UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

BALLOT VOTE SHEET

DATE: DEC - 4 2006

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Patricia Semple, Executive Director

FROM: Page C. Faulk, General Counsel
Jeffrey R. Williams, Assistant General Counsel for Enforcement and Information
Hyun S. Kim, Attorney, OGC

SUBJECT: Petition for Ban on Lead Toy Jewelry, Petition HP 06-1

Ballot Vote Due: DEC 11 2006

The staff's briefing package addresses the petition submitted by the Sierra Club requesting a ban on toy jewelry containing more than 0.06% lead by weight. Staff recommends that the Commission grant the petition and instruct staff to prepare a draft advance notice of proposed rulemaking (ANPR) for Commission consideration. The memorandum and staff briefing package are attached.

Please indicate your vote:

I. Grant Petition HP 06-1 and instruct the staff to prepare a draft ANPR in accordance with the staff recommendation for consideration by the Commission.

_____ _____
Signature Date

12/4/06

NOTE: This document has not been reviewed or accepted by the Commission.
Initial ___ Date 12/4/06

II. Deny Petition HP 06-1 and instruct the staff to prepare a denial letter.

_____ _____

Signature Date

III. Take other action. (Please specify.)

_____

_____

_____

_____ _____

Signature Date

Briefing Package for Petition Requesting Ban of Lead in Toy Jewelry (Petition No. HP 06-1)

For Information Contact:

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Directorate for Health Sciences
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Executive Summary

The U.S. Consumer Product Safety Commission (CPSC or the Commission) received a letter from the Sierra Club addressing lead in children's jewelry. The CPSC General Counsel docketed one portion of the letter—the request for a ban of certain lead-containing toy jewelry—under the Federal Hazardous Substances Act (FHSA) as Petition No. HP 06-1 on May 16, 2006. A Federal Register notice soliciting comments was published June 20, 2006 (71 FR 35416).

In considering this petition, the staff assessed the currently available information on the toxicity of lead, children's behaviors, data on children's metal jewelry, and related economic information. Given this information, the staff recommends that the Commission grant the petition and begin rulemaking that could result in declaring children's jewelry containing more than 0.06 percent lead by weight in metal components to be a hazardous substance.

The staff is focusing on metal jewelry at this time because the available data indicate that such products could be hazardous due to their lead content and potential for exposure. The staff lacks information concerning potential lead hazards of other non-metal materials that may be used in jewelry, but could assess additional types of products at such time as data become available.

The adverse health effects of lead poisoning in children are well-documented, and include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. The staff believes that the data produced by CPSC staff show that excess lead exposure from ingestion of metal jewelry is likely for items that contain more than 0.06 percent lead, and that the amount of exposure likely increases with increasing lead content in the item. On this basis, the staff believes that limiting the lead content of children's metal jewelry could be an effective way to help prevent excess lead exposure in children.

Staff analysis indicates that children of all ages engage in mouthing behaviors, which can be expected to result occasionally in ingestion of objects. From 2000 to 2005 an estimated more than 300,000 children aged 18 years and younger were treated in hospital emergency rooms for injuries associated with foreign object ingestion; nearly 20,000 of the ingestions involved jewelry items. Although the specific products involved in these cases, and whether the items contained lead, cannot be determined from this database, the staff knows of individual cases of children who swallowed lead-containing children's jewelry, including one recent case of a child who died after swallowing a lead-containing metal charm from a bracelet. Based on the potential for lead exposure from lead-containing metal jewelry and the known hazards of lead exposure from ingestion of lead-containing metal jewelry, the staff concludes that children who swallow lead-containing metal jewelry could be exposed to an amount of lead that could result in substantial injury or illness. Furthermore, the staff believes that all children are potentially at risk of being exposed to excessive levels of lead since mouthing and swallowing behaviors continue throughout childhood and since adverse effects of lead have been noted in people of all ages.

The staff recognizes that a clear determination of what constitutes children's jewelry, for all ages of children, is a not a simple matter.

The staff's economic analysis indicated that a CPSC action to regulate lead content in children's jewelry could affect several industries, consisting almost entirely of small businesses. However, specific information that would allow estimation of the costs and benefits of a potential regulation is currently lacking, and if the Commission votes to grant the petition the staff will seek detailed data that could be used to evaluate the costs and benefits of a potential rule.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: DEC - 4 2006

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Page C. Faulk, General Counsel
Patricia Semple, Executive Director

FROM : Jacqueline Elder, Assistant Executive Director, Office of Hazard Identification and Reduction
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

SUBJECT : Petition HP 06-1 Requesting Ban of Lead in Toy Jewelry

This briefing package presents the staff's analysis of the petition requesting a ban of lead in children's jewelry and associated data, and provides a summary of comments received in response to the notice published in the Federal Register (71 FR 35416) and the staff responses to the comments.

Petition HP 06-1

The U.S. Consumer Product Safety Commission (CPSC) received a letter from the Sierra Club, dated April 17, 2006, requesting that the Commission undertake certain actions regarding lead in consumer products, especially toy jewelry (Tab A). While the letter included several requests for actions by CPSC, only the request for a ban of certain lead-containing toy jewelry met the requirements for docketing as a petition. The CPSC General Counsel docketed this request under the Federal Hazardous Substances Act (FHSA) as Petition No. HP 06-1 on May 16, 2006. A Federal Register notice soliciting comments was published June 10, 2006 (71 FR 35416).

The Sierra Club letter was also addressed to the U.S. Environmental Protection Agency (EPA), requesting certain responses from that agency. EPA also published a Federal Register notice soliciting comments (71 FR 30921, May 31, 2006). Subsequently, EPA responded to the Sierra Club with a letter dated July 20, 2006, denying the Sierra Club's requests either because the specific request was deemed not subject to the applicable EPA petition process or because EPA did not believe that the requested regulatory action would be helpful in addressing the issues raised by the petitioner.

The petition to CPSC requested that any toy jewelry containing more than 0.06 percent lead by weight, for which there is a reasonably foreseeable possibility that children could ingest, be declared a banned hazardous substance under the FHSA. The Sierra Club states that the 0.06 percent level may not be low enough to protect children and should be an interim step until a determination of a more appropriate cutoff is made. In addition, the Sierra Club asserts that it

NOTE: This document has not been reviewed or accepted by the Commission.
Initial _____ Date 12/4/06

believes that toy jewelry is any item that is decorative, with no or minimal functional purpose, and that is valued at less than $20 per item, since it believes that people are less likely to store such low-cost jewelry in secure containers or out of reach from children.

Background

Children's Jewelry

The petition requests that CPSC take action on "toy jewelry." The CPSC staff has used both "toy jewelry" and "children's jewelry" to describe the products under discussion. Many of the jewelry products used by children may be termed "toy jewelry," including jewelry that accompanies toys, such as dolls and stuffed animals, jewelry used in pretend and role-play, as well as arts and crafts types of products, such as jewelry-making kits. In addition to toy jewelry, children may use or be given other accessories to be worn or used as jewelry in the common sense of that word. For the purposes of this staff memorandum, the staff uses the term, "children's jewelry," to include both the toy jewelry and accessory items that children use as jewelry.

As described in detail below, children's metal jewelry containing lead is an issue because of the well-known adverse effects of lead exposure in children, and because of the potential for products that contain lead to result in excessive lead exposures due to children's actions such as ingestion of small jewelry items.

Current Requirements

CPSC protects children, and consumers in general, from hazardous exposures to substances such as lead in consumer products under the Consumer Product Safety Act (CPSA) (15 U.S.C. § 2051-2084), and the Federal Hazardous Substances Act (FHSA) (15 U.S.C. § 1261-1278).

Under the CPSA, the Commission has, by regulation, banned paint and other similar surface coatings that contain more than 0.06 percent lead ("lead-containing paint"), toys and other articles intended for use by children that bear lead-containing paint, and furniture articles for consumer use that bear lead-containing paint. 16 C.F.R. Part 1303.

Products other than those covered under the lead in paint rule may be regulated by the FHSA. Under this act, household products that expose children to quantities of lead that may cause substantial personal injury or illness under reasonably foreseeable conditions of handling or use, including ingestion, are "hazardous substances." 15 U.S.C. §1261(f)(1). Further, a toy or other article intended for use by children which bears or contains a hazardous substance in such manner as to be susceptible of access by a child is a banned hazardous substance. Thus, if a harmful level of lead is contained in a children's product and that lead is accessible to children (*e.g.*, through mouthing or ingestion) that product is a banned hazardous substance. 15 U.S.C. §1261(q)(1).

Previous Commission Activity

The Commission has codified guidance to manufacturers, importers, distributors, and retailers to protect children from hazardous exposure to lead in the Guidance Policy on Lead in Consumer Products. 16 C.F.R. 1500.230. This policy highlights certain obligations for the

affected regulated industries under the FHSA, identifies the major factors that the Commission considers when evaluating products that contain lead, and informs the public of its experience with products that have exposed children to potentially hazardous amounts of lead.

CPSC explicitly addressed children's jewelry in the "Interim Enforcement Policy for Children's Metal Jewelry Containing Lead," dated February 3, 2005 (Interim Enforcement Policy). This policy outlines the specific methodology for testing products and describes the process for determining if products may be hazardous substances and subject to enforcement action. Both lead content and accessibility of lead that is present in a product are considered, but the policy states that firms will not be subject to CPSC enforcement action if the total lead content of each component of metal jewelry is below 0.06 percent lead.

Voluntary Standards

The staff did not locate any applicable voluntary standards that address the use of lead in metal jewelry.

Actions by Other Entities

California

In January 2006, the Attorney General of California announced a settlement with 71 retailers and distributors to reduce the levels of lead in costume jewelry under Proposition 65, California's right-to-know law[1]. This settlement was followed by legislation signed into law September 22, 2006[2]. The legislation contains a number of provisions, separated by the type of material used in the product or components, and by whether the product is for children aged six years and younger. The compliance date is September 1, 2007, but certain restrictions are phased in for compliance by August 31, 2009. The law provides that children's products must contain less than 0.06 percent lead in certain metallic components, and certain other materials are limited to less than 0.02 percent lead. Lead content in rubber or plastic is limited to less than 0.06 percent by September 1, 2007 and 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.

Illinois

In 2006, the State of Illinois enacted Public Act 094-0879[3], 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." The 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." The Act covers children aged six years and younger.

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[1] State of California, January 27, 2006 (Available at http://ag.ca.gov/newsalerts/release.php?id=1258).

[2] State of California, September 22, 2006 (Available at http://www.leginfo.ca.gov/pub/bill/asm/ab_1651-1700/ab_1681_bill_20060922_chaptered.pdf).

[3] State of Illinois, June 6, 2006 (Available at http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=094-0879).

Canada

Canada established regulations concerning lead in children's jewelry, "The Children's Jewellery Regulations," effective May 10, 2005[4], published in *Canada Gazette* Part II on June 1, 2005. The regulations established 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."

Laboratory Analysis (Tab B)

Since 1996, CPSC's Directorate for Laboratory Sciences (LS), Division of Chemistry (LSC) staff has analyzed 466 items from 158 samples[5] of children's metal jewelry for lead content and for lead accessibility by one or more methods that provide information about possible exposures to lead during use of the product. These methods and the results of testing are detailed in Tab B. In particular, the staff used a method involving extraction with an acid solution to simulate the effect of stomach acid on an item to assess potential exposures to lead if a child swallows a piece of jewelry. Inspection of the data shows that lead was present in many of the samples. In fact, 57 percent of the 158 samples tested included items with greater than the 0.06 percent lead content specified in the petition. Further, the data show that ingestion of many of the lead-containing pieces could result in exposure to the lead. CPSC's Health Sciences (HS) staff analysis of the data collected on metal jewelry through early 2005 was used in establishing the Interim Enforcement Policy.

Recently, the LSC staff conducted additional acid extraction studies to evaluate whether changing the extraction conditions by extending the amount of time the jewelry item remains in contact with the acid solution changes the amount of lead accessibility. Staff selected a sample of eight items that contained greater than 45 percent lead; extraction times ranged from six hours to one week (168 hours). The data show that increasing the length of the acid extraction period results in increasing accessibility of the lead. All eight samples showed minimal extraction of lead at six hours, but lead extraction was notably greater at 24 hours and increased throughout the one-week extraction period. The staff notes that these are preliminary data and that additional studies are needed to fully characterize the effect of changing the exposure methodology, and to evaluate the relevance of the results to the exposure assessment part of the human health assessment. However, this information may suggest that lead accessibility may be dependent on certain conditions of exposure.

Toxicity and Hazard (Tab C)

CPSC's Health Sciences staff reviewed the toxicology of lead and assessed the risk of excess lead exposures in children who use metal jewelry. This information is discussed below and detailed at Tab C.

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[4] *Canada Gazette* Part II, June 1, 2005 (Available at http://canadagazette.gc.ca./partII/2005/20050601/pdf/g2-13911.pdf).

[5] Some samples contained more than one tested item (*e.g.*, multiple beads, pendant, clasp). The staff notes that the samples do not represent a random sampling of products available in the United States, but were obtained either through convenience sampling or for official activities by the CPSC Office of Compliance.

Lead exposures are assessed by measuring the amount of lead in whole blood (blood lead level, or BLL). In general, lead toxicity exhibits a dose-response relationship; as BLLs increase, the frequency and severity of symptoms increase. The nervous system is the primary target for lead toxicity, especially in children; outcomes include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. At lower levels of exposure, the effects of lead may be subtle. At relatively high exposures, children may suffer severe abdominal pain, vomiting, anemia, fatigue, behavioral changes, and encephalopathy, which can result in death. However, not all children with elevated BLLs (even quite high levels) have signs of exposure. Thus, lead exposures may go undetected.

The scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood (μg/dL) as a level of concern with respect to lead poisoning. 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 BLLs and in the number of children with BLLs exceeding 10 μg/dL. Data from a recent national survey[6] 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 have been documented.

Although the staff is not aware of any systematic study of children's exposure to lead-containing jewelry, the staff knows of at least three cases in which ingestion of a lead-containing jewelry item was associated with health effects. A 4-year-old Oregon boy had a BLL of 123 μg/dL approximately 3 to 4 weeks after swallowing a pendant, which the state laboratory found to contain 38.8 percent lead[7]. A 4-year-old Minnesota boy died with a BLL of 180 μg/dL after ingesting a bracelet charm[8], which the state public health department laboratory determined to contain 99.1 percent lead[9]. A 9-year-old boy's BLLs rose to 27 μg/dL four days after he swallowed a ring. Three days later his BLLs rose to 54 μg/dL, at which time endoscopy was performed to remove the ring. A representative from the company stated that the ring contained 90 percent lead (CPSC files).

As discussed above, CPSC staff released the "Interim Enforcement Policy for Children's Metal Jewelry Containing Lead" on February 3, 2005. The Interim Enforcement Policy outlines firms' obligations under the Federal Hazardous Substances Act, provides detailed information about the potential hazards of lead-containing children's metal jewelry, and provides specific methods that may be used in assessing metal jewelry products for the presence of lead hazards.

In establishing the approach described in the Interim Enforcement Policy, staff considered likely scenarios that could result in lead exposure from children's metal jewelry, as well as the toxicity of lead, and physiological and behavioral aspects of potential exposures.

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[6] CDC (Centers for Disease Control and Prevention). 2005. Blood Lead Levels – United States, 1999-2002. MMWR 54(20): 513-516.

[7] VanArsdale JL, Leiker RD, Kohn M, Merritt TA, Horowitz BZ. 2004. Lead poisoning from a toy necklace. Pediatrics 114(4): 1096-1099.

[8] The length of exposure in this case is unknown.

[9] CDC (Centers for Disease Control and Prevention). 2006. Death of a child after ingestion of a metallic charm – Minnesota, 2006. MMWR 55(Dispatch): 1-2.

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), resulting in chronic exposures, or that occur all at once (*e.g.*, swallowing an entire object), resulting in an acute exposure. Extensive test data developed by the staff indicate that the amount of lead that would be absorbed after ingesting an item is much greater than the amount of lead that would be absorbed by mouthing or handling the same piece. Further, if a jewelry item contains a high enough amount of accessible lead, then 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 smaller amounts of lead.

The staff focused on protecting children from hazardous lead exposures from swallowing lead-containing metal jewelry. To avoid exceeding the 10 µg/dL level of concern from acute exposure, the staff recommended that children not ingest more than 175 µg of accessible lead in a short period, such as from ingesting a piece of jewelry. This value is based on calculating the effect of the ingested lead on the BLL, taking into account a child's body weight and blood volume, and the bioavailability of lead. The specific factors and assumptions used by the staff in its calculations are discussed in detail at Tab C.

Testing by CPSC staff indicates that the extractability of lead from children's metal jewelry (using an acid solution to simulate stomach conditions) is strongly associated with the lead content of items. Based on the available test data, staff determined that there was a lower likelihood of ingesting hazardous levels of accessible lead if a children's metal jewelry item had a total lead content of 0.06 percent or less. Therefore, the Interim Enforcement Policy states that 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 0.06 percent, or that accessible lead is no more than 175 µg.

As discussed above, preliminary data from staff testing show that increasing the length of the acid extraction period results in increasing accessibility of the lead. The staff notes that additional studies are needed to determine the relevance of these laboratory findings to the assessment of potential lead exposures after ingestion of lead-containing metal jewelry items. Nonetheless, these preliminary data suggest that in order to reduce the potential for hazardous lead exposures, the lead content of the jewelry items should be reduced to 0.06 percent or below, as specified in the Interim Enforcement Policy.

Injury Data Analysis (Tab D)

CPSC's Hazard Analysis staff analyzed data from the National Electronic Injury Surveillance System (NEISS) database on emergency-room treated injuries associated with ingestion of consumer products by children. This information is discussed below and detailed at Tab D. The staff searched the data for cases involving ingestion of foreign objects by children aged 18 years and younger and, because NEISS is a probability sample, established national estimates for ingestions by age group and product type. For 2000-2005, the staff estimated 302,587 emergency-room treated injuries, nearly 80 percent of which were children under age seven years. The remaining 20 percent of the estimated injuries were reported in youths aged seven to 18 years. The objects most commonly swallowed were coins, accounting for nearly half of ingestions, followed by jewelry; toys not elsewhere classified; and nails, screws, tacks or

bolts. Other major product categories included batteries; marbles; and non-electric Christmas decorations. Just considering cases involving jewelry, the staff estimated nearly 20,000 total emergency-room treated ingestions, about 62 percent of which were in children under age seven years, with the remaining 38 percent in children aged seven to 18 years. Product details and characteristics such as whether the jewelry item would be considered children's jewelry, whether it had been manufactured using metal, or whether it contained lead cannot be determined from this database.

Human Factors Analysis (Tab E)

The CPSC's Human Factors staff analyzed the factors that distinguish children's jewelry from jewelry products intended for adults. The staff also considered the behaviors that could result in exposure to lead. This information is discussed below and detailed at Tab E.

The age appropriateness for toys and other juvenile products focuses on determining the age of children that would find an item appealing. Characteristics of jewelry products, such as ease of use and appearance, and other factors, such as product labeling, advertising, and marketing, are considered. For example, a one-piece or stretchy bracelet, or a piece made with bright colors or images of cartoon characters may be intended (but not necessarily) for young children. Sometimes, other items packaged with jewelry influence the age determination, and a jewelry item could receive an age determination that is different than what it would have received if it were sold alone (*e.g.*, jewelry packaged with toys). The staff concludes that the presence of features that would be attractive to children would result in an age determination of less than nine years, perhaps as low as 18 months, and that in their pre-teen years—about nine to 12 years old—children begin to choose adult-like jewelry.

The staff also discussed common behaviors of children by age, focusing on mouthing behaviors that could result in ingestion of a lead-containing item and subsequent exposure to lead. A number of studies by CPSC staff and others indicate that children of all ages engage in various levels of mouthing behavior involving non-food items. The data show that the youngest children spend the most time mouthing objects, but that some level of mouthing behavior continues throughout childhood. Studies specifically relating to ingestion of objects, including jewelry items, were not located. However, the staff concludes that the time spent mouthing objects would increase the likelihood of ingestion, and cases of jewelry ingestion by children have been reported (see Toxicity and Hazard section above).

The petitioner indicated that "toy" jewelry should be defined as decorative items with a value less than $20, since people would be less likely to keep such items away from children. The staff believes that "cheap" and "expensive" are relative terms. Further, cost is usually only a small part of the considerations of age determination.

Economic Information (Tab F)

CPSC's Economic Analysis staff evaluated available information on the products and industries related to children's jewelry. This information is discussed below and detailed at Tab F.

The staff prepared preliminary market information that describes the products and industries that may be affected by regulation of children's jewelry. The staff has not located information specific to "children's" or "toy" jewelry, but some data on certain classifications of

jewelry and toy manufacturers could be informative. 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 75 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 indicate that nearly 3,000 establishments produce jewelry items in the U.S. Most of these are relatively small; 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 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, the staff also considered the data on toys. While no category specifically deals with toy jewelry, the 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, the 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 the staff to analyze the specific impact of any potential regulation of lead in children's jewelry. Further, while the 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 not be quantifiable. Therefore, the staff would recommend requesting detailed data from the public that could be used to evaluate the costs and benefits of a potential rule if the Commission grants the petition and directs the staff to proceed with rulemaking.

Public Comments (Tabs G and H)

CPSC received fifteen comments in response to the Federal Register notice published June 20, 2006 (71 FR 35416). Comments were provided by six governmental entities, State of New York (CH 06-3-1), City of New York Department of Health and Mental Hygiene (CH 06-3-9), City of Chicago Department of Public Health Childhood Lead Poisoning Prevention Program (CH 06-3-7), Baltimore City Health Department Division of Environmental Health (CH 06-3-10), State of Illinois (CH 06-3-12), and the Centers for Disease Control and Prevention (CH 06-3-15); five organizations, American Academy of Pediatrics (CH 06-3-3), Kids in Danger (CH 06-3-4), the LEAD Group (Australia) (CH 06-3-6), Consumers Union (CH 06-3-11), and Coalition to End Childhood Lead Poisoning (CH 06-3-13); two individuals, Joseph Ponessa, Ph.D. (CH 06-3-5), and Warren Porter (CH 06-3-14); and from industry representatives, the Fashion Jewelry Trade Association (CH 06-3-2), and the Coalition for Safe Ceramicware jointly with the International Crystal Federation (CH 06-3-8). The index of public comments is in

Tab G. The comments and the staff's responses to the comments are summarized below and detailed at Tab H.

Most of the commenters supported the petitioner's requests, although several commenters would expand its scope. The two comments from the trade associations did not entirely support the petition, but they did not directly oppose it. While these two commenters both agreed that children should not be exposed to lead from children's products, they disagreed with the petitioner about the types of products that should be considered under a potential rule.

Comment: Interim Enforcement Policy.

Two commenters (CH 06-3-9; CH 06-3-11) perceive the CPSC Interim Enforcement Policy for Children's Metal Jewelry Containing Lead as voluntary guidance. Several commenters questioned the effectiveness of the policy and pointed to the occurrence of recalls as evidence that the policy does not work (CH 06-3-1; CH 06-3-2; CH 06-3-3; CH 06-3-4; CH 06-3-10; CH 06-3-14).

CPSC Staff Response: The Interim Enforcement Policy provides firms information about regulation of products under the Federal Hazardous Substances Act and states the approach that CPSC's Office of Compliance will follow in addressing children's metal jewelry containing lead. It provides detailed information about the potential hazards of lead-containing children's metal jewelry, and provides specific methods that manufacturers, importers, distributors and retailers may use in assessing products for the presence of lead hazards. The staff does not consider the occurrence of recalls as evidence that the policy does not work. Most of the recent recalls were of products that entered the market before the Interim Enforcement Policy was put in place, and the staff believes that the recall process is an important mechanism for removing hazardous products from the market. The staff believes that the Interim Enforcement Policy provides information that could help prevent hazardous products from being introduced to the market.

Comment: Testing requirements.

One commenter (CH 06-3-1) stated that testing for lead in products should be required before products can be sold.

CPSC Staff Response: Product test requirements are among the options that could be considered by the Commission if it grants the petition and directs the staff to proceed with rulemaking.

Comment: California's standard.

One commenter (CH 06-3-2) stated that CPSC should adopt the California lead standards for costume and children's jewelry, and opposed the CPSC staff's analytical method for determining accessibility of lead using a leaching test.

CPSC Staff Response: Federal regulations must be based on the applicable statutes administered by the Commission, *e.g.*, the Federal Hazardous Substances Act. A federal standard would generally preempt non-identical state and local requirements. The staff's testing methods are based on relevant published standards, and are designed to simulate exposure to lead from products that occurs during foreseeable use of the products, including ingestion by children.

Comment: Types of products.

The petitioner's request focused on "any toy jewelry containing more than 0.06% lead by weight for which there is a reasonably foreseeable possibility that children could ingest," with a value of less than $20 per item. Nearly all of the commenters agreed with the 0.06 percent lead limit; some (CH 06-3-3; CH 06-3-6; CH 06-3-13) thought that 0.06 percent should be considered an interim limit. One commenter (CH 06-3-8) argued that accessibility of the lead, rather than lead content, is appropriate for regulation. Two commenters (CH 06-3-2; CH 06-3-8) suggested that products for children aged six years and under should be regulated, and that certain materials (*e.g.*, glass, crystal, ceramic) should not be included in regulations of children's jewelry. One of these commenters (CH 06-3-8) did not agree that the $20 limit is an appropriate way to define children's products. Several commenters stated that a regulation should not be restricted to just ingestible children's jewelry products (CH 06-3-4; CH 06-3-5; CH 06-3-9; CH 06-3-11; CH 06-3-12; CH 06-3-14).

CPSC Staff Response: The staff agrees that there are several factors concerning the characteristics and types of products that could be considered in regulating children's jewelry if the Commission grants the petition and directs the staff to proceed with rulemaking. Such factors include lead content or lead accessibility, materials used in the product, price of the product, and age of the intended user.

Comment: Hazards of lead exposure.

Five commenters (CH 06-3-1; CH 06-3-3; CH 06-3-9; CH 06-3-10; CH 06-3-12) questioned the staff's determination that a blood lead level in a child of 10 micrograms of lead per deciliter of blood (10 μg/dL) should be used as the level of concern with respect to lead poisoning from consumer products.

CPSC Staff Response: The staff believes that our approach to assessing the hazards of lead exposure from children's jewelry is appropriate under the Federal Hazardous Substances Act (FHSA) requirements, given the currently available information. The staff considered factors such as the acute exposure expected from children's use of metal jewelry, information from scientific literature, and information from the Centers for Disease Control and Prevention (CDC) concerning the adverse effects of lead at different exposure levels. The 10 μg/dL level of concern was established by the CDC in 1991[10] and is still the level cited by the CDC in its most recent statement[11] on childhood lead poisoning.

Options

The following options are available to the Commission:

Grant the Petition

If the Commission concludes that it is appropriate, the Commission could grant the petition and begin a rulemaking proceeding to ban children's jewelry containing hazardous amounts of accessible lead.

[10] Centers for Disease Control (CDC). 1991. Preventing Lead Poisoning in Young Children.

[11] Centers for Disease Control and Prevention (CDC). 2005. Preventing Lead Poisoning in Young Children.

Deny the Petition

If the Commission concludes that information is not available or likely to be developed to support the findings required by section 2(q)(1)(B) and 3(i)2 of the FHSA to ban children's jewelry containing lead, the Commission could vote to deny the petition.

Defer Decision on the Petition

If the Commission determines that there is insufficient information to make a decision on the petition and that the staff could obtain such information, the Commission could defer the decision and direct the staff to obtain the additional information.

Conclusions and Recommendation

In considering Petition HP 06-1, Request to Ban Lead in Toy Jewelry, the staff assessed the currently available information on the toxicity of lead, children's behaviors, data on children's metal jewelry, and related economic information. In addition, the staff did not find any applicable voluntary standards that address the use of lead in children's metal jewelry. Given the information discussed above, and summarized below, the staff recommends that the Commission grant the petition and begin rulemaking that could result in declaring children's jewelry containing more than 0.06 percent lead by weight in metal components to be a hazardous substance.

Testing by the CPSC staff indicates that the extractability of lead from children's metal jewelry is strongly associated with the lead content of items. The staff believes that the data show that excess lead exposure from ingestion of metal jewelry is likely for items that contain more than 0.06 percent lead, and that the amount of exposure likely increases with increasing lead content in the item. The staff used this information to develop the provisions of the Interim Enforcement Policy for Children's Metal Jewelry Containing Lead. Further consideration of the data suggests that establishing a limit on the lead content of children's metal jewelry could be a more effective way to prevent excess lead exposure in children. In addition, the staff believes that testing for lead content in products is simpler and more straightforward than assessing extractability as described in the Interim Enforcement Policy. Therefore, the staff believes that a limit on the lead content in children's metal jewelry may have advantages over the current Interim Enforcement Policy. Evaluating the effectiveness of the Interim Enforcement Policy, and modifying the Interim Enforcement Policy, as necessary, might be an additional option to consider.

Based on the potential for exposure to lead from lead-containing metal jewelry and the known hazards of lead exposure from ingestion of lead-containing metal jewelry, as demonstrated by the cases discussed above, the staff concludes that children who swallow lead-containing metal jewelry could experience excess lead exposure that could result in substantial illness. The staff is focusing on metal jewelry at this time because the available data indicate that such products could be hazardous due to their lead content and potential for exposure. The staff does not have information concerning potential lead hazards of other non-metal materials that may be used in jewelry, but could assess additional types of products at such time as data become available.

TAB A

HP 06-1

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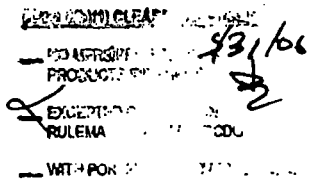

April 17, 2006

Steve Johnson, Administrator
Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Hal Stratton, Commissioner
U.S. Consumer Products Safety Commission
4330 East West Highway
Bethesda, MD 20814

Re: Citizen Petition to CPSC and EPA Regarding Lead in Consumer Products, Especially Toy Jewelry

Dear Commissioner Stratton and Administrator Johnson:

Enough is enough! In February of 2006, a Minnesota child died from lead poisoning after swallowing toy jewelry offered as a "bonus" to buyers of Reebok shoes.[1] This child's death follows a July 8, 2004 voluntary recall of 150 million metal toy jewelry items by four major importers pursuant to an agreement with the Consumer Products Safety Commission.[2] It also follows a severe case of lead poisoning from a toy necklace in that occurred in 2003. Both of these poisonings resulted from products that were distributed in violation of the CPSC's

[1] U.S. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Dispatch, March 23, 2006 / 55(Dispatch);1-2

[2] U.S. Consumer Products Safety Commission, News from CPSC, "*CPSC Announces Recall of Metal Toy Jewelry Sold in Vending Machines: Firms agree to stop importation until hazard is eliminated*", originally issued July 8, 2004 and revised on March 1, 2006. See www.cpsc.gov/CPSCPUB/PREREL/prhtml04/04174.html.

December 22 1998 Codification of Guidance Policy on Lead in Consumer Products.[3] These are not isolated incidents.[4]

The federal government has set a goal of eliminating childhood lead poisoning by 2010. Realizing that goal seems even more distant when we learn of a child dying of lead poisoning and ineffectual efforts by our federal government to prevent the child's death. For poor children and children of color, the implications are even more serious since they are likely to be exposed to dangerous levels of lead. These exposures continue to contribute to the health disparities that characterize lead poisoning.[5] They represent an environmental injustice that must be resolved.

Environmental justice demands that all people live free of the dangers posed by lead. By threatening the health and survival of our children, lead exposure threatens our future generations. We have a responsibility to our future generations to be especially protective of their health and well being.

The current system is not working. CPSC has not fulfilled its responsibilities to the public. EPA and CPSC must take stronger action regarding lead in jewelry and other products which may be ingested by children. The Sierra Club believes that lead in unacceptable in products that children use. There has to be a better way!

Petition to U.S. Consumer Product Safety Commission:
In this letter, the Sierra Club petitions the Consumer Products Safety Commission pursuant to 5 U.S.C. § 553(e)[6] to issue regulations to ban lead in all toy jewelry using its authorities under the Federal Hazardous Substances Act.[7] Specifically, the Sierra Club asks the CPSC act with utmost speed to:

1. **Classify Toy Jewelry Containing Lead as Banned Hazardous Substance**
   Adopt regulations declaring that any toy jewelry containing more than 0.06% lead by weight for which there is a reasonably foreseeable possibility that children could ingest be declared a banned hazardous substance pursuant to Section 2(q)(1)(B)[8] and Section 3.

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[3] U.S. Consumer Products Safety Commission, "Codification of Guidance Policy on Lead in Consumer Products." December 22, 1998 *Federal Register*, Vol. 63, No. 245, pp. 70648-70649.
[4] U.S. Consumer Products Safety Commission, List of Recalled Toys, www.cpsc.gov/cpscpub/prerel/category/toy.html and List of Recalled Infant/Child Products (not including toys), www.cpsc.gov/cpscpub/prerel/category/child.html.
[5] U.S. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Dispatch, March 23, 2006 / 55(Dispatch);1-2.
[6] 5 U.S.C. § 553(e) (2006). "Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."
[7] Federal Hazardous Substance Act, P.L. 86-613, 74 Stat. 372 (1960), codified at 15 U.S.C. 1261-1278,
[8] Federal Hazardous Substance Act Section 2(q)(1)(B) (2006). It states that "any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Secretary by regulation classifies as a "banned hazardous substance" on the basis of a finding 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 of such 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."

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CPSC should begin by immediately issuing an advanced notice of proposed rulemaking pursuant to Section 3(f).[9]

The Sierra Club recommends 0.06% as an interim step because that cutoff has already been established as the concentration cutoff for paint on consumer products.[10] Like jewelry, paint is not intended to be ingested, but children do it anyway. The Sierra Club does not believe that 0.06% of lead by weight in jewelry is low enough to protect children and recommends that EPA undertake other actions in cooperation with CPSC to determine a more appropriate cutoff in a different action described below.

The Sierra Club believes that toy jewelry is any item that serves a decorative but no or minimal functional purpose that is valued at less than $20 per item. People are less likely to store such low-cost jewelry in secure containers or out of reach from children.

2. **Revise Guidance to Reflect Latest Science**
CPSC must revise its December 22, 1998 Codification of Guidance Policy on Lead in Consumer Products[11] to reflect the latest science regarding lead poisoning. In the guidance, CPSC states 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

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[9] Federal Hazardous Substance Act Section 3(f) (2006). It states that "A proceeding for the promulgation of a regulation under section 2(q)(1) classifying an article or substance as a banned hazardous substance or a regulation under subsection (e) of this section shall be commenced by the publication in the Federal Register of an advance notice of proposed rulemaking which shall—

(1) identify the article or substance and the nature of the risk of injury associated with the article or substance;
(2) include a summary of each of the regulatory alternatives under consideration by the Commission (including voluntary standards);
(3) include information with respect to any existing standard known to the Commission which may be relevant to the proceedings, together with a summary of the reasons why the Commission believes preliminarily that such standard does not eliminate or adequately reduce the risk of injury identified in paragraph (1);
(4) invite interested persons to submit to the Commission, within such period as the Commission shall specify in the notice (which period shall not be less than 30 days or more than 60 days after the date of publication of the notice), 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;
(5) invite any person (other than the Commission) to submit to the Commission, within such period as the Commission shall specify in the notice (which period shall not be less than 30 days after the date of publication of the notice), an existing standard or a portion of a standard as a proposed regulation under section 2(q)(1) or subsection (e) of this section; and
(6) invite any person (other than the Commission) to submit to the Commission, within such period as the Commission shall specify in the notice (which period shall not be less than 30 days after the date of publication of the notice), a statement of intention to modify or develop a voluntary standard to address the risk of injury identified in paragraph (1) together with a description of a plan to modify or develop the standard.

[10] 15 U.S.C. § 2681(9), (Toxic Substances Control Act Section 401(9)) (2006). It states the "term ``lead-based paint'' means paint or other surface coatings that contain lead in excess of 1.0 milligrams per centimeter squared or 0.5 percent by weight or (A) in the case of paint or other surface coatings on target housing, such lower level as may be established by the Secretary of Housing and Urban Development, as defined in section 4822(c) of title 42, or (B) in the case of any other paint or surface coatings, such other level as may be established by the Administrator.

[11] U.S. Consumer Products Safety Commission, "Codification of Guidance Policy on Lead in Consumer Products." December 22, 1998 *Federal Register,* Vol. 63, No. 245, pp. 70648-70649.

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lead poisoning. To avoid exceeding that level, young children should not chronically ingest more than 15 micrograms of lead per day from consumer products."[12]

These statements contradict conclusions by the U.S. Centers for Disease Control and Prevention in its August 2005 "Preventing Lead Poisoning in Young Children: A Statement by the Centers for Disease Control and Prevention."[13] CDC states that:

> "In 1991 the CDC recommended lowering the level for individual intervention to 15 µg/dL and implementing communitywide primary lead poisoning prevention activities in areas where many children have BLLs >10 µg/dL. Some activities, such as taking an environmental history, educating parents about lead, and conducting follow-up blood lead monitoring were suggested for children with BLLs of >10 µg/dL. However, this level, which was originally intended to trigger communitywide prevention activities, has been misinterpreted frequently as a definitive toxicologic threshold."
>
> "As the accompanying review of recent studies indicates, additional evidence exits of adverse health effects in children at BLLs <10 µg/dL. The available data are based on a sample of fewer than 200 children whose BLLs were never above 10 µg/dL and questions remain about the size of the effect."[14]

It is clear that CDC never intended for CPSC to use the 10 µg/dL as a level that must not be exceeded. Rather it serves as a trigger for investigation by the community to determine the cause of serious problem. CDC makes it clear that there is no safe level of exposure for children to lead. While Sierra Club believes the evidence for serious adverse health effects at levels less than 10 µg/dL is more compelling than CDC suggests, CDC's doubts about the size of the effect do not justify ignoring these adverse health effects.

3. **Convert Voluntary Guidance into Enforceable Regulations**
After making the revisions called for above, CPSC must convert its December 22, 1998 Codification of Guidance Policy on Lead in Consumer Products from voluntary guidance into enforceable requirements. Clearly the voluntary guidance was insufficient. With enforceable regulations in place, CPSC can more effectively prevent mistakes from happening and more quickly react when they do occur.

[12] Id at 70649.
[13] U.S.CDC, "Lead Levels – United States, 1999-2002", Vol 52 / No. 20, pp 513 to 516.
[14] Id at page 2.

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Petition to U.S. Environmental Protection Agency:
In this letter, the Sierra Club also petitions the U.S. Environmental Protection Agency pursuant to Section 21 of the Toxic Substances Control Act ("TSCA")[15] to take action in coordination with CPSC to protect children from lead in toy jewelry. Specifically, the Sierra Club asks that EPA adopt regulations as follows:

1. **Require TSCA Section 8(d) Health and Safety Data Reporting for Lead and Lead Salts**

In CPSC's December 22, 1998 Codification of Guidance Policy on Lead in Consumer Products, CPSC stated that "to avoid the possibility of a Commission enforcement action, a manufacturer who believes it necessary to use lead in a consumer product should perform the requisite analysis before distribution to determine whether the exposure to lead causes the product to be a ''hazardous substance.'' If the product is a hazardous substance and is also a children's product, it is banned. If it is a hazardous household substance but is not intended for use by children, it requires precautionary labeling. This same type of analysis also should be performed on materials substituted for lead."[16]

CPSC identified the following factors as critical to determining whether a potential hazard exists and whether the product may be a banned hazardous substance:

a. The total amount of lead contained in a product;
b. The bioavailability of the lead;
c. The accessibility of the lead to children;
d. The age and foreseeable behavior of the children exposed to the product;
e. The foreseeable duration of the exposure; and
f. The marketing, patterns of use, and life cycle of the product.

Assuming product manufacturers and importers having taken heed of CPSC's guidance – guidance which deals with lead in all consumer products not just toy jewelry – then EPA needs to use its authority under TSCA §8(d),[17] to obtain information on the six items listed above to enable EPA and CPSC to take more effective action to protect children from lead in consumer products.

EPA must at utmost speed require producers, importers, and processors of lead and its salts that are reasonably likely to be incorporated into consumer products to provide EPA with lists and/or copies of ongoing and completed unpublished health and safety studies related to the six factors identified by CPSC. The health and safety studies include:

a. Epidemiological or clinical studies;
b. Studies of occupational exposure;
c. Health effects studies;

[15] 15 U.S.C.§ 2620 (Toxic Substance Control Act, Section 21) (2006). It states that (a) "Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 2603, 2605, or 2607 of this title or an order under section 2604(e) or 2605(b)(2) of this title.
[16] U.S.CPSC Codification of Guidance Policy on Lead in Consumer Products at page 70649.
[17] 15 U.S.C. § 2607(d) (Toxic Substance Control Act, Section 8(d)) (2006).

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d. Ecological effects studies; and
e. Environmental fate studies (including relevant physicochemical properties).

2. **Submit TSCA Section 9 Report to CPSC Regarding Lead and Lead Salts**
EPA has undertaken several significant rulemaking efforts in the past few months designed to prevent lead poisoning. On January 10, 2006, it proposed a rule to regulate renovation, repair and paint activities in target housing.[18] On December 2, 2005, it sought comments on two volumes of its Air Quality Criteria Document for Lead.[19]

With the wealth of information from these rulemaking efforts as well as the recalls and reports on lead in toy jewelry, EPA needs to exercise its authority under TSCA Section 9.[20] EPA must report to the CPSC that it has a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of lead destined to be used in toy jewelry presents or will present an unreasonable risk of injury to health or the environment and that EPA determines that such risk may be prevented or reduced to a sufficient extent by action taken under the Federal Hazardous Substance Act. This report must be published in the Federal Register. It must describe the risk posed by lead to children and include a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk.

The report shall also request that CPSC:
(A)(i) determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and
(ii) if CPSC determines that such risk may be so prevented or reduced, issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and
(B) respond to EPA with respect to the matters described in subparagraph (A).

Pursuant to TSCA Section 9(a)(2),[21] if CPSC does not respond within 90 days or its response is inadequate, EPA should proceed to use its authorities under Section 6 and adopt regulations declaring that manufacturers and importers may not add lead in excess of 0.06% lead by weight to any toy jewelry for which there is a reasonably foreseeable possibility that children could ingest is prohibited from manufacture or importation.

[18] U.S. EPA Proposed Renovation, Repair and Painting Rule, 71 Fed. Reg. 1588 (2006) (to be codified at 40 C.F.R. Part 745) (proposed January 10, 2006).
[19] U.S. EPA Air Quality Criteria Document for Lead, 70 Fed. Reg. 231 (December 2, 2005) pages 72300-72301.
[20] 15 U.S.C.§ 2608 (Toxic Substance Control Act, Section 9) (2006)
[21] Id at Section 9(a)(2)(2006)

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3. **Issue Significant New Use Notification Regarding Lead and Lead Salts in Toy Jewelry**
On July 8, 2004, CPSC reached an agreement with four toy jewelry importers to eliminate lead in jewelry.[22] Apparently, these companies manufacture or import the vast majority of the toy jewelry. EPA must adopt a Significant New Use Notification Rule pursuant to TSCA Section 5 requiring any business from manufacturing or importing toy jewelry containing lead at levels greater than 0.06% by weight to provide advance notice of its action.[23] While this action would not prevent the importation of manufacture of lead-containing toy jewelry, it would allow EPA to be aware of the pending action and take appropriate action.

4. **Issue Section 6(b) Quality Control Order Regarding Production of Toy Jewelry**
EPA should work with CPSC to identify the manufacturer or processor that produces any toy jewelry with more than 0.06% lead by weight. If EPA identifies any manufacturer or processor that it has jurisdiction over using its TSCA authorities, it should immediately issue Section 6(b) quality control orders.[24] In this order, EPA should require the manufacturer or processor to modify its quality control procedures to the extent necessary to remedy the inadequacy.

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[22] U.S. Consumer Products Safety Commission, News from CPSC, "*CPSC Announces Recall of Metal Toy Jewelry Sold in Vending Machines: Firms agree to stop importation until hazard is eliminated*", originally issued July 8, 2004 and revised on March 1, 2006. See www.cpsc.gov/CPSCPUB/PREREL/prhtml04/04174.html.
[23] 15 U.S.C.§ 2604 (Toxic Substance Control Act, Section 5) (2006)
[24] 15 U.S.C.§ 2605(b) (Toxic Substance Control Act, Section 6(b)) (2006)

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Conclusion
The Sierra Club requests that CPSC and EPA act in the manner described above to protect children from lead poisoning by consumer products. The current system is not working. EPA and CPSC must take stronger action regarding lead in jewelry and other products which may be ingested by children.

There has to be a better way.

The Sierra Club looks forward to EPA's response to this petition within 90 days, as required by TSCA, 15 U.S.C. § 2620(b)(3).[25]

Sincerely,

Ed Hopkins
Director, Environmental Quality Program

[25] 15 U.S.C.§ 2620(b)(3) (Toxic Substance Control Act, Section 21(b)(3)) (2006)

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TAB B

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: November 29, 2006

TO : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

THROUGH: Andrew G. Stadnik, P.E., Associate Executive Director, Directorate for Laboratory Sciences

Joel R. Recht, Ph.D., Director, Division of Chemistry, Directorate for Laboratory Sciences

FROM : David Cobb, Chemist, Division of Chemistry, Directorate for Laboratory Sciences

SUBJECT : Summary of Test Results for Lead in Children's Metal Jewelry[1]

Summary:

This memorandum provides a summary of the test methods and results of U.S Consumer Product Safety Commission (CPSC) staff testing for lead (Pb) in children's metal jewelry. The CPSC Directorate for Laboratory Sciences (LS), Division of Chemistry (LSC) staff has analyzed 466 children's metal jewelry items from 156 official compliance samples since 1996. There were 269 items tested that had total lead of 0.06% or more.

Background:

Under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261(f)(1), children's products, including children's metal jewelry, that expose children to hazardous quantities of lead under reasonably foreseeable conditions of handling or use are banned hazardous substances. Since 1996, CPSC staff has collected and analyzed 466 items (which came from 156 samples) of metal jewelry.

In 2005, CPSC's Office of Compliance issued an Interim Enforcement Policy for Children's Metal Jewelry Containing Lead for manufacturers, importers, and retailers.[2] The policy was accompanied by a two part testing procedure.[3] The procedure calls for

[1]These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.
[2]Interim Enforcement Policy for Children's Metal Jewelry Containing Lead - 2/3/2005.
[3]CPSC Standard Operating Procedure for Determining Lead (Pb) and Its Availability in Children's Metal Jewelry 2/3/05, http://www.cpsc.gov/businfo/pbjeweltest.pdf.

the determination of the total lead content of a metal jewelry item by a specified method. Distinct metal component items within a jewelry sample, such as pendants, hooks, or beads (as shown in Figure 1) are tested separately for total and accessible lead. If the total lead in a metal jewelry item is more than 0.06%, then an acid extraction for 6 hours is conducted by a second specified method. Metal jewelry with more than 175 µg of accessible lead by this method is subject to further review for age grading and other risk factors. A risk assessment may result in enforcement action. Non-metal jewelry is not addressed in the Interim Enforcement Policy, but is also subject to the FHSA.

Test Method Development:

Total Lead

The test procedure for total lead determination used on samples analyzed from 1996 to December 2004 was based on the methodology found in Association of Official Analytical Chemists (AOAC) 974.02 procedure for lead in paint. In late 2004, LSC staff determined that the digestion method, which works well for paint, did not completely dissolve some metal alloys found in some jewelry samples, and a modified digestion procedure was developed.

In the AOAC procedure, used from 1996 to December 2004, an aliquot of the jewelry item weighing 20-100 mg was accurately weighed in a tared test tube. Two ml of concentrated nitric acid were added to the test tube, and the test tube heated at reflux for 6 hours. After cooling, the digested sample was diluted to 10 ml with deionized water and analyzed for lead using an inductively coupled plasma atomic emission spectrometer (ICP).

The current test method[3] for total lead is based on methodology found in Canada Product Safety Bureau Method C-02.4[4], and has been used for samples analyzed since December 2004. This method requires that the aliquots be ground into small particles to increase the rate of dissolution, and the procedure also contains a step for adding hydrochloric acid to assist in dissolving certain metal alloys.

Accessible Lead

From 1996 to December 2004, three test procedures were used to measure accessible lead from children's metal jewelry: a wipe test was used beginning in 1996, and a saline extraction test and an acid extraction test were employed on intact jewelry components beginning in 2001. It was determined during the course of testing that the vast majority of accessible lead was obtained during acid extraction tests. The acid extraction test method[3] for accessible lead calls for an acid extraction that simulates exposure to metal that is ingested into the alimentary tract. The acid extraction involves placing an intact jewelry item in 0.07N hydrochloric acid at 37°C for 6 hours. This

[4] Product Safety Bureau Reference Manual, Book 5 - Laboratory Policies and Procedures, Part B: Test Methods Section, Method C-02.4 "Determination of Total Lead in Metallic Consumer Products," http://www.hc-sc.gc.ca/cps-spc/prod-test-essai/method/chem-chim/c-02_4_e.html.

procedure is based on methodology found in ASTM C927, C738, D5517, and F963. Since the acid extraction was found to be sufficient for assessing risk, test guidelines[3] issued in early 2005 established the acid extraction test procedure as the sole test for determining accessible lead. The methodologies for the additional accessible lead test methods conducted prior to December 2004 are summarized below.

Wipe Test Method

The wipe tests were used on children's metal jewelry samples from 1996 to December 2004 to simulate hand to mouth exposure scenarios, such as children touching or playing with a jewelry item, then placing their hands in their mouth. The wipe tests involved using filter papers moistened with 0.09% saline or Ghost Wipes™ to rub a metal jewelry item. The wipe procedure is as follows:

1. Accessible parts of the jewelry item are gently rubbed 10 times with the wipe.
2. The wipe is placed in a test tube, and the jewelry item is re-rubbed 10 times with a new moist wipe, and the 2nd wipe is placed in a separate test tube. The wipe procedure is repeated a 3rd time with a new moist wipe.
3. The wipes are digested with 2 ml of nitric acid, diluted to 10 ml with deionized water, and then analyzed for lead content using an ICP.

Saline Extraction Method

Saline extractions were used on children's metal jewelry samples from 2001 to December 2004 to simulate a child mouthing a jewelry item. The saline extraction procedure is as follows:

1. Weigh out intact entire piece of jewelry item and put in individual flask.
2. Add 0.09% sodium chloride (NaCl) solution, 50 times the weight of the jewelry item, to the flask.
3. Extraction is done for 1 hour at 37°C on a shaker bath. At 1 hour, the saline solution is removed and retained for analysis.
4. Fresh saline of the same amount is added to the flask and extraction is conducted for 2 hours at 37°C. The extracted solution is again removed and retained for analysis, and fresh saline solution is added.
5. Extraction is done for an additional 3 hours, and extract removed and retained for analysis.
6. Each of the 3 extracted solutions is analyzed for lead content with ICP. The results are totaled for the 3 solutions.

RESULTS AND DISCUSSION:

The test results for the 156 samples are contained in Table 1. The results showed that 57% of the items tested had total lead of 0.06% or more. Acid extractions were done on 342 items; 227 of those items had total lead of 0.06% or more. For the items that had more than 0.06% lead that were tested for accessible lead, 174 (77%) had greater than 175µg of accessible lead.

In a limited additional study, eight metal jewelry samples were tested for accessible lead for extraction periods beyond the 6 hours specified in the Standard Operating Procedure[3] (SOP). The samples selected were eight untested sub samples from previously tested compliance samples that each had total lead content greater than 45% but accessible lead of less than 175µg when tested according to the SOP. For all 8 of these samples, increasing the extraction time from 6 hours to 24-168 hours resulted in exponential increases in the amount of lead extracted. After 24 hours all 8 samples had accessible lead levels greater than 175µg, and at 168 hours the cumulative amount of lead extracted ranged from 20,552µg to 661,626µg.

The testing of children's jewelry as summarized in this document was almost exclusively limited to metal jewelry items; however plastic jewelry items containing lead were tested for 3 of the listed samples, including beads from one sample (LSC ID 145) and cords from each of two samples (LSC ID 146 and 147) with results as shown in Table 1.

Figure 1. Typical Jewelry Necklace or Bracelet Components

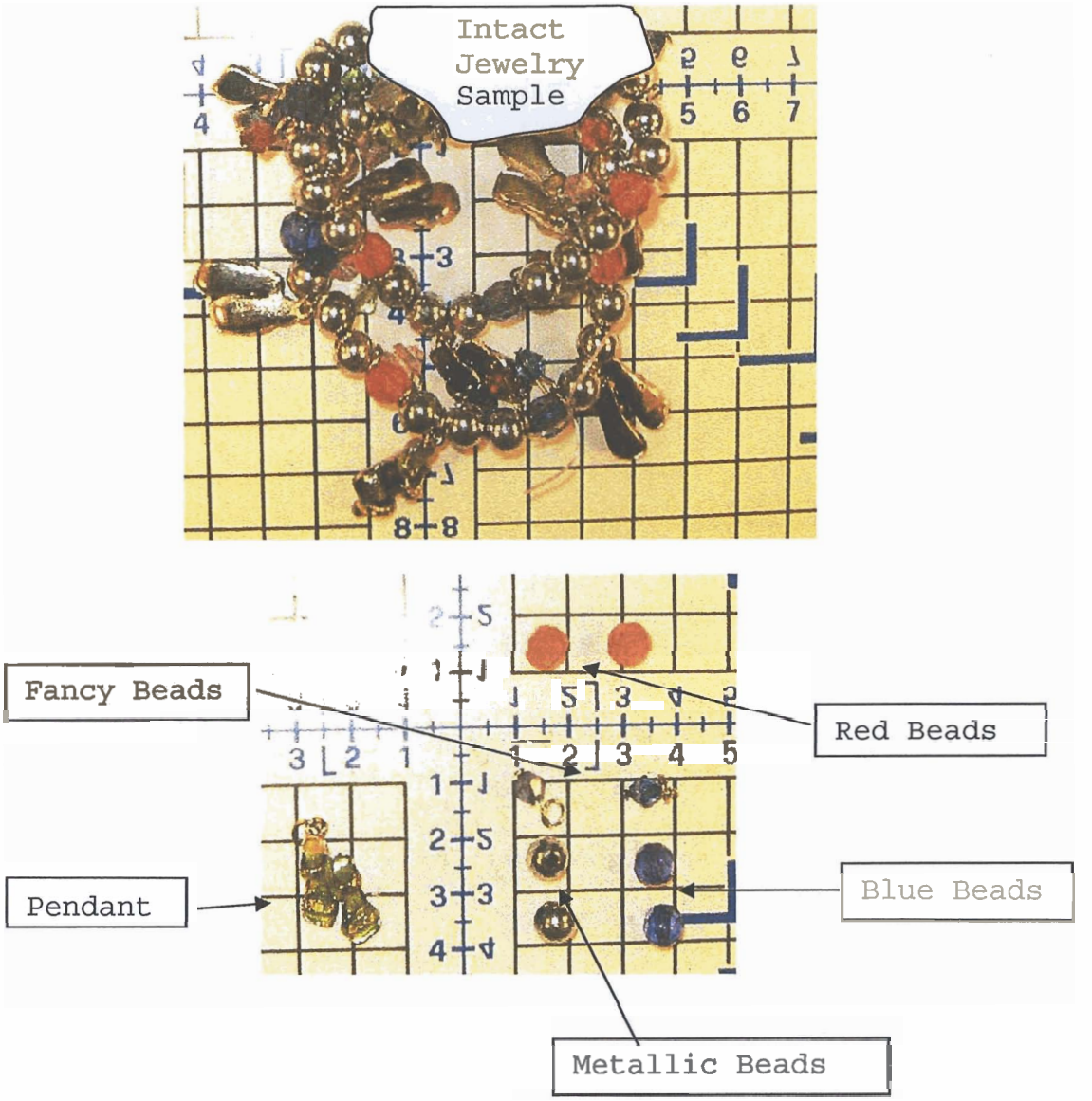

Table 1. Analysis Results

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
1		pendant	69.6	326.3*	NT	NT
2		pendant	70.6	313.8*	NT	NT
3		pendant	71.5	291.5*	NT	NT
4		pendant	72.0	215.3*	NT	NT
5		pendant	75.7	NT	NT	NT
6		pendant	59.0	19.25	NT	NT
7		pendant	47.4	8.3	NT	NT
8		pendant	47.2	8.34	NT	NT
9		pin	32.5	1.18	NT	NT
10		necklace	18.2	0.29	NT	NT
11		Earrings	32.6	0.52	NT	NT
12		necklace	43.3	0.2	NT	NT
13		pendant	29.4	0.24	NT	NT
14		pendant	30.1	0.27	NT	NT
15		pendant	31.8	0.19	NT	NT
16		pendant	33.9	0.24	NT	NT
17		pin	3.2	0.2	NT	NT
18		pin	19.8	0.17	NT	NT
19		pendant	29.2	0.18	NT	NT
20		pendant	27	0.2	NT	NT
21		pin	27.6	0.2	NT	NT
		bracelet	18.2	NT	NT	NT
		necklace	43.3	NT	NT	NT
		pendant	29.4	NT	NT	NT
22		pendant	0.06	0.15	NT	NT
		pin	32.5	1.18	NT	NT
		necklace	57.8	0.31	NT	NT
23		pendant	64.4	0.11	NT	NT
		barrettes	16.4	NT	NT	NT
24		pendant	58.5	0.028	NT	NT
25		Chain of balls	0.011	0.001	26.49	21.95
26		earring	0.015	0	0	0
		pendant	0.049	0	0	0
		barrette	0.006	0	0	0
27		pendant	0.009	0	0	0
		t ring	0.004	0	0	0
		barrette	0.006	0	0	0
28		ring	64.7	0.033**	100.83	3924.2
29		ring	72.1	0.32	227.36	5235.3
30		Beaded choker with pendant	0.003	0	0	0
31		earring	71.51	0:016**	7.35	13.05
32		ring	97.7	0.007	70.6	1335.9
33		earring	2.7	0.059**	7.74	0.182
34		earring pendant	78.0	0.95**	NT	NT

*Wipe test: 1 stroke per filter paper carried out, 3 filter papers used
** Wipe test: 10 strokes per filter paper carried out, 1 filter paper used
NT – Not Tested

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
35		earring with beads	0.01	NT	NT	NT
36		ring	82.5	NT	NT	NT
37		pendant	54.8	NT	NT	NT
38		beaded necklace	78.5	NT	NT	NT
39		pendant	52.0	NT	NT	NT
40		pendant	39	NT	NT	NT
41		Ring base	71.9	NT	NT	NT
		- yellow paint	30.9			
		- blue paint	9.1			
42		ring	58.6	NT	NT	NT
43		pendant	70.6	0.047	99.7	2694.3
44		bracelet pendant	53.6	0	113.4	785.2
45		rings	66.9	0.87	0	12.1
46	1	pendant	65.5	NT	NT	163.7
	2	pendant		0	NT	NT
	3	pendant		0	NT	NT
	4	pendant	64.1	NT	0	NT
	5	pendant	58.3	NT	NT	1422.2
	6	pendant	48.4	NT	0	NT
47	2	pendant	66.1	2.19	478.1	NT
	2	chain	0.03	NT	NT	NT
	3	pendant	81.8	NT	NT	3050.9
	3	chain	0.03	NT	NT	NT
48	1	pendant	50.5	NT	NT	517.3
	1	chain	0.03	NT	NT	NT
	2	pendant	53.4	NT	0	NT
	3	pendant		0.0197	234.8	10963
	4	pendant	37	NT	14.3	NT
	4	chain	0.03	NT	NT	NT
	5	pendant	59.4	NT	NT	63.7
	6	pendant		0.0077	0.508	243.9
49	1	pendant	63.6	0	275.9	17268.6
	1	hook	48.8	NT	NT	NT
	1	chain	0.03	0	NT	NT
	5	pendant	32.7	NT	183.2	3407
50	2	pendant	36.5	0.601	668.7	23149.8
	2	chain	0.04	NT	NT	NT
	2	hook		NT	92.9	774.8
	3	bracelet	42.7	NT	2.31	15.8
	6	pendant	42.5	NT	0	3886.9
	6	chain	0.03	NT	NT	NT
	7	pendant	23.5	0.499	0	1470.3
	9	pendant	43	5.21	375.1	6316.1
	9	chain	0.03	NT	NT	NT
	9	hook	27.7	NT	24.1	227.9

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
51	3	pendant	33.9	0	0	723.5
	10	pendant	30.1	0	0	1742.4
	10	chain	0.03	NT	NT	NT
52	2,4	necklace -chain	0.024	0.002	0.075	9.28
53	1	pendant	0	NT	NT	NT
	1	chain	0.03	NT	NT	NT
	3	pendant	0	NT	NT	NT
	7	pendant	0	NT	NT	NT
	8	pendant	0	NT	NT	NT
	9	pendant	0	NT	NT	NT
54	3	ring	0.03	NT	2.38	0
	3	Bead	3.77	NT	NT	NT
	4	ring	0.03	NT	3.56	37.4
	5	ring	0.04	0	3.1	0.531
	6	ring	0.03	0	1.68	0
	6	Bead	3.35	NT	NT	NT
	7	ring	0.03	NT	2.82	0
55	1	pendant	40	NT	69.5	2007.7
	2	pendant	42.6	0.0167	38	1246.2
	2	chain	0.03	NT	NT	NT
	3	pendant	42.4	NT	99.5	3870.4
	5	pendant	47.8	0.005	115.4	2356.5
	8	pendant	31	0	13.6	513.3
	8	chain	0.03	NT	NT	NT
56	4	pendant	39.6	NT	33	448.9
	4	chain	0.03	NT	NT	NT
	6	pendant	35	0.004	46.8	794.3
	6	chain	0.03	NT	NT	NT
	7	pendant	52.1	NT	28.9	435.6
	8	pendant	69.6	NT	34	403.4
	9	pendant	47.6	0.005	114.2	2460.4
57	1	pendant	33.8	NT	88.3	1013.5
	4	pendant	35.6	0	65.1	1641.2
	4	chain	0.03	NT	NT	NT
	7	pendant	29.7	0.02	50.5	781.7
	7	chain	0.02	NT	NT	NT
	8	pendant	36.8	NT	319.7	2524.3
	9	pendant	38.7	NT	421	3222.8

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
58	1	ring	17.8	0.009	0	249.4
	2	necklace	0.02	NT	NT	NT
	3	pendant	31.2	0.013	0	714.3
	4	pendant	28.2	0.007	7.64	1058.1
	5	pendant	60.5	0.008	75.5	1240.5
	6	pendant	56.2	0.012	33.3	211.9
	7	watch band	0	NT	NT	NT
	8	link bracelet	46.5	0.033	264.8	2421.8
	9	money clip	0.03	NT	NT	NT
	10	pendant	34.2	0.006	232	1925.8
	11	pendant	60.9	0.014	130.4	878.7
59	1	bracelet – charm	50.9	0.031	15.16	16901
	2	bracelet –charm	57	0.019	0.322	331.7
60	1	ring	33.1	0.0057	0	187.9
	2	ring	0.03	NT	NT	NT
	3	ring	23	0.0113	0	560
	4	ring	46	0.011	0	887.8
	5	pendant	25.9	0.022	2.56	1017.1
	6	pendant	45	0.005	499.2	6273.8
	7	pendant	41.5	0.003	158.8	3530.3
61	1	ring	0.05	NT	NT	NT
	2	ring	0.04	NT	NT	NT
	3	chain link necklace	0.02	NT	NT	NT
	4	chain link necklace	0.02	NT	NT	NT
	5	chain link necklace	0.03	NT	NT	NT
62	1	pendant	51.2	0.002	8.47	237.2
	2	pendant	66.7	0	NT	NT
	3	pendant	44.8	0.031	NT	NT
	4	pendant	51.2	0.002	180.7	4599.7
	5	pendant	56.8	0	43.2	1451.5
	6	pendant	49.4	0	106.5	1352.4
	7	pendant	50.6	0	115	685.7
	8	pendant	30.6	0.003	NT	NT
	9	pendant	40	0.023	0.079	702.4
63	1	pendant	26.3	0.05	NT	NT
	2	pendant	43.2	0.013	0	574.1
	3	pendant	48.5	0.111	NT	NT
	4	pendant	47	0.006	NT	NT
	5	pendant	53.6	0.039	NT	NT
	6	pendant	31.3	0	21.03	1277.4
	7	pendant	69.3	0.009	NT	NT

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
64	1	pendant	62.9	0.032	65.6	1555.2
	2	pendant	56.6	0.134	NT	NT
	3	pendant	56.2	0.009	485.9	2753.5
	4	pendant	47.5	1.016	3794.1	29519
	5	pendant	59.9	0.101	825.6	8388.9
	6	pendant	0.04	NT	NT	NT
	7	pendant	52.5	0.004	580.6	13881.8
	8	pendant	52.3	0.01	2815.1	15128.6
	9	pendant	0.02	NT	NT	NT
65	1	pendant	57	0.057	489.2	6428.2
	2	pendant	39.8	0.057	451.2	4371
	3	pendant	42.3	0.054	NT	NT
	4	pendant	39.4	0.139	NT	NT
	5	pendant	65.3	0.035	NT	NT
	6	pendant	63.7	0.095	70.2	2322.9
	7	pendant	56.3	0.035	3.77	783.2
	8	bracelet	65.3	0.016	100.6	2383.4
66	2	bracelet – beads	0.015	0.031	18.5	38.6
	2	bracelet – frame	0.004	NT	NT	NT
67	1	charm	51.1	0.0023	4.08	27.7
	2	charm & hook	31.6	0.033	358.1	2270.4
	3	charm & hook	12.1	0.004	NT	NT
	4	charm & hook	51.9	0.001	NT	NT
	5	charm	51.7	0.186	NT	NT
68	1	ring	51.1	0.072	72.1	783.8
	2	ring	43.2	0.162	8.37	1015.6
	3	pendant	48.5	0.08	17.4	734.3
	4	pendant	47	0.012	19.4	372.6
	5	ring	53.6	0.157	NT	NT
	6	ring	31.3	0.068	NT	NT
69		ring	24.7	0.217	0.5	2301.6
				0.07	0.99	1162
				0.217	3.48	1091.5
70	1	ring	62.8	0.277	196.8	9720.1
	2	ring	77	0.051	240	536.7
	3	ring	71.3	0.003	10.9	159.6
71		bracelet – chain only	0.017	0.074	0	33
72	6,3	necklace - chain	0.016	0.001	0	8.19
	6	necklace - hook	0.007	NT	NT	NT
	6,3	pendant	0.017	0.006	0	191
	6,3	necklace- hook	0.009	NT	NT	NT
73	2	charm	0.005	NT	NT	NT
	2,6	ring	41.4	0.005	165.5	1001.8
	2,6	charm	0.022	0	2.76	5.31

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
74	3	necklace – pendant	57	0.016	0	345.7
	3	necklace – hook	55.6	0.01	22.1	1464.5
	6	pendant	46.8	0.051	0.89	1064.1
75	3	charm	41.5	0.114	2	374
76	2	charm	7.86	0.013	0.479	32.8
	2	bracelet – chain	0.017	NT	NT	0
77	2	bracelet – 1 bead ,	52.4	0.13	18.3	1619.9
78	3	bracelet -charm	10.3	0.091	3.03	205.2
	3	bracelet – chain	0.019	NT	NT	39.9
79	2	bracelet – 5 charms	3.75	0.036	0	7.29
	2	bracelet – chain	0.032	NT	NT	0
80	4	ring	0.021	0.027	0	3.78
81	2	necklace – pendant	0.055	0.037	0	27
82	8	necklace – pendant	0.046	0.008	0	129.1
83	5	necklace – pendant	0.022	0.012	22.8	159
	5	necklace – hook	78.6	0.005	7.11	1541.2
	5	necklace – spring	0.028	NT	NT	4.39
84	8	necklace – pendant	0.031	0.031	0.28	16
85	3	bracelet – charm	51.4	0.009	1.13	15.8
	3	bracelet – charm	74.5	0.003	2.26	23.6
	3	bracelet – charm	81.8	0	1.85	8.58
	3	bracelet – hook	0.027	NT	NT	NT
86	3	bracelet – charm	34.8	0.023	23.4	2802.7
	3	bracelet – hook	0.017	NT	NT	NT
87	3	Jewelry making kit – bead	0.0002	0.004	2	8.24
	3	Jewelry making kit – bead	0.0002	0	1.08	1.63
	3	Jewelry making kit –bead	0.0002	0	0.4	0.34
	3	Jewelry making kit –bead	0.0001	0	0.13	1.38
	3	Jewelry making kit –bead	0.0003	0	0.26	0.12
	3	Jewelry making kit – hook	0.037	0.003	0.7	1.78
	3	Jewelry making kit – bead	0.0002	0	1.37	0.26
88	3	ring	0.056	0.005	0.634	65.3
89	4	necklace – pendant	36.5	0.244	19.6	1792.1
	4	necklace – hook	68.4	0.085	24.8	2934.6
	4	necklace – pendant	0.033	NT	NT	801.5
90	2	necklace – pendant	0.015	0.005	0	4.65
	2	necklace – hook	77.8	0.002	12.98	2078.8
	2	necklace – chain	0.036	NT	NT	1.55
91	1	beaded earring	82.3	0.049	134	11750.2
92	3	beaded earring	57.8	0.171	87.6	1372.9

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
93	3	necklace – pendant	53.8	0.021	0	260.9
	3	necklace - chain	0.025	NT	NT	2.69
94	2	necklace – pendant	64.4	0.015	0.127	36.3
	2	necklace – hook	73.4	0.039	5.61	1618.6
	2	necklace – chain	0.021	NT	1.33	46.3
95	6	necklace – pendant	0.06	0.014	0	5.72
	6	necklace – chain	0.043	0.018	0	0.43
	3	necklace – pendant	0.059	0.015	0	3.28
96	3	necklace – pendant	0.035	0.0067	0	3.57
	3	necklace – chain	0.043	0.0167	0	2.71
	3	necklace – hook	0.019	0.0113	0.121	1.9
	2	necklace – pendant	0.014	0.0047	0	0.95
	6	necklace – pendant	0.012	NT	0	0.45
97	1	ring	0.037	0.014	0	5.64
98	1	Ring	52.6	0.043	0	173.3
99	1	Necklace – charm pendant	0.029	0.004	0	1.52
	1	Necklace – ring pendant	0.026	0	0	1.37
	1	Necklace – hook	0.528	0	16.9	2008.2
100	1	necklace – pendant	22.9	0	0.98	26.2
101	1	necklace – pendant	33.2	0	3.68	175.4
102	1	necklace – pendant	27.4	0.152	40.4	4846
103		ring	0.037	0	0.18	6.39
104	1	ring	83.4	0.003	0	48.6
105	1	Magnetic earring	30.6	0	0	7.05
106	1	Chain-linked bracelet – chain	0.018	0.005	55.9	39.2
	1	Chain-linked bracelet – hook	0.028	0.001	2.33	0.69
107	1	Charm Bracelet – hook	23.6	NT	111.8	8603.5
	1	Charm Bracelet – charm	58.8	0.173	0	1283.3
108	1	Toe Rings	66.2	0.001	3.04	252
109	1	necklace – pendant	59	0.001	6.55	1574.1
110	1	necklace – pendant	14.4	0.009	174.9	2853.6
	1	necklace – hook	23.6	0.004	16.6	668.4
	1	necklace – chain	0.025	NT	NT	NT
111	1	necklace – pendant	41.3	0.006	15.2	899.1
	1	necklace – chain	0.027	NT	NT	NT
	1	necklace – hook	0.027	NT	NT	NT
112	1	necklace – pendant	47.6	0.009	91.1	3234.3
	1	necklace – chain	0.039	NT	NT	NT
	1	necklace – hook	39.21	NT	NT	NT
113	1	necklace – large pendant	26.8	0.0003	13.5	61.1
	1	necklace – small pendant	14.2	0.012	70.7	1905.5
	1	necklace – chain	8.81	NT	NT	NT

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
114	1	necklace – pendant	12.5	0.006	25.5	1187.5
	1	necklace – hook	23.5	0.002	33.3	2596.4
	1	necklace – chain	0.024	NT	NT	NT
115	1	necklace – pendant	54.8	0.003	18.9	4611
	1	necklace – hook	72.8	0.001	31.4	1064.3
	1	necklace – chain	0.025	0.005	NT	NT
116	1	Bracelet – bell bead	69	0.001	0	162.6
	1	Bracelet – large bead	69.8	0.006	54	1957.6
	1	Bracelet – small bead	71.7	0.002	7.65	658.3
117	1	necklace – pendant	71.7	0.043	0	3136.6
	1	necklace – hook	77.3	0.011	28.1	1271.6
	1	necklace – bead	0.024	0.001	0.01	1.64
118	1	necklace – pendant	54.7	0.027	0	402.3
	1	necklace – hook	33.6	0.02	28.39	1687.8
	1	necklace – bead	70	0.008	3.82	866.2
119	1	necklace – pendant	68.8	0.016	120.2	5771.4
	1	necklace – bead	0.023	0.003	--	1.6
120	2	Jewelry set – medallion	66.6	0.009	35.9	215.7
	2	Jewelry set – hook	30	0.004	79.1	2517.2
121	1	ring	0.042	0.002	0.38	17.8
122	6	bracelet	0.049	0.017	2.35	0
123	2	bracelet – charm	0.058	0.014	1.18	3.85
	2	bracelet – hook	0.035	0.002	0.27	0.79
124	5	necklace – pendant	0.02	0.005	1.32	0.21
125	6	bracelet – charm	20.8	0.007	0.54	22.9
	6	bracelet – hook	30.2	0.006	40.8	2,476.5
	6	bracelet – chain	0.06	0.007	3.15	10.34
126	1	bracelet – charm	33.8	0.011	0.98	56.8
	1	bracelet – hook	0.07	0.003	0.62	0.7
127	2	ring	0.05	0.003	1.46	2.54
128	5	necklace – link	0.047	0.0003	9	3.12
	5	necklace – hook	0.048	0.0003	0.69	2.42
129	1	charm bracelet – flat bead	97.2	0.033	122.6	4393.2
	1	charm bracelet – pendant	83.3	0.008	271.0	1884.9
	1	charm bracelet – ball bead	0.009	0.003	0.25	1.47
130	1	bead bracelet – ball bead	0.009	0.007	0.17	2.28
	1	bead bracelet – flat bead	90.4	0.092	63.8	1426.3
131	1	bead bracelet – pendant	87.2	0.004	16.5	200.9
132	1	charm bracelet – charm	59.2	0.003	189.0	1239.0
	1	charm bracelet – hook	70.0	0	130.0	3186.5
133	1	bracelet	92.6	0.034	868.3	4805.5
134	1	jewelry kit – charm	0.012	0.001	1.6	64.7
	1	jewelry kit – hook	0.001	0	2.16	3.02

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
135	1	necklace – pendant	0.015	0.013	0.02	6.81
	1	necklace – hook	37.7	0.072	175.0	2985.6
	1	necklace – chain	0.085	0.005	0	8.47
136	1	necklace – pendant	46.7	0.002	4.33	48.7
	1	necklace – hook	0.031	0.002	0.11	0.98
137	1	ring	0.027	0.003	1.03	0.38
138	1	ring	73.5	0.048	216.0	4243.8
139	1	necklace – pendant	0.025	0.004	1.56	17.07
140	1	Gold stone bracelet – chain	0.013	0.003	9.92	0.4
141	1	charm	77.9	NT	NT	2849.9
	1	charm	83.2	NT	NT	176.7
142	1	charm	87.1	NT	NT	37.2
143	1	charm	89.0	NT	NT	458.7
144	1	charm	86.0	NT	NT	27.7
145	2	bracelet	0.027	NT	NT	2.1
	4	bracelet	0.002	NT	NT	3.05
	[redacted]	[redacted]	0.054	NT	NT	0
	4	bracelet – bead	0.027	NT	NT	8.85
	2	bracelet – hook	0.024	NT	NT	0
	4	bracelet – hook	0.052	NT	NT	3.81
	2	bracelet – pendant	0.025	NT	NT	0
	4	bracelet – pendant	0.04	NT	NT	0.9
146	1	bracelet – bead	4.26	NT	NT	1.56
	1	bracelet – cylinder bead	2.90	NT	NT	5.8
	[redacted]	[redacted]	0.488	0.043	2.05	9.42
	2	bracelet –bead	3.01	NT	NT	12.4
	2	bracelet – cylinder bead	3.04	NT	NT	0
	[redacted]	[redacted]	0.39	0.058	1.87	6.1
147	1	necklace –pendant	20.4	NT	NT	17.7
	1	necklace – hook	0.029	NT	NT	8.99
	[redacted]	[redacted]	0.502	0.044	6.85	11.5
	2	necklace –r pendant	65.9	NT	NT	207.1
	2	necklace – hook	44.0	NT	NT	6496.5
	2	necklace – cord	0.187	0.176	2.4	17.9
	3	necklace – surfer pendant	0.031	NT	NT	28.9
	3	necklace – hook	0.029	NT	NT	2.2
	4	necklace –pendant	0.028	NT	NT	60.7
	4	necklace – hook	0.029	NT	NT	1.75

‡Shading denotes plastic items

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
148	1	zipper pull - hook	0.029	NT	NT	6.7
	1	zipper pull - charm	55.7	NT	NT	41
	2	zipper pull - hook	0.046	NT	NT	33.8
	2	zipper pull - charm	61.8	NT	NT	29.1
	3	zipper pull - hook	NT	NT	NT	8.1
	3	zipper pull - charm	NT	NT	NT	31.6
	4	zipper pull - hook	0.031	NT	NT	6.3
	4	zipper pull - charm	66.1	NT	NT	22
	5	zipper pull - hook	NT	NT	NT	23.8
	5	zipper pull - charm	NT	NT	NT	21.4
	6	zipper pull - hook	NT	NT	NT	2.8
	6	zipper pull - charm	NT	NT	NT	25.9
	7	zipper pull - hook	NT	NT	NT	2.8
	7	zipper pull - charm	NT	NT	NT	20.2
149	1	necklace – hook	86.3	NT	NT	940.8
	1	necklace - pendant	63.6	NT	NT	1873.9
	2	necklace – hook	86.6	NT	NT	114.8
	2	necklace - pendant	64.5	NT	NT	617.7
	3	necklace – hook	NT	NT	NT	360.6
	3	necklace - pendant	NT	NT	NT	910.9
	4	necklace – hook	NT	NT	NT	679.1
	4	necklace - pendant	NT	NT	NT	19.3
	5	necklace – hook	84.9	NT	NT	659.1
	5	necklace – pendant	65.0	NT	NT	NT
	6	necklace – hook	NT	NT	NT	445
	6	necklace - pendant	NT	NT	NT	7514.8
	7	necklace – hook	NT	NT	NT	296.6
	7	necklace - pendant	NT	NT	NT	1936.8
		necklace - springs	NT	NT	NT	3.2
150	5	bracelet –pendant	73.1	NT	NT	10151.0
	5	bracelet – large bead	0.01	NT	NT	2.62
	5	bracelet – small bead	0.16	NT	NT	1.33
	5	bracelet –ring bead	92.6	NT	NT	1286.7
	7	bracelet – heart pendant	96.4	NT	NT	14,617.9
	7	bracelet – heart pendant	0.04	NT	NT	3.68
	7	bracelet – heart pendant	0.02	NT	NT	0.64
	7	bracelet – heart pendant	92.2	NT	NT	1368.7

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
151	7	necklace – yellow paint	0.687	NT	NT	NT
	7	necklace – green paint	2.94	NT	NT	NT
	7	necklace – red paint	2.46	NT	NT	NT
	1	necklace – pendant	65.3	NT	NT	2929.1
	1	necklace - hook	90.0	NT	NT	2961.5
	2	necklace – pendant	60.7	NT	NT	177.9
	2	necklace - hook	82.4	NT	NT	2229.0
	3	necklace – pendant	61.9	NT	NT	1298.7
	3	necklace - hook	89.6	NT	NT	3283.8
	4	necklace – pendant	64.0	NT	NT	318.3
	4	necklace - hook	53.0	NT	NT	5631.1
	5	necklace – pendant	72.0	NT	NT	931.3
	5	necklace - hook	86.1	NT	NT	5742.4
	6	necklace – pendant	78.9	NT	NT	3632.2
	6	necklace - hook	78.7	NT	NT	6375.9
152	1	charm	NT	NT	NT	10.56
	2	charm	0.21	NT	NT	9.06
	1	charm	NT	NT	NT	36.1
	2	charm	0.18	NT	NT	22.0
	1	charm	NT	NT	NT	9.07
	2	charm	0.21	NT	NT	5.81
	1	charm	NT	NT	NT	4.45
	2	charm	0.19	NT	NT	5.55
153	1	pewter charm	NT	NT	NT	4.23
	3	pewter charm	0.001	NT	NT	9.42
	1	pewter charm	NT	NT	NT	2.12
	3	pewter charm	0.003	NT	NT	4.13
	1	pewter charm	NT	NT	NT	10.8
	3	pewter charm	0.001	NT	NT	16.7
	1	pewter charm	NT	NT	NT	4.64
	3	pewter charm	0.017	NT	NT	6.45
154	1	bracelet pendant	0.527	0.013	NT	7.23
	1	bracelet clasp	81.8	0.039	NT	6035.8
	1.	bracelet chain	14.3	0.058	NT	17.6
	2	bracelet pendant	1.46	0.032	NT	7.3
	3	bracelet pendant	0.026	0.043	NT	5.06
	3	bracelet clasp	85.7	0.058	NT	9856.9
	4	bracelet pendant	0.026	0.016	NT	2.45
	5	bracelet pendant	0.019	0.074	NT	3.15
	6	bracelet pendant	0.008	0.014	NT	1.8
	6	bracelet clasp	93.1	0.043	NT	8682.5

LSC ID	Item #	Description	Tot. Pb %	Wipe Test µg Pb/stroke	Saline Extraction µg/6 hrs	Acid Extraction (µg/6 hrs)
155	1	bracelet pendant	0.058	NT	NT	0
	1	bracelet clasp	92.5	NT	NT	8684.8
	1	bracelet chain	0.027	NT	NT	0
	2	bracelet pendant	0.007	NT	NT	0
	2	bracelet clasp	78.9	NT	NT	7612.1
	3	bracelet pendant	0.027	NT	NT	0
	3	bracelet clasp	85.9	NT	NT	3888.7
156	1	bracelet pendant	0.007	NT	NT	0
	1	bracelet clasp	85.6	NT	NT	4606
	1	bracelet chain	0.01	NT	NT	16.2
	2	bracelet pendant	0.073	NT	NT	25.9
	2	bracelet clasp	88	NT	NT	3441
	3	bracelet pendant	0.006	NT	NT	0
	3	bracelet clasp	16.1	NT	NT	6750
	4	bracelet pendant	0.005	NT	NT	20.9
	4	bracelet clasp	102	NT	NT	6174

TAB C

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: November 28, 2006

TO : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Division for Health Sciences

THROUGH: Mary Ann Danello Ph.D, Associate Executive Director, Directorate for Health Sciences
Lori E. Saltzman M.S., Director, Division of Health Sciences

FROM : Joanna M. Matheson Ph.D., Toxicologist, Division of Health Sciences

SUBJECT : Petition HP06-1 Lead in Jewelry Toxicity Review[1]

Background

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. Exposure to lead during childhood can have long-term effects through adulthood. Early childhood lead exposure has been associated with school failure, delinquency and criminal behavior as well as increased mortality, hypertension, renal disease, dental caries, cataracts and infertility (Needleman 2002, Dietrich 2001, McDonald 1996, Moss 1999, Schaumberg 2004, ATSDR 2005).

Toxicity

Because lead accumulates in the body, even exposures to small amounts of it can contribute to the overall level of lead in the blood and to the risk of adverse health effects. Lead exposure occurs primarily through inhalation and ingestion. Very small particles are absorbed through the lungs when inhaled, while larger particles are swallowed. About 20 to 80% of lead is absorbed when ingested, but in general, children absorb about 50% of the lead they ingest. Little dermal absorption of lead occurs (ATSDR 2005).

Lead is poorly absorbed in the stomach and is most efficiently absorbed in the duodenum where bile enhances its absorption (Fergusson 1997). Nutritional deficiencies (e.g., calcium, iron, ascorbate, vitamin D) and fasting will also enhance lead absorption (EPA 2006). Following absorption, lead readily binds to red blood cells in the circulating blood from which lead is carried to soft tissues (e.g., brain, kidneys, bone marrow, gonads) and eventually to bone for long-term storage. Analysis of lead in whole blood is the most common and accurate method of assessing lead exposure; the blood lead level or BLL is the amount of lead in micrograms (µg) in a deciliter (dL) of blood. BLL may be used as an indicator of past or recent lead exposure.

[1] *This report was prepared by the CPSC staff, and has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.*

A dose-response effect is observed for both children and adults; as BLLs increase from 10 µg/dL, the frequency and severity of syrnptoms as well as the number of organ systems affected increases (Table 1, Appendix A). Regardless of route of exposure and the age of the individual, the nervous system is the primary target for lead toxicity. Children appear to be more susceptible to the health effects of lead than adults and, therefore, are the most studied population. At high BLLs, children can have severe abdominal pain, vomiting, anemia, fatigue, behavioral changes, and encephalopathy which can result in death. However, because not all children with high blood lead levels have such obvious specific signs and symptoms (e.g., neurodevelopmental effects are not apparent), lead exposure may go undetected.

The scientific community generally recognizes a blood lead level of 10 µg/dL as a level of concern with respect to lead poisoning. Many states or local programs provide intervention to individual children with BLLs equal to or greater than 10 µg/dL (ATSDR 2005). Recent studies have focused upon the effects of lower BLLs (below 10 µg/dL) on children's health. Studies have reported adverse effects on cognitive function and IQ (Bellinger 2003, Canfield 2003, Chiodo 2004, Lanphear 2000 and 2005, Moss 1999, Schnaas 2006, Tellez-Rojo 2006, Wasserman 2003), and on certain other health endpoints (e.g., increased dental caries and delays in pubertal markers [Moss 1999, ATSDR 2006, Selevan 2003, Wu 2003]). Another well-known effect of relatively low BLLs is the inhibition of the enzyme, δ-aminolevulinic acid dehydratase (ALAD), which could lead to anemia (summarized in ATSDR 2005).

There are limitations in many of these studies, including the small number of directly relevant cohort studies, small study population sizes, and the inherent limitations of cross-sectional studies. One major limitation concerns the lack of information about subjects' lead exposure histories. That is, although BLLs are generally highest in early childhood, studies of lead effects may occur when the children are older, and blood lead measurements done at that time may not provide a true representation of lead exposures. Another key source of uncertainty in some studies arises from the difficulty in controlling confounding factors, particularly socioeconomic factors, during analysis of the data. The authors of one study (Wu 2003) also cautioned that their limited attention to nutritional and genetic factors may affect interpretation of their findings of delayed pubertal markers. Thus, in its recent statement on preventing lead poisoning in children, the Centers for Disease Control and Prevention (CDC) acknowledged the evidence of adverse health effects in children with relatively low BLLs, but concluded that the effects of lead may be "subtle," and that other influences on children's health "make isolating the effect of lead or predicting the overall magnitude of potential adverse health effects exceedingly difficult" (CDC 2005a). The CDC has not changed its blood lead level of concern, which remains at levels $\geq$10 μg/dL.

Experimental animal studies also provide some information about the effects of lead at different levels of exposure, including relatively low exposures, although most studies utilized very high doses of lead. Some of these studies seem to indicate that a lower threshold for significant toxicity occurs at BLLs above 10 µg/dL. In a study in which neonatal rats were exposed to lead for up to 21 days of age via their mother's milk (Widzowski 1994), the lowest exposure group with significant toxicity (decreases in striatal D2 receptor density and differences in dopamine receptor sensitivity and

binding) had BLLs in the 10 to 20 µg/dL range. Another study in which rats were administered lead acetate in drinking water reported significant effects on gonadotropin-releasing hormone system after one-week of exposure only in the treatment groups that resulted in BLLs of about 17 µg/dL or greater (Sokol 2002).

Sources of Lead Exposure

BLLs have significantly declined since the early 1990s largely from the coordinated efforts at the national, state and local levels on the removal of lead from gasoline, food cans, and residential paint products[2]. However, based on NHANES[3] 1999-2002 data, an estimated 310,000 children aged 1 to 5 years (or 1.6% of U.S. children in this age range) have elevated BLLs (≥10 µg/dL, CDC 2005b). Although lead paint in older housing remains the most common cause of excess lead exposure for children in the United States[4], other lead sources (e.g., ceramicware, certain ethnic medicines, imported candy and spices), including consumer products falling under CPSC jurisdiction, are increasingly being documented (CDC 2005c, CDC 2002, Jones 1999).

A search of CPSC databases and published articles (Durback 1989, Fergusson 1997, Greensher 1974, Hugelmeyer 1988, Mowad 1998, Sprinkle 1995) showed that exposures to lead in paint and imported vinyl miniblinds dominate the number of reported cases of lead exposure. In addition, sixty reports from CPSC databases (for the time period of 1975 through March 2006) demonstrated that children ranging in age from 9 months to 17 years have had exposure to lead from products such as jewelry, game pieces, crayons, chalk, lead weights/sinkers/pellets, lead shot/bullets, tea kettles, clay pots, ceramicware, drinking glasses and curtain weights.

Sources of lead poisoning due to consumer products may not be readily ascertained even after extensive testing of a child's environment. In cases where toxicity has occurred, the time of ingestion of an item was not usually known, and the diagnosis was made only after symptoms developed (e.g., abdominal cramping, vomiting, diarrhea, irritability) and abdominal radiographs revealed the presence of an unsuspected foreign body. The case of a 5½ year old girl illustrates how rapidly BLLs can increase after ingestion of a foreign object containing lead (McKinney 2000). The child was observed eating the pellets from an ankle weight. Even with whole-bowel irrigation, the child's BLL was 57 µg/dL, 13 hours after ingestion, at which time chelation was initiated. Her BLL rose to a peak of 79 µg/dL approximately 36 hours after ingestion.

Although limited published data exist on children's exposures to lead-containing jewelry, three recent cases of children ingesting jewelry items provide examples of exposures to high lead levels from such objects. A 4 year old Oregon boy had a BLL of 123 µg/dL approximately 3 to 4 weeks after swallowing a pendant, which the state laboratory found to contain 38.8% lead (VanArsdale 2004). A 4 year old Minnesota boy died with a BLL

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[2] In 1978, the Commission banned paint and other similar surface coatings that contain more than 0.06% lead ("lead-containing paint"), toys and other articles intended for use by children that bear lead-containing paint, and furniture articles for consumer use that bear lead-containing paint.

[3] NHANES (National Health and Nutrition Examination Survey)

[4] Although the use of lead has been banned from gas and paint, lead doesn't degrade to other substances and therefore persists in the environment. Daily background lead exposures can occur from drinking water, diet, air and ingestion of soil/dust; these levels have been decreasing since the 1980s.

of 180 µg/dL after ingesting a bracelet charm for an unknown period of time; the state public health department laboratory determined that the charm contained 99.1% lead (CDC 2006). A 9 year old boy's BLLs rose to 27 µg/dL 4 days after swallowing a ring. Three days later his BLLs rose to 54 µg/dL, at which time endoscopy was performed to remove the ring. A representative from the company that manufactured the ring stated that the ring was 90% lead (CPSC files).

Interim Enforcement Policy for Children's Metal Jewelry Containing Lead

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 result in chronic exposures. Ingestion that occurs all at once (e.g., swallowing a whole 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.

From preliminary LSC data, the staff determined that the amount of lead that would be absorbed by ingesting an item of jewelry was 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 would also provide an even greater protection against the possibility of excess exposure through mouthing and handling of the items.

To address the scenario of a child exceeding the 10 µg/dL blood lead level of concern from ingestion of metal jewelry, CPSC staff developed an Interim Enforcement Policy for Children's Metal Jewelry Containing Lead ("enforcement policy"). In this enforcement policy, CPSC staff recommended that children not ingest more than 175 µg of accessible lead in a short period of time[5]. This value was based upon a review of the current scientific literature (described below) 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[5].

Most published research on lead poisoning focuses upon chronic exposures. For acute exposures, the scientific community has generally assumed a blood lead half-life of 15 to 36 days based on lead isotope tracer studies in adults (Chamberlain 1978, Rabinowitz 1976). However, in a prospective study of young children that experienced short-term exposures to lead, Manton et al. (2000) calculated a blood lead half-life of approximately 10 months. The highest BLL value in these children did not exceed 12 µg/dL. The authors noted that their estimate of blood lead half-life was considerably longer than the half-life measured in adults and suggested that the difference could be due to the greater rate of turnover of bone in young children. CPSC staff used this 10 month blood lead half-life in its analysis. Other assumptions as indicated in the

[5] http://www.cpsc.gov/businfo/pblevels.pdf

enforcement policy were that the blood volume for a 14.5 kg child (average for ages 2 to 5 years) was 1.0 L and that fifty percent of the acid extractable lead is bioavailable (based on the bioavailability of lead in food or water) (EPA 2006). The staff assumes that all bioavailable lead initially enters the blood and that the elimination of lead from the blood follows first order kinetics (in the absence of information to suggest otherwise). The staff assumed that elevation of the blood lead level above the 10 µg/dL level of concern for a one month period is deleterious based on a review of the medical literature that shows that short-term exposures to lead are associated with adverse effects (ATSDR 2006, McKinney 2000).

The available NHANES data at the time the policy was written was from an earlier NHANES survey (CDC 2003) which indicated that the geometric mean BLL for children ages 1 through 5 years was 2.2 µg/dL; 2.2% of the children in this age group exceeded the 10 µg/dL level of concern. Based on the assumed blood lead half-life and first order kinetics, 93% of the initial blood lead concentration remains after one month. Therefore, an initial BLL of 10.6 µg/dL would result in chronic elevation of the BLL above 10 µg/dL. This level represents an increase of 8.4 µg/dL above the NHANES geometric mean of 2.2 µg/dL. Given the above assumptions, this increase would occur with an intake of about 175 µg. CPSC staff acknowledged the simplifications and assumptions that went into this calculation; however, the staff believed that this was a reasonable estimate of the level of lead intake from ingestion of children's jewelry that would be hazardous.

Since 1996 through 2006, CPSC staff has tested 466 items from 156 samples of children's jewelry for lead content and for accessibility of the lead[6]. Since the staff was interested in the accessibility of lead from ingested items, we considered the data from 322 of the 466 tested items for which both total lead content and acid extractability (i.e., the method used to simulate the effect of stomach acid on an item) was measured.

Based on the available data, CPSC staff concluded that there was less likelihood of ingesting potentially hazardous levels of accessible lead (175 µg) if the children's jewelry item had a total lead content of 0.06% or less and that increasing total lead content was associated with increasing accessible lead (Table 2). Fewer than 1.9% (2/108) of the children's jewelry pieces with total lead less than or equal to 0.06% had accessible lead exceeding 175 µg, while 76.2% of the pieces with total lead values greater than 0.06% exceeded the 175 µg level.

[6] David Cobb, CPSC Memorandum to Kristina M. Hatlelid, "Summary of Test Results for Lead in Children's Metal Jewelry," (2006).

Table 2: Distribution of Accessible Lead Based on Total Lead Values

Total Lead (%)	Accessible Lead (µg)[7]
≤0.06	20.27 ± 7.81
> 0.06 and ≤10.0	150.38 ± 90.61
> 10.0 and ≤20.0	1,881.25 ± 900.67
> 20.0 and ≤30.0	1,612.76 ± 502.72
> 30.0 and ≤40.0	2,476.47 ± 893.01
> 40.0 and ≤50.0	3,179.32 ± 1,119.07
> 50.0 and ≤60.0	2,371.84 ± 630.75
> 60.0 and ≤70.0	2,145.88 ± 710.88
> 70.0 and ≤80.0	2,707.68 ± 624.05
> 80.0 and ≤90.0	2,791.10 ± 690.73
> 90.0 and ≤100.0	5,826.63 ± 1,506.42

Conclusions

Published cases illustrate that significant absorption of lead, followed by rapid elevation of BLL, can occur within hours to days after a child's ingestion of lead items and that the lead exposure can result in serious health effects including death. These health effects include neurological damage, delayed development, attention and learning disorders, visual and hearing problems, systemic diseases and death. Exposure during childhood has also been shown to have long-term effects including increased cardiovascular disease, altered reproductive function and development, and increased mortality. Because lead accumulates in the body, studies have shown that exposures to small amounts of lead can contribute to the overall BLL and to the risk of adverse health effects. The staff estimated that children should not ingest more than 175 µg of accessible lead in a short period of time to avoid exceeding the 10 µg/dL level of concern.

Staff analysis of data on children's metal jewelry 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. Therefore, protecting children from ingesting a jewelry item with potentially hazardous levels of lead also provides protection against the possibility of excess exposure through mouthing and handling. Based on the available test data, CPSC staff determined there was a lower likelihood of ingesting potentially hazardous levels of accessible lead if a children's metal jewelry item had a total lead content of 0.06% or less.

[7] Mean values ± standard error

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Appendix A

Table 1: Summary of Adverse Health Effects of Lead
(Sources: ATSDR 2005; EPA 2006)

Children BLL (µg/dL)	Adults BLL (µg/dL)	Signs & Symptoms
≤10	≤10	ALAD* inhibition, dental caries, developmental effects, delayed sexual maturation, decreased height and birth weight and head circumference. Adults only: decreased glomerular filtration rate
10-20	15-20	Erythrocyte protoporphyrin increases, EPO inhibition Adults: subtle, non-specific neurologic effects at 20-60 µg/dL. Children: CNS electrophysiological changes, ADD, reading difficulty, hearing deficits; increases in IgE/decreases in IgG and IgM; decreased Vitamin D.
25-30	30	Cognitive CNS deficits, anemia†, peripheral nerve dysfunction, proteinuria, enzymuria, hypertension. Adults: changes in FSH, LH and testosterone levels (also reported at 40-60µg/dL); changes in immune parameters. Children: decreased appetite, ADD.
	40	Increases in urinary ALA and coproporphyrin, sperm changes, gout, decreased fertility. Changes in T_4 and TSH levels. Neurobehavioral changes.
40-50	50	Decreased hemoglobin production, overt subencephalopathy; decreased play, disturbed sleep, anorexia
60	60	Colic, abdominal pain, arthralgia, clumsiness, vomiting, irritability, inability to concentrate, fatigue, diarrhea, headache, behavioral changes, inhibition of Vitamin D activity, severe renal disease with chronic exposure
70	80	Frank anemia; brain and renal damage in children
70-100	100-120	Encephalopathy with hyperirritability, ataxia, vomiting, convulsions, stupor, constipation, coma; mental retardation, epilepsy, blindness, sterility, severe renal damage. Children: death at 125 µg/dL.

*Abbreviations: ADD (attention deficit disorder); ALA (5-aminolevulinic acid); ALAD (δ-aminolevulinic acid dehydratase); EPO (erythropoietin); FSH (follicle-stimulating hormone); Ig (immunoglobulin); LH (luteinizing hormone);T4 (thyroxine); TSH (thyroid stimulating hormone)

†Anemia can appear at BLLs as low as 20 µg/dL, but may be more commonly associated with higher levels (40 -70 µg/dL in children; 50-80 µg/dL in adults).

TAB D

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: November 30, 2006

TO : Kristina Hatlelid, Ph.D., M.P.H., Toxicologist
Directorate for Health Sciences

THROUGH: Russell Roegner, Ph.D., Associate Executive Director RR
Directorate for Epidemiology

Kathleen Stralka, M.S., Division Director RR for KS
Hazard Analysis Division

Robin L. Ingle, M.A., Health Statistician RI
Hazard Analysis Division

FROM : Craig O'Brien, M.S., Mathematical Statistician
Hazard Analysis Division

SUBJECT : Analysis of Data on Child Ingestions

I. Introduction

This memorandum gives results of an analysis of consumer products swallowed by children. The data source for the analysis is the National Electronic Injury Surveillance System (NEISS), maintained by the Consumer Product Safety Commission (CPSC). Estimates are provided for the number of emergency-room treated injuries involving ingested foreign objects by product and age category.

II. Background

In April of 2006 the Sierra Club petitioned CPSC regarding lead in consumer products, especially toy jewelry (Sierra Club, 2006). One of the concerns mentioned in the petition is the ingestion by children of consumer products containing lead.

III. Injury Data

A. Methodology

The National Electronic Injury Surveillance System (NEISS) is a probability sample of approximately 100 U.S. hospitals having 24-hour emergency rooms (ERs) and more than six beds. NEISS collects injury data from these hospitals. Coders in each hospital code the data from the ER record and the data is then transmitted electronically to CPSC. Because NEISS is a probability sample, each case collected represents a number of cases (the case's *weight*) of the total estimate of injuries in the U.S. Different hospitals carry different weights, based on stratification by their annual number of emergency room visits (Schroeder and Ault, 2001).

Hazard Analysis staff searched NEISS for all cases with diagnosis code 41 (Ingested Foreign Object) and patients 18 years of age or younger. Staff then used SAS® version 9 to categorize the data by product code and age categories by quartile, and to compute estimates and the associated coefficients of variation for the number of injuries as well as the estimated number of injuries with particular characteristics such as age and associated product. A coefficient of variation (C.V.) is the ratio of the standard error of the estimate (i.e., variability) to the estimate itself. This is generally expressed as a percent. A C.V. of 10% means the standard error of the estimate equals 0.1 times the estimate. Large C.V.'s alert the reader that the estimate has considerable variability. This is often due to a small sample size.[1] Estimates and confidence intervals are not reported here unless the number of cases is 20 or more, the estimate is greater than 1,200, and the C.V. is less than 33%.

B. Results

1. Overall

From 2000 to 2005 staff found 11,994 NEISS cases involving ingestion of a foreign object and a child aged 18 years or younger. Based on these 11,994 cases there were an estimated 302,587 emergency-room treated injuries from 2000 to 2005 involving a child 18 years old or younger ingesting a foreign object. The 95% confidence interval about the number of emergency-room treated injuries from 2000 to 2005 for children 18 years of age or younger is 255,120 to 350,055. A breakdown of the incidents by age group is given in Table 1. The age groups in Table 1 were chosen based on quartiles of age using estimated injuries.

Table 1: Emergency-Room Treated Ingestions by Age Group, 2000-2005

Age Range	Estimate[2]	Percent of Total[2]	Sample Size	C.V.	95% Confidence Interval
0 – 21 months	77,380	25.6%	3,241	9.78%	62,554 – 92,205
22 months – 3 years	92,451	30.6%	3,677	8.51%	77,023 – 107,878
4 – 6 years	71,444	23.6%	2,850	7.82%	60,498 – 82,391
7 – 18 years	61,313	20.3%	2,226	7.63%	52,140 – 70,485
Total	302,587	100.0%	11,994	8.00%	255,120 – 350,055

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

The cases were also categorized by the product associated with the ingestion injury. The ten product categories with the highest estimates are shown in Table 2 on the next page. Note that NEISS allows for the coding of one or two products for each incident. An incident with two associated products would be counted twice in the breakdown by product category, once for each product. Of the 11,994 incidents analyzed, 555 incidents had two associated products. There are several situations where two products may be coded for an ingestion. Both products may have

[1] For a more detailed discussion of measures of variation associated with NEISS estimates, see Schroeder and Ault, 2001.
[2] Columns may not sum to totals due to rounding.

been swallowed. If a part of a product is swallowed, such as a battery from a toy, both the part (the battery) and the whole (the toy) may be coded. One product may also be associated with the incident but not swallowed, such as a toddler swallowing a coin found on the floor, with both the coin and the floor being coded.

Table 2: Top Ten Swallowed Products by Individuals 18 Years Old and Younger, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Code Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	147,768	48.8%	6,145	8.82%
1616	Jewelry	19,859	6.6%	807	10.42%
5004	Toys, not elsewhere classified	18,275	6.0%	697	10.58%
1819	Nails, screws, tacks, or bolts	18,187	6.0%	636	8.02%
0884	Batteries	12,053	4.0%	527	12.37%
1354	Marbles	9,663	3.2%	357	13.12%
1650	Desk supplies	6,175	2.0%	219	11.27%
1682	Hair curlers, curling irons, clips, and hair pins	4,996	1.7%	226	13.71%
1729	Christmas decorations (nonelectric)	4,901	1.6%	182	13.80%
1685	Pens and pencils	4,236	1.4%	148	14.12%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

2. Age Groups by Quartile

From 2000 to 2005 staff found 3,241 NEISS cases involving ingestion of foreign objects and children aged 21 months or younger. Based on these 3,241 cases there were an estimated 77,380 emergency-room treated injuries from 2000 to 2005 involving children under the age of 21 months and the ingestion of foreign objects. The cases were categorized by the product associated with the ingestion injury. The ten product categories with the highest estimates are shown in Table 3 on the next page. Of the 3,241 cases analyzed, 203 cases had two associated products.

Table 3: Top Ten Swallowed Products by Children 21 Months Old and Younger, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	31,745	41.0%	1,418	12.27%
1819	Nails, screws, tacks, or bolts	6,248	8.1%	210	10.51%
1616	Jewelry	4,628	6.0%	223	15.29%
5004	Toys, not elsewhere classified	3,998	5.2%	148	21.17%
1729	Christmas decorations (nonelectric)	3,733	4.8%	133	16.06%
0884	Batteries	2,818	3.6%	138	14.42%
1682	Hair curlers, curling irons, clips, and hair pins	2,582	3.3%	122	16.29%
1137	Paper products	2,099	2.7%	76	18.45%
1807	Floors or flooring materials[3]	2,043	2.6%	73	22.59%
1650	Desk supplies	1,823	2.4%	73	16.80%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

From 2000 to 2005 staff found 3,677 NEISS cases involving ingestion of foreign objects and children aged 22 months through three years old. Based on these 3,677 cases there were an estimated 92,451 emergency-room treated injuries from 2000 to 2005 involving a child between the ages of 22 months and three years and the ingestion of a foreign object. The cases were categorized by the product associated with the ingestion injury. The six product categories with the highest estimates are shown in Table 4. Only six product categories are shown in Table 4 due to low, and therefore unreportable, estimates for all other product categories. Note that of the 3,677 cases analyzed, 131 cases had two associated products.

Table 4: Top Six Swallowed Products by Children 22 Months through Three Years Old, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	56,587	61.2%	2,293	8.86%
5004	Toys, not elsewhere classified	6,160	6.7%	238	13.37%
1819	Nails, screws, tacks, or bolts	5,204	5.6%	167	12.62%
0884	Batteries	3,696	4.0%	163	13.64%
1616	Jewelry	3,530	3.8%	167	12.41%
1354	Marbles	2,689	2.9%	107	20.45%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

[3] Note that in the case of product code 1807 (floors and flooring materials), the children are not actually swallowing parts of floors, but rather objects that were found on the floor.

From 2000 to 2005 staff found 2,850 NEISS cases involving ingestion of foreign objects and children aged four through six years old. Based on these 2,850 cases there were an estimated 71,444 emergency-room treated injuries from 2000 to 2005 involving a child between the ages of four and six years and the ingestion of a foreign object. The cases were categorized by the product associated with the ingestion injury. The six product categories with the highest estimates are shown in Table 5. Only six product categories are shown in Table 5 due to low, and therefore unreportable, estimates for all other product categories. Note that of the 2,850 cases analyzed, 77 cases had two associated products.

Table 5: Top Six Swallowed Products by Children Four through Six Years Old, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	41,323	57.8%	1,685	8.13%
5004	Toys, not elsewhere classified	5,345	7.5%	211	11.99%
1354	Marbles	4,573	6.4%	153	16.59%
1616	Jewelry	4,120	5.8%	162	12.39%
1819	Nails, screws, tacks, or bolts	2,722	3.8%	119	13.03%
0884	Batteries	2,555	3.6%	120	20.05%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

From 2000 to 2005 staff found 2,226 NEISS cases involving ingestion of foreign objects and individuals aged seven through 18 years old. Based on these 2,226 cases there were an estimated 61,313 emergency-room treated injuries from 2000 to 2005 involving a child between the ages of seven and 18 years and the ingestion of a foreign object. The cases were categorized by the product associated with the ingestion injury. The ten product categories with the highest estimates are shown in Table 6 on the next page. Note that of the 2,226 cases analyzed, 144 cases had two associated products.

Table 6: Top Ten Swallowed Products by Individuals Seven through 18 Years Old, 2000-2005

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	18,113	29.5%	749	10.46%
1616	Jewelry	7,581	12.4%	255	12.08%
1819	Nails, screws, tacks, or bolts	4,014	6.5%	140	11.63%
884	Batteries	2,984	4.9%	106	19.42%
5004	Toys, not elsewhere classified	2,771	4.5%	100	14.39%
1685	Pens and pencils	2,750	4.5%	93	15.73%
1650	Desk supplies	2,571	4.2%	80	20.10%
1103	Self-contained openers[4]	2,349	3.8%	82	17.43%
1669	Pins and needles	2,037	3.3%	77	16.70%
1354	Marbles	1,941	3.2%	71	18.19%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

IV. Summary

Coins are by far the most common consumer product ingested, accounting for almost half of the estimated injuries (Table 2) when viewed across age. With respect to age quartiles, the highest percentage of injuries due to ingestion of coins is in the 22 month- through three year-old age group (61.2%) and lowest in the seven through 18 year-old age group (29.5%). The next three most commonly ingested product categories are jewelry; toys, not elsewhere classified; and nails, screws, tacks or bolts. These three are always in the top five regardless of age category. The only other product categories to make it into the top five in any age category are batteries, marbles, and nonelectric Christmas decorations.

As jewelry was specifically mentioned in the Sierra Club petition, Table 7 provides a summary of estimated emergency-room treated jewelry ingestion injuries, with confidence intervals.

Table 7: Emergency-Room Treated Jewelry Ingestions by Age Group, 2000-2005

Age Range	Estimate	Percent of Total	Sample Size	C.V.	95% Confidence Interval
0 – 21 months	4,628	23.3%	223	15.29%	3,241 – 6,015
22 months – 3 years	3,530	17.8%	167	12.41%	2,671 – 4,338
4 – 6 years	4,120	20.7%	162	12.39%	3,119 – 5,120
7 – 18 years	7,581	38.2%	255	12.08%	5,787 – 9,357
Total	19,859	100.0%	807	10.42%	15,802 – 23,915

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Saftey Commission, September 2006

[4] Note that product code 1103 (self-contained openers) refers to pop-top openers from soda cans.

References

Schroeder T, Ault K. *The NEISS Sample (Design and Implementation).* U.S. Consumer Product Safety Commission. 2001.

Sierra Club. "Citizen Petition to CPSC and EPA Regarding Lead in Consumer Products, Especially Toy Jewelry." 17 April 2006.

TAB E

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: October 16, 2006

TO : Kristina M. Hatlelid, Ph.D, M.P.H., Lead Jewelry Project Manager

THROUGH: Hugh McLaurin, Associate Executive Director
Directorate for Engineering Sciences
Robert B. Ochsman, Ph.D.
Director, Division of Human Factors (ESHF)

FROM : Jonathan D. Midgett, Ph.D.
Engineering Psychologist, ESHF

SUBJECT : Age Determinations for Children's Jewelry

Background

The Sierra Club petitioned the Commission to address deaths and injuries caused by lead in consumer products, especially jewelry intended for children. This memorandum* describes the characteristics used to distinguish children's jewelry from adult jewelry and provides a tentative estimate of mouthing behaviors in childhood.

The Scope of the Petition

The petitioners refer to "toy jewelry," however Human Factors (ESHF) staff generally considers "toys" as a distinct category within children's products. We believe the petitioners want to address any jewelry intended for children, based on their definition of toy jewelry on page 3 of the petition letter of April 17, 2006 which states, "any item that serves a decorative but no or minimal functional purpose that is valued at less than $20 per item." This would include jewelry for normal wear, as well as toys.

Age Appropriateness

When evaluating toys and other juvenile products, staff determines the age of the children that would find the item appealing. Making age determinations requires considering many relevant factors; whether the manufacturer's stated age recommendation—such as on a label—is a reasonable one; the toy's advertising, promotion, and marketing; and whether the toy is commonly recognized as being intended for children of a particular age range. Age

* These comments are those of the CPSC staff. They have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

determinations match the features of a toy to the characteristics of children in a particular age group.

Making Age Determinations for Jewelry

CPSC staff's Age Determination Guidelines (2002) refer to jewelry in the section on "Dress-Up Materials" (p. 95-103). The youngest children mentioned are 18-months old. Children progress from enjoying brightly colored, robust, easily donned items, like stretch bracelets and necklaces with breakaway clasps, to more complicated, adult-like items. By 6 years, the Guidelines suggest that children's dexterity has progressed to allow using detailed clasps. At this age, the Guidelines say:

> Appealing costumes, accessories, and kits are more realistic looking in size, detail, and function, and may include small beads for stringing jewelry, hand looms, hand sewing to make clothes for dolls and puppets, spool knitting, braiding, and simple needlepoint. They have the fine-motor dexterity to tie multiple knots, like what would be needed for macramé, braiding and knitting. They can work a basic loom, twist plastic strands, string small beads, and use fragile art media like glass and pottery beads or shrinkable colored plastic to make their own accessories (for example, friendship bracelets, necklaces, and pins) and costumes, and enjoy doing so. (p. 99)

By age 9, "children place a greater and greater premium on authenticity with all costumes, accessories, and kits, so they often closely resemble adult versions." (p. 99). Children's regular clothing will reflect this desire for adult-looking clothes, too. Jewelry intended for pre-teens (9 – 12 year olds) is generally indistinguishable from adult jewelry. For this reason, the age grading that denotes adult jewelry could be set at "9+." If the sample has any features that would be attractive to children, such as the features described below, the age determination would be less than 9 years, possibly as low as 18 months.

Key Features of Jewelry Affecting Age Determinations

Jewelry age grading requires a strong emphasis placed on marketing (location, packaging), ease of use (dexterity requirements for donning and doffing, size), appearance (i.e., coloring, level of detail, design themes, etc.), and cost. These features are not always equally weighted, nor are they always prioritized in this order. An item's features are considered according to how *behaviorally prominent* the feature is within the presentation of the item during both marketing and use.

Marketing

In the case of jewelry marketed in vending machines, the likelihood of purchase by children is weighted more heavily than with jewelry marketed over-the-counter. Some adult-sized vending machine jewelry will receive an age determination of 6+ because it is sold in a manner that gives easy access to children in a place normally associated with toys. Ease of purchasing is a behaviorally important feature that overshadows other features when making the age determination. Conversely, if an adult clothing store markets the item, this fact may overshadow other features normally associated with children's jewelry. For instance, fashion statements

involving classic cartoon characters or otherwise childish features are sometimes appropriately expected to be intended for adult use only.

An item's packaging can also help differentiate children's items. Images of users or other symbols on the packaging provide important features for associating the jewelry with adults or children. In addition, jewelry that comes packaged with other items may receive a different age determination than it would have received on its own based on association with other items, for instance jewelry packaged with toys.

Ease of Use

Another behaviorally prominent feature is the ease with which an item can be put on and taken off. Jewelry requiring delicate handling or intricate manipulation of parts will require more dexterity to use and so will get an older age determination. For instance, one-piece or stretch bracelets and necklaces usually receive a lower age grade than items with clasps because even 2 year olds can put them on. Extremely small clasps get an older age grading because they require more fine motor dexterity to use. Bracelets and necklaces are more difficult to grade by size because size is a less important feature for use than it is for a ring, for example.

Appearance

Other features that help differentiate children's from adult's jewelry are appearances, such as coloring, level of detail and design themes. Chunky, bold shapes and bright, primary colors are usually (but not necessarily) intended for children. Any graphic theme that is based in concrete representations of the world, like flowers, plants, animals, machines, faces, cartoon characters, or other graphics of interest to children are less likely to be intended for adults. Jewelry for adults may (but not necessarily) have more stylized, abstract designs that children won't comprehend or that appeal to an older audience, like fine details, intricate sculpting, culturally or religiously significant symbols (crosses, peace signs, political icons), vernacular graffiti (XOXO, dollar signs), or multiple materials including metal and semi-precious stones. Plain, dull, matte, natural and subtle hues are less attractive to younger consumers.

Cost

An item's cost may sometimes determine whether consumers allow children access to it. While the cost of an item is routinely considered, it has historically provided only a small part of the considerations weighed in making an age determination for a product. Cost is less relevant than the previous features because the distinction between "cheap" and "expensive" remains relative. The petitioners mentioned an upper threshold of $20 to distinguish children's jewelry; however, the CPSC has announced recalls of jewelry that cost much more than $20 because the jewelry contained lead.

Mouthing Behavior

While children may mouth objects frequently, even adults regularly mouth objects such as writing implements, hair, fingernails, necklaces, or clothing drawstrings during brief moments of

distraction or worry. How often these behaviors occur in the general adult populace has not been studied in detail, as far as ESHF staff is aware; however, children's mouthing behaviors have been researched.

A mouthing study (Kiss, 2001) was contracted by CPSC to quantify phthalate exposures in children and included 169 randomly recruited participants and 18 observers with high inter-rater reliability. This research provides a baseline average of mouthing events that can be expected for 3-year olds and gives a reasonable estimate of the most actively mouthing consumers. Over 20,000 distinct mouthing events were observed and categorized according to object-type. The mouthing events in the category "fingers/hands" produced a mean of 1.2 minutes of mouthing per hour (SD= 2.5 min.; max.= 13.6) for 30-36 month old children (n= 30). This included a mean of 6.3 distinct mouthing events per hour for this age group (SD= 6.4 events; max.= 30 events) (Greene, 2001). Interestingly, the mean for all the children aged 3 to 36 months was 9.7 events/hour (SD= 9; max.= 55; median= 7.3). Note the high variation observed in this study; one subject mouthed something 55 times in an hour, though the average subject only mouthed something 10 times in the same period. Tulve, et al (2002) studied children up to 5 years old and reported a mouthing frequency as high as 48 events per hour.

The Department of Trade and Industry (DTI) in the UK studied mouthing behaviors of children up to age 5 years (Smith & Norris, 2003). They found that mouthing of fingers and hands increases until age 5 and that the maximum total time spent mouthing at 5 years was 10 hours per day. This number is so high because they included the time spent mouthing fingers. The mean total mouthing time for all categories was 59 minutes. The estimated maximum daily mouthing of "toys" and "other objects" by 5-year olds was estimated at 11 and 52 minutes, respectively. The mean was about 2 minutes for "toys" and about 10 minutes for "other objects."

Freeman, et al (2001) studied mouthing rates of 3- to 12-year old children. More than a third of the 10- to 12-year old group reported "often putting nonfood items in their mouth." They reported almost a three-fold greater hand-to-mouth frequency during indoor activities than during outdoor play. Observations confirmed an average rate of hand-to-mouth activity as high as 8.1 events per hour (+/- 5.5 events) for girls.

These studies give an indication of the complexity of describing estimates of mouthing duration during childhood. Findings have ranged from as few as 1.2 minutes/hour to 10 hours a day, depending on age and objects considered. The Environmental Protection Agency's (EPA) Child Specific Exposure Factors Handbook (Interim Report) (2002) recommends exposure estimates use a mean daily mouthing time of 46 minutes for children up to 5 years old. For children up to 6 years old, the EPA recommends exposure estimates use a mean object-to-mouth contact frequency of 16.3 contacts per hour and 49 contacts per hour for total daily mouthing.

Assuming the 95th percentile mouthing rate is higher than the EPA's recommended mean daily rate of 46 minutes, easily twice as high (probably more), then an *estimated daily maximum* mouthing time for 6 year olds would be about an hour and a half. This is comparable to adding the DTI observations for "toys" and "other objects," which yields about an hour. (Note that this assumes that their observation of 10 hours of mouthing in one day is an extreme outlier.) Older children would be expected to mouth with slightly less total duration each year until adolescence

when they achieve an adult-like rate. At any rate, the incidents of ingesting jewelry in the past show that some accidental (and possibly purposeful) ingestions of non-food items occasionally occur during mouthing of jewelry.

Conclusion

Children begin to choose adult-like jewelry during the late, pre-teen years. Differentiating children's from adult's jewelry requires weighing behaviorally prominent features of the product, including, but not limited to, marketing, ease of use, appearance, and cost. Consumers are likely to mouth objects like jewelry occasionally, increasing the likelihood of ingestion.

Responses to Public Comments

Age 6 and Under

The Fashion Jewelry Trade Association (CH 06-3-2) and the Coalition for Safe Ceramicware and the International Crystal Federation (CH 06-3-8) recommend restricting the scope of the petition to jewelry intended for children 6 years old and younger. The City of New York (CH 06-3-9) recommends including costume jewelry in the scope of the proposed regulation even if it is marketed to teenagers or adults. These are both marketing-based approaches to determining the age appropriateness of a given product. Staff prefers to consider multiple characteristics of products when making age determinations, such as ease of use, appearance, and cost, in addition to marketing information. Jewelry intended for children 9 years old and younger is distinguishable from adult jewelry when a comprehensive set of features is considered.

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TAB F

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: October 6, 2006

TO Kristina M. Hatlelid, Ph.D., M.P.H., HS
Project Manager, Petition to Ban Lead-Containing Children's Jewelry

THROUGH: Gregory Rodgers, Ph.D., AED, EC GBR

Deborah V. Aiken, Ph.D., Senior Staff Coordinator DVA

FROM : Soumaya M. Tohamy, Ph.D. SMT

SUBJECT : Market information on children's jewelry

Attached is the market information on potential manufacturers of children's jewelry and related items.

Market Information on Potential Manufacturers of Children's Jewelry and Related Items*

Soumaya M. Tohamy, Ph.D.
Directorate for Economic Analysis
U.S. Consumer Product Safety Commission

October 6, 2006

*** This analysis was prepared by the CPSC staff, has not been reviewed or approved by, and may not necessarily reflect the views of the Commission.**

Market Information on Potential Manufacturers of Children's Jewelry and Related Items

1. Introduction

In a letter dated April 17, 2006, the Sierra Club petitioned the U.S. Consumer Product Safety Commission to ban lead (more than 0.06 percent by weight) in all toy jewelry. The purpose of this memo is to provide market information on potential manufacturers engaged in the production of children's jewelry (in response to the Sierra Club petition) and to describe the information that may be useful in evaluating a possible regulation.

2. Interim Enforcement Policy

In 2004, CPSC staff learned of an incident involving a child who suffered serious adverse health effects after swallowing a piece of metal jewelry containing lead. Thereafter, CPSC staff collected and tested items of children's metal 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 and conducted voluntary recalls of more than 150 million pieces of children's jewelry. Additionally, in 2005CPSC issued an interim enforcement policy for children's metal jewelry containing lead. The interim policy details the approach that the Office of Compliance will follow in addressing children's metal jewelry containing lead. It is based on the CPSC Federal Hazardous Substances Act and applies to all children's jewelry containing metal.

Under the interim enforcement policy, which became effective on February 3, 2005, CPSC staff first conducts a screening test for an item of jewelry. For example, a necklace may consist of several component types (such as a chain, clasp, pendant, hook, and beads). The screening test would determine the total lead content of each type of metallic component. 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 (ppm)), the staff will not seek any corrective action.

If the screening test shows that the total lead content of any metal component type exceeds 600 ppm, the staff will conduct further testing of that component type using an acid extraction method. The acid extraction method is to 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 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. In making that decision, the staff will

consider 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.

In February of 2006, a Minnesota child died from lead poisoning after swallowing a charm from a bracelet offered as a "bonus" to buyers of shoes. This incident and the 2004 recalls of 150 million metal toy jewelry items led to the Sierra Club petition.

3. Scope of Jewelry for Lead limits

The current CPSC enforcement policy covers all metal jewelry items that are marketed to or for children. Midgett (2006) discusses age determination issues which support the current CPSC policy and lists the key features of jewelry affecting age determinations. These features are marketing (e.g., in vending machines or in sections of a store where toys are sold), ease of use, appearance, and cost.

The Sierra Club petition asks that toy jewelry be defined as any item that serves a decorative but no or minimal functional purpose and is valued at less than $20 per item. It suggests that people are less likely to store such low-cost jewelry in secure containers or out of reach from children. Using a dollar cutoff point may be a problem because not all items whose value is below $20 are intended for children. Similarly, not all items intended for children have a value of less than $20. The current CPSC enforcement policy gives more consideration to marketing, ease of use, and appearance of an item (rather than its cost), because the distinction between "cheap" and "expensive" remains relative (Midgett, 2006).

4. Products and Industries

A. Jewelry Manufacturing Industry

The U.S. jewelry manufacturing industry includes precious and non-precious (costume) jewelry. The U.S. Census Bureau clearly identifies jewelry of silver, platinum, and karat gold as precious. Jewelry clad with precious metal, except silver, is also considered precious. The U.S. Census Bureau does not classify jewelry by age of the user (i.e., children's vs. adult jewelry). The NAICS (North American Industry Classification System) manufacturing codes for jewelry include 339911 (Jewelry (Except Costume) Manufacturing), 339913 (Jewelers' Material and Lapidary Work Manufacturing), and 339914 (Costume Jewelry and Novelty Manufacturing.)

The Jewelry (Except Costume) Manufacturing (339911) category comprises establishments primarily engaged in one or more of the following: (1) manufacturing, engraving, chasing (defined in dictionary.com as decorating by engraving or embossing), or etching precious metal solid or precious metal clad jewelry; (2) manufacturing, engraving, chasing, or etching personal goods (i.e., small articles carried on or about the person, such as compacts or cigarette cases) made of precious solid or clad metal; and (3) stamping coins.

The Jewelers' Material and Lapidary Work Manufacturing (339913) category comprises establishments primarily engaged in one or more of the following: (1)

manufacturing unassembled jewelry parts and stock shop products, such as sheet, wire, and tubing; (2) cutting, slabbing (defined in dictionary.com as rolling metal so that its breadth is at least twice its thickness), tumbling, carving, engraving, polishing, or faceting precious or semiprecious stones and gems; (3) recutting, repolishing, and setting gem stones; and (4) drilling, sawing, and peeling cultured pearls.

The Costume Jewelry and Novelty Manufacturing (339914) category comprises establishments primarily engaged in (1) manufacturing, engraving, chasing, and etching costume jewelry; and/or (2) manufacturing, engraving, chasing, or etching non-precious metal personal goods (i.e., small articles carried on or about the person, such as compacts or cigarette cases). This industry includes establishments primarily engaged in manufacturing precious plated jewelry and precious plated personal goods.

Table 1 shows the value of shipments (domestic production) for all three jewelry manufacturing categories for the years 2002 to 2004. While the value of shipments for non-costume jewelry, jeweler's material and lapidary work, and total jewelry manufacturing is increasing, the value of shipments for costume jewelry has decreased slightly from 2002 to 2004. The share of costume jewelry has declined from 11.3 percent to 10 percent of total jewelry manufactured.

Table 1: Value of (Domestic) Shipments for Jewelry Manufacturing (million $)

Product Category	**2002**	**2003**	**2004**
Jewelry (Except Costume)	5,515	5,804	5,921
Share of Total (%)	74.5	75.2	75.8
Jewelers' Material and Lapidary Work	1,052	1,077	1,108
Share of Total (%)	14.2	14.0	14.2
Costume Jewelry and Novelty Manufacturing	836	839	783
Share of Total (%)	11.3	10.9	10.0
Total	**7,403**	**7,720**	**7,812**

Source: U.S. Census Bureau data.

Table 2 shows the number of establishments producing jewelry in 2002, the most recent year for which detailed data on jewelry manufacturing are available. There were 2,919 establishments producing jewelry in 2002, according to U.S. Census Bureau data. These included 1,962 establishments of jewelry (except costume) manufacturing, 302 establishments of jewelers' material and lapidary work manufacturing, and 655 establishments of costume jewelry and novelty manufacturing.[1] Table 2 also shows the distribution of domestic establishments producing jewelry by employment size. In addition

[1] The corresponding number of firms is 1,875, 313, and 662 respectively. A firm is a business organization consisting of one or more domestic establishments in the same state and industry that were specified under common ownership or control. The firm and the establishment are the same for single-establishment firms. For each multi-establishment firm, establishments in the same industry within a state will be counted as one firm-the firm employment and annual payroll are summed from the associated establishments.

to showing the total, it shows the employment size distribution for the three subcategories: jewelry (except costume) – NAICS code 339911, jewelers' material and lapidary work – NAICS code 339913, and costume jewelry and novelty manufacturing – NAICS code 339914.

Table 2 shows that average employment per establishment for the whole industry is 15.9 employees. Sixty percent of all establishments have one to four employees. The percent of all establishments with less than twenty employees is 84 percent, with an average number of employees of 2.9 per establishment. Costume jewelry manufacturing establishments have a smaller average number of employees per establishment (12.5 employees) than the precious jewelry (except costume) category (16.5 employees). Costume jewelry manufacturing establishments employing less than twenty employees also have a smaller average number of employees per establishment (2.8 employees) than the precious jewelry (except costume) category (4.3). The U.S. Small Business Administration's Office of Advocacy defines a small business as one that is independently owned and operated and not dominant in its fields. A definition for the jewelry and toy manufacturing industries (using all NAICS codes used above) that is used by the Small Business Administration and is less subject to interpretation is a firm with fewer than 500 employees.[2] Using this definition, all but nineteen jewelry firms were considered small businesses in 2002.[3] This represents 99.3 percent of the market ((2850-19)/2850).

In addition to domestic producers, importers could be affected by any action undertaken by the Commission. Table 3 presents the value of U.S. imported jewelry for the years 2002 to 2004. Comparing imports to domestic production reveals that the share of the U.S. jewelry market (defined as domestic production plus imports) that is produced domestically has declined from 26.5 percent in 2002 to 24 percent in 2004.

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[2] *Small Business Size Standards matched to North American Industry Classification System.* United States Small Business Administration. 2006. (http://www.sba.gov/size/sizetable2002.html.)

[3] 2002 County Business Patterns and 2002 Economic Census. (http://www.census.gov/csd/susb/usalli02.xls)

Table 2: Number of U.S. Jewelry Establishments by Employment Size, 2002*

Manufacturing Category	Total	Employment Size of the Establishment							
		1 to 4**	5 to 9	10 to 19	<20	20 to 99	100 to 499	<500	500+
Jewelry (Except Costume) - NAICS Code 339911									
Number of Establishments	1,962	1,162	241	240	1,643	257	57	1,957	5
Percent of Total	100.0%	59.2%	12.3%	12.2%	83.7%	13.1%	2.9%	99.7%	0.3%
Employment^	32,468	2,103	1,656	3,326	7,085	10,092	10,273	27,450	D^^
Annual Payroll ($1000)	1,018,767	59,437	48,406	93,757	201,600	314,613	334,796	851,009	D^^
Average Employment per Establishment	16.5	1.8	6.9	13.9	4.3	39.3	180.2	14.0	D^^
Average Annual Wage	31,378	28,263	29,231	28,189	28,454	31,174	32,590	31,002	D^^
Jewelers' Material and Lapidary Work - NAICS Code 339913									
Number of Establishments	302	188.0	37	30	255	35	12	302	-
Percent of Total	100.0%	62.3%	12.3%	9.9%	84.4%	11.6%	4.0%	100.0%	-
Employment^	5,732	371	252	407	1,030	1,771	2,931	5,732	-
Annual Payroll ($1000)	157,668	9,966	7,186	11,624	28,776	51,617	77,275	157,668	-
Average Employment per Establishment	19.0	2.0	6.8	13.6	4.0	50.6	244.3	19.0	-
Average Annual Wage	27,507	26,863	28,516	28,560	27,938	29,146	26,365	27,507	-
Costume Jewelry and Novelty Manufacturing - NAICS Code 339914									
Number of Establishments	655	408	71	76	555	90	9	654	1
Percent of Total	100.0%	62.3%	10.8%	11.6%	84.7%	13.7%	1.4%	99.8%	0.2%
Employment^	8,167	f	474	1,054	1,528	3,311	1,820	6,659	f
Annual Payroll ($1000)	231,387	D	12,392	26,418	38,810	95,512	43,983	178,305	D
Average Employment per Establishment	12.5	f	6.7	13.9	2.8	36.8	202.2	10.2	f
Average Annual Wage	28,332	D	26,143	25,065	25,399	28,847	24,166	26,777	D
Total									
Number of Establishments	2,919	1,758	349	346	2453	382	78	2913	-
Percent of Total	100.0%	60.2%	12.0%	11.9%	84.0%	13.1%	2.7%	99.8%	0.2%
Employment^	46,367	f	2,382	4,787	7,169	15,174	15,024	37,367	f
Annual Payroll ($1000)	1,407,822	D	67,984	131,799	199,783	461,742	456,054	1,117,579	D
Average Employment per Establishment	15.9	f	6.8	13.8	2.9	39.7	192.6	12.8	f
Average Annual Wage	30,363	D	28,541	27,533	27,868	30,430	30,355	29,908	D

*Source: 2002 Economic Census, Manufacturing Industry Series. Some payroll data for small single-establishment companies with up to 20 employees (cutoff varied by industry) were obtained from administrative records of other government agencies rather than from census report forms. These data were then used in conjunction with industry averages to estimate statistics for these small establishments. "f" indicates 500 to 999 employees. "D" indicates data being withheld to avoid disclosing data of individual companies. Data are included in higher level totals.

^These represent average number of production workers for pay periods including the 12th of March, May, August, and November plus other employees for the pay period including the 12th of March.

** This group includes firms with payroll at any time during the year.

Table 3: Value of U.S. Jewelry Imports (million $)

	2002	2003	2004
Israel	6,090.1	6,336.4	7,422.5
India	3,680.7	3,977.8	4,532.8
Belgium	2,310.4	2,611.8	2,753.6
China	1,232.1	1,522.4	1,881.2
Thailand	908.4	1,008.0	1,157.9
Italy	1,541.1	1,243.5	1,036.0
Hong Kong	862.0	759.0	748.0
South Africa	539.1	709.6	844.2
Mexico	190.1	177.7	321.9
Canada	313.8	332.6	419.1
Turkey	200.4	251.3	373.6
Switzerland	244.7	324.6	309.6
France	150.8	184.0	220.2
Dominican Republic	195.7	204.7	240.4
Indonesia	65.2	73.9	105.5
Austria	86.3	112.2	141.9
United Kingdom	264.8	254.6	202.2
Botswana	22.8	6.0	52.1
Russia	87.9	118.3	151.1
Jordan	11.4	50.0	89.8
All Other	**1,530.39**	**1,477.86**	**1,728.65**
Total Imports	**20,528.2**	**21,736.3**	**24,732.3**
U.S. Domestic Production	7,403.0	7,720.0	7,812.0
Share of total market (%)	26.5%	26.2%	24.0%
Total Market (domestic production + imports)	**27,931.2**	**29,456.3**	**32,544.3**

Source: International Trade Commission and U.S. Census Bureau data. The jewelry industry comprises NAICS codes 339911, Jewelry (Except Costume), 339913, Jewelers' Material and Lapidary Work, and 339914, Costume Jewelry and Novelty Manufacturing.

B. Doll and Stuffed Toy Manufacturing Industry

As the Commission considers the petition, it is important to note that jewelry is sold with/for toys, such as Barbie earrings sold with a Barbie doll or a necklace sold as a set with a stuffed animal (wearing the necklace). There is no NAICS category specifically designated for these accessories, but they are included in the broader category codes: 33993105 (parts for dolls, toy animals, and action figures, including accessories, clothes and playsets for dolls, toy animals, and action figures) and 3399310Y (dolls, toy animals, action figures, and stuffed toys (including parts and accessories), not specified by kind). The value of shipments for these two NAICS codes was $13.6 and $15.8 million respectively in 2002 (the latest year for which data exist for manufacturing

subcategories with 8 digit codes). Trade data are not available at a correspondingly detailed level.

C. Craft Kits and Supplies Manufacturing Industry

Other types of jewelry include beads or other items sold in craft kits. There is no NAICS category specifically designated for jewelry making craft kits, but they are included in the broader category code: 3399326227 (craft kits and supplies, individually packaged and in bulk including beadery, decoupage, embroidery, macramé, and paint by number kits and supplies), excluding glass beads. The value of shipments for craft kits and supplies was 179.8 million dollars in 2002 (the latest year for which data exist for manufacturing subcategories with 8 digit codes). Trade data are not available at a correspondingly detailed level.

5. Possible Benefits and Costs

O'Brien (2006) estimates that jewelry is the second most frequently swallowed item (after coins) by children 18 years old and younger, for the period 2000 to 2005. During that period, there were close to an estimated 20,000 emergency-room treated ingestions by children 18 years old and younger. An estimated 62 percent of all emergency-room treated jewelry ingestions were by children six years old or younger.

Reducing lead content in children's jewelry would be expected to reduce children's exposure to lead. Ingestion of large amounts of lead results in acute lead poisoning, which if left untreated could result in death. Long term exposure to lead impacts children's cognitive and behavioral development and has been documented to lead to lower IQs. (See Matheson (2006) for a lead in jewelry toxicity review.) Grosse *et al.* (2002) estimate an average benefit (in terms of higher IQ points only and based on expected life-time earnings) of $3,720 constant (2000) U.S. dollars for a 1 μg/dL reduction of lead exposure of a two year old. (The range for this estimate is $2,350 to $5,550). Landrigan *et al.* (2002) use somewhat different methodology and have an estimate of $4,197, which falls within the range provided by Grosse *et al.* (2002). Sources of lead poisoning due to consumer products, however, may not be readily ascertained even after extensive testing of a child's environment (Matheson, 2006). Because the incremental contribution of a specific product cannot be isolated from others, assigning a value for and computing benefits of any action may not be possible.

The costs of a possible regulation on the lead content of jewelry are unclear but would depend on the scope of the regulation and the actions that manufacturers would have to take to comply with it. To estimate such costs, staff would consider costs associated with the scope, testing requirements, quality control/quality assurance requirements and record keeping requirements. Staff would also consider alternative metals used in jewelry manufacturing, and additional (material and production) costs that may result from using these alternative metals. Other useful information includes the market share of children's jewelry relative to all jewelry for both precious and costume (non-precious) jewelry, 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, and the distribution of jewelry sales by manufacturing and/or retail price for both precious and costume (non-precious) jewelry.

The CPSC staff would be interested in receiving public comments on ways to specify a possible regulation that would minimize any costs or burdens for small entities, and whether technological developments could reduce the costs of implementing and complying with such a regulation for small entities.

6. Summary and Conclusion

In summary, any CPSC action to regulate lead content in children's jewelry could affect several industries. Almost all of the affected establishments of these industries are considered small businesses. Information that would allow estimating benefits and costs of such a regulation is currently lacking.

References

CPSC Office of Compliance. 2005. *Interim Enforcement Policy for Children's Metal Jewelry Containing Lead.* February.

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TAB G

United States
CONSUMER PRODUCT SAFETY COMMISSION
Bethesda, Maryland 20814

MEMORANDUM

DATE: August 22, 2006

TO : HSHS

Through: Todd A. Stevenson, Secretary, OS

FROM : Martha A. Kosh, OS

SUBJECT: Petition Requesting Ban on Lead Toy Jewelry

ATTACHED ARE COMMENTS ON THE CH 06-3

COMMENT	DATE	SIGNED BY	AFFILIATION
CH 06-3-1	6/15/06	Simon Wynn Asst. Attorney General	State of New York 120 Broadway, 26th Fl New York, NY 10271
CH 06-3-2	7/26/06	Michael Gale Exec. Director	Fashion Jewelry Trade Association 1486 Stony Lane North Kingstown, RI 02852
CH 06-3-3	7/28/06	Eileen Ouellette President	American Academy of Pediarics Dept. of Federal Affairs Homer Bldg, Suite 400N 601 13th St, NW Washington, DC 20005
CH 06-3-4	8/15/06	Nancy Cowles Exec. Director	Kids In Danger 116 W. Illinois St. Suite 5E Chicago, IL 60610
CH 06-3-5	8/15/06	Joseph Ponessa Extension Specialist and Professor	Housing, Indoor Environments and Health Rutgers University New Brunswuck, NJ
CH 06-3-6	8/15/06	Elizabeth O'Brien	United Nations Assoc'n of Australia P.O. Box 161 Summer Hill NSW 2130 Australia

CH 06-3-7	8/16/06	Patrick MacRoy Epidemiologist	City of Chicago Depart. of Public Health Childhood Lead Poisoning Prevention Program 2nd Fl 2133 West Lexington St Chicago, IL 60612
CH 06-3-8	8/18/06	Michael Kershow Counsel to the Coalition for Safe Ceramicware and the International Crystal Federation	Kelley Drye Collier Shannon 3050 K ST, NW, Suite 400 Washington, Dc 20007
CH 06-3-9	8/18/06	Deborah Nagin Director	The City of New York Dept of Health & Mental Hygiene 253 Broadway 11th fl, CN-58 New York, NY 10007
CH 06-3-10	8/18/06	Olivia Farrow Asst. Health Commissioner	City of Baltimore Baltimore City Health Department Division of Environmental Health 210 Guilford Ave, 2nd fl Baltimore, MD 21202
CH 06-3-11	8/11/06	Donald Mays Sr. Director	Consumers Union Product Safety and Consumer Sciences Consumers Union/Consumer Report 101 Truman Ave. Yonkers, NY 10703
CH 06-3-12	8/21/06	Lisa Madigan Atty.	State of Illinois 100 W. Randolph St. 11th floor Chicago, IL 60601
CH 06-3-13 **Rec'd 8/29/06**	8/16/06	Ruth A. Norton Exec. Director	Coalition to End Childhood Lead Poisoning 2714 Hudson St. Baltimore, MD 21224

CH 06-3-14	7/25/06	Warren Porter	10434 Kardwright Ct. Montgomery Village, MD 20886
CH 06-3-15	8/31/06	Mary J Brown Chief Lead Poisoning Prevention Branch	Department of Health and Human Services Centers for Disease Control and Prevention 4770 Buford Highway Mailstop: F-40 Atlanta, GA 30341

TAB H

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: November 28, 2006

TO : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences, Directorate for Health Sciences

FROM : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

SUBJECT : Response to Public Comments on Petition HP 06-1*

Introduction

The U.S. Consumer Product Safety Commission (CPSC) received a request from the Sierra Club dated April 17, 2006, regarding lead in consumer products, especially toy jewelry. This request was docketed under the Federal Hazardous Substances Act (FHSA) as Petition No. HP 06-1 on May 16, 2006.

CPSC received public comments from fifteen organizations and individuals in response to the notice published in the Federal Register on June 20, 2006 (71 FR 35416). This memo provides a summary of those submissions and the staff's responses to them. The index of the public comments on the petition is in Tab G. Six comments were received from governmental entities: State of New York (CH 06-3-1), City of New York Department of Health and Mental Hygiene (CH 06-3-9), City of Chicago Department of Public Health Childhood Lead Poisoning Prevention Program (CH 06-3-7), Baltimore City Health Department Division of Environmental Health (CH 06-3-10), State of Illinois (CH06-3-12), and the Centers for Disease Control and Prevention (CH 06-3-15). Five comments were received from organizations: American Academy of Pediatrics (CH 06-3-3), Kids in Danger (CH 06-3-4), the LEAD Group (Australia) (CH 06-3-6), Consumers Union (CH 06-3-11), and Coalition to End Childhood Lead Poisoning (CH 06-3-13). Two individuals provided comments, Joseph Ponessa, Ph.D. (CH 06-3-5), and Warren Porter (CH 06-3-14). One comment was received from the Fashion Jewelry Trade Association (CH 06-3-2), and one comment represented two trade associations, the Coalition for Safe Ceramicware and the International Crystal Federation (CH 06-3-8).

Most of the commenters supported the petitioner's requests, although several commenters would expand its scope. The two comments from the trade associations did not entirely support the petition, but they did not directly oppose it. While these two commenters both agreed that children should not be exposed to lead from children's products, they disagreed with the petitioner about the types of products that should be considered under a potential rule.

*These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

Discussion

Comment: The Interim Enforcement Policy does not work; a mandatory standard is necessary to eliminate lead from children's products.

Several commenters stated that the CPSC Interim Enforcement Policy for Children's Metal Jewelry Containing Lead is insufficient to protect children from hazardous jewelry (CH 06-3-1; CH 06-3-2; CH 06-3-3; CH 06-3-4; CH 06-3-10; CH 06-3-14). Several commenters pointed to the occurrence of recalls as evidence that the policy does not work. Two commenters (CH 06-3-1; CH 06-3-10) also raised the possibility that while individual parts of a jewelry item could conform to the policy, an ingestion of more than one piece could result in an excess lead exposure. Two commenters (CH 06-3-9; CH 06-3-11) perceive the CPSC Interim Enforcement Policy as voluntary guidance and claim that firms are not sufficiently motivated to ensure that lead is removed from children's products without a mandatory standard.

CPSC Staff Response:

The staff disagrees with the commenters' characterizations of the Interim Enforcement Policy. The Interim Enforcement Policy provides firms information about regulation of products under the Federal Hazardous Substances Act and states the approach that CPSC's Office of Compliance will follow in addressing children's metal jewelry containing lead. It provides detailed information about the potential hazards of lead-containing children's metal jewelry, and provides specific methods that may be used in assessing products for the presence of lead hazards.

The specific provisions of the policy were determined to be reasonable and protective based on the available information, and the results of laboratory analyses of lead-containing children's metal jewelry. The CPSC staff believes that the policy provides valuable information to manufacturers, importers, distributors and retailers and can only serve to improve the safety of children's metal jewelry. The staff does not consider the occurrence of recalls as evidence that the policy does not work. Most of the recent recalls were of products that entered the market before the Interim Enforcement Policy was put in place, and the staff believes that the recall process is an important mechanism for removing hazardous products from the market.

Comment: Firms should be required to have products independently tested before offering them for distribution.

One commenter (CH 06-3-1) stated that testing for lead in products should be required before products can be sold because testing is less costly for the public and manufacturers than exposure to dangerous products and large-scale recalls.

CPSC Staff Response:

Product test requirements are among the options that could be considered by the Commission if it grants the petition and directs the staff to proceed with rulemaking.

Comment: A CPSC regulation should be the same as California's.

One commenter (CH 06-3-2) stated that CPSC should adopt the California lead standards for costume and children's jewelry for several reasons. The commenter claims that these standards have the effect of establishing national standards since firms do not have separate distribution systems for California versus other states. The commenter also claims that the

California standard is preferable from a technical standpoint; *i.e.*, it is based on total lead content which can be determined relatively inexpensively, quickly, and reproducibly for components before finished pieces are assembled. This commenter also claims that the CPSC staff's acid extraction method causes galvanic corrosion that is not reflective of actual product use or even foreseeable misuse.

CPSC Staff Response:

Federal regulations must be based on the applicable statutes administered by the Commission, *e.g.*, the Federal Hazardous Substances Act. A federal standard would generally preempt non-identical state or local requirements.

Regarding the comments concerning the acid extraction test accompanying the CPSC Interim Enforcement Policy for Children's Metal Jewelry Containing Lead, the staff notes that the test is based on similar methodology in ASTM D5517 and F963, used by industry for many years to assess lead and other heavy metals in art materials and the surface coatings of toys. The ASTM test methods entail extraction of samples in a shaken suspension in 0.07 N hydrochloric acid after grinding, cutting, or otherwise finely dividing the sample, which would tend to maximize the extractability of the lead. In contrast, the CPSC staff's methodology, which calls for testing intact items, was chosen to more realistically simulate exposure to products as the consumer experiences them, *e.g.*, a child swallowing a charm from a necklace.

The phenomenon of "galvanic corrosion" refers to the process where at least two different metals are in electrical contact while exposed to an electrolytic solution (such as salt water or acid), leading to one of the metals becoming the anode in a galvanic cell, while another becomes the cathode. The anode metal will corrode at an accelerated rate, while the cathode metal will corrode at a reduced rate due to the galvanic coupling. In the case of the staff's acid extraction test, a piece of children's metal jewelry is immersed in 0.07 N hydrochloric acid in a flask or beaker, with shaking, at 37° C for 6 hours. Although lead-containing jewelry typically consists of at least two different metals, which may become galvanically coupled, the staff considers the occurrence of galvanic corrosion to be reflective of the foreseeable situation of a swallowed jewelry item being submerged in stomach acid at body temperature.

Comment: Several comments addressed the types of products that should or should not be regulated.

The petitioner's request focused on "any toy jewelry containing more than 0.06% lead by weight for which there is a reasonably foreseeable possibility that children could ingest," with a value of less than $20 per item.

Lead Content

Nearly all of the commenters agreed with the petitioner that children's jewelry should contain no more than 0.06 percent lead. Several commenters (CH 06-3-3; CH 06-3-6; CH 06-3-13) also agreed with the petitioner that the 0.06 percent limit should be considered temporary or interim while a lower limit is considered since even that level could be harmful to children. One commenter (CH 06-3-8), however, disagreed with the petitioner, and argued that accessibility of the lead, rather than lead content, is appropriate for regulation.

Age

The two industry commenters (CH 06-3-2; CH 06-3-8) suggested that products for children aged six years and under should be regulated. These two commenters also wrote that jewelry items made with certain materials (e.g., glass, crystal, ceramic) should not be regulated because they do not believe such items would be considered children's jewelry.

Price

One commenter (CH 06-3-8) did not agree that a dollar amount (*e.g.*, the $20 limit suggested by the petitioner) is an appropriate way to define children's products.

Products

One commenter from a city health department (CH 06-3-9) stated that a regulation should cover any costume jewelry that would be available to children. This commenter also stated that plastic items should be included in a regulation. One commenter (CH06-3-15) mentioned that ingestion of the items is not necessary for exposure as handling and mouthing could result in elevated lead exposure, as well; and several commenters (CH 06-3-4; CH 06-3-5; CH 06-3-11; CH 06-3-12) stated that lead should be eliminated from all children's products or all mouthable products, not just ingestible jewelry. Two commenters (CH 06-3-2; CH 06-3-8) wrote that jewelry items made with materials such as glass, crystal, ceramic, or plastic should not be regulated because those materials would not be hazardous.

CPSC Staff Response:

The staff agrees that there are several factors concerning the characteristics and types of products that could be considered in regulating children's jewelry if the Commission grants the petition and directs the staff to proceed with rulemaking.

Lead Content

Testing by the CPSC staff indicates that the extractability of lead from children's metal jewelry is strongly associated with the lead content of items. Further, because testing for lead content in products is simpler and more straightforward than assessing extractability, the staff believes that limiting the lead content of children's metal jewelry could be an efficient and effective way to prevent excess lead exposure in children. Based on the available data, the staff believes that restricting the lead content of children's metal jewelry to no more than 0.06 percent by weight may be appropriate to protect children from the adverse effects of lead.

Age

Excess lead exposure and subsequent adverse effects may occur in children of all ages, although young children draw the most attention in lead poisoning prevention. The staff believes that jewelry intended for children older than six years, in addition to young children, could be considered in determining which products are regulated as lead hazards since we believe that defining products for the purpose of regulation or enforcement too narrowly could continue to place many children at risk from excess lead exposure. At this time, the staff has no information about whether children's jewelry includes materials such as crystal or ceramic.

Price

The staff has concluded that cost is usually only a small part of the considerations weighed in determining the age appropriateness of a product. It is not clear to the staff that all jewelry valued at less than $20 should be considered to be children's jewelry, or that a $20 limit includes all currently available children's jewelry.

Products

Up to now, the staff has focused on children's metal jewelry because the available data indicate that such products could be hazardous due to their lead content and potential for exposure. The staff could assess lead hazards of other types of products at such time as data become available.

Comment: Several commenters expressed concern about the determination of what level of lead exposure constitutes a product hazard.

Five commenters (CH 06-3-1; CH 06-3-3; CH 06-3-9; CH 06-3-10; CH 06-3-12), referring to the CPSC Interim Enforcement Policy for Children's Metal Jewelry Containing Lead, questioned the staff's determination that a blood lead level in a child of 10 micrograms of lead per deciliter of blood (10 µg/dL) should be used as the level of concern with respect to lead poisoning from consumer products. These commenters noted that there is no known lower exposure threshold for adverse effects of lead.

CPSC Staff Response:

The staff believes that our approach to assessing the hazards of lead exposure from children's jewelry is appropriate, even in light of the evidence that there is likely no "safe" level of exposure to lead.

Regulating lead in products under the Federal Hazardous Substances Act (FHSA) requires a determination that the products expose children to quantities of lead that may cause substantial illness under reasonably foreseeable conditions of handling or use, including ingestion. For years, the staff has used 10 µg/dL, the level of concern used by the Centers for Disease Control and Prevention (CDC) and other federal agencies, as its level of concern with respect to lead poisoning (substantial illness) from consumer products. This level was established by the CDC in 1991[1] and is still the level cited by the CDC in its most recent statement[2] on childhood lead poisoning. The CDC statement acknowledges the evidence of adverse health effects in children with blood lead levels below 10 µg/dL, but it also states that the effects of lead may be "subtle" and that other influences on children's health "make isolating the effect of lead or predicting the overall magnitude of potential adverse health effects exceedingly difficult."[3] Although the dose-response relationship for adverse effects of lead has not been unambiguously characterized, it is clear that lower levels of lead exposure are associated with fewer and less severe effects than exposure at higher levels.

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[1] Centers for Disease Control (CDC). 1991. Preventing Lead Poisoning in Young Children.

[2] Centers for Disease Control and Prevention (CDC). 2005. Preventing Lead Poisoning in Young Children.

[3] CDC. 2005. p. 2.