
Children's Products Importers Given 60 Days to Submit Unpublished Lead Studies to EPA

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A new US Environmental Protection Agency (EPA) rule requires importers of products intended for use by children that contain any measurable quantity of lead to submit--by April 28, 2008--copies of certain unpublished health and safety study data concerning lead or lead compounds. 73 FR 5109 (Jan. 29, 2008). Specifically, covered companies must submit all unpublished studies in their possession that either:

1. relate to the lead content of consumer products (other than metal jewelry, and whether imported or not) intended for use by children, or
2. assess children's exposure to lead from these consumer products.

As discussed below, this data call-in is more complicated than it might seem and presents a number of challenges for potentially affected companies. Although EPA's rule is primarily directed at imported products, the particular language of the rule requires importers also to submit any unpublished lead studies in their possession concerning domestically produced children's products. Thoughtful planning will position companies for timely compliance, and prepare them to address the implications of any unexpected findings.

Who Must Report?

By its terms, the rule applies to any entity that, in the previous ten years, both (a) manufactured or imported a consumer product intended for use by children 14 or younger, and (b) manufactured or imported any lead. In this context, "importing lead" includes the unknowing or unintentional importation of lead (e.g., where it is present as an impurity in an imported product). The term "importer" includes those responsible for bringing the goods into the United States and clearing customs, as well as consignees and transferees authorized to draw such goods from a bonded warehouse. It does not include downstream recipients who only acquire imported items from the inventories of US distributors or wholesalers. For covered persons, the duty to report includes a duty to search their files for the existence of covered studies dated after 1977. This is likely to be the greatest burden for most companies. Although such a search is a potentially daunting task for a large enterprise, the Agency's regulations put some bounds on the extent of the necessary

investigation, and provide an enforcement "safe harbor" for companies that conduct and document their investigation in accordance with the rule. EPA expects that a wide variety of manufacturers, wholesalers, retailers and others who import products for children may have reporting obligations under the rule, including those importing costume jewelry, fasteners, buttons, hobby goods, novelties, electronic devices, and dolls, games, children's vehicles and other toys, or components of these products.

Context--Regulation of Lead in Children's Products

The Agency's focus on lead in imported children's goods follows from the recent [spate of discoveries of lead-containing children's products](#)--all involving items that, by EPA's assessment, were imported. The Consumer Product Safety Commission (CPSC) is the primary regulator of potentially hazardous substances in children's and other consumer products, and acts in this area under the authority of the Consumer Product Safety Act and the Federal Hazardous Substances Act (FHSA). Generally, household products that may expose children to hazardous quantities of lead under reasonably foreseeable conditions are subject to precautionary labeling requirements. 15 U.S.C. §1261(p). Products that are intended for use by children and that contain hazardous quantities of lead are banned outright. 15 U.S.C. §1261(q)(1)(B). Generally, any person in the distribution chain associated with introducing or delivering into commerce either a banned product or a product without the proper precautionary labeling is potentially strictly liable under the FHSA. 15 U.S.C. §1263. Moreover, if the person obtains information indicating a substantial risk of injury or an unreasonable risk of serious injury to the public from the product, it also may have an independent duty to immediately notify the CPSC of the circumstances. 15 U.S.C. §2064.

The CPSC has adopted specific lead content standards for children's products containing lead paint--banning toys, furniture and other articles that are intended for use by children and that include paint containing lead or lead compounds in excess of 0.06 percent by weight. 16 CFR 1303.4. The CPSC formally commenced consideration of a lead content standard for children's jewelry in 2007, but has not taken final action. 72 FR 920 (Jan. 9, 2007). For other consumer products potentially subject to lead restrictions, an independent, case-by-case hazard determination must be made. The CPSC released guidance for making these determinations in 1998, indicating that an analysis of lead content should consider "the total amount of lead contained in a product, the bioavailability of the lead, the accessibility of the lead to children, the age and foreseeable behavior of the children exposed to the product, the foreseeable duration of the exposure, and the marketing, patterns of use, and life cycle of the product." 63 FR 70649 (Dec. 22, 1998). Some states (e.g., California and Illinois) have their own lead content standards for certain children's products. Indeed, California's Safe Drinking Water and Toxic Enforcement Act ("[Proposition 65](#)") generally requires warning labels for all consumer products containing lead, unless they can be shown not to result in anticipated human exposure exceeding certain thresholds.

EPA's new reporting requirement was triggered under §8(d) of Toxic Substances Control Act (TSCA) when lead compounds were added to the TSCA Interagency Testing Committee's (ITC) priority testing list (Priority List) last year. 72 FR 41414 (Jul. 27, 2007). Lead was added to the Priority List in connection with an EPA initiative to identify and address risks of childhood lead poisoning from

sources other than lead paint and children's metal jewelry, as well as EPA's settlement of a lawsuit by the Sierra Club. The Sierra Club had challenged the Agency's denial of its request that EPA require health and safety data reporting for lead incorporated into consumer products generally. 71 Fed. Reg. 42,640 (July 27, 2006). "Information obtained [under the new rule] may assist both EPA and CPSC in taking further action as appropriate to protect children from lead poisoning due to lead in products." 72 FR 41417.

Implications for Importers, Distributors, Wholesalers and Retailers of Children's Products

The mandatory data call-in presents several sets of issues for companies that import products and product components intended for use by children. The first concern the challenge of determining applicability--e.g., whether a particular product is "intended for use by children" (as defined by EPA), whether a company's transactions would cause it to be deemed an "importer," and whether imported products contained measurable quantities of lead. The 10-year look-back period may present particular challenges for some companies.

Assuming the rule is applicable to a particular company, a second set of issues arises with respect to completing the necessary investigation and any required submissions by the rule's 60-day reporting deadline--e.g., the logistics of assuring an adequate and timely search, submitting any responsive studies and/or lists of studies, and properly asserting confidential business information claims. Questions may arise concerning the adequacy of the investigation and the significance of documents, such as lead-content certifications from vendors, that may suggest the existence of unpublished data in the possession of others that must be listed in the response to EPA.

Electronics manufacturers and importers may have an easier time determining the applicability of the rule due to their activities in connection with assuring their products conform to the European Union's Regulation of Hazardous Substances (RoHS) regulations. On the other hand, RoHS-related investigations also may have created a larger set of studies to be reported than otherwise would have existed. And companies that have conducted investigations in the wake of the recent discovery of numerous children's products imported from China containing excess lead may similarly have assembled large volumes of responsive information.

A third set of issues concerns the legal and commercial significance and sensitivity of any data discovered. Companies may find data that, in retrospect, raises questions about their past compliance with applicable state and federal consumer product standards and CPSC reporting obligations. Indeed, newly discovered data may trigger new government notification (and product recall) duties under consumer protection laws applicable to mislabeled or banned substances (as described above). Obviously, such discoveries also may have significant commercial implications for a company and its downstream customers. Newly discovered data also may trigger prompt notification duties to EPA under [TSCA §8\(e\)](#), which requires immediate reporting to the Agency upon obtaining data that reasonably supports the conclusion that a particular lead-containing product presents a substantial risk of injury to health. For example, triggering information may include discovery of studies or data indicating:

1. a previously unknown but significant human exposure to lead (e.g., absorption of a lead from an imported product); or

2. the previously unknown presence of lead or other hazardous or toxic constituent in a product.

For all these reasons, companies that may be subject to the rule would be well advised to assess and understand the significance of any information discovered before submitting it to EPA, and consequently, to commence any investigations as early as possible and in consultation with counsel.

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