Regulatory Action on Lead in Children's Jewelry

Baltimore City Health Department

December 7, 2006

I. SUMMARY

The Commissioner of Health of Baltimore City is declaring metal components in children's jewelry with excess levels of lead to be a nuisance to public health.

II. BACKGROUND

A. Legal Authority

The Health Commissioner has the legal authority to regulate health nuisances pursuant to two sections of the Baltimore City Health Code. Title 2 of the Health Code relates generally to the Department of Health, while Title 5 relates more specifically to nuisance control. *See* Health Code §§ 2-101, *et seq.* and §§ 5-101, *et seq.* Title 2 provides that the Commissioner is responsible for "enforcing all laws for the preservation of the health of the inhabitants of the City" and preventing disease and nuisances affecting public health. Health Code § 2-104. It is the duty of the Commissioner "to remove and abate nuisances...." Health Code § 2-105(5). Title 5 of the Health Code sets forth examples of nuisances and states that nuisance "includes...any other health or safety hazard." Health Code § 5-101(b). Excessive levels of lead in children's jewelry are clearly a health hazard, as described below in the fatal case of a child ingesting jewelry with excessive levels of lead. Pursuant to Title 5, "[t]he Commissioner of Health is responsible for...requiring the removal of all nuisances...." Health Code § 5-102. Thus, Titles 2 and 5 of the City Health Code provide the legal authority by which the Health Department and Health Commissioner can regulate health nuisances in the City.

B. Lead in Children's Jewelry Threatens Children's Health

The nuisance addressed by this proposed regulation is lead poisoning from lead-containing children's jewelry.

Lead is a heavy metal and potent toxin that can cause life-threatening poisoning at high doses and insidious damage at low doses. The Agency for Toxic Substances and Disease Registry of the U.S. Department of Health and Human Services has found that lead causes a range of significant adverse effects in children and adults.[1]

Lead is especially toxic to the brains of young children. According to the Agency for Toxic Substances and Disease Registry, high doses of lead – which are associated with blood lead levels above 70 micrograms per deciliter – can cause children to suffer life-threatening encephalopathy and "lasting neurologic and behavioral damage."[2]

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[1] Agency for Toxic Substances & Disease Registry, *Case Studies in Environmental Medicine: Lead Toxicity* (October 2000).

[2] *Id.*

Exposure to low doses of lead has been linked to lower IQ scores, school failure, attention deficit hyperactivity disorder, and deficits in vocabulary, fine motor skills, reaction time, and hand-eye coordination.[3] There is no known lower threshold for the adverse effects of lead on children's development.[4]

The Centers for Disease Control and Prevention (CDC) has determined that an important source of lead exposure for children are consumer products. According to CDC, in some areas of the country, as many as one-third of children with lead poisoning are exposed to items containing lead that can be brought into the home. As a result, CDC recommends "restriction or elimination of nonessential uses of lead in consumer products" as part of a "proactive strategy that prevents exposure to these products and is preferable to relying on case finding to identify lead exposure hazards."[5]

Children's jewelry is among the most prominent consumer products that can expose children to unacceptable levels of lead. Exposure can happen via contact with the hands, direct oral contact, or ingestion.

In June 2004, CDC reported the case of a child who suffered lead poisoning from ingesting a toy necklace.[6] On March 23, 2006, the Reebok Corporation announced that a four-year-old child in Minneapolis died from lead intoxication after swallowing a piece of children's jewelry that was distributed with a new pair of shoes.[7]

According CDC, the four-year-old patient was brought to a hospital in Minneapolis, Minnesota for vomiting. He developed abdominal pain, dehydration, and listlessness before suffering a severe seizure and requiring mechanical ventilation. He then suffered severe brain swelling that required emergency neurosurgery. On the fourth day of hospitalization, he had no brain activity and was removed from life support. Upon autopsy, a heart-shaped pendant bearing the name "Reebok" was removed from his

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[3] *Id.;* American Academy of Pediatrics, *Lead Exposure in Children: Prevention, Detection and Management*, Pediatrics, 1036-1048 (October 2005).

[4] Centers for Disease Control and Prevention, *Preventing Lead Poisoning in Young Children* (August 2005).

[5] Centers for Disease Control and Prevention, *Death of a Child After Ingestion of a Metallic Charm – Minnesota, 2006*, Morbidity and Mortality Weekly Reports (Mar. 23, 2006).

[6] Centers for Disease Control and Prevention, *Brief Report: Lead Poisoning from Ingestion of a Toy Necklace --- Oregon, 2003*, Morbidity and Mortality Weekly Reports, 509-511 (June 18, 2004).

[7] Reebok, *Reebok Recalls Bracelet Linked to Child's Lead Poisoning Death* (Mar. 23, 2006).

stomach. Testing revealed the pendant to be 99.1% lead.[8] Reebok subsequently recalled of 300,000 pieces of the jewelry.[9]

The recall was one of at least 15 recalls of children's jewelry because of dangerous levels of lead in the past four years:

- On May 10, 2006, Liz Claiborne Inc, of North Bergen, New Jersey recalled about 2,800 pieces of Juicy Couture Children's Jewelry with phrases including "Viva La Juicy" printed on the front.[10]

- On April 27, 2006, Selected Trading Corp. of Miami, Florida recalled about 55,000 choker-style necklaces with the phrase "in style" printed on the front.[11]

- On March 30, 2006, American Girl Children's Jewelry of Middleton, Wisconsin recalled 180,000 American Girl necklaces, bracelets, earrings, and hair accessories for girls.[12]

- On March 23, 2006, Dollar Tree Distribution Inc. of Chesapeake, Virginia, recalled about 580,000 necklaces and rings in a variety of designs with a toy "gem" in the center. Among the designs were "mood rings" and "glow in the dark" necklaces.[13]

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[8] Centers for Disease Control and Prevention, *Death of a Child After Ingestion of a Metallic Charm – Minnesota, 2006*, Morbidity and Mortality Weekly Reports (Mar. 23, 2006).

[9] Consumer Product Safety Commission, *Reebok Recalls Bracelet Linked to Child's Lead Poisoning Death* (Mar. 23, 2006) (online at http://www.cpsc.gov/cpscpub/prerel/prhtml06/06119.html).

[10] Consumer Product Safety Commission, *Juicy Couture Children's Jewelry Recalled for Lead Poisoning Hazard* (May 10, 2006)(online at http://www.cpsc.gov/cpscpub/prerel/prhtml06/06160.html).

[11] Consumer Product Safety Commission, *Children's Necklaces Recalled for Lead Poisoning Hazard* (Apr. 27, 2006)(online at http://www.cpsc.gov/cpscpub/prerel/prhtml06/06150.html).

[12] Consumer Product Safety Commission, *Children's Jewelry Sold at American Girl Stores Recalled for Lead Poisoning Hazard* (Mar. 30, 2006) (online at http://www.cpsc.gov/cpscpub/prerel/prhtml06/06123.html).

[13] Consumer Product Safety Commission, *Dollar Tree Stores Inc. Toy jewelry Recalled for Lead Poisoning Hazard to Children* (Mar. 23, 2006) (online at http://www.cpsc.gov/cpscpub/prerel/prhtml06/06118.html).

- On March 23, 2006, Oriental Trading Company Inc. of Omaha, Nebraska, recalled about 25,000 beaded photo charm bracelets.[14]

- On February 23, 2006, Provo Craft & Novelty Inc. of Spanish Fork, Utah recalled about 29,000 metal charms, including some in the shape of pumpkins.[15]

- On November 30, 2005, Stravina Operating Co., LLC, Of Chatsworth California recalled about 6 million metal necklaces and zipper pulls, each bearing a child's name.[16]

- On September 22, 2005, Dollar General Corporation of Goodlettsville, Tennessee recalled about 455,000 necklace and earring sets with floral designs.[17]

- On September 22, 2005, Monogram International Inc., of Pinellas Park, Florida recalled about 145,000 Disney Princess bracelet keyrings.[18]

- On May 12, 2005, Dollar General Corp of Goodlettsville, Tennessee recalled about 80,000 pendants shaped as hearts.[19]

- On January 11, 2005, Riviera Trading Inc. of New York, New York recalled about 7,1000 metallic costume bracelets with phrases including "I like movies" and "I like sports" printed on them.[20]

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[14] Consumer Product Safety Commission, *Lead Poisoning Hazard Prompts Recall of Metal Charm Bracelets* (Mar. 23, 2006) (one at http://www.cpsc.gov/cpscpub/prerel/prhtml06/06538.html).

[15] Consumer Product Safety Commission, *Metal Charms Recalled for Lead Poisoning Hazard to Children* (Mar. 23, 2006) (online at http://www.cpsc.gov/cpscpub/prerel/prhtml06/06093.html).

[16] Consumer Product Safety Commission, *CPSC, Stravina Operating Co. Announce Recall of Children's Metal Necklaces and Zipper Pulls* (Mar. 23, 2006) (online at http://www.cpsc.gov/cpscpub/prerel/prhtml06/06042.html).

[17] Consumer Product Safety Commission, *CPSC, Dollar General Corp. Announce Recall of Costume Jewelry* (Sept. 22, 2005) (online at http://www.cpsc.gov/cpscpub/prerel/prhtml05/05278.html).

[18] Consumer Product Safety Commission, *CPSC, Monogram International Inc. Announce Recall of Bracelet Keyrings* (Sept. 22, 2005)(online at http://www.cpsc.gov/cpscpub/prerel/prhtml05/05277.html).

[19] Consumer Product Safety Commission, *CPSC, Dollar General Corp. Announce Recall of Metal Heart-Shaped Pendants* (May 12, 2005)(online at http://www.cpsc.gov/cpscpub/prerel/prhtml05/05171.html).

- On December 17, 2004, Raymond Geddes Co. Inc. of Baltimore, Maryland recalled about 155,000 necklaces depicting frogs, dolphins and a "sunshine smiley face."[21]

- On July 8, 2004, four children's jewelry importers recalled 150 million pieces of children's jewelry sold in vending machines across America. The four firms were A&A Global Industries, Inc. of Cockeysville, Maryland; Brand Imports, LLC of Scottsdale, Arizona, Cardinal Distributing Company of Baltimore, Maryland, and L.M. Becker & Co. Inc., of Kimberly, Wisconsin. The children's jewelry was sold between January 2002 and June 2004, at a cost of between $0.25 and $0.75 per item.

- On March 2, 2004, Brand Imports LLC of Scottsdale, Arizona recalled 1 million chilren's rings in designs featuring hearts and stars.[22]

- On Sept. 10, 2003, L.M. Becker & Co. of Kimberly, Wisconsin recalled 1.4 million toy necklaces with assorted symbols.[23]

C. Action by Baltimore City Is Necessary To Protect Children

The Consumer Product Safety Commission (CPSC) is responsible for protecting children from lead poisoning from children's jewelry. However, CPSC has failed to do so. CPSC has in place a weak policy that permits unacceptable levels of lead to be present in children's jewelry. Action by Baltimore City is necessary to protect children from harm.

Two federal statutes address the lead content of toys. Under the Consumer Product Safety Act, regulations ban paint containing lead in a concentration of greater than 600 parts per million.[24] The Federal Hazardous Substances Act bans products that

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[20] Consumer Product Safety Commission, *CPSC, Riviera Trading Inc. Announce Recall of Children's Costume Bracelets* (Jan. 11, 2005)(online at http://www.cpsc.gov/cpscpub/prerel/prhtml05/05082.html).

[21] Consumer Product Safety Commission, *CPSC, Raymond Geddes Co. Announce Recall of Children's Necklaces* (Dec. 17, 2004) (online at http://www.cpsc.gov/cpscpub/prerel/prhtml05/05072.html).

[22] Consumer Product Safety Commission, *CPSC, Brand Imports, LLC Announce Recall of Children's Rings* (Mar. 2, 2004)(online at http://www.cpsc.gov/cpscpub/prerel/prhtml04/04090.html).

[23] Consumer Product Safety Commission, *CPSC, L.M. Becker & Co. Inc. Announce Recall of Toy Necklaces* (Sept. 10, 2003)(online at http://www.cpsc.gov/cpscpub/prerel/prhtml03/03178.html).

[24] 16 CFR 1303.

expose children to "hazardous substances" through routine handling or reasonably foreseeable use, including ingestion."[25]

CPSC has the authority to implement these statutes. The agency could establish clear standards for lead content and testing to minimize the likelihood that hazardous products are ever sold. However, CPSC has not done so. Instead, it has provided wide latitude to the industry in conducting testing prior to marketing, with the result that the standardized testing can be grossly inadequate. The agency has also issued a weak and ineffective policy on the acceptable levels of lead in children's jewelry.

Industry testing standards for toys, published by the American Society of Testing and Materials, only include a single test for lead.[26] This test involves bathing a scraping of the outer surface of the toy in a weak hydrochloric acid solution and assessing the lead content of the solution. It does not require an assessment of products without an outer coating. Nor does it require an assessment of the overall lead content of the product. On January 13, 2005, Congressman Henry A. Waxman wrote CPSC summarizing concerns with the industry's testing standard.[27]

On February 3, 2005, CPSC announced a new policy addressing lead in children's metal jewelry.[28] The new policy is premised on the claim that the "scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood ... as a threshold level of concern with respect to lead poisoning."[29] This claim is wrong. CDC has concluded that "no 'safe' threshold for blood lead levels ... in young children has been identified."[30] In fact, CDC has specifically rejected the regulatory approach used by the CPSC of modeling risk based on blood lead levels over 10 micrograms per deciliter.[31]

After starting from a false premise, CPSC's policy sets out a weak and ineffectual approach to protecting children from lead in children's jewelry.

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[25] 15 USC 1261-1278.

[26] American Society of Testing and Materials, *Standard Consumer Safety Specification for Toy Safety* (2003).

[27] Letter from Congressman Henry A. Waxman to Chairman of the Consumer Product Safety Commission Hal Stratton (Jan. 13, 2005).

[28] Consumer Product Safety Commission, *CPSC Announces New Policy Addressing Lead in Children's Metal Jewelry* (Feb. 3, 2005)(online at http://www.cpsc.gov/cpscpub/prerel/prhtml05/05097.html).

[29] Consumer Product Safety Commission, Interim Enforcement Policy for Children's Metal Jewelry Containing Lead (Feb. 3, 2005).

[30] Centers for Disease Control and Prevention, *Preventing Lead Poisoning in Young Children* (Aug. 2005).

[31] *Id.*

Under the new policy, CPSC staff first conducts a screening test to determine the "lead content of each type of component in a piece of jewelry." If the lead content is less than or equal to 600 parts per million, then "no corrective action will be sought."

If a piece of the jewelry exceeds the 600 parts per million threshold, then CPSC proceeds to the second step: testing using an acid extraction method. If the acid extraction yields less than or equal to 175 micrograms of accessible lead, then "no corrective action will be sought."

If, however, a piece of the product yields more than 175 micrograms of accessible lead, then CPSC moves to the third step. In this step, staff "decides whether to pursue a corrective action on a case-by-case basis."[32] According to the CPSC policy, "[s]taff 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. [33]

CPSC's policy fails to protect children from harm. It explicitly permits an unsafe amount of lead – 175 micrograms – to be present in any single component of a single piece of children's jewelry. As a result, a single piece of jewelry could contain significantly more than 175 micrograms. It also establishes no clear level for enforcement. A manufacturer can believe that even children's jewelry with high levels of lead will not face any regulatory action.

Citing the failure of CPSC's policy, Congressman Waxman and Senator Barack Obama have introduced legislation to ban lead from children's products.[34] This legislation has been endorsed by the American Academy of Pediatrics.

Since the CPSC policy announcement, there have been at least 11 recalls of approximately 7 million pieces of children's jewelry because of the threat of lead exposure and one known death.

Because of the ongoing risk to children from lead in children's jewelry, and because of the inadequacy of action by CPSC to protect children, the Baltimore City Commissioner of Health proposes to declare children's jewelry with excess levels of lead to be a nuisance. For the purpose of this regulatory action, "excess levels of lead" would mean any piece of children's jewelry in which any metal component part has a lead concentration exceeding 1200 parts per million prior to September 1, 2007, or 600 parts per million on or after September 1, 2007. This phased in standard imposes a reasonable and attainable safety standard that is consistent with a recent settlement between the state

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[32] Consumer Product Safety Commission, Interim Enforcement Policy for Children's Metal Jewelry Containing Lead (Feb. 3, 2005).

[33] *Id.*

[34] H.R. 668 and S. 2048.

of California and 71 major retailers and distributors in January 2006.[35]. The 600 parts per million standard, in effect as of September 1, 2007, mirrors the federal standard for lead in paint, which was set to be protective of children's health.[36]

The Centers for Disease Control and Prevention has stated "alternatives to lead are available" for children's jewelry.[37] Referring to lead in candy and other consumer products, the chief of the Lead Poisoning Prevention Branch of CDC has stated, "It is ... important to think about why is lead in any of those products, and if it doesn't need to be there, let's get it out."[38]

If one item of children's jewelry is found to contain excess lead, there is a high likelihood of other items having excess lead. As a result, the Commissioner of Health will deem children's jewelry of the same style and from the same manufacturer or distributor a nuisance to the public health.

III. RESPONSES TO COMMENTS

The Baltimore City Health Commissioner accepted comments on the Proposed Regulations during the comment period from August 14, 2006 through September 29, 2006. Responses were received from: the Maryland Lead Poisoning Prevention Commission, Claire's Stores, Inc., and the Fashion Jewelry Trade Association.

The following is the Baltimore City Health Department's (Department) comments based on the responses received.

- Maryland Lead Poisoning Prevention Commission.

The response from the Maryland Lead Poisoning Prevention Commission provided support for the proposed regulation. The organization is comprised of appointed officials from both public and private sector that states its mission as "providing oversight for the implementation of the statewide plan to eliminate childhood head poisoning..."

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[35] *People of the State of California vs. Burlington Coat Factory Warehouse Corporation, et al.*, Case RG 04-162075 (2006)(online at http://ag.ca.gov/newsalerts/cms06/06-009_0a.pdf?PHPSESSID=9e493493a321a5b072cf5baf0f2ed3e8).

[36] 16 CFR 1303.

[37] Centers for Disease Control and Prevention, *Death of a Child After Ingestion of a Metallic Charm – Minnesota, 2006*, Morbidity and Mortality Weekly Reports (Mar. 23, 2006).

[38] *Bill Would Ban Lead in Candy Wrappers*, Orange County Register (Mar. 28, 2005).

The Commission agreed that governmental regulatory action is necessary to protect children from not only traditional sources of lead poisoning, but also from sources in consumer products. The Commission applauded the Department's efforts in an area where there has been a lack of federal intervention.

- Claire's Stores, Inc.

Claire's is a national retailer of products for children and teens. The response from Claire's Stores, Inc. (Claire's), while providing support to legislation for the health and safety of children, enumerated several positions of opposition to the Proposed Regulation.

Claire's first objection to the Proposed Regulation is that the Department "incorrectly states that the proposed action seeks to implement the same standard agreed to in a settlement between the state of California and 71 major retailers and distributors." Claire's states that the standard for glass and crystal and the definition for "children's jewelry" is not the same as is defined in the settlement in California, also known as the Proposition 65 settlement.

After reviewing the issues and in response to these stated concerns, the Department is focusing the regulation on metal components of children's jewelry. Based on the Department's review of this issue, significant amounts of lead do not leach from glass products. The Department takes this action in recognition that many of the recent recalls for children's jewelry, and the cases of harm to children have involved metal components of the jewelry. The Department's 600 ppm standard for metal components is the same as that adopted in the California settlement and passed in recent California legislation.

The second objection is that the testing required by the regulation "fails to include a detailed protocol or methodology." The methodology described in Proposition 65 uses EPA methods 3050B or 3051. Those methods are, by EPA's own documents, for the determination of lead, and other elements, in sludges, soils and sediments. The Department has determined that the Consumer Product Safety Commission methodology, Standard Operating Procedure for Determining Lead and Its Availability in Children's Metal Jewelry, methodology that is designed specifically for the analysis of metal, is adequate to perform the basic testing to identify the hazards in metal components for children's jewelry. The full details of the protocol and methodology will be incorporated into the regulation.

Claire's third objection is that in comparison to the Proposition 65 settlement, the Department's regulation is too dissimilar and thus creates a "patchwork quilt of regulations in the United States, and will not uniformly safeguard the children these regulations are designed to protect." With the revisions made by the Department, as it applies to the components tested, the Department believes that the regulation does not overreach the Proposition 65 settlement and thus does not conflict with the implementation of Prop 65.

Claire's fourth objection is that the regulation fails to provide a means for an adequate due process mechanism. The Department agrees that a hearing process will now be incorporated in the regulations so that due process is afforded to retailers.

Fifth, Claire's finds the regulation language vague as it relates to the "similarly constructed and packaged" verbiage. The Department agrees that the language is better stated as "from the same style and from the same manufacturer." This change is made to specifically help the retailer and manufacturer identify which jewelry product style will be affected once piece of jewelry with excessive lead levels is identified.

Sixth, Claire's states that the regulation fails to report a compliance date. The date of compliance for the 600 ppm standard is September 1, 2006, in California. The Department will establish the following implementation timeline, which provides a two-fold margin for an period of interim compliance: As of the effective date of this regulation, no person shall offer for retail sale children's jewelry with metal components in excess of 1200 ppm of total lead. As of September 1, 2007, no person shall offer for retail sale, children's jewelry with metal components in excess of 600 ppm of total lead.

- Fashion Jewelry Trade Association (FJTA).

The FJTA is a trade association of vendors of costume jewelry. Its comments are specific to certain language used in the regulation.

The principal objection of the FJTA is that of the "similarly constructed and packaged items from the same manufacturer..." language. The FJTA states that supplies of metal for jewelry often comes from a variety of sources and that each individual style should be tested before being deemed a nuisance. As stated earlier, the Department agrees that the language is better stated as "from the same style and from the same manufacturer." This change is made to specifically assist the retailer and manufacturer identify which jewelry style should be pulled from the market upon a showing of an elevated lead level in a piece of children's jewelry.

Based on the comments received and a rigorous review of the issues, the Department puts forth the following revised and final regulations.

IV. REGULATION

A. Children's Jewelry Defined

1. Definition. "Children's jewelry" means jewelry that is made for, marketed for use by, or marketed to, children. "Children's jewelry" includes, but is not limited to, jewelry that meets any of the following conditions:

a) Represented in its packaging, display, or advertising, as appropriate for use by children;

b) Sold in conjunction with, attached to, or packaged together with other products that are packaged, displayed, or advertised as appropriate for use by children;

c) Sized for children and not intended for use by adults; and

d) Sold in any of the following:

(1) A vending machine; or

(2) Retail store, catalog, or online Web site, in which a person exclusively offers for sale products that are packaged, displayed, or advertised as appropriate for use by children; or

(3) A discrete portion of a retail store, catalog, or online Web site, in which a person offers for sale products that are packaged, displayed, or advertised as appropriate for use by children.

B. Standards

1. The Commissioner of Health has determined that any piece of children's jewelry in which any metal component part has a lead concentration exceeding 600 parts per million contains dangerous levels of lead. While any level of lead may be unsafe if ingested by children, the Commissioner of Health issues the following standard in order to reach a reasonable and attainable safety standard.

a) The Department issues the following phased-in standards:

(1) As of the effective date of this regulation, no person shall offer for retail sale children's jewelry with metal components that contain in excess of 1200 ppm of total lead.

(2) As of September 1, 2007, no person shall offer for retail sale, children's jewelry with metal components that contain in excess of 600 ppm of total lead.

2. The Commissioner of Health has determined that any piece of children's jewelry, with any metal component part containing lead levels that exceed the standard set forth in section (1), is a health hazard and a nuisance.

3. If an item of children's jewelry is found to contain any metal component with lead levels exceeding the standards set forth in section (1), the Commissioner of Health will deem all items of the same style and from the same manufacturer a health hazard and a nuisance.

C. Testing

1. The Baltimore City Health Department shall conduct random testing of children's jewelry sold in the City for a period of at least six months. The testing will assess the lead concentration of metal component parts of children's jewelry according to the laboratory method defined by the Consumer Product Safety Commission ("CPSC"). The CPSC methodology – Standard Operating Procedure for Determining Lead (Pb) and Its Availability in Children's Metal Jewelry, dated February 3, 2005, is attached hereto as Appendix A and is hereby incorporated as part of this regulation.

2. At least monthly, the Health Department will release the results of its testing to the public.

D. Notice

1. If a testing result reveals a concentration of 1200 ppm before September 1, 2007, or 600 ppm on or after September 1, 2007, in any metal component part of a piece of children's jewelry, the Health Department will take the following steps:

a) The Health Commissioner may issue a written notice to the owner, operator, or resident agent for the retail establishment at which the children's jewelry containing a metal component with excess lead levels was found. Such written notice shall:

(1) Identify the children's jewelry and the associated health hazard;

(2) Declare all items of the same style and from the same manufacturer to be a nuisance;

(3) Specify the corrective action to be taken (e.g., specify that the establishment must immediately stop the sale and/or distribution of such children's jewelry);

(4) State the time within which that action must be taken; and

(5) Set forth penalties that may be imposed if the corrective action is not timely taken.

2. The notice shall be served in accordance with section 5-204 of the Baltimore City Health Code.

3. The Health Commissioner may publish notice in a newspaper of general circulation in the City that:

a) Identifies the children's jewelry and the associated health hazard;

b) Declares all items of the same style and from the same manufacturer to be a nuisance;

c) Specifies the corrective action to be taken by any establishment containing such an item (e.g., specifying that all establishments must immediately stop the sale and/or distribution of this item;

d) States the time within which that action must be taken; and

e) Sets forth penalties that may be imposed if the corrective action is not timely taken.

E. Penalties and Right to Hearing

1. Penalties

a) Any person who fails to take the corrective action specified in the nuisance notice may be subject to one or more of the following penalties:

b) Any person who fails to comply with a nuisance notice is guilty of a misdemeanor and, if convicted, subject to a fine of not more than $1,000 for each offense. Health Code § 5-210.

c) Any person who "knowingly obstruct[s], resist[s], or interfere[s] with the Commissioner or any officer or employee of the Department while carrying out their powers and duties" is guilty of a misdemeanor and, if convicted, subject to a fine of up to $500 for each offense. Health Code §§ 2-205, 2-212.

d) Any person who "fail[s] to comply with any order or notice issued under this article or under the authority of the Health Commissioner" is guilty of a misdemeanor and, if convicted, subject to a fine of up to $200 for each offense plus $50 for each day that the offense continues. Health Code §§ 2-207, 2-213.

e) An Environmental Control Board citation with a penalty of $100 can be issued for a violation of a nuisance abatement notice issued under the Health code. City Code Art. 1, § 40-14(e)(7).

2. Right to Hearing. Any person aggrieved by a notice, order, or decision of the Health Department may request a hearing as set forth in section 2-302(b) of the Baltimore City Health Code.

F. Severability

The provisions of this regulation are hereby declared severable. If any word, phrase, clause, sentence, paragraph, section or part in or of this regulation or the application thereof to any person, circumstance or thing is declared invalid for any reason whatsoever, the remaining provisions and the application of such provisions to other persons, circumstances or things shall not be affected thereby but shall remain in full force and effect, the Commissioner hereby declaring that he would have ordained the remaining provisions of this regulation without the word, phrase, clause, sentence, paragraph, section or part, or the application thereof, so held invalid.

Approved:

Joshua M. Sharfstein, M.D.
Commissioner
Baltimore City Health Department

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Date effective: December 7, 2006

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Appendix A

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
DIRECTORATE FOR LABORATORY SCIENCES
DIVISION OF CHEMISTRY
10901 DARNESTOWN RD
GAITHERSBURG, MD 20878

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**