資料８

米国における規制状況

米国消費者製品安全委員会（CPSC）による Interim Enforcement Policy for Children's Metal Jewelry Containing Lead（鉛を含有する子供用金属装身具に関する暫定指針）（別添）

概要：

① 金属装飾品における鉛含有量を測定し、その量が 0.06w/w%を超える製品については、更に溶出試験を行い、溶出量が 175μg 以下とする基準を設ける。

② ①の試験において 175μg をこえる製品が判明した場合は、製品毎に対象年齢、鉛の量、鉛を含む構成要素の大きさ、暴露経路、販売状況等を考慮し、是正措置要請の要否を決定する。

※ 是正措置とは、表示の適正化の要請、含有量変更の要請、回収要請等があり、これら是正措置要請に当たっては、個別製品毎に評価を行いその該当性を判断。

施行： 2005 年（平成 17 年）2 月 3 日

経緯： CPSC は 2004 年に鉛を含有するアクセサリーを誤飲した子供に重篤な健康障害が報告されたことを契機に、2005 年 2 月 3 日付けで「鉛を含有する子供用金属装身具に対する暫定指針」を公表した。

試験法： CPSC が定める方法による。

NEWS from CPSC
U.S. Consumer Product Safety Commission
Office of Information and Public Affairs Washington, DC 20207

FOR IMMEDIATE RELEASE
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CPSC Announces New Policy Addressing Lead in Children's Metal Jewelry

WASHINGTON, D.C. ・The U.S. Consumer Product Safety Commission (CPSC) today announced a new enforcement policy (pdf) to reduce the potential for health risks from lead in children's metal jewelry. The new policy gives manufacturers, importers and retailers clear guidance on steps they should take to minimize the risk for children. The CPSC is also specifying the laboratory test procedures (pdf) it will use to analyze lead content.

The new policy explains how the CPSC staff will test for lead in children's jewelry and identifies the lead levels that will trigger further attention. CPSC staff will first conduct a screening test to determine the lead content of each type of component in a piece of jewelry. For example, a necklace may consist of a chain, a clasp, a pendant and one or more types of beads. If the lead content of each component is less than or equal to 600 parts per million (ppm), the staff will not pursue a recall or other corrective action. If the lead content of any component exceeds 600 ppm, Commission staff will then conduct further testing using the acid extraction method. If the acid extraction test yields an amount of accessible lead less than or equal to 175 micrograms (ug), no corrective action will be sought.

Pieces of metal jewelry with accessible lead greater than 175 ug could result in elevated blood lead levels in children. In these instances, CPSC staff will decide what corrective action may be appropriate on a case-by-case basis. Staff will consider the age of the children who are most likely to wear the jewelry, the level of accessible lead, the size and shape of the jewelry components, the probable routes of exposure and other factors.

Commission staff recommends that firms intending to sell children's jewelry in the United States keep lead levels as low as possible and test their own products following our

guidelines to ensure that they contain no more than 600 ppm lead. The do not want children's jewelry to have accessible lead that could cause elevated blood lead levels, ・said CPSC Chairman Hal Stratton. The urge manufacturers to reduce the lead content of their products to the greatest extent possible below the 600 ppm benchmark. ・

While deteriorating lead paint in homes is the leading cause of lead poisoning in children, lead exposures from other sources add to the overall risk. The scientific community generally recognizes a blood lead level of 10 micrograms per deciliter (ug/dl) of blood as a level of concern and recommends various lead poisoning prevention activities. To prevent young children from exceeding the 10 ug/dl blood lead level, CPSC seeks to limit exposure to lead from all consumer products, including children's metal jewelry.

In 2004, CPSC announced recalls of more than 150 million pieces of toy jewelry sold in vending machines and through other outlets. The Commission is aware of several cases in which children developed high blood lead levels after swallowing or repeatedly sucking on jewelry items. Lead poisoning in children is associated with behavioral problems, learning disabilities, hearing problems and growth retardation.

（http://www.cpsc.gov/cpscpub/prerel/prhtml05/05097.html）

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:

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
DIRECTORATE FOR LABORATORY SCIENCES
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Standard Operating Procedure for Determining Lead (Pb) and Its Availability in Children's Metal Jewelry
2/3/2005

This document provides detailed information on two test methodologies that will be used by the U.S. Consumer Product Safety Commission's testing laboratory (LSC) in the analysis of children's metal jewelry. The first methodology is used to determine the total lead content of a jewelry item or component. It will be used as a screening test for purposes of the Interim Enforcement Policy issued by the Office of Compliance on February 3, 2005. The second methodology is an acid extraction test. It is used to quantify the amount of lead that may migrate from jewelry and result in human exposure through ingestion.

These methodologies are provided to inform interested parties of the methods used by LSC for assessing the availability of lead for estimating potential human exposure. They are not required to be followed by other laboratories in making such assessments; however, other laboratories should consider using these procedures to ensure they obtain results that are consistent with CPSC's for purposes of the Interim Enforcement Policy announced by the Office of Compliance.

CPSC staff has concluded that these test methodologies are sufficient to make appropriate determinations concerning children's metal jewelry. Accordingly, we intend to use them in lieu of the test methodologies previously followed.

Definitions

1. Sample – The complete package of a product collected by CPSC field staff and submitted to LSC for analysis. A sample generally contains single or multiple identical units of a particular product. The sample will have an official seal with a sample number, inspector name, and date the package was sealed. Each individual item in a sample is identified with the sample number and sub-numbers, if there is more than one item in the sample. As an example, a sample may contain single or multiple items such as necklaces, rings, bracelets, etc.
2. Item – Individual sub-sample within the total sample, such as a necklace, a ring or a bracelet that can be subjected to lead testing. Ideally, the sample should contain only identical items, not a mix of several different items. An item such as a bracelet may be broken into its component parts such as bead, hook, pendant, with those component parts individually analyzed.

3. Instrument Detection Limit (IDL) – 3 times the standard deviation of 10 replicate measurements of reagent blank. The IDL for Pb is 0.01 ppm.
4. Method Detection Limit (MDL) - Reagent blank fortified with 2-3 times the IDL. Seven replicate measurements are made. Calculate the MDL as follows: MDL = t X S, t= 3.14 (99% confidence level for 7 replicates), S= standard deviation. The MDL determined for Pb is 0.01 ppm.
5. Laboratory Reagent Blank (LRB) – extraction or digestion media used for a particular Pb test. LRB data are used to assess contamination from the laboratory environment.
6. Calibration Blank – deionized water acidified with nitric acid (3 ml concentrated nitric acid diluted to 100 ml with deionized water).
7. Stock Standard Solution – 1000 ppm solution of Pb purchased from reputable commercial source, used to prepare calibration standards. Replace before expiration date.
8. Calibration Standards - Solutions containing 1, 5, 10, and 25 ppm of Pb in 3% nitric acid matrix are used for digests and extracts containing high Pb levels. Solutions containing 0.1, 0.25, 0.5, and 1 ppm of Pb in 3% nitric acid matrix are used for digests and extracts containing lower Pb levels. Calibration standards shall be prepared weekly.
9. Laboratory Performance Check Solution (LPC) - A Pb standard used to evaluate the performance stability of the instrument system. One of the calibration standards is generally used.
10. Quality Control Sample (QCS) - A solution containing Pb that is used to evaluate the performance of the instrument system. QCS is obtained from a source external to the laboratory and Stock Standard Solution.
11. Laboratory Fortified Blank (LFB) – LRBs to which known quantities of Pb are added in the laboratory. The LFB is extracted and analyzed exactly like a sample. Its purpose is to determine whether method performance is within acceptable control limits.

Materials and Reagents: The materials used for sampling and analysis are as follows:

1. Nitric Acid, Trace Metal Grade
2. Hydrochloric Acid, Trace Metal Grade
3. Glass Beakers, 50ml
4. Glass Beakers or Erlenmeyer Flasks - Shall be large enough to contain extract solutions that are 50 times greater than individual jewelry item weight.
5. Water/Shaker Bath
6. Hot Plate
7. Lead-free Insulated Wire.
8. Metal Cutters
9. Parafilm®
10. Distilled Water

I. Screening Test for Total Pb Analysis

Each unique component type from one subsample is analyzed for total Pb content. The procedure for Total Pb Analysis is as follows and is based on methodology found in Canada Product Safety Bureau Method C-02.4:

1. If the children's metal jewelry is coated with paint or a similar surface coating (it may contain Pb), the coating shall be removed and analyzed, separately from the base metal, for lead content as described in the Association of Official Analytical Chemists (AOAC) standard AOAC 974.02 (Lead in Paint). Care should be taken to remove as little of the substrate metal as possible.
2. Weigh out a 30-50 mg piece of children's metal jewelry in labeled 50ml beaker. Children's metal jewelry items generally weigh several grams, and an aliquot piece (with no paint or similar surface coating) will have to be clipped from item using metal cutters. Samples should be cut into several small pieces or ground to increase the rate of dissolution. If used, grinding apparatus must be thoroughly cleaned to prevent cross-contamination. Record actual weight to the nearest 0.1 mg.
3. Add 8ml of concentrated nitric acid to each beaker and evaporate to approximately 3ml on a hot plate.
4. After cooling, add 2ml of concentrated hydrochloric acid and stir.
5. Dilute with distilled water, washing side of beaker, to 20ml.
6. Warm up solution and gently agitate with stirrer or shaker bath for a minimum of 4 hours.
7. Transfer quantitatively into a 50ml volumetric flask and dilute to 50ml with distilled water.
8. Dilute samples so that Pb results are within calibration range of instrument. Generally a 1:50 dilution is sufficient.
9. Analyze diluted samples for Pb concentration using ICP spectrometer. High Pb standard calibration curve will be required. Analysis procedure is based on methodology found in ASTM E 1613. (Note: Method C-02.4 describes alternate procedure for analysis by Atomic Absorption Spectroscopy.)

II. Acid Extraction Test

The acid extraction simulates exposure to metal that is ingested into the alimentary tract. The analysis is generally performed on an intact item or component. The procedure for the acid extraction is as follows and is based on methodology found in ASTM C927, C738, D5517, and F963:

1. Suspend the children's metal jewelry item in a flask or beaker using insulated wire so that the item does not touch the bottom or edge of the flask/beaker, but will be submerged by acid.
2. Add 0.07N hydrochloric acid (HCL) solution to cover the jewelry item. The amount of acid solution added should be equivalent to 50 times the weight of the jewelry item. Record the volume of acid solution added. Ensure that the jewelry item is submerged.
3. Extraction is conducted for 1 hour at 37°C in the shaker bath.
4. After the 1 hour extraction period, all the acid extract is taken out, an aliquot saved for analysis, and fresh acid extract is added. The second extraction is conducted for 2 hours at 37°C on shaker bath.
5. After the 2 hour extraction period, all the acid extract is taken out, an aliquot saved for analysis, and fresh acid extract is added. The third extraction is conducted for 3 hours at 37°C on shaker bath.

6. After the 3 hour extraction period, all the acid extract is taken out, and an aliquot saved for analysis. The product has been exposed to a total time of 6 hours (1 + 2 + 3 = 6 hours) of extraction.
7. Each of the three extracted solutions is analyzed for Pb content using an ICP spectrometer. The high lead standard curve is generally required. Analysis procedure is based on methodology found in ASTM E 1613.

ICP Operating Procedures and Quality Control Measures

Analysis

1. Perform wavelength calibration monthly. This can be done prior to igniting plasma. An internal mercury lamp is used for wavelength calibration.
2. Ignite plasma. Set conditions as follows, these are the conditions recommended by the instrument manufacturer:
    a. R.F. Power = 1150 watts
    b. Auxiliary flow = 1 liter /minute
    c. Nebuliser flow = 30.06psi
    d. Pump rate = 100 rpm
    e. Purge Time = 10 seconds
3. Allow the instrument to become thermally stable before beginning. This requires at least 30 minutes of operation prior to doing peak search for Pb.
4. Open the Lead Method for samples requiring high Pb standards or the Low Lead Method for samples requiring low Pb standards.
5. Ensure the following element and wavelength are selected:
    a. Pb 220.353
6. Perform peak search using 5 ppm Pb standard to ensure optimum setting.
7. Perform calibration using calibration blank and standards. Calibration shall be performed a minimum of once a day when used for analysis, or each time the instrument is set up. Results for each standard shall be within 5% of the true value. If the values do not fall within this range, recalibration is necessary.
8. Analyze the QCS immediately after the calibration. The analyzed value of Pb should be within ±10% of the expected value. If Pb value is outside the ±10% limit recalibration is required.
9. Analyze the LPC following QCS analysis, after every 10^{th} sample, and at the end of the sample run. The analyzed value for Pb should be within ±5% of its expected value. If Pb value is outside the interval, reanalyze the LPC. If the Pb value is again outside the ±5% limit, recalibrate the instrument. All samples following the last acceptable LPC analysis should be reanalyzed.
10. At least one LRB must be analyzed with each sample set. If the Pb value exceeds 3 times the MDL, the laboratory or reagent contamination should be expected. The source of the contamination should be identified and resolved before continuing analyses. The LRBs for the two Pb test procedures are as follows:
    a. Total Pb – 8ml of concentrated nitric acid are placed in a 50ml beaker and heated on a hot plate with samples until concentrated to about 3ml followed by the addition of 2ml of concentrated HCL solution, then diluted to 50ml with deionized water after cooling.

b. Acid – 0.07N HCL solution

11. At least one LFB will be analyzed with each batch of samples. The LFB should be an LRB that is spiked with a known amount of Pb stock solution. LFBs should be prepared so that expected Pb values are within the calibration curve. Analyte recoveries should be within ±20% of expected values. If recoveries are outside this limit, the source of the problem should be identified and resolved before continuing analyses.
12. Dilute any samples that have Pb values exceeding 1.5 times the high calibration standard, and reanalyze.

Calculations and Results Reported

Results for the two Pb test methods are calculated and reported as follows:

1. Total Pb - %Pb (wt./wt.) = 0.10cd/w
   a. c= concentration of Pb detected (in units of ppm)
   b. d= dilution factor (in ml units)
   c. w= weight of aliquot digested (in mg units)

2. Acid Extraction Test - Results for each extraction stage (1, 2, and 3 hour) should be recorded separately as:
   µg Pb extracted = cd
   a. c = concentration of Pb detected (in ppm)
   b. d= dilution factor (in ml)
   - The total weight (in grams) of the jewelry item should be measured

Examples:

Table 1: Total Pb Analysis

	(c)	**(d)**		**(w)**	
Item	**ppm Pb**	**Dilution factor**	**Total Pb (µg)**	**Sample wt. (mg)**	**% Pb**
Pendant 1	20	1000	20,000	50	40

Table 2: Acid Extraction Analysis

		(c)	(d)	
Item	**Extraction time (hr)**	**ppm Pb (measured & corrected for blank)**	**Dilution factor**	**Total Pb (µg)**
Ring 1	1	2.0	40	80
	2	1.5	40	60
	3	1.0	40	40
Total				**180**