
Insight
By Cierra Simpson and Lisa Rippey

Phthalates are chemicals that provide flexibility and durability to a variety of products. They have historically been used in children’s toys, particularly those made of flexible plastics. Phthalates soften plastics, permitting children to play and chew on the product without breaking or cracking it.

Like other chemicals, phthalates may pose various risks to human health. One example being they have been found to be endocrine disruptors, which can lead to serious reproductive problems for children later in life. To address this issue, various states have begun passing legislation regulating the use of phthalates, and several companies have removed phthalates from the children’s products they manufacture and sell.

In 2008, Congress passed the Consumer Product Safety Improvement Act (CPSIA), which banned the use of certain types of phthalates in children’s products, and requires third party testing for certain children’s toys and child care articles. See, 15 U.S.C. § 2057c and 15 U.S.C. § 2063(a)(2). The CPSIA also required the Consumer Product Safety Commission (CPSC) to appoint a Chronic Hazard Advisory Panel (CHAP) to study the effects of phthalates in children’s products. The CPSC may promulgate final rules based on CHAP’s recommendations. Pursuant to this authority, 16 C.F.R. § 1199.1 was enacted in February 2013 and sets forth details regarding the inaccessible component part exception to the phthalate ban. Additionally, the CPSC issued a final rule in March 2013 to address specific third party testing requirements for phthalates. See, 78 Federal Register 15836, codified in 16 C.F.R. §§ 1112 and 1118.
This article will focus on these and other current and proposed regulations related to phthalates in children’s toys and child care products.

**What are Phthalates?**

Phthalates are oily, colorless, odorless liquids that are added to hard plastics to improve their flexibility and durability. They can be found in many different products, such as wall-coverings, cosmetics, medical devices, and laboratory tubing. Phthalates are also found in children’s plastic toys, including teethers, pacifiers, soft rattles, rubber ducks, bath books, and other squeezable plastic toys. Because phthalates are not chemically bound to the plastic to which they are added, they are easily released from the plastic. As such, people may be exposed to phthalates through inhalation, intravenous injection, and skin absorption. Children are especially prone to phthalate exposure through chewing on children’s products containing phthalates.

It was then discovered that some types of phthalates could be endocrine disruptors, which interfere with the production, release, transport, metabolism, or elimination of natural hormones in the body. Exposure to endocrine disruptors may result in poor semen quality, reduced fertility, testicular cancer, and undescended testes. These findings led to a push for a ban on phthalates in children’s products.

**Current Regulations Governing Phthalates**

The CPSIA has permanently banned three types of phthalates, DEHP, DBP, and BBP, in children’s toys and child care products at levels greater than 0.1% (1,000 parts per million). See, 15 U.S.C. § 2057c. A children’s toy is defined as “a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays.” Child care articles are defined in CPSIA as “a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or sleeping.”

The CPSIA also placed an interim ban on DINP, DIDP, and DNOP in children’s toys that can be placed in a child’s mouth or child care articles at levels greater than 0.1% (1,000 parts per million). A toy can be placed in a child’s mouth if “any part of the toy can actually be brought to the mouth and kept in the mouth by a child,” but the toy is not regarded as able to be placed in the mouth if it can only be licked.

The phthalate bans do not apply to components of children’s toys or child care articles that are not accessible through normal and reasonably foreseeable use and abuse of the product. To be considered inaccessible, the phthalate-containing component must be enclosed, encased, or covered by fabric and must pass the use and abuse test. See, 16 C.F.R. § 1199.1(1). However, if the component is smaller than 5 centimeters in one dimension, it is not considered inaccessible.
The CPSIA requires that a product manufacturer or importer submit samples of its children’s toys and child care articles to a third-party lab for testing to ensure compliance with the phthalate standards. See, 15 U.S.C. § 2063(a)(2). Based on the testing, the manufacturer or importer must certify that the children’s product complies with the standards. There are two test methods currently approved by the CPSC for these standards: CPSC Test Method CPSC-CH-1001-09.3, “Standard Operating Procedure for Determination of Phthalates”; and GB/T 22048-2008, “Toys and Children’s Products-Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic.” See, 78 FR 15836-01.

The CPSIA required the CPSC to appoint CHAP to study the effects of phthalates and phthalate alternatives on children’s health. See, 15 U.S.C. § 2057c. CHAP was then required to submit a report to CPSC making recommendations regarding whether the interim bans on certain phthalates should be made permanent. The panel was also tasked with determining whether any additional phthalates or phthalate alternatives should be banned. Finally, after receiving CHAP’s report, the CPSIA requires that the CPSC promulgate a final rule continuing or lifting the interim bans, and to evaluate whether any other phthalates should be banned from use in children’s products.

**CHAP’s Findings and Recommendations**

CHAP issued its report on phthalates in July 2014. It determined that those phthalates that are associated with harmful effects on male reproductive organs should be banned, and phthalates that did not exhibit these harmful effects should not be banned. Specifically, CHAP recommended the following:

- No further action should be taken regarding DEHP, DBP, or BBP, because they were already permanently banned by the CPSIA.
- The interim ban on DINP should be made permanent.
- The interim ban on DNOP and DIDP should be lifted, as these phthalates did not appear to have harmful effects to male reproductive organs.
- A permanent ban should be placed on four additional phthalates that had harmful effects on male reproductive organs - DIBP, DPENP, DHEXP, and DCHP;
- An interim ban should be placed on DIOP until more research was done and more data was available;
- No further action should be taken regarding DPHP, DMP, and DEP, because they were not regulated by the CPSIA;
- The scope of the interim ban should be expanded to all children’s toys and child care articles, instead of only those that can be placed in a child’s mouth; and
- No expansion should be made to the ban beyond children’s toys and child care articles.

The CPSC’s Response to CHAP’s Recommendations and Proposed Rules

In December 2014, the CPSC issued a proposed rule adopting all but one of CHAP’s recommendations. Specifically, the CPSC did not adopt the recommendation that an interim ban be placed on DIOP pending further investigation because the CPSIA “did not provide for an interim prohibition as an option for the Commission’s rule.” The comment period on the proposed rule ended on April 15, 2015. Organizations including the American Chemistry Council filed comments in opposition to the CHAP report and proposed rule. However, the Natural Resources Defense Council and other organizations wrote comments in favor of the report and proposed rule. The proposed rule is currently awaiting final review by the CPSC.

On August 17, 2016, the CPSC posted notice in the Federal Register of another proposed rule related to phthalates. Under this proposed rule, certain plastics with specified additives would not require third party testing if they do not contain the specified phthalates prohibited in children’s toys and child care articles. The comment period has not yet concluded for this proposed rule, but the CPSC suggested that the effective date of the final rule should be 30 days from the date of publication.

Impressions

It appears that phthalates possessing endocrine disruptive properties, thereby having harmful effects on reproductive organs, are in the process of becoming permanently banned from children’s toys and child care products. The Consumer Product Safety Improvement Act of 2008 permanently banned three types of phthalates and placed an interim ban on three additional types. Upon further study, the Chronic Hazard Advisory Panel recommended permanently banning those phthalates that had harmful effects to the male reproductive organs and recommended lifting the ban on those phthalates that did not. The Consumer Product Safety Commission adopted all but one of the CHAP’s recommendations in a proposed rule that is currently pending.

For more information about the regulation of phthalates, please contact Cierra Simpson, Michelle Corrigan or the Stinson Leonard Street attorney with whom you regularly work.

Lisa Rippey, a law student at the University of Missouri-Kansas City School of Law, co-wrote this article while working as a summer associate with Stinson Leonard Street LLP.

1. The following types of phthalates will be discussed in this article: (1) di-(2-ethylhexly) phthalate (“DEHP”); (2) di-isobutyl phthalate (“DBP”); (3) butyl benzyl phthalate (“BBP”); (4) di-isononly phthalate (“DINP”); (5) di-n-octylphthalate (“DNOP”); (6) di-isodecyl phthalate (“DIDP”); (7) di-isobutyl phthalate (“DIBP”); (8) di-n-pentyl phthalate (“DPENP”); (9) di-n-hexly phthalates (“DHEXP”); (10) dicyclohexyl phthalate (“DCHP”); (11) diisooctyl phthalate (“DIOP”).


4. Early Life Exposure to Phthalates and Breast Cancer Risk in Later Years Fact Sheet on Phthalates, BREAST CANCER & THE ENVIRONMENT RESEARCH CENTERS

5. Schettler, supra note 4.


7. Tests for use and abuse test are set out by age group in 16 C.F.R. §§ 1500.50 to 1500.53.


ATTORNEY
Lisa M. Rippey

RELATED CAPABILITIES
Children’s Products
Product Liability