



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 4330 EAST WEST HIGHWAY
 BETHESDA, MD 20814

This document has been electronically approved and signed.

BALLOT VOTE SHEET

Date: January 30, 2013

TO : The Commission
 Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
 Kenneth R. Hinson, Executive Director
 Patricia M. Pollitzer, Assistant General Counsel

FROM : Hyun S. Kim, Attorney

SUBJECT : Children’s Toys and Child Care Articles Containing Phthalates; Final Guidance on Inaccessible Component Parts

BALLOT VOTE Due: February 5, 2013

The Office of General Counsel is providing the attached draft *Federal Register* notice for Commission consideration. In accordance with section 108(d)(3) of the Consumer Product Safety Improvement Act of 2008, Public Law 110-314, as amended by Public Law 112-28, the draft *Federal Register* notice provides guidance on inaccessible component parts for children’s toys and child care articles that contain phthalates.

Please indicate your vote on the following options:

I. Approve publication of the draft notice in the *Federal Register*.

 (Signature)

 (Date)

II. Approve publication of the draft notice in the *Federal Register*, with changes.
 (Please specify.)

 (Signature)

 (Date)

III. Do not approve publication of the draft notice in the *Federal Register*.

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* notice: Children’s Toys and Child Care Articles Containing Phthalates; Final Guidance on Inaccessible Component Parts

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2012-0040]

16 CFR Part 1199

Children's Toys and Child Care Articles Containing Phthalates; Final Guidance on Inaccessible Component Parts

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule

SUMMARY: On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. Section 108 of the CPSIA, as amended by Public Law 112-28, provides that the prohibition on specified products containing phthalates does not apply to any component part of children's toys or child care articles that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product. In this document, the Consumer Product Safety Commission (CPSC or Commission) issues guidance on inaccessible component parts in children's toys or child care articles subject to section 108 of the CPSIA.

DATES: This guidance is effective [Insert date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone (301) 987-2558; khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. Statutory Authority

On August 14, 2008, Congress enacted the CPSIA (Pub. L. 110-314), as amended on August 12, 2011, by Pub. L. 112-28. Section 108 of the CPSIA, titled, “Prohibition on Sale of Certain Products Containing Specified Phthalates,” permanently prohibits the sale of any “children's toy or child care article” containing more than 0.1 percent of three specified phthalates (di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)). Section 108 of the CPSIA also prohibits, on an interim basis, “toys that can be placed in a child’s mouth” or “child care article” containing more than 0.1 percent of three additional phthalates (diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP)). These prohibitions became effective on February 10, 2009. 15 U.S.C. 2057c(a), (b). The terms or phrases “children’s toy,” “toy that can be placed in a child’s mouth,” and “child care article,” are defined in section 108(g) of the CPSIA. 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.” 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 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 a child’s mouth.” The term “child care article” means “a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 years and younger, or to help such children with sucking or teething.” 15 U.S.C. 2057c(g).

Section 108(d) of the CPSIA provides that the prohibitions for the specified phthalates shall not apply to any component part of a children's toy or child care article that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product, as determined by the Commission. That section further provides that a component part is not accessible, if such component part is not physically exposed, by reason of a sealed covering or casing, and does not become physically exposed through reasonably foreseeable use and abuse of the product. Reasonably foreseeable use and abuse includes swallowing, mouthing, breaking, or other children's activities, and the aging of the product. 15 U.S.C. 2057c(d)(1).

The CPSIA directs the Commission to: (A) promulgate a rule providing guidance with respect to what product components, or classes of components, will be considered to be inaccessible; or (B) adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regard to accessibility of lead under section 101(b)(2)(B) (15 U.S.C. 1278a(b)(2)(B)), with additional consideration, as appropriate, of whether such component can be placed in a child's mouth. 15 U.S.C. 2057c(d)(3).

Section 108 of the CPSIA also directed the Commission, not earlier than 180 days after the date of enactment of this Act [enacted Aug. 14, 2008], to appoint a Chronic Hazard Advisory Panel (CHAP), pursuant to the procedures of section 28 of the CPSA (15 U.S.C. 2077), to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles. 15 U.S.C. 2057c(b)(2). The Commission appointed the CHAP on April 14, 2010, to study the effects on children's health of all phthalates and phthalate alternatives, as used in children's toys and child

care articles. The CHAP currently is working on a report, including recommendations, to be sent to the Commission.

Under section 108(d)(2) of the CPSIA, the Commission may revoke any or all exclusions granted based on the inaccessible component parts provision of section 108 of the CPSIA, at any time, and require that any or all component parts manufactured after such exclusion is revoked, comply with the prohibitions of phthalates, if the Commission finds, based on scientific evidence, that such compliance is necessary to protect the public health or safety. 15 U.S.C. 2057c(d)(2).

2. Notice of Proposed Guidance

In the *Federal Register* notice of July 31, 2012 (77 FR 45297), the Commission published a proposed guidance on inaccessible phthalate-containing component parts. As stated in the preamble to the proposed guidance (77 FR 45299), the Commission proposed to adopt the lead guidance for determining inaccessible component parts for phthalates, with the exception of polyvinyl chloride (PVC or vinyl) or other plasticized materials covering mattresses and other sleep surfaces designed or intended by the manufacturer to facilitate sleep of children age 3 and younger. Both the lead guidance and proposed phthalate guidance specified that a children's product, toy, or child care article that is completely enclosed or covered by fabric is considered inaccessible to a child, unless the product or part of the product in one dimension is smaller than 5 centimeters. However, the lead guidance did not exclude vinyl or other plasticized materials covering mattresses and other sleep surfaces. The proposed phthalate guidance found that while lead is unlikely to leach through fabric except in the case of mouthing or swallowing an item, sheets or mattress pads that cover a vinyl sleep or other plasticized

sleep surface should not serve as a barrier to the potential exposure of phthalates for young children. A child's skin comes into close contact with mattresses and similar products for large portions of a day, and a mattress cover could be dampened with a spilled beverage, saliva, sweat, urine, or other liquid, which could facilitate phthalate migration through a fabric covering. 74 FR 39539 (August 7, 2009).

In addition, although section 108 did not specifically disqualify paint, coatings, or electroplating as barriers that would render phthalates inaccessible, the Commission proposed to adopt the same guidance with respect to inaccessibility for phthalates that was adopted by the Commission with regard to inaccessibility of lead. The proposed phthalates guidance stated that paint, coatings, and electroplating may not be considered a barrier that would render phthalate-containing component parts of toys and child care articles inaccessible. The proposed phthalates guidance also noted that in some applications, phthalates are added to paint, printing inks, or coatings. 77 FR45299.

In addition, the Commission determined preliminarily that:

- An accessible component part is one that is capable of being touched or mouthed by a child;
- An inaccessible component part is one that is located inside the product and not capable of being touched or mouthed by a child, whether or not such part is visible to a user of the product;
- An inaccessible part is one that may be enclosed in any type of material, *e.g.*, hard or soft plastic, rubber, or metal (with the exception of vinyl or other plasticized

materials covering mattresses or other sleep surfaces for children age 3 and younger);

- To assess whether a part is inaccessible, the accessibility probes defined in the Commission’s existing regulations for evaluating accessibility of sharp points or sharp metal or glass edges (16 CFR 1500.48 and 1500.49) are appropriate. An “accessible phthalate-containing component part” would be considered one that contacts any portion of the specified segment of the accessibility probe. An “inaccessible phthalate-containing component part” would be considered as one that cannot be contacted by any portion of the specified segment of the accessibility probe; and
- Use and abuse tests are appropriate for evaluating whether phthalate-containing component parts of a product become accessible to a child during normal and reasonably foreseeable use and abuse of the product by a child (with the exception of the bite test). The purpose of the tests is to simulate use and damage or abuse of a product by children and to expose potential hazards that might result from use and abuse. 16 CFR 1500.50-1500.53.

B. Discussion of Comments to the Proposed Guidance and CPSC’s Responses

Five comments were received on the proposed guidance. Two of the comments were from industry and three from consumers or nonprofit consumer and public health organizations. Most comments express general support for the guidance.

1. Fabric materials as a barrier to accessibility of component parts

Comment: One commenter states that fabric should not be considered a barrier, regardless of the size of the component, because children could be exposed to phthalates through the fabric.

Response: As provided in CPSC staff's briefing memo "Guidance for Evaluating Accessibility of Phthalate-Containing Component Parts" dated July 13, 2012, <http://www.cpsc.gov/library/foia/foia12/brief/phthalatesinaccessible.pdf>, CPSC staff is not aware of any studies that show the propensity for phthalates to move from a phthalate-containing material through an intact, non-phthalate-containing material, such as an outside covering, where it could eventually reach the outside of a product. Furthermore, CPSC staff's review showed that the non-vapor passive movement of phthalates within a product, if it exists, would be exceedingly slow and would never account for any more than a small, negligible fraction of the original phthalate content of the inaccessible phthalate-containing part. Based on CPSC staff's analysis, the Commission finds that, in most cases, phthalates that are inaccessible would not result in physical exposure to phthalates, unless it is reasonably foreseeable that a component part will become physically exposed through mouthing, swallowing, breaking, or other children's activities, and aging of the product. Accordingly, a children's toy or child care article that is, or contains, a phthalate-containing part that is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is considered inaccessible to a child, unless the product, or part of the product, in one dimension, is smaller than 5 centimeters; *i.e.*, a fabric-covered component part is not inaccessible if the product, or part of the product, can be placed in a child's mouth.

Moreover, the Commission reiterates that vinyl or other plasticized materials covering mattresses and other sleep surfaces designed or intended by a manufacturer to facilitate sleep for children age 3 and younger should not be considered to be made inaccessible through the use of a fabric covering. As discussed in the preamble of the proposed guidance, the Commission reviewed phthalate-containing vinyl or other plasticized materials covering mattresses and sleep surfaces intended for young children. These mattresses or sleep surfaces are too large to be placed in a child's mouth. Although such mattresses or sleep surfaces may be covered by fabric, such as sheets or mattress pads, additional consideration was given to whether children would become physically exposed to the vinyl or other plasticized materials covering the surface through reasonably foreseeable use and abuse of the products, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product. The Commission determined there may be instances in which a child's skin comes into close contact with a fabric covering over a phthalate-containing item for large portions of a day, such as a vinyl or other plasticized material covering a mattress or other sleep surface. Young children typically spend more than half of each day sleeping or resting, frequently on a mattress or similar item. While a mattress is typically covered with a sheet or mattress pad, such non-permanently affixed coverings that are either supplied with the mattress or provided by the consumer should not be considered to render the underlying material inaccessible. As with the potential transfer of phthalates by saliva during mouthing of an item, a mattress cover dampened with a spilled beverage, saliva, sweat, urine, or other liquid, could facilitate phthalate migration through the fabric. Furthermore, a nonpermanent covering cannot be assumed to be in use at all times; if it is not, the

mattress could no longer be considered inaccessible. For these reasons, vinyl (or other plasticized material) covered mattresses/sleep surfaces, which contain phthalates, designed or intended by a manufacturer to facilitate sleep for children age 3 and younger, should not be considered to be made inaccessible through the use of a fabric covering.

Comment: One commenter states that the proposed guidance “exempts components covered in fabric provided that the underlying component is not smaller than 5 centimeters in any one dimension.” According to the commenter, any exposure to phthalates-containing component parts within fabric coverings is very low and all phthalate-containing components parts covered by fabric should be exempt, irrespective of the size of the part. The commenter also suggests that a *de minimis* exception should be considered for accessible small plasticized parts.

Response: The commenter misinterprets the fabric covering restriction in the proposed guidance on inaccessible phthalate-containing component parts. The proposed guidance states that “a children’s product that is or contains a phthalate-containing part which is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is inaccessible to a child unless the product or part of the product in one dimension is smaller than 5 centimeters.” However, the 5 centimeter measure is applied to the fabric-covered part or product (i.e., a fabric covered plastic button), not to the size of the underlying phthalate-containing component part. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in a child’s mouth (i.e., a fabric covered plastic ear on a stuffed animal). A phthalate-containing component part which is encased by a fabric covering is considered to be accessible to a child if the part or product is smaller than 5 centimeters in any dimension because such a part or product

could be placed in a child's mouth, and the fabric is not expected to perform as a barrier to saliva or other fluids or to prevent direct contact by the child with the saliva or other fluid after a fluid's contact with the phthalate-containing part. Even if a fabric covering passes the applicable use and abuse tests, such a covering is not a barrier to the underlying material if the product can be placed in the mouth because it is smaller than 5 centimeters.

If the phthalate-containing component part that is encased by fabric covering is 5 centimeters or greater in dimension, such a part of product is considered to be inaccessible to a child, because the part or product is not likely to be put in the mouth or swallowed (i.e., plastic electronic box inside a stuffed animal). As discussed above, however, vinyl or other plasticized material covering a mattress or other sleep surface which is designed or intended by a manufacturer to facilitate sleep of children age 3 and younger, even when covered with a sheet or mattress pad, will still be considered accessible given that the foreseeable use and abuse of the product, including spilled beverages, saliva, sweat, urine, or other liquids, may facilitate phthalate migration through the fabric.

The statute does not provide for a *de minimis* exception for accessible component parts, and the Commission is not considering in this guidance such exceptions for accessible phthalate-containing children's toys and child care articles. However, we note that a CHAP has been convened to study the effects on children's health of all phthalates and phthalate alternatives, as used in children's toys and child care articles. Based on the findings and recommendations of the CHAP, any guidance concerning phthalates may be modified and revised, as appropriate.

Comment: The same commenter also states that the exclusion of fabric materials as a barrier to accessibility for phthalate-containing parts or products smaller than 5 centimeters is inconsistent with the Commission’s use and abuse testing.

Response: The proposed guidance provides that accessibility of component parts, as a result of normal and reasonably foreseeable use and abuse of the product, should be evaluated using the use and abuse tests under the Commission’s regulations at 16 CFR 1500.50 through 1500.53 (excluding the bite test in paragraph (c) of §§ 1500.51–1500.53). We disagree that the exclusion of fabric materials as a barrier to accessibility is inconsistent with the Commission’s use and abuse testing. The Commission finds, in general, that fabric coverings can be considered barriers to the underlying materials because such coverings prevent direct physical contact with the phthalate-containing parts. The appropriate use and abuse tests, such as the test for the integrity of seams, should be used to evaluate fabric coverings to ensure that the component parts remain physically inaccessible to a child. Use and abuse testing generally is applied to evaluate whether a component part may become physically accessible as a result of reasonably foreseeable use and abuse of the product, including swallowing, mouthing, breaking, or other children’s activities. Historically, this testing has been used to evaluate the presence of physical hazards, such as small parts, which may be choking hazards, or sharp points and edges. In the case of lead-containing or phthalate-containing component parts, these tests are used to evaluate the potential for physical contact with the parts. The material beneath a fabric covering should not be considered to be inaccessible to a child if the part or product is smaller than 5 centimeters in any dimension because such a part or product could be placed in a child’s mouth, and fabric is not expected to perform

as a barrier to saliva or other fluids or to prevent direct contact by the child with the saliva or other fluid after a fluid's contact with the phthalate-containing part. Even if a fabric covering passes the applicable use and abuse tests, such a covering is not a barrier to the underlying material if the product can be placed in the mouth.

2. Exclusion of the “Bite Test” from use and abuse testing

Comment: Two commenters question the exclusion of the “bite test” from the use and abuse testing and requested that it be included in the guidance.

Response: Currently, the Commission does not use the bite test specified in 16 CFR 1500.51–1500.53), as a result of a court case (*Clever Idea Co., Inc. v. Consumer Product Safety Commission*, 385 F. Supp. 688 (E.D. N.Y. 1974)) that questioned the appropriateness of this test. Because the bite test currently is not applied as part of use and abuse testing for consumer products, it will not be applied for the purposes of evaluating products for accessibility of phthalate-containing component parts. However, this requirement may be modified in a future proceeding if the bite test is reevaluated.

3. Requirements for labeling of art materials

Comment: One commenter requests consistency among the requirements for paints and other surface coatings for lead and phthalates and the requirements under ASTM D 4236 and ASTM F 963 that address art materials. This commenter specifically requests that bottles of paint available in retail stores should comply with all requirements because such paint could be used by children or on products for children.

Response: This comment is outside the scope of this guidance, which addresses the issue of when a phthalate-containing component part of a children's toy or child care

article is considered to be inaccessible to a child. The *Standard Consumer Safety Specification for Toy Safety*, ASTM F 963 requires that all art materials comply with the Labeling of Hazardous Art Materials Act (LHAMA). In addition to the LHAMA requirements discussed above, art materials that are designed or intended primarily for children 12 years of age or younger, are also required, like all children's products, to comply with the requirements of the CPSIA, including third party testing and certification.

C. Effective Date

Although guidance documents do not require a particular effective date under the Administrative Procedure Act, 5 U.S.C. 553(d)(2), the Commission recognizes the need for providing the guidance expeditiously. Accordingly, the guidance will take effect upon publication in the *Federal Register*.

List of Subjects in 16 CFR Part 1199

Business and industry, Infants and children, Consumer protection, Imports, Toys

D. Final Guidance

The Commission is issuing the final guidance without substantive change from the proposed guidance. For the reasons stated above, the Commission adds 16 CFR part 1199, as follows:

PART 1199- CHILDREN'S TOYS AND CHILD CARE ARTICLES CONTAINING PHTHALATES: GUIDANCE ON INACCESSIBLE COMPONENT PARTS

Authority: 15 U.S.C. 1251–1289, 86 Stat. 1207, 125 Stat. 273.

§ 1199 Children’s Toys and Child Care Articles: Phthalate-Containing Inaccessible Component Parts.

(a) Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) permanently prohibits the sale of any “children's toy or child care article” containing more than 0.1 percent of three specified phthalates (di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)). Section 108 of the CPSIA also prohibits, on an interim basis, “toys that can be placed in a child’s mouth” or “child care article” containing more than 0.1 percent of three additional phthalates (diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP)). 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. 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 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. The term “child care article” means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 years and younger, or to help such children with sucking or teething.

(b) Section 108 (d) of the CPSIA provides that the prohibitions in paragraph (a) do not apply to component parts of a children’s toy or child care article that are not accessible to children through normal and reasonably foreseeable use and abuse of such

product, as determined by the Commission. A component part is not accessible if it is not physically exposed, by reason of a sealed covering or casing, and does not become physically exposed through reasonably foreseeable use and abuse of the product, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product.

(c) Section 108(d)(3) of the CPSIA directs the Commission to promulgate a rule to provide guidance with respect to what product components or classes of components will be considered to be inaccessible for a children's toy or child care article that contains phthalates or adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regard to accessibility of lead under section 101(b)(2)(B) (15 U.S.C. 1278a(b)(2)(B)), with additional consideration, as appropriate, of whether such component can be placed in a child's mouth. 15 U.S.C. 2057c(d)(3). The Commission adopts the same guidance with respect to inaccessibility for the phthalates that was adopted by the Commission with regard to accessibility of lead, however, vinyl (or other plasticized material) covered mattresses/sleep surfaces, that contain phthalates that are designed or intended by the manufacturer to facilitate sleep of children age 3 and younger, are considered accessible and would not be considered inaccessible through the use of fabric coverings, including sheets and mattress pads.

(d) The accessibility probes specified for sharp points or edges under the Commission's regulations at 16 CFR 1500.48–1500.49 should be used to assess the accessibility of phthalate-containing component parts of a children's toy or child care article. A phthalate-containing component part would be considered accessible if it can be contacted by any portion of the specified segment of the accessibility probe. A

phthalate-containing component part would be considered inaccessible if it cannot be contacted by any portion of the specified segment of the accessibility probe.

(e) For children's toys or child care articles intended for children that are 18 months of age or younger, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.51 (excluding the bite test of 1500.51(c)), should be used to evaluate accessibility of phthalate-containing component parts of a children's toy or child care article as a result of normal and reasonably foreseeable use and abuse of the product.

(f) For children's toys or child care articles intended for children that are over 18 months, but not over 36 months of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.52 (excluding the bite test of 1500.52(c)), should be used to evaluate accessibility of phthalate-containing component parts of a children's toy or child care article as a result of normal and reasonably foreseeable use and abuse of the product.

(g) For children's toys intended for children that are over 36 months, but not over 96 months of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of 1500.53(c)), should be used to evaluate accessibility of phthalate-containing component parts of a children's toy as a result of normal and reasonably foreseeable use and abuse of the product.

(h) For children's toys intended for children over 96 months through 12 years of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of 1500.53(c)) intended for children ages 37–96 months should be used to evaluate accessibility of phthalate-containing component

parts of a children's toy as a result of normal and reasonably foreseeable use and abuse of the product.

(i) Because the Commission adopts the same guidance with respect to inaccessibility for phthalates that was adopted by the Commission with regard to inaccessibility of lead, paint, coatings, and electroplating may not be considered a barrier that would render phthalate-containing component parts of toys and child care articles inaccessible. A children's toy or child care article that is or contains a phthalate-containing part that is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is considered inaccessible to a child, unless the product or part of the product, in one dimension, is smaller than 5 centimeters. However, vinyl (or other plasticized material) covered mattresses/sleep surfaces that contain phthalates that are designed or intended by the manufacturer to facilitate sleep of children age 3 and younger, are considered accessible and would not be considered inaccessible through the use of fabric coverings, including sheets and mattress pads.

(j) The intentional disassembly or destruction of products by children older than age 8 years, by means or knowledge not generally available to younger children, including use of tools, will not be considered in evaluating products for accessibility of phthalate-containing components.

Dated: _____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission



Staff Briefing Package

Guidance for Evaluating Accessibility of Phthalate-Containing Component Parts: Discussion, Response to Public Comments, and Staff Recommendation

January 30, 2013

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Briefing Memo



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

This document has been electronically
approved and signed.

Date: January 30, 2013

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM : DeWane Ray, Assistant Executive Director, Office of Hazard Identification and
Reduction
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health
Sciences

SUBJECT : Guidance for Evaluating Accessibility of Phthalate-Containing Component
Parts and Response to Public Comments: Discussion, Response to Public
Comments, and Staff Recommendation

I. Introduction

The Consumer Product Safety Improvement Act of 2008 (CPSIA), sections 108(a) and 108(b), established a concentration limit for specified phthalate chemicals in children's toys and child care articles. As amended by Public Law 112-28, CPSIA section 108 provides that the prohibitions against those phthalates do not apply to any component part of children's toys or child care articles that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product, as determined by the Commission. This section also specifies that a component part is not accessible if it is not physically exposed, by reason of a sealed covering or casing, and does not become physically exposed through reasonably foreseeable use and abuse of the product, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product.

Section 108(d)(3) provides that the Commission shall: (A) promulgate a rule providing guidance with respect to what product components, or classes of components, will be considered to be inaccessible; or (B) adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regard to accessibility of lead under section 101(b)(2)(B), with additional consideration, as appropriate, of whether such component can be placed in a child's mouth.

On July 11, 2012, staff transmitted a briefing package¹ to the Commission containing analysis and discussion of potentially inaccessible phthalate-containing component parts. Staff's

¹ Staff Briefing Package: Guidance for Evaluating Accessibility of Phthalate-Containing Component Parts, July 11, 2012. Available at: <http://www.cpsc.gov/library/foia/foia12/brief/phthalatesinaccessible.pdf>.

conclusions with respect to accessibility of phthalate-containing parts are nearly identical to its conclusions regarding lead-containing parts. Thus, staff recommended that the Commission adopt the same guidance for inaccessible component parts with respect to the CPSIA section 108 requirements for phthalates in children's toys or child care articles as contained in the Lead-Containing Parts Interpretative Rule at 16 C.F.R. § 1500.87 for children's products containing lead, with only a minor modification to address sleep surfaces.

II. Lead-Containing Parts Interpretive Rule

The Commission's interpretive rule regarding inaccessible component parts with respect to lead content (Lead-Containing Parts Interpretative Rule), at 16 C.F.R. § 1500.87 (Children's products containing lead: inaccessible component parts), was published in the *Federal Register* on August 7, 2009 (74 FR 39535).²

In the Lead-Containing Parts Interpretative Rule, the Commission considered an "accessible component part" of a children's product as one that a child may touch. An "inaccessible component part" is considered as one that is located inside the product and cannot be touched by a child, even if such a part is visible to a user of the product.

The Commission further found that a lead-containing component part may be inside a product and not fully enclosed by another part of the product and that children then may have opportunities to contact a lead-containing component part with their fingers or tongues.

The Lead-Containing Parts Interpretative Rule is based on accessibility tests that were already in use by the Commission for addressing sharp points and sharp metal or glass edges on toys or other articles intended for use by children under 8 years of age. The regulations at 16 C.F.R. §§ 1500.48–1500.49 provide specific technical requirements for determining accessibility of sharp points or edges through the use of accessibility probes. These sections indicate that an accessible sharp point or edge is present in the product if the test shows that any part of the specified portion of the accessibility probe contacts the sharp part. Thus, the Lead-Containing Parts Interpretative Rule defines an "accessible component part" of a children's product as one that can be contacted by any part of the specified portion of the accessibility probe.

The Lead-Containing Parts Interpretative Rule further notes that both of these sections (16 C.F.R. §§1500.48–49) provide that a test for accessibility of sharp points or edges shall be applied before and after use and abuse tests, referencing 16 C.F.R. §§1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 C.F.R. §§1500.51–1500.53). Likewise, use and abuse testing is to be applied to determinations of accessibility of lead-containing parts. The scope of the use and abuse testing regulations does not cover products for children over 96 months of age. However, the limits on the lead content of children's products apply to products for children ages 12 years or younger. Therefore, the Lead-Containing Parts Interpretative Rule provides guidance for the testing of products intended for children older than 96 months of age through age 12 years. This guidance provides that the testing indicated for products for children 37–96 months of age should also be used to evaluate the products for children up through age 12 years. That is, evaluation of products for children over 36 months of age through 12 years of age will be done using the use and abuse testing established for products for children over 36 months but not over 96 months of age. 16 C.F.R. §1500.53 (excluding the bite test—paragraph (c)).

² Available at: <http://www.cpsc.gov/businfo/frnotices/fr09/leadinaccessibilityfinalrule.pdf>.

The Lead-Containing Parts Interpretative Rule also specifies that a lead-containing part of a children's product that is enclosed or covered by fabric is to be considered inaccessible to a child, unless the product or part of the product in one dimension is smaller than 5 centimeters.³ This provision addresses the possibility that a fabric covering is not a suitable barrier to the potential transfer of lead from the part to a child, if the part can be placed in a child's mouth.

III. Phthalate-Containing Parts

CPSIA section 108, as amended, provides that the restrictions on phthalates in products and component parts of products do not extend to inaccessible parts. The definition of an "inaccessible part" in this section reflects the definition first included with the lead content restrictions in the CPSIA in 2008, and the amended section 108 also includes a provision for "additional consideration, as appropriate, of whether such component can be placed in a child's mouth."

As detailed in the July 11, 2012, briefing package to the Commission, staff's review of the available information, including physical-chemical properties of many phthalate compounds, led to several conclusions.

- 1) The rate of vaporization of common phthalates from plastic parts and the amount of phthalates expected to be released from such plastic parts through vaporization are likely to be so low that actual measurement of vaporization from an inaccessible component part is not feasible at this time;
- 2) Phthalate compounds generally do not remain free in the air but would be found adsorbed onto the nearby surfaces within the toy; and the amount of volatilized phthalate released from the product would be extremely small and could be considered negligible, compared to the amount of phthalates volatilized from non-children's products, such as flooring, furnishings, and other household products and materials;
- 3) Without direct physical contact and mechanical action, in most cases, phthalates present in a part of a product that is inaccessible will remain in the inaccessible part;
- 4) Overall, inaccessible phthalate-containing component parts of the children's products subject to the phthalate content restrictions will not be important contributors to environmental phthalate concentrations or children's potential exposures to phthalates;
- 5) A children's product that is, or contains, a phthalate-containing part that is enclosed, encased, or covered by fabric, and passes the appropriate use and abuse tests on such covers and parts, could be considered to be inaccessible to a child, unless the product or part of the product in one dimension is smaller than 5 centimeters;
- 6) As is the case with lead, if a product or component part can be placed in a child's mouth, a fabric covering may not be a suitable barrier to the potential transfer of phthalates from the part to a child because the chemical that is present could mix with saliva that soaks through the fabric and then transfers back into a child's mouth during further mouthing activity;

³ Section 108(e)(2)(B) of the CPSIA provides that "if a toy or part of toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth."

- 7) Sheets or mattress pads that cover a mattress or another vinyl-covered sleep surface should not be considered to render the underlying material inaccessible, regardless of the dimensions of the product, because a child's skin comes into close contact with mattresses and similar products for large portions of a day, and a mattress cover could be dampened with a spilled beverage, saliva, sweat, urine, or other liquid, which could facilitate phthalate migration through the fabric.⁴

IV. Public Comments

On July 24, 2012, the Commission voted to publish the proposed guidance. A *Federal Register* notice (77 FR 45298) was published on July 31, 2012, requesting comments on the proposed guidance. Five comments were received: two from industry and three from consumers or nonprofit consumer and public health organizations. Comments addressed several points concerning the hazards of phthalate exposure and the specific provision of the proposed guidance. Appendix 1 contains the list of comments received in response to the *Federal Register* notice.

Comments from the five public commenters generally can be organized into four topic areas. The comments in these four areas and staff's responses to them are detailed below.

Comment Topic 1: General comments on the proposed guidance

One comment (CPSC-2012-0040-0003) did not specifically address inaccessible phthalate-containing parts, but it addressed more generally restrictions on harmful materials in products. Three of the remaining four comments expressed general support for the proposed guidance for inaccessible component parts, in addition to providing specific comments and suggestions addressed in other sections of this memorandum.

CPSC Staff Response:

Staff appreciates all of the comments and suggestions received concerning regulation of phthalates in certain children's products.

Comment Topic 2: Fabric materials as a barrier to accessibility of component parts

Two commenters addressed fabric materials as a barrier to accessibility of phthalate-containing parts. The proposed guidance specifies that a children's toy or child care article that is, or contains, a phthalate-containing part that is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is considered inaccessible to a child, unless the product or part of the product, in one dimension, is smaller than 5 centimeters; *i.e.*, a fabric-covered component part is not inaccessible if the product or part of the product can be placed in a child's mouth. The proposed guidance also indicates that accessibility of component parts, as a result of normal and reasonably foreseeable use and abuse of the product, should be evaluated using the use and abuse tests under the Commission's regulations at 16 C.F.R. §§1500.50 through 1500.53 (excluding the bite test in paragraph (c) of §§ 1500.51–1500.53).

⁴ Staff notes that the issue of accessibility of mattresses or other vinyl-covered sleep surfaces—as “child care articles”—applies only to products designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, as specified in CPSIA section 108. Mattresses or sleep surfaces that are not child care articles are not subject to the phthalates prohibitions under section 108 of the CPSIA.

The two comments on this provision essentially express opposite views. A comment from a coalition of consumer and public health groups (CPSC-2012-0040-0005) states that fabrics should not be considered a barrier, regardless of the size of the component because children could be exposed to phthalate dust through the fabric.

Conversely, a toy industry group (CPSC-2012-0040-0004) states that the statute focuses on exposure and that exclusion of fabric coverings as barriers to accessibility for products or component parts that are smaller than 5 centimeters in any one dimension (*i.e.*, able to be placed in a child's mouth) would be an unreasonable limitation because exposure to phthalates in the component parts within fabric coverings is very low, and any fabric covering should serve as an adequate barrier to a phthalate-containing component part, irrespective of the size of the part. The commenter specifically states that the proposed guidance "exempts components covered in fabric provided that the underlying component is not smaller than 5 centimeters in any one dimension."

This commenter also references possible *de minimus* exceptions that could also be applied here (*i.e.*, the phthalate content requirements should not apply to small plastic parts). Lastly, this commenter concludes that exclusion of fabric materials as a barrier to accessibility for certain products would not be consistent with the Commission's use and abuse testing.

CPSC Staff Response:

Staff disagrees with the toy industry assertion that the statute's phthalates requirements are exposure based. For products indicated in the CPSIA, the restriction specifies the maximum concentrations of the chemicals that the products may contain; the statute does not provide for a limit for exposure to the chemicals. However, Public Law 112-28 provides that the phthalate content requirements of CPSIA section 108 are to be applied more narrowly, excluding component parts that are inaccessible to a child, and it requires that the Commission promulgate a rule providing guidance with respect to which product components, or classes of components, will be considered to be inaccessible. While this law established that compliance with the law is based, in part, on assessment of accessibility of component parts, the phthalates requirement for the indicated products continues to be the concentration of the chemicals in the accessible component parts. The requirement is not based on assessment of exposure to phthalates.

CPSIA section 108, as amended by Public Law 112-28, provides that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing. While staff believes that fabric coverings are a special situation of component part coverings, staff believes that, in general, fabric coverings can be considered barriers to the underlying materials because such coverings prevent direct physical contact with the phthalate-containing parts. Further, as discussed in staff's July 11, 2012 briefing package, given the available information on phthalates and phthalate-containing materials, staff believes that in most cases, the phthalates present in a part of a product that is inaccessible will remain in the inaccessible part, even if phthalate chemicals can volatilize or migrate. In any case, staff concluded that "sources of phthalate exposure for most people in the United States, including children, will tend to be dominated by food; cosmetics and other personal care products; and flooring, furnishings, paints, adhesives, and other products that contribute to the phthalates found in air or associated with house dust."

The toy industry comment specifically about this part of the proposed guidance appears to misinterpret the fabric covering restriction in the proposed guidance (and the existing guidance for lead-containing products and component parts). The 5 centimeter measure is applied to the

fabric-covered product or part as a whole, not to the size of the underlying part. An example of a product or component part for which a fabric covering cannot be considered to render the underlying part inaccessible is a fabric-covered button on a toy doll. If the button as a whole is smaller than 5 centimeters in any dimension, then the underlying parts of the button, such as the plastic form, would not be considered inaccessible and would be subject to the applicable phthalates restrictions. On the other hand, a component part that is smaller than 5 centimeters that is located within a product or part that is at least 5 centimeters in all dimensions would be considered inaccessible if it conforms to the provisions of the proposed guidance. An example of such a product would be a plush toy that is at least 5 centimeters in all dimension and that has no external features smaller than 5 centimeters. The fabric covering of this toy would cause all internal parts to be considered to be inaccessible. Another example is an electronic plush toy in the shape of an animal that is larger than 5 centimeters in all dimensions except for plastic-containing ears that are smaller than 5 centimeters in at least one dimension. In this case, the ear parts of the product may be placed in a child's mouth and the plastic inside those parts would be considered to be accessible, while the plastic electronic box within the larger body part of the product would be inaccessible because that portion of the product would not be considered to be able to be placed in the a child's mouth.

The appropriate use and abuse tests, such as for the integrity of seams, should be used to evaluate fabric coverings to ensure that the component parts remain physically inaccessible to a child. Use and abuse testing generally is applied to evaluate whether a component part may become physically accessible as a result of reasonably foreseeable use and abuse of the product, including swallowing, mouthing, breaking, or other children's activities. Historically, this testing has been used to evaluate the presence of physical hazards, such as small parts, which may be choking hazards, or sharp points and edges. In the case of lead- or phthalate-containing component parts, these tests are used to evaluate the potential for physical contact with the parts.

However, chemical hazards may have different exposure and risk patterns than physical hazards. Thus, staff concluded that the material beneath a fabric covering should not be considered to be inaccessible to a child if the part or product is smaller than 5 centimeters in any dimension because such a part or product could be placed in a child's mouth, and fabric is not expected to perform as a barrier to saliva or other fluids or to prevent direct contact by the child with the saliva or other fluid after a fluid's contact with the phthalate-containing part.

On this basis, staff disagrees with the toy industry commenter's assertion that the exclusion of fabric materials as a barrier to accessibility is inconsistent with the Commission's use and abuse testing. Even if a fabric covering passes the applicable use and abuse tests, such a covering is not a barrier to the underlying material if the product can be placed in the mouth.

Furthermore, staff noted in the July 11, 2012 briefing package that any guidance maybe modified and revised, as appropriate, based on the findings and recommendations of the Chronic Hazard Advisory Panel that has been convened to study the effects on children's health of phthalates and phthalate alternatives potentially used in children's toys and child care articles.

Currently, the CPSC is not considering "de minimus" exceptions for the testing of small plastic parts. Therefore, unless otherwise exempted from conformance or testing, products that are subject to the phthalate content regulations must comply with the applicable restrictions.

Comment Topic 3: Exclusion of the “Bite Test” from use and abuse testing

Two commenters (CPSC-2012-0040-0005; CPSC-2012-0040-0006) questioned why the “bite test” is excluded from the use and abuse testing and urge that it be included in the guidance.

CPSC Staff Response:

Currently, the Commission does not consider the bite test in the use and abuse test procedures specified in paragraph (c) of each section CFR 1500.51–1500.53 as a result of a court case that questioned the relevance of this test.⁵ Because the bite test currently is not applied as part of use and abuse testing for consumer products, it will not be applied for the purposes of evaluating products for accessibility of phthalate-containing component parts.

Comment Topic 4: Consistency between requirements of CPSIA and ASTM D 4236 requirements for labeling of art materials

One commenter (CPSC-2012-0040-0002) would like consistency between the requirements for lead and phthalate content of certain toys and other products provided by the CPSIA and the older requirements under ASTM D 4236 and ASTM F 963 that address art materials. This commenter specifically requested that bottles of paint available in retail stores should comply with all requirements because such paint could be used by children or on products for children.

CPSC Staff Response:

This comment is not within the scope of this proceeding, which addresses guidance for phthalates-containing inaccessible component parts of certain products.

As provided by the CPSIA, phthalate and lead content requirements apply to children’s products and child-care articles, as specified in the relevant sections of the statute and supporting regulations. The statute also provides for mandatory testing of children’s products that are subject to product safety rules, including, but not limited to, requirements for lead content and phthalate content of component parts of specified products, and lead content in paints and similar surface coatings applied to toys and other articles intended for children.

The requirements for the labeling of art materials in ASTM D 4236 were established by the Labeling of Hazardous Art Materials Act (LHAMA). LHAMA requires that the manufacturer, importer, or repackager of art materials have a product’s formulation reviewed by a toxicologist for its potential to cause chronic adverse health effects. A conformance statement on the product is used to certify that the product has been so reviewed.

Third party testing for conformance to LHAMA provisions is not required. Therefore, conformance with the provisions for the labeling of art materials does not establish conformance with any other requirement for children’s products, or with the mandatory testing for lead and phthalates in the products subject to those requirements. Every product must conform to each applicable requirement.

Staff recognizes that certain retail products may be used by children. That possibility alone does not establish that the product is a children’s product that is then subject to the relevant children’s product requirements and third party testing requirements for children’s products. CPSIA

⁵ *Clever Idea Company, Inc. v. Consumer Product Safety Commission*, 385 F. Supp. 688 (E.D. N.Y. 1974).

section 235(a) amended section 3(a)(2) the Consumer Product Safety Act (CPSA) by adding a definition of “children’s product.” 15U.S.C. 2052(a)(2). Thus, a children’s product is specifically defined as “a consumer product designed or intended primarily for children 12 years of age or younger.” A manufacturer may choose to use retail products to make children’s products, whether or not those retail products are themselves children’s products, provided that applicable requirements, including testing requirements, are also met.

Guidance for testing products is available in the U.S. Code of Federal Regulations at 16 CFR part 1107—Testing and Labeling Pertaining to Product Certification. Guidance for “component part” testing is available at 16 CFR part 1109—Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party’s Finished Product Testing or Certification, to Meet Testing and Certification Requirements.⁶

V. Conclusions and Recommendation

Staff’s original conclusions with respect to accessibility of phthalate-containing parts were nearly identical to its conclusions regarding lead-containing parts. The public comments in response to the proposed guidance do not contain information or data that change staff’s conclusions.

Therefore, staff recommends that the Commission adopt the same guidance for inaccessible component parts with respect to the CPSIA section 108 requirements for phthalates in children’s toys or child care articles, as contained in the Lead-Containing Parts Interpretative Rule at 16 CFR § 1500.87 for children’s products containing lead, with the addition of guidance addressing sleep surfaces.

Staff recommends that the guidance for phthalates in children’s toys or child care articles specify that phthalate-containing materials of vinyl-covered mattresses and other sleep surfaces should not be considered to be made inaccessible through use of fabric coverings, including sheets and mattress pads.

As noted in the July 11, 2012, briefing package to the Commission, CPSIA section 108 required the CPSC to convene a Chronic Hazard Advisory Panel (CHAP) to study the effects on children’s health of all phthalates and phthalate alternatives potentially used in children’s toys and child care articles. Staff notes that any guidance concerning phthalates may be revised, as appropriate, based on the findings and recommendations of the CHAP.

⁶ 16 CFR Parts 1107 and 1109 are available at: http://www.ecfr.gov/cgi-bin/text-idx?SID=d0ed4b9d795ebfe45905f4c94750bcad&c=ecfr&tpl=/ecfrbrowse/Title16/16cfrv2_02.tpl.

Additional information for each of these rules is included in the Federal Register Notices: Testing and Labeling Pertaining to Product Certification, Final Rule, CPSC Docket No. CPSC-2010-0038, November 8, 2011 (76 FR 69482); Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party’s Finished Product Testing or Certification, to Meet Testing and Certification Requirements, Final Rule, CPSC Docket No. 2010-0037, November 8, 2011 (76 FR 69546). Available at: <http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR&browsePath=2011%2F11%2F11-08%5C%2F3%2FConsumer+Product+Safety+Commission&isCollapsed=false&leafLevelBrowse=false&isDocumentResults=true&ycord=502>.

Appendix 1
Identification of Commenters

Note: The public comments may be found in docket CPSC-2012-0040 at:
<http://www.regulations.gov>.

Commenter Number	Public Docket ID	Commenter Name or Organization
	CPSC-2012-0040-0001	<i>Federal Register</i> notice
No. 1	CPSC-2012-0040-0002	Carolina Pratt Unit Blocks
No. 2	CPSC-2012-0040-0003	David DeLong
No. 3	CPSC-2012-0040-0004	Toy Industry Association
No. 4	CPSC-2012-0040-0005	Patient, Consumer, and Public Health Coalition
No. 5	CPSC-2012-0040-0006	Breast Cancer Fund