



1700 N. Moore Street, Suite 2250, Arlington, VA 22209  
Phone: (703) 841-2300 Fax: (703) 841-1184  
Email: [info@rila.org](mailto:info@rila.org) Web: [www.rila.org](http://www.rila.org)

March 25, 2009

Todd A. Stevenson, Secretary  
Office of the Secretary  
U.S. Consumer Product Safety Commission  
Room 502  
4330 East West Highway  
Bethesda, MD 20814

**Re: Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108.**

Dear Mr. Stevenson:

Please accept the following comments from the Retail Industry Leaders Association (RILA) on behalf of our members in response to the Consumer Product Safety Commission's ("Commission" or "CPSC") Request for Comments and Information, Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108.

By way of background, RILA promotes consumer choice and economic freedom through public policy and industry operational excellence. Our members include the largest and fastest growing companies in the retail industry--retailers, product manufacturers, and service suppliers--which together account for more than \$1.5 trillion in annual sales. RILA members provide millions of jobs and operate more than 100,000 stores, manufacturing facilities and distribution centers domestically and abroad.

## **I. General Approach**

### *A. Comments regarding the staff's approach to determining which products are subject to the section 108 CPSIA requirements*

The CPSC staff's approach to determining which products are subject to the section 108 CPSIA requirements is sound, and the guidance provided is clear. The staff's examples for child care articles are helpful because they encompass a variety of products, and it also clears some confusion regarding primary versus secondary child care products. One consideration the staff should recognize when issuing guidance for toys is that testing facilities have limited or no access to the marketing of a product; therefore, it will be difficult for the testing facilities to determine whether they should test under the requirements of section 108, unless the intent of the manufacturer for a toy is clear from the actual product. If the staff could provide the logic used (*e.g.*, a decision tree) when making its determinations of what is or is not a toy, it would help the testing facilities and others implement the section 108 requirements.

In addition, as noted by Carol Pollack-Nelson, research shows indiscriminate mouthing behavior decreases dramatically at thirty-six months of age. Including toys and childcare articles for children above the age of four in the scope without regard for foreseeable use or misuse by the child or the composition and construction of the product does not provide safeguards consistent with risk. Instead, it imposes unnecessary expense to consumers in this difficult economic environment. The Commission should focus on risk-based characteristics of a product such as practical accessibility of particular components, substrate composition, and age of the intended user.

#### *B. Alternative approach to phthalate guidance*

The staff should consider putting pictures of products in their guidance documents (much like the European Union guidance documents) so users have an image to reference when reading the document. This way, the user can see a picture of what is considered a child care article or a mouthable toy, and the staff can use these pictures to point out components of the product that would or would not make a product subject to the phthalate restrictions. The staff also could show examples of similar products that would not be considered a child care article or a mouthable toy and reference these when explaining why the product is not subject to the section 108 requirements. Of course, the pictures would only be for illustration purposes and not intended to be an all-encompassing list of products, which could be noted on the guidance document.

Also, in addition to guidance documents, the staff should establish an education program during the implementation phase. Allowing the manufacturing and retail industries to educate themselves has failed, so the government needs to step in and provide clarity through awareness and training. In addition, enforcement guidance to the state attorneys general and city health departments would be beneficial so that each agency is taking a consistent approach when enforcing the CPSIA requirements. In addition, an education campaign on the uses of certain chemicals would help to promote awareness in the supply chain. For example, requiring the chemical companies to disclose appropriate substrate uses in specific product categories could be used as a basis for exemptions. Manufacturers will then be put on notice that certain plastics or plastic components cannot be used in child care articles or mouthable toys.

Furthermore, the staff should revisit the definitions used in the CPSIA and CPSA (e.g., “toy” and “play value”) and clarify the statutory definitions to ensure consistency when affected parties are making decisions regarding product classifications. The National Institute of Standards and Technology, in its “A Guide to the EU Safety of Toys Directive” defines “toy” as any product or material designed or clearly intended for use in play by children’s under the age of 14, and notes that some products should not be considered toys “either because they are not intended for children, or because they require supervision or special conditions of use.” Such products are set forth as exclusions, including sports equipment, video toys that can be connected to a video screen and operated at a nominal voltage exceeding 24 volts, and bicycles. Giving more detailed definitions of such terms would allow manufacturers and retailers to speak the same language as the regulatory authorities who will be enforcing the CPSIA provisions.

*C. Additional guidance on products that are subject to section 108 that would be useful to manufacturers*

Additional guidance is requested for nursing shawls and crib dust ruffles, as these products could potentially be classified as children's products or more narrowly, as child care articles. Also, more guidance on products that come into contact with children but are not considered children's products would be helpful. When providing this guidance, the staff could outline its logic for such products in a decision tree, which may be easier for users when applying the logic to their own products.

*D. Foreseeable consequences of staff approach*

The staff's approach may restrict product function to some degree, at a time when there are not readily available and durable alternatives, and product reformulation and performance testing takes time and money. Another consequence may be that manufacturers will attempt to take advantage of the primary versus secondary approach and limit the products that are considered by the staff to be primary. Using the staff's example, if a swing is advertised as helping a child fall asleep, and that advertisement would make the swing subject to section 108, then manufacturers will stop using that advertisement. When the distinction between primary and secondary is not clear, such as in the case of place mats, manufacturers will attempt to steer their product into the secondary category by emphasizing its usefulness to the adult, and not the child.

Further, because phthalates are an additive, if a substrate is not likely to include phthalates, that substrate should be exempted from the phthalates testing requirement. Unless the staff adopts this approach, the testing burden will unnecessarily consume critical capacity in the few currently accredited laboratories, testing products that should not be tested, delaying necessary testing for products which may in fact contain phthalates, and increase costs in an already stressed global economy. There is much we do not know and need to understand about phthalate alternatives that will allow the products to still retain their intended function, and alternatives need to be tested before they are introduced into the products.

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

*A. Should the Commission follow the exclusions listed in ASTM F963?*

In section 106 of the CPSIA, Congress established ASTM as a consumer product safety standard. For purposes of implementing section 106, mandatory toy safety standards, the Commission should follow all the exclusions listed in ASTM F963.

Separately, the Commission has also looked to the definition of a toy in F963 for purposes of implementing section 108. Uniformity and consistency are desirable, and an effort should be made to keep deviations of these definitions to a minimum. At the same time, only some of the exclusions in ASTM F963 were excluded because they are not toys. Other products were excluded from the standard because they were specifically covered by other ASTM standards. Therefore, RILA agrees it may be inappropriate to consider all exclusions in F963 as excluded from the phthalates restrictions.

If the Commission does not exempt all the current ASTM exemptions from the phthalates restrictions, then when determining whether a product is a toy, the Commission should consider making an age limitation (*e.g.*, if the product is marketed, designed, or intended for a child ages 3 and younger, it is considered a toy).

In addition, the staff should take a practical accessibility approach, similar to the primary/secondary child care article approach adopted by the staff. If the components of the product are accessible to a small child (who is more likely to mouth its toys than an older child), then the staff should include such components in the phthalates restriction. However, if the components are inaccessible to a small child, then the staff should exclude such components from the section 108 requirements, which will reduce the overall time and cost necessary for testing such products. A play telescope on a piece of playground equipment can be mouthed by a small child during functional use; however, a swing seat is not.

*B. What characteristics should be considered to determine whether certain electronic devices are or are not toys?*

Electronics are more like sporting goods, in that they are used by children for various functions, but are not necessarily toys, even though children younger than age 4 are likely to mouth such products indiscriminately. One characteristic that should be considered to determine whether certain electronic devices are toys is whether the product is something that would be used by the general population. For example, the products mentioned in this question (*e.g.*, cell phones with games, cameras, and musical devices) may be decorated or marketed in such a way that they are attractive to children ages 12 or younger, but the device is still intended for general public use. Another characteristic that could be considered is whether the product is a learning device intended to teach concepts, which can be distinguished from those commonly used by children but not primarily intended for children (*e.g.*, watches or calculators that teach how to tell time or basic math). Function, material composition, and intended age should be primary considerations for electronic products.

*C. Are there particular art materials, model kits, or hobby items that should be regarded as toys, subject to section 108?*

Most art materials, model kits, and hobby items should be exempted from the phthalate requirements, as they are designed to teach creativity and skills (*e.g.*, cutting, gluing, drawing, following instructions). These activities, while enjoyable, are not considered “playing” within the scope of the CPSIA.

As noted in the ASTM standard and recognized by CPSC, these items are already covered by the Labeling of Hazardous Art Materials Act. Further, under ASTM sections 1.3 and 1.4, the exclusion from “toy” is already limited. Art materials, model kits, and hobby items are excluded from the definition of “toy” only if the finished item is “not primarily of play value.” Selectively including some art materials, model kits and hobby items as “toys” would be redundant, confusing, and potentially conflict with ASTM. If the finished craft, art, or hobby item has primary play value, then it is considered a “toy” and subject to the phthalate restrictions. For

example, a kit that creates shrink art jewelry should not be subject to the section 108 requirements because the end result (a necklace or bracelet) does not have play value. Conversely, an art kit that creates 3-D animals or similar objects would be subject to the phthalate restriction because the end result has play value.

*D. What distinguishes ride-on toys from tricycles?*

As we understand it, the industry has self-designated tricycles as toys; however, the staff needs to consider the mouthing behaviors of users of such products. Children would not be as likely to mouth the wheels, pedals, and seats of tricycles and ride-on toys, compared to the handlebar grips of such products. Therefore, the staff should adopt a risk-based approach, similar to the one taken for child care articles, and limit the phthalate restrictions to parts of such toys that children would be more likely to mouth.

*E. Are there any other classes of products or specific products that should be excluded from the section 108 definition of toy?*

The Commission should rescind the guidance posted Dec. 4, 2008, as an FAQ indicating that cosmetics are subject to CPSIA section 108 restrictions on phthalates when packaged with a toy (please see below). The regulation of cosmetics should remain primarily within the jurisdiction of the U.S. Food & Drug Administration (FDA). Consistent with the Commission's Advisory Opinion No. 319, products that are drugs, devices or cosmetics as defined in section 201 of the federal Food, Drug and Cosmetics Act (FDCA) are excluded from the definition of consumer products as defined at 15 U.S.C. §2052(a). As General Counsel Falvey correctly observes in the opinion, the new limits on phthalates apply only to toys and child care articles, and both terms are defined to include only consumer products. Although diversely regulated products are sometimes packaged together – Easter baskets as an example may include food, toys and cosmetics – the individual products within are subject to regulation based on statutorily defined criteria. Enforcement may be shared or delineated under a memorandum of understanding as was done with the FDA for food contact surfaces under MOU number: 225-76-2003 dated July 26, 1976.

*F. Is the staff's approach to distinguishing between primary and secondary child care articles technically sound?*

The staff's approach to distinguishing between primary and secondary child care articles is technically sound and could be extended to toys as well.

At the same time, the exercise is somewhat laborious. The staff stretched the definition of "facilitate" to include products that no one would consider to be child-care articles, and then the staff used the "primary/secondary" distinction to eliminate those same products. It would be helpful instead to limit the discussion of possible child-care article to those that "facilitate" sleeping or eating based on the normal definition of "facilitate," which is ".to make something easy or easier to do."

Using the staff's example, it is doubtful that a parent buys a breast pump and thinks the pump will "make it easier" to feed the child. They buy the pump to extract breastmilk to feed to the infant, because they choose milk over formula. Similarly, they buy a bottle warmer because infants won't drink cold milk/formula.

The staff should focus its inquiry on how the article makes it easier for the child to eat or sleep. If that were the case, then the breast pump and the bottle warmer would not even enter into the discussion.

*G. Does the staff's approach focus on products for which there is the most potential for exposure to children age 3 and under?*

No, the staff's approach does not adequately focus on products for which there is the most potential for exposure to children ages 3 and younger. The approach taken by the staff includes products and product components that may contain phthalates and be less than 5 cm in depth in any one dimension, but to which a child may never be exposed because the weight or size of the product would prohibit it being brought to the child's mouth. The staff should consider implementing the same risk-based approach that it took regarding child care articles. Inaccessible substrates or components are not a potential source of phthalate exposure to children, but as the law and guidance from the CPSC is currently written, these components would be unnecessarily tested, which is not time- or cost-efficient. Instead, the staff should consider practical accessibility of the component, whether it can be brought to the mouth, despite the size of the component. The balls inside the clear plastic dome of a popcorn push toy, while small enough to be considered mouthable, are inaccessible during foreseeable use and abuse by toddlers and therefore should not be subject to the phthalates restriction. The same is true with the wheels, pedals, and seat of a tricycle or ride-on toy, which was mentioned earlier in these comments.

*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?*

Yes, cribs should be considered child care articles, as they help to facilitate sleep, and the entire crib should be subject to the requirements because children will chew on parts of the crib that are not covered by the teething rail. However, only the crib surface coating should be tested (not the substrate unless it's a plastic crib with a shore hardness of 90).

*I. Are there any classes of articles or particular articles that should be excluded from the section 108 definition of child care article?*

No, so long as the staff adopts the primary and secondary risk-based approach.

*J. Should the following articles be regarded as subject to the requirements of section 108, and if so, how should they be classified?*

*a. bib* – should be classified as a child care article and subject to section 108; the bib is mouthable and likely to be placed in a child's mouth.

*b. pajamas* – As recognized by the European Union (EU) when it issued its official guidance on the Phthalate Directive, “the main purpose of pajamas is to dress children when sleeping and not to facilitate sleep. Pajamas should therefore be regarded as textiles and, like other textiles, do not fall under the scope of the Directive...”<sup>1</sup> Thus the EU makes the distinction among objects based on identifying their main purpose. To say that sleepwear “facilitates sleep” and therefore is a child care article ignores the core intention in defining childcare articles as facilitating sleeping, feeding, sucking or teething in children 3 years and younger.

It makes little sense to use a definition of “facilitate” that could import many other things into facilitating sleep. If one takes the an expansive view of the word “facilitate,” then sleep is facilitated by a lot of other articles that do not accord with the underlying purpose of the restriction, including shades in a child’s bedroom to reduce light or music from a DVD to provide soothing sound. Pajamas should not be considered a childcare article because pajamas are not put on the child to facilitate sleep through mouthing. Infants and children are put in pajamas to save children’s daywear from the abuses of sleep, for convenience of the parent in changing diapers, or just out of convention.

If pajamas are classified as a child care article, then the scope of product subject to the restrictions should be limited to footed pajamas with grippers on the soles, as other types of pajamas are not likely to have phthalates. And only the grippers on the soles should be subject to testing as they are the only component of the pajamas that is likely to contain phthalates.

*c. crib or toddler mattress* – should be classified as a child care article.

*d. mattress cover* – should be classified as a child care article.

*e. crib sheets* – should be classified as a child care article; however, it should be excluded from the phthalates testing requirement, as the component materials are not likely to contain phthalates.

*f. infant sleep positioner* – should be classified as a child care article and subject to section 108; these products are specifically designed to facilitate sleep, as it holds the infant in a certain position to help with breathing and prevent reflux. These products are designed and marketed to help an infant sleep through the night.

*g. play sand* – should be classified as a toy, as it is used by children during pretend play; however, it is not likely to contain phthalates and therefore should be exempt from the phthalates testing requirement.

*h. baby swing* – should be classified as a child care article if it is marketed or advertised as facilitating sleep.

*i. decorated swimming goggles* – should be classified as other articles intended for use by children because they are intended to protect children’s eyes from chlorine or other chemicals in

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<sup>1</sup> Guidance Document on the interpretation of the concept ‘which can be placed in the mouth’ as laid down in the Annex to the 22<sup>nd</sup> amendment of Council Directive 76-769-EEC.

water. Swimming goggles should not be subject to the requirements of section 108. They are not a toy, and they are not used to facilitate feeding, sleeping, sucking or teething.

*j. water wings* – should be classified as other articles intended for use by children because they are arm floatation devices that are used while children play/swim in water, but are not necessarily the item of attention during play activity. Water wings should not be subject to the requirements of section 108. They are not a toy, and they are not used to facilitate feeding, sleeping, sucking or teething.

*k. shampoo bottle in animal or cartoon character shapes* – if the lid is removable and is a toy with play value, then it should be considered a toy and subject to the section 108 requirement; the rest of the bottle should not be subject to the section 108 requirement.

*l. costumes and masks* – should be considered toys because they are used primarily when children play “dress up;” however, the phthalate testing requirements should only apply to substrates that are likely to contain phthalates (e.g., PVC costumes).

*m. baby walkers* – should be considered other article intended for use by children and should not be subject to the requirements of section 108; however, any toys/teethers attached to the walker should be tested to section 108.

*n. wading pools* – if there are components on the pool with which the child will play, then those components only should be tested; however, the actual structure (pool) is not a toy and should not be subject to the phthalates testing requirement.

*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?*

Bouncers and swings should be subject to section 108 if the manufacturer’s intent is to facilitate sleep for children ages 3 and younger. However, any accessories attached to these products and have play value should be considered toys. A stroller should not be covered because the intended use is the transport of a child. Children are just as likely to fall asleep in their car seat as they are in their stroller. However, any accessories that are attached and have play value should be considered toys.

*L. Should some promotional items be regarded as toys, and if so, what are the characteristics that would make these products toys or not toys?*

If the promotional item has play or amusement value, then it should be considered a toy.

*M. Should playground equipment items be regarded as toys, and if so, what types of equipment?*

The playground equipment itself is meant to be played upon, so it should not be considered a toy; however, if the equipment has components attached that have play value, these components should be considered toys. For example, a steering wheel or similar item attached to a piece of

playground equipment is accessible to a small child's mouth during functional use; however, a plastic roof on a playhouse is not.

*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?*

No, pools that do not require a filter and/or the addition of chemicals for maintenance should not be subject to the phthalates restriction. Pools are meant to be played in, not played with; therefore, they are not toys. However, for pools that have attached components that have play value, the components should be considered toys and therefore be subject to the requirements of section 108.

*O. Comments on phthalates test method.*

The standard of procedure for testing phthalates in toys suggested by the CPSC does not follow any current testing program. The procedure will actually significantly slow test turnaround times for products sold in the United States since it is completely different from phthalate testing procedures already in place for product sold in EU countries. All test labs will be required to purchase equipment (and dedicate space for that equipment) which will be used only for product shipped to the United States - this step alone will be a significant expense. Moreover, the CPSC's testing methodologies should be harmonized with existing ones unless there is scientific evidence demonstrating that the proposed testing method is more efficient or more accurate than scientific tests already in place around the world.

### **III. Allow Use of Component Testing**

Although not the topic of this request for comments and information, it bears worth repeating that RILA has previously commented to the Commission in response to rulemakings and requests for comments and information on the need for the Commission to allow for component testing. The Commission has yet to act on this request and we therefore again stress the importance of allowing component testing in order to fulfill obligations of the general conformity certificates. Such component testing would have to be based upon a reasonable program that, when combined with other provisions of the CPSIA (i.e. general conformity certificates, tracking labels, independent third-party certification, etc.) and other laws, help build a multi-layered approach to product safety without adding redundant and costly testing associated with having to test each component after final assembly. The business community currently lacks the certainty and clarity needed to implement the CPSIA with respect to component testing.

In light of the January 16, 2009 guidance letter from the Chairmen of the House and Senate Committees of jurisdiction urging the Commission to promulgate a final rule on this matter before February 10, 2009, we again urge the Commission to act expeditiously to allow the use of component testing to certify final products.<sup>2</sup> RILA is not aware of any products for which

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<sup>2</sup> January 16, 2009 letter from Congressman Henry A. Waxman, Chairman, House Committee on Energy and Commerce, Congressman Bobby L. Rush, Chairman, House Subcommittee on Commerce, Trade, and Consumer

component testing would be inappropriate or ineffective. Nevertheless, if the Commission determines that some products should not be eligible for component testing, RILA suggests that the Commission create a negative list of specific products for which it determines that component testing is not practicable, effective or desirable. Any negative list should be narrow in scope; products should be included in a negative list only when other safeguards, such as periodic confirmation testing of the finished product or supplier certifications, would not eliminate the risk of contamination.

### **Conclusion**

RILA members place the highest priority on ensuring the safety of their customers and the products sold to them. RILA appreciates this opportunity to comment on the Commission's Request for Comments and Information, Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108. Should you have any questions about the comments as submitted, please don't hesitate to contact me by phone at (703) 600-2046 or by email at [stephanie.lester@rila.org](mailto:stephanie.lester@rila.org).

Sincerely,

A handwritten signature in black ink that reads "Stephanie Lester". The signature is written in a cursive style with a horizontal line extending to the right from the end of the name.

Stephanie Lester  
Vice President, International Trade