



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Re: Notice of Availability of Draft Guidance Regarding Which Children's Products are Subject to the Requirements of CPSIA Section 108; Request for Comments and Information.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.¹

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.²



¹ 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."

² <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.³ The European Union has recently identified modeling clay that exceeds the standard for DnOP.⁴ Stamping kits⁵ and jewelry making kits⁶ were also recently identified in the EU as containing high levels of

³ [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

⁴ European Union (EU), Rapid Alert System for Non-Food Products (RAPEX) website:
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.

⁵ EU RAPEX website 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%.

⁶ EU RAPEX website: 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.⁷

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".

⁷ EU RAPEX website:

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.⁸

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.⁹ 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

⁸ 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
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).

⁹ 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.¹⁰

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

¹⁰ 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

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,

A handwritten signature in black ink, appearing to read "Sarah Janssen", with a long horizontal flourish extending to the right.

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