

Published by *Environmental Law360* on December 12, 2012. Also ran in *International Trade; Product Liability; and Public Policy Law360*.

Implications Of EPA Rule On Cadmium In Consumer Products

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Law360, New York (December 05, 2012, 12:41 PM ET) -- A recent announcement from the U.S. [Environmental Protection Agency](#) indicates the agency's continued willingness to play a role in regulating consumer products on the basis of chemical content. The EPA has released a final Toxic Substances Control Act (TSCA) § 8(d) rule that will require manufacturers of cadmium or cadmium compounds and those who import cadmium or cadmium compounds, including products (i.e., "articles") that contain those substances, to report certain unpublished health and safety studies to the EPA when the substances have been or are reasonably likely to be incorporated into consumer products. 77 Fed. Reg. 71561 (Dec. 3, 2012).

This article provides information likely to be of importance not only to entities in the chemicals industry, but also to the makers and importers of consumer products (including toys and electronics) that might contain cadmium and cadmium compounds.

The Broad Scope of Potentially Affected Entities

The new reporting requirements apply not only to manufacturers and importers (for purposes of the TSCA, the term "manufacturers" includes importers) of cadmium or cadmium compounds that have been or are likely to be incorporated into consumer products, but also to countless entities that are likely to be importers of the many categories of products that contain those chemical substances.

In the preamble to the rule, EPA states that cadmium compounds include any chemical substance that contains cadmium as part of that chemical's structure. "Consumer product" is defined in the rule to mean "any product that is sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in or around recreational areas."

The rule extends to those entities that import consumer products that merely incorporate components that contain cadmium compounds, as the definition of "importer" under the existing regulations that the rule modifies incorporates "articles" within its scope.

Thus, the regulation reaches not only those companies that manufacture or import cadmium compounds directly, but also companies that import products such as consumer electronics that are likely to contain on-board components (perhaps manufactured by an upstream supplier) containing cadmium compounds. To complicate matters further, the rule will apply to persons that in the 10 years preceding the effective date of the rule have proposed to manufacture or import or have manufactured or imported the listed substances.

In the preamble to the rule, the EPA gives several examples of entities that may be subject to the reporting requirements. According to the EPA, these entities include:

- manufacturers of basic inorganic chemicals;

- manufacturers (including importers) of inorganic dyes and pigments;
- manufacturers of basic organic chemical products;
- establishments engaged in primary production or refining of nonferrous metals (except copper and aluminum);
- wholesalers of toy and hobby goods;
- discount department stores; and
- warehouse clubs and supercenters.

However, the foregoing list is certainly not exclusive, and it seems reasonable to conclude that manufacturers and importers of complex consumer products — such as cordless power tools or electronic devices with an on-board cadmium-containing battery — will be expected to have an awareness of the chemical content of all of their components and whether there might be available health and safety data concerning the presence of cadmium.

Moreover, the preamble to the rule includes among the examples of health and safety studies to be provided to the EPA “data conducted in compliance with ASTM [American Society for Testing and Materials] certification standards.” Thus, it may be the case that manufacturers and importers obtaining third-party laboratory test reports to show compliance with ASTM standards — including the ASTM F963 toy standard that limits cadmium in the surface coating of toys and that is now a mandatory standard under the Consumer Product Safety Improvement Act of 2008 — could be required to provide to EPA any such test reports that show “any measurable content of cadmium or cadmium compounds.”

The EPA also has announced that it will publish a proposed rule extending the scope of these reporting requirements to entities that are processors and distributors of cadmium compounds and articles containing cadmium compounds. If finalized, this rule would further expand the list of affected entities to include retail distributors of such products in the U.S., a sector of the economy that does not typically collect health and safety information for the purposes of submitting it to the EPA.

What Must Be Reported?

The rule will require affected manufacturers and importers to report a wide variety of unpublished studies related to human and environmental effects of cadmium and cadmium compounds, including information related to potential exposures from consumer products. The EPA’s rule adds manufacturers and importers of cadmium and cadmium compounds to a list of entities to which reporting requirements for health and safety data for previously listed compounds already apply. Types of studies that must be reported include unpublished studies on the following topics:

- human health effects, including studies related to mutagenicity, carcinogenicity, teratogenicity and pharmacology of the chemical substance in question;
- ecological and environmental effects, including those related to invertebrates, fish, other animal, plants and ecosystems;
- human and environmental exposure, including studies relating to workplace exposure, chemical degradation, biomagnification, and chemical and physical properties of the chemical substance in question; and
- monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.

Perhaps more ominously for importers of consumer use products (and at some later date processors and even retail distributors), the agency interprets the definition of health and safety studies to include studies showing “measurable content of cadmium or cadmium compounds in consumer products.” The 40 C.F.R Part 716 rules provide greater detail into the types of studies that must be reported as well as exemptions for the reporting requirements. The rule does not require affected entities to perform studies, it merely requires reporting related to studies that have already been initiated.

Why Did EPA Undertake This Action?

The [Sierra Club](#) and other consumer and environmental groups petitioned the [Consumer Product Safety Commission](#) (CPSC) and the EPA in 2010 to more strictly regulate cadmium in children’s products, particularly toy metal jewelry. Several months later, the EPA responded by announcing the agency would issue a proposed TSCA reporting rule under TSCA § 8(d) authority that would apply to producers, importers and processors of cadmium compounds likely to be incorporated in consumer products, and, on the basis of information received and potential actions by CPSC, would consider the need for more restrictive regulatory actions to be taken under TSCA § 6.

The CPSC announced on Aug. 9, 2012, its finding that compliance with voluntary standards recently adopted by industry in cooperation with the CPSC — ASTM F2923-11 (children’s jewelry) and ASTM F963-11 (toy jewelry) — “will adequately reduce the risk of harm from exposure to cadmium” in these products.[1] Thus, it does not appear that the CPSC will promulgate additional rules regarding cadmium in these products at this time, though the CPSC’s announcement notes that ASTM’s work is “ongoing,” that CPSC is working in cooperation with the EPA, and that the CPSC’s Office of Compliance “will continue to monitor children’s jewelry and children’s toys for products that contain cadmium and other harmful chemicals.”

Despite the EPA’s 2010 pronouncement that it would first issue a proposed TSCA § 8(d) rule, the agency has relied on a procedural mechanism involving recommendations from the TSCA Interagency Testing Committee (ITC) to permit the EPA to assert that it has the authority to issue a final rule affecting manufacturers and importers without the benefit of notice-and-comment rulemaking. The ITC periodically makes recommendations concerning chemical substances the ITC believes are worthy of further testing requirements under the TSCA; such substances are placed on the “priority testing list.”

Pursuant to existing regulations, the EPA adds priority testing list chemicals to the list of chemicals for which § 8(d) reporting is required without first issuing a proposed rule. The ITC added cadmium and cadmium compounds to the priority testing list this past summer, superseding a previous listing for cadmium and 103 separately listed cadmium compounds, arguably enabling the EPA to avoid the list exceeding the 50-substance limit and opening the door for the EPA to issue the § 8(d) rule using the expedited procedures. The EPA’s plan for extending the scope of the new rule to include both processors and distributors will involve notice and comment rulemaking.

Potential Implications Concerning TSCA § 8(e) Obligations and Exposure to Third-Party Claims

TSCA § 8(e) requires manufacturers, processors, and distributors of a chemical substance or mixture to “immediately” report information to the EPA that reasonably supports the conclusion that the substance or mixture presents a substantial risk of injury to health or the environment.

The EPA’s § 8(d) reporting rule creates risk for entities who submit copies of unpublished health and

safety studies if the agency were to interpret those studies as also having been reportable pursuant to TSCA § 8(e) because the studies might reasonably support the conclusion that the compounds present a substantial risk of injury to health or the environment. In recent years, the EPA has advised members of the public that data reflecting the heretofore-unknown presence of lead in a consumer product might trigger reporting obligations under TSCA § 8(e) — and many companies that were distributors of such products submitted reports to the EPA.

In addition, TSCA § 20 allows private citizens to sue entities to enforce certain provisions of the TSCA. In the lead context, the Sierra Club sent letters of intent to sue to several manufacturers and importers, although it appears such suits were never brought. It remains to be seen whether the EPA's cadmium rulemaking could provide the agency, the Sierra Club or other third parties with a basis to allege violations of TSCA § 8(e) have occurred. It seems possible, however, that the rule could increase the likelihood that those entities submitting unpublished data on the previously unknown presence of cadmium in consumer products might be exposed to potential allegations by third parties of a failure to warn consumers of an undisclosed hazard.

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[1] <http://www.cpsc.gov/library/foia/foia10/petition/cadmiumdenial.pdf>.