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: July 13, 2012

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Patricia M. Pollitzer, Acting Assistant General Counsel

FROM : Hyun S. Kim, Attorney

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

BALLOT VOTE Due: July 19, 2012

The attached draft *Federal Register* notice for Commission consideration proposes, 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, guidance on inaccessible component parts for children's toys and child care articles that contain phthalates.

A. 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; Proposed Guidance on Inaccessible Component Parts

[Billing Code 6335-01]

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2012-]

16 CFR Part 1199

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

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed Guidance.

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) proposes guidance on inaccessible component parts in children's toys or child care articles subject to section 108 of the CPSIA.

DATES: Written comments and submissions in response to this notice must be received by [**insert date that is 60 days after publication**]

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2012- , by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through www.regulations.gov.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed guidance. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov.

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, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7254; khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. Prohibition on Certain Phthalates

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 and younger, or to help such children with sucking or teething." 15 U.S.C. 2057c(g).

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 the Commission.

2. Inaccessible Component Parts and the Phthalates Prohibition

Pub. L. 112-28 amended section 108(d) of the CPSIA to provide an exclusion for certain products containing inaccessible phthalates component parts. That section states:

> The prohibitions . . . 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. A component part is not accessible under this paragraph 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 shall include swallowing, mouthing, breaking, or other children's activities, and the aging of the product.

15 U.S.C. 2057c(d)(1).

The Commission was directed within 1 year after the date of enactment of Pub. L. 112-28 [enacted August 12, 2011] 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 regards 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 exclusion for inaccessible component parts for phthalates mirrors the language on inaccessible parts in the CPSIA with regard to the limits on lead content in children's

products. The interpretative rule on lead provided 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. 15 U.S.C. 1278a(b)(2). However, paint, coatings, or electroplating could not be considered to be a barrier that would render lead in the substrate to be inaccessible to a child. 15 U.S.C. 1278a(b)(3). Section 108 did not specifically disqualify paint, coatings, or electroplating as barriers that would render phthalates inaccessible. Because the Commission proposes 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 guidance states 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. Moreover, in some applications, phthalates are added to paint, printing inks, or coatings. However, the Commission seeks comments, information, and data regarding whether certain paint, coatings, or electroplating could ever be considered a barrier in the context of phthalates, and whether such materials could result in sealed covering or casing that would not become physically exposed through reasonably foreseeable use and abuse of the product.

In addition, Pub. L. 112-28 also includes a provision for phthalates, which is not contained in the statutory requirements for assessing inaccessibility for lead in children's products. 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).

B. Proposed Guidance for Inaccessible Component Parts in Phthalates

The Commission's interpretive rule regarding inaccessible component parts with respect to lead content was published in the *Federal Register* on August 7, 2009 (74 FR 39535) and codified at 16 CFR 1500.87 (Children's products containing lead: inaccessible component parts). The Commission proposes to adopt the lead guidance with respect to inaccessibility 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.

Accordingly, this proposed guidance would adopt the same definitions and tests used in the interpretative rule regarding inaccessibility of lead-containing parts. An "accessible component part" is one that a child may touch, and an "inaccessible component part" is 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. An accessible component is defined as one where children may contact a lead-containing component part with their fingers or tongues. The tests to determine whether parts are accessible are identical to those 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. The Commission's regulations under 16 CFR 1500.48–1500.49 provide specific technical requirements for determining accessibility of sharp points or edges through the use of accessibility probes.

These sections provide that an accessible sharp point or edge is present in the product if the test indicates that any part of the specified portion of the accessibility probe contacts the sharp part. Thus, an "accessible component part" of a children's product is defined as one that can be contacted by any part of the specified portion of the accessibility probe. The regulations at 16 CFR1500.48–49 provide that a test for accessibility of sharp points or edges shall be applied before and after use and abuse tests, referencing 16 CFR 1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 CFR 1500.51–1500.53).

Use and abuse testing may also be used to evaluate accessibility of phthalate-containing component parts of children's toys and child care articles as a result of normal and reasonably foreseeable use and abuse of the product. The scope of the use and abuse testing regulations does not cover products for children over 96 months of age. However, 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." Therefore, the proposed guidance for the testing of products for determining accessibility based on the use and abuse tests will be extended to children older than 96 months of age and up through age 12 years. This proposed guidance provides that the testing indicated for products for children aged 37–96 months of age should also be used to evaluate the products for children up through age 12 years. Further, as children 12 years of age or younger grow and mature, they become, in many respects, indistinguishable from children older than 12 years, and even adults. Consequently, the intentional disassembly or destruction of products by children older than age 8 years, by means or knowledge not generally available to younger children, should not be

considered in evaluating products for accessibility of phthalate-containing components. For example, accessibility arising from the use of tools, such as a screwdriver, should not be considered in accessibility and use and abuse testing.

The interpretive rule on lead also specified 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. This provision addressed 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. As is the case with lead, a fabric covering may not be a suitable barrier to the potential transfer of phthalates from a product or component part to a child, if the part can be placed in a child's mouth. If the product can be mouthed, the chemical that is present could mix with saliva that soaks through the fabric and then be transferred back into a child's mouth during further mouthing activity. With the exception of certain vinyl (or other plasticized material) covered mattresses/sleep surfaces, as discussed further below, 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 and parts, would be considered to be inaccessible to a child, unless the product or part of the product, in one dimension, is smaller than 5 centimeters. Such fabric-covered items (including dolls, or plush toys with internal plasticized structural parts or housing for electronic parts) should be evaluated for the integrity of the coverings, including seams, using the appropriate use and abuse tests at 16 CFR 1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 CFR 1500.51–1500.53). In addition, because the material beneath a fabric

covering would be considered to be accessible to a child in the case that mouthing or swallowing of the part may occur, use and abuse testing should be used to evaluate the potential for small components to be removed from products, using the appropriate tests at 16 CFR 1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 CFR 1500.51–1500.53).

Section 108(d)(3)(B) provides that if the Commission elects to 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) of the CPSIA, the Commission must give "additional consideration, as appropriate, of whether such component can be placed in a child's mouth." 15 U.S.C. 2057c(d)(3). Accordingly, with respect to child care articles, the Commission reviewed phthalate-containing vinyl or other plasticized materials covering mattresses and sleep surfaces designed or intended by the manufacturer to facilitate sleep of children age 3 and younger that have removable fabric covers. 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. 15 U.S.C. 2057c(d)(1). 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, likely on a

mattress or similar item.[1] 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.

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. Currently, the CHAP is working on a report, including recommendations to the Commission. Accordingly, any guidance concerning phthalates may be modified and revised, as appropriate, based on the findings and recommendations of the CHAP.

C. Effective Date

The Commission was directed to provide guidance on phthalate-containing inaccessible component parts by August 12, 2012. Although guidance documents do not require a particular effective date under the Administrative Procedure Act, 5 U.S.C.

[1] U.S. EPA (Environmental Protection Agency). (2011) Exposure factors handbook: 2011 edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA, and online at http://www.epa.gov/ncea/efh.

553(d)(2), the Commission recognizes the need for providing the guidance expeditiously. Accordingly, the proposed guidance would take effect upon publication of a final guidance in the *Federal Register*.

List of Subjects in 16 CFR Part 1199

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

D. Conclusion

For the reasons stated above, the Commission proposes to add 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 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, by August 12, 2012, 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 regards 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 regards to accessibility of lead.

(d) The accessibility probes specified for sharp points or edges under the Commissions' regulations at 16 CFR 1500.48-1500.49 will 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)), will 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)), will 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)), will 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 aged 37–96 months will 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 proposes to adopt 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 which 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

July 11, 2012

Table of Contents

Briefing Memo

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

This document has been electronically approved and signed.

Memorandum

Date: July 13, 2012

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, 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

Introduction

The Consumer Product Safety Improvement Act of 2008 (CPSIA), sections 108(a) and 108(b), established a concentration limit for specified phthalate chemicals for 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.

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 CFR § 1500.87 (Children's products containing lead: inaccessible component parts), was published in the *Federal Register* on August 7, 2009 (74 FR 39535).

The Lead-Containing Parts Interpretative Rule is based on the Commission's defining an "accessible component part" of a children's product as one that a child may touch, and an "inaccessible component part" 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.

Sections 1500.48–1500.49 of 16 CFR 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 CFR §§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 CFR §§1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 CFR §§1500.51–1500.53). Use and abuse testing is likewise 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 CFR §1500.53 (excluding the bite test—paragraph (c)).

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. 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.

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, but the amended section 108 includes a provision for "additional consideration, as appropriate, of whether such component can be placed in a child's mouth."

Staff has extensive knowledge of the possibility of exposure to phthalates from direct contact with phthalate-containing parts. Studies by CPSC staff[1] and others have shown that phthalates may be released from polyvinyl chloride[2] products under conditions involving the presence of a liquid and mechanical action, such as in the case of mouthing and chewing a product. If a phthalate-containing part is not physically accessible to a child, then direct contact cannot occur, and no transfer of phthalates through direct contact can occur.

Staff also considered the question of potential transfer of phthalates from inaccessible parts through materials, or through small gaps in the outside covering of the product. That is, if phthalates from an otherwise physically inaccessible phthalate-containing part could migrate through non-phthalate-containing materials or to the outside of a non-phthalate-containing part, then the phthalates in the product would be accessible, even though the original phthalate-containing part remains inaccessible. Staff considered two possible routes of exposure to phthalates other than direct contact with a phthalate-containing component part: (1) evaporation of phthalates into the air, and (2) migration of phthalates from inaccessible parts to accessible parts of a product, where a child may contact the substance.

Migration of Phthalates in Vapor Form

Phthalates, or other substances with similar uses as phthalates, may evaporate (vaporize or volatilize) into the air. A chemical's ability to volatilize is measured as "vapor pressure." The higher that the value is under specified temperature conditions, the more volatile the chemical. A chemical's boiling point is also a measure of the substance's volatility—the lower the boiling point under specified conditions of atmospheric pressure, the more volatile the chemical.

Table 1 contains physical-chemical data for many phthalate compounds or substitutes for phthalates. In general, phthalate compounds most commonly used in manufacturing are not considered to be volatile because the measured vapor pressures[3] are typically low, and boiling points are high.[4] Staff notes that measurements of vapor pressure are not always conducted at room temperature,[5] and measurements of boiling point are not always conducted at standard atmospheric pressure.[6] For these data, test conditions that varied from standard room temperature or atmospheric pressure are displayed in the table.

Staff notes that the characteristics of chemicals within a mixture or formulation, such as phthalates in a plastic material, are not necessarily the same as for the pure compound. Even a very volatile chemical, if part of a mixture or product, may volatilize only very slowly over long

[1] Babich MA, Chen SB, Greene MA, Kiss CT, Porter WK, Smith TP, Wind ML, Zamula WW (2004) Risk assessment of oral exposure to diisononyl phthalate from children's products. Regul Toxicol Pharmacol 40(2): 151-67.

[2] Polyvinyl chloride, commonly called PVC or vinyl, typically contains plasticizer chemicals, such as phthalates.

[3] Pressure can be measured using many different units. Most commonly, vapor pressure is measured in kilopascals (kPa), hectopascals (hPa), or millimeters of mercury (mmHg) (also called torr).

[4] To understand the magnitude of the values in Table 1, consider the following examples of common chemicals: water has a vapor pressure of 23.8 mmHg at 25ºC, and a boiling point of 100ºC at standard atmospheric pressure; methyl salicylate, which is commonly known as the odor and taste of wintergreen, has a vapor pressure of 0.034 mmHg at 25ºC, and a boiling point of 224ºC.

[5] Vapor pressure increases with increasing temperature. Room temperature is 20–25ºC (68–77ºF).

[6] Boiling point decreases with decreasing pressure. Standard atmospheric pressure (at sea level) is most commonly given as 760 mmHg, 101.325 kPa, or 1013.25 hPa.

periods of time (*e.g.*, formaldehyde in certain building materials). Consequently, most phthalates, as relatively nonvolatile substances, when present in a plastic component part of a product also will tend to volatilize only very slowly over time. Staff also notes that, given the physical-chemical data described above, 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 probably not feasible at this time.

Once a substance vaporizes, it becomes a constituent of air and can be inhaled. Vaporized substances also may adsorb onto surfaces and dust particles. When this occurs, the chemical no longer exists freely as a gas in the air. Exposure to the chemical may still occur through inhalation when a person inhales dust particles with the adsorbed chemical. Exposure may also occur when a person touches surfaces or handles items to which the chemical has adsorbed. Children's exposures to such chemicals may then occur through normal hand-to-mouth behavior, or mouthing of affected products.

Studies show that phthalate compounds generally do not remain free in the air. The substances have been found associated mainly with surfaces within a room.[7] If a phthalate compound is present in an inaccessible component part within a larger product, such as coated wiring in an electronic toy, volatilized phthalates would also likely not remain in the air but would be found adsorbed onto the nearby surfaces within the toy (*e.g.*, the inaccessible inside surface of the toy's casing, and electronic circuitry and components). Because most products include non-continuous outside casings, due to air vents, seams, or gaps between parts, some volatilized chemical could escape the confines of the product's interior spaces. Staff believes the amount of volatized phthalate released in this way 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.

Migration of Phthalates in Non-Vapor Form

Staff also considered the possible release and transfer of phthalates in a non-vapor state from an inaccessible component part to an accessible part of a product. Staff is not aware of 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, or along the surface of such a material, where it could eventually reach the outside of a product. Nor is staff aware of studies that show the propensity for phthalates in a liquid form to move from a phthalate-containing material to another non-phthalate-containing material without direct physical contact and mechanical action.

Furthermore, staff believes, based on the physical-chemical data described above, that 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 fraction of the original phthalate content of the inaccessible phthalate-containing part. Therefore, staff believes that in most cases, phthalates present in a part of a product that is inaccessible will remain in the inaccessible part.

[7] Weschler CJ (2003) Indoor/outdoor connections exemplified by processes that depend on an organic compound's saturation vapor pressure. Atmos Environ 37: 5455–5465.

Although phthalates have been detected in environmental samples, indicating that the chemicals are not locked into phthalate-containing materials, the source of the chemicals are all of the phthalate-containing products present in a home, not just the children's products under discussion here. Further, some phthalate-containing products are intended to be used to treat air or be present in air, including fragrance products, perfumes, and other household products. Such products contribute to the levels of phthalates detected in homes. With the CPSIA restriction of certain phthalates in children's toys and child care articles, 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.[8,9]

Therefore, staff expects that, 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.

Fabric Coverings

Because fabric is not necessarily a complete physical barrier between interior component parts and the person using the product, as described in staff's original work on inaccessible lead-containing component parts, staff considered the special circumstances of a fabric covering as a barrier to the potential transfer of phthalates from a component part.

Staff is not aware of any information that shows passive migration of phthalates from a phthalate-containing material through adjacent non-phthalate-containing fabric materials, other than the possibility of volatility discussed above. However, staff believes that, as is the case with lead, a fabric covering may not be a suitable barrier to the potential transfer of phthalates from a product or component part to a child, if the part can be placed in a child's mouth. If the product can be mouthed, 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. However, staff notes that phthalates are not very soluble in aqueous solution (*i.e.*, water and water-based substances). Therefore, saliva or beverages might not allow efficient transfer of phthalates from phthalate-containing materials, although this possibility does not alter staff's conclusion regarding fabric as an unsuitable barrier in the case of mouthing.

There also 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. One such product is a mattress or another vinyl-covered sleep surface. Young children typically spend more than half of each day sleeping or resting,[10] likely on a mattress or similar item. While a mattress is typically covered with a sheet or mattress pad, staff believes that such nonpermanently 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

[8] Wormuth M, Scheringer M, Vollenweider M, Hungerbuhler K (2006) What are the sources of exposure to eight frequently used phthalic acid esters in Europeans? Risk Anal 26(3): 803–824.

[9] Schettler T (2006) Human exposure to phthalates via consumer products. Int J Androl 29(1):134–139.

[10] U.S. EPA (Environmental Protection Agency). (2011) Exposure factors handbook: 2011 edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA, and online at http://www.epa.gov/ncea/efh.

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 both of these reasons, products such as mattresses with vinyl coverings cannot be considered to be made inaccessible through use of a fabric covering.

Staff notes that while, in general, fabric coverings may be considered barriers to contact with underlying materials for products that cannot be placed in the mouth and are not used in sleep surfaces, the integrity of the coverings, including seams, should be evaluated using the appropriate use and abuse tests at 16 CFR §§1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 CFR §§1500.51–1500.53).

In addition, because the material beneath a fabric covering would be considered to be accessible to a child in the case that mouthing or swallowing of the part may occur, use and abuse testing should be used to evaluate the potential for small components to be removed from products, using the appropriate tests at 16 CFR §§1500.50 through 1500.53 (excluding the bite test—paragraph (c) of 16 CFR §§1500.51–1500.53).

CPSIA section 108 includes a definition of toys that can be placed in a child's mouth. Using this definition to consider other products in addition to toys, staff believes that 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. As discussed above, staff believes that products such as mattresses with vinyl coverings cannot be considered to be made inaccessible through use of a fabric covering regardless of the dimensions of the product.

Conclusions and Recommendation

Staff's conclusions with respect to accessibility of phthalate-containing parts are nearly identical to its conclusions regarding lead-containing parts. 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 only a minor modification to address 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.

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. A report from the CHAP, including recommendations to the Commission, is expected to be finalized in 2012. Staff recommends that any guidance concerning phthalates be modified and revised, as appropriate, based on the findings and recommendations of the CHAP.

Table 1. Phthalates and Phthalate Substitutes

Common Name or Abbreviation	Chemical Name	CAS Number	MW	Vapor Pressure*	Boiling Point °C	Water Solubility
Diethyl phthalate (DEP)	1,2-Benzenedicarboxylic acid, diethyl ester	84-66-2	222.2	1.6 $x10^{-3}$ mmHg	298	1 mg/L
Dibutyl phthalate (DBP)	1,2-Benzenedicarboxylic acid, dibutyl ester	84-74-2	278.3	2.7$x10^{-5}$ mmHg	340	11.2 mg/L
Di-n-hexyl phthalate (DnHP)	1,2-Benzenedicarboxylic acid, dihexyl ester	84-75-3	334.5	1.40$x10^{-5}$ mmHg @ 25ºC	210	0.05 mg/L @ 25°C
Dinonyl phthalate (DNP)	1,2-Benzenedicarboxylic acid, dinonyl ester	84-76-4	418.6	0.133 kPa @ 205ºC (1.0 mmHg)	413	1.74$x10^{-5}$ mg/L @ 25°C
Di-n-decyl phthalate (DnDP)	1,2-Benzenedicarboxylic acid, didecyl ester	84-77-5	446.7	7.89$x10^{-9}$ mmHg @ 25ºC (est.)	261 @ 5 mmHg	2.2$x10^{-4}$ mg/L @ 25°C
Benzyl butyl phthalate (BBP)	1, 2-Benzenedicarboxylic acid, butyl phenylmethyl ester	85-68-7	312.4	6$x10^{-7}$ mmHg	370	2.7 mg/L
Di-(2-ethylhexyl) phthalate (DEHP)	1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester	117-81-7	390.6	4.8$x10^{-8}$ to 1.4$x10^{-4}$ mmHg	384	0.0006 to 1.2 mg/L
Dimethoxyethyl phthalate (DMEP)	1,2-Benzenedicarboxylic acid, bis(2-methoxyethyl) ester	117-82-8	282.3	2.28$x10^{-4}$ mmHg @ 25°C	340	8500 mg/L
Di-n-octyl phthalate (DnOP)	1,2-Benzenedicarboxylic acid, 1,2-dioctyl ester	117-84-0	390.6	2.2$x10^{-7}$ to 1.9$x10^{-4}$ mmHg	390	0.00046 to 3.0 mg/L
Dimethyl phthalate (DMP)	1,2-Benzenedicarboxylic acid, dimethyl ester	131-11-3	194.2	6.0$x10^{-3}$ mmHg	284	4.3 mg/L
Diallyl phthalate (DAP)	1,2-Benzenedicarboxylic acid, di-2-propenyl ester	131-17-9	246.3	1.16$x10^{-3}$ mmHg @ 25°C	158-165@ 4 mm Hg	182 mg/L @ 20°C
Diamyl phthalate or dipentyl phthalate	1,2-Benzenedicarboxylic acid, dipentyl ester	131-18-0	306.4	1.96$x10^{-4}$ mmHg @ 25ºC	342	0.8 mg/L @ 25°C
TXIB™	2,2,4-Trimethyl-1,3-pentanediol-diisobutyrate	6846-50-0	286.4	0.0009 hPa @ 20°C (6.6x10-4 mmHg)	280	1-2 mg/L @ 20.5°C
Texanol benzyl phthalate (Monsanto)	1,2- Benzenedicarboxylic acid, 2,2-dimethyl-1-(1-methylethyl)-3-(2-methyl-1-oxopropoxy) propylphenylmethyl ester	16883-83-3	454.6	0.66 hPa (0.5 mmHg)	243 @ 13.33 hPa (10 mmHg)	0.81 mg/L @ 22°C

Common Name or Abbreviation	Chemical Name	CAS Number	MW	Vapor Pressure*	Boiling Point °C	Water Solubility
Benzyl C7-9-branched and linear alkyl phthalates	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	68515-40-2	341.4–369.5	0.667 hPa @ 200°C (0.5 mmHg)	252-390	0.3 mg/L @ 25°C
Di-C7-C9 phthalates, branched and linear	1,2-Benzenedicarboxylic acid, di-C7-9-branched and linear alkyl esters	68515-41-3	362.5–418.6	0.001 hPa @ 100°C ($7.5x10^{-4}$ mmHg)	398 – 454	<1 mg/L $6.1x10^{-7}$ to $170x10^{-7}$ g/L
Branched and linear diheptyl phthalate	1,2-Benzenedicarboxylic acid, diheptyl ester, branched and linear	68515-44-6	362.5	$9.33x10^{-7}$ to $1.08x10^{-5}$ mmHg @ 25°C	364	0.002 to 0.02 mg/L @ 25°C
Branched and linear dinonyl phthalate	1,2-Benzenedicarboxylic acid, dinonyl ester, branched and linear	68515-45-7	418.6	$6.81x10^{-8}$ hPa ($5.1x10^{-8}$ mmHg)	454	0.00031 mg/L
Diisotridecyl phthalate	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich	68515-47-9	475-559	<0.1 hPa @ 20ºC (<0.075 mmHg)	286	<0.1 mg/L volume% @ 20°C
Diisononyl phthalate (DINP)	1,2-Benzenedicarboxylic Acid, Di-C8-C10-Branched Alkyl Esters, C9-Rich	68515-48-0; 28553-12-0	418.6	5 x 10^{-7} mmHg	370	<0.001 mg/L
Diisodecyl phthalate (DIDP)	1,2-Benzenedicarboxylic Acid, Diisodecyl Ester	68515-49-1 and 26761-40-0	446.7	$5.1x10^{-5}$ Pa @ 25ºC ($3.8x10^{-7}$ mmHg)	>400	1.19 mg/L
Mixture of DnDP, DnOP, and DnHP	1,2-Benzenedicarboxylic acid, di-C6-10 alkyl phthalates	68515-51-5 (84-77-5, 117-84-0, 84-75-3)	334.5–446.7	<0.001 hPa @ 20ºC (<$7.5x10^{-4}$ mmHg)	250 @ 5 hPa	< 0.2 mg/L @ 20°C
Mixed hexyl, octyl, decyl phthalates	1,2-Benzenedicarboxylic acid, mixed decyl, hexyl, octyl diesters	68648-93-1	334.5–446.7	$1.33x10^{-7}$ hPa @ 25°C (<$1.0x10^{-7}$ mmHg)	431	0.00088 mg/L @ 25°C
Diisoheptyl phthalate	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	334 – 391	<0.01 hPa @ 20°C (<0.0075 mmHg)	>300 @ 0.01 hPa (0.008 mmHg)	< 0.1 volume% @ 20°C
Diundecyl phthalate	1,2-Benzenedicarboxylic acid, diundecyl ester, branched and linear	85507-79-5	474.7	<0.01 hPa @ 20°C (<0.0075 mmHg)	270 @ 6.66 hPa (5 mmHg)	1.1 mg/L

***Note: the scientific notation used for low vapor pressures, such as DEHP with a range of reported vapor pressures of $4.8x10^{-8}$ to $1.4x10^{-4}$ mmHg, means the reported range is from 4.8 one hundred-millionths of a mmHg to 1.4 ten-thousandths of a mmHg (*i.e.*, 0.000000048–0.00014 mmHg).**