

Notice of Availability of Draft Guidance Regarding Which Children's Products are  
Subject to the Requirements of CPSIA Section 108 (continued)  
Part 2 – Comments 40 thru 69



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March 23, 2009

Office of the Secretary  
Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, Maryland 20814

**RE: Notice of Availability of Draft Guidance Regarding Which Children's Products Are Subject to the Requirements of CPSIA Section 108; Request for Comments and Information**

To the Commission:

The Entertainment Merchants Association (EMA), the national trade association for the retailers and distributors of DVDs and computer and video games, submits these comments on the Draft Guidance Regarding Which Children's Products Are Subject to the Requirements of CPSIA Section 108. Our comments are specifically addressed to Topic II.E., regarding other classes of products or specific products that should be excluded from the Section 108 definition of "children's toy".

EMA recommends that optical discs, cartridges, and flash memory (collectively referred to as "storage media") that are designed for use in DVD players, Blu-ray Disc players, computers, video game consoles, and similar devices ("hardware") and that contain prerecorded entertainment software and associated packaging be specifically excluded from the definition of "children's toy" in Section 108 of the Consumer Product Safety Improvement Act, regardless of whether the prerecorded entertainment software on the storage media is designed or intended for an audience of persons ages 12 or younger.

Storage media that contain prerecorded entertainment software are intended to allow associated hardware to convert data embedded therein to create images on a screen; they are not intended to be played with themselves. In fact, the storage media require additional software contained inside their associated hardware to allow the digital files embedded in them to be viewed; the software inside the hardware reads the digital files and performs functions based on the instructions in those files. The storage media have no active role in creating the images.

When storage media and their associated hardware are properly configured, a child may view the entertainment generated by the digital files contained in the storage media, and may even remotely interact with those images, but the storage media are not part of the playing. The storage media in which entertainment software are embedded reside inside their hardware, in

essence becoming part of those devices, while the child views or interacts remotely with the images generated. The child does not physically interact with the storage media as part of his or her recreational activity.

In sum, storage media are like books. They contain data points that, when read and converted, can create imagery, on the screen or in the mind, respectively. It is the image created that has value as entertainment, that is "played" with, not the item which contains the data points.

Optical discs are in fact prone to scratches, fingerprints, and other marring that can interfere with the ability of DVD and Blu-ray players, computers, and video game consoles to read the data in the discs. Consumers have learned not to let children handle them in order to avoid damage. The common experience of consumers would not support an interpretation that such discs are intended for use by children age 12 or younger.

Even if the commission were to stretch the commonsense meaning of "play" to encompass storage media, the packaging for storage media that contain prerecorded entertainment software designed or intended for an audience of persons ages 12 or younger should not be subject the phthalate restrictions. Storage media packaging may be reusable, but it is simply used to protect the storage media. Packaging plays no role in children's play.

Finally, we note the Commission's clear statement that "[o]rdinary books, including books for small children, are generally not regarded as toys." Given that, any booklets – such as user guides and product promotions – inserted in the packaging for storage media that contain prerecorded entertainment software designed or intended for an audience of persons ages 12 or younger should not be classified as a "children's toy."

### **Entertainment Merchants Association**

The Entertainment Merchants Association (EMA) is the not-for-profit international trade association dedicated to advancing the interests of the \$33 billion home entertainment industry. EMA represents companies throughout the United States, Canada, and other nations. Its members operate approximately 27,000 retail outlets in the U.S. that sell and/or rent DVDs, computer and console video games, and digitally distributed versions of these products. Membership comprises the full spectrum of retailers (from single-store specialists to multi-line mass merchants, and both brick and mortar and online stores), distributors, the home video divisions of major and independent motion picture studios, and other related businesses that constitute and support the home entertainment industry. EMA was established in April 2006 through the merger of the Video Software Dealers Association (VSDA) and the Interactive Entertainment Merchants Association (IEMA).

Thank you for the opportunity to provide these comments.

Sincerely,

  
Sean Devlin Bersell  
Vice President, Public Affairs

**Stevenson, Todd**

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**From:** Sean Bersell [sbersell@entmerch.org]  
**Sent:** Tuesday, March 24, 2009 10:44 AM  
**To:** Section 108 Definitions  
**Subject:** EMA Comments on Sec. 108 Draft Guidance  
**Attachments:** CPSIA\_EMA Comments on Sec108.pdf

The Entertainment Merchants Association (EMA) submits the attached comments on the Draft Guidance Regarding Which Children's Products Are Subject to the Requirements of CPSIA Section 108 (Federal Register, vol. 74, no. 34, p. 8058, Feb. 23, 2009).

\*\*\*\*\*

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**From:** Carolhfuller@aol.com  
**Sent:** Tuesday, March 24, 2009 8:09 AM  
**To:** Section 108 Definitions  
**Subject:** Draft Guidance Regarding the Requirements of CPSIA Section 108  
**Attachments:** CommentsCPSIASection108.doc

*My comments are attached and also pasted in below. Carol Fuller*

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“Notice of Availability of Draft Guidance Regarding Which Children’s Products are Subject to the Requirements of CPSIA Section 108”

(Federal Register notice February 23, 2009, pp. 8058-8061)

I. General Approach.

The guidance appears to be directed to manufacturers. But, it is relevant also for retailers, especially re-sellers, and consumers. Their interests should be considered in the final guidance.

II. Children’s Toys and Child Care Articles.

A. The FR notice asks “Should the Commission follow the exclusions listed in ASTM F963? Those listed in the FR notice should be excluded.

Are these only examples of what’s included in ASTM F963? Or, are there others? Gaining access to the full information in the ASTM standards is prohibitively expensive for many in the public who would be interested in this topic.

B. Electronic devices that are marketed to children 12 years old or younger may be considered to be toys. However, items that “may be attractive to children 12 years old or younger” is too broad to be useful as a criterion. Young children are attracted to many things in their environment. The standard can be reasonably applied only to those products that are intended to be used as toys.

C. Art materials. No comment

D. Tricycles and ride-on toys. For the purpose of implementing Section 108 of the CPSIA, there is no reason to make a distinction. The ride-on toys should be excluded as well as the tricycles.

E. Other exclusions. No comment

F. The approach to distinguishing between primary and secondary child care articles is feasible regarding products that facilitate sleep or feeding indirectly, through the parent (e.g., bottle warmers).

The inclusion of high chairs in the primary category is not reasonable or necessary. The classification of products that “are not necessarily in direct physical contact with the child, but are in close proximity to the child” is too broad. Small children may be in close proximity to a large number of items, especially infants that are carried. The standard can be reasonably applied only to products intended for children that the children are expected to have direct physical contact with. A child cannot be expected to ingest phthalates from an item that the child does not have direct physical contact with.

G. Most potential for exposure to children age 3 years and under. No comment.

H. Cribs.

It is reasonable to include teething rails in the items subject to Section 108. They can be replaced with new products that do not exceed the phthalate limits, without replacing the entire crib. Including the entire crib is not reasonable or necessary. This is particularly relevant to consumers. New cribs are very expensive.

I. Items to be excluded. No comment

J. List of articles.

There is no reasonable basis for including crib or toddler mattresses, mattress covers, infant sleep positioners, baby swings, water wings, baby walkers, or wading pools as items subject to the requirements of Sec. 108. These items are not likely to be a source for the ingestion of phthalates. Crib sheets (and other child care products) made of cotton should be considered to be naturally free of phthalates.

K. Bouncers, swings, and strollers.

Bouncers, swings, and strollers should not be considered to be subject to the requirements of Sec. 108. They definitely don't facilitate sucking or teething. Children might be fed while sitting in a stroller, and they are likely to sleep in them. They might fall asleep in a bouncer or a swing. However, there is no reasonable basis for considering them to be sources for the ingestion of phthalates.

L. Promotional items.

The current factors used to determine whether an item is to be considered a children's toy appear to be adequate for this purpose.

M. Playground equipment.

Playground equipment should be excluded from the definition of toy. There is no reasonable basis to expect that it will be a source for the ingestion of phthalates.

N. Pools.

No pools should be included.

O. Test method. No comment.

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March 24, 2009

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March 25, 2009

Office of the Secretary  
Consumer Product Safety Commission  
4330 East West Highway  
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**Comments of the Breast Cancer Fund, Consumer Federation of America,  
Consumers Union, Kids in Danger, National Research Center for Women & Families,  
Public Citizen, and U.S. Public Interest Research Group  
on  
“Notice of Availability of Draft Guidance Regarding Which Children’s Products are  
Subject to the Requirements of CPSIA Section 108”**

**Introduction**

Our groups representing patient, consumer, science and public health interests submit the following comments regarding the draft approach prepared by CPSC staff for determining which products constitute a children’s toy or child care article and are subject to section 108 of the CPSIA.

Section 108 prohibits the sale of certain children’s toys and products containing six specified phthalates (BBP, DBP and DEHP permanently, and DIDP, DINP and DnOP on a provisional basis).

We welcome the development and publication of these guidelines. While we do not agree with every recommendation of the CPSC staff, we are gratified to see that necessary clarifications are almost complete.

We look forward to working with the CPSC to continue to make the protection of children’s health and safety the primary focus of CPSIA implementation. In several areas of the draft guidance, we agree with staff’s assessment. We have some concerns, however, with staff’s recommendations on secondary products, products in close proximity to children, and products with multiple functions.

### **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 or younger. Section 108 also lists four factors that determine if a product is designed or intended for use by a child 12 or younger. The CPSIA defines a toy that can be placed in a child's mouth as one that "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."

We agree that ASTM F963 excludes certain types of articles from the definition of toy, such as bicycles and athletic equipment, and we agree that if a ball is a toy version of athletic equipment, then it is subject to the CPSIA. We also agree that ordinary books are not toys, but novelty books such as plastic bath books are toys. These are common sense, clearly defined distinctions clarifying what is and is not a toy.

However, some ASTM F963 excluded items, such as kites and model kits, should be subject to section 108 regulations because parts of these items can be put in a child's mouth (and be sucked and chewed) and they are designed for use by a child 12 or younger. Staff notes that art materials are exempt under ASTM F963, but are subject to the Labeling of Hazardous Art Materials Act. Art products that are designed for very young children and have a reasonable expectation of being in or near a child's mouth, such as finger paints, should be subject to section 108 of CPSIA. In addition, CPSC should consider requiring labeling of all art and craft materials and model kits for the presence of phthalates, so consumers can make informed purchases.

We agree with staff that deflated pool toys and beach balls are toys that can be placed in a child's mouth. Children have access to these toys when they are not inflated, and even when they are inflated, the toys can be punctured or lose air making them very easy for children to put into their mouths (and be sucked and chewed).

### **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 3 and younger, or to help these children with sucking or teething.

Regarding child care articles, CPSC staff proposes that products that can be chewed or sucked by infants such as bibs, baby blankets, high chairs, sipper cups, feeding bottles, and crib teething rails are primary products subject to CPSIA section 108. We agree with staff's assessment.

We agree with most of staff assessments regarding secondary products, although we believe that in making final determinations on specific items, emphasis should be placed on the likely proximity of the item to the child's mouth rather than focusing solely on the "intended" function. Many secondary products are designed to be used exclusively by parents, and have little chance of having direct contact with children. We agree with staff that secondary products such as bottle warmers and highchair floor mats would not be subject to the regulations of section 108. However, other secondary products such as mattress covers could expose children to a banned phthalate. We recommend secondary products be looked at on a case-by-case basis and not be given a class-wide exemption to section 108.

Staff also refers to some secondary products as “products in close proximity to the child” such as cribs, crib mattresses, toddler mattresses, mattress covers, or mattress pads. These products should be subject to section 108 of the CPSIA because they facilitate sleep and because infants may be able to get pieces of the product in their mouths and suck or teethe on them. Mattresses with waterproof coatings of PVC are common, and DEHP, one of the banned phthalates that is a suspected carcinogen and reproductive toxicant, is readily found in numerous PVC products.

We urge CPSC to include products that have multiple functions. Staff notes that bouncers, swings and some strollers are generally considered secondary products, but staff also notes that parents use these products to help their children to fall asleep and for other reasons. Staff notes that manufacturers would be subject to section 108 regulations, if they advertise secondary products as facilitating sleeping, or feeding, or other purposes.

In our view, these products are generally known to be used at times to facilitate sleep and should therefore be included regardless of how manufacturers advertise them. The components of the product that the child has contact with when the product is used to facilitate sleep should not contain banned levels of phthalates since such components are present in the child’s sleep environment.

### **Cribs**

Cribs should be considered child care articles. Any part of the crib that a child can chew or teethe on should be subject to the requirements, not merely the teething rail.

### **Other Specific Items**

The CPSC asks if 14 specific items should be subject to the requirements of section 108 and whether they should be classified as toys or child care articles. All 14 items should be subject to section 108 requirements. Most of the items should be considered child care articles (bibs, pajamas, crib/toddler mattresses and mattress covers, crib sheets, infant sleep positioners, baby swings, water wings, and baby walkers) because they can be sucked or teethed on by infants. The remainder should be considered toys (play sand, decorated swimming goggles, wading pools, shampoo bottles in animal or cartoon characters, and costumes and masks). Toy-like packages should be considered toys. For example, children are not likely to discern the difference between animal shaped packages versus plastic animal toys.

### **Promotional Items and Electronic Devices**

If a promotional item is designed for play or part of a marketing campaign aimed at children 12 years or younger or aimed at their parents, it should be considered a toy.

Similarly, electronic products, such as cell phones, that are marketed and packaged to appeal to children 12 years or younger should also be covered. For these products, the same set of criteria should be used to determine coverage under this section as is used to determine if an item is a toy subject to section 108.

### **Conclusion**

Our organizations agree with CPSC staff in several areas of the draft guidance, especially concerning toys. We agree with staff’s assessment regarding primary products for child care

articles, but we strongly urge that staff reconsider their recommendations in a manner to include more secondary products, products in close proximity to children, and products with multiple functions.

We look forward to continuing to work with the CSPC staff on implementation of this statute in a manner that continues to make protecting children's health and safety its top priority.

Respectfully submitted,

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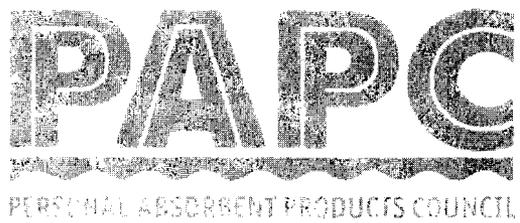
**Stevenson, Todd**

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**From:** Ruth Kubierschky [ruthkubi@earthlink.net]  
**Sent:** Wednesday, March 25, 2009 12:57 PM  
**To:** Section 108 Definitions  
**Subject:** Phthalates comment

My understanding is that phthalates are only in items made of plastic, as well as certain inks. All other materials used in children's items (yarn, fabric, wood, etc.) should be exempt.



**Via Email**

[section108definitions@cpsc.gov](mailto:section108definitions@cpsc.gov)

March 25, 2009

Office of the Secretary  
 Consumer Product Safety Commission  
 4330 East West Highway  
 Bethesda, Maryland 20814

Re: Notice of Availability of Draft Guidance Regarding Which Children's Products Are Subject to the Requirements of CPSIA Section 108, 74 Fed. Reg. 8058 (Feb. 23, 2009)

The Personal Absorbent Products Council ("PAPC") is providing these comments responding to the Consumer Product Safety Commission's ("CPSC") request for comments and information regarding the draft guidance on Section 108 of the Consumer Product Safety Improvement Act ("CPSIA"). We are grateful for the opportunity to comment. PAPC represents companies which manufacture disposable diapers (including training pants), and other hygiene products. Its members include Procter & Gamble and Kimberly-Clark Corp.

As requested, the following comments are responsive as applied to disposable diapers, including disposable training pants, to the following questions:

- Whether CPSC staff's approach to determining which products are subject to the requirements of CPSIA Section 108 results in clear guidance.
- Whether there are any classes of products or articles that should be excluded from the Section 108 definition of toy or child care article.

**I. Disposable Diapers Are Not Within The CPSIA Statutory Products Definition**

PAPC supports the approach and position taken in the draft Guidance Document that diapering products are not subject to Section 108 because they are not "child care" articles whose manufacturers design or intend them "to facilitate" sleep or feeding, sucking, and teething by children age three or younger. Further, disposable diapers and training pants are not toys under CPSIA. The following rationale supports these concepts as reflected in the draft Guidance Document:

1. Disposable diapers and training pants *are not* "child care articles" designed to facilitate sleep. Their primary function and performance are to acquire and contain waste, and they do not facilitate or induce sleep.



2. Disposable diapers and training pants *are not* “child care articles” which are intended or designed by manufacturers to facilitate feeding, sucking or teething. In our view, products which should be subject to the regulation are products to be used directly in the mouth by the child or with close proximity to the mouth, whether or not contact with the mouth may be possible. The intended use and design of diapers and training pants do not facilitate these actions and should not be considered subject to the CPSIA requirements and related regulatory action as reflected in the draft Guidance Document.
3. Disposable diapers and training pants *are not* “children’s toys,” as they are not intended to be played with by a child. A diapering product’s main function and design is for the containment of body wastes. Consumers, parents and caregivers who are the main handlers of disposable diapers and training pants, identify and recognize their main function to be containment of waste, rather than as a toy or facilitating sleep, feeding, teething or sucking.

## **II. Phthalates Test Data Re Disposable Diapers**

Not only do disposable diapering products not meet the statutory definition, these products are inherently free of phthalate contamination that would be detectable using Test Method CPSC-CH-C1001-09, Standard Operating Procedure for the Determination of Phthalates.

Disposable diapers and training pants are made of components that may contain, at most, only ultra-trace levels of various phthalate species. PAPC sponsored a phthalates testing program for disposable diapers made by PAPC members (Pampers<sup>®</sup> and Huggies<sup>®</sup>) as well as a variety of other disposable diaper products available from national retailers including national retailer brands. PAPC contracted an independent third party to pull samples from retail shelves in a major metropolitan area, to provide broad representation of nationwide disposable diapering products across major manufacturers. The third party prepared the samples using a protocol to minimize phthalate contamination, recorded product information including brand, production code data, and applied a blind code labelling system to the samples. Analysis by the lab, and assessment of the resulting data by PAPC members, was thus accomplished under blind coding.

The blind coded samples were sent to Galab laboratories, a DIN EN ISO/IEC 17025 accredited analytical laboratory located in Germany. Laboratory information can be found at [www.galab.de/](http://www.galab.de/). Galab is well known for its ultra-low trace analysis capabilities, which PAPC knew would be required for assessment of phthalate content of our samples as phthalates are not intentionally used in their manufacture. The diaper sampling protocol was developed by the European diaper trade association (EDANA) and involved cutting complete cores from five locations around the diaper so that representative assessments of all diaper raw materials are included in the analysis.

Sample extraction and phthalate analysis was conducted according to the accredited Galab SOP No 31: "Determination of phthalic acid esters in Consumer Goods (materials and articles) and Hygiene Products by means of GC-MSD." Briefly, diaper samples are extracted completely (12 hour shake flask) in hexane with an included internal standard to quantify extraction recovery. The sample is concentrated by evaporation and evaluated by GC-MSD. Using this method, the detection limit for most of the phthalate species is 50 µg/kg (or 0.000005%). Appropriate blanks are conducted to verify that detectable phthalate species are not due to lab contamination artifacts.

Using this method, Galab analyzed seven disposable diapering products for the specific phthalates included in the CPSIA and reported the results shown in Appendix 1. Five of the six specified phthalates were not detected even at this 50 µg/kg ultra-low level of detection. For DEHP, the highest value detected was 0.00039%. This is two orders of magnitude below the 0.03% level of detection for CPSC-CH-C1001-09 SOP for Determination of Phthalates. Based on these results, we are confident that all disposable diapering products are well below both the CPSIA statutory level (0.1%) and the limit of detection using the CPSC official test method. These results indicate inclusion of disposable diapering products in Section 108 of CPSIA would not only be contrary to congressional intent but would also be a poor use of resources as phthalate test results would always be 'non-detect' using the CPSC Method.

### **Conclusion**

PAPC encourages CPSC to publish guidance documents as they are an essential component of an overall program to achieve compliance. We encourage a straight-forward approach to implementation and an ongoing discussion with stakeholders, particularly in light of the proceedings of the CHAP with regard to the interim phthalates ban.

Finally, we encourage CPSC to allow adequate and sufficient time for compliance while exercising its regulatory discretion in implementation and enforcement of CPSIA. We continue to be engaged in the various activities CPSC is undertaking regarding the Act's implementation.

Sincerely,



Dr. C. Tucker Helmes  
Executive Director  
Personal Absorbent Products Council

PERSONAL ABSORBENT PRODUCTS COUNCIL (PAPC) COMMENTS TO CPSC, MARCH 25, 2009-03-23

APPENDIX 1: ULTRA-LOW TRACE ANALYSIS OF PHTHALATES IN DISPOSABLE DIAPERING PRODUCTS (BLINDLY CODED INDUSTRY SAMPLES #1 THROUGH #7).

(ND= not detectable at stated limit of detection, note that 0.1% = 1,000,000 µg/kg)

<i>Phthalate</i>	<i>Limit of detection</i>	<b>#1</b>	<b>#2</b>	<b>#3</b>	<b>#4</b>	<b>#5</b>	<b>#6</b>	<b>#7</b>
DEHP	50 µg/kg	0.0003860%	0.00009390%	0.00004080%	0.0000346%	0.00003860%	0.00006450%	0.00005110%
DBP	50 µg/kg	ND	ND	ND	ND	ND	ND	ND
BBP	50 µg/kg	ND	ND	ND	ND	ND	ND	ND
DINP	50 µg/kg	ND	ND	ND	ND	ND	ND	ND
DIDP	1000 µg/kg	ND	ND	ND	ND	ND	ND	ND
DnOP	50 µg/kg	ND	ND	ND	ND	ND	ND	ND

DEHP= Di-(2-ethylehexyl) phthalate

DINP= diisononyl phthalate

DBP= dibutyl phthalate

DIDP= diisodecyl phthalate

BBP= benzyl butyl phthalate

DnOP= di-n-octyl phthalate

**Stevenson, Todd**

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**From:** Tucker Helmes [HelmesT@socma.com]  
**Sent:** Wednesday, March 25, 2009 11:43 AM  
**To:** Section 108 Definitions  
**Subject:** Comments re. Draft Guidance on CPSIA Section 108  
**Attachments:** CPSC Phthalate Comments 032509.pdf

Office of the Secretary  
Consumer Product Safety Commission

To whom it may concern:

The Personal Absorbent Products Council is pleased to submit the attached letter of comments on CPSC's draft guidance regarding which children's products are subject to the requirements of CPSIA Section 108. Please contact me directly if you have any questions or need any follow up action.

Thank you,  
Tucker Helmes

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**To: Office of the Secretary, Consumer Product Safety Commission**  
**From: Dr. Timothy Zacharewski**  
**Date: 3/15/2009**  
**Re: Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108.**

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The CPSC has requested comments on which children's products should be subject to phthalate requirements under section 108 of the Consumer Product Safety Act of 2008 (CPSIA). While reviewing this issue, it is most important to appreciate the different types of phthalates and exposure pathways. As the CPSC clarifies which products should be subject to CPSIA Section 108, it is important to consider not only the risks phthalates may pose in these products but also the level of exposure in order to make an informed regulatory decision.

The CPSIA permanently restricts the concentration of low molecular weight phthalates (DEHP, DBP, and BBP) based on the potential for reproductive effects in animal testing involving high doses. However, the CPSIA only temporarily restricts the concentration of high molecular weight phthalates (DINP, DIDP, DnOP) pending further study of risk from a specific pathway (i.e. mouthing). High molecular weight phthalates have different toxicity profiles in rodents that do not produce the same effects as low molecular weight phthalates (DEHP, DBP, and BBP). The relevance of these effects in humans has also not been established.

In addition, it is the level of exposure that determines the toxicity. As previously determined by the CPSC's Chronic Hazard Advisory Panel, there is minimal concern regarding the level of exposure to high molecular weight phthalates like DINP in vinyl toys. DINP has been comprehensively assessed by multiple U.S. government agencies, including the Consumer Product Safety Commission (CPSC) and the National Toxicology Program's (NTP's) Center for Evaluation of Risks to Human Reproduction (CERHR) that have determined it to be safe for its intended exposure.

Human exposure to high molecular weight phthalates may result from oral, dermal, and inhalation exposure routes. The most likely exposure a child will have is through mouthing phthalate-containing products and not via dermal or inhalation routes. In fact, the interim restriction on HMW phthalates restricts only those toys that a child puts in its mouth or those products that facilitates an activity which results in high exposure from mouthing (i.e. pacifiers and rattles). The exposure of children to HMW phthalates is negligible and restrictions on these products will not significantly impact the overall exposure to a child and should therefore be excluded from regulation.

For example, the following specific categories would fall under the "no routes of exposure" to the child and should be excluded from regulation:

1. Secondary products as they contact the caregiver and not the child
2. Products that are in close proximity but do not have direct physical contact

3. Parts inaccessible to a child
4. Articles in the deflated state as that would not be given to a child to play with or inflated by the child.

With respect to oral exposure (i.e. mouthing), several government and independent studies have shown that the amount of time children spend mouthing soft-plastic items containing DINP results in exposure that is well below the levels that present a possible risk. As of 1999, phthalates are not present in articles that are routinely mouthed such as teething rings, rattles, and bottle nipples. Although, studies have shown children mouth pacifiers for longer exposures when compared to other objects, the estimated average daily mouthing time of soft plastic toys is actually very low. In 2002, the CPSC observed daily average mouthing times of soft vinyl toys to be 1.3 minutes for children between 3 months and 1 year and 1.9 minutes for children between 1 and 2 years and 0.8 minutes for children between 2 and 3 years. This is well below the time required to achieve the acceptable daily intake limit. As the new CHAP reviews the risks, it is expected that exposure to HMW phthalates from products that can be mouthed will be a primary focus.

Furthermore, the mere presence of phthalates in humans does not equate risk. Studies and testing methods should consider other factors including route and length of exposure, exposure effects, disposal methods, and species differences in sensitivity. Phthalates are quickly metabolized and excreted and do not accumulate in the body. Within the past decade, sophisticated technologies have been developed to detect trace levels of chemicals including phthalates in a variety of matrices. The US Centers for Disease Control (CDC) have used these technologies to detect a number of phthalates in human urine at levels well within the safe limits established by the EPA. Although, low levels (approximately 1 part per billion (ppb)) of phthalate metabolite can be detected in human urine, this does not mean it has any biological significance or consequence.

In conclusion, not only the potential hazard but also the negligible exposure of HMW phthalates in children's articles needs to be considered when assessing the potential risks to children.

## Stevenson, Todd

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**From:** Tim Zacharewski [tzachare@msu.edu]  
**Sent:** Wednesday, March 25, 2009 11:24 AM  
**To:** Section 108 Definitions  
**Subject:** CPSC Sec 108 comments regarding phthalates  
**Attachments:** Sec 108 CPSIA CPSC Exposure comments TZ 032509.doc

Pls see the attached document for comments

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March 25, 2009

Office of the Secretary  
U.S. Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, Maryland 20814  
[section108definitions@cpsc.gov](mailto:section108definitions@cpsc.gov)

**Wilton Products Inc.'s Response to CPSC's Request for Comment.**

Wilton Products Inc. and all of its divisions ("Wilton") support the position on phthalates presented to the CPSC by the Craft & Hobby Association Inc. ("CHA").

Wilton earnestly supports reasonable testing programs to verify the safety of all products and the elimination of banned hazardous substances from commerce. However, the requirement to generate a certificate of compliance for each SKU, for each shipment, to each customer, respectfully, is neither reasonable nor manageable.

In addition to the above-referenced comments, Wilton proposes the CPSC develop a more precise definition of products excluded from the phthalate ban. More precise guidance would eliminate the unnecessary requirement of Certificates of Compliance requirement for some benign categories of products. Section 108 of CPSIA permanently prohibits the sale of any "children's toy or child care article" containing banned phthalates. This includes "a consumer product designed or intended by the manufacturer primarily for a child 12 years of age or younger *for use by the child when the child plays.*" § 108(e)(1)(B) (emphasis added). A fair reading of Section 108 suggests that products that are not intended or designed for children 12 years of age or younger for use when a child plays, are exempt, whether there is a remote perception of possible play value or not.

Craft and hobby products are generally not intended to be children's toys and do not have inherent play value. Congress fully adopted ASTM F963-07 within CPSIA Section 106, including those items that are excluded from the definition of "toys", particularly Art and Craft materials. Many of these products are also covered within Labeling of Hazardous Art Materials Act (LHAMA). The following items are excluded from ASTM F963-07, and therefore should be exempt from CPSIA certification requirements:

-Art Supply Products including but not limited to airbrush supplies, brushes, paints, inks, varnishes, canvases, easels, pencils, pens, markers, sketch pads, paper, stickers etc.

-Craft beads, links, jewelry making clasps, chains, metals, wood, ceramic, semi precious and precious gemstones, etc.

-Floral supplies, tools, stems, containers, adhesives, dried floral material, foam board, ceramic, metal or wood containers, etc.

-General craft supplies, adhesives, glues, textiles, clays, tapes, foam, candle wax, soaps, leathers, leather crafting tools, ribbon, etc.

-Framing kits, wood, fasteners, paper boarder stock, mounting wire, picture hooks, picture eyelets, etc.

-Yarn and needle crafts, crochet and knitting needles/hooks, yarns, threads, strings and cords, trim, cutting tools, pattern books, etc.

-Paper crafts, cutting tools, stencils, templates, paper stock, trimmers, tapes, adhesives, glues, pens markets, inks, print pads, dies and stamps, invitations, etc.

-Decorative crafts, baskets, frames, glassware, shells, textile trim, paint applicators, etc.

Wilton Products Inc. urges the Commission to exempt, by definition, the foregoing categories of hobby and craft supplies from an overly inclusive application of Section 108. In this regard, Wilton concurs with the conclusion articulated by the CHA in response to the CPSC's request for comment:

“With the exception of finished products, specifically designed, manufactured and marketed as toy products, almost all of the materials used for art material, craft and hobby activities are sold as raw materials for use by a broad range of the U.S. population (as opposed to sale for primary use by children 12 years of age or younger). In addition these products are generally not available for sale as finished toys or childcare products as defined under Section 108 of the CPSIA, or under ASTM F-963-07, simultaneously adopted under CPSIA as a mandatory toy safety standard. In addition instructional literature and craft books are not customarily defined as toys and should also be excluded. Indeed such standard generally excludes such art, craft and hobby materials from the scope of such standard as a toy. Therefore, CHA urges the Commission to exclude such material from the scope of Section 108 requirements.”

Respectfully submitted,



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## Stevenson, Todd

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**From:** Vreeman, Anne-Louise [avreeman@wilton.com]  
**Sent:** Wednesday, March 25, 2009 11:13 AM  
**To:** Section 108 Definitions  
**Cc:** Merfeld, Mary; O'Connell, David; Kevin Fick; Kasvin, Tom; Dan Kochenash; Sheehan, Susan  
**Subject:** Response to Request for Comments on Section 108 Definitions - Wilton Products Inc.  
**Attachments:** Signed Wilton Comments to CPSC on Phthalates.pdf

Dear Secretary-

As requested, Wilton Products Inc. is respectfully submitting comments on Phthalates testing and certification requirements as listed in Section 108 of CPSIA 2008.

Regards-  
Anne-Louise

*Anne-Louise Vreeman*

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Toy Industry Association, Inc.

March 25, 2009

Mr. Todd Stevenson  
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**Comments on Staff's Draft Guidance Regarding Section 108's Phthalate Requirements for Certain Defined Toys and Child Care Articles**

Dear Mr. Stevenson,

In response to the request of the Commission, *see* 74 Fed. Reg. 8058 (Feb. 23, 2009), the Toy Industry Association Inc. ("TIA") submits the following comments on the Staff's Draft Guidance regarding which children's products are subject to Section 108 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA" or the "Act"), which prohibits the sale of certain products containing specified phthalates. TIA hopes that these comments will assist the Commission in effectively implementing first time regulations governing the use of phthalates in certain children's products in the United States. Since these regulations specifically target our members' products, these issues are extremely important to TIA's 500 members. TIA has previously, on January 12, 2009, submitted extensive comments on Section 108 in response to the Staff's request for general comments. The purpose of the present comments is to provide our initial views on the Draft Guidance, and to address approaches that could be applied to particular product classes. TIA reserves the right to supplement or amend its comments as appropriate.

As we explain below, the Draft Guidance is a good one, but it would benefit from clarification or refinement on certain points. First, we support the proposed test method as most consistent with the statute and because alternatives would be difficult to develop and implement. Second, we generally support the proposed approach to determining what is a "children's toy" but believe it would benefit from a clearer focus on whether the function of a particular product is, in the words of Section 108, to be used by a child "when the child plays." Third, the proposed approach to the mouthability of children's toys, under Section 108's interim ban on the phthalates known as DINP, DIDP, and DNoP, is generally sound but would benefit from clarification of the "5 centimeters" standard in Section 108(e)(2) and from clearer focus on whether mouthing is likely when a product is being used in play. Finally, the staff's "primary / secondary" distinction for applying Section 108 to child care articles is helpful and consistent with the statute, for reasons explained in our prior comments, but could benefit from a clearer focus on the likelihood of mouthing and by recognizing bases for drawing clearer lines between products that do and do not "facilitate" sleep or feeding.

**I. The Proposed Test Method Is the Most Viable Approach Under the Statute.**

The Staff issued a phthalate test method on February 9, 2009, and revised it on March 3, 2009. The Commission has requested comment on the test method. The current version is known as Test

Method CPSC-CH-C1001-09.1. Its general approach is to grind up a sample “to a powder,” and then test the phthalate concentration in that powder. A sample is an “individual consumer product” or group of identical products and by grinding it up the tester converts it into “a homogenous mixture of component parts.” Alternatively, one can “[d]etach easily separable parts,” weigh and test each of the parts separately (without testing parts that “would be considered as phthalate-free,” such as “unpainted metal, glass or ceramic parts”), and then combine the results. This is a sound approach both under the statute and practically.

The test method is consistent with Section 108’s focus on whole products and articles. This focus is particularly evident if Section 108 is compared to Section 101 of the CPSIA, whose lead restrictions specifically mention component parts (§ 101(a) (2)) and which contains special provisions regarding component parts (§ 101(b)). Section 108, by contrast, defines “children’s toy” by reference to the use of the whole toy. (§ 108(e) (1) (B)) The word “article” in the term “child care article” directly indicates a focus on the whole product, and the statutory definition of that term, like that of “children’s toy,” requires one to consider how the product as a whole would be used. (§ 108(e)(1)(C)) In addition, Section 108’s factors for determining the ages for which a manufacturer has designed or intended a product likewise focus on the expected use of the whole product. (§ 108(e)(2)) To determine the applicability of the interim phthalate prohibition for children’s toys “that can be placed in a child’s mouth,” Section 108 does require one to consider whether “any part” can be mouthed, but this is only to determine whether the toy as a whole could in any degree be mouthed. (§ 108(e) (2) (B).) Finally, concerns about laboratory over testing of internal components of products for phthalates (especially when those internal components are not exposed and could not become exposed without using tools and removing several outer layers of materials) have illustrated problems with a piecemeal approach to testing regardless of likelihood real world health risks. This was a departure from how the labs tested internal components for phthalates under European law and although we understand that there is no express exemption for inaccessible parts, neither does there exist a requirement to separately test such parts. The lack of clear guidance on how to test for phthalates under the CPSIA, until issuance of this protocol resulted in needless expensive redundant testing of the same product different results because of the lack of a consistently applied test methodology. Therefore, the CPSC test method is desirable as a way to eliminate variability in test approaches and is consistent with Section 108’s focus on whole products and articles

Further support for this approach appears in the language of the phthalate prohibitions themselves. Both in Section 108(a) and in 108(b) (1), the CPSIA refers to a children’s product “that contains concentrations of more than 0.1 percent of” the specified phthalates. The phrase “contains concentrations” is undefined and at least ambiguous. It allows for interpretation in light of Section 108’s overall concern with children’s exposure to phthalates (discussed in our prior comments) as well as the particular provisions just discussed that emphasize the use of the whole product. In addition, the grammatical subject of the phrase “contains concentrations” is “toy” or “article,” rather than “part” or “component part” (terms not directly mentioned). Thus, the Commission can reasonably determine whether a product has an impermissible concentration of any of the six specified phthalates by considering the product as a whole.

Of course, the Consumer Product Safety Act defines “consumer product” as an “article, or component part thereof.” 15 U.S.C. § 2052(a) (1). And “children’s toys” and “child care articles” are consumer products. But they are only subsets of this general term, and, as explained, the more specific definitions in Section 108 focus on whole products and articles designed or intended for a particular use.

Some may believe that *testing* should focus on the likelihood and results of mouthing and other possible means of exposure. The better view, however, is that Congress addressed such risks through

the concentration level it set and its definitions of the products to which the phthalate prohibitions apply.

Furthermore, possible alternatives would be difficult to develop and implement, for several reasons. First, the Commission would need to articulate a statutory basis for a different approach, such as a component- or exposure-based one, and that basis is far from evident. Second, the Commission would need to investigate the possibility of migration of phthalates from one component part to another, and then determine how any component- or exposure-based testing method should account for this. The existing whole-product approach avoids that issue. Third, changing the approach to testing may affect approaches to other implementation questions under Section 108. Fourth, it would be essential that any changes to testing protocols be made only upon notice with opportunity to comment and pursuant to the due process requirements of the Administrative Procedure Act (“APA”), and with adequate advanced notice prior to any changes. Otherwise the production, testing and availability of product could be negatively and significantly impacted. There is no reason for the Commission to run such risks by reading Section 108 to require more than it actually does.<sup>1</sup>

## **II. The Proposed Approach to Determining What are “Children’s Toys” is Generally Sound.**

The Staff has previously addressed a number of questions concerning applicability of phthalate limits through FAQs, General Counsel Opinions, and press releases. These, together with the Draft Guidance, provide some help to manufacturers, importers, retailers and consumers in determining what products are covered by the phthalate limits. But further clarity would help.

Initially, we have noted and fully support the decision by the Commission, in the discretion afforded it, to focus its resources on enforcement efforts directed at the products most likely to pose a risk of phthalate exposure to children. With regard to children’s toys, we agree with the Commission’s focus, as articulated in a press release of February 12, 2009, on “bath toys and other small, plastic toys (especially those made of polyvinyl chloride) that are intended for young children and can be put in the mouth.” That focus should continue even after the Draft Guidance is finalized. To the same end, it also would be helpful if the Commission would state definitively that children’s toys (and child care articles) that do not contain any materials with the potential to include phthalate plasticizers are not subject to Section 108 and need not undergo testing under any method. An official list of such materials would be helpful; in our prior comments, we identified some materials that could and could not contain phthalates (p. 1-2).

### **A. Factors for Assessing What Is a “Children’s Toy”: Manufacturer Design or Intention Regarding Both Age and Play.**

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.*” (CPSIA §108(e) (1) (C)). The Staff has indicated, both in FAQs and in its Draft Guidance, that 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:  
*-Whether the intended use of the product is for play, including a label on the product if such statement is reasonable.*

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<sup>1</sup> If the Commission does reject or revise the Staff’s test method notwithstanding the points above, then the EU’s approach, based on an assessment of the risk of exposure, may provide helpful guidance. European Commission, Enterprise and Industry Directorate-General, *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*

*-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.*

These factors are drawn almost verbatim from Section 108(e) (2) of the CPSIA, the only change being to the first factor.

There is one aspect of the Draft Guidance's reliance on these factors that would benefit from clarification. The relevant portion of the definition of "children's toy" has two elements regarding the manufacturer's design or intention: (1) that the product is "for a child 12 years of age or younger," and (2) that it is "for use by the child when the child plays." In Section 108(e) (2), the four factors bear only on the first element. In the Draft Guidance, by contrast, the four factors apparently bear on both elements together. Given this discrepancy, the Draft Guidance could cause the Commission in determining what is a "children's toy" to lose sight of "when the child plays" as a distinct requirement, treating the expected age of use as largely conclusive.

Prior guidance has kept this distinct "play" requirement in mind, and we urge the Commission to continue to do so in any final guidance. For example, the eighth FAQ posted on December 4, 2008, recites the factors as actually stated in Section 108(e) (2) and then appropriately adds the following: "A manufacturer must apply these factors [to] their products *and then* consider whether it is 'for use by the child when the child plays' to determine whether a product meets the definition of a child's toy. The use of the product by the child for play is a fundamental aspect of such determination." (Emphasis added.) Similarly, the General Counsel has emphasized that a product must have "inherent play value." Letter from Cheryl A. Falvey, General Counsel, to Mr. Allan R. Adler 3 (Dec. 23, 2008) (Advisory No. 323). Although children can play with any object in their possession, it does not necessarily follow that all such products used by children in imaginative and multifaceted ways are "toys" with inherent play value. In this regard a manufacturers stated intent, how the product is marketed and whether it is commonly recognized as a toy significantly limits toys products to traditionally defined and promoted toy products.

In considering "inherent play value," as in considering the age of use, the statutory definition of "children's toy" requires a focus on what is "designed or intended by the manufacturer." This will require some adjustment to the way CPSC has traditionally evaluated children's products and will require that a narrower range of products truly be considered toys.

## **B. ASTM F963's Definition and Exclusions.**

Particularly given Section 108(e)(1)'s distinct "play" requirement, we support the CPSC staff's consideration of the definition of "toy" in the context of the ASTM F963-07 toy safety standard, which provides clearer guidance as to which products should be considered toys and which should not. Section 106(a) of the CPSIA made most of the provisions of ASTM F963-07 a mandatory CPSC standard on February 10, 2009. This is particularly significant to interpreting Section 108 for two reasons.

First, ASTM F963-07 illuminates "children's toy" in general. As noted, Section 108 is singular in the CPSIA in using the term "children's toy," meaning that the rest of the CPSIA provides little guidance in expounding that term. Yet ASTM F963-07 consists, as Section 106(a) indicates, of "Consumer Safety Specifications for *Toy Safety*." (Emphasis added.) Section 106(a) is thus a valid indicia in the CPSIA regarding "toy" in Section 108. And ASTM F963-07 actually defines "toy"—as "any object designed, manufactured, or marketed as a plaything for children under 14 years of

age.” (§ 3.1.72.) This definition should illuminate the Commission’s understanding of the definition of “children’s toy” in Section 108(e) (1), particularly its requirement regarding play: The ASTM definition indicates the need to focus on the use of the “object” as a “plaything,” as well as reinforcing the need to consider manufacturer design and intention.

Second, ASTM F963-07 specifically excludes certain types of articles: 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; Sporting goods; camping goods; athletic equipment; musical instruments; and furniture (except for toy versions); and Powered models of aircraft, rockets, boats, and land vehicles. (§ 1.4.) When Congress in Section 106(a) made ASTM F963-07 a consumer product safety standard, it expressly incorporated these exclusions into federal law. We know this was intentional because Congress in Section 106(a) exempted some other parts of ASTM F963—“section 4.2 and Annex 4”—from inclusion in the standard. The fact that, while considering ASTM F963 in such detail, it did not exempt the exclusions in Section 1.4 reasonably indicates that it intended that such exclusions should apply as part of the regulatory definition of which products are considered a “toy” under the only other section of the CPSIA that specifically addresses toys—Section 108.

At the very least, the Commission is entirely within its statutory discretion in taking guidance from the ASTM F963 definition and exclusions in expounding and enforcing Section 108. The Commission thus was correct in its February 6, 2009, press release to reiterate “that it will follow the definition of toy in the mandatory toy standard which exempts such things as bikes, playground equipment, musical instruments, and sporting goods (except for their toy counterparts).”

### **C. The Importance of Considering Functional Performance.**

In line with this reasoning, the CPSC staff appropriately considered various types of balls (generic rubber or plastic balls that bounce to regulation-size baseballs). Generally, regulation-size baseballs, basketballs, footballs, and soccer balls are sporting goods or athletic equipment 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. We support this approach. In contrast, the staff has regarded general purpose balls as toys and therefore, subject to the requirements of the CPSIA section 108. The staff also considers a “toy version” of actual athletic equipment, such as a toy glove with a foam ball, as a toy for the purpose of the CPSIA Section 108 requirements. In addition, they suggest that small balls handed out as promotional items might be also be regarded as toys. We believe that such distinctions are valid. However, we also urge the CPSC staff to view products that function in an identical fashion to their athletic counterparts as sporting goods or athletic equipment.

More generally, we urge the Commission to recognize and emphasize that functional performance is an essential dividing criterion between actual toys and mere children’s versions of non-toy products. For example simulated role playing headgear (i.e. Police, firefighter or military helmets) are vastly different than actual gear used in those professions. Yet it may also be true that bicycle helmets and sports protective gear sold in toys stores and used to “play or learn sports” are functionally protective athletic equipment that deserve to be treated as such since they function that way and should not be considered “toys”.

Ordinary books, including books for small children, are generally not regarded as toys. However, some novelty books, such as plastic books marketed as bath toys, or books that incorporate games, may be regarded as toys under both ASTM F963 and CPSIA section 108. Yet, the CPSC staff should not overly generalize in this regard either. There are many educational books that include functional learning related activities, which in and of themselves should not be treated as “toys or games”. The

publishers stated intent needs to be given due accord in making such assessments. Unless the activity is clearly related to game play, such activity books should not broadly be categorized as toys.

We also urge the CPSC staff to evaluate combined products as distinct from one another for application of the standard. For example, if a book is packaged with a plush toy, each should be considered as a distinct product (i.e. excluded book with included toy). Similarly 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 and should be excluded from consideration as a defined toy. While phthalates may be restricted in some of these products, to avoid needless testing to the extent considered as part of such toxicological review, this should be deemed adequate for toy items within this category of product. In addition we note that although some electronic devices (such as cellular phones with incorporated games, cameras or musical devices) may be decorated or marketed such that they may be attractive to children 12 years old or younger, they are not generally recognized as “primarily” a children’s product under the Act or considered “toys” under the mandatory ASTM F-963-07.

The following types of electronic products are additional examples of items that should not be considered toys for purposes of Section 108 of the CPSIA: Carrying cases and storage cases for video game consoles or other electronic products; Recharging units for handheld video game consoles and other electronic products; USB and RCA cables; AC Adapters; Headphones for video game consoles and other electronic devices; Electronic products, associated software and curricular materials that are sold to schools and other educational institutions; and Educational DVDs.

For all of all of the above examples we believe that graphic decorations with cartoon or licensed characters should not have any bearing on whether products are considered toys that are subject to the phthalate requirements under section 108, regardless of the character used. We note that increasingly branded character licensing appeals to people in wide age ranges and not just children 12 years of age and younger. For example Mickey Mouse, Sponge Bob, Peanuts Characters and Sesame Street, Super Hero Characters have broad appeal across many age ranges. As noted above we believe the function of the product should be the primary factor determining whether the product is a toy version of the excluded products or not.

We do recognize that there may be particular games or kits that include art materials or craft items that are generally recognized as excluded from classification as “toys”. The fact that such materials can be used to make toys, should not in and of itself lead to a characterization of these materials as goods primarily intended to be toys. In addition, as previously noted we believe if products can be considered separately from one another, although marketed together, that they should be regarded separately for the purposes of subjecting them to treatment as a toy under Section 108, unless they are likely to be inserted in the mouth chewed and sucked. Finally, we believe that the CPSC’s previously issued FAQ’s that indicated that traditional Halloween costumes should generally be considered wearing apparel, to the extent intended to be worn as festive, occasional attire subject to the Federal Flammable Fabrics Act (“FFA”) was appropriate and should continue to be adhered to. These products are distinct in their use patterns from dress up games.

### **III. The Proposed Approach to “Toys That Can Be Placed in a Child’s Mouth” Should Be Clarified in Two Ways.**

The CPSIA interim-phthalate ban applies to children’s toys only if they “ can be placed in a child’s mouth.” That requirement is satisfied 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.” In addition, “[i]f a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth.” (§ 108(e)(2)(B)). Thus,

even if a manufacturer determines that an article is a “toy” under section 108 of the CPSIA, the interim-phthalate prohibition does not apply unless the manufacturer also determines that the toy can be mouthed. There are two aspects of the Draft Guidance on this subject on which the Commission should consider modifications.

First, the Commission should clarify that a children’s toy is not mouthable if a part that is smaller than 5 centimeters in one dimension is not accessible to a child for mouthing. At the least, a children’s toy should not be subject to testing regarding the interim prohibition on account of such a part. To conclude otherwise would make the statute absurd. For example, the screen of an “Etch a Sketch” type product is arguably a distinct “part” and will be less than 5 centimeters in thickness, but it is plainly not mouthable, because the frame surrounds it. It is particularly not mouthable if the screen is more than 5 centimeters from the edge of the framing. Similarly, a label that adheres to the surface of a children’s toy will be less than 5 centimeters in thickness, but its mouthability should depend on the dimensions of the surface to which it adheres. Other products will have parts smaller than 5 centimeters in one dimension that are interior, with no possibility of a child’s ever mouthing them. In that circumstance, application of Section 108’s interim prohibition would be even more absurd.

Second, we believe that the 5 cm criterion should be applied to inflatable toys in the inflated state. The fundamental difficulty we encounter when applying the restriction of Section 108(b) (1) to inflatable toys is the fact that the CPSC staff’s indiscriminate application of the Standard to all inflatables in a deflated state is misplaced. Most if not all inflatable toys will be less than 5 cm in at least one dimension in their deflated state and would therefore be considered “mouthable” under such a definition. Additional refinement to this policy is required.

Such refinement needs to consider whether a “toy” is mouthable with reference to Section 108’s definition of “children’s toy.” That definition depends on a product’s “use by the child when the child plays.” Whether a product is a toy that can be placed in a child’s mouth should correspondingly depend on its *use when the child plays*. Thus, toys that cannot be played with in a deflated state should be measured in their intended inflated state. This is consistent with the CPSC’s approach in its existing test manual and previous determinations related to toy testing that has traditionally indicated that use and abuse testing of toys occur in their assembled state. Some inflatable toys are very unlikely to be “mouthed” (as that term is limited narrowly defined in the Act) in their deflated state. We can only conclude that in the exercise of its discretion, the CPSC staff should harmonize with comparable determinations of the European Commission Enterprise and Industry Directorate General on inflatables. It is interesting to note that the 5 cm rule found in Section 108(e)(2)(B) is borrowed directly from the European Commission’s guidance, thus indicating that Congress was fully aware of the fact that Section 108 as drafted would be interpreted in a consistent manner when applied to larger inflatable toys.

If an inflatable toy is designed to be inflated by the consumer by mouth, particularly by the child rather than parent, then we recognize that the result may differ. But that is because such inflation is part of the process of making the product play-able. Large inflatables such as swim rafts, punching bags, air castles and large beach balls, however, whether inflated by continuous air flow devices or valves, should be considered as products that are not likely to be placed in a child’s mouth as statutorily defined (if in an inflated state they don’t have protrusions that meet the dimensional criterion). Under these circumstances the staff should revisit their previous determination. In addition general purpose balls that are inflated by the manufacturer should be considered in the inflated (normal) state. Inflatable regulation-size athletic equipment, such as basketballs, footballs, and soccer balls excluded by ASTM F963, regardless of size if intended to be used to learn a sport, should not be considered toys.

#### **IV. With Regard to Child Care Articles, the Draft Guidance’s Distinction Between “Primary” and “Secondary” Uses Is Generally Sound But Could Benefit From Further Refinement.**

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.*” The definition of “*child care article*” is much narrower than one would assume. It does not extend to all use of the product by a child three years or younger; rather, such use must directly facilitate sleep, feeding, sucking, or teething. A product to “*help*” a child “*with sucking or teething*” will be one on which a child sucks or teethes—creating a particular risk of exposure. A plain reading indicates that the activities referenced involve mouthing behavior as a prerequisite. Similarly, the statutory reference to a product designed or intended “*to facilitate sleep or the feeding of*” a young child (including a pacifier) is most reasonably understood as one that the child will use for that purpose, meaning that he will come into contact with it and likely mouth it. The requirement that the product actually “*facilitate*” the activity further indicates a narrower requirement than “*use*” of the product. Obviously a plain reading of the language indicates that there must be an intentional causal relationship between the product and the activity that results in sleep, feeding, or aid in sucking and teething. This is why use alone is an insufficient basis for subjecting a child care product to these requirements. Moreover, for the reasons explained in our prior comments (p. 6-7), a focus on mouthing also protects against the overwhelmingly primary exposure pathway of children to phthalates.

The Staff’s Draft Guidance goes far to recognize this in drawing a distinction between “primary” and “second” products based on whether they “facilitate” (or “help”) feeding, sleeping, sucking, or teething “for the child directly” or “only indirectly through the parent.” 74 Fed. Reg. at 8059. The Commission should, however, make explicit what is implicit in the five different categories that the Draft Guidance lays out: A necessary requirement is whether part an article is likely to be placed in a child’s mouth. As the Draft Guidance explains, the two categories of products that are definitely primary are (1) those “used directly in the mouth” and (2) those that “have direct contact with the child” and “may . . . have direct mouth contact.” Correspondingly, the Staff is correct in identifying the fourth category, of products that are “secondary” because they “have no contact with the child,” which means they will not be mouthed.

The Staff considers to be borderline 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 “may or may not be considered to facilitate sleep.” But if there is no contact between the child and product, there is no possibility of mouthing and no “direct” facilitation of sleep. That should be sufficient for the product not to be a child care article. Moreover, by the Staff’s admission, products falling in this category are subject to uncertainty as to whether Section 108 applies, and the Draft Guidance proposes no means of resolving that uncertainty. Section 108 does not require such limbo, and it would be helpful for manufacturers seeking to comply with the statute for the Commission to clarify this.

We are not saying that no product in this “borderline” category should be subject to Section 108. It may be that under reasonably foreseeable misuse, some part of these or other products may be placed in a child’s mouth or at least directly contact the child. But the Commission can and should eliminate uncertainty by simply stating that the question is whether a part of the article is likely to be mouthed.

Finally, the Staff’s recognition of and general approach to a fifth category—articles with “multiple functions” that may include facilitation of sleep—is sound but could benefit from further clarification. The Commission should not only consider mouthability as a necessary condition but

also emphasize that Section 108's definition of "child care article" depends on the *manufacturer's* design and intent. If the manufacturer has designed or intended the product primarily to soothe or entertain a young child, then it has not designed or intended it to facilitate the child's sleep, and it is not a child care article even if some part of it is mouthable.

As the Draft Guidance recognizes, typically, these articles are larger products that offer parents/caregivers an alternative to holding their child. While manufacturers recognize that infants sleep in a variety of products, since newborns and young infants spend the majority of their time sleeping, many such products have a primary function (and thus a design and intent) unrelated to sleeping or feeding and should be considered as Secondary products under the CPSC staff's bifurcated categorizations of such products. The four factors that the Staff lists in its proposed guidance should, especially with regard to multiple-function articles, be clarified to more clearly take into account the manufacturer's design or intent with regard to the product's facilitating sleep (or any other activity listed in the definition of "child care article"). Significant considerations should include (1) whether the product contains entertainment features; and (2) whether the product contains warnings or instructions against leaving a child unattended. This comment parallels our comment regarding the factors the Staff has proposed regarding "children's toy": The Commission should keep distinct the question of the intended age of the child using the product and the intended use of the product.

While the Association expects others to comment in greater detail about these products, we believe our comments related to mouthing exposure and how products primarily function should be consistently applied to this narrower category of defined childcare articles as well. Functional performance directly related to the regulated product activity is an essential added criterion that needs to be applied to these products as well.

## CONCLUSION.

Thank you for the opportunity to continue our participation in your deliberations concerning the implementation of the CPSIA Section 108 requirements. With toys as specific target of regulation under this section, we believe our experience in defining the categorization and scope of which products are reasonably considered defined toys within our industry and which are not should be helpful to the Commission. As noted we reserve the right to provide specific product exemplars. Please contact us if additional information is required.

Thank you for the opportunity to continue our participation in you deliberations on how to implement the Consumer Product Safety Improvement Act. Should you have any questions or need clarification on the above comments, please do not hesitate to contact Ed Desmond at [edesmond@toyassociation.org](mailto:edesmond@toyassociation.org) or at 202-857-9608.

Sincerely,



Carter Keithley  
President  
Toy Industry Association

## Stevenson, Todd

---

**From:** Desmond, Edward [edesmond@toyassociation.org]  
**Sent:** Wednesday, March 25, 2009 10:21 AM  
**To:** CPSC-OS; Wolfson, Scott; Falvey, Cheryl; Parisi, Barbara; Smith, Timothy; Mullan, John  
**Cc:** Keithley, Carter  
**Subject:** TIA Comments on Section 108  
**Attachments:** TIA Sec. 108 Phthalates Comments -- FINAL.pdf

Good morning,

Attached please find comments by the Toy Industry Association on draft guidance regarding Section 108's phthalates requirements. We appreciate your consideration of our views and are happy to add further clarification if you deem it necessary.

If any questions arise, please do not hesitate to contact me.

Ed

Ed Desmond  
Executive Vice President, External Affairs  
Toy Industry Association  
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Date: 3-25-09

To: Consumer Product Safety Commission

From: Water Sports Industry Association

Re: Request for Comments regarding requirements of CPSIA, sec.108

On behalf of the members of the Water Sports Industry Association (WSIA), we appreciate the opportunity to comment on the Consumer Product Safety Commission's (CPSC) staff approach for determining which products are subject to the requirements of section 108 of the CPSIA, and to provide information regarding an exemption of water sports products, athletic equipment and recreational equipment from the phthalate requirements. We respectfully urge the CPSC to grant an exemption from section 108 of the CPSIA for legitimate water sports products, athletic equipment and recreational equipment as they are used to develop an interest and skill-set for participation in water sports activities.

Action by the Commission is urgently needed in light of the February 5, 2009 court decision in *NRDC vs. CPSC* regarding the retroactive application of §108 as well as the passing of the effective date of this section on February 10, 2009. Issuance of a final rule is particularly critical since the statute's deadlines do not mesh with other deadlines and requirements. An example of this confusion and inconsistency is represented by ASTM F963, the Children's Toy Standard, which also becomes mandatory on February 10, 2009. In other words, the CPSIA specifies that a pending rulemaking will not delay implementation of the effective dates for such limits, but does not adequately provide for an orderly implementation of a comprehensive rule that clarifies definitions to a sufficient degree so that manufacturers can deal with inventory as well as the distribution of new products in commerce.

As a result, the Water Sports Industry Association submits this comment in response to the CPSC's request for comments regarding CPSIA section 108. The WSIA, the trade association of leading industry water sports brands, enhances industry vitality and fosters water sports participation through research, thought leadership, product promotion and public policy. WSIA represents the industry on trade and consumer issues and is considered the collective voice of the industry.

The membership of the Association is extremely concerned about the classification of water sporting and recreational goods used for legitimate water sports activities under section 108 of the Act. Subsection 108(e) defines "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." A "child care article" is defined 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." A toy is considered 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 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 WSIA takes the position that legitimate performance water sports products are not "children's toys" as defined in section 108. Legitimate performance water sports products are designed and primarily intended to teach skill sets to younger participants in order to increase interest and participation in water sports, develop coordination, and to promote physical activity to reduce the risk of childhood obesity. Whether the product is made for children's water sports should not be the determining factor. As long as the water sports product is intended to develop a child's interest and skill set in a legitimate water sports activity, and is not truly a toy, then that product should not be classified as a "toy" for purposes of section 108. For instance, the mere fact that towable inflatables, trainer skis, wakeboards, kneeboards, and accessories are intended for children 12 years of age and younger does not make these products "toys". Indeed, these products and many others are made with the intent of promoting youth to engage in truly legitimate water sports activities, to develop coordination, and to reduce the risk of childhood obesity.

The WSIA lauds the CPSC in the subject request for comment for its recognition and analysis of sporting goods, athletic equipment, and playground equipment in the context of ASTM F963-07 which became mandatory on February 10, 2009. The Toy Standard excludes sporting goods, athletic equipment, and playground equipment from the definition of "toy". The WSIA agrees with the CPSC staff analysis that even if these products are designed and primarily intended for children 12 years of age or younger then those articles should be exempted from the CPSIA section 108 requirements. For instance, a towable inflatable is primarily used by a child only when it is being towed by a powerboat driven by an adult and the child is under the supervision of the adult. In addition to providing family fun, it helps to promote a child's interest in water sports, and most definitely helps in improving a child's balance and coordination. Towable inflatables are not kept in a child's bedroom, family room, or swimming pool. The child probably has less than an hour's actual contact with the inflatable, and only when the family decides to go on vacation or take the boat out on the lake. There is virtually no risk that a child would start chewing on a towable inflatable.

Likewise, large water trampolines and bounce platforms used only in lakes are essentially playground equipment on water, and therefore likely would be exempted under ASTM F963-07. These products should be exempted from section 108 for the same reasons as the towable inflatables.

The WSIA takes the position that skis, wakeboards, kneeboards, and accessories to use them are in fact legitimate water sports products exempted under ASTM F963-07 and should likewise be exempted under section 108. These products are undeniably intended to promote participation in legitimate water sports, teach and improve children's skill sets, balance, and coordination, and reduce the risk of childhood obesity.

The CPSC staff has made it clear in public meetings and presentations that currently the focus will be on the products that most likely pose a risk of phthalate exposure to children, especially those toys intended for young children and toys that can be placed in a child's mouth. Products predominately mentioned include pacifiers, bibs, plastic bats and so on. None of the water sports products named above involve any perceptible risk of exposure to phthalates given the conditions under which they are used and stored. These products are not intended to be used by very small children nor is there a significant likelihood that they can be mouthed. On the other hand, the WSIA agrees that all bath toys, many pool toys, and all toddler wading pools and pool toys should be considered "toys" and subject to section 108.

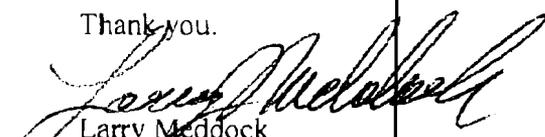
For the reasons stated above, the WSIA agrees with the general approach of the CPSC in that legitimate water sports products and equipment, whether designed and primarily intended for adults, teens or children 12 years of age or younger are not "toys" and, therefore, are exempt from the provisions of section 108 of the CPSIA. On the other hand, bath toys, many pool toys, and toddler wading pools are "toys" and must comply with section 108 of the CPSIA. Reliance on the ASTM F963-07 exclusions of sporting goods, athletic goods, and playground equipment is appropriate.

This guidance is clear and is generally consistent with the understanding that water sports product manufacturers have been working with for years. Simply said, products designed and intended to introduce children to and help them learn particular skill sets to eventually participate in legitimate water sports and recreational activities are sporting goods and should be exempted from section 108. Only "toy" versions such as wading pools and wading pool toys should be required to meet the phthalate section.

Concerning foreseeable consequences, if the Commission staff takes a different approach than stated in this request for comments, manufacturers will have little guidance to determine gray areas. As a result, tens of millions of dollars of inventory may be deemed non-compliant when in fact the CPSC might not believe that to be so. Further, the ability of manufacturers to move product into the stream of commerce would be inhibited as there would be no meaningful, understandable bright lines to judge compliance from non-compliance.

In conclusion, the WSIA believes that it is critical for the CPSC to once and for all formally adopt the proposed position stated in this request and to grant an exemption for all legitimate water sports products from the phthalate provision of the CPSIA.

Thank you.



Larry Meddock  
WSIA Executive Director



PO Box 56812  
 Orlando, Florida 32815-8512  
 Email: [wsiaheadquarters@earthlink.net](mailto:wsiaheadquarters@earthlink.net)  
 Phone/Fax: 407-251-9039

# F A X

**DATE:** 3-25-09

**TO:** CPSC

**FAX NUMBER:** 301-504-0127

**FROM:** Larry Meddock  
 WSIA Headquarters

**FAX NUMBER:** 407-251-9039

**REGARDING:** Request for Comments  
 CPSIA Section 108

**NO. PAGES (INCL THIS PAGE):** 4

**MESSAGE:**  
 As Requested

**Stevenson, Todd**

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**From:** DANIEL CAROLINE RIEPLER [carodaniriepler@msn.com]  
**Sent:** Wednesday, March 25, 2009 10:57 AM  
**To:** Section 108 Definitions  
**Subject:** from Caroline Riepler (Little Journeys Baby World)

Dear CPSC,

I am writing to you to exempt this products from the phthalate testing:

- Quilts
- Burping Cloths
- Bibs (If they are made out of cotton and safe materials)

My products are made out of 100 % Cotton except for the Batting for the Quilts

Which is 80 % polyester Flame Retard and the rest is 100 % Cotton

You would be putting a lot of handmade good quality products out of business, because of this testing for phthalates.....

I truly believe that these products do not have any phthalates in them, so why do you want this products tested????

Please helps small business like us to survive, and not to close down.

Best regards,

Caroline Riepler  
Little Journeys Baby World

March 25, 2009

**Via Electronic Mail**

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

RECEIVED  
MARCH 26 2009  
U.S. CONSUMER PRODUCT SAFETY COMMISSION

**Re: CTIA Comments on Draft Guidance Regarding  
Products Subject to CPSIA Section 108**

Dear Mr. Stevenson:

On behalf of CTIA -- The Wireless Association ("CTIA"), we appreciate this opportunity to submit these comments in response to the Consumer Product Safety Commission's (CPSC) 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> Specifically, the CPSC staff has requested comments on whether electronic devices such as cellular (or "wireless") phones should be considered "children's toys" that are subject to the phthalate requirements under section 108 of the CPSIA.<sup>2</sup>

For the reasons set forth in CTIA's Comments, CTIA respectfully submits that wireless phones, whose primary function and purpose is as a communication device, are not "children's toys" as defined by the CPSIA and fall outside the scope of Section 108. CTIA urges the Commission to make clear that wireless phones are not subject to the requirements of Section 108.

Sincerely,



Kerrie L. Campbell

cc: Michael F. Altschul, Sr. V.P. and General Counsel, CTIA – The Wireless Association

<sup>1</sup> See 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, 74 Fed. Reg. 8058 (Feb. 23, 2009).74

<sup>2</sup> Fed. Reg. 8058, 8060 (Feb. 23, 2009).

**BEFORE THE  
UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION**

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**Notice of Availability of Draft Guidance )  
Regarding Which Children's Products )  
Are Subject to the Requirements of )  
CPSIA Section 108; Request for ) SECTION 108 PHTHALATES  
Comments and Information )  
)  
74 Fed. Reg. 8058 (Feb. 23, 2009) )  
)**

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**COMMENTS OF  
CTIA - THE WIRELESS ASSOCIATION**

**March 25, 2009**

## CTIA COMMENTS

### **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**

#### **I. INTRODUCTION**

CTIA - The Wireless Association is an international nonprofit membership organization founded in 1984, representing all sectors of wireless communications, including cellular, personal communication services and enhanced specialized mobile radio.

As an organization, CTIA represents over 300 service providers, manufacturers, wireless data and internet companies, as well as other contributors to the wireless universe.<sup>3</sup> They range from small regional service providers to large, publicly traded multi-national corporations. CTIA advocates on their behalf before the Executive Branch, the Federal Communications Commission, Congress, and state regulatory and legislative bodies. CTIA works to ensure that common sense public policy objectives relating to wireless communications are implemented in a consistent, uniform and cost-efficient manner.

CTIA also coordinates the industry's voluntary efforts to bring consumers a wide variety of choices and information regarding their wireless service, and supports important industry initiatives such as Wireless AMBER Alerts, and the "When it comes to Wireless, Safety is Your Call" safe driving public service announcement campaign. CTIA operates the industry's leading trade shows, as well as equipment testing and certification programs to ensure a high standard of quality for consumers. CTIA's members consistently have been on the forefront of efforts to provide consumers, businesses and governments with safe and economical wireless service to facilitate communication.

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<sup>3</sup> A list of our current members is contained on our website. See [http://www.ctia.org/membership/ctia\\_members/](http://www.ctia.org/membership/ctia_members/).

## II. RELEVANT SECTION 108 STATUTORY LANGUAGE

Section 108 prohibits the sale, distribution or importation of any “toy” or “child care article” that “contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP).” Section 108(a). The terms “children’s toy” and “child care article” are defined in Section 108, and these definitions apply only to this section of the Act. Section 108 defines “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.” Section 108(e)(1)(B).

As noted in the staff’s draft guidance and request for comment, the following factors are to be considered in determining whether a particular product is designed or intended for use by a child 12 years or age or younger during play:

- 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.

“Child care article” is defined 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.” Section 108 (e)(1)(C).<sup>4</sup>

Section 108 imposes an “interim prohibition” on the sale, distribution or importation of any “children’s toy that can be placed in a child’s mouth or child care article that contains

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<sup>4</sup> There has been no suggestion – nor should there be -- that wireless phones can be considered a “child care article” as defined under Section 108, nor has the staff requested any comment in this regard. For the record, CTIA comments that wireless phones plainly are not “child care articles” subject to the requirements of Section 108 of the CPSIA

concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP).” 108(b)(1). For purposes of the Act, a “toy that can be placed in a child’s mouth” includes all toys containing any part which “can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed.” Section 108 (e)(2)(B). It also includes all toys that contain at least one dimension that is smaller than 5 centimeters. *Id.*

As set forth below, cellular (or “wireless”) telephones are not a “children’s toy,” or a “toy that can be placed in a child’s mouth” as defined by the CPSIA, and therefore, are not subject to the phthalate requirements under Section 108.

### **III. COMMENTS ON DRAFT GUIDANCE REGARDING PRODUCTS THAT SHOULD NOT BE CONSIDERED “TOYS” SUBJECT TO SECTION 108**

#### **A. Wireless Telephones Are Communications Devices Subject To Comprehensive Regulatory Requirements Administered By The Federal Communications Commission**

Wireless telephones are communications devices that are subject to a comprehensive regulatory scheme promulgated and enforced by the Federal Communications Commission (“FCC”). The FCC requires all radio frequency (“RF”) devices, including all wireless telephones, to be certified, registered, and labeled as compliant with FCC safety and health regulations concerning radio frequency emissions and exposure. To ensure that wireless phones perform the proper communications function, they must meet all applicable FCC regulations before they can be marketed and sold. As one example, FCC regulations provide, in pertinent part:

#### **Marketing of radio frequency devices prior to equipment authorization.**

(a) Except as provided elsewhere in this section, no person shall sell or lease, or offer for sale or lease (including advertising for sale or lease), or import, ship, or

distribute for the purpose of selling or leasing or offering for sale or lease, any radio frequency device unless:

(1) In the case of a device subject to certification, such device has been authorized by the Commission in accordance with the rules in this chapter and is properly identified and labeled as required by § 2.925 and other relevant sections in this chapter . . . .<sup>5</sup>

Section 2.295, in fact, requires all wireless telephones to bear a nameplate with the FCC Identifier Number, as well as any other statements or labeling requirements provided for by the rules, indicating that the product meets federally mandated communications device standards.

**B. Wireless Telephones Are Not “Children’s Toys” Designed Or Intended For Children 12 Years Of Age Or Younger for Use When the Child Plays**

In order to qualify as a “children’s toy” under Section 108, a product must be both (1) designed or intended by the manufacturer for a child 12 years of age or younger, and (2) for use by the child when the child plays. Section 108(1)(B). Wireless telephones do not satisfy these criteria, and thus fall outside the scope of Section 108.

As noted above, the CPSIA specifies that, when determining whether a product is designed or intended for use by a child 12 years of age or younger, the following factors “shall” be considered:

- (i) A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable.
- (ii) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children of the ages specified.
- (iii) Whether the product is commonly recognized by consumers as being intended for use by a child of the ages specified.

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<sup>5</sup> 47 C.F.R. § 2.803 (2008).

- (iv) The Age Determination guidelines issued by the Commission staff in September 2002 and any successor to such guidelines.

Section 108(e)(2)(A).

**1. Wireless Telephones Are Not Designed or Intended for Use by Children 12 Years of Age or Younger**

An evaluation of the relevant factors concerning the design and intended user of wireless telephones demonstrates that they do not meet the definition of a “children’s toy.”

- ***Manufacturer’s Statement***

CTIA has no position as to the appropriate age for wireless telephone use, since parents must decide when their child is old enough to have a wireless phone. Accordingly, wireless telephones are primarily marketed to adults and, to a somewhat lesser degree, to teenagers. Certainly 12 years old would fall at the very bottom end of the spectrum, and wireless telephone use by children 12 years old and younger is the exception rather than the rule.

To the extent that wireless telephones are marketed beyond adults, they are marketed to families with teenagers who have recently obtained some degree of independence. As teenagers begin participating in extracurricular activities outside of school, such as sports, and begin working part time jobs outside of the home, wireless telephones allow them to remain connected to – and in communication with – their families and others.

- ***Packaging, Advertising And Marketing***

Because a wireless telephone’s utility is derived from its ability to connect the user with other users, a user almost always purchases a service plan along with the wireless telephone. Wireless carriers offer customers a choice of both “prepaid” plans and monthly payment plans. Most wireless customers (approximately 80% of all subscribers) elect to make monthly payments to the wireless service provider pursuant to a contract, in exchange for a bundle of services that includes telephone service and a “bucket” of minutes that can be used by all members of a

family, along with “call waiting,” voicemail and sometimes e-mail or text messaging service. In addition, wireless service providers typically offer a free or discounted telephone to subscribers who agree to purchase wireless service for a fixed period. Since post-paid wireless service is provided pursuant to contract (and not a tariff), a wireless customer must have reached the age of majority to lawfully contract for wireless service.<sup>6</sup> To qualify for these offers, wireless customers must fill out a detailed application and provide information such as income and employment history, and, typically allow the wireless service provider to run a credit check on the user. Only where the user is able to demonstrate an ability to consistently pay the monthly service fees will the service provider approve the service contract. Clearly, this is not a product marketed to children 12 and younger, who are not eligible to enter into such contractual agreements, lack reliable sources of income and have no credit histories.

Even “pre-paid” wireless service, which requires a user to purchase a telephone and then periodically purchase blocks of “minutes” in the form of coded phone cards, is predicated on a legally binding service agreement and the wireless service provider’s expectation that the customer will generate consistent usage on the carrier’s network. Although pre-paid users are not billed on a consistent monthly basis, they are required to periodically purchase additional phone cards in order to obtain service. While wireless service providers offer customers a range of service plans and choices, regardless of how a customer purchases wireless service, all users are required to engage in transactions and make regular payments to maintain their service, not the conduct that is either sought through marketing or exhibited by children 12 years and younger.

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<sup>6</sup> The age of majority in most states is 18, except for two states with the age of 19 (Nebraska and Alabama) and one state with the age of 21 (Mississippi).

In response to the staff's question whether the incorporation of game, camera or music options in some wireless telephones makes them "toys," the answer is no, they do not. These options are ancillary to the wireless phone's primary function and use as a communication device. And while some wireless phones may be brightly colored, and an even smaller percentage may have cartoon characters on them, the primary function of all wireless phones remains to originate and terminate communications. Wireless telephones are competitively marketed based on their ability to provide clear, reliable telephone service on a wireless network.

- ***Consumer Perception***

Not surprisingly, the belief that children 12 years old and younger should not have wireless telephones is widely and deeply held by consumers. In fact, one poll found that only five percent of consumers believed that a child in fifth grade or younger should have a wireless telephone.<sup>7</sup> By contrast, 61 percent believed that high school or college was appropriate.<sup>8</sup> Clearly, wireless telephones are widely recognized as not appropriate -- let alone intended for or commonly used by -- children 12 and younger.

- ***CPSC Age Guidelines***

These widely held consumer beliefs are also reflected in the CPSC Age Guidelines. Indicating that wireless telephones are not designed or intended for children, the guidelines make no reference to actual wireless telephones. Instead, the Guidelines reference mock versions of wireless telephones, which are marketed as toys.<sup>9</sup> At 12 to 18 months, for example, "regardless of whether realistic detail is present, young toddlers hold toy telephones to their ear because they

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<sup>7</sup> See Parker, J. "How young is too young for kids to have cell phones?", available at <http://www.thesunnews.com/news/local/story/830198.html> (discussing 2007 poll by MSN/Zogby) (last viewed March 23, 2009).

<sup>8</sup> *Id.*

<sup>9</sup> CPSC, "AGE DETERMINATION GUIDELINES: Relating Children's Ages To Toy Characteristics and Play Behavior" (Smith, T., ed.) (U.S. Consumer Product Safety Commission, Sept. 2002), at 117, available at <http://www.cpsc.gov/BUSINFO/adg.pdf>.

often see their elders do so. Soon they begin to imitate a phone conversation with babbling and later with words. They also like the cause-and-effect stimuli from pushing buttons and making sounds.”<sup>10</sup> Likewise, children are attracted to mock versions of other “adult” items, including “cash registers, medical kits, [and] kitchen/cooking sets.”<sup>11</sup> These toy versions are distinct from the adult items upon which they are modeled, something that the Guidelines implicitly recognize. In particular, wireless phones are not designed for a child’s play since the “play” activities of pushing buttons and making sounds on a wireless phone will originate a call on a wireless network, at a minimum tying up network resources and generating usage charges, and in the worst case, completing a 9-1-1 call to a Public Safety Answering Point.

- *Practical Considerations*

Finally, in addition to the criteria set forth above, practical considerations indicate that wireless telephones are not primarily intended for use by children 12 years and under. As discussed above, wireless service entails the regular payment of money – not the conduct of children contemplated by the CPSIA. The wireless telephone itself requires responsible care and is not designed for the rough and often careless treatment that younger children accord their toys. Finally, because a wireless telephone is an electronic device, it is not intended to get wet – either by being placed in a child’s mouth or otherwise. Wireless telephones are intended for use by responsible individuals, capable of adhering to important instructions and warnings concerning safe and proper use. All of these factors and considerations demonstrate that wireless telephones are not primarily intended for children 12 and under, as contemplated by Section 108.

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<sup>10</sup> *Id.*

<sup>11</sup> *Id.* at 118.

## 2. Wireless Telephones Are Not Playthings

Wireless phones plainly are not intended “for use by the child when the child plays” as specified by Section 108(e)(1)(B). The additional essential requirement is that the product is intended for “play.” The staff’s guidance posted on the CPSC’s website reiterates that “[t]he use of the product by the child for play is a fundamental aspect” of the determination of what constitutes a “children’s toy” under Section 108.<sup>12</sup>

As the CPSC has recognized, the CPSIA does not define “play.”<sup>13</sup> In the absence of a statutory definition, the staff has looked to the dictionary definition of “play,” ultimately articulating the following language:

- “To occupy oneself in amusement, sport, or other recreation: children playing with toys”
- “Recreational activity; *especially*: the spontaneous activity of children”
- “Exercise or activity for amusement or recreation”<sup>14</sup>

Given the ordinary and reasonable meaning of these words, these definitions of “play” simply do not apply to wireless telephones – whose primary function is communication. To the contrary, these definitions and the word “play” indicate action, exercise, activity and physical exertion. As to the first definition, the terms “amusement” and “sport” are qualified by the phrase “or other recreation.” While wireless telephones are not used in sports, the term “amusement” refers to activity that may be characterized as “recreation.” A wireless telephone does not qualify as recreation.

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<sup>12</sup> CPSC FAQ Regarding Section 108: Products Containing Certain Phthalates, “How do you determine whether a product is a children’s toy for purposes of compliance with the phthalate limits?” *available at* <http://www.cpsc.gov/about/cpsia/faq/108faq.html#108q8> (viewed on March 25, 2009).

<sup>13</sup> CPSC Phthalates Meeting, held March 12, 2009, *video available at* <http://www.cpsc.gov/vnr/asfroot/phthalates03122009.asx> (definition of “play” discussed beginning at 8:22) (*last viewed on* March 23, 2009).

<sup>14</sup> *Id.*; *see also* “CPSIA and PHTHALATES, Scope of Section 108,” presentation slides prepared by Celestine Kiss, CPSC Engineering Psychologist, at page 3, *available at* <http://www.cpsc.gov/about/cpsia/phthalates-kiss.pdf> (*last viewed* March 22, 2009).

This is also made clear by the standard set forth in ASTM F963, which Congress has incorporated by reference into the CPSIA. The Commission staff has indicated that it plans to use the definition of toy in the ASTM F963-07 toy standard for guidance.<sup>15</sup> That standard defines “toy” as “any object designed, manufactured, or marketed as a *plaything* for children under 14 years of age.”<sup>16</sup> As set forth above, wireless telephones are designed and marketed as communications devices – and not as “*playthings*.” Under ASTM F963, they are not “toys.”

### **3. Wireless Telephones Are Not “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.” In addition, if any part of a toy is less than 5 cm in any dimension, then it can be mouthed. 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.

As detailed above, wireless phones do not meet the criteria for a “children’s toy” as defined under Section 108 in the first instance. They are sophisticated communication devices, with complex circuitry required to connect to a carrier’s network, and plainly are not “toys” that can be “mouthed” as contemplated by the statute.

### **4. The Staff Has Publicly Indicated The View That Wireless Telephones Are Not “Children’s Toys” Under Section 108**

At the March 12, 2009 CPSC Public Meeting on Phthalates, the issue of whether a wireless telephone should be considered a “children’s toy” under Section 108 was raised and

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<sup>15</sup> See CPSC FAQ Regarding Preemption, available at <http://www.cpsc.gov/about/cpsia/faq/preemption.html> (last viewed on March 25, 2009) (“The provision mandating the voluntary toy safety standard ASTM F963-07 as a mandatory consumer product safety standard is also preemptive although there Congress has provided a mechanism to grandfather in certain existing state laws on toy safety.”)

<sup>16</sup> *Id.* at 9:05 (emphasis added) (discussing ASTM F963); see also “CPSIA and PHTHALATES, Scope of Section 108,” presentation slides prepared by Celestine Kiss, CPSC Engineering Psychologist, at page 4, available at <http://www.cpsc.gov/about/cpsia/phthalates-kiss.pdf> (last viewed March 22, 2009).

addressed by the staff. Specifically, during the question and answer period of the meeting, the CPSC staff was directly asked whether they considered wireless telephones to be “children’s toys.” The staff, in our view, correctly responded that wireless phones should not be considered a “children’s toy” for purposes of the phthalates requirements under Section 108:

**Question:** “What happens to a cell phone that has games in it? Would that be a toy, or is that covered here?”

**Response:** (Michael Babich, PhD, CPSC Chemical Hazards Program Coordinator) “Well, I think a cell phone is primarily a phone and not a – that happens to have games. If its primary purpose is a toy like a video game, then it’s a toy.”

**Response:** (Joel Recht, Director, CPSC Division of Chemistry): “There’s also the question ‘is it primarily intended for children 12 and under?’ Most cell phones are not primarily intended for children 12 and under.

We submit that even without having the benefit of the additional and specific information supplied in these comments, the staff’s indication that wireless phones are not a “children’s toy” as contemplated under Section 108, with or without ancillary camera, music or game functions, was – and is – the reasonable and correct determination. This determination is consistent with both the purpose and content of the CPSIA.

#### **IV. CONCLUSION**

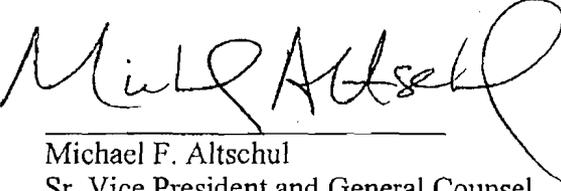
CTIA appreciates the opportunity to submit these comments on a matter of utmost concern to our members and looks forward to working with the CPSC staff to address any questions or concerns the staff may have. We submit that ancillary options and colors and decorations attractive to younger people or the young at heart do not change the primary communications function and purpose of the phone. In other words, the use of bright colors or even cartoon characters as options for the external appearance of the product simply does not transform the wireless phone from a communications device into a “toy” intended for use when a child “plays.” Such a determination, in our view, would be contrary to reason and inconsistent

was – and is – the reasonable and correct determination. This determination is consistent with both the purpose and content of the CPSIA.

#### IV. CONCLUSION

CTIA appreciates the opportunity to submit these comments on a matter of utmost concern to our members and looks forward to working with the CPSC staff to address any questions or concerns the staff may have. We submit that ancillary options and colors and decorations attractive to younger people or the young at heart do not change the primary communications function and purpose of the phone. In other words, the use of bright colors or even cartoon characters as options for the external appearance of the product simply does not transform the wireless phone from a communications device into a “toy” intended for use when a child “plays.” Such a determination, in our view, would be contrary to reason and inconsistent with the intent and purpose of Section 108 of the CPSIA. For all of the reasons stated, CTIA respectfully urges the staff to make clear that wireless phones are communications devices that are not “children’s toys” subject to the phthalates requirements of Section 108.

Respectfully submitted,



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(202) 736-3248

Dated: March 25, 2009



**VIA ELECTRONIC MAIL**

March 25, 2009

Michael A. Babich, Ph.D.  
Directorate for Health Sciences  
U.S. Consumer Product Safety Commission  
4330 East-West Highway  
Suite 600  
Bethesda, MD 20814

Re: Comments of the Phthalate Esters Panel of the American Chemistry Council on "Notice of Availability of Draft Guidance Regarding Which Children's Products Are Subject to the Requirements of CPSIA Section 108"; 74 Fed. Reg. 8058

Dear Dr. Babich,

The Phthalate Esters Panel of the American Chemistry Council (the Panel) is pleased to submit these comments on the U.S. Consumer Products Safety Commission's (CPSC or the Commission) "Notice of Availability of Draft Guidance Regarding Which Children's Products Are Subject to the Requirements of CPSIA Section 108." 74 Fed. Reg. 8058.

**I. INTRODUCTION**

The Panel's members are the BASF Corporation, Eastman Chemical Corporation, ExxonMobil Chemical Company, Ferro Corporation, and Teknor Apex Company. These members represent that vast majority of phthalate esters production in the United States. The Panel hopes its comments will assist the CPSC in effectively and efficiently implementing the requirements in Section 108 of the Consumer Product Safety Improvement Act (CPSIA).

Phthalate esters are a broad category of widely used compounds employed primarily to soften – or plasticize – polyvinyl chloride (PVC). The largest and most important uses are for products used in building and construction, wire and cable, automotive manufacturing, and flooring. Some phthalates have been used in vinyl toys and child-care articles, but vinyl toys and child care articles are a relatively small market for phthalate esters. Phthalates are among the most widely studied chemical compounds in the scientific literature: a number of risk assessments in the U.S. and Europe have shown that they may be safely used in applications due to the low exposure from flexible vinyl products.



As the Commission is undoubtedly well aware, the exact scope of the Section 108 requirements is unclear to the regulated community and has caused widespread confusion and anxiety. CPSC Acting Chairman Nancy Nord's March 20, 2009, letter to Congressman John Dingell highlights the angst, confusion, and unanticipated effects that CPSIA Section 108 has had on manufacturers, retailers and other impacted parties. The Panel thus supports CPSC's efforts to issue clear and concise guidance on what consumer products are subject to the Section 108 requirements and urges the Commission to move forward deliberately and in a common sense fashion.

## **II. THE COMMISSION SHOULD APPLY RISK-BASED ASSESSMENTS THAT CONSIDER AGE AND EXPOSURE**

The February 10, 2009 effective date of the CPSIA has passed, and it thus may be too late to do anything to mitigate the significant economic impact of that deadline. The Panel believes, however, that the CPSC can inject a common sense and scientific approach to its implementation of the CPSIA by regulating products based on the probability of exposure in relation to age. This could be done by applying risk-based assessments that combine mouthing and ingestion data at various ages to help define any group at risk for any given product. The Panel believes that the Commission thus should seek the necessary authority to exercise flexibility in determining the relevant hazards and in determining exemptions based on assessment of risks. The Panel further believes that the Commission should have the discretion to adjust the age limit for certain groups of products where the exposure is low. This approach will ensure the proper focus of the Commission's resources.

## **III. THE COMMISSION SHOULD CLARIFY THE SCOPE AND APPLICABILITY OF SECTION 108'S REQUIREMENTS**

Section 108 of the CPSIA restricts the use in certain children's products of six specified phthalates, which the statute bifurcates into two groups of three phthalates each. The first group consists of DEHP, DBP, and BBP. Section 108(a) makes it unlawful for a children's toy or child care article to "contain[ ] concentrations of more than 0.1 percent" of any of these three. 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.*" § 108(e)(1)(B) (emphasis added). This definition amounts to the definition of "children's product" in Section 235(a) plus the italicized phrase. A "child care article" is defined 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 and teething." § 108(e)(1)(C) (emphasis added).

The second group of regulated phthalates consists of DINP, DIDP, and DnOP. It is unlawful under Section 108(b)(1) for a "children's toy that can be placed in a child's mouth or child care article" to "contain[ ] concentrations of more than 0.1 percent" of each of these. This restriction is interim, pending the creation and report of a Chronic Hazard Advisory Panel (CHAP) and the

Commission's promulgation of a rule in response to the Panel's report. § 108(b)(2)&(3). The applicable definitions of "children's toy" and "child care article" are the same as for the first group, but the restriction regarding a children's toy is expressly limited to a toy "that can be placed in a child's mouth." Section 108(e)(2)(B) defines this quoted phrase.

**A. CPSC Should Ensure That The Scope of Section 108 Addresses Risk Of Children's Exposure and Not Simply the Use of a Regulated Product.**

In determining what products are subject to the restrictions in Section 108 of the CPSIA, the Panel believes that the Commission must consider whether a child is exposed to phthalates through the product and the routes of exposure. For example, the Chronic Hazard Advisory Panel mandated by Section 108(b)(2), whose report should play a significant role in determining the future of these interim prohibitions, must consider "the likely level of . . . exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of" products for children. § 108(b)(2)(B). It also must consider "the cumulative effect of total exposure to phthalates." *Id.* And it specifically must consider "ingestion," "dermal," and "hand-to-mouth" exposure, as well as any "other exposure." *Id.* Finally, the CHAP is to take into account "uncertainties regarding exposure." *Id.*

Moreover, the statutory definitions of "children's toy" and "child care article" reinforce this overarching concern of Section 108 with exposure. A "children's toy" is a product designed or intended for "*use by the child*" when the child plays. "Use" indicates contact, which is a potential source of exposure. The definition of "child care article" is even narrower. It does not extend to all uses of the product by a child three years or younger; rather, such use must directly facilitate sleep, feeding, sucking, or teething. A product to "help" a child "with sucking or teething" will be one on which a child sucks or teethes—creating a particular risk of exposure. The activities referenced above involve mouthing behavior as a pre-requisite. That is why the Commission's prior efforts regarding phthalates, as far back as the 1980s, have focused on teething rings, rattles, and pacifiers—all items that a child puts in his mouth. Similarly, the statutory reference to a product designed or intended "to facilitate sleep or the feeding of" a young child (including a pacifier) is most reasonably understood as one that the child will use for that purpose, meaning that he will come into contact with it.

Section 108(e)'s definition of mouthability and Section 108(b)(1)'s express limitation of the regulation of three high molecular weight (HMW) phthalates in children's toys to those that are mouthable, reinforce the clear intent that these restrictions be based on oral exposure or use. The definition contrasts a toy that "can be sucked and chewed" with one that only can "be licked." Both common sense and (as explained below) the legislative and scientific evidence indicate that the former is a much greater potential source of exposure than the latter, even though licking also may cause exposure. With the three interim-restricted phthalates, Congress (consistent with the European Union and California) sought to focus on this primary risk of oral exposure. The European Union's phthalate regulations reinforce this point.

**B. Section 108(b)'s Interim Prohibition Focuses on Mouthability and Applies Only to Mouthable Products or Component Parts.**

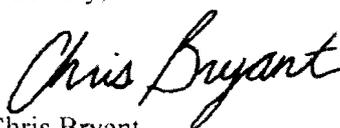
The Commission should clarify that the interim prohibition Section 108(b)(1) applies only to product components that can be mouthed, whether the components are in children's toys or child care articles. Congress limited the interim prohibition regarding children's toys to those that can be mouthed but did not include a similarly explicit qualification regarding child care articles. But that is because Congress defined the term "child care article" so as implicitly to require mouthability or at least be consistent with such a qualification. By contrast with the definition of "children's toy" there is a close parallel between Section 108's definition of mouthability and its definition of "child care article." This parallel readily allows the Commission to read "child care article" as an article that can be placed in the mouth.

The European Union's Directive distinguishes between DEHP, DBP, and BBP, on the one hand, and DINP, DIDP, and DNOP, on the other. *See* Directive 2005/84/EC, Annex. Also like Section 108, the Directive imposes a 0.1% limitation on the presence of the former category of phthalates in plasticized material in any toys and child care articles without regard to mouthability, but includes a mouthability qualification in regulating the latter category of phthalates. Specifically, the EU provides that the three phthalates at issue in Section 108(b)'s interim prohibition "[s]hall not be used as substances or as constituents of preparations at concentrations greater than 0.1% by mass of the plasticized material, in toys and childcare articles which can be placed in the mouth by children." *Id.* California too distinguishes between the two categories of phthalates and, likewise, for the second category has a mouthability qualification for both toys and child care articles.

\* \* \*

The Panel appreciates the opportunity to comment on this important issue. We look forward to working with the CPSC on its implementation of the CPSIA and the forthcoming CHAP. If you have any questions or require additional information, please do not hesitate to contact me at [chris\\_bryant@americanchemistry.com](mailto:chris_bryant@americanchemistry.com) or (703) 741-5609.

Sincerely,



Chris Bryant  
Managing Director  
Chemical Products and Technology Division  
American Chemistry Council

**Stevenson, Todd**

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**From:** Palfrey, Heather [Heather\_Palfrey@americanchemistry.com]  
**Sent:** Wednesday, March 25, 2009 4:50 PM  
**To:** Section 108 Definitions  
**Subject:** FW: Section 108 Guidance Comments  
**Attachments:** Section 108 Guidance Comments.pdf

Submitted on behalf of Christopher Bryant and the Phthalate Esters Panel of the American Chemistry Council:

Please find appended Comments of the Phthalate Esters Panel of the American Chemistry Council on "Notice of Availability of Draft Guidance Regarding Which Children's Products Are Subject to the Requirement of CPSIA Sections 108"; 74 Fed. Reg. 8058

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aquatic sports suppliers association

VIA ELECTRONIC MAIL: [section108definitions@cpsc.gov](mailto:section108definitions@cpsc.gov)

March 25, 2009

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

**Re: 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**

Dear Secretary of the U.S. Consumer Product Safety Commission:

On behalf of various manufacturers, importers and retailers involved in the production, distribution and retail sale of products intended for use at the beach and in swimming pools, the Aquatic Sports Suppliers Association is filing these timely comments in response to the request by the U.S. Consumer Product Safety Commission ("CPSC") for comments (due March 25, 2009) concerning the agency's above-referenced draft guidance published in the Federal Register on Monday, February 23, 2009. Specifically, we respectfully request that CPSC not classify certain pool and beach products as "children's toys" subject to the phthalate restrictions of Section 108(a) of the Consumer Product Safety Improvement Act ("CPSIA"), or as toys that can be placed in a child's mouth and therefore subject to the additional phthalate restrictions of Section 108(b).

**BACKGROUND**

Our membership strongly believes that most pool and beach products (with some exceptions) should be treated as a product class that is exempt from the restrictions of Section 108. As discussed below, while many pool and beach products can certainly be used during play by children 12 and under, most are geared to consumers of all ages and cannot be limited to this age range. In addition, a large percentage of pool and beach products serve a functional purpose as swimming and safety aids that should not be categorized as "children's toys" (which are defined in Section 108(e)(1)(B) as consumer products "designed or intended by the manufacturer for a child 12 years of age and younger for use *when the child plays*" (emphasis added)). Finally, many pool and beach items are the functional equivalent of land-based playground and athletic equipment, and

as such, should not be considered children's toys. This position is supported by CPSC's own reference to exclusions for playground and sporting equipment from the ASTM F963 toy definition.

In its request for comments, CPSC has cited a few pool and beach items as examples of products for which it is contemplating Section 108 coverage (i.e., decorative swim goggles, water wings, and wading pools). We believe that the inclusion of this list, along with other statements in the draft guidance document, gives the impression that CPSC is intending to treat all products intended for play or other recreational activities at the pool or beach as *children's* toys, regardless of their specific use or function, or age range of their intended users, simply because children 12 and under might use them. The draft guidance also indicates that all inflatable products that might be used by children would be considered as toys that can be placed in a child's mouth when in the deflated state, regardless of the fact that children would not use them for play in the deflated state.

On behalf of our membership, we respectfully submit comments addressing these and other points below.

## COMMENTS

### A. Pool and Beach Products Not Considered "Children's Toys"

Although some of our members' products are clearly designed solely as "children's toys", we believe that products designed as swimming and safety aids for children are not toys at all, because they are not primarily designed for play, but rather to help children to learn to swim and to stay afloat in water. In addition, many of our members' products are designed for wider age groups, including teenagers and sometimes adults as well, or for entire families in general, and we believe that Section 108 should not apply to them merely because children 12 and younger might be among a wider group of individuals that plays with them. We discuss such products in Points (i) and (ii) below.

#### *(1) Pool and Beach Products that Serve a Functional Purpose*

The following are examples of products that are **designed to help children swim, learn to swim, or stay afloat in water**. They serve sporting, training or safety functions, regardless of whether the child is swimming, floating or otherwise playing, and should not be considered as toys of any sort:

- Child-sized goggles, masks, snorkels and flippers (whether or not decorated)
- Nose clips
- Swim caps
- Swim gloves
- Inflatable water wings, arm bands and chest-encircling rings
- Flotation vests and suits

- Life vests<sup>1</sup>
- Kick boards
- Floating infant and toddler seats

Items such as nose clips, swim caps and kick boards are also used by adults when swimming. In addition, child-sized goggles, masks, snorkels and flippers are examples of products that should be considered sporting goods and athletic equipment subject to exclusion from the definition of a “toy” consistent with the exclusion for sporting goods under ASTM F963-07. Floating infant and toddler seats should not be considered toys any more than are their land-based equivalents (e.g., infant seats and walkers).

(2) ***Products Intended for, and Used by, Individuals of All Ages, Including Sporting Goods and Athletic Equipment***

The following are examples of inflatable products that are designed for use in the pool or on the beach. The use of such products is not restricted by the size and, therefore, the age of the individual. These products are **designed for use by individuals of all ages**. Accordingly, they should not be categorized as “children’s toys” subject to Section 108(a) of the CPSIA. :

- Larger Beach balls
- Larger flotation rings
- Rafts in the shape of fish or animals that one simply lies on or sits astride
- “Noodles”

The following are examples of inflatable products that are designed to accommodate older and larger children (including adults) as well as those 12 and younger, and should therefore not be categorized as “children’s toys” subject to Section 108(a) of the CPSIA:

- Tube slides
- Floating cubes and other shapes
- Floating islands
- Floating lounge chairs
- Floating habitat systems
- Other floats with ride-on capability

The following are examples of **sporting goods and athletic products** that, although not “regulation-sized”, are designed to be used by older and larger individuals in addition to children 12 and younger, including entire families. They should also not be categorized as “children’s toys” subject to Section 108(a) of the CPSIA, consistent with the exemptions for similar items from the definition of toys under ASTM F963.

- Pool basketball kits with floating or pool-side nets
- Water polo kits with floating goals

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<sup>1</sup> Regulated by the US Coast Guard, not the CPSC.

- Volleyball kits with floating nets
- Badminton kits with pool-wide nets
- Ping-pong kits with floating tables
- Floating pool golf
- Paddle games, including those with floating nets
- Floating ring toss
- Dive games
- Other underwater games

In addition to the products above, we respectfully submit that **inflatable pools** (without filtration systems), including toddler wading pools, should be exempt from the classification as “children’s toys” because they are not themselves items that can be played with. Though they may not be in the same category as sporting goods or athletic equipment, such items are simply structural products that allow consumers to wade or swim, and are not playthings in and of themselves.

**B. Inflatable Products Not Considered Toys in Deflated State**

Section 108(e)(2)(B) of the CPSIA considers a toy as one 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 by a child so that it can be sucked and chewed (but not simply licked), or if the toy or a part of the toy is smaller than 5 cm in any one dimension. Many of the products distributed and sold by our member companies, such as small pools, rafts, raft-like floating pool toys, and beach balls, are inflatable, being sold in the deflated state and designed to be inflated and deflated by the consumer. The draft guidance indicates that CPSC staff has concluded that some of these products must be considered in the deflated state when determining whether they are toys that can be placed in the mouth. However, we respectfully submit that (a) inflatable toys designed for a wider age group than just children 12 and younger should, once again, not be considered children’s toys, regardless of their dimensions when deflated, and (b) an inflatable toy designed for children 12 and younger should not be considered a “children’s toy” at all when in the deflated state, since it no longer has any play function in that state – it does not become a toy until it is inflated. This is comparable to a self-assembly furniture kit, for example, which cannot be considered a usable item of furniture until it is actually assembled.

The following are examples of inflatable products which might be toys when inflated, but which should not be considered to be toys when in the deflated state, since in that state they serve no play function. Therefore, if they are not toys in the deflated state, they cannot be considered toys that can be placed in a child’s mouth and subject to Section 108(b) of the CPSIA, regardless of their dimensions in the deflated state. Moreover, all but the smallest items normally require a pump, such as a bicycle pump, foot pump or even electric pump, to inflate, in many cases by an older child or adult, and therefore, there would be no unavoidable oral contact when inflating the product. Deflated pool and beach equipment is no more a toy than a deflated adult raft or air mattress, a tent groundsheet or a folded tarpaulin.

- Any products described in the previous section above
- Boats, child-sized rafts, animal-shaped rings
- Castles, vehicles, see-saws, water wheels, igloos and other shapes with child-sized seats and open compartments
- Boats and rings with attached water squirters
- Floating arcades and games

**C. Even If Considered Aquatic Toys Such Products Require Adult Supervision**

Pursuant to voluntary industry standards, “aquatic toys and their packages” are required to bear warning labels conveying that the aquatic toys are not lifesaving devices and that children should not be left unattended while the device is in use. [See Section 5.4 of ASTM F963-07: *Standard Consumer Safety Specification for Toy Safety*]. Accordingly, even if any of the above-described products may be considered toys for the purposes of Section 108, the warning labels affixed to these products would direct consumers to always supervise children while these products would be used by children. As such, the likelihood of any hazardous exposure to any phthalate content (i.e., mouthing or other ingestion) would be minimized due to such supervision.

**D. Dermal Absorption of Phthalates Not Likely from Pool and Beach Products**

As noted above, we believe that the categories of pool and beach products discussed previously should be exempt from the Section 108 phthalate restrictions because they are not considered “toys” for the purposes of the CPSIA. Notwithstanding whether a product may be classified as a toy, sporting good, or other commodity, we believe that it is important to consider the current scientific literature concerning the likelihood of dermal phthalate absorption from plastic products.

Most of the scientific research on human absorption of phthalates has concentrated on two exposure routes: (i) the oral route (primarily through products designed to be placed in the mouth and chewed or sucked, such as pacifiers, baby bottle nipples, and teethers, or directly through phthalates in the diet); or (ii) the parental route (intravenous administration of fluids via polyvinyl chloride [PVC] tubing). Transfer and transdermal absorption of phthalates from PVC products by humans has been widely assumed but barely investigated. Furthermore, phthalates, especially the higher molecular weight species typically used in PVC, have high solubility in organic solvents such as hexane and dichloromethane, but low solubility in water and, by extension, human sweat, indicating that such low solubility would present a considerable obstacle to transfer and absorption. As a result, we believe that any phthalate content that may exist in a plastic pool or beach item would not likely be absorbed transdermally through normal contact in a pool or beach setting.

A 2007 study by Janjua et al.<sup>2</sup> was reportedly the first to attempt to measure transdermal absorption of phthalates by humans, and is the only such study cited in a recent report on phthalate exposure by the National Research Council.<sup>3</sup> This study actually tested phthalates in a skin cream preparation applied directly to the skin of the entire body. The study compared transdermal absorption of two phthalates (including just one of the six, DBP, that are listed in Section 108), and showed that DBP, the phthalate with the higher molecular weight, appeared to be absorbed to a far lesser extent than DEP, the one with the lower molecular weight. The other five phthalates banned by CPSC are of even higher molecular weights than those evaluated in this study, and therefore, it is likely that transdermal absorption of these phthalates, if it were to occur to any detectable extent, would be even lower, since molecular weight is a determining factor in transdermal absorption. Moreover, phthalates contained in a plastic pool or beach product would be less likely to be absorbed transdermally than phthalates in a skin cream applied directly to the surface of the skin.

In conclusion, measurable transfer of any phthalates from a PVC product via the transdermal route in humans remains unproven. In the case of inflatable products used in the pool or at the beach, the pool water or ocean water itself would likely offer virtually infinite dilution of any phthalates hypothetically transferred from the products to the surface of the skin via the sweat. Thus, any risk of transdermal absorption of these phthalates as a result of using inflatable products in a pool or beach setting appears infinitesimal.

#### **REQUEST FOR MEETING**

The Aquatic Sports Suppliers Association would like to meet with CPSC staff to further discuss our comments and exemption requests. We believe that a meeting would allow us to better display and demonstrate the use and functionality of the pool and beach products discussed herein. In addition, we would like to discuss the serious economic impact that Section 108 retroactivity is having on the pool and beach product industry, especially where the industry relied in good faith on the advisory opinion of the CPSC

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<sup>2</sup> Janjua NR, Mortensen GK, Andersson AM, Kongshoj B, Skakkebaek NE, Wulf HC. Systemic uptake of diethyl phthalate, dibutyl phthalate, and butyl paraben following whole-body topical application and reproductive and thyroid hormone levels in humans. *Environ Sci Technol.* 2007 Aug 1; 41(15): 5564-5570. In this study, Janjua et al. investigated not the more relevant transfer of phthalates from PVC plastic onto and through the skin, but absorption from a 2% (w/w) skin cream preparation applied directly to the entire body once a day for one week. The only phthalates tested were of low molecular weight, namely diethyl phthalate (DEP) and dibutyl phthalate (DBP). DEP, which has the lower molecular weight of the two, is not banned under the CPSIA, and is not normally used in plastics. DBP, although it has the higher molecular weight of the two tested phthalates, has the lowest molecular weight of the six phthalates banned by the CPSIA. Molecular weight is a determining factor in transdermal absorption, with higher molecular weight compounds more resistant to absorption than similar compounds with lower molecular weights. In the Janjua et al. study, initial metabolites of both compounds (the monoesters monoethyl phthalate, MEP, and monobutyl phthalate, MBP) were detected in the serum following application of the whole-body skin cream, but the peak level of the higher molecular weight MBP was *20 times lower* than that of MEP, indicating a sharp drop-off in absorption with increased molecular weight.

<sup>3</sup> National Research Council of the National Academies. "Phthalates and Cumulative Risk Assessment." 2008; National Academies Press, Washington, D.C.

General Counsel that Section 108 would not be retroactive, and the likelihood that such retroactivity is an unconstitutional “taking” of property (i.e., in the form of unsold inventory that would require destruction). We would also like to discuss difficulties that our membership is encountering with phthalate testing protocols being employed by independent laboratories in terms of exorbitant testing fees, variable results, and the reluctance of laboratories to issue conclusory reports using the CPSC’s most current proposal for testing phthalate content under Section 108.

Thank you for your consideration of this submission.

*Aquatic Sports Suppliers Association*

**Stevenson, Todd**

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**From:** Huber, Cathi [HuberC@ARENTFOX.COM] on behalf of Ravitz, Georgia [Ravitz.Georgia@ARENTFOX.COM]  
**Sent:** Wednesday, March 25, 2009 4:50 PM  
**To:** Section 108 Definitions  
**Cc:** Ravitz, Georgia; Cohn, Scott; Edwards, Robert G.  
**Subject:** Comment Letter  
**Attachments:** Document.pdf

Please see attached comments that we are filing on behalf of our client, the Aquatic Sports Suppliers Association. If you have any questions, please do not hesitate to contact our offices.

*Cathi Huber  
Legal Assistant to Georgia C. Ravitz, Esq.  
James R. Ravitz, Esq., Amy Swift Colvin, Esq. &  
James H. Hartten  
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IRS Circular 230 disclosure: To ensure compliance with requirements imposed by the IRS, we inform you that, unless expressly stated otherwise, any U.S. federal tax advice contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.



Association of the  
Nonwoven Fabrics Industry

March 25, 2009

**VIA EMAIL**

Office of the Secretary  
Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, Maryland 20814

**Re: Notice of Availability of Draft Guidance Regarding Which Children's Products Are Subject to the Requirements of CPSIA Section 108, 74 Fed. Reg. 8058 (Feb. 23, 2009)**

I am writing on behalf of INDA, Association of the Nonwoven Fabrics Industry in response to the U.S. Consumer Product Safety Commission's (CPSC) February 23, 2009 request for public input on CPSC's staff's draft guidance addressing which products constitute a "children's toy or child care article" and are subject to the requirements of Section 108 of the of the Consumer Product Safety Improvement Act (CPSIA). For the reasons discussed below, INDA urges the CPSC to adopt the staff's conclusion that disposable diapers are not subject to the requirements of Section 108.

By way of background, INDA is the recognized trade association of the nonwoven fabrics industry, a multi-billion dollar industry in the United States. Products made by INDA members are used in scores of end-use applications, among them hygiene absorbent products like disposable diapers, training pants, adult incontinence products and more. INDA members who manufacture these items include familiar names like Procter & Gamble and Kimberly-Clark Corporation, to name just a few.

INDA would like to express support for the CPSC staff's position in the draft guidance that "diapering products" do not fall within the scope of Section 108 of the CPSIA. As we will elaborate upon below, CPSC staff was correct to exclude things like disposable diapers and training pants from the Section 108 requirements because they neither meet the statutory definition of "children's toy or child care article," nor do they pose any significant risk of exposure to the identified phthalates.

**I. Diapers Do Not Meet the Statutory Definition of Section 108 Impacted Products**

Section 108 of the CPSIA prohibits the sale of any "children's toy or child care article" containing more than 0.1 percent of three specified phthalates and on an interim basis, 0.1 percent of three additional phthalates. Under the law, 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." As parents, caregivers and other consumers know, diapers are designed with one function in mind: to contain waste. Clearly, they are not designed or intended "for use by the child when the child plays."

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Phone: (703) 521-0545 Email: jfranken@inda.org

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Moreover, disposable diapers and training pants do not fall under the CPSIA's statutory definition of "child care articles" -- consumer products, "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." Again, although somewhat axiomatic, these products are not designed with the intent of inducing sleep or facilitating eating, nor are they designed to help children with sucking or teething. The primary function of these products is to contain waste -- nothing more.

## **II. Testing Reveals Diapers, Training Pants Pose No Significant Phthalate Exposure Risk**

Perhaps more significant than the statutory definitions, these products have been appropriately tested under established protocols and determined to be free of detectable levels of phthalates. Accordingly, they pose no significant risk of exposure to these substances.

INDA notes with approval the comments submitted by the Personal Absorbent Products Council (PAPC),<sup>1</sup> where it describes testing of diapers and training pants under Test Method CPSC-CH-C1001-09, Standard Operating Procedure for the Determination of Phthalates. PAPC sponsored a phthalates testing program for disposable diapers, testing a representative sample from seven major disposable diaper manufacturers. Those samples were sent to an accredited analytical laboratory known for its ultra-low trace analysis capabilities. The laboratory conducted sample extraction and phthalate analysis for the six specific phthalates included in the CPSIA using test methods capable of detecting phthalates at the ultra-low level of 0.000005%.

Using this method, the lab was unable to detect the presence of five of the six specified phthalates. For the one phthalate that did register, DEHP, the highest value detected was 0.00039%, two orders of magnitude below the 0.03% level of detection for CPSC-CH-C1001-09 Standard Operating Procedure for the Determination of Phthalates. The tests make clear that disposable diapering products are well below both the CPSIA statutory level of concern (0.1%), as well as the limit of detection using the CPSC official test method.

### **Conclusion**

INDA and its members would like to thank the Commission for the opportunity to provide input on the appropriate scope of the Section 108 requirements. Should you have any questions or need any further information, please do not hesitate to contact me directly at 703/521-0545 or at [jfranken@inda.org](mailto:jfranken@inda.org).

Sincerely,



Jessica E. Franken  
Director of Government Affairs

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<sup>1</sup> PAPC is a trade association representing absorbent products manufacturers, and, as such, has an overlapping membership with INDA. However, the two associations are not affiliated organizations.

## Stevenson, Todd

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**From:** JFranken@aol.com  
**Sent:** Wednesday, March 25, 2009 5:03 PM  
**To:** Section 108 Definitions  
**Subject:** INDA Comments on CPSIA Sec.108 Draft Guidance  
**Attachments:** INDACommentsSec108.3.25.09.pdf

Office of the Secretary  
Consumer Product Safety Commission

To whom it may concern:

INDA, Association of the Nonwoven Fabrics Industry is pleased to submit the attached comments responding to CPSC's draft guidance regarding which children's products are subject to the requirements of CPSIA Section 108.

Please feel free to contact me directly if you have any questions or need any further information.

Thank you,

Jessica Franken  
Director of Government Affairs  
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March 25, 2009

Office of the Secretary  
Consumer Product Safety Commission  
4330 East West Highway  
Room 502  
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 Sir/Madam:

Thank you for the opportunity to comment on the CPSC staff's draft approach for determining which products are subject to the requirements of section 108 of the CPSIA.

National Paint & Coatings Association, Inc. (NPCA), is a voluntary, nonprofit, trade association representing some 400 manufacturers of paints, coatings, adhesives, sealants, and caulks, raw materials suppliers to the industry, and product distributors. As the preeminent organization representing the coatings industry in the United States, NPCA's primary role is to serve as ally and advocate on the legislative, regulatory, and judicial issues at the international, federal, state, and local levels.

NPCA's Caulks, Sealants and Adhesives Committee is comprised of members that manufacture glue and adhesive products for industrial, institutional, field-applied, and consumer uses, including non-toxic glue and glue sticks for use in schools and in art projects. Our members also include those companies who supply raw materials for caulks, sealants and adhesives.

NPCA's CSA Committee has long been involved in regulatory activities that impact the manufacture, packaging, marketing and use of caulks, sealant and adhesive products in states and the Federal level. Our goal is to assist a regulatory agency achieve its goals without unduly damaging our products' characteristics. In this instance, we hope to be able to demonstrate to the CPSC staff that "toys and children's products" should be appropriately defined so as to include those consumer items that are play items for children. While NPCA believes that the Consumer Product Safety Improvement Act (CPSIA) will undoubtedly increase the ability of the CPSC to protect the nation's children from

potentially harmful toys and children's products; however, the CPSC needs to take action to ensure that the global supply chain for other consumer products is not unduly burdened by the General Conformity Certification requirements in this new law.

## **General Comments**

### **Glues and adhesives are not "children's toys" under section 108 of the CPSIA**

Glues and adhesive products, such as glue sticks, are not toys as defined by Section 108 of the CPSIA. "Children's toys" are 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*." (emphasis added). The phrase "when the child plays" is very important and serves to qualify the entire definition. Clearly, the definition is not intended to include every single consumer product that a child may use up until the time the child becomes 12 years of age. This phrase "when the child plays" makes it clear that only a subset of those consumer products will be considered a toy.

According to Websters.com, a toy is defined as "an object, often a small representation of something familiar, as an animal or person, for children or others to play with; plaything." As you can see, even in the common definition of toy, one point is made clear -- the item's purpose is for play. Consequently, the intrinsic play value of an item is what distinguishes a toy from a consumer product that could be used by children.

Clues to the intrinsic play value of a toy can be ascertained by examining how the item is used, how the item is packaged and marketed. For instance, glues and adhesives are not used by very small children under the age of three (3). Generally speaking, these glue and adhesive products like glue sticks are used by children in school and other highly supervised situations. In fact, glue sticks are usually included on a list of school supplies for elementary school children. These items are tools for school children and their play value is very low.

The packaging and marketing of the glue sticks and other adhesive products also support a very low "play value". Most of the glue sticks products actually make a claim on the label that they are appropriate for use in school or for education purposes. In addition, shelf placement in retail stores for these products indicates that they are not found in the toy aisle, rather they are placed in the school and office supply section of retail stores. This packaging and marketing behavior further supports the argument that glue sticks and similar adhesive products are not toys -- they are art materials and tools.

Glues and adhesives are art materials and tools. The Age Determination Guidelines do not include these products as appropriate for children under the age of 3. And even for children at age 3 and above, these items are referred to as tools used by children mostly in classroom or supervised situations when engaging in creative activities. As such art materials, glues are regulated under the Labeling of Hazardous Art Materials Act and subject to more stringent oversight in its manufacture, packaging and labeling.

## **CPSC Questions**

### **I. General Approach**

NPCA agrees that a protocol or other specific guidance should be issued to help manufacturers determine which particular products fall under the purview of Section 108 of the CPSIA. While NPCA appreciates the complexity of this question, we do not believe that the staff's approach results in clear guidance as to whether a particular product is subject to the testing and certification requirements of Section 108.

The draft guidance is problematic for two reasons; First, two of the initial questions do not focus on the "play" value of these consumer products. While the first question properly asks whether the intended use of the product is "for play", the next two questions do not. These two questions merely inquire as to whether the products are intended for "use" by a child. See 74 FR 8058, 8059 (February 23, 2009). NPCA believes that the "use" by a child is not sufficient to bring a product under the jurisdiction of Section 108 as Congress intended to include only those products that are "children's toys or child care articles".

The second problem with the draft guidance is that there appears to be a discrepancy between the Age Determination Guidelines and the ASTM F963-07 Standard with regard to the treatment of art materials, specifically glue and adhesive products. While the Age Determination Guidelines includes non-toxic glue as an appropriate art material for children at the age of three (3) and beyond, it is not clear that this document designates all art materials as toys. ASTM F963, however, clearly excludes art materials from the definition of toy. Therefore, the staff's guidance includes consideration of two documents which could lead to opposite results for certain art materials, including non-toxic glues.

The two questions can be addressed by making it clear that the focus of the questions must be on the play value of the items in question. For instance, “whether the product is represented in its packaging, display, promotion or advertising as appropriate for use by the ages specified” should be modified to focus the question on the play value of the item as follows: “whether the product is represented in its packaging, display, promotion or advertising as appropriate for *play use* by the ages specified”. The next question should be focused in a similar fashion: “whether the product is commonly recognized by consumers as being intended for *play use* by a child of the ages specified”.

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

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

NPCA recommends that CPSC staff follow the exclusions discussed in the ASTM F963-07 standard. Art and craft materials are generally excluded from the standard as these products are subject to the requirements of the Labeling of Hazardous Art Materials Act (LHAMA). Not only are the product formulations required to be reviewed by a qualified toxicologist, but these products are subject to more stringent labeling requirements.

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

Other classes of products which should be excluded from the definition of a toy include those items that are manufactured to appeal to children but, because of the nature of the product, have no play value. Examples of these types of products include wallpaper, pictures, hangers and hooks. Many of these products are manufactured to appeal to children by using child-friendly decorations or color schemes.

NPCA argues that the presence of child-friendly decoration should not be a determining factor as to whether the product should be considered a toy or even a children's product. We reiterate the fact that the critical factor is the intrinsic play value of the consumer product should determine its status as both a children's product and a children's toy. Furthermore, we believe that items with child friendly decoration that are intended for use as utility items, such wallpaper, pictures, hangers and hooks are not children's products at all. While a child may come in contact with these items on a limited basis, the product is designed and intended for adult use.

## Conclusion

NPCA appreciates the opportunity to share its concerns and suggestions with regard to the draft guidance for determining which products constitute a “children’s toy or child care article.” As discussed above, NPCA believes that the draft questions need to focus intently on the “play value” of a consumer product and that child-friendly decorations are not a determining factor. In addition, NPCA recommends that the ASTM standard F963’s list of products excluded from the definition of a toy should be controlling. Further, NPCA argues that art materials and tools should be exempt from the Section 108 definition due to the stringent requirements of the LHAMA.

NPCA’s Caulks, Sealants and Adhesives Committee is happy to provide any further clarification or information regarding these products and our arguments. Please do not hesitate to contact me if there is additional information that we can provide.

Respectfully submitted,

Heidi K. McAuliffe, Esq.  
Counsel, Government Affairs  
National Paint & Coatings Association, Inc.

**Stevenson, Todd**

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**From:** Heidi McAuliffe [HMcauliffe@paint.org]  
**Sent:** Wednesday, March 25, 2009 5:06 PM  
**To:** Section 108 Definitions  
**Cc:** Heidi McAuliffe  
**Subject:** Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108.  
**Attachments:** CPSIA 108 comment letter.doc

Dear Mr. Stevenson,

Please accept the attached comment letter from the Caulks, Sealants and Adhesives Committee of the National Paint & Coatings Association, Inc. on the Draft Guidance regarding which children's products are subject to the requirements of CPSIA Section 108. If you have any questions or are unable to open the attachment, please do not hesitate to contact me.

Best regards,

*Heidi K. McAuliffe*

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March 25, 2009

Mr. Todd Stevenson  
Office of the Secretary  
Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, Maryland 20814

**RE: JPMA Supplemental Comments on CPSIA Section 108's Draft Guidance Phthalate Requirements for Certain Toys and Child Care Articles**

The Juvenile Products Manufacturers Association (JPMA) is a not-for-profit trade association representing the producers, importers, or distributors of a broad range of childcare articles that provide protection to infants and assistance to their caregivers. JPMA is submitting these comments in response to the Commission's request for additional comments on the Staff's Draft Guidance regarding which children's products are subject to Section 108 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA" or the "Act") (see 74 Fed. Reg. 8058, Feb. 23, 2009).

JPMA believes that these comments will assist the Commission in effectively implementing first time U.S. regulations governing the use of phthalates in certain children's products. Since these regulations specifically target many of our members' products, these issues are extremely important to the Association's nearly 300 members. JPMA has previously submitted comments on Section 108 in response to the Staff's request for general comments. The purpose of the present comment is to provide our supplemental views on the Draft Guidance, and to address issues related to particular product classes within the narrowly defined regulated childcare articles. The Association reserves the right to amend or supplement these comments.

Section 108 of CPSIA permanently prohibits the sale of any further defined "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) and also prohibits on an interim basis "toys that can be placed in a child's mouth" 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 terms in Section 108, and the definitions apply only to this section of the Act. However, the language of other provisions of the Act has a direct bearing on how these terms may be interpreted. In addition, the genesis of the adopted phthalates restrictions should be considered since they have a direct bearing the potential risks, or the lack thereof, and the nature of implementing regulations that should reasonably be developed. The CPSC in requesting additional comment has provided illustrations of the staff's approach to establishing a framework for evaluating products subject to restriction, but have recognized that conclusions that are generally true for a class of products may not necessarily apply to each specific product in that class. Also given the statutory language, the

manufacturers stated intent and the manner in which a product is marked, advertised, marketed and promoted may have a significant impact on whether or not the product falls within or outside the scope of standard. The requirements of Section 108 apply to subsets of “consumer products” as defined by the Consumer Product Safety Act (CPSA). Similarly the requirements may also be considered as a further subset of “children’s products” as defined under the Act.

Complicating matters even further, some products may fall under the jurisdiction of other agencies. For example, articles such as infant bottles, cups, breast pumps, and teethers (with a claimed medical benefit) are primarily under the jurisdiction 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 has contended that it generally has jurisdiction over the outer portion of the product that may have additional entertainment value which directly contacts the consumer user. However, Section 108 is based on phthalate concentration within the product and does not distinguish between exposure pathways. Congress established the phthalate bans as a CPSA standard, notwithstanding the fact that “feeding, sucking, and teething” products often would fall squarely within the jurisdiction of the U.S. Food and Drug Administration under the Food Drug and Cosmetics Act (“FDCA”). Therefore, for the purpose of CPSIA, CPSC staff has asserted that under Section 108, articles such as infant bottles, cups, certain teething products, and pacifiers may be regarded as consumer products under the CPSA, only for such the purpose of applying these restrictions.

## **GENERAL APPROACH**

The CPSC staff has requested comments on staff’s approach to determining which products are subject to the requirements of CPSIA Section 108, whether the limited guidance provided thus far has been clear, whether modifications are warranted and whether alternative approaches should be employed.

### **Scope and Applicability of Statutory Requirements**

As we’ve noted a “children’s toy” is defined as “a consumer product designed or intended by the manufacturer primarily for a child 12 years of age or younger *for use by the child when the child plays.*” § 108(e) (1) (B) (emphasis added). This definition amounts to the definition of “children’s product” in Section 235(a) plus the italicized phrase. A “child care article” is defined 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 and teething.” § 108(e) (1) (C) (emphasis added). The second group of regulated phthalates consists of those known as DINP, DIDP, and DnOP. This restriction is interim, pending the creation and report of a Chronic Hazard Advisory Panel pursuant to § 108(b) (2) & (3). The applicable definitions of “children’s toy” and “child care article” are the same as for the first group, but the restriction regarding a children’s toy is expressly limited to a toy “that can be placed in a child’s mouth.” Section 108(e) (2) (B) defines this quoted phrase.

### **Risks of Children’s Exposure to the Specified Phthalates, Not Mere Use of a Product Should Govern**

There are several reasons that the Commission, at least in applying Section 108(b)'s interim prohibitions on DINP, DIDP, and DnOP, may and should, consistent with the statutory text, consider the potential for exposure of a child to phthalates from a toy. The Chronic Hazard Advisory Panel mandated by Section 108(b)(2), whose report will play a large role in determining the future of these interim prohibitions, must consider "the likely level of . . . exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of" products for children. § 108(b) (2) (B). It also must consider "the cumulative effect of total exposure to phthalates." *Id.* And it specifically must consider "ingestion," "dermal," and "hand-to-mouth" exposure, as well as any "other exposure." *Id.* Finally, the Panel is to take into account "uncertainties regarding exposure." *Id.* Second, the statutory definitions of "children's toy" and "child care article" reinforce this overarching concern of Section 108 with exposure. A "children's toy" is a product designed or intended for "*use by the child*" when the child plays. "Use" indicates contact, which is a potential source of exposure. The definition of "child care article" is even narrower. It does not extend to all use of the product by a child three years or younger; rather, such use must directly facilitate sleep, feeding, sucking, or teething. A product to "help" a child "with sucking or teething" will be one on which a child sucks or teethes—creating a particular risk of exposure. A plain reading indicates that the activities referenced involve mouthing behavior as a pre-requisite. That is why the Commission's prior efforts regarding phthalates, have focused on teethingers, rattles, and pacifiers—all items that a child puts in his mouth. Similarly, the statutory reference to a product designed or intended "to facilitate sleep or the feeding of" a young child (including a pacifier) is most reasonably understood as one that the child will use for that purpose, meaning that he will come into contact with it. The requirement that the product actually "facilitate" the activity indicates a narrower requirement than mere "use" of the product. Obviously a plain reading of the language indicates that Congress intended a direct causal relationship between the product and the activity that results in sleep, feeding, or aids in sucking and teething. This is why use alone is an insufficient basis for subjecting a child care product to these requirements.

The definition of mouthability, and Section 108(b) (1)'s express limitation of the regulation of three phthalates in children's toys to those that are mouthable, also reinforce this point. The definition contrasts a toy that "can be sucked and chewed" with one that can only "be licked." In doing so Congress recognized that although licking may cause exposure, only the significant exposure created by chewing and sucking material inserted into a child's mouth presented a potential hazard that would subject product to the limitations on phthalate content. As regards the interim-banned phthalates, Congress (consistent with the European Union) sought to focus on this primary risk of exposure, whereas with the permanently prohibited phthalates it cast a wider net. That Congress has cast a wider net in some cases than in others does not mean that exposure fails to remain the touchstone. Rather, it merely means that in some cases Congress used mouthability as a bright line and in others it did not. The underlying policy concern remains exposure of children to phthalates.

The European Union's phthalate regulations reinforce this point. Among the findings in the preamble of the relevant Directive is that "the exposure of children to all practically avoidable sources of emissions of [phthalates], *especially from articles which are put into the mouth by children*, should be reduced as far as possible." Directive 2005/84/EC, preamble ¶ 9 (emphasis added). The EU's Directive, like Section 108, draws a distinction between DEHP, DBP, and BBP, on the one hand, and DINP, DIDP, and DnOP, on the other. *See* Directive 2005/84/EC, Annex. A CPSC study in 2004 also emphasized that, "because plasticizers are not tightly bound to PVC, they

may be released *when children place PVC products in their mouths,*” and only mentioned offhand that “[s]ome dermal exposure from soft plastic toys is likely to occur.”<sup>1</sup> The European Union’s committee for considering such questions similarly has recognized that “[t]he plasticizer can be transferred to the skin via direct physical contact,” but that “[f]or small children, however, the oral exposure is probably the most effective route as they suck and ‘chew’ the toys.”<sup>22</sup> Thus, text, legislative precedent, and policy all indicate that a toy should, in the context of its usage in Section 108(b)(2), be read as implicitly requiring a product’s mouthability. That is also why, as noted, the Commission’s recently announced Enforcement Policy reasonably focuses on use of phthalates in teething, rattles, and pacifiers. That also is why, as noted, the EU is “especially” concerned with “articles that are put into the mouth by children.”

### **Children’s Toys**

The U.S. Consumer Product Safety Commission (CPSC) staff has previously addressed a number of questions concerning applicability of phthalate limits and recently issued its request for comment on what may or may not constitute defined toys and childcare articles. Although the guidance was intended to help manufacturers, importers, retailers and consumers determine what products are covered by the phthalate limits, the guidance documents issued thus far do not provide the definitive determinations necessary for manufacturers, importers, distributors and retailers to adequately discern which products are clearly within the scope of the requirements and which are not. As a result inconsistent determinations abound.

Until standards are clearly established, we fully support the decision by the CPSC staff, in the discretion afforded it, to focus its resources only on enforcement efforts directed at products, already noted as most likely to pose a risk of phthalate exposure to children. Specifically, we believe such products traditionally encompass polyvinyl chloride (“pvc”) bath toys and other small, pvc toys that are designed and reasonably intended by the manufacturer for young children and that can be put in the mouth, chewed or sucked, such as rattles, teething and pacifiers, but not other toy products.

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.*” [CPSIA §108(e) (1) (C)]. 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:

- *Whether the intended use of the product is for play, including a label on the product if such statement is reasonable.*

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<sup>1</sup> See, for example, Dr. Wind’s testimony, including discussion of substitution of DINP for DEHP, and the materials relating to the Commission’s denial in February 2003 of a petition to ban PVC in children’s products that focused on DINP.

<sup>22</sup> Michael A. Babich *et al.*, *Risk Assessment of oral exposure to diisononyl phthalate from children’s products*, 40 *Regulatory Toxicology and Pharmacology* 151, 151-52, 164 (2004).

- *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.*

### **ASTM F963-07 Consumer Specification for Toy Safety Provides Useful Guidance on What Is and What Is Not a “Toy”**

We also support the CPSC staff's consideration of the definition of “toy” in the ASTM F963-07 toy safety standard for guidance as to which products should be considered toys and which should not. The CPSIA makes ASTM F963 a mandatory CPSC standard on February 10, 2009. ASTM F963 excludes certain types of articles from the definition including: 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; sporting goods; camping goods; athletic equipment; musical instruments; and furniture (except for toy versions); and powered models of aircraft, rockets, boats, and land vehicles. Congress expressly adopted the full terms of such Standard, including exclusionary terms, expressly by under CPSIA Section 106. The fact that Congress eliminated adoption of the flammability Annex to such standard, demonstrates that had Congress intended that the listed exclusions for the above listed product categories, it would have similarly acted to strike adoptions of such provisions. The fact that it did not, reasonably indicates that it intended that such exclusions should apply as part of the regulatory definition of which products are considered within (or outside) the scope of defined toy products.

In line with this reasoning, the CPSC staff appropriately considered various types of balls (generic rubber or plastic balls that bounce to regulation-size baseballs). Generally, regulation-size baseballs, basketballs, footballs, and soccer balls are sporting goods or athletic equipment 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. We support this approach. In contrast, the staff has regarded general purpose balls as toys and therefore, subject to the requirements of the CPSIA Section 108. The staff also considers a “toy version” of actual athletic equipment, such as a toy glove with a foam ball as a toy for the purpose of the CPSIA Section 108 requirements. In addition, they suggest that small balls handed out as promotional items might be also be regarded as toys. We believe that such distinctions are valid. However, we also urge the CPSC staff to view products that function in an identical fashion to their athletic counterparts as sporting goods or athletic equipment. Functional performance is an essential dividing criterion between children's version of such products and “toy” version that simulate sporting activities. Ordinary books, including books for small children, are generally not regarded as toys. However, some novelty books, such as plastic books marketed as bath toys, or books that incorporate games, may be regarded as toys under both ASTM F963 and CPSIA Section 108. We also urge the CPSC staff to evaluate combined products as distinct from one another for application of the standard. For example, if a book is packaged with a plush toy, each should be considered as a distinct product (i.e. excluded book with included toy). Similarly 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 and should be excluded from consideration as a defined toy. In addition we note that although some electronic devices (such as cellular phones with incorporated games, cameras or musical devices) may be decorated or marketed such that they may be attractive to children 12 years old or younger, they are not generally recognized as “primarily” a children’s product under the Act or considered “toys” under the mandatory ASTM F-963-07.

We do recognize that there may be particular games or kits that include art materials or craft items that are generally recognized as excluded from classification as “toys.” As previously noted we believe if products can be considered separately from one another, although marketed together, that they should be regarded separately for the purposes of subjecting them to treatment as a toy under Section 108, unless they are likely to be inserted in the mouth chewed and sucked. Also we believe that the CPSC’s previously issued FAQ’s that indicated that traditional Halloween costumes should generally be considered wearing apparel, to the extent intended to be worn as festive, occasional attire subject to the Federal Flammable Fabrics Act (“FFA”) was appropriate and should continue to be adhered to. These products are distinct in their use patterns from dress up games.

Finally, it’s essential that the CPSC adhere to the definition of toys that can be placed in a child’s mouth, particularly for large inflatable toys that are made from interim restricted phthalates without protrusions less than 5cm in dimension that are not likely to be inserted in the mouth, chewed and sucked (but not licked) as required in the Act.

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.” 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. Please note above comments. We believe that the 5 cm criterion should be applied to inflatable toys in the inflated state.

### **Inflatable Toys**

The fundamental difficulty we encounter when applying the restriction of Section 108(b) (1) to inflatable toys is the fact that the CPSC staff’s indiscriminate application of the Standard to all inflatables in a deflated state is misplaced. Most if not all inflatable toys will be less than 5 cm in at least one dimension in their deflated state and would therefore be considered “mouthable” under such a definition. Additional refinement to this policy is required. Toys that cannot be played with in a deflated state should be measured in their intended inflated state. Just as the determination of whether a product is a toy at all depends in part upon its likely use, so should the determination of whether a toy is capable of being inserted into a child’s mouth, chewed and sucked but not licked. The above-stated general rule and exceptions take account of the fact that some inflatable toys are very unlikely to be “mouthed” (as that term is limited narrowly defined in the Act) in their deflated state. We can only conclude that in the exercise of its discretion, the CPSC staff should harmonize with comparable determinations of the European Commission Enterprise and Industry Directorate General on inflatables. It is interesting to note that the 5 cm rule found in Section 108(e)(2)(B) is borrowed directly from the European Commission’s guidance, thus indicating that Congress was fully aware of the fact that Section 108 as drafted would be interpreted in a consistent manner when

applied to larger inflatable toys. In addition general purpose balls that are inflated by the manufacturer should be considered in the inflated (normal) state. Inflatable regulation-size athletic equipment, such as basketballs, footballs, and soccer balls excluded by ASTM F963, should not be considered toys.

While small novelty inflatable toys designed to be inflated by the consumer, may commonly be available to children in deflated form, large inflatables, punching bags, air castles and large beach balls whether inflated by continuous air flow or valves, should be considered as products that are not likely to be placed in a child's mouth as statutorily defined (if in an inflated state they don't have protrusions that meet the dimensional criterion).

### **Inflatable Swim Aids and Juvenile Furniture**

In addition inflatable pool flotation products and swim aids although children's products subject to the lead restrictions under the Act, should not be considered toys. Although not excluded (compare: Coast Guard regulated flotation devices excluded from regulation under the CPSA as a "Consumer Product") they are not regulated toys. They fall within a class of a variety of swim aids that functionally keep children afloat as a part of a process of aquatic acclimation and learning to swim. They are not play items or part of a game that provides play value. In this regard they are more akin to sporting goods and learning aids. In the alternative, even if considered toys, to the extent they are made with the "interim" restricted phthalates, of a configuration in an inflated state that does not evidence protrusions less than 5cm should not be considered toys and the staff should revisit their previous contrary determination set forth in FAQs. In addition inflatable baths and juvenile furniture are not toys or childcare articles and cannot reasonably construed as such under Section 108 of the Act.

### **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." While the law uses the word "facilitate," it is not defined. The CPSC staff has indicated that 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 definition of "*child care article*" is much narrower than one would assume. It does not extend to all use of the product by a child three years or younger; rather, such use must directly facilitate sleep, feeding, sucking, or teething. A product to "*help*" a child "*with sucking or teething*" will be one on which a child sucks or teethes—creating a particular risk of exposure. A plain reading indicates that the activities referenced involve mouthing behavior as a pre-requisite. (74 Fed. Reg. at 8059). The Commission should make explicit that necessary requirement is whether part an article is likely to be placed in a child's mouth. Moreover, a focus on mouthing also protects against the overwhelmingly primary exposure pathway of children to phthalates.

Similarly, the statutory reference to a product designed or intended "*to facilitate sleep or the feeding of*" a young child (including a pacifier) is most reasonably understood as one that the child will use

for that purpose, meaning that he will come into contact with it and likely mouth it. The requirement that the product actually “*facilitate*” the activity further indicates a narrower requirement than “*use*” of the product. Obviously a plain reading of the language indicates that there must be an intentional causal relationship between the product and the activity that results in sleep, feeding, or aid in sucking and teething. This is why we believe mere use alone is an insufficient basis for subjecting a child care product to these requirements. Clearly then, “Functional Performance” directly related to the regulated product activity is an essential added criterion that needs to be applied to these products as well. This is why products such as swings, bouncers, stationary activity centers, jumpers, walkers, carriers, backpack carriers, strollers should not be characterized as either toys or childcare articles that directly are marketed as intended to facilitate sleep or feeding. They are not primarily involved in facilitating such activities. The function of these products is generally unrelated to the regulated activity.

The staff has considered the level of involvement or proximity of the child and product during the feeding, sleeping, sucking, or teething processes. This is a good approach. However the analysis needs further elucidation. The staff proposes that products used directly in the mouth by the child are primary products subject to the regulation. Products that have direct contact with the child, but may or may not have direct mouth contact, would also be considered primary products. CPSC staff has indicated that examples of such primary products are teethers and pacifiers that go directly into the child’s mouth; and a bib that is used during the feeding process. However a bib is also used when infants are teething and feeding to keep their clothing dry. In this regard the primary function of the product is not to directly make feeding easier, but rather to protect the infant’s clothing requiring fewer changes and cloths washing. The fact that it has direct contact with the infant because of the close proximity to the infant’s mouth and because infants explore their environment through mouthing, is irrelevant to whether it can reasonably be construed as facilitating feeding. Similarly the fact that can be chewed, sucked, and licked by infants does not in and of itself indicate that it should be considered a primary product subject to the regulation. Many products in an infant’s environment may be mouthed, but that is not the criteria for regulation. Congress anticipated prolonged exposure from eating sleeping chewing and sucking as the defining activity. A spoon may be mouthed, chewed and sucked for prolonged periods during eating; a pacifier may be sucked for long periods to help induce sleep and teethers may be gnawed for prolonged periods of time to provide relief or pleasure to a teething infant. We believe that other examples of primary child care products include pacifiers, teethers, drinking cups, sipper cups, plates, bowls, eating utensils, feeding bottles, and crib teething rail covers which are products directly used to facilitate the specified regulated activities under the statutory language.

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, and bedding or mattress pads. These products should not be considered as products that directly facilitate sleep. Although used by an infant when they sleep they are unlikely to be inserted into the mouth sucked and chewed. Many are insulated from access by coverings or contain large areas with exposure unlikely to occur. Similarly many are not made of materials which would inherently contain added phthalates (see previous comments on need to altogether exclude certain materials from testing, even for regulated products). In addition they do not directly induce 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. We fully agree with this approach. The CPSC should make it clear that if there is no contact between the child and product, there is no possibility of mouthing and no "direct" facilitation of sleep, so it is clear that such products would not be a child care article.

A third 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. The fact that infants will sleep in bouncers, swings, and some strollers and although consumers commonly report these products helping their child to fall asleep is irrelevant to manufacturers stated intent and the primary function of these products. The fact remains whether basic or full featured strollers primarily are intended to make transportation of children easier and are not intended as a product that primarily and directly facilitates sleep, feeding, sucking or teething activity. Clearly, newborns and young infants spend the majority of their time sleeping and, therefore, are likely to sleep anywhere, so that cannot be a reasonably determinative factor. The CPSC staff considers bouncers, swings, and most strollers to be secondary products and we agree they should be. If manufacturers do not explicitly advertise or market their products as directly facilitating sleep, they should not be subject to Section 108 restrictions, since the *manufacturer's* design and intent should be given deference. Most of these products are not a defined child care article. We do recognize that some products contain other products that may be subject to regulation. Swings, bouncers, walkers and activity products are sold with mobiles, music and other features to entertain the infant. Some also contain trays intended to hold food and drinks for the child occupant. In this regard such products should be separately assessed. The same rationale should apply to high chairs whose main function is to safely secure and seat an infant. The tray area should be treated separately from the seating structure for assessment purposes. Significant considerations should include (1) the manufacturer's intent in how products are labeled and marketed; (2) whether the product contains entertainment features; and (3) whether the product contains warnings or instructions against leaving a child unattended.

### **Licensed Intellectual property**

For all of all of the above examples we believe that graphic decorations with cartoon or licensed characters should not have any bearing on whether products are considered toys that are subject to the phthalate requirements under Section 108, regardless of the character used. We note that increasingly branded character licensing appeals to people in wide age ranges and not just children 12 years of age and younger. For example Mickey Mouse, Sponge Bob, Peanuts Characters, Sesame Street, and Super Hero Characters have broad appeal across many age ranges. While such intellectual property may have a bearing on age grading, it is irrelevant to the determination of

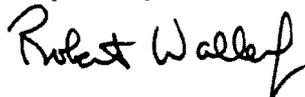
whether a product is a toy or childcare article. As noted above we believe the function of the product should be the primary factor determining whether or not the product is a toy or childcare.

### **Testing**

We support the CPSC's approach to product assessment testing and note that the use of the phrase "contains concentrations" in Section 108 is undefined and allows for such interpretation in light of Section 108's overall concern with children's exposure to phthalates. For example, given that the grammatical subject of this phrase is "toy" or "article" in Section 108(b) (1), as well as Section 108(a), rather than "part" or "component part" (terms not directly mentioned), it can be contended that whether a product has an impermissible concentration of any of the six specified phthalates is determined on the basis of the whole product. This is reflected in the recently published CPSC test protocol. Such protocol reflects the fact that the whole-product assessment is required (p.4). We are however cognizant that this is a difficult approach to testing and that adjustments may be required to be based upon the likelihood of mouthing and exposure to a part of children's product that can be "sucked and chewed, but not licked." [A basis may be found in the Consumer Product Safety Act that defines "consumer product" as an "article, or component part thereof." 15 U.S.C. § 2052(a) (1)]. However, given the lack of clear common sense testing (i.e. testing and rejection of inaccessible parts from intentionally disassembled product, regardless of exposure hazard or inconsideration of the whole product) it is essential that any changes to testing protocols, once published, must be made only upon notice with opportunity to comment and pursuant to the due process requirements of the Administrative Procedure Act ("APA"). Otherwise the disruption to production, testing and availability of product could be negatively and significantly impacted. There is no reason for the Commission to run such risks by reading Section 108 to require more than it actually does without with adequate advanced notice and time prior to any changes.

Thank you for providing us with the opportunity to submit comments. If you require additional information or examples, please do not hesitate to contact the undersigned.

Respectfully submitted,



Robert Waller, Jr., CAE  
President  
(856) 642-4402

**Stevenson, Todd**

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**From:** Yarissa Reyes [yreyes@ahint.com]  
**Sent:** Wednesday, March 25, 2009 5:23 PM  
**To:** Section 108 Definitions  
**Subject:** CPSIA Section 108's Draft Guidance Phthalate Requirements for Certain Toys and Child Care Articles  
**Attachments:** CPSIA Section 108 Supplemental Comments-Phthalates.pdf

To Whom It May Concern:

Attached please find additional comments from the Juvenile Products Manufacturers Association on CPSIA Section 108's Draft Guidance Phthalate Requirements for Certain Toys and Child Care Articles.

Respectfully Submitted,

The Juvenile Products Manufacturers Association (JPMA)  
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## CPSIA Section 108 The Phthalate Enigma.

This document is provided in response to the invitation by the staff of the CPSC for comments related to Section 108 of the CPSIA. Thanks for your consideration.

First of all it is acknowledged by this writer and long-time practitioner of toys and children's products safety that the CPSIA, as written, contains ambiguities and examples of seemingly inflexible direction, without providing the appropriate tools and levels of authority to fully allow the CPSC to make sensible interpretations and apply the regulations accordingly.

Regardless of how Section 108 of the Act is written, what Congress thought they were achieving and the interpretations placed on the contents of Section 108 by the experienced staff of the CPSC, from a purely unscientific point of view, as far as my personal knowledge and experience extend, the plain facts, as I see them, along with my opinions related to the hazards of exposure to certain phthalates, are as follows:

1. Certain phthalates identified by the CPSIA (and the European Union for numerous past years) have been proven, over a period of time, to be hazardous to the development of humans, particularly during the ages between birth and 3 years of age.
2. The hazardous effects of such phthalates have been attributed to studies of the concentrated exposure to lab animals over an extended period of time and the results of such studies being likened to small children mouthing and sucking on plastic materials, primarily those materials in the Vinyl and PVC family that have been manufactured intentionally to be soft, pliable and mouthable for infants.
3. From a common sense point of view, the exposure and hazardous effects of the named phthalates must be based on the concentration of the chemicals in a specific part or component that is able to be mouthed and/or sucked (not licked), rather than the entire product to which such part or component is attached. It does not make any sense at all to pulverize an entire crib into a fine powder to determine the level of phthalates in the plastic 'teether rail' on top of the side any more than grinding up a complete plush toy to measure the level of phthalates contained in a PVC nose. This is just plain wrong.
4. Children generally stop using their mouths to 'explore' things by the age of 3 years, at the same time developing a growing awareness of the world around them along with the motor capability and hand/eye coordination skills to use their hands and fingers to manipulate and explore. This is supported by the fact that the 'small parts' ban in toys is lifted for ages over 3 years, albeit with the mandated 'small parts' choking hazard warning.
5. Based on the 4 points above, logic dictates that the so called 'phthalate ban' should be limited to toys and children's products that are specifically designed or intended to be mouthed and sucked by children from birth to 3 years of age – and, OK, maybe a few 'child care' items that are very likely to be mouthed and sucked.
6. Referring to the list of articles that are excluded from the definition of a toy according to the ASTM F963-07e1, I am in favor of excluding the same articles from the phthalate testing requirements, namely:
  - a. Bicycles
  - b. Tricycles
  - c. Slingshots and sharp-pointed darts
  - d. Playground equipment
  - e. Non-powder guns
  - f. Kites
  - g. Art materials, model kits and hobby items – as described
  - h. Sporting goods, camping goods, athletic equipment, musical instruments and furniture, except for toy versions of these items
  - i. Powered models of aircraft, rockets, boats and land vehicles
7. With regard to versions of the balls, sporting goods, play baseball gloves with a foam ball, plastic bats, etc. I refer back to point 5 above and state that if the product is intended for ages over 3

The opinions stated in this document are purely those of the writer and not representative of the company by whom the writer is employed, nor any other persons or groups of persons.

years and not designed or intended to be mouthed or sucked, it should not be subject to a phthalate ban. My opinion is the same for books, arts & craft materials, hobby materials and model kits, which are typically not toys. For bath, pool and wading pool toys, dolls, action figures, costumes, masks for children aged 3 and up along with balloons (which are banned in toys for children under the age of 8 years), I believe, again, should not be subject to a phthalate ban.

8. Inflatable products, inflated or un-inflated, are generally not products that are designed or intended to be mouthed or sucked for extended periods of time by children under the age of three. Even though the valves through which air is blown are intended to come into contact with the mouth, the exposure time for this contact is limited. In the event that an inflatable product is designed or intended for mouthing or sucking by a child under the age of 3 years, it should be treated as an exception.
9. Child care articles that are likely to result in hazardous exposure to the banned phthalates are, in my opinion, limited to articles that are actually designed or intended to be mouthed for extended periods of time by an infant between the ages of birth and 3 years of age,
  - a. Pacifiers
  - b. Teethers
  - c. Rattles
  - d. The above three items when/if attached to an activity center, stroller, car seat, baby 'gym', etc.
  - e. Feeding implements (spoons, forks, sippy cups, etc) bottle nipples, etc.

In this particular category I would also include articles that are 'likely' to be mouthed, chewed or sucked over an extended period of time,

  - a. Plastic teething rail on a crib (as a stand-alone component – not tested as part of a complete crib)
  - b. Toys and activity products that attach to crib sides
  - c. Any so-called 'crib' toy
  - d. Plastic bib
  - e. The padded bar on a car seat
  - f. Soft (or hard) bath toys (including shampoo or bubble bath bottles shaped like animals or cartoon characters) specifically designed and intended for infants, etc.
10. In the category of 'child care' articles that should be subject to the phthalate ban, based on the likelihood of extended periods of mouthing, chewing or sucking, I would NOT include the following:
  - a. Pajamas
  - b. Crib or toddler be mattress
  - c. Mattress cover
  - d. Crib sheets
  - e. Infant sleep positioned
  - f. Play sand??
  - g. Baby swing
  - h. Decorated swimming goggles
  - i. Water wings
  - j. Costumes and masks
  - k. Baby walkers
  - l. Wading pools
  - m. Bouncers
  - n. Swings
  - o. Strollers
  - p. Playground equipment
  - q. Pools

I am in complete agreement and will support any legislation that is realistic in its intention and approach toward preventing the exposure of children to hazardous chemicals or other dangerous substances however, please note the word 'realistic'. In my opinion, although well intended, Section 108 of the CPSIA is not realistic as written.

The opinions stated in this document are purely those of the writer and not representative of the company by whom the writer is employed, nor any other persons or groups of persons.

**Stevenson, Todd**

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**From:** Fred Mills-Winkler [fmills-winkler@emc1.com]  
**Sent:** Wednesday, March 25, 2009 5:27 PM  
**To:** Section 108 Definitions  
**Subject:** Comments on CPSIA Section 108 - phthalates ban  
**Attachments:** The Phthalate Enigma - FMW 03-25-09 .pdf

To the CPSC Staff.

The attached comments are respectfully submitted for consideration in response to the Commission's invitation for comments.

Many thanks and best regards,

*Fred.*

Fred Mills-Winkler  
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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,



Stephanie Lester  
Vice President, International Trade

## Stevenson, Todd

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**From:** Andrew Szente [Andrew.Szente@retail-leaders.org]  
**Sent:** Wednesday, March 25, 2009 5:28 PM  
**To:** Section 108 Definitions  
**Cc:** Stephanie Lester; Jim Neill  
**Subject:** COMMENTS: Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108  
**Attachments:** RILA Section 108 Phthalates Determination Comments - Final - 03 25 09.pdf

Dear Mr. Stevenson:

Please accept the attached comments from the Retail Industry Leaders Association (RILA) on behalf of our members in response to the Consumer Product Safety 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. Thank you for this opportunity to provide comments.

Sincerely,

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**From:** Todd Mitchem [tmitchem@simmons.com]  
**Sent:** Wednesday, March 25, 2009 5:36 PM  
**To:** Section 108 Definitions  
**Subject:** Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108

Consumer Product Safety Commission  
Office of the Secretary  
Room 502  
4330 East West Highway  
Bethesda, Maryland 20814

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

Simmons Kids fully endorses the separately submitted comments of the International Sleep Products Association (ISPA) on behalf of the mattress manufacturing industry in response to several questions that CPSC staff have posed regarding the interpretation of the term "child care article" as defined by section 108 of the Consumer Product Safety Improvement Act (CPSIA) in draft guidance published in the Federal Register (74 FR 8059).

Simmons Kids contends, based on the nature of crib and toddler mattresses, consumer behavior, patterns of use and scientific findings, that mattresses, including crib and toddler mattresses, are secondary child care articles, and thus not subject to section 108 for at least the following reasons:

1. Unlike pacifiers, teethingers and chew toys – products that are deliberately designed for a child to mouth – mattresses are neither intended nor designed for mouthing by a small child. The large rectangular shape and size of a mattress makes it difficult and awkward for a child to mouth.
2. Scientific research (see <http://www.cpsc.gov/LIBRARY/FOIA/Foia01/os/dinp.pdf>) shows that many children do not mouth products, but those that do spend the vast majority of their time mouthing pacifiers, teethingers and other products designed for them to mouth.
3. Given a young child's propensity to bed wetting, he or she usually sleeps on a mattress that has either a water repellent or resistant outer fabric or mattress protector placed over the sleep surface. This outer mattress cover or mattress protector further protects the mattress itself from being mouthed by a child.
4. Mattresses are seldom if ever used without sheets and other bed linens. In the unlikely event that a child was to mouth his or her sleep surface, these bedding products would further prevent the child from accessing the mattress itself.

In summary, Simmons Kids supports the CPSC staff's approach to provide guidance for the section 108 requirements of the CPSIA. The proposed distinction between "primary" and "secondary" products is helpful in determining whether section 108 applies to certain classes of products. Applying these criteria to toddler and crib mattresses intended for children under three, Simmons Kids urges the CPSC to conclude that these are secondary child care articles and thus not subject to the phthalates regulations under section 108 of the CPSIA.

Thank you for your attention to these comments.

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March 25, 2009

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

**VIA ELECTRONIC MAIL**

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

Dear Mr. Stevenson:

This letter is submitted to the Consumer Product Safety Commission (CPSC) to provide comments on the Draft Guidance Regarding which Children's Products are Subject to the Phthalate Ban under Section 108 of the Consumer Product Safety Improvement Act (CPSIA). The law prohibits the sale of any children's toy or child care article containing more than 0.1 percent of certain phthalates.

The term children's toy means 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." The law does not specifically define what is meant by the terms "toy" or "play," but looks to the design and intentions of the manufacturer. This is a matter of some subjectivity, but the courts have in the past weighed-in on the determination of what is and is not a toy.

My comments particularly concern the class of products that includes luggage, backpacks, rolling bags, purses, hand bags, messenger bags, cosmetic bags, lunch bags, duffels, fanny-packs, totes, sling bags, beach bags, gym bags, sports cases, wallets and traveling bags. These products are not toys in any classic sense for use when a child plays. They are receptacles to convey materials from point A to point B. Any play value would be incidental to their primary purpose and design.

In 2006, the Federal Circuit Court reviewed a U.S. Customs decision that classified a children's backpack as a traveling bag, rather than a toy. See, Processed Plastic Company v. United States, 473 F. 3d 1164 (Fed. Cir. 2006). The Court agreed with the Court of International Trade which found that the bags did not have "play value" which is the '*sine qua non*' of a "toy."

The merchandise at issue in the Processed Plastic case was a "Pooh backpack", a "Barbie backpack" and a "Barbie beach bag." The front, back and side panels of the backpacks were made of PVC materials with plastic mesh on the bottom. The backpacks included imprints

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of the licensed characters. The backpacks and beach bags were imported as finished products and then were filled with plastic toys which were inserted into the bags.

In consideration of whether the backpacks and bags were toys, the Federal Circuit Court adopted a standard used by the Court of International Trade in Minnetonka Brands, Inc. v. United States, 110 F. Supp. 2d 1020 (Ct. Int'l. Trade 2000). The Court held that the principal use of a "toy" is amusement, diversion or play rather than practicality.

The Minnetonka Brands case is instructive because it held that "play value" is the dominant factor in determining whether a product should be classified as a toy, and to be a toy, the amusement value of the merchandise cannot be incidental to its utilitarian aspects. *Id.*

The Minnetonka Brands Court also outlined several factors useful to determine how to characterize merchandise and the question of play value, including:

- (1) general physical characteristics of the merchandise;
- (2) expectations of the ultimate purchaser;
- (3) channels, class or kind of trade in which merchandise moves;
- (4) environment of sale, (i.e., accompanying accessories and manner in which merchandise is advertised and displayed);
- (5) usage, if any, in same manner as merchandise which defines the class;
- (6) economic practicality of using the import; and
- (7) recognition in trade of use.

Minnetonka Brands, 110 F. Supp. 2d. at 1027.

While the Minnetonka Brands factors are not definitive and do not carry equal weight in defining whether a product is a toy, they are "areas of inquiry that may prove useful in determining what is the principal use of merchandise alleged to be a toy." See, Processed Plastic at 1170.

In a similar Customs opinion in 1995, the agency concluded that a stuffed Tasmanian Devil backpack was not a toy. See, U.S. Customs HQ 958308 (November 7, 1975). Despite the fact that the backpack had a semi-plush body, arms and legs with an oversized head into which items could be placed, Customs concluded that the essential purpose of the product was a practical one, and that play value was incidental to utilitarian value. Customs further noted:

It has been Customs' position that the "amusement" requirement means that toys should be designed and used principally for amusement and that they should not serve a utilitarian purpose....

When amusement and utility become locked in controversy, the question becomes one of determining whether the amusement is incidental to the utilitarian purpose, or the utilitarian purpose is incidental to amusement....

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The Tasmanian Devil, though amusing to children, also clearly serves the practical purpose of doubling as a backpack. The question then becomes the principal use by the target age group, in this case children. The primary function ... of the Tasmanian Devil is to carry the small personal belongings of children in a manner that is most delightful (while also being practical) to them....

Though we do not argue with the statement that this item will be amusing to children, that does not detract from the fact that the Tasmanian Devil was also designed to carry out a functional purpose, i.e., to be used as a backpack by children, and thus to carry a variety of their personal belongings.<sup>1</sup>

In conclusion, for purposes of determining whether a product is a toy subject to phthalate regulation, we suggest that consideration be given to the formulations enumerated by the Courts and Customs. Is the principal use of the product for amusement, diversion or play rather than practicality? Is the amusement value incidental to the utilitarian purpose, or the utilitarian purpose incidental to amusement? Last, what was the intent of the manufacturer? Under what classification was the product imported and what duties were paid?

For the category of products that include luggage, backpacks, rolling bags, purses, messenger bags, cosmetic bags, lunch bags, duffels, fanny-packs, totes, sling bags, beach bags, gym bags, sports cases, wallets and traveling bags, we believe these products are not toys and thus not subject to the phthalate ban.

Thank you for your consideration of these comments.

Very truly yours,



Mark R. Kaster

MRK/aj

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<sup>1</sup> In the 1995 Tasmanian Devil case, the National Import Specialist at Customs noted that the travel bag industry has long recognized that children have a need for travel bags to carry their personal belongings. For additional discussion of backpacks and carrying cases, see U.S. Customs HQ 963221 (October 11, 2001) (holding that a plush Dr. Seuss Grinch coin purse is a novelty coin purse and not a toy).

## Stevenson, Todd

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**From:** Kaster, Mark [Kaster.Mark@dorsey.com]  
**Sent:** Wednesday, March 25, 2009 5:58 PM  
**To:** Section 108 Definitions  
**Subject:** Comments to Notice  
**Attachments:** Severson, Todd Ltr 3-25-09.PDF

Dear Secretary Stevenson,

Please find enclosed our comments to the Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108.

Thank you for your consideration.

<<Severson, Todd Ltr 3-25-09.PDF>>

**Mark R. Kaster**

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March 25, 2009

Office of the Secretary  
Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, Maryland 20814

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

Dear Commissioners and Staff:

Thank you for the careful consideration the Commissioners and staff are giving to interpreting CPSIA. However, I am deeply concerned by the Commission's leaning toward weakening of the broad reach of the phthalate ban set forth in Section 108 of the Act. Specifically, the interpretation the CPSC proposed for what is and what is not a "children's toy" is too restrictive, and does not encompass all of the products Congress sought to ban.

Congress, by specifically defining "children's toy" in the law, made clear what products are covered by the bans and restrictions it chose to make the law of the land. Congress does not simply use the word "toy" in the Act and then leave it up to the CPSC to decide what is and what is not a toy. Congress chose to be its own lexicographer, and the CPSC is not free to change the definition selected by Congress. Congress defined "children's toy" as a consumer product "for use when the child plays". The definition is very specific and encompasses products other than what one may commonly understand to be a toy. It does not matter if the CPSC, ASTM, or anyone else thinks that something fitting the definition set forth by Congress is more akin to a sporting good. Congress has already decided that while it may be a sporting good, it is also a "children's toy" as defined by the Act. While the CPSC is free to interpret the words contained therein, it is not free to interpret the word to eviscerate the scope defined by Congress, or otherwise supplant the definition chosen by the legislature. The CPSC cannot independently determine that Congress did not intend the scope of the ban to apply to certain classes of products that children use during play.

The arguments for exempting sporting equipment and regulation sized balls are rather contrived. A child plays catch, a child plays basketball. A parent hands the child a soccer ball and tells her to “go out and play”. The child certainly is not participating in these types of activities, commonly known as playing, for the purpose of employment, yet some would suggest that the activity is not play if the child is using a regulation ball or the glove the child uses is defined by the industry as a piece of sporting equipment. It does not matter if he is playing with regulation sized equipment, he is still playing. It is absurd to believe that a child is playing when he uses a plastic bat and plastic ball in his backyard, but is not playing when he uses a child sized bat, glove, and regulation baseball in the same friendly confines.

Is the classic school gym game of dodgeball any less or more an act of playing because it uses a general purpose ball rather than a regulation ball? Of course not, the children are playing dodgeball whether it is a general purpose ball or a regulation soccer ball that is hurled at the opponent. Let’s suppose the general purpose ball industry forms a School Playground League, and sanctions a general purpose ball to be the official regulation ball for the playing that takes place on school playgrounds. Did Congress intend that such sanctioning could make the ball immune to the phthalate ban just because it meets the regulations of a sanctioning body? I think not.

And to consider that a child does not play on playground equipment defies all logic. It is found on a playground. Other than playing on the equipment, what else do children do with it? The whole purpose of the product is for play.

Nor can the CPSC rely on an independent body, such as the ASTM and its standards, to take the place of the Congressional definition. If Congress wanted to adopt the ASTM definition for “children’s toy” with respect to phthalates, they could have done so.

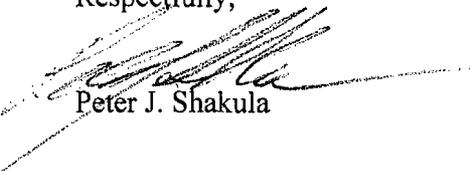
Congress had the good sense to broadly define “children’s toy” to include anything for “use by the child when the child plays” By controlling the definition, and hence the products covered by the phthalates ban, Congress chose to broaden the application of the ban beyond the products covered by the ASTM regulations. Separately, in a different portion of the act, Congress chose to adopt the ASTM toy safety standards. It is important that the adoption of the ASTM standards is in addition to, and not part of the same section of the act as the phthalate ban. The phthalates ban and the ASTM standards are different section of the legislation, and each may have their own definition of “children’s toy”, and thus have different, though overlapping coverage. By drafting and passing the phthalate ban with a specific and broad definition for the products it covers, Congress manifested its intent to control what products are covered by the ban, and not rely upon an industry body to define the reach of the ban. One only needs to look at the exceptions to see that industry lobbying plays a significant role in shaping the industry regulations.

If Congress wanted the phthalates ban to apply to the same range of products as the ASTM standards, then they would have simply defined “children’s toy” as “any

product regulated by ASTM F963.” They did not adopt that definition. There is no need, other than the convenience of particular industries in avoiding the regulation, to interpret the phthalates ban to cover the same range of goods and provide the same exceptions as the ASTM standards. If Congress did not intend the unfortunate scope of its own action, then it is up to Congress, not the CPSC to correct the problem.

The CPSC, just as with other aspects of the CPSIA, is not free to change the stated will of Congress and adopt a definition with less scope. Congress did not provide the Commission with the flexibility to take into account policy issues when determining what is within and what is outside of the definition chosen by Congress. Indeed, by adopting a broad definition, Congress has intended that policy considerations, such as the detrimental effect on the sporting goods industry and Little League Baseball, are not to be considered in applying the ban. While such an approach may be somewhat hard-line, other provisions of the Act, such as the applicability of the lead and phthalate bans to existing inventory, are just as strict and difficult on industry. Congress, not the CPSC, is the competent authority to change the scope of the definition of “children’s toy”, and fix any other problems with the Act.

Respectfully,



Peter J. Shakula

## Stevenson, Todd

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**From:** Peter J. Shakula [PJShakula@woodphillips.com]  
**Sent:** Wednesday, March 25, 2009 6:15 PM  
**To:** Section 108 Definitions  
**Subject:** Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108  
**Attachments:** cpsc108.pdf

Please see the attached letter.

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NATURAL RESOURCES DEFENSE COUNCIL

March 25, 2009

To: Consumer Product Safety Commission  
Office of the Secretary  
Submitted by email: section108definitions@cpsc.gov

Re: 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.

These comments are submitted by Natural Resources Defense Council (NRDC), who on behalf of our 1.2 million members and online activists, uses law and science to ensure a safe and healthy environment for all living things. NRDC has no financial interest in phthalates, PVC, or children's toys or childcare articles.

The CPSC has requested information and comments on which children's products are subject to the requirements of Consumer Product Safety Improvement Act (CPSIA), Section 108, including, but not limited to, the following topics which are answered individually below:

*I. General Approach*

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

The intent of the CPSIA Sec. 108 provisions was to limit phthalate exposure in children from children's toys and childcare articles. Exposures are known to occur because of the mouthing of phthalate-containing materials. However, exposures could also reasonably be anticipated to occur because of the release of phthalates from plastics during normal use. Phthalates that leach from plastics could be absorbed across the skin or could attach to dust particles that are inhaled or ingested by a child. These routes of exposure should also be considered by CPSC when determining which products are subject to Section 108 requirements and for the SOP for phthalate testing.

CPSC's approach for determining which products are subject to the requirements of CPSIA section 108 relies on the ASTM F963 definition of a toy. NRDC disagrees with this approach as it does not meet the statutory criteria of the CSPIA section 108. (More comments on this below in Section II.A.)

Because certain products that are likely to contain phthalates are excluded under CPSC's proposed definition of toys, there will be continued phthalate exposure in children. Children's products that could contain phthalates include modeling clays, playground structures, or tricycles.

The statutory criteria for childcare articles in the CSPIA section 108 is "a consumer product is designed or intended by the manufacturer to facilitate sleep or the feeding of children 3 years of age or younger, or to help such children with sucking or teething." The approach proposed by CPSC is to designate childcare articles as being primary or secondary facilitators of sleeping, feeding, sucking or teething. CPSC is proposing to subject only primary facilitators to the Section 108 requirements.

NRDC disagrees with this approach because the CSPIA section 108 definition of a childcare article does not make this distinction and all products that meet this definition should be subject to section 108 requirements. Certain products that CPSC has identified as "secondary facilitators" will contain phthalates and can be reasonably anticipated to result in continued phthalate exposure in children. For example, CPSC has identified the following products as "secondary facilitators" which could all contain phthalate and result in continued children's exposure: breast pumps, mattresses, mattress covers and pad, strollers, bouncy seats and swings.

CPSC's approach should meet all the statutory criteria of CSPIA section 108: for children's toys, that a toy is intended for children under 12 to play with; for child care articles, that a product is meant to facilitate sleep or the feeding of children 3 years of age or younger. This should include toys and childcare articles that are designed or sized for use by children and that could reasonably be anticipated to contain phthalates because of their external plastic material content. Furthermore, materials which can reasonably be anticipated to be phthalate-free should be exempt from the phthalate-testing requirements. This includes things made from wood or metal materials; fabrics such as wool, cotton or silk; yarns and natural dyes.

More specific comments follow below.

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

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

No. NRDC disagrees with this approach as it does not meet the statutory criteria of the CSPIA section 108.

The relevant definition of "children's toy" is included in Section 108 of the CPSIA which enacts the phthalate ban. Section 108 defines "children's toy" as "a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use when

the child plays." The definition makes no exceptions for products not defined as toys by ASTM F963-07. Any product which meets this definition is therefore subject to the phthalate ban. The Commission's reliance on ASTM F963-07 to assess the toys that are subject to the phthalate ban is inappropriate.<sup>1</sup>

Congress did make ASTM F963-07 a minimum standard for toy safety in a separate section (Section 106) of the CPSIA. However, it is a tenet of statutory construction that where a specific statutory provision conflicts with a general one, the specific provision governs. *See, e.g., Edmond v. U.S.*, 520 U.S. 651, 657 (1997); *Morales v. Trans World Airlines*, 504 U.S. 374, 384-85 (1992). To the extent that the ASTM F963-07 conflicts with the more specific definition of children's toys subject to the phthalate ban in Section 108, Section 108's definition supersedes ASTM F963-07. Thus, all consumer products, including those not defined as a toy by ASTM F963-07, which are designed or intended for use by a child under 12 years of age when the child plays are subject to the phthalate ban.

NRDC disagrees with this approach because certain products that are not included in this definition could contain phthalates and will result in continued phthalate exposure in children. Bicycles, tricycles and playground equipment with plastic components should be subject to CPSIA Section 108 requirements. Children don't discriminate which toys they will put in their mouths based on an ASTM definition and photos such as the one below demonstrate why all materials with plastic external components and designed and sized for children should be subject to this requirement.<sup>2</sup>



<sup>1</sup> Moreover, even if Section 108 had not explicitly defined "children's toy," Section 106 established ASTM F963-07 as a minimum standard, i.e. a floor; nothing prevents the Commission from going further. In fact, in Section 101 of the CPSIA, Congress explicitly stated that "[t]o the extent that any regulation promulgated by the Commission" under any Act enforced by the Commission "is inconsistent with the ASTM F963 standard, such promulgated regulation shall supersede the ASTM F963 standard to the extent of the inconsistency."

<sup>2</sup> <http://www.flickr.com/photos/43927576@N00/1246459345/> and <http://www.flickr.com/photos/8484303@N05/514276792/>

B. 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?

CPSC should include in section 108 all toys that are designed for children 12 years old or younger or sized for use by children and that could reasonably be anticipated to contain phthalates because of their external plastic material content.

C. Are there particular art materials, model kits, or hobby items that should be regarded as toys subject to section 108? Why or why not?

Yes, model kits, art materials and jewelry making kits should be regarded as toys and subject to the requirements of CPSIA section 108.

There is evidence that modeling clays contain the phthalates, DnOP, BBP and DEHP, and there is potential for significant exposure.<sup>3</sup> The European Union has recently identified modeling clay that exceeds the standard for DnOP.<sup>4</sup> Stamping kits<sup>5</sup> and jewelry making kits<sup>6</sup> were also recently identified in the EU as containing high levels of

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<sup>3</sup> Inhalation and ingestion of phthalate compounds from use of synthetic modeling clays. Maas RP, Patch SC, Pandolfo TJ. Bull Environ Contam Toxicol. 2004 Aug;73(2):227-34

<sup>4</sup> European Union (EU), Rapid Alert System for Non-Food Products (RAPEX) website: [http://ec.europa.eu/consumers/dyna/rapex/create\\_rapex\\_search.cfm](http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm)  
Accessed on March 24, 2009.

Reference number: 22 0335/09. Product: Modelling clay - Polyform oven-bake clay Brand: Sculpey III Description: Rectangular slabs (4.5 x 6 x 2 cm) of 57 g in various colours. Warning: "suitable only for children over the age of 8 years – to be used under adult supervision." Country of origin: United States

**The product poses a chemical risk because it contains more than 0.1% by weight of di-n-octyl phthalate (DNOP), respectively 2.1% and 2.3% in the yellow and green clays.**

<sup>5</sup> EU RAPEX website [http://ec.europa.eu/consumers/dyna/rapex/create\\_rapex\\_search.cfm](http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm)  
Accessed on March 24, 2009.

Reference: 17 0304/09. Brand: Play-N-Fun; Bob & Jean. Description: Pink and purple plastic letters and numbers for stamping, Country of origin: Hong Kong

**The product poses a chemical risk because letters in the stamp set contain 38.9% di-"isononyl" phthalate (DINP).**

Reference: 21 0842/08. Product: Set of pens with roller stamps Description: 8 fibre-tipped pens in various colours; motif-roller stamp with transparent plastic cap on one end, fibre-tip on the other end with plastic cap in the same colour of the fibre-tip; length approx. 11 cm

**The product poses a chemical risk because the roller stamp contains 11.8% by weight of di-2-ethylhexylphthalate (DEHP) which exceeds the limit value of 0.1%.**

<sup>6</sup> EU RAPEX website: [http://ec.europa.eu/consumers/dyna/rapex/create\\_rapex\\_search.cfm](http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm)  
Accessed on March 24, 2009.

Reference: 11 1435/08. Brand: THE TOY COMPANY Description: A craft set for making fashion jewellery. Country of origin: China

**The product poses a chemical risk because the pink cord contains 15.78% plasticiser phthalic acid diisononyl ester (DINP).**

banned phthalates. Also, phthalates are used as adhesives and therefore any glues that are included in modeling kits intended for children should also be subject to the requirements of section 108.

D. 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?

As previously conveyed, it is not appropriate for CPSC to rely on ASTM F963 for determining which types of toys are subject to section 108 requirements. There should be no exemptions for toys that are excluded under ASTM F963.

Tricycles are 3 wheeled toys that are designed and sized for the play of children. All 3 and 4 wheeled ride-ons that contain plastic components should be designated as toys and subject to the requirements of CPSIA section 108.

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

CPSC should include in section 108 all toys and products that are designed or sized for use by children and that could reasonably be anticipated to contain phthalates because of their external plastic material content. Furthermore, materials which can reasonably be anticipated to be phthalate-free should be exempt from the phthalate-testing requirements. This includes things made from wood or metal materials; fabrics such as wool, cotton or silk; yarns and natural dyes.

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

No. NRDC disagrees with this approach because the CSPIA section 108 definition of a childcare article does not make a distinction between primary and secondary child care articles and all products that meet the statutory definition should be subject to section 108 requirements. Certain products that CPSC has identified as "secondary facilitators" will contain phthalates and can be reasonably anticipated to result in continued phthalate exposure in children. For example, CPSC has identified the following products as "secondary facilitators" which could all contain phthalates and result in continued children's exposure: breast pumps, mattresses, mattress covers, strollers, bouncy seats and swings. Breast pumps and their components and nipple shields come in direct contact with breast milk and because of the lipophilic nature of phthalates, could result in phthalate contamination of breast milk. This is arguably just as significant an exposure to phthalates as would occur from feeding out of a phthalate containing bottle or cup.

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?

CPSC has identified many of the children's products that are most likely to result in phthalate exposure in children younger than 3 years old such as bibs, bottles, blankets and high chairs. However, CPSC should not exclude products that "indirectly" facilitate childcare such as strollers, bouncy seats, floor mats or mattresses because of their potential to contribute to phthalate exposure.

While the law has defined "facilitate" to include sleeping, feeding, teething or sucking, it is clear that diapering and bathing are also an integral part of childcare and there is potential for exposure through the use of personal care products, diapers, changing pads and tables that could result in phthalate exposure. Notably, the EU has recently identified and a voluntary recall was issued for a changing pad that was found to contain high levels of DEHP.<sup>7</sup>

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?

The entire crib and all crib materials including the mattress, mattress coverings, and pads should be considered to be childcare articles and subject to the requirements of section 108. These products often contain "vinyl" components as waterproofing material and are likely to contain phthalates. For something such as a mattress or covering, this represents a large surface area that children will be exposed to for long periods of time. Phthalates are capable of not only crossing across the skin, but also volatilize and can be found in dust particles that can be ingested or inhaled, having phthalates in these products could result in exposure through multiple routes.

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?

No, rather than exempting classes of articles, CPSC should include in section 108 all childcare articles that could reasonably be anticipated to contain phthalates because of their external plastic material content. Because of the potential for phthalates to leach from plastic materials and attach to dust particles and because of their potential for dermal absorption, childcare articles should not be exempted because they are considered to be "secondary products".

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<sup>7</sup> EU RAPEX website:

[http://ec.europa.eu/consumers/dyna/rapex/create\\_rapex\\_search.cfm?zoek=phthalates&vanaf=41&jaartal=ALL](http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm?zoek=phthalates&vanaf=41&jaartal=ALL)  
Accessed on March 24, 2009.

Reference number: 28 1493/08. Product: Changing mat Brand: JUMBO BEBE

Description: Light blue changing mat (approx. dimensions: 79cm x 47cm x 9cm), packed in a transparent plastic bag. Country of origin: China

**The product poses a chemical risk because it contains 12.7% by weight of bis (2-ethylhexyl) phthalate (DEHP).**

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?

The following articles should be subject to the requirements of section 108 because of their plastic contents and potential for contributing to phthalate exposure to children. Specific comments follow.

a. Bib -

Since bibs are often worn for long periods of time, can contain plastic linings and are in contact with the skin or are potentially mouthed by children wearing them, they should be subject to section 108 as a childcare article. The EU has recently identified several bibs as containing high levels of DiNP and DEHP.<sup>8</sup>

b. Pajamas

Pajamas should be considered to be childcare articles and subject to section 108 because they are used to facilitate sleep. Phthalates have been found in the inks and designs on major brand pajamas previously.<sup>9</sup> Furthermore, the foot bottoms of pajamas are often made from a plastic material and could contain phthalates.

c. Crib or toddler mattress

d. Mattress cover

e. Crib sheets

The entire crib and all crib materials including the mattress and mattress coverings should be subject to the requirements of section 108 as childcare articles for facilitating sleep. Because these products often contain "vinyl" components to make them waterproof, they are likely to contain phthalates. For something such as a mattress or covering, this represents a large surface area that children will be exposed to for long

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<sup>8</sup> EU RAPEX website. 3 examples of bibs found to contain phthalates, more available at: [http://ec.europa.eu/consumers/dyna/rapex/create\\_rapex\\_search.cfm?zoek=phthalates&vanaf=41&jaartal=ALL](http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm?zoek=phthalates&vanaf=41&jaartal=ALL). All accessed March 24, 2009

Reference number: 12 1436/08. Product: Baby's bib "Kiti" . Brand: Unknown. Description: Baby's plastic bib with printed figures. Country of origin: China

**The product poses a chemical risk because it contains 16% of di-"isononyl" phthalate (DINP).**

Reference: 37 1461/08. Brand: PETIT CADEAU

Description: Opaque plastic bib with arms, yellow edging and a picture of a duck. The front of the bib has a clear plastic pocket. Country of origin: China

**This product poses a chemical risk because the clear plastic front pocket contains 4.5 % di(2-ethylhexyl)phthalate (DEHP).**

Reference: 11 1329/08. Product: Child's bib - Soft pelican bib Brand: Libra

Description: Child's bib with a pocket, printed with a picture of dogs and flowers.

Country of origin: Poland

**The product poses a chemical risk because it contains 20.3% by weight of bis (2-ethylhexyl) phthalate (DEHP) and 10.2% by weight of di-"isononyl" phthalate (DINP).**

<sup>9</sup> Greenpeace UK phthalate testing. Published October 2003. Accessed March 25, 2009. <http://www.greenpeace.org.uk/toxics/warning-disney-pyjamas-may-damage-the-health-of-your-children>

periods of time. Since we know phthalates are capable of not only crossing across the skin, but also volatilize and can be found in dust particles that can be ingested or inhaled, having phthalates in these products could result in exposure through multiple routes of exposure.

Crib sheets that are made from natural fabrics such as cotton or wool should be excluded from the testing requirements unless there is a plastic design on the material.

f. Infant sleep positioner

This product should be subject to the requirements of section 108 as childcare articles for facilitating sleep. Because these products often contain "vinyl" components to make them waterproof, they are likely to contain phthalates. Phthalates are capable of not only crossing across the skin, but also volatilize and can be found in dust particles that can be ingested or inhaled, having phthalates in these products could result in exposure through multiple routes of exposure.

g. Play sand

No comment

i. Baby swing

See comments in section K.

j. Decorated swimming goggles

CPSC should consider these to be a children's toy and subject to the requirements of section 108 because of their external plastic material content that is in contact with the skin and could result in dermal exposure.

k. Water wings

See comments under wading pools below.

l. Shampoo bottle in animal or cartoon character shapes

Packaging of children's personal care products in the shape of an animal or cartoon character should also be subject to the requirements of section 108 as a child may play with this as a toy in or out of the bathtub and these bottles can be made from PVC and may contain phthalates. Phthalates may also leach from this packaging material into the product which is applied to the skin, resulting in potential dermal exposure.

m. Costumes and masks

CPSC should consider these to be a children's toy and subject to the requirements of section 108 because of their external plastic material content which is in contact with the skin and could result in dermal exposure.

n. Baby walkers

Baby walkers should be classified as children's toys and subject to the requirements of section 108 if they contain external plastic components.

o. Wading pools

CPSC should consider all inflatable toys that are used in the bathtub or swimming pool as children's toys that are subject to the requirements of section 108. Wading pools, water wings, inflatable swimming rings, inflatable balls and other toys are often made from vinyl and could be reasonably anticipated to contain phthalates. The EU has identified a number of different banned phthalates at high levels in these types of products.<sup>10</sup>

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.

All bouncers, swings, or strollers should be subject to section 108 and classified as childcare articles because they are frequently used to facilitate sleep, feeding or soothing. All products with similar functions (e.g. a stroller) should be subject to the same standards otherwise a simple labeling change would remove the testing requirement but functionally the product will be used the same way by a caregiver. There should not be any exemptions for childcare products such as strollers, bouncy seats, and swings regardless of how they are labeled or marketed.

L. Should some promotional items be regarded as toys? What are the characteristics that would make these products toys or not toys?

Products that are designed and sized for use by children should be considered to be toys. CPSC should consider promotional items that meet this definition to be a children's toy and subject to the requirements of section 108 because of their external plastic material content.

M. Should playground equipment be excluded from the definition of toy? If so, what types of equipment?

Playground equipment that contains external plastic components should be defined as a children's toy and subject to the requirements of section 108. Children don't discriminate which toys they will put in their mouths based on an ASTM definition of a toy and as demonstrated earlier, children will mouth toys that have been excluded under this definition.

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 comment

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<sup>10</sup> See EU RAPEX website. Accessed March 24, 2009. Search term "inflatable"  
[http://ec.europa.eu/consumers/dyna/rapex/create\\_rapex\\_search.cfm?zoek=phthalates&vanaf=41&jaartal=ALL](http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm?zoek=phthalates&vanaf=41&jaartal=ALL)

O. Please comment on our phthalates test method which can be found on our [web site](#) (pdf).

NRDC does agree that CPSC should require that each individual plastic component is tested separately, because if the whole toy is tested, it will dilute the total phthalate content and underestimate the amount of phthalate in the product.

However, as written, CPSC's phthalate test methods are cumbersome and impose unnecessary steps that will increase inter-laboratory variability, increase laboratory turn around time and therefore increase cost to the manufacturers.

Specifically, CPSC is requiring the each component is ground up into a fine powder (< 500 microns), for determining phthalate content. Whereas this will allow for a very precise calculation of the phthalate content, this step is time consuming and adds additional expense to the testing methods. Further, because there will be variation in how different laboratories will conduct this step, it introduces the possibility of significant inter-laboratory variability. This step also does not recognize the exposure route for phthalate exposure. Since phthalates leach from plastics, it is the surface of the component that will come into contact either with a child's mouth or skin, or will be the surface from which phthalates leach into house dust. Therefore, the component could be surfaced tested to determine phthalate content.

Instead of requiring the component to be ground up, CPSC could develop a methodology for surface testing of components. For example, a representative sample could be submerged in an appropriate solvent (THF) for a specified amount of time (24 hours), sonicated and warmed to optimize leaching, and then the solvent extracted for phthalates. Products tested for lead don't require the material to be ground into a fine powder and there is no obvious rationale for why testing components of children's products should be approached any differently.

Secondly, CPSC is requiring that each component is tested in triplicate and then a mathematical average is calculated to determine the phthalate content. This increases the testing cost three times as well as the testing time. Both could be reduced if instead composite testing were done. Three representative samples of each component could be combined and subjected to the same extraction as a group. As long as the laboratory has quality control samples and measures, this should result in a representative estimate of the phthalate content.

The SOP proposed by CPSC will result in a very precise calculation of the phthalate content of product components but will triple the cost and substantially increase the turn around time for testing. Section 108 stipulates that the phthalate content is no more than 0.1% which will require laboratory methods that are able to detect levels to 4 decimal places, not to such a precise degree as would be obtained with CPSC's proposed methodology. Detection limits that reach the standard of section 108 could easily be achieved with changes described above and would substantially reduce the testing costs and time.

NRDC looks forward to an open and transparent process as CPSC continues their evaluation of toxicity of phthalates in children's toys. We encourage CPSC to issue a final and clear guidance to the public on the phthalate guidelines as soon as possible after the close of this comment period. CPSC did not issue this phthalate guidance until after the implementation date of the CSPIA and this delay has created considerable frustration for and confusion in all stakeholders.

We welcome any opportunity to participate in or give further clarification on these comments or other matters relevant to the implementation of CSPIA section 108.

Respectfully submitted,



Sarah Janssen, MD, PhD, MPH  
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## Stevenson, Todd

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**From:** Janssen, Sarah [sjanssen@nrdc.org]  
**Sent:** Wednesday, March 25, 2009 6:45 PM  
**To:** Section 108 Definitions  
**Subject:** NRDC comments on phthalate guidance  
**Attachments:** NRDC comments on CPSC phthalate guidance.doc

Please find attached public comments from NRDC on the CPSC draft phthalate guidance.

Respectfully submitted,

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**Stevenson, Todd**

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**From:** Nicola O'Reilly [ncoreilly@comcast.net]  
**Sent:** Wednesday, March 25, 2009 7:10 PM  
**To:** Section 108 Definitions  
**Subject:** Pthalate testing - CPSIA

CPSC staff

As a mother of children I am closely following the CPSIA, however, I believe that phthalate testing should be excluded for items made from materials that clearly do not use this in their manufacture such as yarn, fabric and wood.

Testing is very costly, and with these materials is redundant and a waste of testing materials and lab time.

sincerely  
Nicky O'Reilly

**RESPONSE TO CPSC's REQUEST FOR COMMENTS AND INFORMATION  
Draft Guidance Regarding Which Children's Products are Subject to the Requirements of  
CPSIA Section 108**

March 25, 2009

Sent via email to: [section108definitions@cpsc.gov](mailto:section108definitions@cpsc.gov)

Office of the Secretary  
U.S. Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

To Whom It May Concern,

ExxonMobil Chemical would like to take this opportunity to commend the U.S. Consumer Product Safety Commission (CPSC) for its effort to clarify which products will be subject to the requirements of Section 108. The following information is provided by ExxonMobil Chemical in response to the CPSC request for information on the Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108, 74 Fed. Reg. 8058 (Feb. 23, 2009).

ExxonMobil Chemical is a producer of two of the phthalates, DINP and DIDP, which are subject to the CPSIA Section 108(b)(1) temporary restriction and will undergo a scientific review by the Chronic Hazard Advisory Panel (CHAP). ExxonMobil strongly believes that testing and prior governmental reviews have demonstrated that DINP and DIDP are safe for their intended use including toys and childcare articles. As confirmed by the CPSC's own 2002 CHAP review, the panel found DINP exposure to be "extremely low or non-existent" and found "no demonstrated health risk posed by PVC toys". We welcome further study by the 2009 CHAP and believe that the findings will result in the removal of the CPSIA's temporary restrictions.

We agree with CPSC's suggestion to use the existing ASTM F963 standard to define the universe of toys that are covered by Section 108 and also support limiting the definition of childcare articles to only those articles with the potential for exposure to a child.

ExxonMobil Chemical has also provided additional information on identification of the HMW phthalates DINP and DIDP. We are aligned with CPSC's Chemical Division's view that definitive testing of phthalates is technically difficult and expensive. For this reason, ExxonMobil Chemical believes that CPSC can and should use a supplier certification program for determining compliance with DINP and DIDP temporary restrictions while managing the technical difficulties and costs. We request an opportunity to meet with CPSC to discuss steps that can be taken to meet the challenge of certifying compliance with the CPSIA on the DINP and DIDP provisions.

For more information regarding this submission please contact:

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**RESPONSE TO CPSC's REQUEST FOR COMMENTS AND INFORMATION**  
**Draft Guidance Regarding Which Children's Products are Subject to the Requirements of**  
**CPSIA Section 108**

**Introduction**

ExxonMobil Chemical produces di-isononyl phthalate (DINP) and di-isodecyl phthalate (DIDP), two of the three high molecular weight (HMW) phthalates that are subject to the temporary prohibition in the CPSIA. Pending the outcome of the CHAP review, these phthalates are restricted from use in "toys that can be placed in a child's mouth" or in "child care articles" at concentrations greater than 0.1 weight percent. It is important for the CPSC to recognize that Congress did not make a judgment on the safety of DINP and DIDP in its decision to temporarily restrict them. Instead, they instituted "precautionary" temporary restrictions until a Chronic Hazard Advisory Panel has reviewed the scientific evidence around DINP, DIDP, and other phthalates and non-phthalate alternatives. We do not agree that the temporary restrictions are necessary based on previous scientific assessments and government reviews which have found DINP and DIDP to be safe for their intended use. With that said, it is important to note that DINP and DIDP can and should continue to be used in other PVC toys and children's products that do not fit the above definitions.

ExxonMobil Chemical appreciates the work that CPSC has undertaken to prepare this draft guidance as it is necessary for the marketplace to clearly understand where the provisions of Section 108 apply and where they don't apply. Clarity and consistency of definition is needed to ensure that the temporary restrictions on DINP and DIDP products are properly and pragmatically implemented. This will prevent the unnecessary testing costs and potential negative economic impacts that could result from the removal of products where the use of DINP (the primary phthalate used in toys) or DIDP is still permitted.

Our comments relate primarily to items that may be covered by the temporary prohibition and where exposure potential can and cannot exist. We also address identification issues for DINP and DIDP as it is important to ensure the temporary restrictions are properly implemented for these products.

**Exposure Considerations**

As recently stated in a CPSC staff memorandum transmitted by the CPSC Acting Chairman Nancy Nord, "Both the likelihood of exposure and the route of exposure are factors to consider in deciding what products should be subject to lead limits".<sup>1</sup> This statement very much applies to phthalates as well.

**Routes of exposure:**

Humans may be exposed to chemicals through a variety of exposure pathways, including oral ingestion, dermal contact with consumer products and inhalation of air and dust. Based on biomonitoring data<sup>2,3</sup> exposure to HMW phthalates from **all sources** is extremely small and **well below acceptable daily intakes** for DINP and DIDP.

Specifically for young children, oral ingestion and dermal contact are the two most relevant routes of exposure where oral ingestion via mouthing children's objects is the primary contributor<sup>4,5,6</sup>. The most recent

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<sup>1</sup> Responses to Letter from the Honorable John D. Dingell, Memorandum to Acting Chairman N. Nord and Commissioner T. Moore from CPSC General Counsel and Assistant Executive Directors, March 20, 2009, attached to Letter from N. Nord to J Dingell, March 20, 2009, p. 13.

<sup>2</sup> CDC (2005). Third National Report on Human Exposure to Environmental Chemicals. Phthalates. Centers for Disease Control and Prevention. Atlanta, GA.

<sup>3</sup> Wittasek M et al. (2007). Internal phthalate exposure over the last two decades – A retrospective human biomonitoring study. *Int J Hyg Environ-Health* 10, 319-333.

<sup>4</sup> ECB (2003). 1,2-Benzenedicarboxylic acid, di-C8-10branched alkyl esters, C9 rich and di-isononyl phthalate. Risk Assessment. European Chemicals Bureau, Institute for Health and Consumer Protection, Joint Research

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evaluation by Clark, 2008, supports oral ingestion as the primary source for estimated intake for children, toddlers and infants. In comparison to oral ingestion, dermal exposure is a minimal contributor to the overall exposure of children<sup>7</sup>. Studies performed in rats<sup>8,9</sup> indicate that the estimated dermal absorption rate is low and calculated maximal daily intakes attributable to dermal contact are significantly less than those attributable to oral ingestion<sup>10</sup>. It should be noted that the physical size of the HMW phthalates impedes the passage of the chemical through the skin. Additionally, exposure to children via indoor and outdoor air is considered negligible due to the very low vapor pressure of HMW phthalates<sup>11,12</sup>. Therefore, the temporary restrictions, as defined by Section 108 for high molecular weight phthalates on only toys that can be placed in the mouth, are attempting to control the primary route of exposure to children - oral exposure. The dermal and inhalation routes were not controlled as they do not significantly impact the overall exposure.

Likelihood of exposure:

For the purposes of the draft guidance and to avoid unintended adverse impacts on manufacturers, products that do not come into contact with the child but are in close proximity to the child should be excluded from regulation because they represent a "de minimus" exposure. Additionally, parts that are inaccessible to a child should also be excluded from regulation since they present no exposure potential. The CPSC should utilize this reasoning when defining the items that fall under the interim prohibition.

**Definition of Toys that can be Placed in a Child's Mouth**

ExxonMobil Chemical agrees with the CPSC proposal to use the existing ASTM F963 standard to determine is the definition of a toy. This definition provides industry a recognized standard that is pragmatic as well as providing a basis for exclusion of products that should not be considered.

Congress provided a narrow definition for toys that can be placed in the mouth and thus are subject to the Section 108 interim restriction for high molecular weight (HMW) phthalates. Under Section 108(e)(2)(B), the interim restriction applies only to those toys with dimensions less than 5 cm that can be brought into the mouth to be sucked or chewed, not merely licked. The basis for this distinction among toys that can be placed in the mouth is the fact that oral exposure is the main route of HMW phthalate exposure for children. Furthermore, the action of holding the item in the mouth and/or chewing, which agitates the article, is what may result in

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Center of the European Commission. EFSA. 2005. Opinion of the scientific panel on food additives, flavourings, processing aids, and materials in contact with food on a request from the commission related to di-isononyl phthalate for use in food contact materials. Question NO. EFSA-Q-2003-194. Adopted July 30, 2005. The EFSA Journal 244:1-18

<sup>5</sup> Gill US et al. (2001). Diisononyl phthalate: Chemistry, environmental path, and toxicology". In: Reviews of Environmental Contamination and Toxicology, ed. GW Ware, Springer-Verlag, New York. 172, 87-127.

<sup>6</sup> Clark K. (2008). Report on update to the phthalate ester concentration database – 2007. Prepared for American Chemistry Council. June.

<sup>7</sup> Clark K. (2008). Ibid.

<sup>8</sup> Deisinger P, Perry L and Guest D. (1998). In vivo percutaneous absorption of [14C]DEHP from [14C]plasticized polyvinyl chloride film in male Fischer 344 rats. Food Chem Toxicol. 36, 521-527.

<sup>9</sup> Elsisi A, Carter D and Sipes I. (1989). Dermal absorption of phthalate diesters in rats. Fund & Appl Toxicol. 12, 70-77.

<sup>10</sup> ECB (2003). Ibid.

<sup>11</sup> Wechsler C. (1984). Indoor-outdoor relationships for nonpolar organic constituents of aerosol particles. Environ Sci Technol. 18, 648-652.

<sup>12</sup> Tienpont B, David F, Sandra P and Vanwalleghem F. (2000). Evaluation of sorptive enrichment for the analysis of phthalates in air samples. J Microcolumn Separations 12, 194-203.

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potential exposure not the mere licking of an article. That distinction is highlighted in the definitions of toys that can be placed in a child's mouth.

The dimension of the toy should be measured when the toy is in its "play" state. For example, an uninflated pool toy has no real "play" value to a child, even though it could be chewed on. We do not believe that uninflated pool toys, beach balls, and water wings should be included as toys that can be placed in a child's mouth. These items are intended to be inflated by adults and kept away from children in the deflated state as they were not intended by the manufacturer to be played with in a deflated state. If, in the inflated state, the dimensions are greater than 5 cm, then the toy can not be placed in a child's mouth to be sucked or chewed.

Taking the ASTM F963 as the toy definition and following the CPSIA definition of a toy that can be placed in the mouth will allow industry to consistently and clearly determine which products fall under the CPSIA toy definition.

Bath toys, dolls, and action figures, to the extent that they can be placed into the child's mouth and be sucked or chewed, should be considered toys under Section 108's temporary prohibition. Other products, such as wading pools, costumes/masks and riding toys like "Big Wheels" should not, because they don't meet the CPSIA definition of less than 5 cm and can not be placed in a child's mouth so pose a minimal chance of exposure. Additionally, a vinyl-covered bicycle seat or sporting goods and athletic equipment made with DINP or DIDP would not pose any risk to a child as the potential exposure is extremely negligible (i.e. de minimus).

Some toys such as dolls, stuffed animals, and action figures may contain internal parts that give a movement or voice effect to the toy. Movement is usually powered by a battery power source and in this power source, it is common to find low voltage electrical wire which contain PVC coating connecting the power source and the switches. Although the vinyl-coated wires are smaller than 5cm, these are not accessible and cannot be sucked or chewed nor should they be for electrical safety reasons. As there is no exposure potential to the child, wiring that is internal should be excluded from regulation.

**Definition of Childcare Article**

Childcare articles are very specifically defined in Section 108(e)(1)(C) as "...consumer products 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." Unfortunately, the term "facilitate" is not clearly defined in the legislation. However, the mere fact that a product is used while a child sleeps or feeds does not mean that it "facilitates" sleep or feeding. Further, we believe that for the HMW phthalates interim prohibition Congress intended the articles that "facilitate" these listed activities (i.e. sucking, teething, feeding and sleeping) are those that come into contact with the mouth and thus result in oral exposure. A teething ring, for example, is a childcare article that helps provide comfort when a child is teething and is placed into the mouth. Additionally, a pacifier is a childcare article that helps a child go to sleep and is placed into the mouth. These articles have been identified as items of study in previous government reviews because of their exposure potential through the child's mouth and US manufacturers voluntarily removed DINP from these items in 1999.

We understand the CPSC's designation of childcare articles as "primary" -- those where the child has the most potential for exposure due to direct use by the child, and "secondary" --those products intended for use by the parent or those where the product does not "facilitate" sleep or feeding. However, we do not agree with the CPSC's categorization of articles into the "primary" category. We believe "primary" childcare articles should be defined as those items of less than 5 cm that can be mouthed or sucked by a child and not merely licked. These should be the only childcare articles subject to the temporary prohibition and the consistency in

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definition between toys and childcare articles will further clarify CPSIA application for manufacturers and consumers.

Secondary childcare articles should include all articles which can't be mouthed or sucked by the child and whose primary purpose is not facilitation of sleeping and feeding or sucking and teething and thus do not provide significant oral exposure. For example, a bib, while present during feeding, does not facilitate feeding; its primary function is to keep the baby's clothes clean from spilled food. We do not believe that bibs should be subject to the temporary prohibition. Additionally, pajamas or sleepwear may have non-slip feet provided by a vinyl (PVC) coating on the bottom of the feet. The purpose of the non-slip feet is not to facilitate sleep, but to keep the child from slipping and falling. Not only does sleepwear not facilitate sleep (it's possible to sleep wearing a variety of clothes or even no clothes) but it's also not likely for a child to suck or chew on the non-slip feet of pajamas for any significant period of time. We do not believe that sleepwear or apparel should be subject to the temporary prohibition. Similarly, mattress covers or mattress pads do not facilitate sleep but rather protect the mattress and keep it dry. Additionally, these articles are highly unlikely to come into direct contact with the child as they are typically covered with sheets and therefore should not be subject to restriction. Cribs or high-chairs that utilize PVC for parts of the chair that are not likely to have direct oral contact with the child (i.e. non-skid surfaces that touch the floor) should not be subject to regulation.

**Phthalates Certification**

Many phthalates that are in the same carbon number range are complex, contain many isomers, and are structurally similar. For example, phthalates with Carbon numbers 9 & 10, such as DINP, DIDP, DPHP, and L9P, share chromatographic elements when identified by the CPSC's phthalate testing protocol. Differentiation between these phthalates is technically difficult, expensive and not possible with the current CPSC phthalate method. This offers a unique challenge when certification labs are identifying the presence of these particular products that contain isomers in the same carbon number range. The CPSC needs to define a different certification technique to enable a clear, consistent and simple identification of the plasticizer contained in the PVC. This will avoid confusion and costly lab tests prone to misidentification. We believe that, to deal with these identification complexities of commercial plasticizer products in a more appropriate way, the CPSC must use a broader approach to certify that a PVC article is in compliance with CPSIA Section 108.

The CPSIA mandate to the CPSC is not to issue a phthalate testing method *per se*, but rather to accredit "third party conformity assessment bodies" (CABs).<sup>13</sup> The role of a CAB is to test samples of a children's product as provided by the manufacturer "for compliance with [a] children's product safety rule."<sup>14</sup> Based on that testing, the manufacturer then issues "a certificate that certifies that such children's product complies with the children's product safety rule based on the assessment of a third party conformity assessment body accredited to conduct such tests."<sup>15</sup>

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<sup>13</sup> CPSIA Section 102(a)(2). The Act does not define the meaning of "conformity assessment body"; in connection with the CPSIA the CPSC has treated it as meaning a "laboratory." *See, e.g.* 73 Fed. Reg. 67838 (Nov. 17, 2008) ("The [CPSIA] directs the [CPSC] to publish this notice of requirements for accreditation of third party conformity assessment bodies ("third party laboratories") to test children's products for conformity with the Commission's regulations at 16 CFR part 1501 . . . .");

<sup>14</sup> CPSIA Section 102(a)(2)(A).

<sup>15</sup> CPSIA Section 102(a)(2)(B).

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**CPSIA Section 108**

Neither the CPSIA nor the CPSC defines “test”, “testing”, or “reasonable testing program.” Further, the CPSIA does not specify the number or types of tests that must be conducted by the CAB.<sup>16</sup> However, the CPSIA grants the CPSC broad authorization to “issue regulations, as necessary, to implement this Act.”<sup>17</sup> Further, the Consumer Product Safety Act (CPSA), as amended by the CPSIA, authorizes the CPSC to promulgate rules to “prescribe *reasonable testing programs* for any product which is subject to a consumer product safety rule under this Act . . . and for which a certificate is required.”<sup>18</sup>

Within this framework, we believe that the CPSC has authority and discretion to accredit CABs and/or to promulgate a testing program on the basis of a procedure that combines analytical and certification elements for commercial plasticizer products. Therefore, simply analyzing quantitatively by gas chromatography for certain phthalate molecules is insufficient to enable accurate identification of commercial DINP and DIDP products. For a *reasonable* testing program, a qualitative check is also needed. This can be provided by a certification to the third party laboratory by the manufacturer and/or its phthalate supplier that the plasticizer used to manufacture the children’s product was not a commercial DINP or DIDP product or a blend of a commercial DINP or DIDP product and another plasticizer. While a certification is not a chemical analysis, it can be a “test” in the broader sense of an examination or proof.

We believe that such an approach would best enable the role of the CAB to test the children’s products “for compliance with [the] children’s product safety rule”<sup>19</sup> -- that is, to test whether the children’s product contains the commercial DINP and DIDP products for which there is an interim restriction, as opposed to other commercial plasticizers not restricted. ExxonMobil Chemical has manufactured these products for more than 40 years and has much expertise regarding composition and analysis. We request an opportunity to meet with the CPSC to discuss specific solutions that can be implemented to address the commercial DINP and DIDP product identification challenges.

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<sup>16</sup> CPSIA Section 102(a)(2)(A).

<sup>17</sup> CPSIA Section 3.

<sup>18</sup> CPSA Section 14(b), 15 U.S.C. 2063(b), as amended by CPSIA Section 102(d) (emphasis added).

<sup>19</sup> CPSIA Section 102(a)(2)(A).

## Stevenson, Todd

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**From:** worth.a.jennings@exxonmobil.com  
**Sent:** Wednesday, March 25, 2009 7:50 PM  
**To:** Section 108 Definitions  
**Subject:** ExxonMobil Comments On Draft Guidance Document  
**Attachments:** ExxonMobil Information submitted to CPSC March 25 2009.pdf

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March 25, 2009

Mr. Todd Stevenson  
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Dear Mr. Stevenson:

**Halloween Industry Association Comments CPSC Section 108's Draft Guidance Phthalate Requirements for Certain Toys and Child Care Articles**

The Halloween Industry Association (HIA) is a national trade organization representing the interests of manufacturers, importers and distributors of Halloween products (notably costumes) marketing under their own brands to consumers. HIA promotes the safe celebration of Halloween within the industry and general public and supports member interests through advocacy, awareness and education.

The Halloween Industry Association ("HIA") is submitting these comments in response to Commission's request for additional comments on the Staff's Draft Guidance regarding which children's products are subject to Section 108 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA" or the "Act") (*see* 74 Fed. Reg. 8058, Feb. 23, 2009). We hope these comments are useful in developing common sense policies governing the use of phthalates in certain children's products. Since these regulations impact many of our members' products, these issues are extremely important to the Association. The purpose of the present comment is to provide our supplemental views on the CPSC Draft Guidance Document, and to address issues related to particular product classes within the narrowly defined regulated Toy category. Our members do not manufacture import or distribute childcare articles as that term is defined under Section 108 of the Act. The Association reserves the right to amend or supplement these comments.

**Halloween is a Festive and Religious Occasion**

Halloween (or, by semantic correctness: Hallowe'en) is a holiday celebrated on October 31st. It has roots in the Celtic Festival of Samhain and the Christian holy day of All Saints. It is a secular celebration, but both Christians and Pagans have expressed strong feelings about its religious overtones. The day is often associated with costume attire with revelry and remembrance of the dead. The colors orange and black, and is strongly associated with symbols such as the jack o lantern. In North America, Christian attitudes towards Halloween are quite diverse. In the Anglican Church, some diocese have chosen to emphasize the tradition of All Saints Day, while some other Protestants celebrate the holiday as Reformation Day, a day

of remembrance and prayers for unity. Celtic Christians may have Samhain services that focus on the cultural aspects of the holiday. Christianity embraced the Celtic notions of family, community, the bond among all people, and respect for the dead. Throughout the centuries, pagan and Christian beliefs intertwine in a gallimaufry (hodgepodge) of celebrations commencing on October 31, all of which appear both to challenge the ascendancy of the dark and to revel in its mystery. The Occasion and the varied customs and festive products associated with it should not all automatically be mistakenly presumed to be “toys”.

### **Section 108 of the CPSIA**

Section 108 of CPSIA permanently prohibits the sale of any further defined “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) and also prohibits on an interim basis “toys that can be placed in a child’s mouth” 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” and “toy that can be placed in a child’s mouth,” are defined terms in section 108, and the definitions apply only to this section of the Act. However the language of other provisions of the Act has a direct bearing on how these terms may be interpreted. In addition the origins of the adopted phthalates restrictions should be considered since they have a direct bearing the risks and the implementation of common sense regulations. The CPSC in requesting additional comment has provided illustrations of the staff’s approach to establishing a framework for evaluating products subject to restriction. Also the statutory language, the manufacturers stated intent and the manner in which a product is used, marked, advertised, marketed and promoted may have a significant impact on whether or not the product falls within or outside the scope of standard. The requirements of section 108 apply to subsets of “consumer products” as defined by the Consumer Product Safety Act (CPSA). Similarly the requirements may also be considered as a further subset of “children’s products” as defined under the Act. Generally Section 108 is based on phthalate concentration within the product and does not distinguish between exposure pathways. Congress established the phthalate bans as a CPSA standard. It’s been noted that a “children’s toy” is defined as “a consumer product designed or intended by the manufacturer primarily for a child 12 years of age or younger *for use by the child when the child plays.*” § 108(e) (1) (B) (emphasis added). This definition amounts to the definition of “children’s product” in Section 235(a) plus the italicized phrase. The statute regulates groups of phthalates differently. One group consists of those known as DINP, DIDP, and DnOP. The restriction on this is interim, pending the creation and report of a Chronic Hazard Advisory Panel pursuant to § 108(b) (2) & (3). The applicable definitions of “children’s toy” and “child care article” are the same as for the first group, but the restriction regarding a children’s toy is expressly limited to a toy “that can be placed in a child’s mouth.” Section 108(e) (2) (B) defines this quoted phrase.

The CPSC staff has requested comments on staff’s approach to determining which products are subject to the requirements of CPSIA section 108, whether the limited guidance provided thus far has been clear, whether modifications are warranted and whether alternative approaches should be employed.

### **Risks of Children’s Exposure to the Specified Phthalates is Limited for Product Not Intended to be Mouthed**

There are several reasons that the Commission, at least in applying Section 108(b)’s interim prohibitions on DINP, DIDP, and DnOP, may and should, consistent with the statutory text, consider the potential for exposure of a child to phthalates from a toy. The Chronic Hazard Advisory Panel mandated by Section 108(b)(2), whose report will play a large role in determining the future of these interim prohibitions, must consider “the likely level of . . . exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of” products for children. § 108(b) (2) (B). It also must consider “the cumulative effect of total exposure to phthalates.” *Id.* And it specifically must consider “ingestion,”

“dermal,” and “hand-to-mouth” exposure, as well as any “other exposure.” *Id.* Finally, the Panel is to take into account “uncertainties regarding exposure.” *Id.* Second, the statutory definitions of “children’s toy” as a product designed or intended for “*use by the child*” when the child plays, presume sustained contact during prolonged periods of play, as a potential source of exposure. The Commission’s prior efforts regarding phthalates have focused on squeeze toys, teething rings, rattles, and pacifiers because these are all items that a young child can reasonably be expected to mouth chew and suck. Similarly, the statutory reference to a product designed or intended “to facilitate sleep or the feeding of” a young child (including a pacifier) is most reasonably understood as one that the child will use for that purpose, meaning that he will insert it into his mouth for prolonged periods of time and those very limited activities which lead to the potential for exposure. Obviously a plain reading of the whole language in context indicates that Congress intended a direct causal relationship between the product and the activity that results in the potential for prolonged mouthing, chewing, sucking or teething. This is why use alone is an insufficient basis for subjecting all products to these requirements.

The definition of mouthability, and Section 108(b) (1)’s express limitation of the regulation of three interim restricted phthalates in children’s toys to those that are mouthable, also reinforces these concepts. The definition contrasts a toy that “can be sucked and chewed” with one that can only “be licked.” In doing so Congress recognized that although licking may cause exposure, only the significant exposure created by chewing and sucking material inserted into a child’s mouth presented a potential hazard that would subject product to the limitations on phthalate content. As regards the interim-banned phthalates, Congress (consistent with the European Union) sought to focus on this primary risk of exposure, whereas the permanently prohibited phthalates were more restricted. Either way exposure only from narrowly defined toys and childcare articles remain a fundamental requirement.

Certainly the European Union’s phthalate regulations also reinforce this point. EU’s Phthalate Directive 2005/84/EC also draws a distinction between DEHP, DBP, and BBP, on the one hand, and DINP, DIDP, and DNoP, on the other. The EU has recognized that oral exposure from children sucking and chewing toys is the most likely route. Thus legislative text, precedent, and scientific policy all indicate that a toy should, in the context of its usage in Section 108(b) (2), be read as implicitly requiring a product’s mouthability. The Commission’s own recently announced Enforcement Policy recognizes this when it is focused on use of phthalates in squeeze toys teething rings, rattles, and pacifiers. Until standards are clearly established, we fully support the decision by the CPSC staff, in the discretion afforded it, to focus its resources only on enforcement efforts directed at products, already noted as most likely to pose a risk of phthalate exposure to children.

### **Halloween Costumes and Decorations Are Not Children’s Toys**

The U.S. Consumer Product Safety Commission (CPSC) staff has previously addressed a number of questions concerning applicability of phthalate limits and recently issued its request for comment on what may or may not constitute defined toys and childcare articles. Although the guidance was intended to help manufacturers, importers, retailers and consumers determine what products are covered by the phthalate limits, the guidance documents issued thus far do not provide the definitive determinations necessary for manufacturers, importers, distributors and retailers to adequately discern which products are clearly within the scope of the requirements and which are not. Unfortunately, inconsistent determinations remain in the marketplace. We are specifically providing comments to urge a plain reading of the statutory language so as to expressly exclude Halloween Costumes and decorations from classification as “toys” or “Childcare articles”.

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.*” [CPSIA §108(e) (1) (C)]. 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:

*-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.*

### **ASTM F963-07 Consumer Specification for Toy Safety Provides Useful Guidance on What Is Not a “Toy”**

We also support the CPSC staff’s consideration of the definition of “toy” in the ASTM F963-07 toy safety standard for guidance as to which products should be considered toys and which should not. The CPSIA makes ASTM F963 a mandatory CPSC standard on February 10, 2009. ASTM F963 excludes certain types of articles from the definition including: Books, Apparel, Art materials; model kits and hobby items in which the finished products is not primarily of play value; furniture (except for toy versions). Congress expressly adopted the full terms of such Standard, including exclusionary terms, expressly by under CPSIA Section 106. The fact that Congress eliminated adoption of the flammability Annex to such standard, demonstrates that had Congress intended that the listed exclusions for the above listed product categories, it would have similarly acted to strike adoptions of such provisions. The fact that it did not, reasonably indicates that it intended that such exclusions should apply as part of the regulatory definition of which products are considered within (or outside) the scope of defined toy products.

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In line with this reasoning, the CPSC staff appropriately considered various types of sporting goods and athletic equipment (regulation-size baseballs, basketballs, footballs, and soccer balls are sporting goods or athletic equipment) excluded from regulation under Section 108 as it is under 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. We support this approach. In contrast, the staff has regarded general purpose balls and a “toy version” of actual athletic equipment as a toy for the purpose of the CPSIA Section 108 requirements. We believe that such distinctions are valid. However, we also urge the CPSC staff to view products that function in an identical fashion to their real world counterparts as sporting goods or athletic equipment, not toys. Following this rationale, functional performance is an essential dividing criterion between products and “toy” versions that simulate real world activities. Ordinary books, including books for small children, are generally not regarded as toys. However, some novelty books, such as plastic books marketed as bath toys, or books that incorporate games, may be regarded as toys under both ASTM F963 and CPSIA section 108. Regarding books, it has been additionally noted that paper products and educational and learning functional materials should be excluded from regulation. We concur with this as well. Similarly 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 and should be excluded from consideration as a defined toy. In addition we note that although some electronic devices such as cellular phones with incorporated games, cameras, musical devices, lighting products may be decorated or marketed such that they may be attractive to children 12 years old or younger, yet they are not generally recognized as “primarily” a children’s product under the Act or considered “toys” under the mandatory ASTM F-963-07. Therefore, sporting goods, Books, Arts and Craft material, electronic lights, electronic Room Decor with a “Halloween theme” should also inherently be excluded from regulation as a toy for the purposes of applying Section 108 requirements. However we do recognize that children 12 years of age and younger may incorporate toys with their festive attire. In this regard a generally recognized toy

weapon or Halloween themed game or action figure, would generally be expected to be considered a “toy” in both the traditional meaning and under the ASTM Standards definitional framework.

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### **CPSC Should Exclude Wearing Apparel; Regardless of Festive Theme or Nature.**

Also we believe that the CPSC’s previously issued FAQ’s that indicated that traditional Halloween costumes should generally be considered wearing apparel, to the extent intended to be worn as festive, occasional attire subject to the Federal Flammable Fabrics Act (“FFA”) was appropriate and should continue to be adhered to. These products are distinct in their use patterns from toys or games specifically marketed as dress up games. As regards Costume attire and all actual footwear, gloves, hats, scarves, belts used in conjunction therewith we support the previous determinations as reflected in the CPSC General Counsel’s Opinion letter to the extent applicable to such apparel. [*See. Cheryl Falvey’ Esq.’s Correspondence dated October 17 and November 25, 2008 to the American Apparel & Footwear Manufacturers Association, Inc.*]. In all regards Halloween festive attire and accessories should not in and of themselves be treated differently than any other secular or religious celebratory garb.

### **Inflatable Costumes and Décor Items Should also be Excluded; For Toys a Mouthing Standard should Apply.**

Finally, it’s essential that the CPSC adhere to the definition of toys that can be placed in a child’s mouth, particularly for large inflatable toys that are made from interim restricted phthalates without protrusions less than 5cm in dimension that are not likely to be inserted in the mouth, chewed and sucked (but not licked) as required in the Act. 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.” 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. Please note above comments. We believe that the 5 cm criterion should be applied to inflatable toys in the inflated state. Most if not all inflatable toys will be less than 5 cm in at least one dimension in their deflated state and would therefore be considered “mouthable” under such a definition. Additional refinement to this policy is required. Toys that cannot be played with in a deflated state should be measured in their intended inflated state. Just as the determination of whether a product is a toy at all depends in part upon its likely use, so should the determination of whether a toy is capable of being inserted into a child’s mouth, chewed and sucked but not licked. The above-stated general rule and exceptions take account of the fact that some inflatable toys are very unlikely to be “mouthed” (as that term is limited narrowly defined in the Act) in their deflated state. We can only conclude that in the exercise of its discretion, the CPSC staff should harmonize with comparable determinations of the European Commission Enterprise and Industry Directorate General on inflatables. It is interesting to note that the 5 cm rule found in Section 108(e)(2) (B) is borrowed directly from the European Commission’s guidance, thus indicating that Congress was fully aware of the fact that Section 108 as drafted would be interpreted in a consistent manner when applied to larger inflatable toys. While small novelty inflatable toys designed to be inflated by the consumer, may commonly be available to children in deflated form, large inflatables, room décor and inflatable Halloween costumes whether inflated by continuous air flow or valves, should be considered as either “Not A Toy” or alternatively as toy products that are not likely to be placed in a child’s mouth as statutorily defined (if in an inflated state they don’t have protrusions that meet the dimensional criterion).

### **Licensed Intellectual property**

For all of all of the above examples we believe that graphic decorations with cartoon or licensed characters should not have any bearing on whether products are considered toys that are subject to the phthalate requirements under section 108, regardless of the character used. We note that increasingly

branded character licensing appeals to people in wide age ranges and not just children 12 years of age and younger. For example Mickey Mouse, Sponge Bob, Peanuts Characters and Sesame Street, Super Hero Characters have broad appeal across many age ranges. While such intellectual property may have a bearing on age grading, it is irrelevant to the determination of whether a product is a toy or childcare article. As noted above we believe the function of the product should be the primary factor determining whether or not the product is a toy or childcare.

## **Testing**

We support the CPSC's approach to product assessment testing and note that the use of the phrase "contains concentrations" in Section 108 is undefined and allows for such interpretation in light of Section 108's overall concern with children's exposure to phthalates. For example, given that the grammatical subject of this phrase is "toy" or "article" in Section 108(b) (1), as well as Section 108(a), rather than "part" or "component part" (terms not directly mentioned), it can be contended that whether a product has an impermissible concentration of any of the six specified phthalates is determined on the basis of the whole product. This is reflected in the recently published CPSC test protocol. Such protocol reflects the fact that the whole-product assessment is required (p.4). We are however cognizant that this is a difficult approach to testing and that adjustments may be required to be based upon the likelihood of mouthing and exposure to a part of children's product that can be "sucked and chewed, but not licked." [A basis may be found in the Consumer Product Safety Act that defines "consumer product" as an "article, or component part thereof." 15 U.S.C. § 2052(a) (1)]. However, given the lack of clear common sense testing (i.e. testing and rejection of inaccessible parts from intentionally disassembled product, regardless of exposure hazard or consideration of the whole product) it is essential that any changes to testing protocols, once published, must be made only upon notice with opportunity to comment and pursuant to the due process requirements of the Administrative Procedure Act ("APA"). Otherwise the disruption to production, testing and availability of product could be negatively and significantly impacted. There is no reason for the Commission to run such risks by reading Section 108 to require more than it actually does without with adequate advanced notice and time prior to any changes.

Thank you for providing us with the opportunity to submit comments. If you require additional information or examples, please do not hesitate to contact the undersigned. In providing these comments we do not intend to scare anyone.

Sincerely,

A handwritten signature in black ink, appearing to read "Stanley Geller". The signature is fluid and cursive, with a long horizontal stroke at the end.

Stanley Geller  
HIA Chairman

**Stevenson, Todd**

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**From:** Mike Dwyer [mdwyer@ahint.com]  
**Sent:** Wednesday, March 25, 2009 9:42 PM  
**To:** Section 108 Definitions  
**Subject:** Section 108 Comments from the Halloween Industry Association  
**Attachments:** HIA comments 3-25-09.pdf

Good Evening -

We appreciate due consideration of the Halloween Industry Association's comments on Section 108 of the CPSIA which are attached.

Regards,

Michele Biordi  
Executive Director  
Halloween Industry Association

Stevenson, Todd

65

**From:** sarahschimeck@comcast.net  
**Sent:** Wednesday, March 25, 2009 10:32 PM  
**To:** Section 108 Definitions  
**Subject:** Phthalates Testing

Hello. My name is Sarah Schimeck, I am a mother of three children, and I have a small business making baby blankets and bibs which I sell in online venues. My business is tiny, but the income I earn pays for groceries and other necessities. I am not of a scale that can hire attorneys or consultants to draft comments for me, but I felt it important to be heard on this issue. I don't have quotes from testing facilities; even to investigate cost is pointless at my economy of scale, as the cost of even one test is prohibitive. One test costs more than I earn in three weeks (and, as a digestive test, I would be left with no product to sell). My company doesn't generally purchase fabrics direct from manufacturers yet. However, I have compiled some testing reports from textiles companies. None of the results indicates phthalates present. There are those companies that are not testing (or haven't yet planned to), as their products are not necessarily directed toward use in children's items, but would be considered more "general use."

I use primarily all cotton fabrics, some polyester fabrics, and commonly purchased notions (velcro, thread, trims, etc.) to make these items. While I would have no reason to believe that any of these components would have phthalates in them, because they are used to make "child care items" as defined by the CPSC, they are subject to phthalates testing.

It is understandable to apply testing protocols to items such as pacifiers and teethingers made of plastics or other non-natural materials. As these may be in a young child's mouth for extended periods of time, and as these non-natural materials do sometimes contain phthalates, testing is merited. Holding bibs and blankets made of materials that do not inherently contain phthalates to the same testing standard seems illogical. While the case can be made that proximity to the mouths of infants and toddlers necessitates testing, there are two facts that argue to the contrary. First, if these items are made from non-coated textiles and, as textiles do not inherently contain phthalates, testing for these compounds seems unnecessary. Second, the relative time that these items would spend in a child's mouth as compared to a teether or pacifier lessens the risk for any "dose."

Certainly, it seems reasonable and at no inherent risk to consumers and their families to exempt textiles from the phthalates testing for such items as fabric teethingers, bibs, and blankets where no paint, decal, screen print or other application has been applied.

I appreciate the opportunity to be heard on this issue.

Yours,

Sarah Schimeck  
Ada, MI



March 25, 2009

Office of the Secretary  
Consumer Product Safety Commission  
Room 502  
4330 East West highway  
Bethesda, MD 20814

Subject: **Consumer Product Safety Improvement Act (CPSIA);  
Notice of Availability of Draft Guidance Regarding Which  
Children’s Products are Subject to the Requirements of Section  
108**

The Information Technology Industry Council (ITI), Consumer Electronics Association (CEA), and IPC – Association Connecting Electronics Industries®, represent numerous manufacturers of a wide range of components, computers, televisions, video display devices, wireless devices, MP3 players, printers, printed circuit boards, and other electronic equipment. We appreciate the time you have taken to work with industry and ensure that the concerns of the high-tech electronics industry are addressed.

Our member companies have long been leaders in innovation and sustainability. Many of our members go beyond requirements on product safety, environmental design and energy efficiency, and lead the way in product stewardship efforts. We appreciate the opportunity to provide feedback to the Consumer Product Safety Commission (CPSC) on the draft guidance and request for comments on Section 108 and appreciate the effort CPSC is putting forth to ensure stakeholder involvement. We look forward to continuing to work with the CPSC to address issues relating to compliance and implementation of the Act and thank the Commission for their timely work in providing guidance.

Based on our evaluations, most electronic devices will not be considered children’s products or toys as defined in the Act. For the most part, our members’ products are intended for general consumer use and are neither primarily intended for children age 12 years and younger nor or they for use in play; and therefore are not subject to the phthalate limits under CPSIA.

Responses to the Request for Comments:

I.A. Comments on Staff’s approach to determining products subject to Section 108

Overall, ITI, IPC and CEA support the approach in the draft guidance document. However, we believe that some additional clarity in certain parts could be helpful. Specifically, the biggest concern is with the lack of a definition of “play.” If one of the criteria for determining whether a device is a “toy” is “whether the intended use of the product is for play,” it is critical that a clear definition of “play” is established. The CPSC proposed some potential definitions of “play” at the March 12 phthalates meeting. We believe that the

definitions tending toward “action” are necessary in order to differentiate between a child simply “enjoying” a product and being “entertained” by it and “playing” with it.

ITI, IPC and CEA agree with the Commission’s “tiered” approach to feeding and child care articles, in which “secondary” articles that are not directly used by the child are not in scope.

### I.C. Additional guidance

As with the definition of “children’s product,” the CPSC must address the issue of functionality in the determination of whether a product is in scope. While the act does not include “primarily” in the factors to consider for whether a product is a “toy” (as is in the definition of “children’s product in Section 101), the Commission has already stated in the public meeting that “simulations” of devices, such as toy cell phones or computers, are different from the products they are simulating. Therefore, simply because a device “may” be used, and perhaps used in play, by a child does not automatically make a product a toy. A clearer definition of “play” may also be helpful in avoiding confusion between a “general purpose” device and a “toy” analog.

In determining what electronic devices may be considered toys, the basic guiding principle is the one that CPSC has already established. That principle is "if a product is intended for adults or for general use by consumers of all ages, then it is not intended primarily for children." The fact that people may “play” with an electronic device is not a valid indicator that such an item is a toy. People (not just children) “play” with devices such as cell phones, video games, personal musical devices, etc. in the same sense that they “play” with sports equipment, playing cards or musical instruments. The fact that an electronic device may have the ability to have its content tailored for different age groups, including children, is also not a valid indicator of whether that electronic device is a toy, or not. If the same physical device is intended for adults or for general use by consumers of all ages, then such a device, by the CPSC's own definition, is not a toy.

The Commission should also more clearly differentiate between devices that are “children’s products” and “toys.” For example, some manufacturers of general use electronic devices, such as computers and calculators, will design and market electronic devices that are intended for use by children under 12 years of age. This might include a “student” model of a device that is designed and intended primarily for older children (typically 6 – 12 years old) for use in supervised education settings. These “student” or “children’s” versions of a device are designed, marketed and distributed separately from general use devices of the same product class, but are not sold as “toys” and are not designed for use when a child plays. Toy versions of these devices generally have limited functionality and are generally designed for children under 6 years of age. ITI, IPC and CEA view “toys” and “child care articles” as defined in Section 108 as a subset of “children’s products” as defined in Section 235 and ask that the Commission note this in the final rule. Finally, we believe the proposed rule should explicitly state that products that are not children’s products are also not toys and therefore not subject to the requirements in Section 108.

## II.B. Electronic devices with decorations or cartoon characters

For the purposes of Section 108 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.” We believe decorated general use electronic products (e.g., computers, video game consoles, cameras, mobile phones, printers, radios and other music players) should not be considered toys as they do not meet the above definition. General use electronic products are not designed or intended primarily for children aged 12 and under. They are designed and intended for a wide range of consumers. Moreover, these products have no obvious play value. They are not used when a child plays. Decoration of, or a decorative cover on, a general use electronic product does not automatically convert the product into a child’s toy. Regardless of decoration the underlying function of the product remains unchanged.

## II.F. and II.G Staff approach to priority products.

ITI, IPC and CEA agree with the staff’s approach to dealing with primary and secondary child care articles. In fact, we believe that it would be helpful for the guidance to clarify that, for example, a device that plays lullabies in a nursery, whether the device is sold specifically as a sleep aid or a generic music device (such as a stereo), is not a child care article even though it may help a child fall asleep. Congress made an attempt in the legislation to include some level of risk assessment, for example by designating in section 108(b) (1) that the interim ban applies only to toys that can be placed in the child’s mouth. It is entirely consistent with the intent of Congress to focus on the types of products with which younger children are most likely to have intimate contact, and primarily through oral contact. Using this approach would relieve the makers of many consumer electronic products from the testing requirement and the need to issue certificates of conformity, and would preserve valuable laboratory resources for the types of products that are more likely to be used directly by younger children. We note that Congress failed to include in Section 108 an express provision focusing on “accessible” components of a toy or child care article, as it did with regard to lead in children’s products under section 101. It is clear, however, that the use of the phrase “toy that can be placed in a child’s mouth” is evidence that Congress intended for accessibility to be a key aspect of the risk-based approach. In the case of certain consumer electronic products intended for the general population, the potential for small concentrations of phthalates to be present in internal components that would not be accessible to any users through foreseeable use and abuse should not force those products to be required to be tested for phthalates. This is because there is no reasonable exposure pathway for very young children who ordinarily would not be entrusted with the products in the first place.

## II.L. Promotional Items

Consumer electronics are sometimes marketed in connection with promotional items, such as replicas of characters in a movie or video game or other souvenir type products associated with a brand. We believe the fact that an electronics item is “promotional” does not automatically imply that it is a toy. For example, some promotional electronic items

are not "toys" as defined in CPSIA because they are not intended for play by children of any age. Instead, these electronic items are intended to be collected and displayed by enthusiasts. In some cases the promotional electronic products may have considerable value because they are produced in limited numbers and may be scarce. In some cases, parents, caretakers, or other adults can clearly identify that certain promotional items may be unsuitable for younger children because of many factors such as fragility, intricate parts or decoration, or may contain small parts or other choking hazards. Consistent with this, parents are unlikely to entrust these products to younger children and, as a result, there is no serious risk of exposure. Therefore, promotional items should be subject to the same factors in Section 108 to determine whether they are "toys." In addition, the inclusion of a promotional item in the same package with a consumer electronic product should not automatically convert that product into a "toy" for purposes of section 108.

### Concluding Comments

On behalf of our combined membership, we appreciate the opportunity to provide comments on the draft guidance. We hope to continue working with the CPSC as the guidance progresses into a rule and as additional rules and actions implementing the Act are developed. We would welcome the opportunity to have a small number of technical experts from our industry meet with CPSC to discuss these comments in more detail and answer any questions that you might have.

We look forward to continued, close cooperation as this important legislation is interpreted and implemented. Please do not hesitate to contact Megan Hayes, CEA, at [mhayes@CE.org](mailto:mhayes@CE.org) or 703-907-7660; Chris Cleet, ITI, at [ccleet@itic.org](mailto:ccleet@itic.org) or 202-626-5759; or Ron Chamrin, IPC, at [RonChamrin@ipc.org](mailto:RonChamrin@ipc.org) or 703-522-0225 if you have any questions.

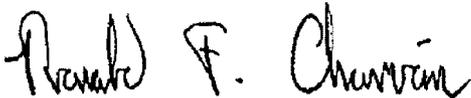
Sincerely,



Brian Markwalter  
Vice President, Technology & Standards  
Consumer Electronics Association



Christopher Cleet  
Director of Environmental Affairs  
Information Technology Industry Council



Ronald F. Chamrin  
Manager of Government Relations  
IPC – Association Connecting Electronics Industries®

**Stevenson, Todd**

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**From:** Cleet, Christopher [ccleet@itic.org]  
**Sent:** Wednesday, March 25, 2009 10:35 PM  
**To:** Section 108 Definitions  
**Cc:** Brian Markwalter; Ron Chamrin  
**Subject:** ITI/IPC/CEA comments on draft guidance of CPSIA Section 108  
**Attachments:** ITI-CEA-IPC Comments on draft guidance on section 108.pdf

Dear Sir or Madam;

Please see the attached comments on the Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108 from the Information Technology Industry Council (ITI), the Consumer Electronics Association (CEA), and IPC - Association Connecting Electronics Industries.

Regards,

Chris Cleet

Director of Environmental Affairs

Information Technology Industry Council (ITI)

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Washington, DC 20005

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**Stevenson, Todd**

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**From:** A.R. [jittybittyrevolution@yahoo.com]  
**Sent:** Wednesday, March 25, 2009 10:56 PM  
**To:** Section 108 Definitions  
**Subject:** Pthalate testing requirements

Dear CPSC Administration:

I feel that certain amendments should be made requiring pthalate testing when it concerns products made of natural cloth and other organic substances. Pthalates by their very nature are man made ingredients used to aid in the softening of plastic items as well as for other industrial purposes. As such, it becomes a waste of time and products to require pthalate testing for all products regardless of the nature of the product.

It places an unfair burden on companies who are manufacturing natural/organic goods, especially those that have been expressly manufactured for the purposes of providing an alternative to those items that are made with pthalates. If the requirements for pthalate testing are mandated across the board regardless of the actual product, the end result will be nothing more than a silly exercise of bureacratic excess in action. It is not smart to rid a home of termites by dynamiting the entire neighborhood block.

Sincerely,  
Arnikka L. Robinson

**Stevenson, Todd**

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**From:** Michelle Mathews [michellemathews8@gmail.com]  
**Sent:** Thursday, March 26, 2009 12:07 AM  
**To:** Section 108 Definitions  
**Subject:** Comments on CPSIA Phthalates requirement

To Whom It May Concern:

Please consider exempting materials that do not contain plastic, as it is well known that phthalates are only present in plastics. Toys and baby care items made using fabric, yarn, thread, paper, wood and other non-plastic materials should be exempted since it is impossible for anything that does not contain plastic to contain phthalates.

Phthalates testing presents a financial hardship on small and micro businesses (such as my own), especially those manufacturing items without the use of plastics. Many artisans make one-of-a-kind items that would have to be destroyed in order to test for phthalates, many of these items don't even contain plastics.

Additionally, manufacturers of children's toys and baby care items that do use plastics should be allowed to rely on the testing results of the company that manufactures the supplies they use. For example, if a bib has a velcro closure, the person who makes the bib (i.e. the artisan or crafter) should be allowed to rely on the testing results of the company who manufactured the velcro. This eliminates redundant testing.

Sincerely,

Michelle Mathews  
916.508.0332

**Stevenson, Todd**

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**From:** Lp [reruns@tds.net]  
**Sent:** Thursday, March 26, 2009 12:20 AM  
**To:** Section 108 Definitions  
**Subject:** [Possibly Spam]: comment on CPSIA

**Importance:** Low

Hello,

I want to add another comment before the deadline. I had written previously about how horrible I think the rules are for handmade crafters.

About Children's Books.

Shall we just burn all of the literature prior to 1985? What are you thinking!?!?!?!?

You must act fast. Thrift stores are destroying books by the millions.

Green Eggs and Ham

Charlotte's Web

Little House on the Prairie

Mother Goose

Superman Comics

Lynn Pagel

Sheboygan WI