PHTHALATES: A COMPREHENSIVE GUIDE

A PRODUCT LIABILITY ATTORNEY COMPARES AND CONTRASTS CPSIA, CALIFORNIA'S PHTHALATE BAN AND PROPOSITION 65, EXPLAINING WHAT YOU NEED TO KNOW AND WHEN.

By Sarah Esmaili

CONSUMER PRODUCTS CONTAINING PHTHALATES have been used for decades, but you may have not heard the word until recently when a firestorm of phthalate-centered controversy, litigation and legislation erupted. Now concern over phthalates is invading the promotional products industry.

Phthalates (pronounced tha·lates) are a family of chemicals used primarily to make plastics soft and flexible. They are mainly found in PVC or vinyl material and can be seen in a wide variety of products, such as lunchboxes, toys, bags, baby bibs, sporting equipment, clothing and hand tools.

Due to widespread use, the products you sell may potentially contain phthalates. What does this mean for you? Recently, the safety of these chemicals in consumer products has come under increased scrutiny and regulation. Understanding laws regulating phthalate use and recognizing how they impact you is critical to staying competitive and protecting the livelihood of your business.

The Consumer Product Safety Improvement Act (CPSIA)

The CPSIA limits the amount of certain phthalates in children's toys and child-care articles, sets stringent safety standards for consumer products and establishes testing, labeling and certification requirements. Among other things, the CPSIA restricts the use of certain phthalates.

- For a children's toy or child-care article, the chemicals DEHP, DBP or BBP may not be present in concentrations exceeding 0.1 percent.

- For a children's toy that can be placed in a child's mouth or for any child-care article, the chemicals DINP, DIDP or DnOP may not be present in concentrations exceeding 0.1 percent.

A children's toy is a product intended for a child 12 years of age or younger for use when playing. A child-care article is a product that a child three years of age or younger would use when sleeping, feeding, sucking or teething.

Although CPSIA's definition of a toy is broad, the U.S.

Consumer Product Safety Commission (CPSC) has announced that it is considering whether to apply the exclusions from the term toy used in the industry toy safety standard—ASTM F963-07.

Testing And Certification

Manufacturers and importers of children's products will be required to have products tested by a CPSC-accredited independent laboratory and certify that those products meet the applicable standards. Although the deadline to begin complying with these testing and certification requirements for phthalates was February 10, 2009, shortly before that deadline the CPSC adopted a one-year stay of enforcement of phthalate testing and certification requirements under the CPSIA.

Despite CPSC's temporary delay of testing and certification requirements, children's toys and child-care articles must still comply with the phthalates limits that went into effect February 10, 2009.

Do Limits Apply To Inventory Manufactured Prior To This Law?

Although CPSC initially announced that phthalates restrictions would not apply to children's toys and child-care articles manufactured before the law went into effect February 10, 2009, two environmental groups challenged this enforcement policy in a federal lawsuit. The federal court ruled in favor of the environmental groups and invalidated CPSC's position. After this court ruling,

the CPSC stated that the phthalate restrictions will apply to pre-existing inventory. Thus, children's toys and child-care articles manufactured before the CPSIA's effective date of February 10, 2009, are nonetheless subject to phthalate limits.

Enforcement

A knowing violation of these requirements is punishable by a civil penalty. The maximum civil penalty is increasing from $8,000 to $100,000 per violation, and the maximum penalty for any related series of violations is increasing from $1.83 million to $15 million. In some cases, violations may also be punishable by criminal penalties, which have been made more severe under the CPSIA.

California's Phthalates Ban

This law limits the amount of certain phthalates in children's toys and child-care articles for companies doing business in California. It covers the same six phthalates as the CPSIA; however, the restrictions are similar but not identical.

- For toys and child-care articles, the chemicals DEHP, DBP or BBP may not be present in concentrations exceeding 0.1 percent.
- For toys and child-care articles intended for use by a child under three years of age and which can be placed in the child's mouth, the chemicals DINP, DIDP or DnOP may not be present in concentrations exceeding 0.1 percent.

A toy is defined as a product designed or intended by the manufacturer to be used by children when they play. A child-care article is defined as a product designed or intended by the manufacturer to facilitate sleep, relaxation or the feeding of children, or to help children with sucking or teething.

These restrictions apply generally to anyone manufacturing, selling, distributing or offering for sale toys or child-care articles in California.

Enforcement

California's Phthalates Ban does not contain any enforcement provisions, nor does it assign enforcement to any particular state agency. The California Attorney General recently stated that enforcement would take place through California's main consumer protection statute, the Unfair Competition Law. Under that

Review And Compliance

In light of these laws, it is important to evaluate the use of phthalates in your products. Clear communication among suppliers, distributors and retailers is critical to compliance. There are also a wide variety of factors to consider in testing products, such as using the appropriate testing methods, selecting random test samples and using accredited laboratories. In light of the technical challenges, some companies have moved away from regulated phthalates altogether. Even so, companies must use care not to substitute regulated phthalates with other chemicals of concern. For example, California's Phthalates Ban requires a substitute chemical to be the least toxic alternative and prohibits the use of alternatives identified as carcinogens or reproductive toxicants.

In addition to determining the phthalate content of products that you sell, you may want to consider contractual arrangements that specify how liability is to be allocated among parties in the distribution chain in the event an issue arises.

There are various compliance strategies you may want to consider and use as an opportunity to strengthen communication with parties in the distribution chain. Although everyone's efforts in the distribution chain are critical to success, it is important to remember that each business has its own obligation to keep in step with these laws.

Side-By-Side Comparison Of CPSIA, California Phthalates Ban And Proposition 65

	CPSIA	California Phthalates Ban	California Proposition 65
Covered Phthalates	DEHP, DBP, BBP, DINP, DIDP, DnOP	Same as CPSIA	DEHP, DBP, BBP, DIDP and DnHP
Level	0.1% (1,000 ppm)	Same as CPSIA	Regulates exposures not concentration, but recent Proposition 65 settlements involving phthalates generally range from 200 ppm to 1,000 ppm for concentration limits.
Toys	For children 12 years of age or less For DINP, DIDP and DNOP, only those toys that can be placed in the mouth CPSC is considering the exclusions in ASTM F963-07	Age limit not defined for DEHP, DBP or BBP For DINP, DIDP and DNOP toys for children less than three years of age, and only those toys that can be placed in the mouth	All ages and all products that can result in an exposure to listed phthalate(s)
Child-care Articles	For children three years of age or less To facilitate sleeping, feeding, sucking or teething	Age limit not defined for DEHP, DBP or BBP Child-care articles for children three years of age or less, and only those toys that can be placed in the mouth for DINP, DIDP and DNOP Includes products designed to facilitate relaxation	All ages and all products that can result in an exposure to listed phthalate(s)
Using Alternative Chemicals	Certain alternative chemicals may be banned based on findings of Chronic Hazard Advisory Panel	Must use least-toxic alternative and not carcinogens or reproductive toxicants identified by EPA or California agencies	Using alternative chemicals that are listed under Proposition 65 may require warnings

Source: Arnold & Porter LLP

law, a penalty of up to $2,500 for each violation may be assessed. The court may also impose injunctive relief, restitution and attorneys' fees. Public enforcers, as well as private enforcers acting as private attorneys general, may file suit under California's Unfair Competition Law.

Do Limits Apply To Inventory Manufactured Prior To This Law?

The California Attorney General has stated that inventories of toys and child-care articles that were manufactured before the state law's effective date of January 1, 2009, may not be sold in California unless they meet the limits imposed by the phthalates ban.

California Proposition 65

Proposition 65 does not directly regulate the concentration of phthalates allowed in consumer products. Instead, it obligates companies to provide warnings for products containing certain types of phthalates. Also unlike the CPSIA and California's Phthalates Ban, Proposition 65 applies to any consumer product, regardless of whether it is intended for children or adults.

Proposition 65 was passed by voter initiative in California in 1986. It contains a warning requirement that prohibits anyone doing business in California from knowingly and intentionally causing exposures to listed carcinogens and reproductive toxicants without first providing a clear and reasonable warning. More than 700 chemicals are on the Proposition 65 list.

With limited exceptions, Proposition 65 applies to anyone in the distribution chain. If a retailer sells a product without a required warning, the retailer can be liable under Proposition 65 even if the manufacturer failed to include the warning or failed to notify the retailer that a warning is necessary.

Listed Phthalates

Four phthalates that are regulated under the CPSIA and California's Phthalates Ban are listed under Proposition 65: DEHP, DBP, BBP and DIDP. One additional phthalate not covered by the CPSIA or California's Phthalates Ban is listed under Proposition 65: DnHP.

Enforcement And Defenses

Proposition 65 enforcement is carried out through civil lawsuits. Under Proposition 65, an enforcement action may be brought by the California Attorney General, other California public enforcers and private plaintiffs suing in the public interest. A plaintiff may seek injunctive relief, civil penalties of up to $2,500 per violation per day and reasonable attorneys' fees and costs. The majority of Proposition 65 lawsuits are brought by private plaintiffs.

It is a Proposition 65 plaintiff's burden to show that a business knowingly and intentionally caused exposures to a listed chemical without a warning. To meet its burden of proof, a Proposition 65 plaintiff does not need to show that it—or any member of the public—suffered any actual harm from the alleged exposures. Nor does a plaintiff need to show the exposures exceeded any particular levels or standards.

If a Proposition 65 plaintiff meets its burden of proof, a company must prove a defense to avoid liability. One defense is to show the exposures at issue will not exceed health risk thresholds, which are extremely conservative. For carcinogens, this threshold is the level at which an exposure will not cause one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. For reproductive toxicants, this threshold is the lowest level at which reproductive effects are observed, and divided by a safety factor of 1,000. The California agency in charge of implementing Proposition 65 has established safe harbor levels for a handful of listed chemicals. Exposures that occur at levels below these safe harbor levels do not require warnings.

Proving exposures occurred below these thresholds can, therefore, be a complex undertaking. For this reason, many people have commented that Proposition 65 places the greater legal and scientific burden of proof on the defendant.

Exposure Limits, Not Concentration Limits

Unlike the CPSIA and California's Phthalates Ban, Proposition 65 contains exposure limits, not concentration limits. Translating an exposure limit to a concentration limit can be complicated. Businesses often refer to past Proposition 65 settlements for guidance on the appropriate concentration levels. These settlements often specify how much of a listed chemical may be present in a product without triggering the requirement to provide warnings.

Trends

Phthalates (in particular, DEHP) have been the subject of a number of recent Proposition 65 lawsuits involving consumer products such as book bags, plastic gloves, children's toys and sporting goods to name a few. Although phthalates limits set in these settlement agreements vary on an individual settlement basis, they generally (with some exceptions) range between 200 and 1,000 parts per million (ppm). In light of the increased attention on phthalates, this litigation may represent a growing trend. ppb

This information is current as of July 2009. This article is intended to be a general summary and does not constitute legal advice. You should consult with counsel to determine applicable legal requirements in a specific fact situation.

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Looking For More Info On Product Safety?

PPAI's Product Safety website is filled with resources for managing your business in the face of the Consumer Product Safety Improvement Act (CPSIA), California's Phthalates Ban, California Proposition 65 and other regulations. Visit www.ppai.org and click on Members, Business Management, PPAI Product Safety to find:

- CPSIA presentations and guides,
- FAQs about CPSIA and California Proposition 65,
- Guidance, important dates and opinions concerning phthalates,
- Past *PPB* articles covering product safety regulations, and
- Other product safety and responsibility information from PPAI.