



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

OFFICE OF COMPLIANCE

Interim Enforcement Policy for Children's Metal Jewelry Containing Lead - 2/3/2005

This document describes the approach that CPSC's Office of Compliance will follow in addressing children's metal jewelry containing lead. The policy stated here focuses on metal content and does not modify the Commission's ban of toys and other consumer products (including jewelry) bearing paint or other similar surface coating with a lead content of more than 0.06% by weight. *See* 16 C.F.R. part 1303.

Background

In 2004, the CPSC learned of an incident involving a child who suffered serious adverse health effects after swallowing a piece of jewelry containing lead. Thereafter, CPSC collected and tested many items of children's jewelry and found that many contained high levels of accessible lead. Based on these test results, the Office of Compliance sought recalls in a number of cases. Several major importers and manufacturers agreed to cooperate with the CPSC and conducted voluntary recalls of more than 150 million pieces of children's jewelry.

To address this issue for the future, CPSC staff may recommend rulemaking to establish specific limits for lead content in jewelry. In the meantime, this Interim Enforcement Policy explains how the Office of Compliance will exercise its authority to address this hazard from children's metal jewelry.

The Law

Under the Federal Hazardous Substances Act (FHSA), articles of metal jewelry are deemed "hazardous substances" if they contain toxic quantities of lead sufficient to cause substantial illness as a result of reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children. 15 U.S.C. § 1261(f)(1)(A). If such jewelry is intended for use by children and its toxic lead content is accessible by a child, then it constitutes a "banned hazardous substance" under the FHSA. 15 U.S.C. § 1261(q)(1)(A).

The Hazard

The adverse health effects of lead poisoning in children are well-documented. These effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. Because lead accumulates in the body, even exposures to small amounts of lead can contribute to the overall level of lead in the blood (BLL) and to the risk of adverse health effects. Therefore, any unnecessary exposure of children to lead should be avoided.

The scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood (10 µg/dL) as a threshold level of concern with respect to lead poisoning. To avoid exceeding that level, young children should not chronically ingest more than 15 micrograms of lead (15 µg) per day from consumer products.

Children who wear metal jewelry containing accessible lead can ingest the lead by handling jewelry and putting their hands in their mouths, by putting jewelry directly in their mouths, or by ingesting either parts or whole pieces of the jewelry. These are behaviors that may occur over time (*e.g.*, every day that a child has access to an item) and so result in chronic exposures. Ingestion that occurs all at once (*e.g.*, swallowing an entire object) may result in an acute exposure.

If a jewelry item contains a high enough amount of accessible lead, then even an acute exposure could result in the blood lead level being chronically elevated. This is because lead has a long half-life in the blood, especially in younger children. This situation would be as deleterious as chronic exposure to small amounts of lead.

To avoid exceeding the 10 µg/dL level of concern from acute exposure, CPSC staff recommends that children not ingest more than 175 µg of accessible lead in a short period. This value is based upon a review of the scientific literature and calculation of the effect of the ingested lead on the BLL, taking into account a child's physiology (*e.g.*, body weight, blood volume), the bioavailability and body compartmentalization of lead, and normal elimination of an ingested item from the GI tract.

Extensive test data developed by the staff indicates that the amount of lead that would be absorbed by ingesting an item of jewelry is much greater than the amount of lead that would be absorbed by mouthing or handling the same piece. Accordingly, keeping lead content low enough to give reasonable protection against excess exposure by ingestion will provide even greater protection against the possibility of excess exposure through mouthing.

Enforcement Policy

An item of jewelry (such as a necklace) may consist of several component types (such as a chain, clasp, pendant, hook and beads). In determining whether to pursue enforcement under the FHSA, CPSC staff will first conduct a screening test to determine the total lead content of each type of metallic component, following the test methodology detailed in the attached paper. If the lead concentration of each component type is less than or equal to 0.06 percent by weight (equivalent to 600 parts per million), the staff will not seek any corrective action. If the screening test shows that the total lead content of any component type exceeds 600 ppm, the staff will conduct further testing of that component type using the acid extraction method, which is

also described in the attached document. The acid extraction test will be performed on an intact sample of the component type(s) in question. If the acid extraction test yields an amount of accessible lead that is less than or equal to 175 micrograms (μg) for all tested component types, the Office of Compliance will not seek a corrective action.

If the total lead concentration of any component type exceeds 600 ppm and the accessible lead from the same component type exceeds 175 μg , the staff will decide whether to pursue a corrective action on a case-by-case basis (as it has done in all cases previously). In making that decision, the staff will consider a number of factors, including the age grading of the jewelry item, the level of accessible lead, the dimensions of the components having accessible lead, the probable routes of exposure, and the number of items sold or offered for sale. In some cases, labeling rather than recall may be appropriate.

Guidance

The Commission has urged manufacturers generally to reduce the lead content of their products to the greatest extent possible. *See* 16 C.F.R § 1500.230 (guidance for lead in consumer products). The Office of Compliance recommends that persons intending to sell children's metal jewelry in the United States have representative samples tested periodically according to the screening test methodology used by the Commission staff. Firms can avoid CPSC enforcement action by ensuring that the total lead content of each component of metal jewelry they offer for sale is below the 600 ppm benchmark.

Effective Date

This policy will become effective on February 3, 2005 and will remain effective until further notice.

Contact Info

For further information on this Interim Enforcement Policy, please contact the Office of Compliance, Recalls and Compliance Division, as follows:

Terri Rogers, Associate Director

e-mail: TRogers@cpsc.gov phone: (301) 504-7584

Mary F. Toro, Associate Director

e-mail: MToro@cpsc.gov phone: (301) 504-7586