, it did encourage federal agencies to obtain additional information and monitor exposure to these chemicals.

SCOPE OF THE NEW EXTENDED PHTHALATE BANS

CPSC's proposed permanent ban of DINP would expand the scope of the interim ban to all toys and child care articles, whereas the interim ban applies only to mouthable toys and child care articles. For the remaining phthalates subject to bans, CPSC decided not to extend the scope beyond children's toys and child care articles, declining to ban phthalates from all children's products as it had authority to do under Section 108(b)(3)(B) of the CPSIA. This was due to insufficient information suggesting that expanding the ban beyond children's toys and child care articles would impact exposure levels, as well as evidence that oral exposure is generally higher than dermal exposure.

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NO CHANGE IN CONCENTRATION LIMITS

Finally, CPSC decided not to change the 0.1% (1,000 part per million) concentration limit, agreeing with the CHAP's finding that there was "no compelling reason to support lowering or raising the concentration limit." 79 Fed. Reg. at 78338. CPSC noted that there was insufficient information to determine a risk-based limit and, instead, the 0.1% limit was practical, designed to "prohibit intentional phthalate use while allowing trace levels." *Id.* CPSC also found that "[a] lower limit would make it more difficult to perform the testing required of third party laboratories, which may lead to increased testing costs. Compliance testing would also be more difficult." *Id.*

COMMENT PERIOD OPEN UNTIL MARCH 16, 2015

The CHAP report has been criticized by the American Chemistry Council, an industry trade association that faulted CPSC for not allowing public comment on a draft report, or public participation in any meetings with peer reviewers of the CHAP report.¹ Expect to see more industry challenges and comments, and perhaps even some litigation, before the rule is final. Interested parties can submit comments until March 16, 2015, and must participate in the comment process in order to preserve their rights to mount a legal challenge to a finalized rule if they determine that they can't live with it.

Morrison & Foerster has counseled and represented numerous businesses on CPSIA requirements, including with respect to phthalates. We also assist companies with a wide variety of CPSC issues, and have the largest and most sophisticated Proposition 65 practice in the world. If you are interested in our services, with respect to the CPSC's comment process or otherwise, please feel free to contact:

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¹ See ACC Challenges the Conclusions of the CPSC CHAP Report on Phthalates Based on a Flawed CPSC Process (Jul. 19, 2014), available at <http://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Challenges-the-Conclusions-of-the-CPSC-CHAP-Report-on-Phthalates-Based-on-a-Flawed-CPSC-Process.html>.

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