

NOTICE OF AVAILABILITY OF DRAFT GUIDANCE REGARDING WHICH  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<sup>1</sup>

February 12, 2009

**Introduction**

Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)<sup>1</sup> permanently prohibits the sale of any “children’s toy or child care article” containing more than 0.1 percent of three specified phthalates.<sup>2</sup> Section 108 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.<sup>3</sup> 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, and the definitions apply only to this section of the Act. The staff of the U.S. Consumer Product Safety Commission (CPSC) has received many inquiries from manufacturers seeking clarification on which products are subject to the requirements of section 108 and, in response, has developed a possible approach to guide manufacturers in determining which products might be subject to the requirements.

The purpose of this notice is to seek public comment on the CPSC staff’s approach for determining which products are subject to the requirements of section 108 of the CPSIA, and to seek additional information on how the approach could be applied to particular product classes. The examples discussed below are not comprehensive. Rather, they are intended to illustrate the staff’s approach. Additionally, conclusions that are generally true for a class of products may not necessarily apply to each specific product in that class, for example, due to the way the product is advertised.

The requirements of section 108 apply to subsets of “consumer products” as defined by the Consumer Product Safety Act (CPSA).<sup>4</sup> Products such as food, cosmetics, and medical devices that are regulated by other federal agencies are generally not considered “consumer products.” However, some products may fall under the jurisdiction of more than one agency. For example, articles such as infant bottles and cups are under the jurisdiction of both CPSC and the U.S. Food and Drug Administration (FDA). FDA has jurisdiction over indirect food additives, that is, when there is a possibility that a chemical may migrate from the article into a food or beverage. CPSC generally has jurisdiction over the outer portion of the product, which directly contacts the consumer. However, section 108 is based on phthalate concentration within the product and does not distinguish between exposure pathways. Therefore, for the purpose of CPSIA section 108, articles such as infant bottles and cups are regarded as consumer products.

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<sup>1</sup> This report was prepared by the CPSC staff; it has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

## Children's Toys

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.”<sup>5</sup> Any determination as to whether a particular product is designed or intended for use by a child 12 years of age or younger during play will be made after consideration of the following factors:<sup>6</sup>

- Whether the intended use of the product is for play, including a label on the product if such statement is reasonable.
- Whether the product is represented in its packaging, display, promotion or advertising as appropriate for use by the ages specified.
- Whether the product is commonly recognized by consumers as being intended for use by a child of the ages specified.
- The Age Determination Guidelines issued by the Commission staff in September 2002, and any successor to such guidelines.

In addition, as part of the staff’s proposed approach, the CPSC staff looked to the definition of “toy” in the ASTM F963-07 toy safety standard for guidance.<sup>7</sup> The CPSIA makes ASTM F963 a mandatory CPSC standard on February 10, 2009. ASTM F963 excludes certain types of articles from the definition of toy:

- Bicycles
- Tricycles
- Sling shots and sharp-pointed darts
- Playground equipment
- Non-powder guns
- Kites
- Art materials, model kits, and hobby items in which the finished products is not primarily of play value<sup>8</sup>
- Sporting goods, camping goods, athletic equipment, musical instruments, and furniture, except for toy versions of these
- Powered models of aircraft, rockets, boats, and land vehicles

The staff considered various types of balls, from generic rubber or plastic balls that bounce to regulation-size baseballs. Generally, regulation-size baseballs, basketballs, footballs, and soccer balls are athletic equipment and, therefore, are excluded by ASTM F963. Accordingly, even if they are designed or sized for use by children, the staff’s proposed approach would exclude them from the CPSIA section 108 requirements. In contrast, the staff has regarded general purpose balls as toys and therefore, subject to the requirements of the CPSIA section 108. A toy version of actual athletic equipment, such as a toy baseball glove with a foam ball would be considered by the staff to be a toy for the purpose of the CPSIA. A plastic bat and ball used by small

children would also be considered by the staff to be toys. Small balls handed out as promotional items might be regarded as toys.

Ordinary books, including books for small children, are generally not regarded as toys.<sup>9</sup> However, some novelty books, such as plastic books marketed as bath toys, or books that incorporate sounds, may be regarded as toys under both ASTM F963 and CPSIA section 108.

Art and craft materials and model kits generally are excluded by ASTM F963. These products are subject to the requirements of the Labeling of Hazardous Art Materials Act (LHAMA), which applies to a broad range of chronic hazards and requires the product formulation to be reviewed by a qualified toxicologist.

Other examples of toys that might be subject to section 108 include: bath toys, pool toys, toddler wading pools, dolls, action figures, costumes, masks, and balloons.

### **Toys That Can Be Placed in a Child's Mouth**

The CPSIA considers a toy to be a “toy that can be placed in a child’s mouth” if “any part of the toy can actually be brought to the mouth and kept in the mouth...so that it can be sucked and chewed.”<sup>10</sup> In addition, if any part of the toy is less than 5 cm in any dimension, then it can be mouthed. Thus, if the manufacturer determines that an article is a “toy” under section 108 of the CPSIA, then the manufacturer must determine whether the toy can be mouthed.

Some manufacturers have asked whether the 5 cm criterion should be applied to inflatable toys in the inflated or deflated state. Pool toys and beach balls, for example, are designed to be inflated by the consumer, but are commonly available to children in deflated form. Therefore, the staff concludes that articles such as these must be considered in the deflated state. However, some general purpose balls are permanently inflated by the manufacturer and cannot be re-inflated by the consumer. Therefore, these articles may be considered in the inflated (normal) state. Inflatable regulation-size athletic equipment, such as basketballs, footballs, and soccer balls excluded by ASTM F963, are not considered toys.

### **Child Care Articles**

Section 108 of the CPSIA defines a “child care article” 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.”<sup>11</sup> While the law uses the word “facilitate,” it is not defined. According to *Webster’s Dictionary*, facilitate means to “to make easier.” As the staff began identifying products, it became clear that some products “facilitate” feeding, sleeping, sucking, or teething for the child directly, while other products “facilitate” those processes only indirectly, through the parent. The staff then considered the level of involvement or proximity of the child and product during the feeding, sleeping, sucking, or teething processes.

The staff proposes that products used directly in the mouth by the child are primary products subject to the regulation. For example, teethingers and pacifiers go directly into the child’s mouth. Products that have direct contact with the child, but may or may not have direct mouth contact,

would also be considered primary products. For example, a bib is used during the feeding process, it helps protect the infant's clothing, and it has direct contact with the infant. A bib is also used when infants are teething to keep their clothing dry. Because of the close proximity to the infant's mouth and because infants explore their environment through mouthing, bibs can be expected to be chewed, sucked, and licked by infants, so they are considered primary products and would be subject to the regulation. Other examples of primary child care products might include: baby blanket, high chair, sipper cup, feeding bottle, and crib teething rail.

Another class of products to be considered includes consumer products that are not necessarily in direct physical contact with the child, but are in close proximity to the child, such as cribs, crib mattresses, toddler mattresses, mattress covers, or mattress pads. These products may or may not be considered to facilitate sleep.

Products that are used by the parent, but have no contact with the child, are considered secondary products and would not be subject to the regulation under the staff's proposal. For example, a consumer may use a bottle warmer to prepare the bottle to feed the infant. While the bottle warmer "makes the process easier" for the adult feeding the infant, the bottle warmer and child have no interaction. Therefore, the staff considers the bottle warmer a secondary product. The staff proposes such secondary products to be outside the intended coverage of the law. Other examples of secondary child care articles might include: bottle cleaning products, breast pumps, nursing shield/pads, and highchair floor mats.

Another category of child care articles includes products that have multiple functions. Typically, these child care articles are larger products that offer parents/caregivers an alternative to holding their child, such as bouncers, swings, and some strollers. The law states that if the product is "designed or intended by the manufacturer to facilitate sleep or feeding" it is subject to this ban and interim ban. In staff review of various baby product websites, manufacturers acknowledge that infants will sleep in bouncers, swings, and some strollers and consumers commonly report these products helping their child to fall asleep. However, facilitating sleep is not the only function of these products. Swings and bouncers are sold with mobiles and music and other features to entertain the infant. While strollers are promoted as comfortable transportation, some also offer reclining seat backs for sleeping and trays for holding food and drinks for the child. Other strollers are very basic with a simple upright back design and no other features. Clearly, newborns and young infants spend the majority of their time sleeping and, therefore, are likely to sleep anywhere. The CPSC staff considers bouncers, swings, and some strollers to be secondary products. However, since some manufacturers may advertise their products as facilitating sleep, they may be subject to section 108. For example, if a product such as a reclining stroller is intentionally designed to facilitate sleeping, then this product may be regarded as a "child care article" for the purpose of section 108 of the CPSIA.

Any determination as to whether a particular product is a "child care article" as defined in section 108 of the CPSIA will be made after consideration of the following factors:

- Whether the intended use of the product is to facilitate sleeping, feeding, sucking, or teething, including a label on the product if such statement is reasonable.
- Whether the product is intended for use by children age 3 or younger.

- Whether the product is a primary or secondary facilitator of sleeping, feeding, sucking, or teething. In other words, does it facilitate the process for the child directly or indirectly through the parent/caregiver.
- Whether the product is commonly recognized by consumers as being intended to facilitate sleeping, feeding, sucking, or teething.

Some food contact products, such as infant bottles, cups, and eating utensils are under the jurisdiction of both CPSC and FDA. The staff regards these products as being subject to the requirements of CPSIA section 108, because they meet the definition of “child care article.”

The definition of child care article includes only sleeping, feeding, sucking, and teething. Thus, products associated with other aspects of child care, such as bathing and diapering, are not subject to section 108.

### **Request for Comment**

The Commission solicits written comments from all interested parties, including, but not limited to, the following topics:

#### *I. General Approach*

- Provide comments on staff’s approach to determining which products are subject to the requirements of CPSIA section 108. Explain.
  - Does it result in clear guidance? Why?
  - Do you have suggested changes to the approach? Why?
- Is there an alternative approach that should be used? Please describe.
- Is there any additional guidance on products that are subject to section 108 that would be useful to manufacturers? Describe.
- What are the foreseeable consequences of the staff’s approach?

#### *II. Children’s Toys and Child Care Articles*

- Should the Commission follow the exclusions listed in ASTM F963?
- Some electronic devices (such as cellular phones with incorporated games, cameras or musical devices) are decorated or marketed such that they may be attractive to children 12 years old or younger. For example, they may be decorated with cartoon characters. Should these be considered toys that are subject to the phthalate requirements under section 108? What are the characteristics that would either make these products toys or not toys?
- Are there particular art materials, model kits, or hobby items that should be regarded as toys subject to section 108? Why or why not?
- The staff proposes that tricycles are not covered by section 108, because they are excluded by ASTM F963. However, the staff has generally regarded 3- and 4-wheel ride-ons, including “Big Wheels,” as toys. What distinguishes ride-on toys from tricycles?

- E. Are there any other classes of products or specific products that should be excluded from the section 108 definition of toy? Why?
- F. Is the staff's approach to distinguishing between primary and secondary child care articles technically sound? Explain.
- G. Does the staff's approach focus on products for which there is the most potential for exposure to children age 3 years and under?
- H. Should cribs be considered child care articles? Should the entire crib be subject to the requirements or only specific parts such as the teething rail? Why or why not?
- I. Are there any classes of articles or particular articles that should be excluded from the section 108 definition of child care article? Why or why not?
- J. Should the following articles be regarded as subject to the requirements of section 108? Why or why not? Should they be classified as toys, child care articles, or not included?
  - a. Bib
  - b. Pajamas
  - c. Crib or toddler mattress
  - d. Mattress cover
  - e. Crib sheets
  - f. Infant sleep positioner
  - g. Play sand
  - h. Baby swing
  - i. Decorated swimming goggles
  - j. Water wings
  - k. Shampoo bottle in animal or cartoon character shapes
  - l. Costumes and masks
  - m. Baby walkers
  - n. Wading pools
- K. Should all bouncers, swings, or strollers be subject to section 108 or only those advertised with a manufacturer's statement that the intended use is to facilitate sleeping, feeding, sucking, or teething? How should these be classified with respect to section 108? Toys? Child care articles? Not covered? Explain.
- L. Should some promotional items be regarded as toys? What are the characteristics that would make these products toys or not toys?
- M. Should playground equipment be excluded from the definition of toy? Is so, what types of equipment?
- N. Should pools required to meet the standard be defined as those pools that do not require a filter and the addition of chemicals for maintenance?
- O. Please comment on our phthalates test method which can be found on our web site (add link).

## Comments

Comments should be filed by e-mail to [section108definitions@cpsc.gov](mailto:section108definitions@cpsc.gov). Comments are due within 30 days after this document is published in the *Federal Register*. Comments also may be filed by telefacsimile to (301) 504-0127 or mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7530. Comments should be captioned "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.”

### **For Further Information**

For information about the purpose or subject matter of this notice call or write Michael A. Babich, Ph.D., Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Suite 600, Bethesda, MD 20814; telephone (301) 504-7253; e-mail [mbabich@cpsc.gov](mailto:mbabich@cpsc.gov).

### **References**

- <sup>1</sup> Public Law 110-314.
- <sup>2</sup> Di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP).
- <sup>3</sup> Diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-*n*-octyl phthalate (DnOP).
- <sup>4</sup> 15 USC 1261 (f)(2), 1960; it should be noted, however, while certain products are carved out of the definition of consumer product, they may be regulated by the Commission under the FHSA, should they pose a health hazard within the meaning of that Act.
- <sup>5</sup> CPSIA §108(e)(1)(C).
- <sup>6</sup> Section 108: Products Containing Certain Phthalates.  
<http://www.cpsc.gov/about/cpsia/faq/108faq.html>
- <sup>7</sup> Ibid.
- <sup>8</sup> Art and craft materials are subject to the requirements of the Labeling of Hazardous Art Materials Act.
- <sup>9</sup> General Counsel advisory no. 323.
- <sup>10</sup> CPSIA §108(e)(2)(B).
- <sup>11</sup> CPSIA §108(e)(1)(C).