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VIA E-MAIL
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Office of the Secretary
U.S. Consumer Product Safety Commission
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RE: Notice of Availability of Draft Guidance Regarding Which Children's Products Are Subject to the Requirements of CPSIA Section 108, 74 Fed. Reg. 8058 (Feb. 23, 2009)

Dear Sir or Madam:

We are writing in response to the February 23, 2009, request for comments on CPSC's phthalate test method and on CPSC staff's draft approach for determining which products are subject to the requirements of section 108 of the Consumer Product Safety Improvement Act ("CPSIA") (Pub. L. No. 110-314 (2008)).

Like the CPSIA, California law bans the use of six phthalates in toys and childcare articles. Because California's A.B. 1108 (Cal. Health & Saf. Code § 108935 et seq.) and the CPSIA use nearly identical language to ban the same six phthalates in toys and child care articles and both derive from the European Union's pre-existing phthalate ban, we anticipate that interpretations of both federal and California law can be harmonized.[1] To the extent that CPSC's interpretations of CPSIA section 108 would support the purposes of A.B. 1108, we expect to enforce the requirements of A.B. 1108 consistent with CPSC's interpretations of the CPSIA.

[1] For example, while A.B. 1108 does not specify an age range for "children" as used in that statute, we do not see any reason for California to depart from CPSIA section 108's age range of "12 years of age or younger."

Definition of toy – ASTM exclusions

CPSC requests comments on whether "toys" covered by CPSIA section 108 should include the same products as "toys" covered by ASTM F963-07. 74 Fed. Reg. 8058, 8060 § II.A (Feb. 23, 2009). The exclusions found in ASTM F963-07 may be too broad for the purposes of applying CPSIA section 108. Those exclusions may be based in part on whether other voluntary safety standards exist for a given product, not on whether such product is commonly considered to be a toy. Because CPSIA section 108 applies to all "toys," the fact that ASTM F963-07 does not apply to an item does not seem to be a basis to exclude that item from coverage of CPSIA section 108.

We suggest that CPSC consider more narrow exclusions, or tailor the exclusions to specific materials or parts of products that inherently do not contain phthalates. For instance, bicycles are excluded from ASTM F963-07. Bicycles are mostly made of metal alloys, which do not contain phthalates, but plastic parts of bicycles or decorations and accessories sold with them could contain phthalates to which children could be exposed. Also, the distinction between a "tricycle" and other ride-on toys for young children may be difficult to make in practice, and many such products for young children have significant plastic components. Many remote controlled toys excluded by ASTM F963-07 as "powered models" also are used by children when they play and could cause exposure if phthalates are present in those products. In determining what is a "toy" under CPSIA section 108, CPSC should analyze the specific ways in which a product is used and marketed instead of simply adopting the categorical exclusions of ASTM F963-07, much as it plans to do when determining what is a "child care article."

Regulation of products with multiple functions

CPSC requested comments on whether all bouncers, swings, or strollers should be subject to CPSIA section 108, or only those that are "advertised" as facilitating sleeping, feeding, sucking, or teething. 74 Fed. Reg. 8058, 8060 § II.K. How a product is advertised does not, of course, determine how the child will actually physically interact with the product and whether it will in fact be used for, say, sleeping. While the way a product is advertised should be one consideration in determining whether the product is a "child care article," we suggest that it be considered along with the other factors outlined by CPSC – intended use, age grading, the primary/secondary facilitation concept, and consumer understanding. We also note that it appears that the European Union considers car seats, strollers, and baby carriers to be child care articles to which its phthalate ban applies.[2]

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[2] European Comm'n, Enterprise & Indus. 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 22nd amendment of Council Directive 76/769/EEC, available at* http://ec.europa.eu/enterprise/toys/documents/gd008.pdf.

Test method

We do not believe that the sample preparation method described in CPSC's March 3, 2009, "Standard Operating Procedure for Determination of Phthalates" (CPSC-CH-C1001-09.1) is consistent with the language or the purposes of the phthalate bans in CPSIA section 108 or, for that matter, in California's A.B. 1108.[3] CPSC's proposed method is more than simply a test protocol. Its practical effect is to establish what parts of a product must comply with the CPSIA section 108 prohibition of phthalate concentrations greater than 0.1 percent. By considering the entire product to be the relevant point of compliance instead of each component to which a child could be exposed, CPSC's proposed method undermines the purpose of the CPSIA phthalate ban. It creates a loophole through which materials with far higher phthalate content than Congress intended can continue to be used in toys and child care articles.

To avoid this result, we intend to enforce California's A.B. 1108 phthalate ban against toys and child care articles with *individual parts or materials* that contain greater than 0.1 percent phthalate concentration. We urge CPSC to adopt the same interpretation for the CPSIA.[4]

CPSC's proposed method considers the "sample" to be analyzed as the entire product. Thus, the total concentration of phthalates in an entire product would be measured for purposes of determining whether the 0.1-percent regulatory threshold has been met. This would allow high-phthalate components to be "diluted" by components that do not contain phthalates, with the result that CPSC could consider products with high levels of phthalates in some materials but not others to be in compliance with CPSIA section 108.

The sample preparation method CPSC has proposed leads to results that are plainly contrary to Congress's intent. Consider, for example, a baby swing with an attached teething ring that contains phthalates. Under CPSC's proposed method, the manufacturer would not need to ensure that the teething ring meets the 0.1-percent threshold. Rather, CPSC would determine compliance of the product only after including all parts of the swing – fabric seat, metal springs, internal mechanical components – even though it may be impossible for the child to get those

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[3] We are not expressing a preference on technical aspects of CPSC proposed Standard Operating Procedure, such as methods of extraction or sample analysis.

[4] We also note that following CPSC's proposed method would not necessarily help determine compliance with California's Proposition 65 (Health & Saf. Code § 25249.6). The duty to warn under Proposition 65 is triggered by an exposure to certain phthalates, not by any particular phthalate concentration. Because a person can be exposed to phthalates from a single part of a product with high phthalate levels, determining the overall phthalate concentration for a heterogeneous product is unlikely to provide sufficient information to determine whether a Proposition 65 warning is required. As we said in our December 3, 2008, letter to CPSC General Counsel Cheryl Falvey, however, we expect that in most cases products made from materials with less than 0.1 percent of the regulated phthalates would not require a Proposition 65 warning for those phthalates.

parts into its mouth and those parts may have no phthalates whatsoever.[5] Congress did not intend to permit companies to sell toys and child care articles with mouthable plastic parts that contain high phthalate levels, so long as the mouthable parts are part of a larger product whose non-phthalate, non-mouthable mass dilutes the overall phthalate concentration to less than 0.1 percent.

Allowing companies to use phthalate-rich materials that are part of a larger product is contrary to the plain language of the statute. The CPSIA prohibits the manufacture, sale, and distribution of "any children's toy or child care article that contains *concentrations* of more than 0.1 percent" of the regulated phthalates.[6] But CPSC's proposed test method looks for a single concentration of each regulated phthalate within a product, not for concentrations, as the statute mandates. Even if Congress intended to treat the concentration of each of the six phthalates separately, which we understand is CPSC's view, Congress would not have made "concentration" plural unless it contemplated more than one concentration of each phthalate within a product. Otherwise, Congress would have prohibited products with a "concentration" of "more than 0.1 percent of [DEHP, DBP] or [BBP]," for instance. The only reasonable way to construe the plain language of the statute is that the ban on phthalate *concentrations* greater than 0.1 percent contemplates that there may be more than one concentration of each phthalate within a single product.

We recognize that, arguably, differences between language Congress used in section 101 (banning lead) and section 108 could support CPSC's view that the compliance point for the phthalate ban is the entire product. Congress specified that the CPSIA section 101 lead standards apply to "total lead content by weight for any part of the product," and further specified that inaccessible parts need not meet those lead standards, but the section 108 phthalate ban applies without specific reference to parts or accessibility. Therefore, the argument goes, Congress must not have intended that separate parts of children's toys and child care articles be free of phthalates. *See, e.g., Russello v. U.S.*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") This interpretation is not required by the language of the CPSIA and is not a reasonable interpretation of Congress's intent.

The tiered lead standards in CPSIA section 101 need not constrain CPSC's interpretation of the very different phthalate ban in section 108. As discussed above, we believe the language is clear. To the extent there is ambiguity, CPSC has the authority to make reasonable

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[5] Similarly, CPSC requests comments on whether a crib is a child care article that must meet the 0.1-percent limits, or must only the teething rail meet that limit. 74 Fed. Reg. at p. 8060 § II.A. Regardless of whether the "child care article" is defined as the entire crib or merely the teething rail (i.e., the specific part designed to facilitate teething), it is important that the portion of any product subject to CPSIA section 108 meet the 0.1-percent threshold. Children are unlikely to chew on the underside of a crib, so it is illogical to average the mass of the wood and metal parts of that piece of furniture into the calculation of how much phthalate is in the teething rail.

[6] CPSIA § 108(a) & (b) (emphasis added).

interpretations of what Congress intended in enacting the CPSIA's phthalate ban. *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984). Any reasonable interpretation of the CPSIA section 108 phthalate ban must take account of the fact that Congress did not craft it in parallel with the section 101 lead restrictions. It imported the phthalate ban from preexisting bans in the European Union and California. Congress made some modifications, but the structure of the phthalate ban remained the same. By contrast, Congress developed the lead restrictions on its own. Moreover, the section 108 phthalate ban has a very different structure from the section 101 provisions setting lead levels. Because of the difference in the history and structure of the lead and phthalate provisions of the CPSIA, CPSC should not interpret the use of certain words and phrases only in section 101 to mean that Congress intentionally excluded such concepts from section 108. *City of Columbus v. Ours Garage and Wrecker Service, Inc.*, 536 U.S. 424, 435-436 (2002) ("The *Russello* presumption that the presence of a phrase in one provision and its absence in another reveals Congress' design-grows weaker with each difference in the formulation of the provisions under inspection.")

As stated, the phthalate ban in CPSIA section 108 originated with the pre-existing California and European Union phthalate bans. The current European Union phthalate ban was issued in 2005. In July 2006 San Francisco banned the same six phthalates in certain children's products. California's A.B. 1108, which passed the Legislature on September 4, 2007, was intended to impose the San Francisco ban statewide.[7] Eight weeks later, on October 31, 2007, Senator Diane Feinstein of California introduced a bill in the U.S. Senate to apply the same phthalate ban nationwide.[8]

But the CPSIA lead prohibitions had their origins primarily in CPSC reform bills introduced into the U.S. House of Representatives and U.S. Senate in the fall of 2007. The bill that would become the CPSIA – H.R. 4040 – was introduced in the House by Representative Bobby Rush on November 1, 2007, the day after Senator Feinstein's introduced the phthalate bill. On December 19, 2007, the House passed H.R. 4040. The bill did not mention phthalates at all. H.R. 4040 as passed by the House contained almost exactly the same language limiting lead in children's products as does the CPSIA, and both set the numerical lead concentration limits based on "total lead content by weight for any part of the product."[9] In other words, the lead limits applied to each part, not to the product as a whole. Both as introduced and as initially passed by the House, H.R. 4040's lead prohibitions did not apply to parts that were not accessible to a child.

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[7] Cal. S. Rules Comm., Analysis of Assemb. Bill No. 1108, 2007-2008 Sess., at 3-5 (July 12, 2007) (explaining that the European Union ban applied to the same phthalates as the San Francisco ordinance and that that ordinance itself "mirrors" A.B. 1108).

[8] S. 2275, 110th Cong. (2007); 153 Cong. Rec. S13628-29(daily ed. Oct. 31, 2007) (statement of Sen. Feinstein explaining that S. 2275 is "modeled" on the European Union ban; "I urge my colleagues to support this legislation, and to provide all American children with the same safe toys available in Europe and California.")

[9] *Compare* H.R. 4040 § 101(a)(2)(A), (B) & (C) (as passed by House), 153 Cong. Rec. H16874 (daily ed. Dec. 19, 2007), *with* CPSIA § 101(a)(2)(A), (B) & (C).

The principal Senate bill, S. 2045, was introduced by Senator Mark Pryor on September 12, 2007, and proposed to regulate lead content of "any part of the [children's] product" that contained lead above a certain percentage "by weight of the total weight of such part."[10] Thus, the Senate bill also regulated lead on a part-by-part basis. This Senate language remained unchanged as the text of S. 2045 was amended and inserted into S. 2663[11] on February 25, 2008, and remained unchanged as the Senate passed its version of H.R. 4040 on March 7, 2008[12]. The Senate lead limitations also applied only to accessible parts of a children's product. Ultimately, the House's original "total lead content by weight for any part of the product" construction – introduced on November 1, 2007 – became the final compliance point for lead under CPSIA section 101.[13]

Returning to the phthalate provisions, they did not enter into the CPSC reform bills until March 4, 2008, when Senator Feinstein offered an amendment to S. 2663 that contained a phthalate ban that was nearly identical to the separate phthalate bill she had earlier introduced. This amendment was explicitly based on the California A.B. 1108 ban and the European Union ban and was intended to mirror those bans.[14] Three days after the phthalate amendment was introduced, the Senate passed its version of H.R. 4040 (which replaced the House-passed version with the language of S. 2663) with that phthalate ban. The compromise between the House and Senate bills that became the CPSIA included a modified phthalate ban. The legislative history shows that at the time it passed the CPSIA, Congress was aware that the federal phthalate ban was based on the California and European Union phthalate bans.[15] In fact, in the final version of

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[10] S. 2045 § 23(b) (as introduced), 153 Cong. Rec. S11504 (daily ed. Sept. 12, 2007).
[11] S. 2663 § 22(b) (Feb. 25, 2008, version), 154 Cong. Rec. S1134 (daily ed. Feb. 25, 2008).
[12] H.R. 4040 § 22 (passed by Senate as amended), 154 Cong. Rec. S1775 (daily ed. Mar. 7, 2008).
[13] Conference Report on H.R. 4040, Consumer Product Safety Improvement Act Of 2008, H.R. Rep. No. 110-787, 154 Cong. Rec. H7194 (daily ed. Jul. 29, 2008).
[14] Senator Feinstein's comments introducing the phthalate amendment include the following:

> The amendment would replicate what will be California law in 2008 and ban the use of the chemical phthalates in toys as California has done . . . . I think it is time for the rest of the country to follow the lead of California, the European Union, and other nations because without action the United States risks becoming a dumping ground for phthalate-laden toys that cannot legally be sold elsewhere. . . . This amendment follows the same standards already set by the European Union and California.

154 Cong. Rec. S1511 (daily ed. Mar. 4, 2008).

[15] *See* 154 Cong. Rec. S7874 (daily ed. Jul. 31, 2008) (statement of Sen. Boxer):

> The United States is often behind the rest of the world when it comes to chemical policy. The same has been true for phthalates. These chemicals have been restricted in at least 31 nations, including European Union . . . . It took action from three States—California, Washington and Vermont—before we have reached this point. . . . With the passage of this legislation, parents throughout this country will have the same assurances as parents in the E.U., in Argentina, in Japan, and all of these other counties.

the bill Congress borrowed language for the definition of "toy that can be placed in a child's mouth" nearly verbatim from a European Union guidance document on the same subject.[16]

The European Union, California's A.B. 1108, and the CPSIA also have created the same two-tiered structure for the phthalate ban. In all three laws, three phthalates (DEHP, DBP, BBP) are banned in all toys and child care articles, regardless of whether those products can be placed in the mouth by children. In the European Union and California bans, the other three phthalates (DINP, DIDP, DNOP) are banned only in toys and child care articles that can be placed in the mouth, and they are banned under the CPSIA for toys that can be placed in the mouth and all child care articles. The European Commission justified this two-tiered approach based on the greater evidence of toxicity of the first three phthalates, whereas "the restrictions for DINP, DIDP and DNOP should be less severe than the ones proposed for DEHP, DBP and BBP for reasons of proportionality."[17]

The record thus establishes that the phthalate ban in section 108 and the lead ban in section 101 have different origins. An additional reason not to construe the two provisions in relation to each other is that Congress used different words in each section to describe the same concept, apparently without any scientific reason for doing so. The European Union, California's A.B. 1108, and the CPSIA all regulate the "concentrations" of certain phthalates.[18] By contrast, section 101 (and the bills leading up to it) regulate "total lead content by weight," and express lead limits in parts per million, not as a percentage. But whether expressed as a

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See also 154 Cong. Rec. H7582 (daily ed. Jul. 30, 2008) (statement of Rep. Barton, Ranking Member of House Energy and Commerce Committee):

> Some States have begun to ban these products. The European Union has banned certain of these phthalates and, as a result, in the other body, the Senate bill had a prohibition based on a California standard on a large number of these particular compounds.

[16] *Compare* European Comm'n, Enterprise & Indus. 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 22nd amendment of Council Directive 76/769/EEC, available at* http://ec.europa.eu/enterprise/toys/documents/gd008.pdf, *with* CPSIA § 108(e)(2)(b). We also note that this European Commission guidance says that the phthalate ban only applies to "accessible" parts of some child care articles.

[17] Parliament and Council Directive 2005/84/EC, 2005 O.J. (L 344/40), at ¶¶ 10-12, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:344:0040:0043:EN:PDF.

[18] *Compare* Parliament and Council Directive 2005/84/EC, 2005 O.J. (L 344/40), Annex (stating that specified phthalates "Shall not be used as substances or as constituents of preparations, at concentrations of greater than 0,1 % by mass of the plasticized material, in toys and childcare articles") *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:344:0040:0043:EN:PDF, *with* Cal. Health & Saf. Code § 108937(a) & (b) ("A.B. 1108") (banning toys and child care articles that contain the phthalates "in concentrations exceeding 0.1 percent") *with* CPSIA § 108(a) & (b)(1) (banning any toy or child care article "that contains concentrations of more than 0.1 percent of" the phthalates).

concentration or as content by weight, both mean the same thing: the proportion of the regulated chemical within the mix of chemicals that make up the material being tested. It would make no sense to assume that, because Congress used different words to describe the same concept, Congress meant for the proportion to be calculated differently in sections 101 and 108. Rather, the different words Congress used to express the same concept in each section again show that CPSIA sections 101 and 108 do not have common legislative origins. They should not be treated as if they do.

In short, the history and structure of the CPSIA lead and phthalate provisions demonstrate that they developed completely independently from each other and should not be construed in conjunction with each other. The phthalate ban in section 108 is modeled on the European Union and California phthalate bans, and was not developed alongside the lead prohibition. There is no evidence in the legislative history that Congress attempted to reconcile the lead and phthalate compliance schemes. Based on this history, there is no reason to think that Congress intended the two provisions to be read such that concepts included in one were excluded in the other. *See City of Columbus*, 536 U.S. at 435-436. Thus, instead of presuming that, because Congress mandated part-based compliance for lead and excluded inaccessible parts, it intended *not* to do so for phthalates, CPSC should make a reasonable interpretation of CPSIA section 108 in light of its origins and Congress's intent.

By including section 108 in the CPSIA, Congress intended to reduce children's exposures to high phthalate concentrations in toys and in child care articles. That intent cannot be effected by setting the phthalate ban compliance point as the whole product, as CPSC's proposed Standard Operating Procedure would do. Instead, CPSC should modify the sample preparation method to measure phthalate concentrations in individual parts of toys and child care articles to which a child might be exposed.

Thank you for the opportunity to comment on CPSC's proposals. Please contact me at the number or e-mail above, or Harrison Pollak at (510) 622-2183, harrison.pollak@doj.ca.gov, if you would like to discuss these comments further with somebody in our office.

Sincerely,

Tim Sullivan by

TIMOTHY E. SULLIVAN
Deputy Attorney General

For EDMUND G. BROWN JR.
Attorney General

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