

Prohibition on the Sale of Certain Products Containing Specified Phthalates
Section 108 of the Consumer Product Safety Improvement Act (CPSIA)
Request for Comments and Information*

The staff of the U.S. Consumer Product Safety Commission (CPSC) invites comments on Section 108 of the Consumer Product Safety Improvement Act (CPSIA), “PROHIBITION ON SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES”.

Subsection 108(a) prohibits the manufacture, import, distribution, or sale of children’s toys or child care articles containing more than 0.1% of benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), or di-(2-ethylhexyl) phthalate (DEHP), beginning February 10, 2009.

Subsection 108(b)(1) further prohibits, on an interim basis, the manufacture, import, distribution, or sale of “children’s toys that can be placed in a child’s mouth” or child care articles containing more than 0.1% of diisodecyl phthalate (DIDP), diisononyl phthalate (DINP), or di-*n*-octyl phthalate (DnOP), beginning February 10, 2009. The Commission will determine whether to continue the interim ban, as described below.

Subsection 108(b)(2) requires the Commission to begin the process of appointing a Chronic Hazard Advisory Panel (CHAP) “not before” February 10, 2009. The purpose of the CHAP is to review the potential effects on children’s health of all phthalates and phthalate alternatives in children’s toys and child care articles. In doing so, the CHAP will consider the cumulative effects of exposure to multiple phthalates from all sources, including personal care products. The CHAP will recommend to the Commission whether to continue the interim ban and whether additional bans on phthalates or phthalate alternatives are needed.

Subsection 108(e) defines “children’s toy” 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.” A “child care article” is defined 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 teething.” A toy is considered a “toy that 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 so that it can be sucked and chewed. If the children’s product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth.”

* This document was prepared by the CPSC staff, has not been reviewed or approved by, and may not necessarily represent the views of, the Commission.

The CPSC staff is interested in comments and information regarding:

Use of Polyvinyl Chloride (PVC) in Children's Products

- What types of toys for children up to age 12, as defined in the CPSIA, may contain PVC or vinyl plastic, and why?
- What types of toys that can be mouthed or child care articles, for children up to age 3, as defined in the CPSIA, may contain PVC or vinyl plastic, and why?
- What children's products other than toys, toys that can be mouthed, or child care articles contain PVC or vinyl plastic, and why?
- Considering that phthalates may have uses other than as plasticizers for PVC, are there any other types of children's toys, toys that can be mouthed, or child care articles that may contain phthalates or phthalate alternatives?

Use of Non-PVC Plastics in Children's Products

- What non-PVC types of plastics, polymers, rubbers, and elastomers are currently used in children's toys, toys that can be mouthed, or child care articles?
 - In which types of products are they commonly used?
 - Are they used in other types of children's products other than toys or child care articles?
- What plastics, polymers, rubbers, and elastomers will be used after the effective date of section 108 of the CPSIA, February 10, 2009?
- Are phthalates used as plasticizers, solvents, or for any other purpose in any of the plastics, polymers, rubbers, or elastomers that may be used in children's products?

Use of Phthalates and Phthalate Alternatives in Children's Products

- What phthalates or phthalate alternatives are currently used in children's toys, toys that can be mouthed, or child care articles, and why?
- What phthalates or phthalate alternatives will be used after February 10, 2009, and why?
- Are phthalates or phthalates alternatives used in plastics other than PVC, and why?
- Are phthalates or phthalate alternatives used in children's products for purposes other than as PVC plasticizers? Which products?
- Are there any additional phthalates or phthalate alternatives that may be used or are likely to be used in children's products in the future?

Measurement of Phthalates in Children's Products

- What analytical method(s) may be suitable for the routine identification and measurement of total phthalate concentration for each of the covered phthalate chemicals in children's products?
 - Include information on repeatability and reproducibility, such as inter-laboratory ("round-robin") studies.
- Are there any standard reference materials available for phthalates or phthalate substitutes in PVC?
- Are there any screening methods or technologies that may be suitable for the rapid identification of plasticizers in children's products?

Toxicity of Phthalates and Phthalate Alternatives. The staff is interested in any new[†] (since 2002) or unpublished data relating to:

- The toxicity of phthalates or phthalate alternatives.
- The toxicity of PVC or other materials that may contain phthalates or phthalate alternatives.

Exposure to Phthalates and Phthalate Alternatives. The staff is interested in any new (since 2002) or unpublished data or analyses relating to:

- Migration of phthalates or phthalate alternatives from PVC or children's products.
 - Information on how migration studies relate to human exposure from mouthing, handling, or inhaling phthalates or phthalate alternatives, or products containing these chemicals.
- Human (including children's and pregnant women's) exposure to phthalates or phthalate alternatives from all sources, including building materials, consumer products, personal care products, and food.
- Levels of phthalates or phthalate alternatives in human tissues, milk, or body fluids, including those of children.
- The presence of phthalates or phthalate alternatives in indoor air or household dust.

Comments must be received by the Office of the Secretary not later than February 11, 2009. Comments may be filed by e-mail to phthalates-info@cpsc.gov. Comments may also be filed by facsimile to (301) 504-0127 or by mail or delivery to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, MD 20814. Comments should be captioned "Section 108: Phthalates in Children's Products." Interested persons will also have additional opportunities to comment following publication of any notices of rulemaking proceedings in the *Federal Register* which are commenced under these sections.

[†] The CPSIA directs the staff to evaluate all available data as part of a "de novo review." The staff has copies of many studies on phthalates prior to 2002 and is not requesting duplicate copies of studies it already has in its files or are readily available in peer-reviewed publications.