

## **FEDERAL AND CALIFORNIA REGULATION OF LEAD AND PHTHALATES IN CHILDREN'S PRODUCTS**

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### **I. Introduction**

Various chemicals in children's and other consumer products have come under increased regulatory scrutiny over the last several years. In 2007, there were numerous highly publicized recalls of children's products containing lead by major toy manufacturers. In August 2008, these recalls were a large part of the impetus for the adoption of the Consumer Product Safety Improvement Act ("CPSIA"), a sweeping piece of legislation that significantly increases the federal regulation of consumer products, and children's products in particular. Specifically, lead, and a family of chemicals called phthalates, are now subject to strict limits in children's products under the CPSIA. The Consumer Product Safety Commission ("CPSC") has been adopting regulations and issuing guidance on a rolling basis to implement the various statutory provisions of the CPSIA, a process that is likely to continue over the next year or more. In this respect, both federal and state regulation of toxic chemicals in consumer products continues to evolve, with plastics an area of particular focus since they can contain lead, phthalates, and another as yet largely unregulated chemical called Bisphenol A ("BPA").

Although the CPSIA is intended to displace inconsistent state law in the regulation of lead and phthalates in children's products, certain states continue to regulate both in this area. In particular, California continues to enforce Proposition 65, which requires warnings for certain consumer products containing lead, phthalates and other listed carcinogens and reproductive toxins. Further, California has its own separate statutes specifically regulating lead content in children's jewelry and phthalate content in children's toys and childcare articles. Given this regulatory overlap, it is important for companies that manufacture, distribute and sell consumer products to have a basic understanding of the CPSIA and California law regulating lead and phthalates. It is also important to understand recent guidance concerning the CPSIA's testing and certification requirements, and the different implications for retailers and manufacturers, all of which are discussed below.

### **II. The CPSIA's Lead And Phthalate Standards For Children's Products**

The Federal Consumer Product Safety Act (15 U.S.C. §§ 2051 *et seq.*) has long regulated consumer products sold in the United States, and defines a "consumer product" as any article produced or distributed for sale to a consumer for use in or around a household or residence, or in recreation, or for personal use. 15 U.S.C. 2052(a)(5). The Federal Hazardous Substances Act ("FHSA") likewise regulates or bans certain products and materials deemed hazardous. 15 U.S.C. §§ 1261 *et seq.* Regulations issued under the FHSA

previously limited the amount of lead in paint and surface coatings used on certain consumer products and children's toys to 600 parts per million ("ppm") (*see* 16 C.F.R. § 1303.1 *et seq.*), but did not limit the amount of lead in substrate materials. Further, neither the Consumer Product Safety Act nor the FHSA directly regulated the phthalate content in children's products, a family of chemicals that are used to make plastics more flexible.

**A. The CPSIA Strictly Limits Lead in Children's Products**

Following a number of studies suggesting that even relatively low level lead exposure in children can have significant adverse health effects, the CPSIA effectively amended the Consumer Product Safety Act and the FHSA to much more strictly limit lead in surface paint used on children's products, reducing the limit from 600 ppm to 90 ppm effective August 14, 2009. CPSIA § 101(f).<sup>1</sup> For purposes of the lead limitation, the CPSIA defines a "children's product" as a "consumer product designed or intended primarily for children 12 years of age or younger." 15 U.S.C. § 2052(a)(2). In addition to lowering the lead paint limitation, the CPSIA also enacted for the first time specific restrictions on the amount of lead that can be contained in the substrate material beneath any coating that may be used on the product. The CPSIA gradually phases in lead substrate restrictions from an initial limitation of 600 ppm on February 10, 2009, to 300 ppm by August 14, 2009, and then to 100 ppm by August 14, 2011, subject to feasibility studies demonstrating that the 100 ppm level is commercially achievable. CPSIA § 101(a)(2).

The CPSIA authorizes the CPSC to issue regulations (and it has) excepting inaccessible component parts or component materials that do not create a risk of lead exposure in children. CPSIA § 101(b). Those regulations essentially except from the CPSIA's testing and certification requirements (discussed below) materials like natural fabrics, wood and certain precious gems and metals because reliable studies have found they do not exceed the 300 ppm lead limits. *See* 74 Fed. Reg. 43031 (August 26, 2009). Recently issued regulations also provide that the lead limits do not apply to "inaccessible" component parts, such as those encased in a sealed covering that can withstand use and abuse testing (other than mere electroplating), or that are unreachable by a child using accessibility probes already specified for use in testing children's toys for sharp points or edges. *See* 74 Fed. Reg. 39535 (August 7, 2009).

**B. The CPSIA Restricts Phthalates in Children's Toys**

The CPSIA also strictly limits phthalate levels in "children's toys" and "childcare articles." CPSIA § 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." CPSIA § 108(e)(1)(B). A "childcare article" is defined in a

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<sup>1</sup> The CPSIA was enacted as Public Law 110-314, and citations herein are to that law, except in instances where it is easier and more understandable to cite to the Consumer Product Safety Act or the FHSA as amended, in which case citations are to the relevant United States Code provisions as modified.

more limited manner as a “consumer product designed or intended by the manufacturer to facilitate sleep or feeding of children age three and younger, or to help such children with sucking or teething.” CPSIA § 108(e)(1)(C). The CPSIA limits the content of six specific phthalate chemicals in these products. In particular, phthalates known by the acronyms DEHP, DBP and BBP are limited to levels of .1% in both children’s toys and childcare articles. Similarly, three additional phthalates known by the acronyms DINP, DIDP, and DnOP are temporarily limited to levels of .1% for childcare articles and children’s toys that can be placed in a child’s mouth, pending further government study. Unlike lead, the phthalate restrictions are not subject to any exception for inaccessible component parts.<sup>2</sup>

### **III. The CPSIA Requires General Certification, Third-Party Testing, and Tracking Labels For Children’s Products**

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The CPSIA also requires manufacturers and importers of any consumer product (not just children’s products) to certify compliance with all rules, bans, standards or regulations applicable to the product under any Act enforced by the CPSC. These products must be certified through a test of each product, or a “reasonable” testing program. CPSIA § 102(a)(1). Children’s products are subject to heightened “third-party” testing requirements. CPSIA § 102(a)(2). In particular, children’s products must be certified by an accredited third-party testing body showing that they meet applicable consumer product safety standards, including lead and phthalate limitations. *Id.* Importantly, general conformity certificates and third-party testing requirements for most consumer and children’s products are stayed until February 10, 2010, pending the issuance of more specific implementing regulations. *See* 74 Fed. Reg. 6396 (Feb. 2009).<sup>3</sup>

Although largely stayed until February 2010, the CPSC recently published a November 3, 2009 draft statement of policy providing guidance on the testing and certification requirements under the CPSIA.<sup>4</sup> The draft statement attempts to identify all

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<sup>2</sup> In addition to regulating lead and phthalate content, the CPSIA adopts ASTM F 963-07 (“ASTM F 963”) as a mandatory consumer product safety standard for children’s toys, effective February 10, 2009. CPSIA § 106(a). ASTM F 963 contains guidelines and testing methods regarding choking hazards, sharp objects, flammability, and other hazards including soluble heavy metals such as lead. Under the CPSIA, ASTM F 963 operates as a consumer product safety standard pending further study by the CPSC as to whether its provisions are adequate to protect children from harm through their play with children’s toys. CPSIA § 106(b).

<sup>3</sup> The CPSC has also issued guidance streamlining the general certificate of conformity requirements. That guidance states that for foreign manufactured product, only the importer needs to provide the certificate. For domestically manufactured product, only the manufacturer must provide it. Private labelers are generally relieved of any obligation to provide the general certificate of conformity unless they are also the manufacturer or importer. *See* [www.cpsc.gov/cpsc/pub/prerel/prhtml09/09042.html](http://www.cpsc.gov/cpsc/pub/prerel/prhtml09/09042.html).

<sup>4</sup> The draft statement of policy is at [www.cpsc.gov/library/foia/foia10/brief/102testing.pdf](http://www.cpsc.gov/library/foia/foia10/brief/102testing.pdf).

categories of products subject to both the general certification and third-party testing requirements. *See* Draft Statement of Policy at Exhs. A and B. For non-children's products, the statement of policy provides that a "reasonable" testing program required by the CPSIA should contain, at a minimum, the following five elements: (1) product specifications that describe the consumer product and list the standards with which it must comply; (2) certification tests performed on representative manufacturer samples; (3) a production testing plan describing tests to be performed at reasonable intervals in the manufacture of the product; (4) a remedial action plan to deal with nonconforming product; and (5) documentation of the reasonable testing program and how it was implemented. *Id.* at pp. 2-3.

The draft statement of policy also addresses issues related to third-party testing for lead and phthalates in children's products. *Id.* at pp. 4-11. Currently, third-party testing is stayed except for lead in children's jewelry and for lead in surface paint and similar surface coatings. Additional third-party testing for lead in substrates and for phthalates will become effective once the current stay is lifted and 90 days have passed from accreditation of third-party laboratories to perform the testing required. *Id.* at p. 4. The statement of policy makes clear that third-party testing is required every time there is a material change in the product's design or manufacturing process. *Id.* at p. 6. In addition, the draft statement of policy recommends periodic testing of randomly selected samples of children's items at least once a year, irrespective of any such changes. *Id.* at pp. 7-8. Finally, the draft statement of policy provides guidance on when the CPSC will accept certifications based on component or material testing done by suppliers of such items to the ultimate product manufacturer. *Id.* at p. 10.

Manufacturers, distributors and retailers of children's products will have to continue to track closely regulatory developments under the CPSIA in this area to ensure they adhere to the general certificate of conformity and third-party testing requirements as they are implemented. In the interim, parties must still comply with all lead and phthalate restrictions under the CPSIA. To help track children's products, the CPSIA requires manufacturers and private labelers to label the product's packaging with production location, date, and cohort information. CPSIA § 103. Labels must enable the manufacturer to identify the specific source of the product and allow the consumers to identify the manufacturer or private labeler, production location, date and cohort information. *Id.* These requirements became effective on August 14, 2009, and are designed to facilitate an ability to locate and isolate a product that may fail to meet consumer product safety standards. *Id.*

#### **IV. CPSIA Enforcement And Penalties For Noncompliance**

The CPSIA greatly increases civil penalties for violations of the Consumer Product Safety Act, the Flammable Fabrics Act and the FHSA. Civil penalties are increased to up to \$100,000 for each violation, with a maximum cap of \$15,000,000 for a related series of violations (previous limits were \$8,000 and \$1.825 million respectively). CPSIA § 217. The

Congressional Budget Office estimates that these amendments will increase federal revenues from civil penalties by \$43 million over the next 10 years.

The CPSIA also significantly increases criminal penalties for violations of the Consumer Product Safety Act and the Federal Hazardous Substances Act. *See, e.g.*, 15 U.S.C. § 2070(a). Importantly, any director, officer or agent of a corporation who knowingly and willfully authorizes, orders, or performs any of the acts or practices constituting a violation of the CPSIA is subject to individual penalties without regard to any penalties to which the corporation may be subject. 15 U.S.C. § 2070(b). Sanctions for a criminal violation of the Act or any other act enforced by the Commission may include the forfeiture of assets associated with the violation. 15 U.S.C. § 2070(c)(1).

Prohibited acts include selling, offering for sale, manufacturing for sale or importing into the United States any consumer product that is not in conformity with an applicable Consumer Product Safety rule. 15 U.S.C. § 2068(a)(1). It is likewise unlawful for any person to sell, offer for sale, import or distribute a banned hazardous substance within the meaning of the Federal Hazardous Substances Act. 15 U.S.C. § 2068(a)(2)(D). It is further unlawful for anyone to fail or refuse to make reports or provide information required under the Act, or to fail to furnish a certificate required by the Act. 15 U.S.C. § 2068(a)(3), (6).

Of particular importance, it is unlawful to fail to furnish information required by Section 15(b) of the Consumer Product Safety Act, a provision which states that the CPSC must be immediately informed about a product that fails to comply with an applicable Consumer Product Safety rule where the person obtains information which “reasonably supports” the conclusion that such product fails to comply. 15 U.S.C. § 2068(a)(4); 15 U.S.C. § 2064(b). Retailers who receive manufacturer or importer certificates of conformity with Consumer Product Safety standards, however, are largely relieved of liability under the Act where they rely in good faith on those certifications. 15 U.S.C. § 2068(b).<sup>5</sup>

Significantly, the CPSIA now authorizes state attorneys general to enforce violations of the Consumer Product Safety Act, provided they give notice to the CPSC first. CPSIA § 218. In addition, the CPSIA incorporates whistle-blower protections for employees who report violations of the Act. CPSIA § 219. Finally, the Act requires the CPSC to develop a risk assessment methodology to identify shipments into the United States that likely contain consumer products in violation of provisions of the Consumer Product Safety Act. CPSIA § 222.

#### **V. CPSIA Intersection With California State Law**

The CPSIA lead and phthalate standards generally preempt non-identical state standards. The State of California has taken the position, however, that the CPSIA does not

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<sup>5</sup> The CPSC recently published guidance on new civil penalty criteria at 74 Fed. Reg. 45101 (September 1, 2009).

preempt *identical* state standards, state standards governing products *not* subject to federal standards, Proposition 65 warning requirements, and consent judgments entered into by agreement of the parties.<sup>6</sup> In this regard, two recent California state laws regulate lead in jewelry and the phthalate content in childcare articles, products also subject to regulation under the CPSIA. California's regulation of lead in jewelry began with Proposition 65 litigation that ultimately resulted in a separate statute adopted by the State of California to limit lead in jewelry that essentially incorporates the lead standards established in the Proposition 65 litigation. *See* Cal. Health & Safety Code §§ 25214.1 *et seq.* Although California's 600 ppm lead standard for metal in children's jewelry has now been overtaken by the more restrictive CPSIA standards, the CPSIA does not regulate lead in adult products. Accordingly, lead in adult jewelry continues to be regulated in California either by the separate jewelry statute or the multiple Proposition 65 consent judgments entered into by parties to the litigation.<sup>7</sup>

In addition, there have been numerous Proposition 65 consent judgments entered into for a wide variety of consumer products setting lead standards above which Proposition 65 warnings are required. Although not binding on non-parties to the judgments, many of these consent judgments have established *de facto* lead standards for the products at issue in order to avoid litigation under Proposition 65. Recently, the Attorney General's Office filed a Proposition 65 case against manufacturers and retailers of children's toys containing lead that were subject to recall in 2007. *See People v. Mattel, et al.*, Alameda County Superior Court Case No. RG-07-356892. In settlements with these defendants, the Attorney General's Office essentially agreed to lead levels identical to those set forth in the CPSIA, beneath which no Proposition 65 warnings will be required. While not binding for other non-children's items, these settlements suggest that most products that meet CPSIA children's lead standards should also be in compliance with Proposition 65.<sup>8</sup>

Finally, California has also adopted a separate statute regulating phthalate content in children's products in a manner very similar to the CPSIA. *See* Cal. Health & Safety Code

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<sup>6</sup> Although the CPSIA generally preempts non-identical state law requirements related to lead and phthalates, it preserves Proposition 65 (Cal. Health & Safety Code § 25249.6 *et seq.*) by expressly stating that it does not preempt state law warning requirements in effect on August 31, 2003 (Proposition 65 has been in effect for over 20 years). *See* CPSIA § 231(b). The extent to which newer warning laws for lead (such as those recently adopted in Illinois) are preempted remains to be seen.

<sup>7</sup> It is worth noting that under California's separate jewelry statute, PVC material in jewelry (as opposed to metal) is limited to 200 ppm lead, lower than the current CPSIA standard. Cal. Health & Safety Code §25214.1(f)(3)(B).

<sup>8</sup> Like many other states, California has also enacted a statute specifically limiting the use of lead and other toxic chemicals in product packaging. *See* Cal. Health & Safety Code §§ 25214.12 *et seq.*

§§ 108935 *et seq.* Like lead in jewelry, Proposition 65 litigation concerning phthalates preceded the effective date of California's separate statute regulating phthalates. Mirroring the CPSIA restrictions, the California law restricts DEHP, DBP and BBP to .1% or less for any toy or childcare article, and restricts the phthalates DINP, DIDP, and DnOP to .1% in any mouthable toy or childcare article for children less than three years of age. California's separate phthalate law does not have its own enforcement mechanism, and therefore has to be enforced under Business & Professions Code § 17200.<sup>9</sup>

## **VI. Compliance Issues**

In the future, one can expect the Attorney General and other public prosecutors to focus on cases where products violate *both* federal and California law concerning lead and phthalates in consumer products. Stringent federal standards allow this, and it is likely to minimize disputes over preemption. In general, retailers will be able to avoid significant civil and criminal penalties under the CPSIA where they receive manufacturer and/or importers' certificates of conformity with consumer product safety standards for products covered by the Act. Retailers, therefore, should seek certificates of conformity from vendors when the CPSIA's certification requirements come into effect. Retailers can also use vendor terms and conditions and/or compliance letters to mitigate CPSIA and state law exposure.<sup>10</sup>

For manufacturers, direct importers and private labelers, CPSIA requirements are considerably more burdensome than for retailers. The Consumer Product Safety Act defines a "manufacturer" as any person "who manufactures *or* imports a consumer product". 15 U.S.C. § 2052(a)(12) (emphasis added). A "private labeler" under the Act means an "owner of a brand or trademark on the label of a consumer product which bears a private label" 15 U.S.C. § 2052(a)(12). As set forth above, for manufacturers and importers, the CPSIA requires a mandatory "reasonable" testing program to support a general certificate of conformity with applicable consumer product safety standards, and a separate third-party testing requirement for children's products (as opposed to adult consumer products). Manufacturers and direct importers will therefore have to develop and implement the testing and certification requirements as the CPSC's draft statement of policy evolves to the issuance of more definitive regulations implementing the statutory requirements.

## **VII. Conclusion**

Both federal and state regulation of toxic chemicals in consumer products continues to evolve. Although the CPSIA attempts to preempt inconsistent state law other than

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<sup>9</sup> A copy of the Attorney General's December 3, 2008 letter to the CPSC explaining California's views on continued enforcement of its separate phthalate statute after enactment of the CPSIA can be found at [www.ag.ca.gov/prop65/pdfs/CA\\_phthalate\\_letter.pdf](http://www.ag.ca.gov/prop65/pdfs/CA_phthalate_letter.pdf).

<sup>10</sup> The following link provides CPSIA guidance for retailers, and makes clear that retailers are not expected to test products subject to the Act:  
[www.cpsc.gov/cpscpub/prerel/prhtml09/09086.html](http://www.cpsc.gov/cpscpub/prerel/prhtml09/09086.html).

Proposition 65, California and a number of other states clearly intend to enforce their own parallel requirements regulating lead and phthalate content. Plastics, in particular, are an area of focus, as they can contain lead, phthalates, and another chemical called BPA that is coming under increased scrutiny. California has considered its own law regulating BPA, and industry studies of the chemical have been ongoing for some time. Several class action lawsuits have already been filed concerning BPA in baby bottles, and more are likely to follow. In this environment, manufacturers, distributors and retailers need to pay particular attention to the evolving regulatory landscape to ensure compliance.