

*EPA Requires
Manufacturers
and Importers
of Children's
Products
to Report
Information on
Potential Lead
Content and
Exposure*

On the heels of a year that had dozens of recalls of children's products due to excessive lead content, the U.S. Environmental Protection Agency ("EPA" or "the Agency") has issued a final rule requiring manufacturers (including importers) of lead-containing consumer products intended for use by children to report certain health and safety data to the Agency. 73 Fed. Reg. 5109 (Jan. 29, 2008). The rule was promulgated under Section 8(d) of the Toxic Substances Control Act ("TSCA") and becomes effective on February 28, 2008.

Specifically, the rule applies to manufacturers of consumer products intended for use by children if they also manufacture lead or lead compounds. The term "manufacture" is defined broadly and includes importation. Importers of consumer products intended for use by children are deemed to "manufacture" any lead or lead compounds contained in those products¹. The rule excludes metal jewelry, which is subject to separate reporting requirements promulgated by the Consumer Product Safety Commission ("CPSC") last year.

The rule requires reporting of unpublished² health and safety studies that

1 Domestic producers would be covered if lead or lead compounds are manufactured during the production process. Whether such manufacture occurs is a case-specific, and often technically complicated, determination.

2 "Unpublished" studies include those that previously have not been published in the scientific literature or submitted to the EPA

(1) relate to the lead content of consumer products intended for use by children (with the exception of metal jewelry); or (2) assess children's exposure to lead from such products (including bioavailability studies). Studies showing any measurable lead content must be submitted. The term "health and safety studies" is intended to be interpreted broadly and is not limited to the results of a "formal, disciplined study."

Under the rule, companies must report existing studies by April 28, 2008 (i.e., within 60 days of the February 28, 2008 effective date of the rule).

BACKGROUND

The rulemaking was prompted by the settlement of a petition filed by the Sierra Club in April 2006, which called for EPA to use TSCA to take actions to protect children from lead and lead compound exposure. Specifically, the petition asked EPA to gather more information on lead, ban lead in toy jewelry (above a minimum threshold), draft a report detailing the risks posed by lead in toy jewelry, and advise the CPSC on how such risks could be reduced or prevented. By making lead and lead compounds a priority chemical for TSCA purposes, the Agency is able to require certain manufacturers and importers to hand over previously unreleased health and safety data. EPA's end goal, in conjunction

Office of Pollution Prevention and Toxics.

with the CPSC, is to review the submitted data and address any identified concerns with respect to lead-containing products. In adopting the rule, EPA formally adds lead and lead compounds to the list of substances subject to the Agency's Health and Safety Data Reporting rule under TSCA section 8(d). This action follows the decision last year by the Interagency Testing Committee ("ITC") to add lead and lead compounds to the "priority testing list" under TSCA section 4(e). Once the ITC takes such action, EPA is obliged to add the listed substances to the list of chemicals subject to reporting under TSCA section 8(d). While the Health and Safety Data Reporting rule generally requires submission of a broad range of health and safety studies, the rule narrowed the reporting requirement only to the studies specified above.

The Agency, in its economic impact assessment, was unable to pinpoint the number of companies potentially affected by the rule. However, EPA identified a list of industry sectors likely to be affected by the rule, including (1) costume jewelry and novelty manufacturing; (2) doll and stuffed toy manufacturing; (3) game, toy and children's vehicle manufacturing; (4) fastener, button, needle and pin manufacturing; (5) toy and hobby goods and supplies wholesalers; (6) discount department stores; and (7) warehouse clubs and "supercenters." However, because importers are included within the definition of manufacturers under TSCA, the rule will

have a broader scope and will reach more industries than those identified. In fact, the Agency states that the number of studies that might be submitted in response to this rule is "likely to be larger than for other chemicals that have been listed under amendments to the TSCA section 8(d) model rule." EPA estimates that per industry, the cost of compliance will be approximately \$866,000.

IMPORTERS COVERED

Under TSCA, "importer" is "any person who imports a chemical substance, including a chemical substance as a part of a mixture or article, into the customs territory of the United States and includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his behalf." See 40 C.F.R. §716.3. Importer also includes: the consignee, the importer of record, the actual owner (if an actual owner's declaration and superseding bond has been filled in accordance with 19 C.F.R. §141.20), and the transferee (if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 C.F.R. part 144). Therefore, to the extent a distributor meets this definition of "importer," they would be subject to the rule and its reporting requirements.

"INTENDED FOR USE BY CHILDREN"

The term "intended for use by children" is defined to include products that specifically intended for use by children age 14 or younger. 40 C.F.R. §710.43. Under that definition,

a product is deemed to be intended for use by children if it is “commonly recognized” as being intended for use by children age 14 or younger; product labeling or other written materials state that it is intended for use by children age 14 or younger; and/or advertising, promotion or marketing of the product is aimed at children age 14 or younger.

OTHER REPORTING REQUIREMENTS

Consumer product manufacturers, importers, and distributors also should bear in mind that TSCA imposes additional, ongoing reporting requirements. In particular, Section 8(e) of TSCA requires the submission of information that “supports the conclusion” that a substance or mixture “presents a substantial risk of injury to health or the environment.” While this obligation applies to toxicity information that a company may receive, it also covers the discovery of (1) previously unknown and significant human exposure to a chemical known to cause serious health effects (such as the potential absorption of lead from consumer products), and (2) the presence of a previously unknown hazardous or toxic constituent in a product. Accordingly, consumer product manufacturers that discover the presence of lead in a product may be obligated to divulge that information to EPA.

EPA has explained that, under TSCA Section 8(e):

Reporting of the presence of a hazardous or toxic constituent that was previously unknown to be contained in a product, including manufactured articles, should occur under TSCA section 8(e) where

data shows that widespread or significant exposure to the toxic component has occurred or is substantially likely to occur, and such exposure presents a substantial risk of injury to health or the environment. Persons subject to TSCA 8(e) reporting should consider the toxicity of the constituent, the constituent’s concentration in the product, and whether significant exposure to the toxic component has occurred or is likely to occur at any stage in the product’s lifecycle from production through disposal. In cases of extremely toxic chemical substances in products in commerce, exposure may generally be presumed.

This guidance obliges each company that discovers previously unknown – or, potentially, significantly elevated – quantities of lead in a consumer product to consider their reporting obligations under Section 8(e).

Companies must file Section 8(e) reports with EPA within 30 days of obtaining the requisite information.

CONCLUSION

The rule will impose costs across a wide variety of industries that manufacture, import and distribute consumer products intended for use by children. The most significant direct costs will be associated with each firm’s responsibility to identify submissible reports and tests (either ongoing or already completed), copy these reports, and submit them to EPA. Perhaps more important are the ramifications from reporting previously undisclosed data concerning the presence of lead

in a consumer product and/or potential consumer exposures. Companies need to be cognizant of the potentially significant legal and public relations issues involved. For example, the CPSC has existing regulations that prohibit the sale of furniture, toys, or other products intended for use by children that bear a coating containing more than .06% lead. Health and safety studies submitted to EPA could be used by the CPSC or consumers to allege that the tested product violate the CPSC regulations. Moreover, in fulfilling the stringent reporting requirements, companies should take care to protect confidential information³.

KELLEY DRYE & WARREN LLP

ENVIRONMENTAL LAW PRACTICE

Kelley Drye & Warren attorneys have significant expertise working with EPA on behalf of clients subject to TSCA reporting and testing requirements. We also routinely provide counsel to firms and industries needing to navigate the complex legal and public relations issues associated with TSCA and other environmental regulations, including the disposal of lead materials that have been recalled.

CONSUMER PRODUCT SAFETY PRACTICE

Members of Kelley Dye & Warren's Consumer Product Safety practice have a long and successful history representing

³ Confidentiality claims are restricted under TSCA §8(e) to information pertaining to confidential manufacturing processes (including import and processing of the product), quantitative mixture composition, and company identification, financial statistics, and product coding.

clients before the CPSC. We have the experience to provide advice on the difficult issues of how and when potentially hazardous consumer products must be reported to the CPSC. If product recalls are necessary, we work with our clients and CPSC staff to quickly develop and implement cost-effective communications programs that satisfy product liability concerns and minimize potential penalties. When the CPSC threatens or brings enforcement actions, we advise our clients on appropriate strategies.

FOR MORE INFORMATION

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