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[Proposed Rules]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Children's Jewelry Containing Lead; Advance Notice of Proposed Rulemaking; Request for Comments and Information

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) is considering whether there may be a need to ban children's metal jewelry containing more than 0.06% lead by weight in metal components. This advance notice of proposed rulemaking (ANPR) initiates a rulemaking proceeding under the Federal Hazardous Substances Act (FHSA). The Commission is soliciting written comments concerning the risks of injury associated with children's jewelry containing lead, the regulatory options discussed in this notice, other possible ways to address these risks, and the economic impacts of the various regulatory alternatives. The Commission also invites interested persons to submit an existing standard, or a statement of intent to modify or develop a voluntary standard, to address the risk of injury described in this notice.

DATES: Written comments and submissions in response to this document must be received by March 12, 2007.

ADDRESSES: Comments should be e-mailed to cpsc-os@cpsc.gov. Comments should be captioned ``Children's Jewelry Containing Lead ANPR.`` Comments may also be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814, or delivered to the same address (telephone (301) 504-7923). Comments also may be filed by facsimile to (301) 504-0127.

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, PhD, M.P.H., Directorate for Health Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7254, e-mail khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

On May 16, 2006, the CPSC docketed Sierra Club's request for a ban on children's jewelry containing more than 0.06% lead by weight as a petition under the Federal Hazardous Substances Act (FHSA) (Petition No. HP 06-1). 71 FR 35416. Information obtained from the petition and CPSC staff investigations indicate that excess lead exposure may result when children ingest metal jewelry containing more than 0.06% lead by weight in metal components. On December 11, 2006, the Commission voted to grant the petition and begin a rulemaking proceeding to address the risk of injury described in this notice.\1\

\1\ Acting Chairman Nancy A. Nord filed a statement which is available from the Office of the Secretary or on the Commission's Web site at <http://www.cpsc.gov>.

B. The Risk of Injury

The scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood ($[\mu\text{g}/\text{dL}]$) as a level of concern with respect to lead poisoning in children. Continuing national, state and local efforts to remove lead hazards from children's environments (e.g., eliminating lead from household paint, gasoline, and food cans) have resulted in reductions in mean blood lead levels (BLLs) and in the number of children with BLLs exceeding 10 $[\mu\text{g}/\text{dL}]$. Data from a recent national survey indicated that an estimated 310,000 U.S. children aged one to five years have BLLs exceeding this level (about 1.6 percent of children aged one to five years). Currently, lead-based paint in older housing remains the most common source for excess lead exposure for children, but exposures from other sources of lead, such as certain ethnic medicines, imported candy and spices, ceramicware, and other types of consumer products, including jewelry, have been documented.

Investigations by the CPSC Laboratory staff indicated that the extractability of lead from children's metal jewelry is strongly associated with the lead content of these items. Staff investigations

also indicated that when metal jewelry is ingested by children, excess lead exposure is likely for items that contain more than 0.06% lead, and that the amount of exposure likely increases with increasing lead content in the item.

C. Statutory Authority

This proceeding is conducted pursuant to the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261 et seq. Section 2(f)(1)(A) of the FHSA defines ``hazardous substance'' to include any substance or mixture of substances which is toxic and may cause substantial illness as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children. 15 U.S.C. 1261(f)(1)(A).

Under section 2(q)(1)(B) of the FHSA, a substance is a ``banned hazardous substance'' if the Commission determines that, ``notwithstanding such cautionary labeling as is or may be required under this Act for that substance, the degree or nature of the hazard involved in the presence or use

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of such [hazardous] substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce'' 15 U.S.C. 1261(q)(1)(B).

A ban under section 2(q)(1)(B) of the FHSA may be used to reach articles intended for use in the household that are determined to be hazardous substances under section 3(a)(1). Section 3(a)(1) of the FHSA provides that the Commission may, by regulation, declare to be a ``hazardous substance'' any substance or mixture of substances which meets the requirements of section 2(f)(1)(A). 15 U.S.C. 1262(a)(1). If the section 3(a)(1) proceeding resulted in a determination that jewelry containing more than 0.06% lead was a hazardous substance, then, if the article is ``intended for use by children,'' the jewelry would be banned automatically under section 2(q)(1)(A) of the FHSA. 15 U.S.C. 1261(q)(1)(A). Section 3(a)(2) specifies the procedures for issuance of a regulation declaring a substance or mixture of substances to be a ``hazardous substance.'' 15 U.S.C. 1262(a)(2).

Sections 2(q)(2) and 3(f) through 3(i) specify the procedures for issuing a rule classifying a substance as a banned hazardous substance under section 2(q)(1)(B) of the Act. 15 U.S.C. 1261(q)(2), 1262(f)-(i). In accordance with section 3(f), this proceeding is commenced by issuance of this ANPR. 15 U.S.C. 1262(f). After considering any comments submitted in response to this ANPR, the Commission will decide whether to issue a proposed rule and a preliminary regulatory analysis in accordance with section 3(h) of the FHSA. 15 U.S.C. 1262(h). If a

proposed rule is issued, the Commission would then consider the comments received in response to the proposed rule in deciding whether to issue a final rule and a final regulatory analysis. 15 U.S.C. 1262(i).

D. Regulatory Alternatives

One or more of the following alternatives could be used to reduce the identified risks associated with children's metal jewelry containing lead.

1. Mandatory rule. The Commission could issue a rule declaring children's metal jewelry containing lead to be a banned hazardous substance.

2. Labeling rule. The Commission could issue a rule requiring specified warnings and instructions for children's metal jewelry containing lead.

3. Existing standard. The Commission could adopt an existing standard, in whole or in part, as a proposed regulation.

4. Voluntary standard. If the industry developed, adopted, and substantially conformed to an adequate voluntary standard, the Commission could defer to the voluntary standard in lieu of issuing a mandatory rule.

5. Corrective Actions under Section 15 of the FHSA. The Commission has authority under section 15 of the FHSA, 15 U.S.C. 1274, to pursue corrective actions on a case-by-case basis if the Commission determines that a product constitutes a banned hazardous substance.

E. Existing Standards

CPSC staff reviewed existing State standards relevant to lead in children's metal jewelry promulgated in California and Illinois. On September 22, 2006, legislation was enacted in California on lead containing jewelry, A.B. No. 1681. This law provides, in part, for phased-in compliance of specified materials to be used in jewelry for retail sale in California. This law contains a number of provisions separated by type of material used in the product or components, and by whether the product is for children aged six years and younger. Children's products must contain less than 0.06 percent lead in certain metallic components, and certain other components are limited to less than 0.02 percent lead. Lead content in children's jewelry is limited to less than 0.06 percent by September 1, 2007, and plastic and rubber components to less than 0.02 percent by August 31, 2009. The use of glass or crystal is limited to a total of one gram in the product unless it contains less than 0.02 percent lead by weight and has no intentionally added lead.

On June 20, 2006, the State of Illinois enacted Public Act 094-

0879, which amends the Illinois Lead Poisoning Prevention Act to define a ``lead bearing substance'' as, in part, ``any item containing or coated with lead such that the lead content is more than six-hundredths of one percent (0.06%) lead by total weight.'' This act restricts the use of lead bearing substances and bans their use ``in or upon any items, including, but not limited to, clothing, accessories, jewelry, decorative objects, edible items, candy, food, dietary supplements, toys, furniture, or other articles used by or intended to be and chewable by children.'' This act covers children aged six years and younger.

Canada has also established regulations concerning lead in children's jewelry under ``The Children's Jewellery Regulations,'' effective May 10, 2005. The regulations provide limits both for lead content (600 mg/kg; equivalent to 0.06 percent) and ``migratable'' or accessible lead (90 mg/kg) for children's jewelry items imported, advertised, or sold in Canada. Children's jewelry is defined as ``jewellery item(s) which is (are) designed, sized, decorated, packaged, and/or otherwise produced, advertised or sold in such a manner as to make it reasonably apparent that the item(s) is intended to attract, appeal to, or be worn primarily by a child under the age of 15 years.''

These standards offer vastly differing requirements for test methods, test materials, product categories, age categories, and so forth. Provisions in standards that do not address jewelry do not fall within the scope of this proceeding. At this time, CPSC staff is focusing on metal jewelry containing lead because the available data indicate that such products could be hazardous due to their lead content and potential for exposure. More information concerning potential lead exposure of other non-metal materials that may be used in jewelry is needed before staff can assess whether other non-metal materials used in jewelry present a hazard. Furthermore, additional information and data must be obtained before staff can properly assess the appropriate test or test methodology to be used, the appropriate product or products to be addressed, and the appropriate age group to be covered under any proposed regulation.

F. Economic Considerations

CPSC staff gathered data on certain classifications of jewelry and toy manufacturers. The U.S. Census Bureau, using the North American Industry Classification System, provides data on three types of manufacturers: Jewelry (Except Costume); Jewelers' Material and Lapidary Work; and Costume Jewelry and Novelty Manufacturing. Of these, the Jewelry (Except Costume) manufacturers, which deal primarily with precious metals, constitute about 76 percent of the value of jewelry manufacturing shipments; the Costume category accounts for about ten

percent of shipments. For 2004, the total value of shipments for all three classifications was more than \$7.8 billion. The data indicated that nearly 3,000 establishments produce jewelry items in the U.S. Most of these are relatively small; almost 60 percent have one to four employees and 84 percent have fewer than 20 employees. All but 19 firms have fewer than 500 employees (the definition of small business used by

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the U.S. Small Business Administration). As of 2004, domestic production was about 24 percent of the total U.S. market, with products from Israel, India, Belgium, China, Thailand, and Italy making up about three-quarters of jewelry imports by value.

Because children's jewelry may include toy jewelry, staff considered data for toy, doll, and stuffed animal accessories that may include jewelry items. The value of shipments of these products is approximately \$30 million annually, although this figure includes many products that would not be considered jewelry. Finally, staff considered manufacturing of craft kits and supplies, which would include jewelry-making kits. The value of shipments for this category is about \$180 million annually. This figure also includes many products that would not be considered jewelry.

While this information provides an overview of U.S. manufacturing of jewelry and related toy products, the data do not allow staff to analyze the specific impact of any potential regulation of lead in children's jewelry. Further, while staff has information about the overall economic impact of excess lead exposure in children, there is no information available that addresses the effect of lead exposures specifically from children's jewelry. While reducing lead in children's jewelry could result in reduced lead exposure in children, the extent of the reduction and the resulting benefits may be difficult to quantify. Comments on these issues and on costs and benefits of a potential rule are specifically solicited.

G. Solicitation of Information and Comments

This ANPR is an initial step in a proceeding that could result in a mandatory rule banning children's metal jewelry containing more than 0.06% lead by weight in metal components. All interested persons are invited to submit to the Commission their comments on any aspect of the alternatives discussed above. In particular, CPSC solicits the following additional information:

1. Information on any children believed to have been injured or killed as a result of ingesting metal jewelry containing lead, including the ages of such children, and their BLLs;
2. The circumstances under which these injuries and deaths occurred, including information on the suspected metal jewelry product;

3. The costs to manufacturers of redesigning children's metal jewelry to remove the risk from lead or the cost of removing children's metal jewelry containing lead from the market;

4. A description of substitutes for children's metal jewelry containing lead that could reduce the described risk of injury;

5. Comparisons of the costs and utility of using lead in children's metal jewelry versus any available substitute products;

6. Other information on the potential costs and benefits of potential rules;

7. Steps that have been taken by industry or others to reduce the risk of injury to children due to lead from metal jewelry products;

8. The likelihood and nature of any significant economic impact of a rule on small entities;

9. Alternatives the Commission should consider, as well as the costs and benefits of those alternatives to minimize the burdens or costs to small entities;

10. The costs and benefits of mandating a testing requirement;

11. The costs and benefits of mandating a quality control/quality assurance program requirement and/or recordkeeping requirement;

12. The market share of children's jewelry relative to all jewelry for both precious and costume (non-precious) jewelry;

13. The estimated average expected life of a piece of jewelry (precious and non-precious) and/or an estimated number of jewelry pieces in U.S. households;

14. The distribution of jewelry sales by manufacturing and/or retail price for both precious and costume (non-precious) jewelry; and

15. Information on the lead content and accessibility of lead in non-metallic materials and components used in children's jewelry containing lead including, but not limited to, plastics, rubber, crystals, glass and ceramics.

Also, in accordance with section 3(f) of the FHSA, the Commission solicits:

1. Written comments with respect to the risk of injury identified by the Commission, the regulatory alternatives being considered, and other possible alternatives for addressing the risk.

2. Any existing standard or portion of a standard which could be issued as a proposed regulation.

3. A statement of intention to modify or develop a voluntary standard to address the risk of injury discussed in this notice, along with a description of a plan (including a schedule) to do so.

Comments should be e-mailed to cpsc-os@cpsc.gov. Comments should be captioned ``Children's Jewelry Containing Lead ANPR.'' Comments may also be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814, or delivered to the same address (telephone (301) 504-7923). Comments also may be filed by facsimile to

(301) 504-0127. All comments and submissions should be received no later than March 12, 2007.

H. FHSA Enforcement During the Pendency of the Rulemaking

Manufacturers, importers and retailers of children's jewelry are reminded that the Federal Hazardous Substances Act of its own force bans articles of children's jewelry that meet the statutory definition of a ``banned hazardous substance.'' 15 U.S.C. 1261(q)(1). The CPSC Compliance staff therefore intends to continue enforcing the statute as appropriate during the pendency of this rulemaking. To avoid problems, manufacturers, importers and retailers are advised to follow the guidance provided in the Interim Enforcement Policy for Children's Metal Jewelry Containing Lead (February 3, 2005) which is available on the CPSC Web site at <http://www.cpsc.gov/BUSINFO/pbjewelgd.pdf>.

Dated: January 4, 2007.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.
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