The Office of the General Counsel is forwarding to you a draft Statement of Policy concerning section 108 of the Consumer Product Safety Improvement Act ("CPSIA").

Please indicate your vote on the following options.

I. Approve the draft Statement of Policy and the issuance of the draft Federal Register Notice of Availability as drafted.

II. Approve the draft Statement of Policy and the issuance of the draft Federal Register Notice of Availability with the following changes (please specify):

Signature  Date

Note: This document has not been reviewed or accepted by the Commission.

Initials  Date

III. Do not approve the draft Statement of Policy or the issuance of the draft *Federal Register* Notice of Availability.

__________________________________________  ____________
Signature                                      Date

IV. Take other action. (Please specify.)

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__________________________________________
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__________________________________________  ____________
Signature                                      Date
Memorandum

Date: July 30, 2009

TO: The Commission
    Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
          Jacqueline Elder, Acting Executive Director

FROM: Robert J. Howell, Assistant Executive Director
       Office of Hazard Identification and Reduction
       Michael A. Babich, Ph.D., Project Manager for Phthalates
       Directorate for Health Sciences

SUBJECT: Section 108 of the Consumer Product Safety Improvement Act—
         Staff Recommendation to Test the Plasticized Components Rather than the
         Entire Product

Introduction

The Consumer Product Safety Improvement Act of 2008 (CPSIA)\(^1\) was enacted on August 14, 2008. Section 108 of the CPSIA permanently prohibits the sale of any “children’s toy or child care article” containing concentrations of more than 0.1 percent of three specified phthalates.\(^2,3\) Section 108 also prohibits on an interim basis the sale of “any children’s toy that can be placed in a child’s mouth” or “child care article” containing concentrations of more than 0.1 percent of three additional phthalates, pending the recommendation of a Chronic Hazard Advisory Panel (CHAP).\(^4,5\) The CHAP will recommend to the Commission whether any phthalates or phthalate alternatives other than those permanently banned should be declared banned hazardous substances. The terms “children’s toy,” “children’s toy that can be placed in a child’s mouth,” and “child care article” are defined in section 108. These prohibitions became effective on February 10, 2009. In addition, manufacturers of certain children’s products, including those subject to section 108, will be required to certify that their products comply with section 108 based on testing by a third party conformity assessment body that is accredited by CPSC.\(^6\) The testing and certification requirements have been stayed by the Commission until February 10, 2010, insofar as compliance with the section 108 requirements is concerned.\(^7\)

Discussion

The CPSC staff issued a test method for measuring the concentration of phthalates in articles subject to section 108 of the CPSIA.\(^8\) This test method measures the phthalate concentration in the entire product, rather than the component parts of the product. However, measuring phthalates in the entire product raises a number of concerns about this approach: sample
preparation is more difficult, the phthalate concentration may be diluted by the presence of non-plasticized components, and this approach differs from similar regulations issued by other jurisdictions. Public comments and questions on the test method tend to support the staff’s concerns. Furthermore, the CPSC staff believes and public comments support, that, given the expense of phthalate testing, testing for phthalates should be done on only those parts of children’s toys and child care articles likely to contain phthalates, which are referred to below as “plasticized parts.” Materials that are likely to contain phthalates are discussed later in this memorandum.

Testing the entire product as opposed to each of the plasticized parts may not reflect the intent of Congress; rather, it may result in a less stringent and less health-protective regulation. For these reasons, the CPSC staff recommends that: (1) each component part of a “children’s toy” or “child care article” (as those terms are defined in the CPSIA) be required to meet the 0.1% phthalates limit individually, and (2) third party testing be required on only those component parts of those products that are likely to contain phthalates. While non-plasticized parts would not require third-party testing, they would still be required to meet the 0.1% limit on the specified phthalates. Manufacturers must test all components that contain the specified phthalates. This memorandum discusses the practical implications of testing only plasticized component parts, as opposed to the entire product, and the scientific basis to support the staff recommendation.

Testing

The current CPSC staff test method for measuring phthalate concentrations, which was published in March 2009, provides two approaches to sample preparation. First, the entire product may be mechanically ground into a homogeneous powder. Then, the powder is tested to determine the phthalate concentration in the entire product. However, a sufficiently homogeneous powder can be difficult to achieve, especially if the product is large or contains metal parts. The grinding process itself can create dusts that could present a hazard to laboratory personnel, especially if the product contains electronic or other components that may contain hazardous materials. In the second approach of the current test method, each individual component of the product is tested, except for metal, glass, or ceramic parts. Then the overall concentration of phthalate in the entire product, including the metal, glass, or ceramic parts, is calculated mathematically. The staff has prepared a revised test method based on testing only the plasticized component parts. In the revised method, the phthalate concentration is measured and reported individually for each plasticized part.

Other Phthalates Regulations

The European Commission (EC) has previously issued regulations on phthalates in children’s products. The EC limits the specified phthalates to 0.1 percent by weight in the “plasticized material.” The State of California has also issued a phthalates regulation for children’s products. The California Deputy Attorney General has informed the CPSC staff that the California regulation will be applied to only the plasticized material. The differences between the CPSIA and other similar regulations have created some confusion on the part of manufacturers and test laboratories.
Harmonization with other jurisdictions and entities presents certain advantages to manufacturers and retailers. While this alone is not a compelling reason to amend a regulation or change its interpretation, it is reasonable to consider the benefits of harmonization as part of the regulatory process.

**Testing Component Parts, as Compared to Entire Products**

This section discusses the effect of measuring the phthalate concentration on the basis of component parts, as compared to the entire products. Suppose a product contains a plastic component part with a high concentration of a banned phthalate. If the entire product is tested, it might still meet the requirements of section 108, because the phthalate content in the plastic component is essentially diluted by the non-plasticized components comprising the rest of the product. Thus, a product that would be banned in Europe could be allowed for sale in the U.S. Furthermore, it would be reasonable to conclude that the component part containing the high concentration of a banned phthalate violates the spirit, if not the letter, of the CPSIA. In this regard, the current CPSC approach (where the phthalate concentration is not more than 0.1% of the entire product), results in a less stringent and presumably less health-protective regulation, compared to the European and California regulations.

For example, suppose a toy weighs 1,000 grams (about 2 pounds), including a 10 gram plasticized part with 10% DEHP. If we consider the test results of only the plasticized component part, the part exceeds the 0.1% limit and the toy would be banned in Europe. However, if we consider the entire toy, then the overall DEHP concentration is based on the weight of the entire toy (1,000 grams) and would therefore be 0.1%; the toy could be sold in the U.S.

**Burden of Testing**

Many manufacturers, especially small companies and individuals, have commented that the cost of third-party testing and certification requirements in section 102 of the CPSIA presents a significant economic burden and has resulted in the closing of numerous small businesses. These manufacturers also commented that the requirement to test materials such as yarn and wood for phthalates is unreasonable and unnecessarily burdensome. The cost of testing would be reduced if it were not necessary to test all materials. One advocacy group has stated that there is no need to test all materials for phthalates, and that the current CPSC approach is less health protective.

**Materials That May Contain Phthalates**

Phthalates are primarily used as plasticizers (softeners) in polyvinyl chloride (PVC) plastics. PVC is used in a plethora of products including, toys, floor and wall coverings, household furnishings, building materials, wire and cable insulation, footwear, rainwear, and automobile interiors. Phthalates may be used as plasticizers in other plastics including polyvinyl acetate (PVA), polyvinylidene chloride (PVDC), and polyurethane (PU). Phthalates are also used as solvents and/or plasticizers in paints, inks, adhesives, sealants, air fresheners, and scented
products. Phthalates are more likely to be used in paints, adhesives, or sealants when the finished product must be flexible, such as a printed design on apparel or other flexible substrates.

Because phthalates are widely used, and because manufacturers are not required to disclose the ingredients in their products to the Commission, the CPSC staff does not know all of the possible uses of phthalates in consumer products. Nonetheless, certain materials are generally known not to contain phthalates. For example, unfinished metals, unfinished wood, and natural fibers such as cotton and wool are not expected to contain phthalates, which are synthetic chemicals. However, any coatings or printing on these materials may contain phthalates. Adhesives and finishes used to manufacture wooden toys, for example, may contain phthalates. Printed designs, non-slip coatings, back coatings, and elastic materials on apparel (specifically, sleepwear) may also contain phthalates.

Certain plastics, such as polyethylene and polypropylene, generally do not require plasticizers. However, surface coatings and adhesives may contain phthalates. In addition, phthalates could be used in some plastics even though they are not required. Phthalates might also be used in some elastomers or synthetic rubbers. Most natural and synthetic fibers and textiles are not expected to contain phthalates,15 except for PVC and related materials. However, printed designs, surface treatments, and elastic components may contain phthalates.

Some examples of materials that may contain phthalates include:

- Polyvinyl chloride (PVC) and related polymers, such as polyvinylidene chloride (PVDC) and polyvinyl acetate (PVA). These materials should always be tested.
- Soft or flexible plastics, except polyolefins.
- Soft or flexible rubber, except silicone rubber and natural latex.
- Foam rubber or foam plastic, such as polyurethane (PU).
- Surface coatings, finishes, decals, and printed designs.
- Adhesives and sealants.
- Electrical insulation.

Some examples of materials that do not normally contain phthalates and, therefore, might not require testing include:

- Unfinished metal.
- Natural wood, except for coatings and adhesives.
- Textiles made from natural fibers, except for printed decorations, water-proof coatings or other surface treatments, back coatings, and elastic materials.
- Textiles made from common synthetic fibers, such as polyester, acrylic, and nylon, except for printed decorations, water-proof coatings or other surface treatments, and elastic materials. However, any textiles containing PVC or related polymers must be tested.
- Polyethylene and polypropylene (polyolefins).
- Silicone rubber and natural latex.
- Mineral products such as play sand, glass, and crystal.

Recommendaition

Under section 108 of the CPSIA, the sale of children’s toys and child care articles containing more than 0.1% of certain phthalates is prohibited. The CPSC staff recommends that this phrase be interpreted to mean that the sale of children’s toys and child care articles containing more than 0.1% of the specified phthalates in each individual plasticized component part is prohibited. This interpretation has two effects. First, the phthalate concentration will be calculated on the basis of the weight (mass) of the plasticized component part, rather than the entire article. Second, it will not be necessary to test components or materials that are not plasticized. While non-plasticized parts would not require third-party testing, they would still be required to meet the 0.1% limit on the specified phthalates. Manufacturers must know whether their products contain phthalates and will be responsible for testing those components to ensure compliance with the limits. The staff’s recommendation would make section 108 more stringent and more health-protective. It would also simplify the testing process, eliminate the unnecessary testing of products that do not contain phthalates, reduce the cost of testing, and harmonize with the European Commission and the State of California.
References

1 Public Law 110-314.

2 Di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP).

3 CPSIA §108(a).

4 Diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP).

5 CPSIA §108(b)(1).

6 CPSIA §102(a)(2).


9 Ibid.


Statement of Policy: Testing of Component Parts With Respect To Section 108 of the Consumer Product Safety Improvement Act
Statement of Policy: Testing of Component Parts With Respect To
Section 108 of the Consumer Product Safety Improvement Act

A. Background

The Consumer Product Safety Improvement Act (CPSIA) was enacted on August 14, 2008 (Pub. L. 110-314). Section 108 of the CPSIA permanently prohibits the sale of any “children’s toy or child care article” containing concentrations of more than 0.1 percent of three specified phthalates.1,2 Section 108 also prohibits, on an interim basis, the sale of “any children’s toy that can be placed in a child’s mouth or child care article” containing concentrations of more than 0.1 percent of three additional phthalates pending the recommendation of a Chronic Hazard Advisory Panel (CHAP).3,4 The CHAP will recommend to the Commission whether to make the interim ban permanent and whether other phthalates or phthalate alternatives should be declared banned hazardous substances. The terms “children’s toy,” “children’s toy that can be placed in a child’s mouth,” and “child care article” are defined in section 108 of the CPSIA. These prohibitions became effective on February 10, 2009.

To gather comments and information about implementation of this section of the CPSIA, the Commission published a “Notice of Availability of Draft Guidance Regarding Which Children’s Products Are Subject to the Requirements of CPSIA Section 108; Request for Comments and Information,” on February 23, 2009 (74 FR 8058). Comments in response to the Notice demonstrate that many questions and concerns exist about the requirement that products comply with the phthalates limits of section 108 of the CPSIA and, specifically, the testing procedures used to determine the percentage of phthalates in such products.

In the present statement of policy, the Commission describes its current position on component part testing with respect to section 108 of the CPSIA. It does not create or confer any rights for or on any person and does not operate to bind CPSC or the public beyond the existing statutory requirements of the CPSIA. You can use an alternative approach if the approach satisfies the requirements of the CPSIA.

B. Purpose of Section 108 of the CPSIA

The purpose of section 108 of the CPSIA, generally, is to ensure that children are not exposed to certain specified phthalates while playing, sleeping, or eating. In general, phthalates are chemicals that are added to plastic to make the plastic more flexible or resilient, and concerns have been raised about possible adverse health effects resulting from exposure to phthalates.

In March of 2009, the Commission staff sought comment on a method for testing phthalate content as a percentage of the entire toy or child care article. Given that testing the phthalate

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1 Di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP).
2 Section 108(a) of the CPSIA.
3 Diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP).
4 Section 108(b)(1) of the CPSIA.
content of an entire children’s toy or child care article presents certain difficulties, may lead to
dilution of the phthalate concentrations compared to that in one or more of its component parts,
differs from similar regulations issued by other jurisdictions, and can be prohibitively expensive,
the Commission believes that phthalate testing should be limited to those plastic parts or other
product parts which could conceivably contain phthalates ("plasticized component parts").
Testing component parts to the phthalates limits established in section 108 is more protective of
human health and effectuates the intent of Congress to limit children’s exposure to phthalates.
The benefits of the component approach are two-fold, in addition to providing more protection
for children, it also may significantly reduce the testing costs for manufacturers in certain
circumstances.

In addition, requiring component part testing is supported by the statutory language. The CPSIA
permanently bans the sale of any children’s toy or child care article containing concentrations of
more than 0.1% of DEHP, DBP or BBP. A “children’s toy” is defined in the CPSIA 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.”5 The term “child care article” is defined in
the CPSIA as “...a consumer product designed or intended by the manufacturer to facilitate sleep
or the feeding of children age 3 and younger, or to help such children with sucking or teething.”
Both definitions use the term “consumer product,” which section 3 of the Consumer Product
Safety Act (CPSA) defines, in part, as:

any article, or component part thereof, produced or distributed (i) for sale to a consumer
for use in or around a permanent or temporary household or residence, a school, in
recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a
consumer in or around a permanent or temporary household or residence, a school, in
recreation, or otherwise . . . (Emphasis added.)

This definition of consumer product also applies to the more limited definition of “children’s toy
that can be placed in a child’s mouth” to which the interim ban on DINP, DIDP and DnOP
applies.

Because the term consumer product includes components of an article, the Commission believes
that the phthalate limits in section 108 of the CPSIA apply to each component part of any article.
The Commission has developed a method to test component parts for the specified phthalates and
will only require testing of plasticized component parts as defined above.

Therefore, when testing for phthalates in children’s toys and child care articles subject to section
108 of the CPSIA, CPSC staff will use test method CPSC-CH-C1001-09.2, which is published
separately and in conjunction with this Policy. This test method can be found on our website at
[insert web address after vote].

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5 Section 108(e) of the CPSIA.

Phthalates are primarily used as plasticizers (softeners) in polyvinyl chloride (PVC) plastics. PVC is used in many products, including, toys, floor and wall coverings, household furnishings, building materials, wire and cable insulation, footwear, rainwear, and automobile interiors. Phthalates may be used as plasticizers in other plastics including polyvinyl acetate (PVA), polyvinylidene chloride (PVDC), and polyurethane (PU).\textsuperscript{6,7} Phthalates also are used as solvents and/or plasticizers in paints, inks, adhesives, sealants, air fresheners, and scented products. Phthalates are more likely to be used in paints, adhesives, or sealants when the finished product must be flexible, such as a printed design on apparel or other flexible substrates.

Not all plastics, however, contain phthalates. Certain plastics, such as polyethylene and polypropylene, generally do not require plasticizers. However, surface coatings and adhesives may contain phthalates. In addition, phthalates could be used in some plastics even though they are not required. Phthalates might also be used in some elastomers or synthetic rubbers. Most natural and synthetic fibers and textiles are not expected to contain phthalates,\textsuperscript{8} except for PVC and related materials. Printed designs, coatings, surface treatments, and elastic components may contain phthalates.

Examples of materials that may contain phthalates are:

- Polyvinyl chloride (PVC) and related polymers, such as polyvinylidene chloride (PVDC) and polyvinyl acetate (PVA). These materials should always be tested.
- Soft or flexible plastics, except polyolefins.
- Soft or flexible rubber, except silicone rubber and natural latex.
- Foam rubber or foam plastic, such as polyurethane (PU).
- Surface coatings, non-slip coatings, finishes, decals, and printed designs.
- Elastic materials on apparel, such as sleepware.
- Adhesives and sealants.
- Electrical insulation.


Examples of materials that do not normally contain phthalates and, therefore, might not require testing or certification are:

- Unfinished metal.
- Natural wood, except for coatings and adhesives added to wood.
- Textiles made from natural fibers, such as cotton or wool, except for printed decorations, waterproof coatings or other surface treatments, back coatings, and elastic materials (especially sleepwear).
- Textiles made from common synthetic fibers, such as polyester, acrylic, and nylon, except for printed decorations, waterproof coatings or other surface treatments, and elastic materials. However, any textiles containing PVC or related polymers must be tested.
- Polyethylene and polypropylene (polyolefins).
- Silicone rubber and natural latex.
- Mineral products such as play sand, glass, and crystal.

D. Who Is Responsible for Deciding Whether to Test for Phthalates?

Manufacturers either know or should know what materials and components go into the products they make, and if the product or its components contain one of the plasticizers specified in section 108 of the CPSIA, the manufacturer or importer certifying the product must test the component or product to ensure that it complies with the CPSIA. Failure to comply with section 108 of the CPSIA is a prohibited act under section 19 of the Consumer Product Safety Act (CPSA) and can result in civil and criminal penalties. Likewise, failure to have a product subject to section 108 of the CPSIA tested by an accredited third-party laboratory and have the appropriate certification for that product is also a prohibited act under section 19 (CPSA).
Draft Federal Register Notice
Notice of Availability of a Statement of Policy: Testing of Component Parts With Respect to Section 108 of the Consumer Product Safety Improvement Act
Notice of Availability of a Statement of Policy: Testing of Component Parts With Respect to Section 108 of the Consumer Product Safety Improvement Act

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Availability.


ADDRESSES: The Statement of Policy is available from the Commission’s website at [INSERT CITE]. Copies also may be obtained from the Consumer Product Safety Commission, Office of the Secretary, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; 301-504-7923.

FOR FURTHER INFORMATION CONTACT: Michael A. Babich, Ph.D., Consumer Product Safety Commission, 4330 East West Highway,
SUPPLEMENTARY INFORMATION:

On August 14, 2008, the CPSIA (Public Law 110-314) was enacted. 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 articles” 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.

The terms “children's toy,” “toy that can be placed in a child’s mouth,” and “child care article” are defined in section 108 of the CPSIA. For example, section 108 of the CPSIA defines a “children's toy” as a “consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays.” It is noteworthy that the definition uses the term...
"consumer product" because section 3(a)(5) of the Consumer Product Safety Act (CPSA) defines "consumer product," in relevant part, as "any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise..."

In the FEDERAL REGISTER of February 23, 2009 (74 FR 8058), the Commission published a notice of availability regarding a draft guidance discussing which children's products are subject section 108 of the CPSIA. The notice invited comment on various questions and also on the Commission's test method for phthalates. The test method (Test Method: CPSC-CH-C1001-09.1, "Standard Operating Procedure for Determination of Phthalates," dated March 3, 2009) generated some controversy in that it suggested testing the entire product or testing components and then mathematically combining the results.

The Commission has reexamined the question of product testing and has prepared a document titled "Statement of Policy: Testing of Component Parts with Respect to Section 108 of the Consumer Product Safety Improvement Act." The
Statement of Policy describes the Commission's position regarding component testing, and the Commission will issue a new test method in the near future. The Statement of Policy is available on the Commission's website at [INSERT CITE] and from the Commission's Office of the Secretary at the location listed in the ADDRESSES section of this notice.

Dated: ________________

Todd Stevenson, Secretary
Consumer Product Safety Commission