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

BALLOT VOTE SHEET

DATE: FEB 10 2011

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF
Kenneth R. Hinson, Executive Director KRH

FROM: Hyun Sun Kim, Attorney HSK for HSK

SUBJECT: Petition HP10-2; Request for Regulations on Cadmium

BALLOT VOTE Due: FEB 16 2011

Attached is a briefing package from CPSC staff concerning a petition submitted by the Empire State Consumer Project, the Sierra Club, the Center for Environmental Health, and Rochesterians Against the Misuse of Pesticides regarding cadmium in toy metal jewelry. Staff recommends that the Commission defer its decision on the petition for six months and direct staff to participate in the ASTM F15.24 subcommittee to develop a voluntary standard addressing accessible cadmium from children's metal jewelry, and to work with the ASTM F15.22 subcommittee on the ASTM F963 standard with respect to toy jewelry (Defer Option II). If the Commission votes to defer its decision for six months, at the end of the six month period staff will provide the Commission with an update on the progress of the voluntary standards for children's jewelry and toy jewelry. At that time, the Commission could make a determination to continue to defer its decision on the petition and proceed with the voluntary standards process or to pursue other Commission action.

Please indicate your vote on the following options.

I. Grant the petition.

_____ _____
(Signature) (Date)

(a) Direct staff to draft an Advance Notice of Proposed Rulemaking.

_____ _____
(Signature) (Date)

RH 2/10/2011

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

(b) Direct staff to draft a Notice of Proposed Rulemaking.

_____ _____
(Signature) (Date)

II. Defer the petition for six months and direct staff to participate in the ASTM F15.24 subcommittee to develop a voluntary standard addressing accessible cadmium from children's metal jewelry, and to work with the ASTM F15.22 subcommittee on the ASTM F963 standard with respect to toy jewelry.

_____ _____
(Signature) (Date)

III. Deny the petition.

_____ _____
(Signature) (Date)

IV. Take other action (Please specify).

_____
_____
_____
_____

_____ _____
(Signature) (Date

Attachment:

Staff Briefing Package: Petition HP10-2 Requesting Restriction of Cadmium in Toy Jewelry from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences, February 2011.

Staff Briefing Package

Petition HP 10-2
Requesting Restriction of Cadmium in Toy Jewelry

February 9, 2011

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table of Contents

Briefing Memo iii

TAB A: Laboratory Analysis 16

TAB B: Toxicity and Hazard 82

TAB C: Injury Data Analysis 125

TAB D: Human Factors Analysis 134

TAB E: Economic Information 140

TAB F: Public Comments 157

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Briefing Memo

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

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

This document has been electronically approved and signed.

Memorandum

Date: February 9, 2011

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM : Robert J. Howell, 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 10-2 Requesting Restriction of Cadmium in Toy Jewelry

This briefing package presents the U.S. Consumer Product Safety Commission (Commission or CPSC) staff's analysis of the petition requesting restrictions of cadmium in toy jewelry and associated data, and provides a summary of comments received in response to the notice published in the Federal Register (75 FR 51246) and the staff responses to the comments.

Petition HP 10-2

The CPSC received a request from the Empire State Consumer Project, the Sierra Club, the Center for Environmental Health, and Rochesterians Against the Misuse of Pesticides, dated May 28, 2010, regarding cadmium in toy jewelry (Tab A).[1] This request was docketed under the Federal Hazardous Substances Act (FHSA) as Petition No. HP 10-2. A Federal Register notice soliciting comments was published August 19, 2010 (75 FR 51246).

The petition to the CPSC requests that the Commission adopt regulations declaring that any toy metal jewelry containing more than trace amounts of cadmium by weight that could be ingested by children is a banned hazardous substance. If the Commission finds that it lacks sufficient information to determine the appropriate level of cadmium in products, the petitioners request that the Commission, as an interim measure, adopt the maximum levels established for lead. The petitioners assert that they believe toy jewelry is "any item that serves a decorative but no or minimal functional purpose and that is valued at less than $20 per item," because they believe

[1] The request was also addressed to the U.S. Environmental Protection Agency (EPA), asking for certain responses from that agency. The EPA responded to the petitioners with a letter dated August 30, 2010, that said it was granting the request and will propose a rule to require submission of unpublished health and safety studies relevant to the determination on whether a potential hazard exists and whether a product may be a banned hazardous substance under CPSC guidelines. The letter further stated that the EPA would work closely with the CPSC to determine the most effective means of addressing cadmium in toy metal jewelry and to consider initiating additional rulemaking, if necessary.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

that people are less likely to store such low-cost jewelry in secure containers or out of the reach of children.

In addition, the petitioners request a test method that is based on total cadmium content. The petitioners further state that if a requirement is to be based on extractable cadmium, then the test method must account for a child chewing the jewelry before swallowing. They suggest that metal jewelry be cut in half and that the extractability of cadmium from children's metal jewelry be evaluated using a 24-hour acid extraction period. The petitioners also assert that if the CPSC has insufficient information regarding cadmium, it should obtain additional information under the Interagency Testing Commission (ITC) through the Toxic Substances Control Act (TSCA) administered by the U.S. Environmental Protection Agency (EPA) by including metal jewelry in the scope of reporting under section 8(d) of the TSCA, and requiring importers and processers to test toy metal jewelry for cadmium.

Background

Children's Jewelry and Toy Jewelry

The petition requests that the CPSC take action on metal "toy jewelry." Based on the products described in the petition, CPSC staff has interpreted the petition as seeking rulemaking on "children's jewelry," rather than "toy jewelry." Children's jewelry refers to decorative, accessory items, such as necklaces and rings, which are designed and intended for children. Toy jewelry refers to products that might accompany toys, such as dolls and stuffed animals, and to jewelry used in pretend and role play.

The term "children's jewelry" may include toy jewelry, but not all children's jewelry is toy jewelry. Because toy jewelry is a distinct type of product that currently is subject to the mandatory toy safety standard,[2] the discussions here will distinguish toy jewelry from children's jewelry by using the latter term to refer to all children's jewelry, except toy jewelry. In addition, the petition is focused on metal jewelry. Thus, these discussions concern children's metal jewelry and toy metal jewelry.

As described in detail below, children's metal jewelry containing cadmium is an issue because of the known toxicity of cadmium and because of the potential for products that contain cadmium to result in excessive cadmium exposures to children who ingest small jewelry items.

Current Requirements

The CPSC protects children, and consumers in general, from hazardous exposures to substances such as cadmium 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 provisions of the Consumer Product Safety Improvement Act of 2008, the ASTM International Standard F 963 Consumer Safety Specifications for Toy Safety shall be considered consumer product safety standards issued by the Commission under section 9 of the Consumer Product Safety Act. 15 U.S.C. 2058. Currently, toy jewelry is subject to this standard, which includes requirements for solubility of cadmium from paints and surface coatings of toys.

[2] ASTM F963, Standard Consumer Product Safety Specification for Toy Safety.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Products that are not covered by the ASTM F 963 toy safety standard may be regulated by the FHSA. Under this act, household products that expose children to quantities of cadmium that may cause substantial personal injury or illness under reasonably foreseeable conditions of handling or use, including ingestion, may be considered "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, may be considered a banned hazardous substance. Thus, if a harmful level of cadmium is contained in a children's product, and that cadmium is accessible to children (*e.g.*, through mouthing or ingestion), that product may be considered a banned hazardous substance. 15 U.S.C. §1261(q)(1).

A children's product, in general, is defined as a consumer product designed or intended primarily for children 12 years of age or younger under the Consumer Product Safety Act, as amended by the CPSIA. 15 U.S.C. 2052(a). The Commission published the definition, with additional guidance, at 16 C.F.R. Part 1200.

Previous Commission Activity

Children's jewelry containing cadmium has been the subject of several enforcement actions. In 2010, the CPSC recalled 26 items of jewelry in four separate recalls and issued a warning about two additional jewelry items.[3]

Voluntary Standards

The Commission is required to rely upon voluntary consumer product safety standards, rather than promulgate a mandatory standard, if it determines that a voluntary standard will eliminate or adequately reduce an injury risk, and it determines that there will be substantial compliance with the voluntary standard. 15 U.S.C. 2056(b), 15 U.S.C. 1262(g)(2). However, the Commission may not deny a petition on the basis of a voluntary standard, unless the voluntary standard is in existence at the time of the denial of the petition, the Commission has determined that the voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury identified in the petition, and it is likely that there will be substantial compliance with the standard. 15 U.S.C. 1262(j).

Although an applicable voluntary standard is not in existence yet that addresses the use of cadmium in metal jewelry, staff is aware of, and is participating in, the development of a new voluntary standard for children's jewelry that currently is under consideration by the ASTM International F15.24 subcommittee on Children's jewelry. The subcommittee is considering including in a standard limits for migration of cadmium from jewelry items based on CPSC staff estimates of acceptable intake levels for cadmium. The standard also may include a cadmium content level that could be used for screening products.[4] In addition to CPSC staff, the subcommittee members include representatives from jewelry manufacturers, retailers, children's

[3] Press releases available at: http://www.cpsc.gov/cpscpub/prerel/prhtml10/10127.html; http://www.cpsc.gov/cpscpub/prerel/prhtml10/10227.html; http://www.cpsc.gov/cpscpub/prerel/prhtml10/10287.html; http://www.cpsc.gov/cpscpub/prerel/prhtml10/10297.html; http://www.cpsc.gov/cpscpub/prerel/prhtml10/10162.html.

[4] While CPSC staff have not identified a cadmium content level that is associated with the potential solubility of the cadmium (see "Laboratory Analysis" below and Tab A), a cadmium content screening level could be chosen based on the idea that all of the cadmium that is present in an item would become accessible to a child during use of the product, including ingestion. That is, if an item contains less cadmium than would exceed the exposure limit, then the solubility testing of the product never could exceed the established migration limits.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

products manufacturers, and nongovernmental organizations. The voluntary standard is expected to be completed in 2011.

As discussed above, currently, toy jewelry is subject to the ASTM F 963 toy safety standard, which includes requirements for solubility of cadmium from paints and surface coatings of toys. Recently, a working group under this subcommittee was established to consider aligning ASTM F 963 with international standards for accessible soluble heavy metals in toys. The proposed changes in the ASTM standard would expand the requirements for toys with respect to chemical substances, including cadmium.

Other Standards

Several mandatory standards have been, or are expected to be, established for cadmium in jewelry. These are described below and summarized in Table 1.

California[5]

Legislation signed into law on September 25, 2010 (Senate Bill 929 of 2010), amends California's Health and Safety Code to restrict cadmium, in addition to lead, in children's jewelry to no more than 0.03 percent cadmium (300 parts per million) by weight. The restriction is effective January 1, 2012. Children are defined as six years of age and younger; children's jewelry means jewelry that is made for, marketed for use by, or marketed to, children, and broadly includes products used for ornamentation, such as rings, bracelets, necklaces, hair accessories, watches, brooches, charms, beads, chains, and similar items. The legislation does not apply to toys regulated for cadmium exposure under the Consumer Product Safety Improvement Act of 2008.

Connecticut[6]

Connecticut Public Act 10-113, signed into law on June 4, 2010, restricts cadmium in children's jewelry to 75 parts per million (ppm) by weight, effective July 1, 2014. Children's jewelry is defined as jewelry for children 12 years of age or younger. The act does not address toy jewelry specifically.

Illinois[7]

In 2010, the State of Illinois enacted Public Act 096-1379, the Cadmium-Safe Kids Act, which restricts cadmium in children's jewelry to 75 ppm, as determined through solubility testing for heavy metals, defined in the ASTM International Safety Specification on Toy Safety, ASTM Standard F 963, and subsequent versions of this standard, unless superseded by a federal standard applicable to children's jewelry. The legislation applies to paints and surface coatings and substrate materials of children's jewelry (children under age 12 years), manufactured after July 1, 2011. The legislation does not apply to products regulated for cadmium exposure by ASTM F 963.

---

[5] State of California. Health and Safety Code Sections 25214.1–25214.4.2. Available at http://www.leginfo.ca.gov/calaw.html. Last accessed 1/3/2011.

[6] State of Connecticut. Available at http://www.cga.ct.gov/2010/ACT/PA/2010PA-00113-R00HB-05314-PA.htm. Last accessed 1/3/2011.

[7] State of Illinois. Chapter 430 Public Safety. 430 ILCS 140/ Cadmium-Safe Kids Act. Available at http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=3270&ChapterID=39. Last accessed 1/3/2011.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Minnesota[8]

In 2010, the state of Minnesota enacted a restriction for cadmium in any surface coating or accessible substrate material of metal or plastic components of children's jewelry (for children age six years and younger). The restriction is for soluble cadmium, at 75 ppm, based on ASTM Standard Consumer Safety Specification for Toy Safety (F 963). The law is effective January 1, 2011, for manufacturers and wholesalers, and March 1, 2011, for retailers. The legislation does not apply to toys regulated for cadmium exposure by ASTM F 963.

European Union

An update of the restrictions on marketing and use of cadmium currently given in Annex XVII of the European Community regulation "Registration, Evaluation, Authorisation and Restriction of Chemical substances" is expected in 2011. The amendment would restrict cadmium content of metal jewelry to 100 ppm by weight. The draft amendment does not address specifically toy jewelry or children's jewelry. The restriction would go into effect six months after adoption.

Table 1. Summary of Existing Standards

Jurisdiction	Scope	Standard	Effective Date
California	Children's jewelry; six years of age and younger; does not apply to toys	Total content: 0.03 percent cadmium (300 parts per million) by weight	January 1, 2012
Connecticut	Children's jewelry; 12 years of age or younger	Total content: 75 parts per million (ppm) by weight	July 1, 2014
Illinois	Paints, coatings, and substrate materials of children's jewelry; under age 12 years; does not apply to toys	Soluble: 75 ppm soluble cadmium based on ASTM F 963 toy safety standard, unless superseded by a federal standard applicable to children's jewelry	Manufactured after July 1, 2011
Minnesota	Surface coating or accessible substrate material of metal or plastic components of children's jewelry; age six years and younger; does not apply to toys	Soluble: 75 ppm soluble cadmium based on ASTM F 963	Effective January 1, 2011 for manufacturers and wholesalers; March 1, 2011 for retailers
European Union	Metal jewelry	Total content: 100 ppm cadmium by weight	Expected 2011; six months after adoption of amendments

[8] State of Minnesota. 2010 Statutes 325E.3891 Cadmium in Children's Jewelry. Available at https://www.revisor.mn.gov/statutes/?id=325E.3891. Last accessed 1/3/2011.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Laboratory Analysis (Tab A)[9]

The CPSC's Directorate for Laboratory Sciences, Division of Chemistry staff analyzed 34 items from 20 samples[10] of children's metal jewelry for cadmium content and for cadmium migration. 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 cadmium if a child swallows a piece of jewelry, and a saline solution to assess potential exposures to cadmium if a child mouths or sucks a piece of jewelry. Staff also obtained eight samples of metal wire from different cadmium-containing alloys. The jewelry items contained from about 0.03 percent cadmium by weight to more than 99 percent cadmium. The metal wires contained less than 0.01 percent to 78 percent cadmium.

The results of the extraction testing indicate varying amounts of cadmium migrating from the jewelry and wire samples. For many products, assessment by the CPSC's Health Sciences staff indicates that the potential exposure would exceed acceptable daily intake levels for exposure scenarios involving acute exposure if a child swallows the item, or longer-term exposure if a child mouths the item. Tests of the wire samples also show that increasing the length of the acid extraction period results in increasing migration of the cadmium.

For this small set of samples, the data on extraction of cadmium from jewelry items show that there is no clear relationship between the cadmium content of children's metal jewelry or other metal items and the migration of cadmium from those items. That is, the cadmium content level of the samples did not predict the solubility of the cadmium from those items. However, for many samples, relatively high levels of extraction were associated with higher total cadmium content.

Toxicity and Hazard (Tab B)[11]

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

Humans may be exposed to cadmium from food, drinking water, cigarette smoke, other environmental sources, or particular sources of cadmium, including consumer products. Cadmium has effects on numerous organ systems and cells within the body, principally the kidneys and bones. Although cadmium exposure through inhalation in workers is associated with lung cancer, there is insufficient evidence in humans or experimental animals to determine whether cadmium is carcinogenic from oral exposure. While cadmium is absorbed poorly by the body following exposure, once absorbed, cadmium is excreted from the body very slowly. Absorbed cadmium may be retained, especially in the liver and kidneys, for years or decades.

Documented acute exposures (*i.e.*, single exposure or exposure only during a short period of time) in humans generally have involved exposure to relatively large amounts of cadmium compounds, resulting in severe adverse effects, including death. Acute exposure involving lower doses causes gastrointestinal illness, including nausea, vomiting, and diarrhea. Exposure over

[9] Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials, August 2010.

[10] 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 CPSC's Office of Compliance and Field Operations.

[11] Staff Report on Cadmium in Children's Metal Jewelry, October 2010.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

longer periods of time, with the accumulation of cadmium in the body, is associated with chronic kidney disease and weakening of the bones. Unless an exposure is high enough to cause obvious adverse effects, such as vomiting, cadmium exposure may go undetected. Further, symptoms may not be linked to cadmium exposure, even if they do occur, because the nonspecific symptoms could be attributed to many common illnesses.

Staff's assessment focused on the children likely to participate in the behaviors that could result in excess exposure to cadmium, and who are also the most vulnerable to the effect of the possible exposures. In this case, staff has chosen to consider young children ages two through six years old. Children in this age group still have significant mouthing behaviors, and occasionally may swallow—accidentally or intentionally—small objects.

The assessment of cadmium-containing children's metal jewelry considered both acute exposure (*e.g.* from swallowing) and longer-term exposures (*e.g.* from repeated mouthing behaviors over time).

Based on a study in experimental animals, staff derived an acceptable daily intake level (ADI)[12] for acute exposure of 11 µg/kg/day. For children two to six years old, with an average weight of 18.2 kg (40 pounds), given the 11 µg/kg/day acute ADI, the maximum allowable acute exposure is about 200 µg/day. For longer term exposures, staff used epidemiological studies in humans to derive a chronic ADI for cadmium of 0.1 µg/kg/day. Given the 18.2 kg body weight for children ages two to six years old, and the 0.1 µg/kg/day ADI, the maximum allowable chronic exposure for young children is about 1.8 µg/day.

A key consideration in the toxicology of cadmium is that once absorption of cadmium occurs, it remains in the body, particularly in the kidneys and liver, for many years. Given the very long half-life of cadmium in the body, exposures that occur from swallowing an object or from mouthing an object over time could impact the overall exposure to cadmium from all sources and contribute to the risk of adverse health effects from cadmium exposures.

The staff is not aware of any systematic study or documented cases of exposure to cadmium in children from cadmium-containing jewelry. However, the staff has reviewed cases of lead exposure from lead-containing jewelry items. A four-year-old boy was diagnosed with severe lead poisoning about three to four weeks after swallowing a pendant, which the state laboratory found to contain 38.8 percent lead.[13] Another four-year-old boy died of lead poisoning after ingesting a bracelet charm,[14] which the state public health department laboratory determined to contain about 99 percent lead.[15] A nine-year-old boy experienced increasing levels of lead in his blood over seven days, after he swallowed a ring. 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, testing by CPSC staff of cadmium-containing children's metal jewelry and other metal items (using an acid solution to simulate stomach conditions) indicates that cadmium can migrate from products in amounts that could be associated with adverse health effects in

[12] The ADI is the level of exposure that should not be exceeded to avoid adverse health effects.

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

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

[15] 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.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

children. The data on migration of cadmium from jewelry, along with the known cases of lead exposure from ingested jewelry items described above, support a conclusion that if a child swallows a cadmium-containing product, excess exposure to cadmium may occur if the cadmium migrates from the item and the cadmium is absorbed into the body. In addition, the cases of lead exposure and other data about ingested foreign bodies support the staff's conclusion that the testing conditions for swallowable products must account for the possibility that the ingested item will remain in the gastrointestinal tract for extended periods of time, because the amount of migration of the cadmium from a product generally depends on the length of the exposure to the acid environment of the stomach or the acid solution in the laboratory.

Injury Data Analysis (Tab C)

The CPSC's Hazard Analysis staff analyzed data from the CPSC's 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 C. Staff searched the data for cases involving ingestion of foreign objects by children ages 18 years and younger and, because NEISS is a probability sample, established national estimates for ingestions by age group and product type. For 2000–2009, staff estimated 557,791 emergency room-treated injuries, approximately 75 percent of which were children under age six years. The remaining 24.5 percent of the estimated injuries were reported in youth ages six to 18 years. The objects swallowed most commonly were coins, accounting for nearly half of ingestions, followed by toys not elsewhere classified; jewelry; nails, screws, tacks or bolts; and batteries. Other major product categories involved in ingestions included marbles; desk supplies; items from the category of hair curlers, curling irons, clips, and hair pins; and nonelectric Christmas decorations. Just considering cases involving jewelry, the staff estimated approximately 38,100 total emergency-room treated ingestions, about 63 percent of which were in children under age six years, with the remaining 37 percent in children aged six 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 cadmium cannot be determined from this database.

Human Factors Analysis (Tab D)

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

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. Such products, with features and characteristics indicating attractiveness and appropriateness for children, could result in a CPSC staff age determination of less than nine years. These products could be considered to be designed and intended for children ages 12 years or younger, the definition of a children's product. Between ages nine and 12 years, children begin to choose adult-like jewelry. For some products, then, additional factors, especially packaging and marketing, may indicate the products that will be considered children's products.

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Staff also discussed common behaviors of children by age, focusing on mouthing behaviors that could result in ingestion of a cadmium-containing item and subsequent exposure to cadmium. 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. As presented above in the Injury Data Analysis section and the Toxicity and Hazard section, children of all ages may also swallow objects such as jewelry.

The petitioners 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. Staff believes that cost should only be one of the considerations of age determination, since many pieces of children's jewelry could be more expensive than $20, and many less expensive items may not be intended or suitable for children.

Economic Information (Tab E)

The CPSC's Economic Analysis staff prepared an evaluation of the markets for cadmium and children's jewelry, and a preliminary discussion of the benefits and costs that might result from issuing a rule banning the use of cadmium in children's jewelry. This information is discussed below and detailed at Tab E.

Major uses of cadmium include batteries, pigments, corrosion-resistant coatings, and production of polyvinylchloride (PVC). All other uses account for about 0.5 percent of all cadmium use, indicating that cadmium's use in the production of jewelry, including children's jewelry, comprises a minuscule share of the total use of cadmium. Cadmium has been used in some alloys, usually at relatively low concentrations, to produce certain types of jewelry. However, some jewelry items have been found to contain a high percentage of cadmium.

Sales of children's jewelry may amount to about 70 million pieces annually, with a retail value of about $250 million. The amount of leachable cadmium in children's jewelry is not well documented but is believed to be small and, based on recent market trends, is probably declining. However, to the extent that it is present, it could result in chronic exposures by means of children's mouthing behaviors and acute exposures by means of swallowing the jewelry items.

Given that most cadmium intake is dietary, and because the effects of cadmium ingestions are cumulative over an individual's lifetime, the incremental benefits of reducing cadmium chronic intake from the mouthing of children's jewelry are difficult to quantify, but are probably small. Acute exposure to cadmium could occur from children swallowing jewelry items. However, no cases have been documented and their frequency is unknown.

The costs of testing for cadmium in children's jewelry could be substantial under the third-party testing requirements of section 102 of the CPSIA, especially if a regulatory action required tests to determine the leachability of the cadmium. Costs might be reduced if testing were based on cadmium content, because cadmium content analysis could be conducted along with the lead content tests that manufacturers are already required to do. However, at this time, the available data do not show a clear relationship between the cadmium content of a metal jewelry item and migration of cadmium from such items.

A more detailed evaluation of the benefits of possible regulatory actions would require additional information on cadmium exposure from children's jewelry, including the proportion of products containing cadmium and the potential cadmium exposures from mouthing and swallowing

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

jewelry items. Additional information about possible testing requirements is needed to provide better estimates of the costs of regulating cadmium in children's jewelry.

Public Comments (Tab F)

The CPSC received public comments from 85 organizations and individuals in response to the notice published in the Federal Register on August 19, 2010 (75 FR 51246). Seventy-three comments were form letters from individuals indicating affiliation with the Sierra Club. Comments were received from five organizations: American Academy of Pediatrics (CPSC-2010-0087-0076), Consumer Federation of America (CPSC-2010-0087-0077), Consumers Union (CPSC-2010-0087-0081), Kids in Danger (CPSC-2010-0087-0083), and U.S. Public Interest Research Group (CPSC-2010-0087-0087). Two individuals provided comments, Ada Brewster (CPSC-2010-0087-0003) and Frederick Locker of Locker Greenberg & Brainin (CPSC-2010-0087-0084). Comments were received from one firm, X-Ray Optical Systems, Inc. (CPSC-2010-0087-0079), and from four industry associations, Coalition for Safe Ceramicware (CPSC-2010-0087-0078), International Cadmium Association (CPSC-2010-0087-0080), Jewelry Safety Coalition (CPSC-2010-0087-0082), and Retail Industry Leaders Association (CPSC-2010-0087-0085). The comments and the staff's responses to the comments are summarized below and are detailed at Tab F.

Most of the commenters supported the petitioners' interest in restricting the potential exposure to cadmium from children's jewelry, although commenters offered differing views about the scope and form of possible Commission actions.

Comment 1: Cadmium is toxic and a potential risk to children.

Many commenters expressed concern about the toxicity of cadmium and the potential for exposure of children from products. Three comments from industry groups indicated that cadmium in products does not necessarily cause harm.

CPSC Staff Response 1:

CPSC staff recognizes the toxicity of cadmium and the potential for hazardous exposures from some consumer products, including from ingestion. Exposure testing and risk assessment by the staff has identified hazardous products, resulting in Commission action, including recalls. However, staff recognizes that the mere presence of cadmium in a product does not indicate that a hazard exists, because exposure to hazardous amounts of the chemical may not be likely for all products.

Comment 2: Cadmium is being used as a replacement for lead.

Many commenters stated that cadmium is being used as an inexpensive substitute for lead. One commenter representing the jewelry industry stated that there is no widespread practice of substituting cadmium for lead in children's jewelry.

CPSC Staff Response 2:

Although cadmium has been found in some jewelry products, staff has no information confirming that it has been intentionally chosen as a replacement for lead.

Comment 3: Scope and form of possible requirements

Several commenters stated that requirements for cadmium should extend to more categories of children's products. One commenter indicated that requirements should exclude ceramicware,

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

because cadmium used in the decorations is inaccessible to a child. Three commenters indicated that the terms "toy jewelry" and "children's jewelry" need clarification, and two commenters indicated that price does not distinguish children's jewelry from jewelry for adults.

Most of the comments indicated that a standard should be for the total cadmium content of the product. Three commenters said they believe that a standard should be based on solubility or accessibility of the cadmium in a product. Two other comments emphasized that there is no relationship between the cadmium content of a product and the amount of cadmium that might be accessible to a consumer. Several comments indicated that the CPSC should address other toxic heavy metals to prevent substitution of one harmful substance for another.

CPSC Staff Response 3:

Staff agrees that there are several factors concerning the characteristics and types of products that should be considered in evaluating the potential hazards of children's jewelry. CPSC staff is focused on children's jewelry because the available data indicate that such products could be hazardous due to their cadmium content and potential for exposure. For other types of products, there is limited available testing and risk assessment information.

Toys, including toy jewelry, are currently subject to testing for cadmium content in paints and surface coatings through the ASTM F 963 toy safety standard. Consideration of additional requirements for toy jewelry is an option available to the Commission.

While staff has focused on metal jewelry because of the available data indicating potential hazards associated with cadmium content, staff could assess additional types of products when data become available. With respect to ceramicware, in addition to requirements under CPSC statutes and regulations, certain ceramicware articles, including dinnerware, are currently subject to food safety standards under the U.S. Food and Drug Administration.

The results of testing by CPSC staff of metal jewelry and other metal items do not show a clear relationship between the cadmium content of the tested items and the extractability of cadmium from those items. Thus, whether a product may be considered a hazardous substance under the FHSA may be determined best by using a test for soluble cadmium.

The Commission may consider evaluating the potential hazards associated with other chemicals.

Comment 4: Mandatory standard or voluntary standard

Many commenters prefer a mandatory rule and stated that manufacturers and importers must be required to test and certify products. Two commenters preferred a voluntary standard. One commenter supports a national, risk-based standard, such as the ASTM children's jewelry standard under development.

CPSC Staff Response 4:

Both voluntary standards and mandatory standards are among the options that may be considered by the Commission.

Comment 5: Test methods

Many commenters called for revised test methods that would reflect the real scenarios, including children swallowing, chewing, and breaking their toys. Another commenter stated that the methods in the European toy safety standard EN 71-3 are conservative and health protective of children.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

CPSC Staff Response 5:

Staff has evaluated data from solubility testing of metal jewelry and other metal items, and analyzed information related to children's ingestion of small objects, including cases of serious adverse effects and death from exposure to the chemical content of some of the items. Staff concluded that the two-hour test specified in the European toy safety standard EN 71-3 may not identify some products that could result in hazardous exposures and that, for items that may be swallowed by a child, a longer, more stringent test is necessary to identify products that could result in hazardous exposures. CPSC staff provided this information to the ASTM children's jewelry subcommittee for use in the development of the voluntary standard.[16]

Comment 6: Request EPA adopt requirements

Many comments repeated the petitioners' request that the CPSC ask the EPA to adopt testing and reporting requirements to gather information for decision making.

CPSC Staff Response 6:

If the Commission or staff concludes that additional information is needed, procedures are already in place to facilitate the collection and dissemination of data from other federal agencies such as the EPA.

Comment 7: Evaluate ASTM F 963

One commenter stated that the CPSC also should evaluate the ASTM F 963 toy safety standard test methods.

CPSC Staff Response 7:

CPSC staff is engaged actively in the review and refinement of the ASTM F 963 standard. Evaluating this standard for toy jewelry, which is currently subject to the standard, is among the options the Commission may consider.

Comment 8: Use of cadmium in jewelry

One commenter representing the jewelry industry indicated that jewelry may consist of a wide variety of materials, and that cadmium may be found in metal, either in trace amounts or as part of certain alloys, especially for adult jewelry, at levels up to 2000 ppm (0.2 percent).

CPSC Staff Response 8:

CPSC staff analysis of numerous jewelry items, including children's jewelry, shows that cadmium is sometimes present in metal jewelry items at levels of more than 99 percent.

Comment 9: Data on migration of cadmium from metal jewelry

A comment from the jewelry industry reported the results of some testing of items for migration of cadmium, along with the conclusion that very little cadmium migrates from plated samples even under worst-case 24-hour test conditions with constant agitation and higher total cadmium content levels, and that a cadmium content level of 1000 ppm (0.1 percent) should result in negligible exposure and may be a useful screening level.

---

[16] Combined Cadmium Package for ASTM F15.24 Children's Jewelry, including: Staff Report - Cadmium in Children's Metal Jewelry, October 2010; and Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials (pdf), August 2010. Available at http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

CPSC Staff Response 9:

Although the study is limited, the information provided contributes to the knowledge about the potential for exposure to cadmium from cadmium-containing metal jewelry items. Staff does not agree with the conclusion that the data show that very little cadmium migrated from the samples, because, in fact, it shows cadmium migration of up to several hundred micrograms of cadmium per gram of jewelry. Additional work is needed to determine the appropriateness of any specific screening level.

Comment 10: Other jurisdictions' requirements

Two commenters mentioned that because some states have acted to limit cadmium in jewelry, consumers are asking for, and are supportive of, mandatory rules. One comment stated that the CPSC should look at the other jurisdictions for guidance on developing mandatory requirements for cadmium in children's products.

CPSC Staff Response 10:

The staff is reviewing existing cadmium standards, including state standards.

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 cadmium. The Commission also may choose to address toxic substances other than cadmium that may be used in children's jewelry and may choose to address toy jewelry specifically in the context of the ASTM F 963 toy safety standard.

Thus, the Commission may vote to grant the petition and choose one of the following options, or provide another option:

1) Direct the staff to begin work on a rule for cadmium in children's jewelry other than toy jewelry.
2) Direct the staff to begin work on a rule for cadmium in children's jewelry and also for toy jewelry under the ASTM F 963 toy safety standard.

One advantage of choosing to grant the petition and proceed with the development and adoption of a mandatory standard is that such a rule would preempt conflicting state and local standards.

Alternatively, the Commission could conclude that there is insufficient evidence to proceed with a rule at this time. One disadvantage of rulemaking is that it could take as long as several years to complete. Additionally, a lack of data concerning the potential benefits and costs of a rule may hamper the staff's ability to provide the required findings necessary for a rule.

Defer Decision on the Petition

If the Commission determines that there is insufficient information to make a decision on the petition and believes that staff could obtain such information, or concludes that appropriate voluntary standards could be developed that would address the issue under consideration, the Commission could defer the decision for a specified period of time and direct staff to obtain the additional information or work on the voluntary standards.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

The Commission may vote to defer a decision on the petition for six months and choose one of the following options, or provide another option:

1) Direct staff to work with the ASTM F15.24 subcommittee on children's jewelry to develop a voluntary standard for cadmium in children's jewelry.
2) Direct staff to work with the ASTM F15.24 subcommittee on children's jewelry to develop a voluntary standard for cadmium in children's jewelry, and to work with the ASTM F15.22 subcommittee on requirements for cadmium in toy jewelry under the ASTM F 963 toy safety standard.

One advantage of choosing to defer a decision on the petition includes the efficiencies related to allowing the voluntary standard that is already in development to proceed. Voluntary standards are an important tool in addressing consumer product safety, and by statute, the Commission is to give preference to voluntary standards over promulgating mandatory standards. The standard for cadmium in children's jewelry is nearing completion, expected in early 2011, and includes input from CPSC staff and other stakeholders in its development.

Likewise, if the Commission was to also consider toy jewelry specifically, a standard addressing cadmium in toys already exists, and proposals have been advanced that would expand the requirements in this standard for cadmium and other toxic substances in toys.

Deny the Petition

If the Commission concludes that information is not available or unlikely 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 cadmium, the Commission could vote to deny the petition. However, as discussed above, staff has concluded that children's metal jewelry containing cadmium may be toxic if a child swallows or mouths a cadmium-containing product, because excess exposure to cadmium could occur. Based on staff analysis of toxicity studies in humans and experimental animals, staff derived exposure limits in the form of acceptable daily intake levels (ADI) for acute exposure, such as swallowing a jewelry item and for longer term exposures, such as from repeated mouthing of jewelry over time. Therefore, an argument may be made that the Commission already has sufficient information to develop a rulemaking under the FHSA.

Conclusions

In considering Petition HP 10-2, Requesting Restriction of Cadmium in Toy Jewelry, staff assessed the information currently available on the toxicity of cadmium, children's behaviors, data on children's metal jewelry, and related economic information. Evaluation of incidents and possible behaviors in children support a conclusion that children may sometimes swallow jewelry; and testing of cadmium-containing children's metal jewelry and other metal items by CPSC staff indicates that cadmium can migrate from products in amounts that could be associated with adverse health effects in children. Based on the potential for exposure to cadmium from cadmium-containing metal jewelry and the known hazards of ingestion of cadmium, staff concludes that children who swallow cadmium-containing metal jewelry could experience excess cadmium exposure that could result in substantial illness.

A new voluntary standard that would include limits for migration of cadmium from children's jewelry items is under development. Staff believes that the standard will be completed and implemented in 2011.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

In addition, a working group has been established to consider changes to the ASTM F 963 toy safety standard that would expand the requirements for toys, including toy jewelry, for cadmium and other chemicals.

Testing by CPSC staff indicates that there is no clear relationship between the extractability of cadmium from children's metal jewelry or other metal items and the cadmium content of items. Therefore, at this time, the available data indicate that setting exposure limits and establishing testing methods for soluble cadmium may be the most appropriate way to determine whether a product may be considered a hazardous substance. Based on the toxicity of cadmium and testing of cadmium-containing products, staff has developed testing methods and exposure limits that can be used to establish standards for testing and evaluation of children's metal jewelry.

At this time, staff is focusing on metal jewelry because the available data indicate that such products could be hazardous due to their cadmium content and potential for exposure. Staff does not have information concerning potential cadmium hazards of nonmetal materials that may be used in jewelry, but could assess additional types of products when data become available.

Recommendation

Staff recommends that the Commission defer its decision on the petition for six months and direct staff to participate in the ASTM F15.24 subcommittee to develop a voluntary standard addressing accessible cadmium from children's metal jewelry, and to work with the ASTM F15.22 subcommittee on the ASTM F 963 standard with respect to toy jewelry (Defer option 2) based on the information discussed above. If the Commission votes to defer its decision for six months, at the end of the six-month period staff will provide the Commission with an update on the progress of the voluntary standards for children's jewelry and toy jewelry. At that time, the Commission could make a determination to continue to defer its decision on the petition and proceed with the voluntary standards process or to pursue other Commission action.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB A: Laboratory Analysis

T
A
B

A

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials

August 2010

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table of Contents

Staff Report iii

TAB A: Summary of Test Results for Lead in Children's Metal Jewelry 9

TAB B: Assessment of Cadmium Migration from Materials 28

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Staff Report

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

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

Memorandum

Date: August 10, 2010

TO : Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences
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 : CPSC Staff Discussion of Toy Standard Test Methods[1]

Background

U.S. Consumer Product Safety Commission (CPSC) staff, as part of its work on possible hazards of children's jewelry and other products has considered the toy safety standards with respect to the requirements and test methods for certain chemical elements, such as cadmium. This discussion and the accompanying staff technical reports consider methods that CPSC staff has used to test and evaluate certain children's products, describe the current toy safety standards, and provide the staff's preliminary conclusion about testing methods for certain types of products.

Toxicological evaluation

Assessment of children's products for regulation under the Federal Hazardous Substances Act (FHSA) involves identification of possible hazards, including toxicity. Staff evaluates chemicals through toxicological review and quantitative dose-response analysis. With sufficient data on the chemical of interest, staff may estimate the level of exposure that if exceeded would be associated with adverse health effects, generally termed the acceptable daily intake level (ADI).

Exposure to elements from consumer products

To assess whether use of a product could result in excess exposure to a child, staff estimates possible chemical exposure through testing of products.

[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.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Children may be exposed to chemicals in products from direct mouthing of objects, from handling such objects and subsequent hand-to-mouth activity, or from ingesting a small item or a portion of a product.

CPSC's Directorate for Laboratory Sciences (LS), Division of Chemistry (LSC) staff evaluates possible exposures to chemicals from children's products that may be mouthed or swallowed by measuring leaching of the chemical from the item using a saline solution to mimic the effects of mouthing, and a mild acid solution to simulate the effects of swallowing an item. In some cases in which exposure might occur from handling a product and subsequent hand-to-mouth activity, staff may use a procedure that simulates hand contact with a product through repeated swiping of the surface with a moistened wipe. Both the saline and acid leaching methods involve placing the item in the solution for specified time periods of at least six hours. For mouthing, the staff assumes that each minute of extraction in the saline solution represents a minute of mouthing of the object by a child. For the ingestion scenario, staff assumes that the leaching time represents the time the item is exposed to the acidic environment of the stomach.

Staff has used an acid extraction test carried out over six hours to reflect the length of time it takes for food to move through the stomach and small intestine, where the absorption of chemicals generally takes place. However, in the course of testing and evaluation of children's metal jewelry containing lead over the past several years, staff learned that these test conditions may not necessarily mimic the circumstances of ingestion of products.

As part of a previous staff project on lead in children's metal jewelry, the staff examined data from three cases in which ingestion of a lead-containing jewelry item was associated with prolonged exposure to an item. A four-year-old Oregon boy had a blood lead level (BLL)[2] of 123 μg/dL approximately three to four weeks after swallowing a pendant containing 38.8 percent lead (VanArsdale et al. 2004). The pendant was surgically removed from the child. A 4-year-old Minnesota boy died with a BLL of 180 μg/dL after ingesting a bracelet charm[3], determined by the state public health department laboratory as containing 99.1 percent lead (CDC 2006). A nine-year-old boy's BLL rose to 27 μg/dL four days after he swallowed a ring containing 90 percent lead. Three days later his BLL rose to 54 μg/dL, at which time endoscopy was performed to remove the ring (CPSC files).

Numerous other reports in published literature and CPSC databases demonstrate that children ranging in age from 9 months to 17 years have had exposure to lead from ingesting products such as jewelry, game pieces, crayons, chalk, lead weights/sinkers/pellets, lead shot/bullets, and curtain weights (Durback 1989, Fergusson 1997, Greensher 1974, Hugelmeyer 1988, Mowad 1998, Sprinkle 1995; CPSC databases).

As demonstrated by these cases, ingested foreign bodies may not be eliminated quickly from the body, but can be retained within the digestive tract for an extended period of time. This has been shown in a 1998 study of 100 children aged 9 months to 13 years who ingested various foreign bodies (objects included coins, ball bearings, pins, marbles, screws, buttons, a light bulb, a novelty nail file and a clothespin) (Macgregor and Ferguson 1998). The total transit time for

[2] BLL is a measure of recent exposure to lead. From a recent national survey, the geometric mean BLL in children aged 1-5 years was 1.9 μg/dL (CDC 2005). There is no known threshold for adverse effects of lead; CPSC staff has evaluated product exposures using 10 μg/dL as the level that should not be exceeded in order to avoid serious adverse health effects.

[3] The length of exposure in this case is unknown, but several days passed between initial presentation of illness and the discovery of the object in the gastrointestinal tract.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

passage (from ingestion to elimination through the rectum) of these items ranged from 1 to 46 days. The peak time of passage was two days with a median time of six days. The authors noted that the mean transit time for an ingested object increased with age; it was greater than 15 days for 13-year-olds while it was typically five days for 4 through 10-year-olds.

Ingestion of items such as jewelry is not an infrequent occurrence for children of all ages. As presented in Tab D of the Briefing Package for Petition Requesting Ban of Lead in Toy Jewelry (Petition No. HP 06-1)[4], CPSC's Directorate for Epidemiology, Division of 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. 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 seven years of age. 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.

Data: Lead in Jewelry

In 2004, CPSC staff increased efforts to protect children from lead in products. In particular, the staff focused on hazardous lead exposures from swallowing lead-containing metal jewelry. To avoid exceeding the 10 µg/dL blood lead level (BLL) 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 might occur if a piece of jewelry were ingested. Therefore, children's metal jewelry samples that resulted in extraction of more than 175 µg of lead would be considered to be potentially associated with excess lead exposure if ingested by a child.

Staff analyzed hundreds of jewelry items such as beads, pendants, and other components of jewelry using the mild acid extraction test. The acid extraction test to simulate the effect of stomach acid on an ingested item was typically carried out for six hours to reflect the length of time it takes for food to move through the stomach and small intestine. Results of testing children's metal jewelry for lead content and lead solubility after six hours of extraction were presented in the staff briefing package for the petition on lead in toy jewelry (Tab B of the petition package).

Since CPSC staff was interested in the accessibility of lead from ingested items that might remain in the gastrointestinal tract for longer periods of time, an additional extraction period of 18 hours (for a total extraction time of 24 hours) was added to the extraction protocol. The staff's test protocol for each sample involved a one-hour extraction, followed by a two-hour extraction with fresh extraction solution, followed by a three-hour extraction with fresh solution, for a total of six hours. The latter time point was followed by an addition of fresh extraction

[4] Available at http://www.cpsc.gov/library/foia/foia07/brief/LeadToyJewelry.pdf.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

solution for the remaining 18 hours of extraction. Results of testing using this revised protocol for samples collected in and tested in fiscal year 2007 are presented in Tab A.

Both the 2004 and 2007 data sets described above showed that, for most samples, the amount of lead that migrated from the item generally depended on the amount of lead present in the sample, with larger levels of extraction from samples with higher total lead content, although there is no strict relationship between content and solubility.

The 2007 report shows that migration of lead generally increases with increasing time in the acid extraction solution. However, in many cases, there is little change in the amount of lead migration over the first several time points. The staff also observed for many samples that low levels of lead extraction at the early time points were followed by large increases in lead release either at the six-hour point or the 24-hour point.

This report included acid extraction results for 378 metal jewelry items. For the 197 items that had more than 0.06 percent total lead that were tested for accessible lead, 110 (56%) had accessible lead greater than 175 μg after 6 hours, and 125 (63%) had accessible lead greater than 175 μg after 24 hours. Of the 218 metal items that had less than ten percent total lead, six had accessible lead greater than 175 μg after six hours, and ten had greater than 175 μg after 24 hours.

Thus, increasing the extraction time for metal items from six hours to 24 hours showed an increase in the proportion of product samples with accessible lead more than 175 μg, as well as levels of accessible lead that were much higher at the later time point. The average amount of accessible lead after 24 hours (8,200 μg) was about five times larger than the average after six hours (1,600 μg).

While the focus of the staff's jewelry analyses was on metal items, a number of non-metal samples were tested for lead accessibility. Of 71 non-metal items tested, 31 were crystal. Some of the crystal items had total lead content up to 25 percent, but none had extractable lead greater than 175 μg after testing for up to 48 hours. Plastic items accounted for most of the remainder of the items tested. Only polyvinyl chloride (PVC) types of plastics had significant lead content. As with the metal items, lead migration tended to increase with increasing length of extraction time. Of nine PVC plastic items, containing lead up to 0.8 percent, two had extractable lead results greater than 175 μg after 24 hours of testing, and an additional two samples exceeded 175 μg after 48 hours. All four of these samples were relatively large necklace cords or choke collar necklaces.

Data: Cadmium in Jewelry

Recently, staff has evaluated the potential for hazardous exposures to cadmium that might occur from mouthing or swallowing cadmium-containing children's metal jewelry (Tab B). At this time, the amount of data on cadmium-containing children's metal jewelry is limited compared to that for lead-containing children's metal jewelry. Also, the staff has not identified a specific total cadmium content level that might indicate a possible hazard, or a level of cadmium exposure that children should not exceed that would be used to identify products with the potential to cause excess exposure to cadmium or to define a cadmium extraction limit for certain products.

Staff evaluated 20 cadmium-containing jewelry items (*i.e.*, finished products of various sizes and designs, generally including electroplating or other surface finishes), several non-product metal

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

alloy samples in wire or powder form, and several non-product plastic samples. The extraction test methods used were the same methods used to evaluate lead content and lead extraction from children's metal jewelry.

The limited data on extraction of cadmium from jewelry items show that, like lead, there is no strict relationship between cadmium content and cadmium solubility. However, for many samples, those with higher total cadmium content generally had higher levels of extraction. The staff did not collect as much data for cadmium-containing jewelry as is available for the lead-containing samples. Thus, the staff does not have data on the extraction of cadmium over time from electroplated jewelry samples.

Data from testing cadmium-containing alloys that were not electroplated or coated show proportionally increasing extraction of cadmium over time. The staff would hypothesize that the presence of electroplating would have resulted in initially low levels of extraction, followed by increasingly higher amounts of extraction, but this cannot be shown at this time.

As with the testing of plastic for lead migration, cadmium extraction from plastics was considerably less than extraction from metals. Again, an extraction limit for cadmium from children's products has not been defined. Therefore, the staff cannot conclude whether cadmium leaching from plastic items would be excessive or not.

Toy Standards: ASTM F963, EN71-3

The ASTM International *Standard Consumer Safety Specification for Toy Safety* (ASTM F963) covers migratable (*i.e.,* soluble, leachable) elements from paints and coatings on toys, with a specific test method.

The current European *Standard Safety of Toys-Part 3: Migration of certain elements* (EN 71-3:1994) covers any toy material, clay, and finger paint, in addition to paints and coatings, with specified test methods. Thus, the materials included in the scope of EN 71-3 exceed the scope of ASTM F963. However, EN 71-3 does not apply to all toys. This standard is for toys that are likely to be sucked, licked, or swallowed, especially toys for children up to age six years, as well as cosmetic toys, writing instrument toys, and toys for food contact. Jewelry is not included in the scope of either the ASTM or EN standard, except for toy jewelry. Children's jewelry is generally not toy jewelry. Staff is not aware of a European standard for jewelry, except for the nickel directive[5], which restricts the amount of nickel that may contact skin due to the potential for health effects from sensitization.

Except for the differences in scope, the two standards have similarities. Both standards include requirements for migratable chemicals, not total chemical content. The test methods in both indicate that certain types of materials are to be ground or homogenized, such as paints and coatings. In EN 71-3, some materials are extracted whole, such as glass/ceramic/metallic materials, if the toy or component fits entirely within the small parts cylinder. Both standards indicate the amount of material to be tested, how the test material is to be prepared, the amount of acid to be used for the test, and other details for different materials; but generally, the test methods are similar, and the migration limits are the same.

[5] Directive 2004/96/EC of the European Parliament and of the Council of 27 September 2004 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of nickel for piercing post assemblies for the purpose of adapting its Annex I to technical progress.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

A key aspect of the methods in both standards that differs significantly from the CPSC staff approach to evaluating certain products for the presence of a chemical hazard is that the extraction period in the toy standards is two hours. In contrast, CPSC staff typically uses an extraction period of at least six hours.

The basis of EN 71-3 is that a child is assumed to have an average daily intake (ingestion) of toy material of 8 milligrams (mg) per day. The standard acknowledges that in certain individual cases this figure might be exceeded. CPSC staff believes that the 8 mg/day assumption might be reasonable for paints and coatings, or materials that can be scraped off or that break up into small bits. As the language of the standard acknowledges, this level of ingestion could be exceeded in some cases.

To understand the implications of conditions of a test, consider the case of ingestion of small amounts of a toy material, such as paint or other scrapings or small bits. In this case, a two-hour extraction period may reasonably indicate whether excess leaching might occur. For such small bits, we might expect that ingestion would be followed by a relatively normal rate of elimination from the body as the small scrapings or pieces become mixed up in food and are transported through the gastrointestinal tract. Even if such small bits were not eliminated from the body within a day or two, as is the typical transit time for food, the exposure to chemicals that might migrate from the ingested materials is limited by the small size of the particles.

On the other hand, items such as the glass/ceramic/metallic components that fit within the small parts cylinder and are tested intact, or any other item that is ingested as a piece rather than as a scraping or small bit, generally are considerably larger than 8 mg, with mass perhaps up to about 5 grams. These large items might remain in the stomach or GI tract for longer periods of time.

As we learned from the jewelry ingestion cases, and from a report in the literature on ingested foreign bodies (Mcgregor and Ferguson 1998), an object may remain in the body for days or weeks. For these larger objects, a two-hour test may not be adequate to determine whether excessive leaching might occur. On the other hand, for certain materials such as glass, a longer extraction time may not result in significantly more leaching than a shorter time. This is because some materials are not susceptible to dissolving under the test conditions of the standards, and only chemicals at the immediate surface of the product are available for leaching.

Another reason that the shorter test might not be appropriate for some products is that plating or coating, if present on the product or component, could initially block the migration of the elements. Again, from the staff's jewelry investigations, we know that such coatings will eventually weaken and allow the acid to reach the underlying material. In these cases, leaching would be evident only after several hours in the acid solution.

New EU standard

There is a new EU toy safety directive[6] that will result in significant changes in the EN 71-3 migration of elements standard. The new requirements for chemicals in toys are to go into effect in 2013. The exact form of the new standard is not known, since some of the details for implementing the new directive need to be worked out. However, the new standard will include a ban of certain fragrance chemicals and restrictions on chemicals that are carcinogenic, mutagenic, or reproductive toxicants; it adds more elements to the migration standard, sets

[6] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

different migration limits for the elements that are in the current standard, and sets different migration limits for different types of materials. The staff has not yet evaluated the appropriateness of including the additional chemicals, or the revised migration limits, and cannot address methods that are not yet available. It is not clear to staff at this point if the scope of products or materials covered by the standard will change, or whether the test methods will be significantly revised. The staff does not know when the revised standard will be available.

Conclusion

Considering the available data on small swallowable metal jewelry items and the information about children's ingestion of small objects, including cases of serious adverse effects and death from the chemical content of some of the items, the staff has concerns about the appropriateness of the two-hour solubility test in both the ASTM F963 and EN 71-3 toy safety standards. Because an ingested foreign body may remain in the gastrointestinal tract for extended periods of time, and some materials are susceptible to excessive leaching of chemicals in the acid conditions of the stomach, the two-hour test may not identify products that could lead to excess exposure. As demonstrated with the results of the staff's testing of lead- or cadmium-containing jewelry and metal alloys, increasing the length of time in an acidic solution generally results in increasing solubility of the chemicals from products. Therefore, for small, swallowable items, especially metal items, the staff preliminarily recommends that the test procedure be carried out for 24 hours.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

References

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

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.

Durback LF, Wedin GP, Seidler DE (1989) Management of lead foreign body ingestion. J Toxicol Clin Toxicol 27(3): 173-82.

Fergusson J, Malecky G, Simpson E (1997) Lead foreign body ingestion in children. J Paediatr Child Health 33: 542-544.

Greensher J, Mofenson HC, Balakrishnan C, Aleem A (1974) Lead poisoning from ingestion of lead shot. Pediatrics 54(5): 641-643.

Hugelmeyer CD, Moorhead JC, Horenblas L, Bayer MJ (1988) Fatal lead encephalopathy following foreign body ingestion: case report. J Emerg Med 6(5): 397-400.

Macgregor D, Ferguson J (1998) Foreign body ingestion in children: an audit of transit time. J Accid Emerg Med 15: 371-373.

Mowad E, Haddad I, Gemmel DJ (1998) Management of lead poisoning from ingested fishing sinkers. Arch Pediatr Adolesc Med 152(5): 485-488.

Sprinkle JD, Hingsbergen EA (1995) Retained foreign body: associations with elevated lead levels, pica, and duodenal anomaly. Pediatr Radiol 25(7): 528-529.

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

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB A: Summary of Test Results for Lead in Children's Metal Jewelry

T
A
B

A

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

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

Memorandum

Date: Aug 1, 2007

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[1,2]

Summary:

This memorandum provides a summary of the test results of U.S. Consumer Product Safety Commission (CPSC) staff testing for lead (Pb) in children's metal jewelry in fiscal year 2007. The CPSC Directorate for Laboratory Sciences (LS), Division of Chemistry (LSC) staff has analyzed 384 children's metal jewelry items from 104 official compliance samples and 73 non-metal items such as plastic and crystal from 27 official compliance samples. There were 198 metal items tested that had total lead of 0.06% or more. In general, the staff notes that by visual inspection or XRF (data not shown), the metal items and components were finished with non-lead metallic coatings or platings, *e.g.*, copper, nickel. While the integrity of such coatings was not specifically evaluated, the data show that coatings do not necessarily prevent accessibility of lead from the item.

Background:

Under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261(f)(1), children's metal jewelry items that expose children to hazardous quantities of lead under reasonably foreseeable conditions of handling or use are banned hazardous substances. In 2005, CPSC's Office of Compliance issued an Interim Enforcement Policy for Children's Metal Jewelry

[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] Note this document was initially prepared in 2007 as part of a briefing package considering a ban on lead in children's metal jewelry, and does not reflect changes due to the enactment of the Consumer Product Safety Improvement Act of 2008 (CPSIA) and other later changes. Current testing methods and summaries of regulations for lead in children's products according to the CPSIA can be found at http://www.cpsc.gov/about/cpsia/sect101.html

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Containing Lead for manufacturers, importers, and retailers.[3] The policy was accompanied by a two part testing procedure.[4] The procedure calls for 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 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 and a risk assessment may result in enforcement action. Non-metal jewelry is not addressed in the Interim Enforcement Policy, but is subject to the FHSA.

Test Method:

Total Lead in Metal

The current test method[4] for total lead is based on methodology found in Canada Product Bureau Method C-02.4, 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.

Total Lead in Plastic

Plastic items were ashed in a muffle furnace at 600°C. 10-50 mg aliquots of the ashen item were dissolved in 2-3 ml of nitric acid on a hot plate. The digests were analyzed using inductively coupled plasma atomic emission spectroscopy (ICP) to determine lead content.

Total Lead in Crystal

Aliquots of crystal items were microwave digested with 2 ml of nitric acid and 1 ml of hydrofluoric acid. The digests were diluted with 4% boric acid to neutralize any free fluoride and analyzed by ICP to determine lead content.

Accessible Lead

The acid extraction test method[4] 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 (HCl) at 37°C for 6 hours. This procedure is based on methodology found in ASTM C927, C738, D5517, and F963. Extended acid extractions to 24 hours were performed on metal items. Plastic and crystal items were extracted with 0.07N HCl at 37°C for up to 48 hours.

---

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

[4]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.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

RESULTS AND DISCUSSION:

The test results for the samples are contained in Tables 1 and 2. The results showed that 197 out of 381 metal items tested (52%) had total lead of 0.06% or more. Acid extractions were done on 378 metal items; for the 197 items that had more than 0.06% total lead that were tested for accessible lead, 110 (56%) of those items had accessible lead greater than 175µg after 6 hours, and 125 (63%) had accessible lead greater than 175µg after 24 hours. Of the 218 metal items that had less than 10% total lead, 6 of those had accessible lead greater than 175µg after 6 hours, 10 had greater than 175µg after 24 hours. One item that had less than 0.06% total lead had accessible lead greater than 175µg after 24 hours.

Increasing the extraction time for metal items from 6 hours to 24 hours showed an increase in the proportion of products with accessible lead greater than 175 µg. The results also showed that the levels of accessible lead were much higher after 24 hours compared to 6 hours. The average 24 hour accessible lead (8183µg) was about 5 times as large as the average 6 hour accessible lead (1564µg).

There were 71 non metal items tested. Crystal accounted for 31 of those items. Some of the crystal items had total lead up to 25%, but none of the crystal items had extractable lead greater than 175µg. Plastic items accounted for most of the remainder of the items tested. Only polyvinyl chlorine (PVC) types of plastics had significant total lead. There were 9 PVC plastic items tested with lead levels up to 0.8%. Four of these items, with extractable lead results greater than 175µg after 48 hours of testing, were relatively large necklace cords or collars, weighing several grams.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 1. Metal Jewelry Results

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+ 18=24
						1.0	2.0	3.0	18		
06-810-3976	3	necklace	chain		0.015						
06-810-3976	3	necklace	teardrop pendant		96.2						
06-810-3976	3	necklace	hook		98.7						
06-810-3976	3	necklace	heart pendant		97.8						
06-810-3976	4	necklace	chain	0.38		2.5	0.4	0.0	0.9	2.9	3.8
06-810-3976	4	necklace	teardrop pendant	0.38(2)		494	684	659	8265	1838	10103
06-810-3976	4	necklace	hook	0.68		1207	1030	1203	7276	3440	10717
06-810-3976	4	necklace	heart pendant	5.04		5.0	12.6	47.9	3150	65.5	3216
06-810-3976	5	necklace	chain	0.38		2.3	0.8	0.6	1.1	3.7	4.8
06-810-3976	5	necklace	teardrop pendant	0.42(2)		466	735	1014	7476	2215	9691
06-810-3976	5	necklace	hook	0.66		544	1052	1065	1019	2663	3683
06-810-3976	5	necklace	heart pendant	5.18		12.9	5.2	20.7	1347	38.8	1386
06-810-3976	6	necklace	chain		0.002						
06-810-3976	6	necklace	teardrop pendant		99.2						
06-810-3976	6	necklace	hook		87.3						
06-810-3976	6	necklace	heart pendant		93.5						
06-840-7517	1	anklet	charm	3.3	87.6	892	1685	3143	23362	5720	29082
06-840-7517	2	anklet	charm	3.1	80.9	405	766	1279	17658	2450	20108
06-840-7642	3	bracelet	charm	2.69	0.44	7.7	0.5	0.4	9.0	8.6	17.6
06-840-7642	4	bracelet	charm	2.57	0.43	5.8	2.3	4.6	5.1	12.8	17.9
07-810-4655	3	Necklace	Charm back	6.615	95.3	31.8	65.9	98.3	7259	196	7455
07-810-4655	6	Necklace	Charm back	5.867	92.1	750	1202	3168	36372	5120	41492
07-302-0045	1	necklace	pendant	5.55	25.1	6936	14238	22312	104706	43486	148192
07-302-0046	1	necklace	cross pendant	4.64	44.2	559	988	1791	15776	3338	19114
07-302-0046	1	necklace	cross pendant clasp		3.5						
07-302-0046	1	necklace	star pendant	4.18	44.4	62.7	130	234	1521	426	1948
07-302-0046	1	necklace	star pendant clasp		42.5						
07-302-0075	1	key chain	pendant	20.32	0.023	0.0	0.0	0.0		0.0	
07-302-0075	2	key chain	pendant	20.38	0.068	17.4	0.0	0.0		0.0	
07-302-0075	3	key chain	pendant	20.10	0.025	43.0	0.0	0.0		0.0	
07-302-0075	4	key chain	pendant	20.89	4.27	226	284	356	1569	866	2435
07-302-0075	5	key chain	pendant	21.88	0.121	118	0.0	0.0		118	
07-302-0075	6	key chain	pendant	20.81	0.131	0.0	0.0	0.0		0.0	
07-302-0075	4	key chain	chain	3.50	0.235	2.0	0.0	0.0	1199	2.0	1201
07-302-0075	5	key chain	chain	3.47	0.009	2.7	2.0	0.0	407	4.7	412

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+18 =24
						1.0	2.0	3.0	18		
07-302-0075	4	key chain	key ring	3.92		10.8	2.6	0.0	236	13.4	249
07-302-0075	5	key chain	key ring	3.92		3.1	0.0	0.0	46.5	3.1	49.6
07-302-0075	6	key chain	key ring		0.008						
07-302-0075	6	key chain	key ring		0.002						
07-302-0093	1	Token	Token	16.208		0.0	0.0	8.3	11865	8.3	11874
07-302-0093	6	Token	Token	14.808		0.0	0.0	0.0	12.1	0.0	12.1
07-302-3734	1	Ring		0.576	76.9	253	418	758	2678	1429	4107
07-302-3734	2	Ring		0.622	55.5	587	1189	1523	7239	3299	10538
07-810-1371	1	necklace	hook	4.46	0.229	16.8	2.8	0.4	2.6	20.0	22.6
07-810-1371	1	necklace	Clasp	1.16	84.4	2820	1906	2834	18854	7560	26414
07-810-1371	1	necklace	pendant		0.011						
07-810-1371	2	necklace	hook	4.71	0.026	2.7	0.5	0.5	0.3	3.7	4.0
07-810-1371	2	necklace	Clasp	1.33	95.7	918	1471	2021	11990	4410	16401
07-810-1371	2	necklace	pendant		0.01						
07-810-1372	1	Ring		8.82	0.003	3.8	2.1	0.0	1.5	5.9	7.4
07-810-1372	2	Ring		5.6	0.001	1.8	1.5	0.5	0.0	3.8	3.8
07-810-4100	1	bracelet		4.02	0.01	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4100	2	bracelet		4.7	0.043	0.0	0.0	4.7	9.4	4.7	14.1
07-810-4126	1	key chain	charm	22.6	100	1021	2863	5396	92950	9280	102230
07-810-4126	2	key chain	charm	22	96.4	921	2245	3390	67779	6556	74335
07-810-4127	1	Ring		9.16		77.9	257	540	5083	875	5959
07-810-4127	2	Ring			88.5						
07-810-4127	4	Ring			90.5						
07-810-4127	5	ring		11.97		186	496	797	7727	1474	9201
07-810-4172	1	necklace	hook	0.4739	0.062	0.8	0.7	0.0	1.5	1.6	3.1
07-810-4172	1	necklace	pendant-lock	0.4279	0.008	0.2	0.0	0.0	0.0	0.2	0.3
07-810-4172	1	necklace	pendant-heart	0.7316	0.075	19.1	0.0	0.0	1.3	19.1	20.4
07-810-4172	2	necklace	hook	0.4222	0.107	9.1	1.3	0.7	2.1	11.1	13.2
07-810-4172	2	necklace	pendant-lock	0.4496	0.007	31.0	1.9	0.2	0.9	33.1	34.0
07-810-4172	2	necklace	pendant-heart	0.6730	0.038	0.2	0.0	0.0	0.0	0.2	0.2
07-810-4173	1	necklace	hook	0.4	0.062	15.9	31.6	0.7	0.6	48.2	48.8
07-810-4173	1	necklace	Pendant	1.815	0.004	8.0	0.2	0.0	0.0	8.1	8.1
07-810-4173	1	necklace	Pearl earring-setting	0.124	0.001	0.9	13.8	5.7	0.4	20.5	20.9
07-810-4173	2	necklace	hook	0.4631	0.072	20.5	1.4	0.9	1.1	22.9	23.9
07-810-4173	2	necklace	Pendant-metal	1.475	0.022	55.8	12.1	12.1	1.8	80.0	81.8
07-810-4173	2	necklace	"diamond" earring-setting	0.4082	0.032	15.9	0.2	0.0	0.1	16.1	16.2
07-810-4173	2	necklace	Pearl earring-setting	0.1762	0.015	39.2	22.8	10.6	4.0	72.7	76.7

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+18 =24
						1	2	3	18		
07-810-4294	1	Ring	dark blue stone	1.76		65.1	110	176	1548	351	1899
07-810-4294	2	Ring	dark blue stone		92.5						
07-810-4294	3	Ring	blue stone	2.09	81.2	18.9	108	288	4084	415	4499
07-810-4294	3	Ring	no stone	1.6	71.9	53.6	103	169	952	326	1278
07-810-4294	4	Ring	no stone	0.68	0.031	1.4	1.0	2.0	23.1	4.4	27.5
07-810-4294	5	Ring	green stone	1.19	68.9	6.0	0.0	3.6	49.2	9.6	58.8
07-810-4294	5	Ring	pink stone	1.79	80.5	0.0	0.0	9.0	388	9.0	397
07-810-4294	5	Ring	blue stone	1.92	73.7	82.6	280	720	5260	1083	6344
07-810-4294	6	Ring	no stone/thin ban	1.8	75.9	3.6	24.3	70.2	1863	98.1	1961
07-810-4470	1	necklace	pendant	13.36	0.004	0.0	0.0	0.0	7.3	0.0	7.3
07-810-4470	1	necklace	hook	0.49	0.009	0.7	0.0	0.0	1.2	0.7	1.9
07-810-4470	1	necklace	tear drop charm	0.17	4.15	0.1	0.1	0.1	86.4	0.3	86.7
07-810-4470	3	necklace	pendant	13.39	0.004	0.0	0.0	14.4	6.1	14.4	20.5
07-810-4470	3	necklace	hook	0.49	0.011	0.3	0.5	1.5	2.0	2.3	4.3
07-810-4470	3	necklace	tear drop charm	0.17	3.71	0.0	0.2	0.0	3.4	0.2	3.6
07-810-4471	1	zipper	pull	0.02	4.37	9.4	2.0	0.0	0.0	11.4	11.4
07-810-4471	1	zipper	hook	0.007	0.71	15.9	25.7	30.3	23.1	71.9	95.0
07-810-4471	4	zipper	pull	0.023	4.35	7.7	2.8	2.1	2.4	12.6	15.0
07-810-4471	4	zipper	hook	0.012	0.65	0.0	0.0	0.0	4.5	0.0	4.5
07-810-4471	5	zipper	pull	0.153	4.37	4.0	0.0	0.0	3.0	4.0	7.0
07-810-4471	5	zipper	hook	0.012	0.72	13.7	22.5	32.2	51.0	68.4	119
07-810-4502	3	necklace	charm	9.529	0.037	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4502	3		hook	0.477	0.022	0.2	0.0	0.0	0.0	0.2	0.2
07-810-4502	6		charm	9.626	0.01	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4502	6		hook		0.023	0.0	0.0	0.0	2.2	0.0	2.2
07-810-4502	3 and 6		tear drops	0.304	4.48	1.8	0.1	0.6	344	2.5	346
07-810-4519	1	bracelet	pendant	11.37		1829	2891	6248	77362	10968	88330
07-810-4519	1	bracelet	hook	1.11		957	2244	3481	22600	6682	29282
07-810-4519	2	bracelet	pendant	10.38		296	270	441	8874	1007	9882
07-810-4519	2	bracelet	hook	1.08		643	2214	4358	32098	7214	39312
07-810-4519	3	bracelet	pendant	10.98	102	115	225	1290		1631	
07-810-4519	3	bracelet	hook		83.6						
07-810-4519	4	bracelet	pendant	11.2	90.6	5.6	28.0	89.6		123	
07-810-4519	5	bracelet	pendant		97.4	475	520	6817		1676	
07-810-4519	5	bracelet	hook	11.43	92.4						
07-810-4519	6	bracelet	pendant	10.77	91.3	0.0	21.6	64.7		86.3	
07-810-4599	4	Ring		1.9	0.01	0.0	0.0	0.0	3.8	0.0	0.0
07-810-4599	5	Ring		0.31	0.001	1.1	0.0	0.0	0.0	1.1	0.0

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+ 18=24
						1	2	3	18		
07-810-4600	1	Ring		1.799	0.063						
07-810-4600	3	Ring		1.557	0.076						
07-810-4601	3	Bracelet				0.0	0.0	0.0	0.0	0.0	0.0
07-810-4601	6	Bracelet				0.0	0.0	0.0	0.0	0.0	0.0
07-810-4654	1	ring		13.48		3321	4252	5042	28552	12622	41175
07-810-4654	2	ring			80.2						
07-810-4654	5	ring		12.71		1794	2620	2932	13546	7339	20886
07-810-4654	6	ring			85.5						
07-810-4655	3	necklace	charm	6.615	95.3	31.8	65.9	98.3	7259	196	7455
07-810-4655	6	necklace	charm	5.867	92.1	750	1202	5120	34419	7072	41491
07-810-4656	1	necklace	Clasp	0.4136	65.6						
07-810-4656	2	necklace	Clasp	0.439	68.0						
07-810-4656	3	necklace	Pendant (pink)		0.808						
07-810-4656	3	necklace	Clasp			536	758	1128	7242	2421	9664
07-810-4656	4	necklace	Pendant (pink)			4.9	1.5	0.3	0.9	6.7	7.6
07-810-4656	4	necklace	Clasp			459	623	1203	6730	2285	9015
07-810-4656	5	necklace	Pendant (blue)			1.9	0.6	0.4	2.2	2.9	5.1
07-810-4656	6	necklace	Pendant (blue)		0.192						
07-810-4674	1	necklace	pendant	1.82	0.05	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4674	1	necklace	hook	0.16	0.012	0.2	0.0	0.0	0.2	0.2	0.4
07-810-4674	2	necklace	pendant	1.84	0.068	0.9	0.0	0.0	0.0	0.9	0.9
07-810-4674	2	necklace	hook	0.16	0.017	0.2	0.0	0.0	0.5	0.2	0.7
07-810-4675	1	necklace	pendant	5.373		3.7	0.6	1.4	3.9	5.7	9.2
07-810-4675	1	necklace	hook	0.177		0.1	0.1	0.0	0.0	0.2	0.2
07-810-4675	2	necklace	pendant	5.333		1.7	1.4	0.0	2.6	3.1	8.2
07-810-4675	2	necklace	hook	0.171		0.0	0.1	0.0	0.0	0.1	0.2
07-810-4675	4	necklace	pendant	5.14	0.02						
07-810-4675	4	necklace	hook	0.174	0.015						
07-810-4675	5	necklace	pendant	5.28	0.198						
07-810-4675	5	necklace	hook	0.166	0.014						
07-810-4703	2	necklace	Hook	0.557	81.7	263	709	1180	11085	2152	13237
07-810-4703	2	necklace	pendant	3.274	77.6	616	1028	1634	16926	3278	20204
07-810-4703	3	necklace	Hook	0.537	72.2	979	2037	2485	20878	5501	26379
07-810-4703	3	necklace	pendant	3.037	75.5	1427	2544	4189	21535	8160	29695
07-810-4704	3	necklace	Hook	0.514	76.2	584	1446	2289	17316	4319	21635
07-810-4704	3	necklace	pendant	2.964	92.1	244	52.0	57.0	846	353	1199
07-810-4704	4	necklace	Hook	0.587	70.3	572	1629	2608	18961	4809	23770
07-810-4704	4	necklace	pendant	2.345	89.8	52.0	14.0	25.0	198	91.0	289
07-810-4705	1	necklace	Hook	0.572	91.6	572	1404	2228	17058	4204	21262
07-810-4705	1	necklace	pendant	2.471	86.9	14.0	42.0	24.0	2198	80.0	2278
07-810-4705	2	necklace	Hook	0.581	85.6	1189	2958	5352	22800	9499	32299

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+18 =24
						1	2	3	18		
07-810-4705	2	necklace	pendant	2.184	79.9	133	42.0	53.0	1853	228	2081
07-810-4711	4	earring	metal	1.058	0.049	8.4	3.3	2.5	2.5	14.2	16.7
07-810-4711	5	earring	metal	1.426	0.051	6.5	6.1	5.2	4.4	17.8	22.2
07-810-4724	6	hair clip, green			0.001						
07-810-4724	6	hair clip, purple			0.003						
07-810-4724	6	hair clip, red		0.529		0.3	0.0	0.0	0.5	0.3	0.8
07-810-4724	6	hair clip, yellow		0.547		0.0	0.0	0.0	0.5	0.0	0.5
07-810-4725	1	pin		11.02	88.4	334	1303	7660	90173	9297	99471
07-810-4725	3	pin		10.94	90.1	440	1142	3881	66501	5463	71964
07-810-4946	1	anklet	pendant	3.18	53.4	448	1217	3070	17505	4734	22240
07-810-4946	3	anklet	pendant	3.16	50.5	1821	3197	6849	35960	11867	47828
07-810-4946	5	anklet	pendant	2.58	16.5	90.7	166	377	7424	634	8058
07-810-4946	6	anklet	pendant	2.86	54.7	28.1	111.4	224.5	8375	364	8739
07-810-4947	3	Bracelet	Connector	0.1209	0.010	0.1	0.1	0.1	0.1	0.4	0.5
07-810-4947	3		Pendant 1	0.9423	0.201	0.5	0.3	0.4	1.0	1.2	2.2
07-810-4947	3		Pendant 2	1.1407	0.100	2.0	0.9	0.7	0.4	3.6	3.9
07-810-4947	5		Connector	0.1213	0.013	0.2	0.1	0.1	0.3	0.4	0.7
07-810-4947	5		Pendant 1	0.8961	0.481	0.4	0.3	0.4	0.8	1.2	2.0
07-810-4947	5		Pendant 2	1.3189	0.104	0.8	0.4	0.4	0.3	1.6	1.9
07-810-4948	2	Bracelet	charm, P	1.064	0.059	2.9	0.0	0.0	0.0	2.9	2.9
07-810-4948	2		charm, S	1.035	0.093	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4948	4		charm, P	1.081	0.077	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4948	4		charm, S	1.151	0.046	4.7	0.0	0.0	0.0	4.7	4.7
07-810-5001	1	kit	chain	3.11	0.04	64.4	5.8	2.0	0.5	72.2	72.7
07-810-5001	1	kit	hook	0.495	0.017	1.1	0.3	0.2	0.3	1.6	1.9
07-810-5001	1	kit	charm-bag	0.872	0.019	0.2	0.2	1.5	0.2	1.9	2.1
07-810-5001	1	kit	charm-dog	0.997	0.017	0.2	0.2	0.3	0.0	0.6	0.7
07-810-5001	2	kit	chain	3.301	0.006	5.7	1.5	0.2	0.0	7.4	7.4
07-810-5001	2	kit	hook	0.485	0.024	0.5	0.4	0.5	0.5	1.3	1.8
07-810-5001	2	kit	charm-bag	0.758	0.013	0.4	3.0	0.6	0.1	3.9	4.1
07-810-5001	2	kit	charm-dog	0.933	0.009	1.2	0.3	0.2	0.3	1.7	2.0
07-810-5002	1	necklace	pendant	1.505	79.5	33.1	75.3	98.0	1625	206	1832
07-810-5002	1	necklace	hook	0.188	0.018	0.0	0.2	0.0	0.1	0.2	0.3
07-810-5002	5	necklace	pendant	1.37	74	161	227	302	1506	691	2197
07-810-5002	5	necklace	hook	0.186	0.255	0.0	0.0	0.0	0.5	0.0	0.5
07-810-5027	3	earring			0.024						
07-810-5027	4	necklace	chain	1.24	0.007	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5027	4	necklace	pendant	1.93	0.011	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5027	4	necklace	hook	0.27	0.016	0.0	0.0	0.0	0.3	0.0	0.3
07-810-5027	4	earring		0.44		0.2	0.0	0.0	0.0	0.2	0.2

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+18 =24
						1	2	3	18		
07-810-5027	6	necklace	pendant	1.79	0.023	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5027	6	necklace	hook	0.25	0	0.4	0.0	0.0	0.0	0.4	0.4
07-810-5027	6	earring		0.4	0.011	0.0	0.6	0.0	0.2	0.6	0.8
07-810-5028	1	necklace	charm		0.021						
07-810-5028	1	necklace	hook		85.5						
07-810-5028	2	necklace	charm		0.041						
07-810-5028	2	necklace	hook		0.021						
07-810-5028	4	necklace	charm	2.24	0.159	1.2	0.0	0.0	0.0	1.2	1.2
07-810-5028	4	necklace	hook	0.49	0.045	0.4	0.3	0.0	0.0	0.7	0.7
07-810-5028	5	necklace	hook	0.75	94.5	249	583	1105	9331	1937	11269
07-810-5028	6	necklace	charm	1.93	0.041	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5028	6	necklace	hook	0.49	0.027	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5032	1	spring bracelet		2.580	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5032	5	spring bracelet		2.618	0.002	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5033	2	metal ring		1.3285	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5033	5	metal ring		2.3045	0.015	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5035	3	necklace	charm	0.721	0.101	55.1	0.0	0.0	0.9	55.1	56.0
07-810-5035	6	necklace	charm	0.653	0.085	190.5	5.2	1.8	4.6	198	202
07-810-5121	4	necklace	pendant	7.1	81.92	32.0	5.3	17.4	73591	54.7	73646
07-810-5121	4	necklace	hook	0.77	85.7	947	2214	2566	23251	5727	28979
07-810-5121	6	necklace	pendant	7.36	84.67	475	310	379.4	40443	1164	41608
07-810-5121	6	necklace	hook	0.61	82.28	976	1879	1190	3128	4045	7174
07-810-5122	5	ring			0.006	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5122	6	ring			0.008				0.0	33.0	33.0
07-810-5126	2	necklace	chain	3.62	0.005	0.0	0.0	1.9	9.4	1.9	11.3
07-810-5126	5	necklace	chain	2.81	0.012	0.0	0.0	1.5	6.9	1.5	8.4
07-810-5126	5	necklace	pendant	2	0.004	0.0	0.0	0.0	2.5	0.0	2.5
07-810-5127	1	ring		1.88	0.005	0.0	0.0	0.0	5.9	0.0	5.9
07-810-5127	6	ring		2.91	0.005	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5128	2	necklace	pendant	0.996	0.017	0.0	0.8	0.5	1.3	1.3	
07-810-5128	3	necklace	pendant	1.081	0.004	2.6	2.6	1.7	4.8	6.9	11.7
07-810-5128	4	necklace	pendant	1.187	0.006	0.7	1.0	1.1	3.6	2.8	6.4
07-810-5128	5	necklace	pendant	0.872	0.008	0.0	0.4	0.7	1.9	1.1	3.0
07-810-5176	1	necklace	key shaped pendant		0.004						
07-810-5176	1	necklace	heart shaped pendant		0.001						
07-810-5176	1	necklace	crown shaped pendant		0.002						
07-810-5176	4	necklace	key shaped pendant	0.539	0.029	0.3	0.3	0.3	0.3	0.9	1.2

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+18 =24
						1	2	3	18		
07-810-5176	4	necklace	heart shaped pendant	0.394	0.003	0.2	0.2	0.2	0.5	0.6	1.1
07-810-5176	4	necklace	crown shaped pendant	1.099	0	0.5	1.0	0.3	0.6	1.8	2.4
07-810-5176	6	necklace	key shaped pendant	0.561		0.0	0.0	0.0	0.0	0.0	0.0
07-810-5176	6	necklace	heart shaped pendant	0.396		0.0	0.2	0.0	0.5	0.2	0.7
07-810-5176	6	necklace	crown shaped pendant	1.021		0.0	0.0	0.0	0.0	0.0	0.0
07-810-5177	2	Bracelet	key shaped cross pendant	1.465	86.5	7928	1649	8389	43384	17966	61350
07-810-5177	2	Bracelet	curved shape cross pendant	1.473	57.3	896	506	938	7560	2340	9900
07-810-5177	2	Bracelet	square cross	1.264	60.4	993	155	524	3166	1672	4838
07-810-5177	2	Bracelet	thick cross pendant	2.897	92.5	6840	2909	6944	34119	16693	50812
07-810-5177	2	Bracelet	Hook	0.922	81.3	657	199	3643	36763	4499	41262
07-810-5177	6	Bracelet	key shaped cross pendant	1.754	92.7	1460	348	2498	14250	4306	18556
07-810-5177	6	Bracelet	curved shape cross pendant	1.347	63.7	678	267	1071	3623	2016	5639
07-810-5177	6	Bracelet	square cross pendant	1.219	68.6	1452	374	2761	5051	4587	9638
07-810-5177	6	Bracelet	thick cross pendant	2.909	83.1	3450	1572	2262	44240	7284	51524
07-810-5177	6	Bracelet	Hook	1.096	80.6	700	34.2	4194	33726	4920	38646
07-810-5178	4	Choker	Large Butterfly charm	3.838	82.5	2083	774	4825	31284	7362	38986
07-810-5178	4	Choker	small butterfly charm	1.827	90.9	968	1028	2002	9746	3998	13744
07-810-5178	4	Choker	large heart charm	3.472	53.3	4447	2298	3591	35057	10336	45393
07-810-5178	4	Choker	Heart with crystal charm	2.197	91.6	2859	2716	3678	191066	9253	28359
07-810-5178	4	Choker	Hook	0.754	78.1	293	956	1820	7128	3069	10197
07-810-5178	6	Choker	Large Butterfly charm	4.254	88.6	1957	2189	5292	34428	9438	43866
07-810-5178	6	Choker	small butterfly charm	1.937	91	1418	1724	4385	23742	7527.0	31269

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+18 =24
						1	2	3	18		
07-810-5178	6	Choker	large heart charm	3.074	77.9	10158	2311	6428	34604	18897	53501
07-810-5178	6	Choker	Heart with crystal charm	2.094	97	2416	5191	1929	7602.	9536	17138
07-810-5178	6	Choker	Hook	0.753	86.4	153	617	1201	3145	1971	5116
07-810-5221	4	charm		2.677	0.007	0.0	0.0	0.0	1.6	0.0	1.6
07-810-5221	6	charm		2.684	0.008	1.4	0.0	0.0	1.5	1.4	2.9
07-810-5259	2	Ring	Pendant	0.8	4.18	2.4	0.4	0.4	0.4	3.2	3.6
07-810-5259	2	necklace	Pendant	0.88	2.2	1.3	0.0	0.4	0.4	1.7	2.1
07-810-5259	6	Ring	Pendant	0.84	0.5	1.3	0.0	0.4	0.8	1.7	2.5
07-810-5259	6	necklace	Pendant	0.8	0.59	0.4	0.0	0.0	0.4	0.4	0.8
07-810-5260	2	Ring	pendant	0.47	0.303	0.2	0.2	0.2	0.2	0.7	1.0
07-810-5260	2	necklace	pendant	2.01	0.166	1.0	0.0	1.0	0.0	2.0	2.0
07-810-5260	5	Ring	pendant	0.49	2.333	0.5	0.3	0.5	0.3	1.3	1.5
07-810-5260	5	necklace	pendant	2	0.363	0.0	0.0	1.0		1.0	2.0
07-810-5260	5	necklace	shoe pendant	1.64	0.118	0.8	0.0	0.8	1.6	1.6	3.3
07-810-5261	1	necklace	butterfly pendant	1.66	0.114	0.0	0.0	0.8	0.8	0.8	1.7
07-810-5261	1	necklace	ladybug pendant	1.36	1.922	0.0	0.0	0.0	0.7	0.0	0.7
07-810-5261	1	necklace	clover pendant	1.26	1.188	2.5	0.6	0.6	0.6	3.8	4.4
07-810-5261	4	necklace	butterfly pendant	1.62	1.305	4.9	0.8	0.8	0.8	6.5	7.3
07-810-5261	4	necklace	ladybug pendant	1.42	0.556	4.3	0.0	0.7	0.7	5.0	5.7
07-810-5261	4	necklace	clover pendant	1.2	0.435	0.0	0.0	0.0	0.6	0.0	0.6
07-810-5275	2	Bracelet	charm	1.135	0.015	26.0	0.9	1.4	2.1	28.4	30.4
07-810-5275	5	Bracelet	charm	1.154	0.007	0.4	0.0	0.0	1.2	0.4	1.5
07-810-5276	2	Bracelet	charm	0.494	0.013	116.1	4.7	1.8	2.9	122	125
07-810-5276	2	Bracelet		0.53	0.008	4.5	0.6	0.2	2.0	5.2	7.3
07-810-5276	5	Bracelet	charm	1.377	0.578	29.5	21.1	29.8	391	80.4	471
07-810-5276	5	Bracelet		0.476	0.008	1.0	0.4	0.2	1.7	1.7	3.3
07-810-5277	2	necklace	clasp	0.494	0.116	19.0	0.1	2.3	45.7	21.4	67.1
07-810-5277	2	necklace		0.53	0.385	5.5	3.1	2.0	12.8	10.6	23.4
07-810-5277	5	necklace	clasp	1.377	0.117	2.0	2.8	4.8	33.5	9.6	43.0
07-810-5277	5	necklace		0.476	0.24	4.7	2.0	1.5	12.6	8.2	20.8
07-810-5645	2	ring			0.086						
07-810-5645	3	ring			0.091						
07-810-5645	6	ring				4.6	2.3	4.4		11.3	
07-840-6040	2	ring		0.904	0.043	4.3	2.2	2.5	43.6	9.0	52.6
07-840-6040	3	ring		0.702	0.042	1.6	1.5	2.4	13.5	5.5	19.0

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+ 18=24
						1	2	3	18		
07-840-6041	2	necklace	pendant	2.857	0.005	0.0	0.0	0.0	1.1	0.0	1.1
07-840-6041	2		chain	2.526	0.006	0.0	0.0	0.0	2.9	0.0	2.9
07-840-6041	6	ring		0.485	0.005	0.0	0.0	0.3	0.0	0.3	0.3
07-840-6042	1	body claps	charm	0.708	0.015	1.0	0.0	0.0	0.6	1.0	1.6
07-840-6042	4	body claps	charm	0.384	0.006	0.3	0.0	0.0	6.4	0.3	6.7
07-840-6042	5	body claps	charm	0.526	0.01	0.0	0.4	0.0	0.0	0.4	0.4
07-840-6137	2	necklace	pendant	2.51		0.0	0.0	0.0	0.0	0.0	0.0
07-840-6137	2	necklace	hook	0.48		0.5	0.3	0.0	0.7	0.8	1.5
07-840-6137	4	necklace	pendant		0.012						
07-840-6137	4	necklace	hook		0.03						
07-840-6137	5	necklace	pendant	2.66		6.7	0.0	0.0	0.0	6.7	6.7
07-840-6137	5	necklace	hook	0.55		0.3	0.0	0.0	0.0	0.0	0.3
07-840-6137	6	necklace	pendant		0.058						
07-840-6137	6	necklace	hook		0.055						
07-840-6138	5	necklace	Pendant	5.3	0.036	10.4	0.0	0.0	0.0	10.4	10.4
07-840-6138	5	necklace	Hook	0.48	0.006	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6138	6	necklace	Pendant	5.26	0.036	11.5	0.0	0.0	0.0	11.5	11.5
07-840-6138	6	necklace	Hook	0.5	0.012	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6139	1	charm	charm		0.013						
07-840-6139	2	charm	charm		0.01						
07-840-6139	4	charm	charm	2.34		0.0	0.0	0.0	0.0	0.0	0.0
07-840-6139	5	charm	charm	2.32		0.0	0.0	0.0	0.0	0.0	0.0
07-840-6143	1	necklace	Clasp	0.99	0.009						
07-840-6143	2	necklace	Pendant	0.6342	0.031						
07-840-6143	3	necklace	Pendant			1.1	0.3	0.1		1.4	2.9
07-840-6143	4	necklace	Clasp	0.0985	0.012						
07-840-6143	5	necklace	Pendant	0.6301	0.008						
07-840-6143	7	necklace	Pendant			0.4	0.7	0.1		1.1	2.3
07-840-6143	3,7,2, 5	necklace	4 Clasps			1.0	0.2	0.0		1.1	2.3
07-840-6169	3	necklace	Pendant	2.6156	87.4	357	6054	8620	59429	15031	74461
07-840-6169	4	necklace	Pendant	1.9664	84.3	1610	3038	4132	52938	8780	61717
07-840-6170	3	necklace	Pendant	5.289	0.02	12.4	4.7	2.8	5.4	19.9	25.3
07-840-6170	4	necklace	Pendant	4.851	0.46	2.4	2.1	2.4	71.4	6.9	78.4
07-840-6187	1	necklace	pendant	3.14	0.867	0.0	0.0	0.0		0.0	0.0
07-840-6187	4	necklace	pendant		0.144						
07-840-6187	5	necklace	pendant	2.84		0.0	0.0	0.0		0.0	0.0
07-840-6187	6	necklace	pendant	2.1		4.1	0.9	0.0	0.0	5.0	5.0
07-840-6188	1	necklace	pendant		0.064						
07-840-6188	2	necklace	pendant	1.34		7.2	0.0	0.0	0.0	7.2	7.2
07-840-6188	3	necklace	pendant		0.045						
07-840-6188	4	necklace	pendant	1.64		2.3	0.0	0.0	1.2	2.3	3.5
07-840-6188	6	necklace	pendant	1.3		3.7	0.0	0.0	1.0	3.7	4.7

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+ 18=24
						1	2	3	18		
07-840-6190	1	necklace	chain		0.007						
07-840-6190	4	necklace	chain		0.013						
07-840-6224	3	Ring necklace	Ring	2.969	0.002	0.0	0.4	0.6	0.0	1.0	1.0
07-840-6224	3	Ring necklace	pendant	2.800	0.008	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6224	5	Ring necklace	Ring	2.946	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6224	5	Ring necklace	pendant	2.885	0.004	0.3	0.0	0.0	0.0	0.3	0.3
07-840-6225	4	necklace	pendant	3.712	0.006	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6225	4	necklace	pendant	3.455	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6225	6	necklace	pendant	3.525	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6225	6	necklace	pendant	3.544	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6238	1	necklace	pendant	6.166	91.1	10.4	55.6	75.9	585	142	727
07-840-6238	1	necklace	tear drops	0.474	84.8	228	286	318.	1576	833	2409
07-840-6238	1	necklace	clasp	0.62	88.9	1210	1975	2806	15891	5990	21881
07-840-6238	2	necklace	pendant	5.702	52.5	38.3	75.5	98.7	647	212	859
07-840-6238	2	necklace	tear drops	0.474	84. 7	3.4	0.3	4.6	6921	8.2	6929
07-840-6238	2	necklace	clasp	0.636	85.2	1585	3110	5372	31218	10067	41285
07-840-6320	1	Bracelet	bracelet	5.73	0.128	0.0	0.4	1.0	2.6	1.4	3.9
07-840-6320	2	Bracelet	bracelet	5.57	0.021	0.0	0.0	1.8	3.2	1.8	5.0
07-840-6321	1	Ring	Ring	2.99	0.063	0.0	0.0	0.0	4.7	0.0	4.7
07-840-6321	2	Ring	Ring	3.26	0.063	0.0	0.3	5.5	0.0	5.9	5.9
07-840-6356	2	necklace	charm	3.184	0.021	2.0	1.5	10.0	14.2	13.5	27.7
07-840-6356	2	necklace	clasp	0.35	0.031	2.3	1.7	3.5	0.3	7.4	7.7
07-840-6356	5	necklace	charm	2.901	0.034	3.8	3.5	4.9	12.2	12.2	19.5
07-840-6356	5	necklace	clasp	0.35	0.03	86.1	4.7	3.1	93.9	93.9	94.9
07-840-6357	2	necklace	pendant	2.316	0.005	15.5	0.3	0.7	1.1	16.5	17.6
07-840-6357	5	necklace	pendant	2.281	0.006	1.7	0.0	0.6	0.3	2.3	2.5
07-840-6397	4	Bracelet	hook	0.0988	0.002	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6397	5	Bracelet	hook	0.0974	0.000	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6397	4	Bracelet	chain	0.5115	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6397	5	Bracelet	chain	0.529	0.006	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	4	Bracelet	chain	0.4098	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	4	Bracelet	hook	0.0826	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	4	Bracelet	charm	0.8434	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	6	Bracelet	chain	0.3988	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	6	Bracelet	hook	0.0919	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	6	Bracelet	charm	0.8075	0.000	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6399	1	Bracelet	chain	0.3781	0.000	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6399	1	Bracelet	hook	0.085	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6399	1	Bracelet	charm	0.5921	0.001	1.4	1.5	3.5	0.0	6.4	6.4
07-840-6399	2	Bracelet	chain	0.361	0.001	0.0	0.0	0.5	0.0	0.5	0.5

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+ 18=24
						1	2	3	18		
07-840-6399	2	Bracelet	hook	0.095	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6399	2	Bracelet	charm	0.573	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6400	5	Bracelet	hook	0.0925	0.002	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6400	5	Bracelet	chain	0.542	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6400	6	Bracelet	hook	0.1001	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6400	6	Bracelet	chain	0.5167	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6401	2	ring	Ring	0.326	0.002	0.2	0.0	0.0	0.0	0.2	0.2
07-840-6401	3	ring	Ring	0.293	0.001	0.3	0.1	0.0	0.0	0.4	0.4
07-840-6402	2	ring	Ring	0.2545	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6402	6	ring	Ring	0.327	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6411	2	necklace	pendant	1.432	0	0.6	0.2	0.1	0.3	0.8	1.1
07-840-6411	1	necklace	pendant	0.965	0	0.8	0.2	0.4	2.0	1.5	3.5
07-840-6412	1	necklace	pendant	6.958	0	1.6	0.5	0.5	0.7	2.6	3.3
07-840-6412	2	necklace	pendant	11.306	0	7.9	0.3	0.6	1.6	8.9	10.4
07-840-6428	4	ring set	ring 1	1.024	0.218	1.4	0.7	1.1	4.5	3.2	7.7
07-840-6428	4	ring set	ring 3	1.141	0.065	5.0	4.2	0.8	0.8	10.0	10.8
07-840-6428	6	ring set	ring 1	1.296	92.7	14.4	29.0	48.1	255	91.5	346
07-840-6428	6	ring set	ring 3	1.238	0.048	0.6	0.0	0.0	0.9	0.6	1.5
07-840-6429	3	necklace	Pendant	1.493	0.031	0.0	0.0	0.0	0.7	0.0	0.7
07-840-6429	4	necklace	Pendant	1.574	0.03	0.0	0.0	0.0	1.0	0.0	1.0
07-840-6465	1	necklace	Pendant			19.0	37.9	7.5	56.8	64.4	121
07-840-6465	2	necklace	Pendant			4.8	1.6	4.8	6.4	11.2	28.8
07-840-6465	5	necklace	Pendant	7.996	0.062						
07-840-6465	6	necklace	Pendant	8.0217	0.045						
07-840-6466	1	bracelet		850		8.5	0.0	0.0	0.0	8.5	8.5
07-840-6466	3	bracelet			0.006						
07-840-6466	4	bracelet			0.005						
07-840-6466	5	bracelet		867		0.0	0.0	0.0	0.0	0.0	0.0
07-840-6518	1	necklace	pendant	9.317	0.011	1.6	0.0	0.1	0.5	1.7	2.8
07-840-6518	1	necklace	pendant	2.891	0.01	1.1	0.2	0.0	0.2	1.3	1.5
07-840-6518	2	necklace	pendant	9.066	0.008	1.0	1.6	0.5	0.7	3.1	3.8
07-840-6518	2	necklace	pendant	2.845	0.01	0.8	0.3	0.6	0.3	1.7	2.0
07-840-6519	1	mixed	pendant	2.206	0.01	4.2	0.8	0.2	0.2	5.2	5.4
07-840-6519	2	mixed	pendant	2.265	0.01	1.3	0.6	0.2	0.1	2.1	2.2
07-840-6520	1	necklace	pendant	3.261	nd	2.4	0.5	0.6	0.3	3.5	3.8
07-840-6520	1	necklace	pendant	4.183	nd	1.6	0.2	0.0	0.0	1.7	1.7
07-840-6520	2	necklace	pendant	2.503	nd	0.6	0.7	0.0	0.3	1.3	1.6
07-840-6520	2	necklace	pendant	4.238	nd	2.7	0.0	0.2	1.6	2.8	4.4

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+ 18=24
						1	2	3	18		
07-840-6787	1	necklace	charm	10.08	0.023	8.5	0.0	0.0	37.1	8.5	45.6
07-840-6787	1	necklace	clasp	0.39	0.063	2.5	2.5	5.6	23.6	10.6	34.2
07-840-6787	2	necklace	charm	9	0.193	0.0	0.0	0.0	38.9	0.0	38.9
07-840-6787	2	necklace	clasp	0.42	0.066	1.0	1.9	4.0		6.9	6.9
07-840-6788	1	Bracelet	bracelet	4.48	0.028	1.6	0.0	0.0	2.1	1.6	3.6
07-840-6788	2	Bracelet	bracelet	4.54	0.047	0.7	0.0	0.0	1.1	0.7	1.8
07-840-6969	3	necklace	Hook	0.432	67.5	629	1392	3566	8954	5587	14541
07-840-6969	5	necklace	Hook	0.615	52.2	472	1608	3380	10029	5460	15489
07-840-7061	6	Bracelet	charm		88.7	353	734	1165	17474	2252	19726
07-840-7061	6	Bracelet	ring 1		87.2	234	549	1130	13529	1914	15443
07-840-7061	6	Bracelet	ring 2		87.1	63.4	51.8	53.9	2573	169	2742
07-840-7061	6	Bracelet	hook		84.8	874	1696	2291	29050	4860	33910
07-840-7061	6	Bracelet	tear drop		89.9	144	182	239	1277	565	1842
07-840-7061	8	Bracelet	charm		85.4	810	1210	1415	10858	3435	14293
07-840-7061	8	Bracelet	ring 1		89	806	1756	2757	27871	5320	33191
07-840-7061	8	Bracelet	ring 2		84.8	767	1459	1875	16097	4101	20198
07-840-7061	8	Bracelet	hook		86	737	1801	2495	18704	5032	23736
07-840-7061	8	Bracelet	tear drop charm		85.4	226	340	366	1955	931	2887
07-840-7064	21	Bracelet	charm	11.52	89.2	1931	4205	16685	137393	22822	160214
07-840-7064	21	Bracelet	link	2.597	89.3	2223	3300	3869	30166	9292.4	39459
07-840-7064	21	Bracelet	clasp	2.539	91.8	2220	3699	4799	38513	10612	49125
07-840-7064	22	Bracelet	charm	10.015	94.5	2412	6228	13298	109385	21938	131323
07-840-7064	22	Bracelet	link	2.701	87.0	2805	3591	3676	25696	10072	35768
07-840-7064	22	Bracelet	clasp	2.262	94.9	430	5675	7267	39761	13372	53134
07-840-7171	3	ring		5.78	11.9	85.0	114	167	968	366	1334
07-840-7171	5	ring		5.57	6.52	238	288	457	2923	983	3906
07-840-7172	4	necklace	pendant	9.57	1.37	5.8	0.0	0.0	33.3	5.8	39.1
07-840-7172	4	necklace	hook	0.55	88.9	274	459	673	2233	1406	3638
07-840-7172	7	necklace	pendant	8.14	0.50	0.00	0.00	0.00	0.00	0.00	0.00
07-840-7172	7	necklace	hook	0.54	89.3	663	931	1735	9702	3329	13030
07-840-7173	8	ring #1	solder	5.676	13.7	404	572	733	3175	1710	4885
07-840-7173	8	ring Crown	solder	5.626	1.65	130	85	39	230	254	484
07-840-7173	8	ring	ring metal		0.006						
07-840-7174	5	ring		1.559	0.266	764	1023	1572	4862	3358	8220
07-840-7174	5	chain		0.973	0.001	2.8	0.0	0.0	0.0	2.8	2.8
07-840-7174	8	ring		1.589	1.21	690	1198	1872	7281	3759	11041
07-840-7174	8	chain		0.99	0.006	0.7	1.0	0.0	0.0	1.7	1.7

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 2. Non-Metal Jewelry Results

Sample	Sub	Sample Type	Parts	Material	Weight g	* XRF		% Pb	µg Pb 1st 24 hours	µg Pb 2nd 24 hours	Total µg Pb 48 hours
						Pb Lα	Pb Lß				
07-302-0045	1	necklace	cord	PVC	1.68	7.6	3.3	0.039	26.9	14	41
07-302-0046	1	necklace	crystal	crystal		116.9	107.6	23.5			
07-302-0046	1	necklace	crystal	crystal		88	101	17.3			
07-810-4076	2	bracelet		plastic (ABS)		nd	nd				
07-810-4076	2	ring		plastic(ABS)		nd	nd				
07-810-4076	2	hair clip		plastic (ABS)		nd	nd				
07-810-4076	3	false nails		plastic (ABS)		1.3	nd				
07-810-4076	3	ring		plastic (ABS)		nd	nd				
07-810-4076	6	false nails		plastic (ABS)		nd	nd				
07-810-4077	4, 5	Ring		plastic	0.7258	0.283/2.283	0/0.8	0.0013			
07-810-4173	1	necklace	Crystal from pendant	crystal		465	507	13.57			
07-810-4173	2	necklace	Crystal from "diamond" earring	crystal				13.68			
07-810-4294	1		beads/stone)	Epoxy Resin		ND	ND				
07-810-4294	3		beads/stone)	Epoxy Resin		ND	ND				
07-810-4294	5	Ring	beads/stone)	Epoxy Resin		ND	ND				
07-810-4294	5	Ring	beads/stone)	crystal				14.8			
07-810-4294	5	Ring	beads/stone)	Epoxy Resin		ND	ND				
07-810-4654	2	ring		plastic(methyl acrylate) gemstone		nd	nd				
07-810-4711	4	earring	crystal	crystal				0.015			
07-810-4711	5	earring	crystal	crystal				0.051			
07-810-4948	2		Beads(5x)	plastic (PVC)	0.4416	388	361	0.198	2.74	1.82	4.56
07-810-4948	4		Beads(5x)	plastic (PVC)	0.4428	388	361	0.202	4.80	0.24	5.04
07-810-5027	2	necklace	pendant	glass crystal				0.064			
07-810-5027	3	earring		glass crystal		92	65	0.549			
07-810-5027	3	necklace	pendant	glass crystal	0.083				2.6	1.3	3.9
07-810-5034	2	necklace	bead	plastic (ABS) with metal foil		3.5	ND	0.01	0.4	0.8	1.2
07-810-5034	4	necklace	bead	plastic (ABS) with metal foil		6.5	ND	0.014	0.6	0.3	0.9
07-810-5034	5	necklace	green bead	plastic (ABS) with metal foil		3.2	ND	0.014	0.2	0.4	0.6
07-810-5034	5	necklace	gold bead	plastic (ABS) with metal foil		2.8	ND	0.026	0.2	0.2	0.4
07-810-5222	3	necklace	cord	plastic (PVC)	2.45			0.596	85.2	105.1	190.3

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Material	Weight g	* XRF		% Pb	µg Pb 1st 24 hours	µg Pb 2nd 24 hours	Total µg Pb 48 hours
						Pb Lα	Pb Lß				
07-810-5222	3	necklace	bead	plastic	0.4026				0	0	0
07-810-5222	4	necklace	cord	plastic (PVC)	2.58			0.604	81.1	101.2	182.3
07-810-5222	4	necklace	bead	plastic	0.4205				0	0	0
07-810-5178	4	Choker		crystal	0.0387			12			
07-810-5178	4	Choker	collar	plastic (PVC)		166	202	0.48	298	292	590
07-810-5178	6	Choker		crystal	0.0347			17.2			
07-810-5178	6	Choker	collar	plastic (PVC)				0.83	146	117	262
07-810-5259	2&6	Ring	Pendant	crystal				0			
07-810-5259	2&6	necklace	Pendant	crystal				0			
07-810-5260	2	Ring	bead	crystalline bead				0.035	6.5	1.2	7.7
07-810-5260	2	necklace	bead	crystalline bead				0	22.3	0.9	23.3
07-810-5260	5	Ring	bead	crystalline bead				0.041	22.2	12	34.2
07-810-5260	5	necklace	bead	crystalline bead				0	0	0	0
07-810-5260	2&5	necklace	pendant	crystal				0			
07-810-5261	1	necklace	beads	crystalline bead				0.01	0		0
07-810-5261	4	necklace	beads	crystalline bead				0.018	0		0
07-810-5261	1&4	necklace	butterfly pendant	crystal				0			
07-840-6137	4	necklace	crystal	glass crystal				5.9			
07-840-6137	6	necklace	crystal	glass crystal				7.54			
07-840-6137	**	necklace	crystal	glass crystal	0.0705				0.8	0.4	1.2
07-840-6171	4	necklace	charm	plastic	6.136			0.01	0	0	0
07-840-6171	4	necklace	chain	plastic	13.78			0.01	0	0	0
07-840-6171	8	necklace	charm	plastic	6.167			0.012	0	0	0
07-840-6171	8	necklace	chain	plastic	13.85			0.005	0	0	0
07-840-6172	5	bracelet	bead	plastic	0.474			0.001	0.4	0	0.4
07-840-6172	5	bracelet	battery holder	plastic	0.534			0.008	1.9	1.3	3.2
07-840-6172	8	bracelet	bead	plastic	0.432			0.0004	0.5	0	0.5
07-840-6172	8	bracelet	battery holder	plastic	0.527			0.005	1.2	0.3	1.5
07-840-6189	1	necklace	pendant	plastic PA		nd	nd				
07-840-6190	1	necklace	pendant	plastic PA		nd	nd				
07-840-6220	4	jeans	yellow rhinestone	crystal metal backing		483	360	3.34	30.6	19.8	50.4
07-840-6220	4	jeans	orange rhinestone	crystal metal backing				0.035	23.5	14.5	38
07-840-6220	4	jeans	silver rhinestone	crystal (metal backing)		933	970	10.4	0.5	11.7	12.2

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Sample	Sub	Sample Type	Parts	Material	Weight g	* XRF		% Pb	µg Pb 1st 24 hours	µg Pb 2nd 24 hours	Total µg Pb 48 hours
						Pb Lα	Pb Lß				
07-840-6224	1	Ring necklace	Ring	crystal				0.147			
07-840-6224	2	Ring necklace	Ring	crystal				0.146			
07-840-6466	3	bracelet		glass crystal				22.8			
07-840-6466	4	bracelet		glass crystal				25.2			
07-840-6466	***	crystal		glass crystal	0.148				2.4	1.8	4.2
07-840-6519	1	mixed	plastic band	plastic (PVC)	0.787	30.26	28.36	0.102	24.38	5.43	29.81
07-840-6519	2	mixed	plastic band	plastic (PVC)	0.796			0.022	5.86	1.77	7.63
07-840-6970	1	necklace		painted wood		nd	nd				
07-840-7642	3	necklace	coated plastic beads	plastic				0.004	2.8	0	2.8
07-840-7642	4	necklace	coated plastic beads	plastic					11.6	0	11.6

*Note: XRF = x-ray fluorescence spectroscopy. Items were screened using XRF to determine presence of Pb. The analysis done was qualitative, not quantitative although intensity values for Pb La and Lb are related to amount of lead present. nd= not detected

** -4 subs used

***- 12 subs used

PA -Polystyrene Acetonitrile

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB B: Assessment of Cadmium Migration from Materials

T
A
B

B

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

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

Memorandum

Date: June 3, 2010

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

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

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

FROM : Ian A. Elder, Ph.D.
Chemist, Laboratory Sciences, Division of Chemistry

SUBJECT : Assessment of Cadmium Migration from Materials[1]

1.0 EXECUTIVE SUMMARY

In response to concern about cadmium in children's consumer products, the primary goal of this study is to produce data that can be used in determining the public health and clinical significance of exposure to cadmium at levels that may migrate from metal and plastic materials. Study results may be useful with derived exposure limits for acute and chronic cadmium toxicity in the establishment of total cadmium content limits similar to regulations for lead. Products tested for cadmium under the Federal Hazardous Substances Act are currently evaluated for estimates of exposure levels using the time-consuming migration tests described in this memorandum.

The test procedures used in this study were designed to estimate exposure from products like children's jewelry. Migration of cadmium from material surfaces was characterized with solutions that simulate saliva and gastric acid. The study attempted to correlate total cadmium content levels with extractable cadmium within specific material types. For metal-based materials, the study found that product composition factors, such as element content and coatings, have a larger effect on cadmium migration than does total cadmium content. Alloys containing zinc were found to leach less cadmium than those that are free of zinc. Plastics did not leach detectable levels of cadmium.

[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.

The study plan was also designed to produce information on the accuracy and precision of analytical techniques used by the U.S. Consumer Product Safety Commission (CPSC) staff for measuring cadmium content and migration. The development of efficient concentration-based referral levels for metal products may be complicated by the effect of coatings on x-ray fluorescence (XRF) analyzer accuracy and the effects of coatings and zinc content on soluble cadmium migration.

2.0 SCOPE AND APPLICABILITY

Some children's jewelry products have been found to contain very high levels of cadmium (Ref. 1). There is concern that migration of cadmium from these products may result in exposure to toxic levels of cadmium for the children who use such products. The study described herein examines the accessibility of cadmium in metal and plastic materials containing different levels of cadmium. The cadmium-containing materials include reference standards and children's jewelry products. An understanding of cadmium leach rates may be useful when developing content regulations to ensure that exposures are less than health-based limits. The study also evaluates analytical techniques employed by CPSC staff for the identification of children's products that are likely to contain hazardous levels of accessible cadmium.

Since 2007, CPSC staff has tested a variety of jewelry items for cadmium content and cadmium solubility. Dilute hydrochloric acid (HCl) and saline are used to simulate the leaching expected during the digestion and mouthing of materials, respectively. As confirmed by Figures 1 and 2, staff perception has been that cadmium solubility is highly variable and not necessarily proportional to a material's cadmium concentration (data included in Table 1). It seems reasonable to expect reduced cadmium migration relative to total cadmium content when a base material is coated (e.g., painted or electroplated) with cadmium-free material. Likewise, a coating with cadmium or a cadmium-containing material without such a coating could represent a worst-case scenario. The primary issue this study sought to resolve was whether cadmium solubility is proportional to cadmium content in homogenous materials.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

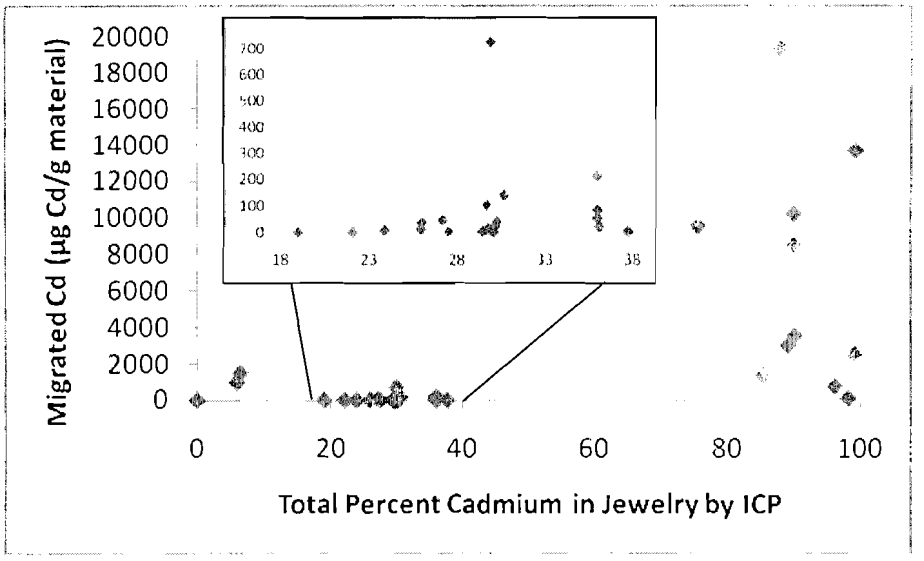

Figure 1. Soluble migrated cadmium from jewelry components with 24 hours of exposure to 0.07N HCl.

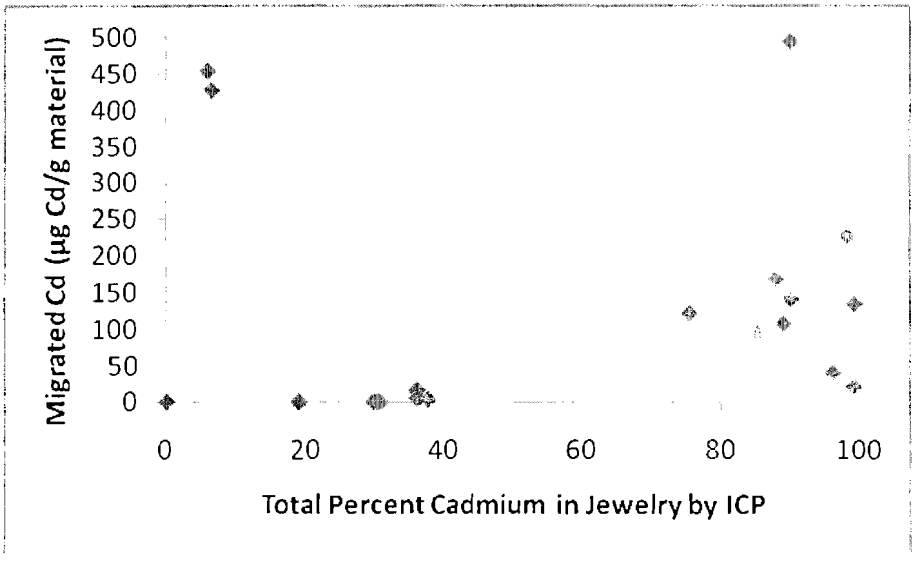

Figure 2. Soluble migrated cadmium from jewelry components with six hours of exposure to 0.9% NaCl.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 1. Cadmium Data from Jewelry Analysis

Component	Content by ICP-OES (%)	Content by XRF (%)	Migrated into 0.07N HCl, 24h (µg/g)	Migrated into 0.9% NaCl, 6h (µg/g)
08-302-2601 Charm	1.32	1.16	-	-
08-302-2600 Charm	1.02	0.923	-	-
08-302-2599 Charm	1.35	1.30	-	-
08-302-2598 Charm	1.32	1.04	-	-
08-810-5399 Ball	22.1	-	0.84	-
08-810-5399 Big Tree	23.9	-	7.20	-
08-810-5399 Tree	30.1	-	0.85	-
08-810-5399 Hat	27.5	-	3.04	-
08-810-5399 Stocking	29.5	-	4.08	-
08-840-7192 Globe	37.7	15.4	-	-
08-840-7192 Bird	43.6	13.8	-	-
08-840-7306 Charm	36.0	-	83.3	16.7
08-840-7306 Charm	36.0	-	212	15.5
08-840-7306 Charm	36.0	-	54.8	-
09-810-7596 Hook	33.4	11.3	-	-
09-810-7596 Link	36.2	12.1	-	-
10-302-2023 Clasp	5.98	1.20	988	455
10-302-2023 Flake	98.2	28.4	110	228
10-302-2023 Man	99.1	30.2	2519	21.6
10-302-2024 Clasp	6.47	1.50	1520	429
10-302-2024 Tree	85.3	34.1	1374	95.3
10-302-2024 Cane	96.1	31.7	773	40.6
10-302-2024 Deer	99.3	33.2	13668	135
10-302-2206 Heart	89.9	42.6	10215	495

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 1 Continued. Cadmium Data from Jewelry Analysis

Component	Content by ICP-OES (%)	Content by XRF (%)	Migrated into 0.07N HCl, 24h (µg/g)	Migrated into 0.9% NaCl, 6h (µg/g)
10-302-2206 Key	0.0285	0.0248	1.21	0.67
10-304-3090 Flower	19.0	12.3	0.72	0.08
10-304-3415 Metal	75.5	27.1	9552	122
10-304-3415 Star	30.3	19.1	40.8	0.88
10-304-3416 Star	30.7	18.2	140	0.35
10-304-3417 Heart	36.1	17.2	21.6	5.23
10-304-3417 U	29.7	13.4	103	0.64
10-304-3418 Heart	37.7	14.7	3.76	3.90
10-304-3418 Crown	30.2	16.3	22.7	-
10-304-3419 Bracelet	87.8	23.7	19362	169
10-304-3420 Bracelet	90.0	34.2	3545	142
10-304-3421 Bracelet	89.9	29.7	8506	143
10-304-3422 Bracelet	89.0	25.4	3008	108
10-304-3815 Pendant	16.0	13.8	-	-
10-304-3816 Pendant	15.4	6.94	-	-
10-304-3817 Pendant	16.4	5.39	-	-
10-304-3818 Pendant	15.6	8.97	-	-
10-810-5600 Tag	29.8	8.11	16.4	-
10-810-5600 Pendant	29.9	15.5	726	-
10-810-5600 Clamp	26.0	9.17	12.3	-
10-810-5601 Tag	27.2	16.2	45.6	-
10-810-5601 Pendant	26.0	18.5	36.5	-

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

3.0 SUMMARY OF METHOD

3.1 Selection of Test Materials

A brief survey of 20 metal components from 14 children's jewelry products (submitted to the laboratory due to expected cadmium content) found that copper and zinc were the most prevalent metals (Figure 3). Other elements preliminarily identified by XRF include: tin, silver, bismuth, antimony, titanium, nickel, lead, and iron. These elements were present less frequently and at lower concentrations than copper and zinc. A variety of commercially available materials was acquired for use as standards in this study. Metal alloy and plastic standards include materials similar to the substrates and coatings used in the jewelry products described above. Study materials contain a range of cadmium concentrations and, unlike most children's jewelry, the study materials are homogenous. Certificates of chemical analysis are included in the Appendix[2].

A material's surface area is expected to affect its soluble cadmium. In an effort to standardize the exposed area between study alloys, materials were acquired in wire form with diameters of 2.36-2.39 mm whenever possible. Plastics and some alloys were not available with these dimensions, so extractions were also conducted using powdered material. Powdered materials represent a surface area limit that is significantly greater than what is expected for accessible areas on children's products.

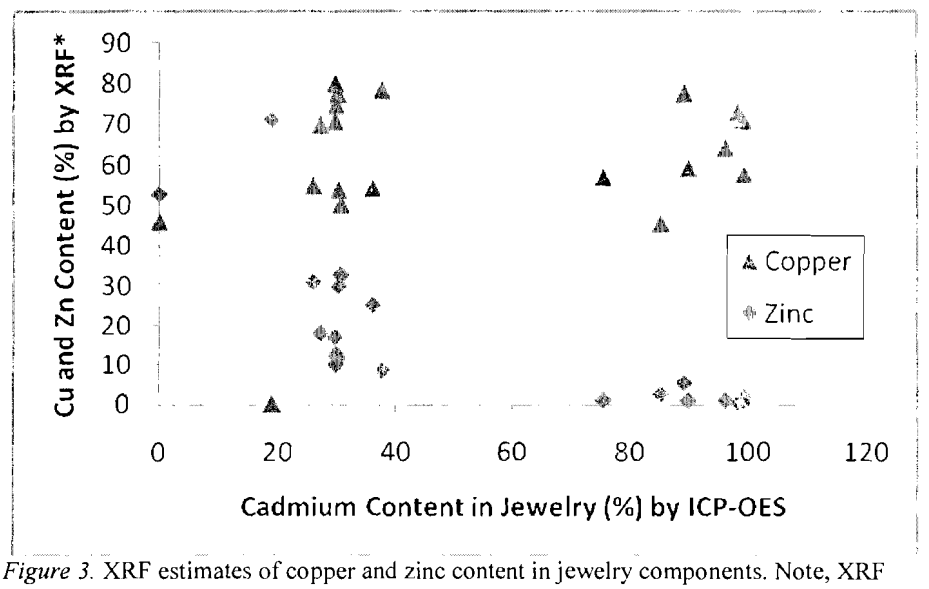

Figure 3. XRF estimates of copper and zinc content in jewelry components. Note, XRF accuracy for copper and zinc have not been determined at CPSC. The values presented above should be considered relative estimates only. As shown elsewhere in this memorandum, cadmium XRF measurements for real-world (inhomogeneous) metal samples generally have poor accuracy.

[2] Manufacturer specific information has been coded and certificates of analyses redacted pursuant to section 6 (b) of the Consumer Product Safety Act.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

3.2 Test Material Preparation

Plastic materials and metals purchased in powder form were used without cleaning or sanding. Metal materials received in wire, disc, or bar form were cleaned using standard practices for the preparation of corrosion test specimens (Ref. 2). In brief, the materials were each washed in hexanes, and then sanded with 600-grit silicon carbide abrasive paper. Sanded materials were washed thoroughly with deionized water followed by acetone and then dried with hot air. Powdered metal material was made from cleaned bulk solids with a rotary grinding tool. Plastics purchased in pellet form were ground to powder with a cryogenic mill.

3.3 Data Collection and Handling

The instrumentation and procedures described in this report are routinely used (with adaptations as necessary) by CPSC staff and are similar to those that were used to evaluate the migration of lead from children's products (Ref. 3). Each of the study materials was tested for cadmium content by XRF and inductively coupled plasma-optical emission spectrometry (ICP-OES), and for cadmium migration in saline and dilute acid.

Twelve replicate measurements were made for each determination of cadmium content and for each soluble cadmium migration test of a reference alloy. Measurements that were outside of plus or minus three times the replicate set's standard deviation were not included in calculations of cadmium content, accuracy, and precision data. The final values include a minimum of ten replicate measurements. Measurement precision is illustrated in plots with error bars at plus and minus two times the standard deviation. For plastic materials, cadmium migration was found to be less than the method detection limits, so only six replicate measurements were made. Due to the difficulties involved in quantitatively transferring small portions of material, replicate XRF measurements were not performed for study materials in powder or pellet form.

3.4 Cadmium Screening by Portable X-ray Fluorescence Analysis

XRF measurements were made using a Thermo NITON XL3t XRF Analyzer in either TestAll mode or Alloy mode. Measurement duration was at least 60 seconds. XRF detection limits were estimated for plastics and metals by taking the average of individual detection limits from multiple non-detect measurements. The XRF limit of detection was 2 ppm for plastics and 48 ppm for metals. Non-detect results (i.e., less than the analyzer's limit of detection) are included in tables as "nd". Non-detect results are included in plots as half the limit of detection and are indicated with a black square (■).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

3.5 Soluble Cadmium Migration in Saline

Extractions were performed on 0.49-0.51 g portions of plastic pellets, 0.148-0.152 g portions of powders, 3 cm segments of 2.4 mm diameter wires (~ 1 g), and 23 cm segments of 0.8 mm diameter wire (~ 1 g). Samples were weighed and then placed in a 0.9% sodium chloride (NaCl) solution with a volume equal to 50 times the sample weight (e.g., 50 mL saline solution per gram of sample). The extraction occurred over six hours at 37.5 °C in a shaker bath. Extraction solutions were collected and analyzed by ICP-OES. Samples were diluted further and reanalyzed if cadmium values exceeded 1.5 times the concentration of the high calibration standard. The amount of migrated soluble cadmium was calculated by multiplying the measured concentration by the total dilution volume (e.g., 20 µg/mL x 50 mL = 1,000 µg).

3.6 Soluble Cadmium Migration in Dilute Acid

Extractions were performed on 0.49-0.51 g portions of plastic pellets, 0.148-0.152 g portions of powders, 3 cm segments of 2.4 mm diameter wires (~ 1 g), and 23 cm segments of 0.8 mm diameter wire (~ 1 g). Samples were weighed and then placed in a 0.07 N HCl solution with a volume equal to 50 times the sample weight (e.g., 50 mL acid solution per gram of sample). The extraction occurred at 37.5 °C in a shaker bath. For wires and plastic pellets, extraction solutions were collected at 6, 24, and 48 hours after the extraction start time (i.e., samples were placed in fresh acid solutions at the 6 and 24 hour time points). For powders, separate sample portions were used for each time point. Extraction solutions were collected from powders using syringe filtration units (0.45 µm). Extraction solutions were analyzed by ICP-OES. Samples were diluted further and reanalyzed if cadmium values exceeded 1.5 times the concentration of the high calibration standard. The amount of migrated soluble cadmium was calculated by multiplying the measured concentration by the total dilution volume (e.g., 20 µg/mL x 50 mL = 1,000 µg). For metal wires and plastic pellets, the 24 hour-cumulative soluble cadmium was calculated by summing the cadmium extracted over the initial six hours and the subsequent 18 hours. The 48-hour value is the sum of measurements taken at the three time points.

3.7 Sample Preparation for Total Cadmium Content

Samples were digested following standard operating procedures for determining total lead in children's products (Ref. 3). Metals were digested by the hot block method and plastics were digested using a microwave digestion system.

3.8 ICP-OES Calibration and Analysis

Calibration standards were prepared at 0.00, 0.10, 0.25, 0.50, 1.00, 5.00, 10.0 and 20.0 µg/mL by the dilution of a 1,000 µg/mL cadmium standard (SCP Science, Champlain NY; Cat# 140-051-480). A quality control standard was prepared at 0.50 µg/mL by the dilution of a 100 µg/mL multi-element standard (SPEX CertiPrep, Metuchen NJ; Cat# CL-QC-21). An internal standard solution of 2 µg/mL yttrium in

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

2% nitric acid was prepared using a 1,000 µg/mL standard (SPEX CertiPrep, Metuchen NJ; Cat# PLY2-2Y). Standards, blanks, and samples were analyzed on a Varian VISTA-MPX CCD Simultaneous ICP-OES system (plasma flow: 15.0 L/min; nebulizer flow: 0.75 L/min; pump speed: 20 rpm; auxiliary gas flow: 1.5 L/min; cadmium wavelength: 214.439 nm; yttrium wavelength: 324.228 nm; power: 1.20 kW; and replicates: 3). The 0-20 µg/mL calibration curves had correlation coefficients greater than 0.9990 with less than 5% error for the quality control standard. Samples with on-instrument concentrations less than 5 µg/mL were measured using a calibration range of 0-5 µg/mL. All other samples were evaluated against the full calibration range.

ICP-OES instrument detection limits were determined for each method by multiplying three times the standard deviation of seven replicate measurements of reagent blanks. Method detection limits for ICP-OES were determined using reagent blanks fortified with 2-3 times the instrument detection limits. The method detection limits were calculated as follows: MDL = t x S, t=3.14 (99% confidence level for 7 replicates), S = standard deviation. The instrument and method detection limits are included in Table 2. Non-detection ICP-OES measurements (i.e., less than the method detection limit) are listed in tables as "nd". Non-detect results are included in plots using estimated ICP values equal to half of the method detection limit. Non-detect data points are indicated in plots with a black square (■).

Table 2. Instrument and Method Detection Limits for ICP-OES

Method	**Instrument Detection Limit (µg/mL)**	**Method Detection Limit (µg/mL)**
Cadmium Content in Plastic	0.005	0.009
Total Cadmium in Metal	0.010	0.042
Acid Extraction of Cadmium	0.001	0.045
Saline Extraction of Cadmium	0.001	0.001

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

4.0 RESULTS AND DISCUSSION

4.1 Characterization of Materials and Analytical Techniques

Figure 4 compares XRF and ICP-OES measurements for cadmium content in jewelry samples tested at CPSC (data included in Table 1). XRF measurements for cadmium in jewelry have significantly greater error than what is seen with homogenous alloys (Figure 5-C). In general, the relative error was found to increase with cadmium content (Panel 4-B). Figures 5-A and B demonstrate agreement between manufacturer certificates of analysis for metals and cadmium content measurements made at CPSC by ICP-OES and XRF. Panel 5-C shows good correlation between ICP-OES and XRF. Figure 6-A shows moderate agreement between vendor-certified cadmium levels and ICP-OES measurements for plastic test materials. Panels 6-B and C indicate that XRF readings did not agree very well with either the certificates of analysis or ICP-OES measurements. XRF measurements of cadmium in polyvinyl chloride standards were significantly lower than expected.

Precision and accuracy information for cadmium measurements are included in Tables 3 and 4 for metals and plastics, respectively. Accuracy was evaluated with comparisons of XRF and ICP-OES cadmium content measurements to vendor-certified values (also see Figures 5 and 6). The precision of replicate measurements was determined as the relative standard deviation for each material available in wire or pellet form. Relatively good accuracy and precision was obtained with ICP-OES for most alloy materials. The precision of XRF readings for alloys was also good but the accuracy was off by more than 5% for half of the metals. While the accuracy and precision of ICP-OES analysis for plastic materials was acceptable, XRF measurements could be classified as having moderate to poor accuracy.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

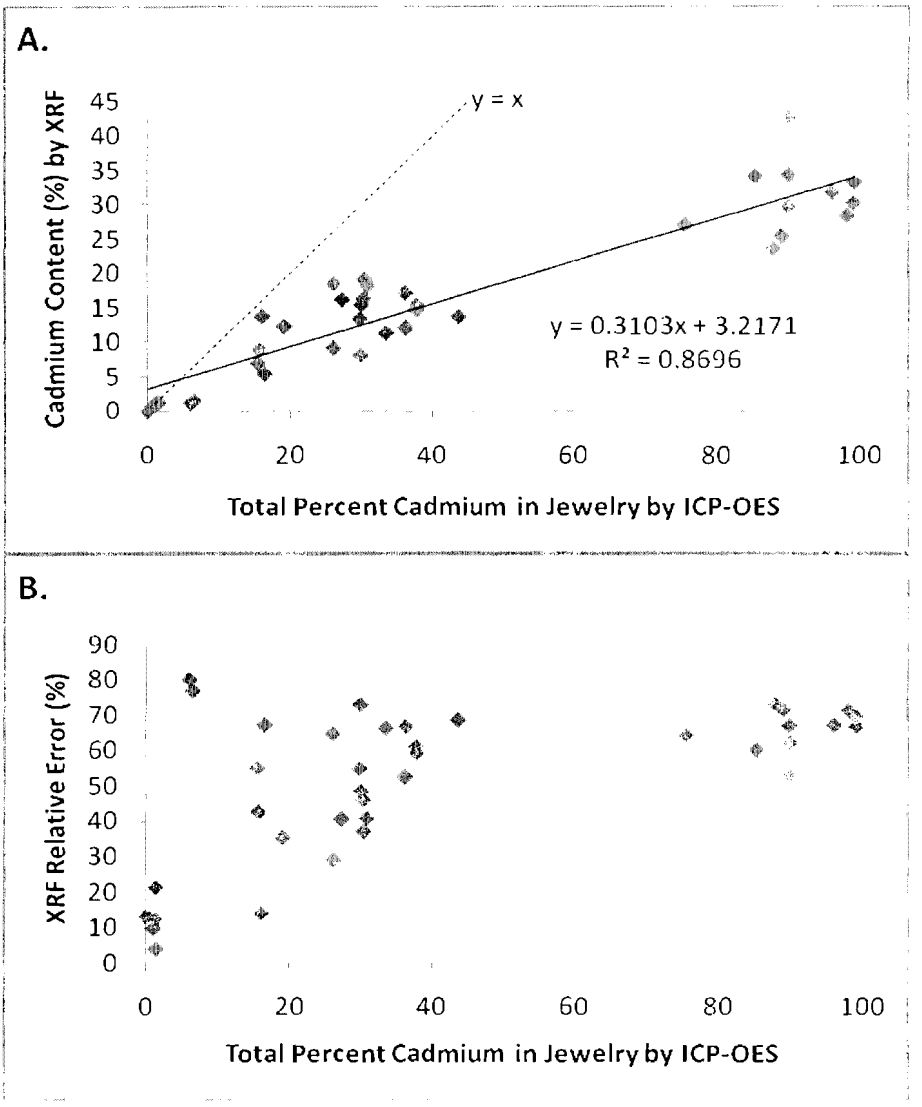

Figure 4. Effect of coatings on XRF accuracy (compare with Figure 5 for homogenous materials). Panel A: XRF and ICP-OES cadmium measurements for jewelry components. Panel B: Relative error of XRF measurements compared to ICP-OES measurements (relative error = -(XRF concentration-ICP concentration)/ICP concentration x 100).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

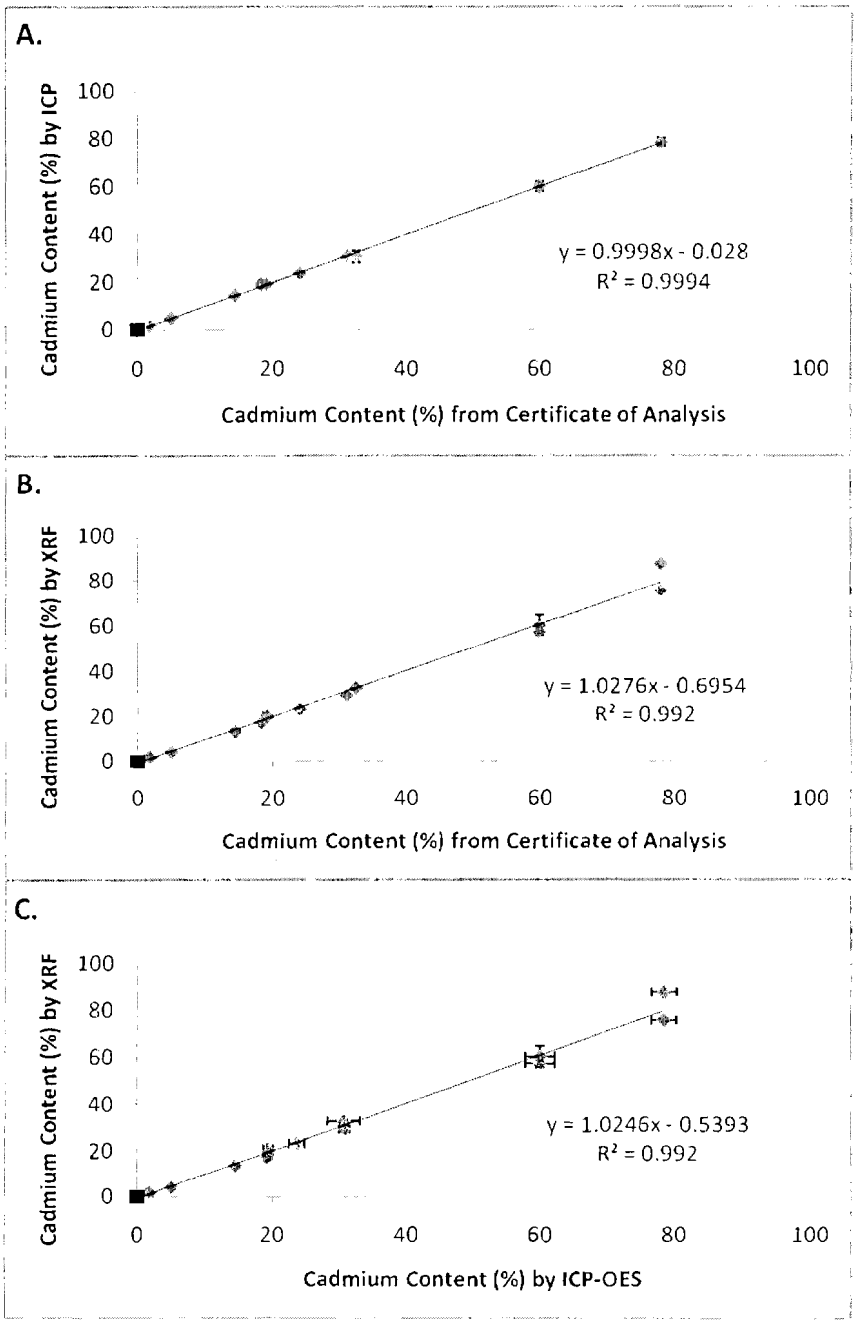

Figure 5. Confirmation of vendor-certified cadmium levels in metal test materials by ICP-OES (Panel A) and XRF (Panel B) analysis. Panel C shows a linear relationship between ICP-OES and XRF measurements. Note: plots contain XRF measurements for both wires and powders.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

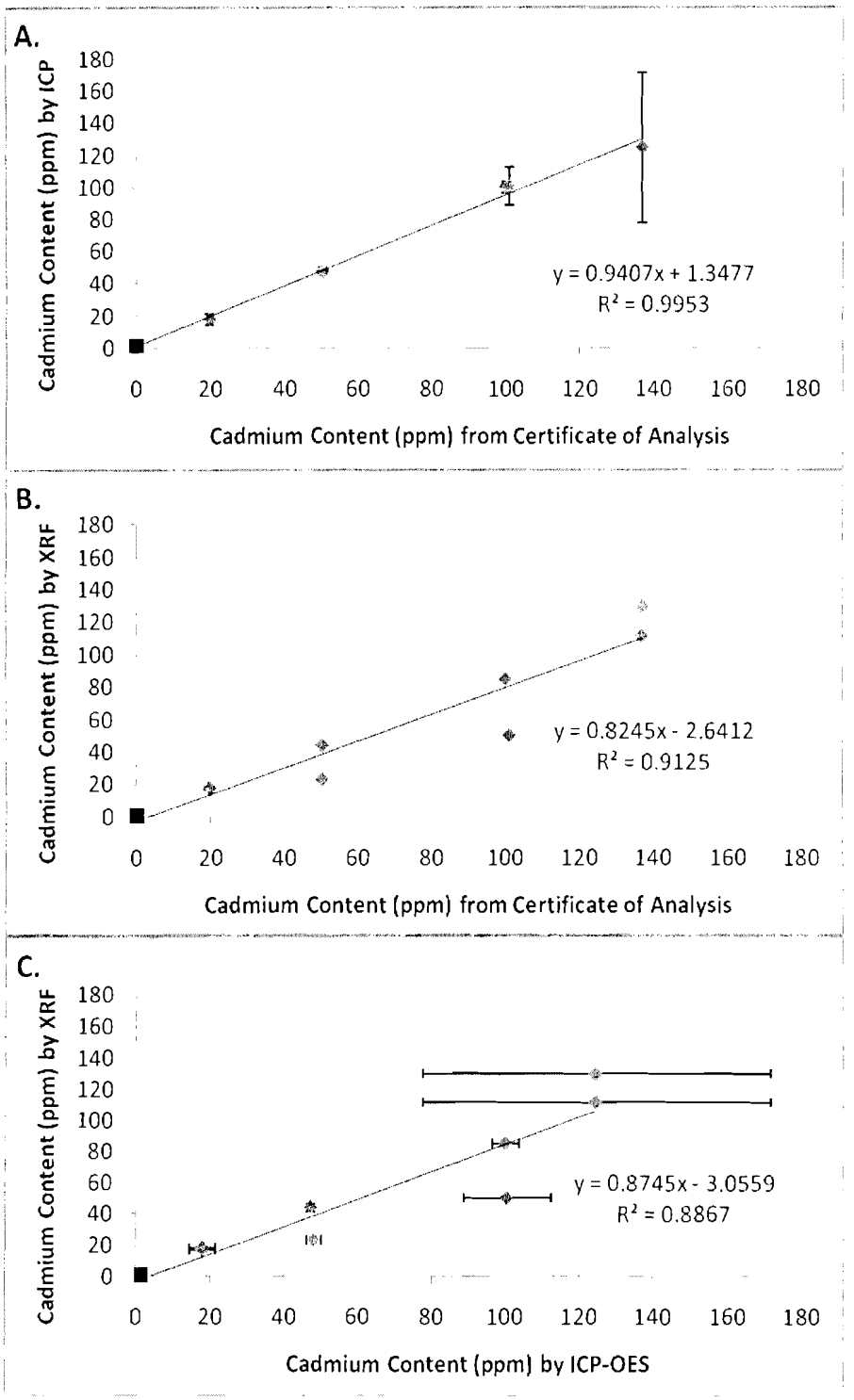

Figure 6. Confirmation of vendor-certified cadmium levels in plastic test materials by ICP-OES (Panel A). Panels B and C show XRF readings are low compared to certificates of analysis and ICP measurements. Note: plots contain XRF measurements for both pellets and powders.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 3. Analysis of Cadmium Content in Metal Test Materials.

		ICP-OES				XRF			
Material	**Certificate of Analysis (%)**	**Mean (%)**	**Standard Deviation (%)**	**RSD (%)**	**Recovery (%)***	**Mean (%)**	**Standard Deviation (%)****	**RSD (%)****	**Recovery (%)***
M001 Wire	32.398	30.601	1.213	4.0	94	32.456	0.047	0.1	100
M001 Powder	32.398	-	-	-	-	32.875	-	-	101
M002 Wire	59.92	59.99	1.09	1.8	100	60.27	2.27	3.8	100
M002 Powder	59.92	-	-	-	-	57.33	-	-	96
M003 Wire	19.042	19.322	0.382	2.0	101	20.588	0.507	2.5	108
M003 Powder	19.042	-	-	-	-	19.378	-	-	102
SRM 629 Powder	0.0155	0.0185	0.0028	15.1	119	nd***	-	-	N/A
SRM 683 Powder	0.00011	nd	N/A	N/A	N/A	nd	-	-	N/A
SRM 1129 Powder	0.006	0.006	0.000	0.9	100	nd	-	-	N/A
M004 Wire	14.42	14.44	0.10	0.7	100	13.36	0.18	1.4	93
M004 Powder	14.42	-	-	-	-	13.54	-	-	94
M005 Wire	18.22	19.30	0.26	1.3	106	17.02	0.36	2.1	93
M005 Powder	18.22	-	-	-	-	17.28	-	-	95
M006 Wire	24.01	23.63	0.56	2.4	98	23.13	0.19	0.8	96
M006 Powder	24.01	-	-	-	-	23.17	-	-	96
M007 Wire	78.01	78.44	0.95	1.2	100	87.65	0.38	0.4	112
M007 Powder	78.01	-	-	-	-	75.82	-	-	97
M008 Wire	< 0.01	0.02	0.00	3.9	N/A	nd	-	-	N/A
M008 Powder	< 0.01	-	-	-	-	nd	-	-	N/A
M009 Powder	31.0	30.8	0.40	1.3	99	29.2	-	-	94
M010Powder	1.75	1.73	0.02	1.3	99	1.90	-	-	108
M011Powder	4.99	5.02	0.04	0.9	101	4.10	-	-	82
M012 Powder	0.33	0.34	0.00	0.7	103	0.35	-	-	107
M013 Powder	0.37	0.38	0.00	0.5	103	0.40	-	-	108

* Percent recovery was calculated using cadmium concentrations reported in certificates of analysis.

** A single XRF measurement was taken for powders so standard deviation and relative standard deviation data are not available.

*** nd = non-detect.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 4. Analysis of Cadmium Content in Plastic Test Materials.

Material	Certificate of Analysis (ppm)	ICP-OES				XRF	
		Mean (ppm)	Standard Deviation (ppm)	RSD (%)	Recovery (%)*	Mean (ppm)	Recovery (%)*
PVC001 Sample 1	0	nd**	N/A	N/A	N/A	nd	N/A
PVC001 Sample 2	50	48	1	2.1	96	23	46
PVC001 Sample 3	101	100	6	6.0	99	50	50
PE001 Sample 1	0	nd	N/A	N/A	N/A	nd	N/A
PE001 Sample 2	50	47	0.5	1.1	94	44	88
PE001 Sample 3	100	100	2	1.8	100	85	85
ERM-EC680k Pellet	19.6	17.9	1.7	9.5	91	18	92
ERM-EC680k Powder	19.6	17.9	-	-	-	17	87
ERM-EC681k Pellet	137	125	24	19	91	130	95
ERM-EC681k Powder	137	125	-	-	-	112	82

* Percent recovery was calculated using cadmium concentrations reported in certificates of analysis.

** nd = non-detect.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

4.2 Soluble Cadmium Migration

Tables 5 and 6 include data for soluble cadmium migration from metals into dilute acid and saline, respectively. All measurements of soluble cadmium migration from plastics were less than the method detection limits. Figures 7 and 8 illustrate the migration of cadmium over time from metal wires and powders, respectively. Substantially different behavior is seen for the materials, including comparisons between alloys. Interestingly, the amount of migrated cadmium decreased over time for some powdered alloys. This effect was not observed for any of the samples in wire form. The decrease in migrated cadmium over time seems to be more prevalent in powders containing high levels of zinc (32-93%), with the exception of NIST SRM 1129 which contains only 0.006% cadmium and no documented zinc. The observed effect could come from differences in the test procedures for wire and powder samples. For wires, extract solutions were removed at each time point and the samples were placed in fresh solution. Extract solutions were not filtered prior to analysis. The cumulative soluble migrated cadmium for the 24-hour time point is the sum of measurements from the initial 6-hour extraction and subsequent 18-hour extraction. The 48-hour value is the sum of measurements from all three time points. For powders, different sets of materials were used for each time point (i.e., test materials remained exposed to extract solutions for full 6, 24, and 48-hour periods). Extract solutions were filtered away from powder samples using 0.45 μm syringe filter units. Filtration may have removed suspended cadmium precipitates.

No soluble cadmium was detected in saline or acid extract solutions for plastic study materials. The plastics contained low cadmium concentrations compared to most of the metals examined in the study. Plastic standards with high cadmium content were not commercially available. The plastic cadmium content levels are comparable to those in the NIST alloy materials and M008. It may be worthwhile to survey cadmium-containing plastic products to ensure that cadmium content and migration data from study plastics are representative of real-world products.

Figures 9-A and B show the amount of cadmium leached from metal wires and powders containing different levels of cadmium after 48 hours of exposure to dilute acid. Migrated cadmium was not proportional to cadmium content. This suggests that alloy composition and/or other material properties play a role in accessible cadmium. Figures 10-A and B show measurements of cadmium leached from metal wires and powders using a saline solution. In general, materials that produce elevated levels of migrated cadmium in saline also produce elevated levels in dilute acid (Figure 11).

Figure 12 illustrates the apparent effect of zinc on soluble cadmium migration from alloys. Plotting levels of migrated cadmium against the concentration of elements present in many of the test materials indicates an apparent trend with respect to zinc content. Panel A shows that cadmium migration into dilute acid decreased rapidly as zinc content increased, regardless of cadmium content. Panels B and C separate alloy powders into groups based on elemental composition. Materials high in zinc had relatively low migrated cadmium. Alloy materials with intermediate levels of zinc

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

plus intermediate levels of silver and copper were found to produce moderate levels of migrated cadmium compared to materials with little or no zinc.

As seen in Figures 1, 2, 9, and 10, soluble cadmium migration is not proportional to total cadmium content. This is due to variable composition and the presence of coatings (e.g., paint, electroplating) on many commercial products. Since surface properties are important factors in both XRF measurements and soluble cadmium migration, plots were made to look for a relationship between the two parameters. A linear correlation would be useful for predicting cadmium exposure risk using only the XRF data collected in the field. However, as seen in Figure 13, the overall data pattern is much like that in Figures 1 and 2, with cadmium concentrations shifted to lower values. This result is not unexpected when one considers the moderately good correlation seen in Figure 4-A and the relative error shown in Figure 4-B.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 5. Migration of Soluble Cadmium from Metals into 0.07N Hydrochloric Acid.

	6h Migrated Cadmium			24h Migrated Cadmium			48h Migrated Cadmium		
Material	**Mean (µg/g)**	**Standard Deviation (µg/g)**	**%RSD**	**Mean (µg/g)**	**Standard Deviation (µg/g)**	**%RSD**	**Mean (µg/g)**	**Standard Deviation (µg/g)**	**%RSD**
M001 Wire	1449.8	101.46	7.00	5148.8	542.91	10.54	9944.6	1215.3	12.22
M001 Powder	17791	7754.8	43.59	47789	16538	34.61	59997	21940	36.57
M002 Wire	nd*	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
M002 Powder	2807.4	2638.2	93.97	785.91	1316.0	167.45	76.25	128.01	167.90
M003 Wire	nd	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
M003 Powder	57.94	22.76	39.29	44.63	36.46	81.70	25.30	13.16	52.02
SRM 629 Powder	nd	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
SRM 683 Powder	nd	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
SRM 1129 Powder	24.51	0.53	2.18	23.64	5.12	21.65	24.68	0.22	0.91
M004 Wire	86.35	7.92	9.18	319.73	39.29	12.29	753.13	77.69	10.32
M004 Powder	1712.4	78.09	4.56	3065.1	324.65	10.59	3302.1	366.95	11.11
M005 Wire	25.59	2.18	8.53	84.54	4.82	5.71	160.79	7.42	4.62
M005 Powder	1267.1	119.27	9.41	2156.7	203.58	9.44	3311.0	263.29	7.95
M006 Wire	52.31	5.69	10.87	136.54	13.43	9.84	231.70	19.52	8.43
M006 Powder	1772.2	199.64	11.27	4481.4	217.03	4.84	7474.4	213.07	2.85
M007 Wire	1137.5	35.34	3.11	3493.2	195.60	5.60	5269.0	364.17	6.91
M007 Powder	13695	1964.8	14.35	12407	2852.0	22.99	17176	4487.4	26.13
M008 Wire	nd	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
M008 Powder	4.26	1.43	33.49	9.21	3.12	33.89	11.76	2.70	22.94
M009 Powder	606.09	130.99	21.61	425.95	80.48	18.89	469.76	149.78	31.88
M010Powder	8457.5	339.22	4.01	9669.4	184.08	1.90	9721.2	381.83	3.93
M011Powder	1593.2	451.52	28.34	3509.3	646.65	18.43	4859.4	1016.3	20.91
M012 Powder	532.58	82.08	15.41	1059.0	59.17	5.59	1355.2	54.35	4.01
M013 Powder	674.82	50.90	7.54	1326.1	82.04	6.19	1844.9	56.99	3.09

* nd = non-detect.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 6. Migration of Soluble Cadmium from Metals into 0.9% Saline.

	6h Migrated Cadmium		
Metal Material	**Mean (µg/g)**	**Standard Deviation (µg/g)**	**%RSD**
M001 Wire	55.21	4.40	7.96
M001 Powder	286.70	60.75	21.19
M002 Wire	nd*	N/A	N/A
M002 Powder	64.30	18.12	28.17
M003 Wire	nd	N/A	N/A
M003 Powder	59.29	17.53	29.57
SRM 629 Powder	nd	N/A	N/A
SRM 683 Powder	nd	N/A	N/A
SRM 1129 Powder	3.42	0.30	8.76
M004 Wire	25.47	1.92	7.53
M005 Powder	140.91	20.71	14.70
M006 Wire	4.08	1.20	29.44
M006 Powder	152.93	23.05	15.07
M007 Wire	168.83	23.44	13.88
M007 Powder	165.81	23.54	14.20
M008 Wire	nd	N/A	N/A
M008 Powder	0.59	0.56	94.97
M009 Powder	63.12	12.92	20.48
M010Powder	284.74	15.98	5.61
M011Powder	128.89	32.33	25.09
M012 Powder	11.28	1.31	11.59
M013 Powder	6.44	1.33	20.60

* nd=non-detect.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

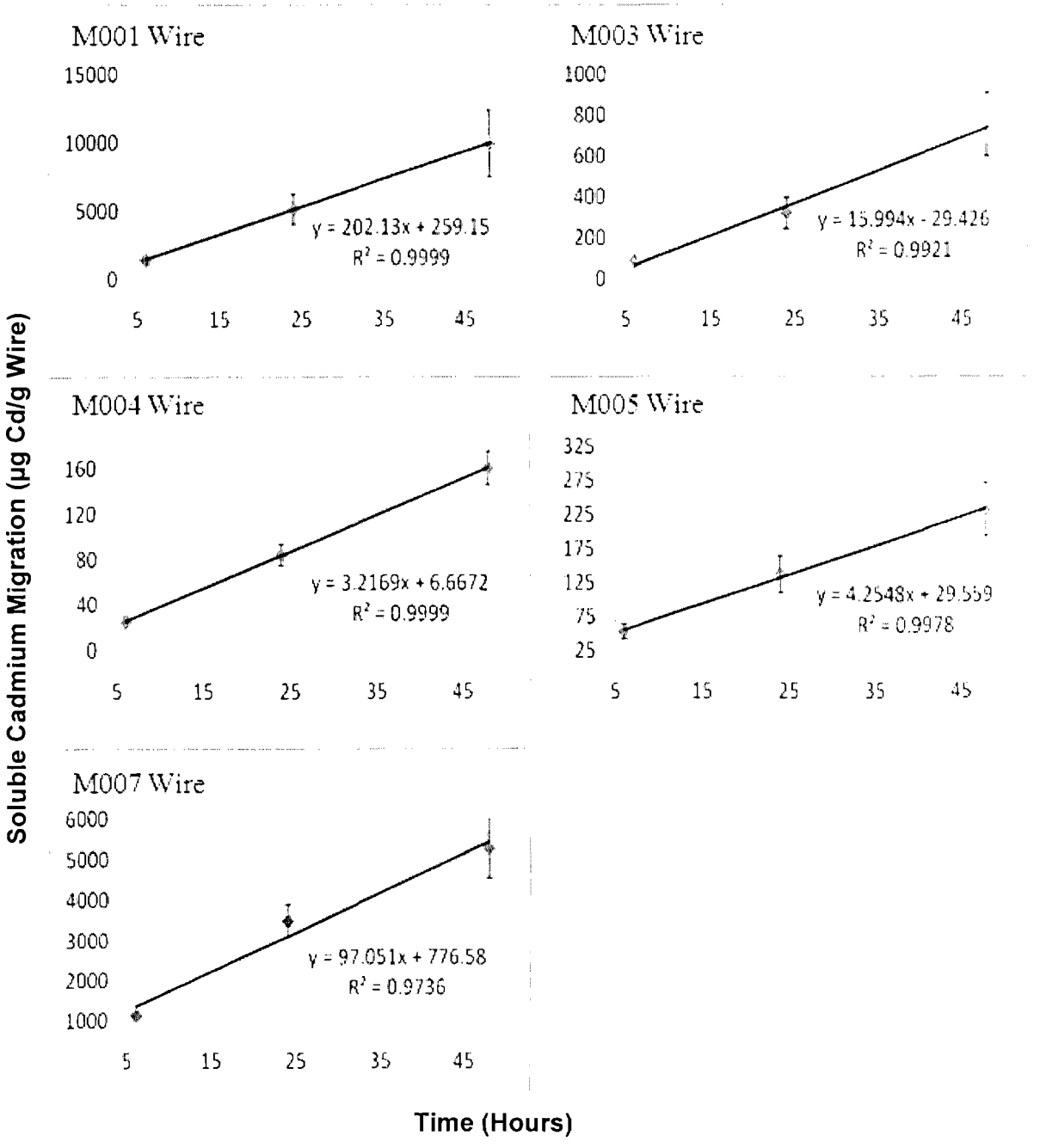

Figure 7. Cummulative cadmium migration from wires over 6, 24, and 48 hours. Measurements taken at the 24 and 48 hour timepoints were summed with values from previous timepoints.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

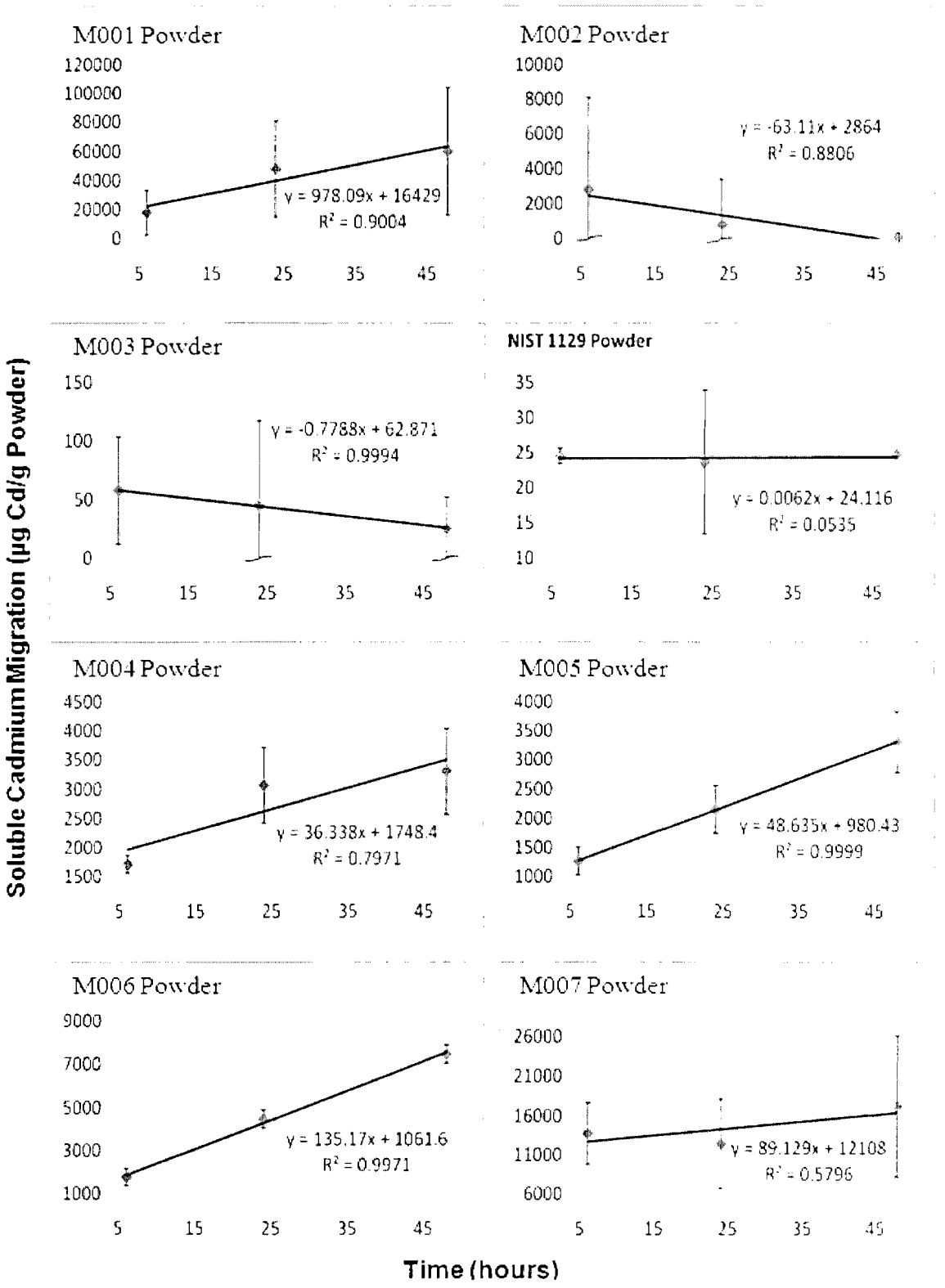

Figure 8. Cadmium migration from metal powder after 6, 24, and 48 hours. Each point is from a unique set of powders (i.e. values are not cummulative as with wires).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

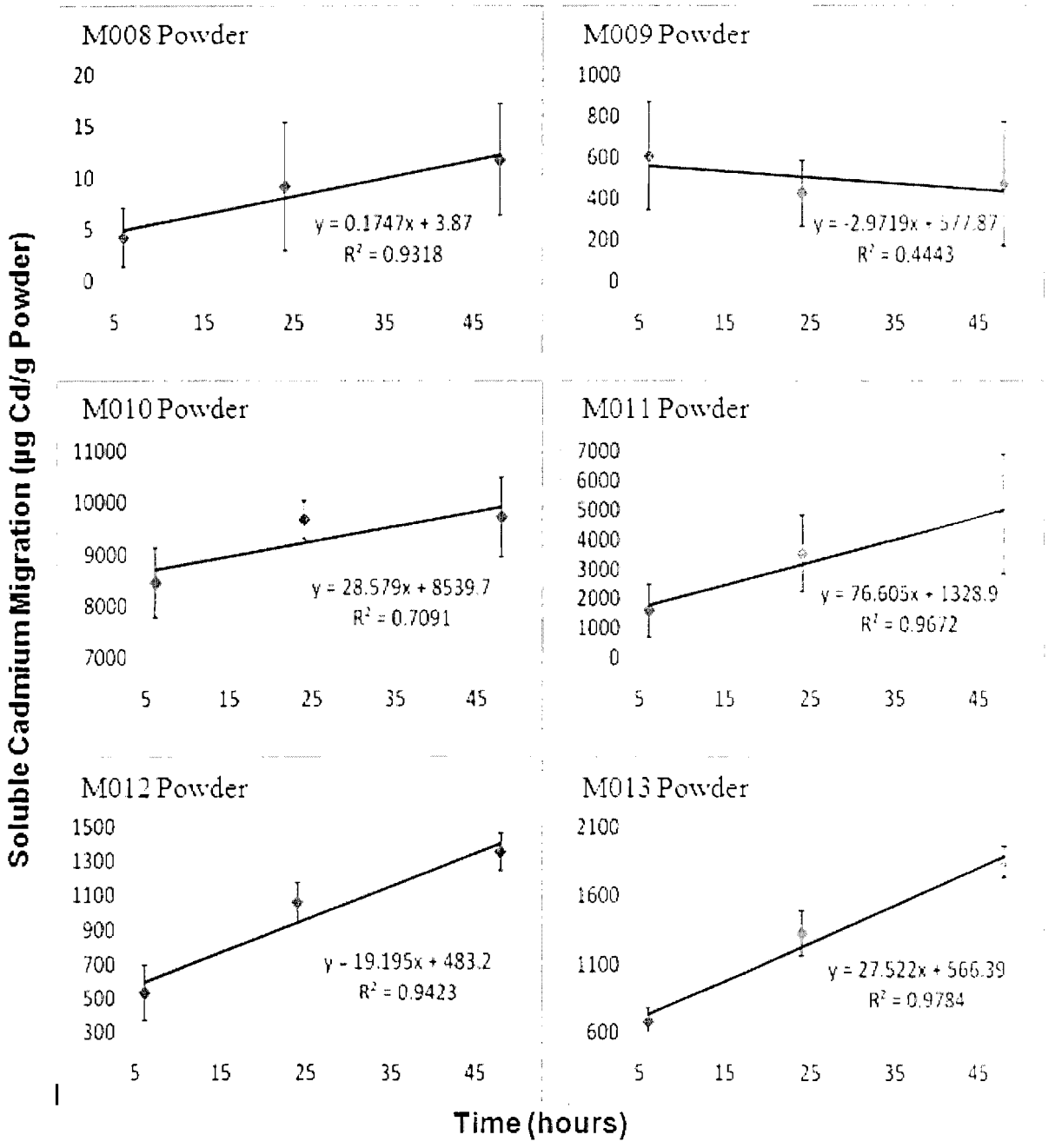

Figure 8 (Continued). Cadmium migration from metal powder after 6, 24, and 48 hours. Each point is from a unique set of powders (i.e. values are not cummulative as with wires).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

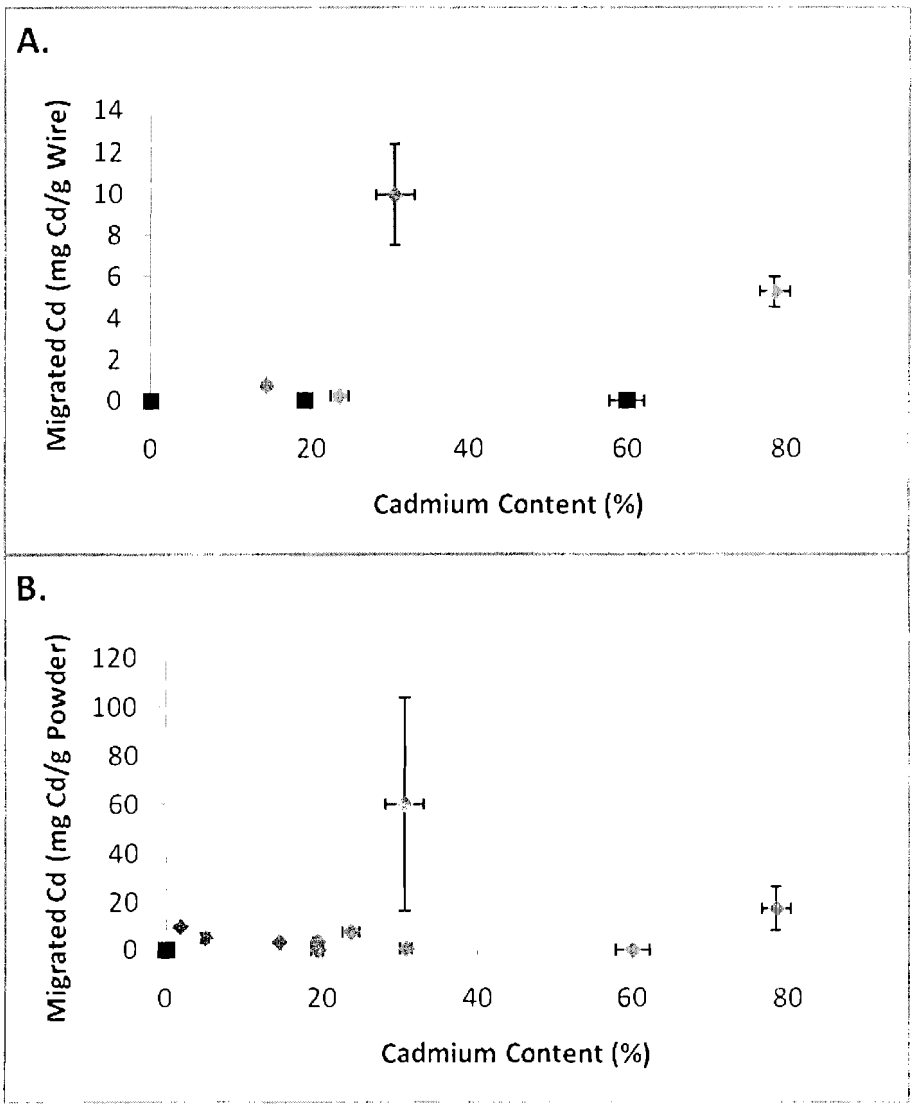

Figure 9. Cadmium leached from metal wires (Panel A) and powders (Panel B) containing different levels of cadmium after 48 hours of exposure to 0.07N HCl.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

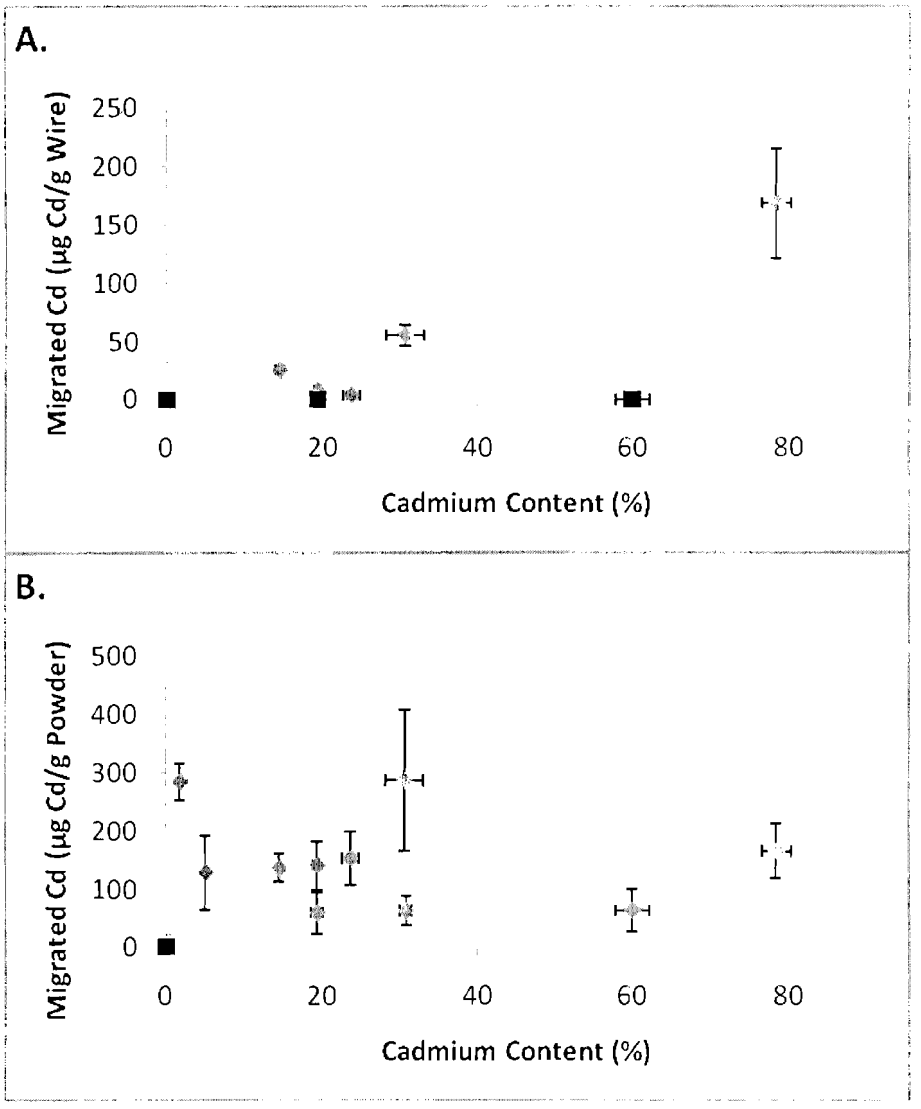

Figure 10. Cadmium leached from metal wires (Panel A) and powders (Panel B) containing different levels of cadmium after 6 hours of exposure to 0.9% NaCl.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

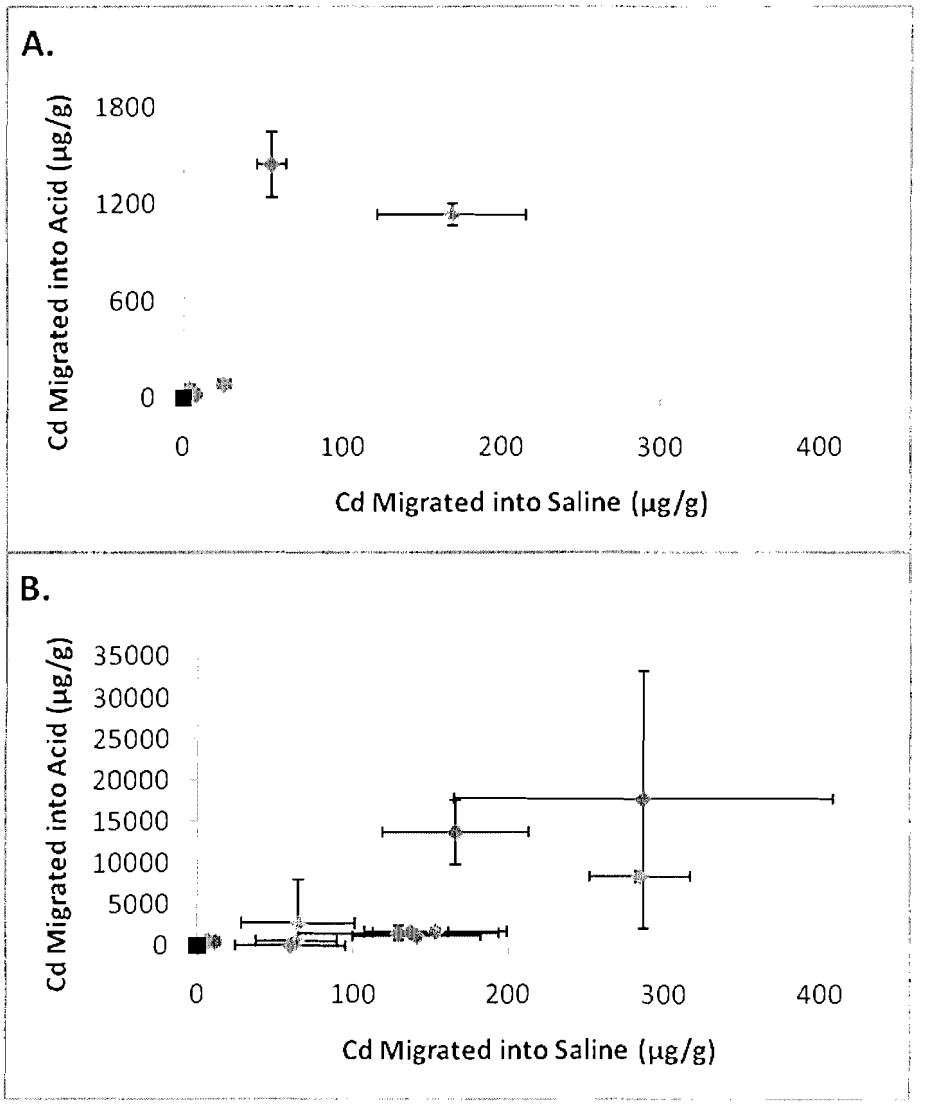

Figure 11. Comparisons of cadmium migration from alloys into dilute acid and saline over 6 hours. Panel A includes study wires and Panel B includes powder.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

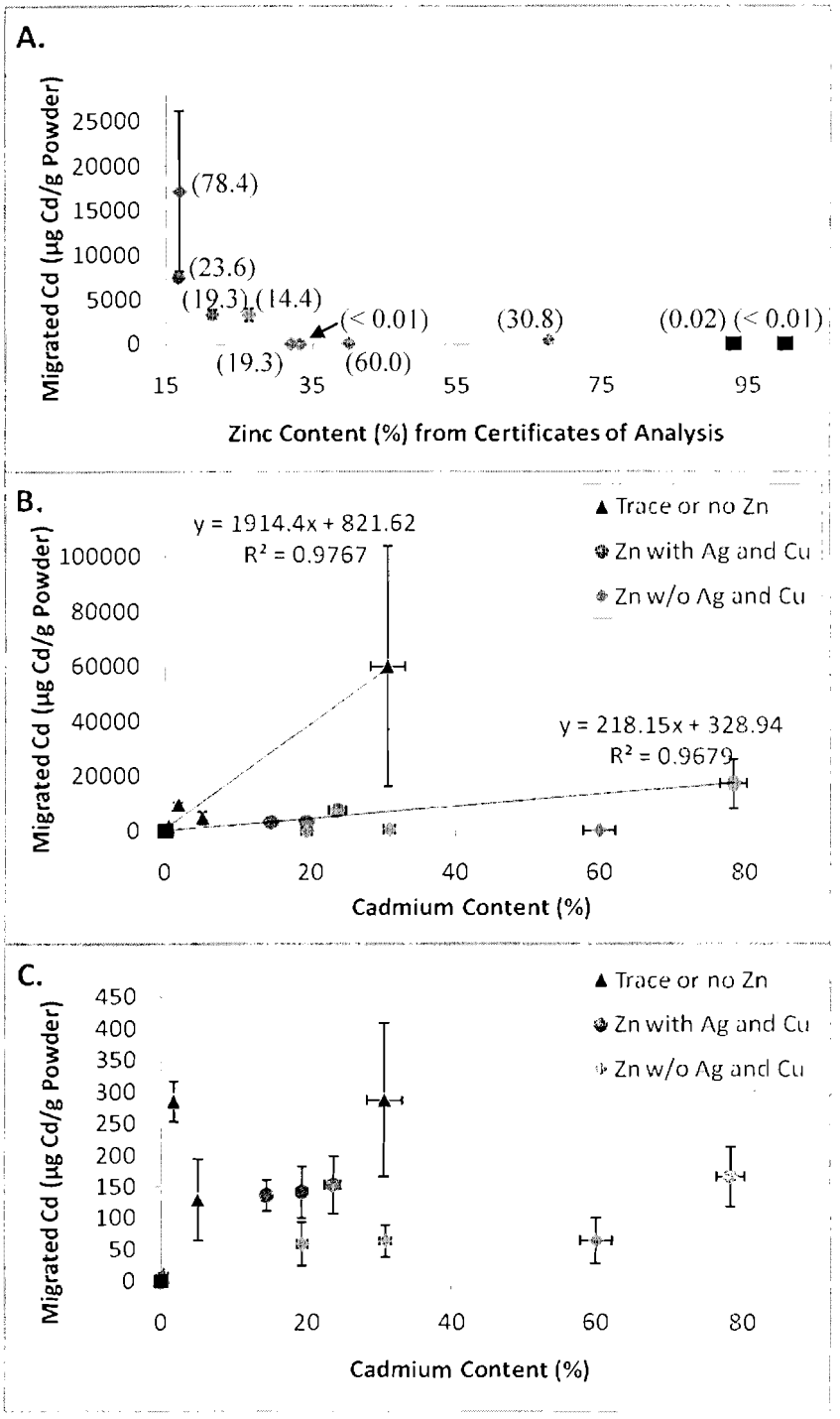

Figure 12. Effect of zinc on cadmium migration from alloy powders. Panel A: Cadmium migration into dilute acid (48h) as a function of zinc content. Cadmium content (%) is in parentheses. Panel B: Effect of alloy composition on 48h cadmium migration into dilute acid (-•-: 16-33% Zn with 5-67% Cu and/or Ag; -+-: 32-93% Zn with ≤1.5% Cu and Ag). Panel C: Effect of alloy composition on cadmium migration into saline.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

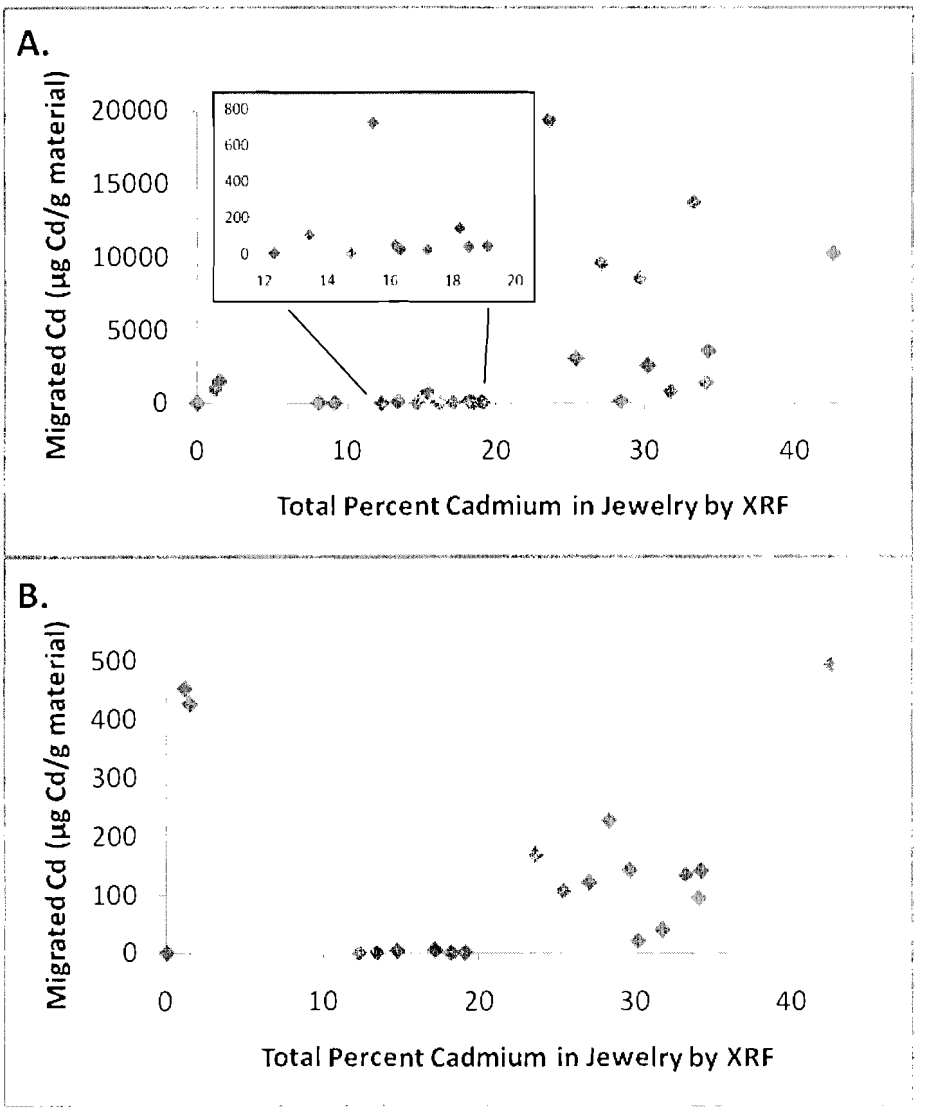

Figure 13. Soluble migrated cadmium from jewelry compared to cadmium content measurements by XRF. Panel A: Cadmium migrated into 0.07N HCl over 24 hours. Panel B: Cadmium migrated into 0.9% NaCl over 6 hours.

5.0 CONCLUSIONS

The primary goal of this study was to characterize the migration of cadmium from a variety of metal and plastic materials. The study found that soluble cadmium migration is not generally proportional to cadmium content. For alloys, product composition factors such as element content and coatings have a larger effect on cadmium migration than does total cadmium content. The presence of zinc reduces cadmium migration, and the addition of co-alloyed elements such as silver and copper, seems to mitigate zinc's effect. No detectable cadmium was found to migrate from plastic materials.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Efforts to define regulatory limits of total cadmium concentration based on cadmium migration tests may be complicated by coatings and the alloy effects associated with zinc. While one cadmium-containing metal (either as a coating or coating-free material) can have high cadmium migration, another metal with similar cadmium content may not yield hazardous levels of soluble cadmium for a variety of reasons (e.g., elemental content, coating type, coating thickness).

A secondary goal of this study was to provide accuracy and precision information for cadmium tests performed at CPSC. This information may be useful when adjusting field-XRF sample referral levels for products that require laboratory analysis. While agreement between XRF and ICP-OES cadmium content measurements for homogenous alloy materials was good (Figure 5-C), the relative error for XRF measurements in real-world (inhomogeneous) samples (Figure 4) ranged from -1 to -80%. As seen in Figure 4-A, a cadmium XRF reading of 20% could relate to a 30-85% total cadmium measurement by ICP-OES. This error can be attributed to the common use of coatings (e.g., paint, electroplating). No linear relationship was observed between XRF cadmium measurements and cadmium migration from jewelry samples. For these reasons, plus the apparent effect of zinc content on cadmium accessibility, the development of efficient concentration-based referral limits would be difficult. Even jewelry with relatively low XRF readings for cadmium can yield relatively high levels of soluble migrated cadmium (Figure 13).

6.0 REFERENCES

1. a) United States Consumer Product Safety Commission. "FAF Inc. Recalls Children's Necklaces Sold Exclusively at Walmart Stores Due to High Levels of Cadmium," http://www.cpsc.gov/cpscpub/prerel/prhtml10/10127.html, 2010; b) United States Consumer Product Safety Commission. "CPSC Issues Warning on Children's Winter and Holiday-Themed Charm Bracelets with High Levels of Cadmium," http://www.cpsc.gov/cpscpub/prerel/prhtml10/10162.html, 2010; c) United States Consumer Product Safety Commission. "Claire's Recalls Children's Metal Charm Bracelets Due to High Levels of Cadmium," http://www.cpsc.gov/cpscpub/prerel/prhtml10/10227.html, 2010.
2. a) "Standard Practice for Preparing, Cleaning, and Evaluating Corrosion Test Specimens," ASTM G 1 – 90, American Society for Testing and Materials, 1999; b) "Standard Guide for Conducting Corrosion Tests in Field Applications," ASTM G 4 – 01, American Society for Testing and Materials, 2008.
3. a) United States Consumer Product Safety Commission. "Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)," http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08.pdf, 2008; b) United States Consumer Product Safety Commission. "Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products," http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08.pdf, 2009; c) United States Consumer Product Safety Commission. "Standard Operating Procedure for Determining Lead (Pb) and Its Availability in Children's Metal Jewelry," http://www.cpsc.gov/businfo/pbjeweltest.pdf, 2005.

APPENDIX

Certificates of Analysis

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Institute for Reference Materials and Measurements

European Reference Materials

CERTIFICATE OF ANALYSIS

ERM®- EC680k

LOW DENSITY POLYETHYLENE		
	Mass Fraction	
	Certified value [1] [mg/kg]	Uncertainty [2] [mg/kg]
As	4.1	0.5
Br	96	4
Cd	19.6	1.4
Cl	102.2	3.0
Cr	20.2	1.1
Hg	4.64	0.20
Pb	13.6	0.5
S	76	4
Sb	10.1	1.6

1) Unweighted mean value of the means of 5-14 accepted sets of data, each set being obtained in a different laboratory and/or with a different method of determination. The value is traceable to the International System of Units (SI)

2) The certified uncertainty is the expanded uncertainty estimated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM) with a coverage factor k = 2.78 for Cr and k = 2 for all other elements, corresponding to a level of confidence of about 95 %.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 150 mg.

NOTE

European Reference Material ERM®-EC680k was produced and certified under the responsibility of the IRMM according to the principles laid down in the technical guidelines of the European Reference Materials® co-operation agreement between BAM-IRMM-LGC. Information on these guidelines is available on the internet (http://www.erm-crm.org).

Accepted as an ERM®, Geel, May 2007

Signed:

Prof. Dr. Hendrik Emons
Unit for Reference Materials
EC-DG JRC-IRMM
Retieseweg 111
2440 Geel, Belgium

All following pages are an integral part of the certificate

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Institute for Reference Materials and Measurements

European Reference Materials

CERTIFICATE OF ANALYSIS

ERM®- EC681k

LOW DENSITY POLYETHYLENE			
	Mass Fraction		
	Certified value [1]	Uncertainty [2]	Unit
As	29.1	1.8	mg/kg
Br	0.77	0.04	g/kg
Cd	137	4	mg/kg
Cl	0.80	0.05	g/kg
Cr	100	5	mg/kg
Hg	23.7	0.8	mg/kg
Pb	98	6	mg/kg
S	0.63	0.04	g/kg
Sb	99	6	mg/kg

1) Unweighted mean value of the means of 5-14 accepted sets of data, each set being obtained in a different laboratory and/or with a different method of determination. The value is traceable to the International System of Units (SI)

2) The certified uncertainty is the expanded uncertainty estimated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM) with a coverage factor k = 2.78 for Cr and k = 2 for all other elements corresponding to a level of confidence of about 95 %.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 150 mg.

NOTE

European Reference Material ERM®-EC681k was produced and certified under the responsibility of the IRMM according to the principles laid down in the technical guidelines of the European Reference Materials® co-operation agreement between BAM-IRMM-LGC. Information on these guidelines is available on the internet (http://www.erm-crm.org).

Accepted as an ERM®, Geel, May 2007

Signed:

Prof. Dr. Hendrik Emons
Unit for Reference Materials
EC-DG JRC-IRMM
Retieseweg 111
2440 Geel, Belgium

All following pages are an integral part of the certificate

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material® 629

Spectrographic Zinc-Base Die-Casting Alloy E

This Standard Reference Material (SRM) is intended primarily for evaluating chemical and instrumental methods of analysis of zinc-base die-casting alloys. SRM 629 is one of a series of reference materials (SRMs 625 through 630) for this purpose. A unit of SRM 629 consists of a bar segment approximately 44 mm square and 19 mm thick. The metallurgical condition is that resulting from a continuous chill casting process.

Certified Values: The certified values for 11 elements are listed in Table 1. The test methods used for certification are listed in Table 2. All values are reported as mass fractions [1] calculated as the unweighted mean of the mean values from the individual laboratories. The uncertainty listed with each value is an expanded uncertainty (approximately 95 % confidence level [2]) the standard deviation of the mean of means and calculated in accordance with the method in ISO and NIST Guides [3].

Table 1. Certified Values with Expanded Uncertainties

Element	Mass Fraction (%)			Element	Mass Fraction (%)		
Aluminum	5.15	±	0.05	Magnesium	0.094	±	0.003
Cadmium	0.0155	±	0.0021	Manganese	0.0017	±	0.0002
Chromium	0.0008	±	0.0003	Nickel	0.0075	±	0.0004
Copper	1.50	±	0.01	Silicon	0.078	±	0.003
Iron	0.017	±	0.004	Tin	0.012	±	0.001
Lead	0.0135	±	0.0014				

Expiration of Certification: The certification of this SRM is valid indefinitely provided the SRM is handled and stored in accordance with the instructions given in this certificate. However, the certification will be nullified if the SRM is damaged or otherwise altered. NIST will monitor this material and will report any significant changes in certification to the purchaser. Registration (see attached sheet) will facilitate notification.

The overall direction and coordination of the technical measurements leading to certification of this SRM were performed by R.E. Michaelis of the National Bureau of Standards (NBS) Spectrographic Standards Laboratory and R.K. Bell of the NBS Nonferrous Laboratory.

The support aspects involved in the issuance of this SRM were coordinated through the NIST Measurement Services Division.

Stephen A. Wise, Chief
Analytical Chemistry Division

Gaithersburg, MD 20899
Certificate Date: 20 September 2005
See Certificate Revision History on Last Page

Robert L. Watters, Jr., Chief
Measurement Services Division

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

National Bureau of Standards

Certificate of Analysis

Standard Reference Material 683

Zinc Metal

This Standard Reference Material (SRM) is intended for the calibration of instruments and the evaluation of chemical methods used in the analysis of zinc materials. SRM 683 is in the form of a semicircular bar segment, 57 mm diameter (2 1/4 inch), 25.4 mm (1 inch) deep at mid-diameter and 19 mm long (3/4 inch).

Element[1]	Recommended Value (ppm by wt.)	Range of Values Reported[2] (ppm by wt.)	Method of Analysis[3]
Lead	11.1	[9.6 - 11.3]	a,b
Copper	5.9	[5.3 - 6.1]	a,b
Iron	2.2	[1.7 - 3.1]	b,c
Silver	1.3	[1.0 - 1.4]	a,d
Cadmium	1.1	[1.0 - 1.2]	a,b
Thallium	(0.2)[4]	[0.17 - 0.18]	a
Tin	(0.02)	[0.013 - 0.023]	a

[1] Additional elements were sought by neutron activation. The following elements were not detected and are reported with an estimated upper limit of detection in parts per million by weight:

As (<0.002)	Mn (<0.2)	Sc (<0.003)
Ga (<.0002)	Mo (<.02)	V (<.005)
In (<.02)	Rh (<.3)	W (<.0001)

Potassium was not detected by either flame emission spectroscopy or by neutron activation at the 0.2 ppm level.

Aluminum, antimony, and sodium were detected by several techniques. The results were variable, but in no case are these elements present in concentrations greater than 3 ppm. Gold appears to be 0.02 ppm.

[2] The range of values reported is the extreme variation of the individual results reported by the methods of analysis used. The recommended value is based on considerations of the estimated systematic bias of each of the methods employed. From 7 to 13 individual determinations were made for each element certified.

[3] a. Spark-Source Mass Spectrometry - Isotope Dilution (R. Alvarez and P. Paulsen)
b. Polarography (E.J. Maienthal)
c. Spectrophotometry (E.R. Deardorff)
d. Neutron Activation Analysis (B.A. Thompson and D.A. Becker)

[4] Values in parentheses are not certified as only one method of analysis was used. They are provided for information only.

Gaithersburg, MD 20899
January 15, 1988
(Revision of certificates
dated 7-9-68 & 10-1-81)

Stanley D. Rasberry, Chief
Office of Standard Reference Materials

(over)

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material 1129

Solder

(63Sn - 37Pb)

(In Cooperation with the American Society for Testing and Materials)

This Standard Reference Material (SRM) is in the form of atomized powder and sized between 75 and 45 micrometers (200 and 325 mesh size sieves) respectively. It is intended for use in chemical methods of analysis.

Element	Percent by Weight[1]	Estimated Uncertainty[2]
Tin	62.7	0.1
Antimony	0.13	.01
Arsenic	.055	.005
Bismuth	.13	.01
Cadmium	.006	.001
Copper	.16	.01
Nickel	.010	.002
Silver	.075	.005
Gold	.0175	.0005

[1] The certified value listed for a constituent is the present best estimate of the "true" value based on the results of the cooperative program for certification.

[2] The estimated uncertainty listed for a constituent is based on judgment and represents an evaluation of the combined effects of method imprecision, possible systematic errors among methods, and material variability. No attempt was made to derive exact statistical measures of imprecision because several methods were involved in the determination of most constituents.

The overall direction and coordination of the technical measurements leading to certification were performed under the direction of J.I. Shultz, Research Associate, ASTM/NIST Research Associate Program.

The technical and support aspects involved in the preparation, certification, and issuance of this Standard Reference Material were coordinated through the Office of Standard Reference Materials by W.P. Reed and R.L. McKenzie.

May 8, 1989
Gaithersburg, MD 20899

Stanley D. Rasberry, Chief
Office of Standard Reference Materials

(over)

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB B: Toxicity and Hazard

T
A
B

B

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Staff Report

Cadmium in Children's Metal Jewelry
October 2010

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table of Contents

Staff Report iii

TAB A: Staff Responses to Peer Review Comments 14

TAB B: Toxicity Review of Cadmium 19

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Staff Report

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

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

Memorandum

Date: October 14, 2010

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

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

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

SUBJECT : Children's Cadmium-Containing Metal Jewelry[1,2]

Introduction

The U.S. Consumer Product Safety Commission (CPSC) administers federal laws concerning children's products and other consumer products. Federal laws and CPSC regulations apply nationwide to the consumer products in interstate commerce that are within its jurisdiction. Since its inception, the CPSC has played a prominent role in protecting the public, especially children, from the hazards of exposure to toxic chemicals. While the CPSC and other federal agencies, as well as local, state, and other organizations, have paid close attention to the potential for exposure to lead, many other chemicals may be found in products that, if exposure occurs, could result in adverse health effects in the users of those products.

Young children may be exposed to chemicals in consumer products from the direct mouthing of objects, from handling such objects and subsequent hand-to-mouth activity, or from swallowing a small object or a small part of a product. The specific types and frequency of behavior that a child will engage in depends on the age of the child and the characteristics and pattern of use of the product.

Recently, CPSC staff identified a number of products, particularly jewelry intended for use by children that presented a risk of adverse health effects from exposure to cadmium.

Regulatory framework

The CPSC protects children, and consumers in general, from hazardous exposure to substances, such as cadmium in consumer products, under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. §§ 1261–1278). The Federal Hazardous Substances Act requires that certain hazardous household products ("hazardous substances") bear cautionary labeling to alert

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

[2] A draft of this document was disseminated for external peer review. A summary of the peer review comments and the staff responses to the comments may be found in Tab A.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

consumers to the potential hazards that those products present and to inform them of the measures they need to take to protect themselves from those hazards. Any product that is toxic, corrosive, flammable or combustible, an irritant, a strong sensitizer, or that generates pressure through decomposition, heat, or other means requires labeling, if the product may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

The FHSA gives the Commission authority to ban by regulation a hazardous substance if it determines that the product is so hazardous that the cautionary labeling required by the act is inadequate to protect the public. Any toy or other article that is intended for use by children and that contains a hazardous substance is also banned under the FHSA if a child can gain access to the substance.

Regulating products under the FHSA generally requires assessment of exposure and risk. Assessments are generally conducted on a case-by-case basis, considering the specific characteristics of the product, the intended consumers of the product, and the interaction between the consumer and the product.

This document provides the staff's approach to assessing products under the FHSA, summarizes the relevant toxicology of cadmium, derives limits for exposure that, if exceeded, could result in adverse health effects, and discusses the results from analytical tests that could result in further scrutiny of products that may cause excessive exposure to cadmium in children who use the products.

Cadmium Toxicology

This section includes a brief overview of cadmium toxicology. The staff prepared a separate toxicity review that includes a broader discussion of the available data,[3] which may be found in Tab B.

The adverse health effects of cadmium exposure in humans have been documented largely in occupational settings, and mostly through inhalation, although nonworker populations have been studied as well. The principal effects of long-term exposures are chronic obstructive pulmonary disease and emphysema from inhalation of cadmium and cadmium compounds, and chronic renal tubular disease from inhalation and oral exposures. Depending on the dose and duration of exposure, effects have been observed in multiple organ systems and tissues, including kidney, liver, and bone. Although cadmium exposure in workers through inhalation is associated with lung cancer, there is insufficient evidence in humans or experimental animals to determine whether cadmium is carcinogenic from oral exposure.

Cadmium and cadmium compounds are poorly absorbed following ingestion, unless the levels are high enough to cause damage to the gastrointestinal tract. Absorbed cadmium accumulates largely in the kidney and liver, with a very long half-life, which is measured in decades. Only a small portion of the absorbed cadmium is excreted in the urine or in feces. Consequently, cadmium exposures are cumulative.

[3] "Toxicity Review of Cadmium." CPSC Memorandum from Dominique J. Williams and Kristina M. Hatlelid, Ph.D., M.P.H. to Mary Ann Danello, Ph.D. August 2010.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

The forms of cadmium in consumer products vary from cadmium metal in certain metal alloys, including materials used in soldering and electroplating, to cadmium salts and other compounds used in materials such as paints and plastics. Cadmium is found widely in the environment, in foods, and in tobacco. Diet is the major source of cadmium exposure for most people.

Exposure to cadmium also may occur through contact with some consumer products. Exposures from products, especially in children, are most likely from handling objects and then transferring material from the hands to the mouth, through direct mouthing of objects, and from swallowing small objects or parts of products. Staff identified information relating to ingestion of cadmium and cadmium compounds as most relevant to the assessment of cadmium exposures from consumer products.

Existing Exposure Limits

Several limits for exposure to cadmium have been established for regulatory or other purposes. For example, the World Health Organization (WHO) has developed a Provisional Tolerable Monthly Intake level (PTMI) of 25 micrograms per kilogram body weight per month[4] (25 μg/kg/month) (or 0.8 μg/kg/day) (JECFA, 2010). The U.S. Environmental Protection Agency (EPA) developed an oral reference dose (RfD[5]) of 1 μg/kg/day for food intake and 0.5 μg/kg/day for cadmium in drinking water (different levels of absorption of cadmium from food or from water account for the different RfD values) (EPA, 1994). The Agency for Toxic Substances and Disease Registry (ATSDR) developed a minimal risk level (MRL[6]) for chronic[7] oral exposure of 0.1 μg/kg/day (ATSDR, 2008). These limits were based on studies of kidney effects in humans.

The ATSDR's 2008 draft toxicological profile also includes an MRL for intermediate length exposure of 0.5 μg/kg/day based on effects on bone in experimental animals. Due to inadequacies in the acute oral exposure database, the ATSDR has not derived an acute duration MRL.

The preceding exposure limits are for general use (*e.g.*, PTMI, MRL) or apply to specific exposure media (*e.g.*, RfD for food or water). A child-specific standard for cadmium exposure exists in the form of the European toy safety standard EN 71-3 (European Standard EN 71-3, 1994). Under this standard, the limit for exposure to cadmium from toys for young children is 0.6 μg per day, based on information concerning normal background cadmium intake levels and a policy decision to limit cadmium exposure from toys to 5 percent of the assumed background exposure. Recently, the EC toy safety directive (Council Directive, 2009) established new health-based exposure limits for toys, using recent data on kidney effects in humans, including studies considered by the ATSDR (2008) and CPSC staff in the current evaluation. Effective July 20, 2013, the European toy safety standard for cadmium exposure from toys is based on an exposure limit of about 0.2 μg per day. Note that these toy safety standard daily limits are not

[4] Exposure limits are generally expressed in terms of milligrams of exposure per kilogram body weight. Since 1 mg = 1,000 μg, 1 μg/kg/day is equivalent to 0.001 mg/kg/day.

[5] The EPA's RfD is defined as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

[6] The ATSDR's MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure.

[7] As defined in the ATSDR toxicological profiles, chronic exposure is exposure to a chemical for 365 days or more; intermediate exposure is 15 through 364 days; acute exposure is 1 through 14 days.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

expressed in terms of body weight, but are daily limits for cadmium exposure that have been adjusted to account for the weight of a young child (7.5 kilograms for the revised standard—about 16.5 pounds).

Long-Term Exposure

A number of additional chronic exposure studies are now available that allow for dose-response analysis, and can be used to estimate an acceptable daily intake level (ADI). The staff's calculations generally are based on the study reporting the lowest exposure levels associated with adverse effects (lowest observed adverse effect level or LOAEL) or a dose that was not associated with an adverse effect (no observed adverse effect level or NOAEL). A number of high quality studies have considered cadmium-related adverse effects in the kidney and bone, reporting quantitative estimates for the level of cadmium intake that is associated with adverse effects ranging across about one order of magnitude (i.e., the high end of the range is about 10 times the low end of the range).

Staff chose the analysis of an epidemiological study by Suwazono *et al.* (2006) as the key study for a number of reasons, including that the study was based on a large, well-characterized population without any identified source of environmental or occupational exposure; the modeling included multiple covariates to account for potential confounders; and the estimated cadmium exposures associated with adverse health effects were among the lowest of several studies. Suwazono *et al.* (2006) used a benchmark dose[8] approach to analyze the data from a study of 820 Swedish women. The analysis estimated the concentration of cadmium in urine associated with urinary protein markers for adverse effects in the kidney. These researchers reported 0.5 micrograms cadmium per gram creatinine[9] in the urine (0.5 μg/g creat.) as the lower confidence limit of the cadmium concentration benchmark dose level (*i.e.*, BMDL associated with a 5 percent excess risk of protein in the urine). Similar results were reported by Uno *et al.* (2005) and Järup *et al.* (2000).

Because the BMDL is a measure of cadmium excreted in urine, additional analysis is required to estimate the corresponding level of cadmium intake into the body. This can be done using modeling techniques. The derivation of the MRL presented in the draft ATSDR Toxicological Profile for Cadmium (ATSDR, 2008) has applied such an analysis using the results of several studies of European populations, including Suwazono *et al.* (2006). For a 0.5 μg/g creat. urinary concentration, the analysis published by the ATSDR (2008) estimated a level of cadmium intake of 0.33 μg/kg/day. This is the intake level chosen by CPSC staff as the critical exposure level.

The scientific community generally addresses uncertainty in the comprehension of toxicology and dose-response through the use of uncertainty factors. CPSC staff also uses an uncertainty factor approach in evaluating exposure levels to account for a lack of robust data from animal studies or a lack of information from human exposures (CPSC, 1992). CPSC staff may apply up to three uncertainty factors, depending on the completeness and relevance of the available data. An uncertainty factor may be used if data are available only in studies of animals and not in humans. An uncertainty factor is applied if the available studies do not identify a dose or

[8] A benchmark dose approach uses mathematical modeling to characterize exposure-response relationships.

[9] Urinary cadmium concentrations were normalized to the amount of creatinine also present in the urine, a common method that accounts for the variations in excretion of urine and that allows comparison of urinary measurements over time, between subjects, or from different studies.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

exposure level that is not associated with an adverse effect (NOAEL). When a benchmark dose approach is used, the BMDL is treated as a NOAEL. The third type of uncertainty factor is applied to account for sensitive populations if the available studies do not adequately address such concerns.

In this case, only one uncertainty factor is needed, which is intended to account for the possibility of sensitive members of the population. The staff has chosen to apply a reduced uncertainty factor of 3, rather than the factor of 10 that is more typically used because of lack of knowledge of effects throughout a population. The reduced uncertainty factor is appropriate in this case because of the strength of the data that supports the identified critical exposure level, which is based on multiple studies of large numbers of people in different parts of the world. Therefore, an uncertainly factor of 3 applied to the intake level of 0.33 μg/kg/day results in an acceptable daily intake (ADI) of 0.1 μg/kg/day. This is the level of chronic exposure that should not be exceeded to avoid adverse health effects.

The key study used to estimate the ADI (Suwazono *et al.*, 2006) was based on data from adult women in a population that had no particular source of exposure to cadmium. Because the study participants likely experienced exposures to cadmium throughout their lives, such as through normal dietary sources, staff believes that the ADI may be applied to various scenarios involving exposures from consumer products during childhood and later in life.

Another issue to consider is the use of toxicokinetic modeling to relate intake of cadmium to absorption into the body, distribution within the tissues and organs of the body, and elimination from the body. Recent data indicate that children ages 6 through 11 years and females show increased urinary excretion of cadmium (Ruiz *et al.* 2010). This finding could indicate important differences in exposure and uptake of cadmium in these populations. Again, the epidemiological study that was used to estimate the acceptable daily intake level was conducted in women who likely experienced exposures to cadmium throughout their lives, including childhood. Although uncertainty remains on the implications of possible differences among various groups, the relatively large body of literature concerning long-term exposure and effects of cadmium supports the staff's approach.

Intermediate and Acute Duration Exposure

Documented acute[10] exposures in humans generally have involved exposure to relatively large amounts of cadmium compounds, resulting in severe adverse effects, including death. One report of a nonfatal exposure in humans was published by Nordberg *et al.* (1973). This case involved gastrointestinal symptoms in boys 13 through15 years old following ingestion of a beverage containing cadmium from a soda machine. Investigation of this case included analysis of a sample of water from the machine that contained 16 milligrams of cadmium per liter (16 mg/L). It is not clear from the report when the water sample was collected or how it was handled prior to testing for cadmium content. Based on information collected from the boys about five months after the incident, symptoms began within 15 minutes of consumption of the drink, and included headache, nausea, vomiting, abdominal pain, and diarrhea. All symptoms resolved within seven hours, and most of the boys returned to school when classes resumed after the weekend three days later. The children reported consuming 0.5 to 2.5 glasses of the drink,

[10]Acute exposures, 14 days or less, 16 C.F.R. §1500.3(c)(2)(i). Intermediate exposure duration is not defined within CPSC regulations, but generally means longer than acute exposure, but less than chronic; this term is defined in the ATSDR toxicological profiles as 15 to 364 days.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

with an average of about one glass. Although the volume of beverage consumed was not reported, information in the publication's discussion suggests that the investigators considered a glass to be about 0.15 L. Using this estimate for the average intake, the toxic dose of cadmium was about 2.4 mg. Because of the high level of uncertainty in this quantitative estimate and inadequate documentation of the case, staff finds this study unacceptable for further quantitative analysis or derivation of an exposure limit. Staff has not located other studies or reports of health effects from short-term oral exposure in humans at doses that are not associated with severe adverse health effects or death. Nor has staff located any reports of persistent effects after a brief exposure has ended, or studies that measured long-term effects resulting from an acute exposure to cadmium.

Several studies in animals have been conducted involving single exposures or short-term dosing, usually at relatively high doses. Adverse effects have been reported for multiple tissues and organ systems, including death, and effects in the liver, kidney, and bones. Most of the studies are not suitable for use in dose-response analysis for deriving exposure limits because of the severity of the adverse effects associated with the dose levels chosen for the studies. Of the studies that are appropriate for use in extrapolating to an acceptable intake level for humans, the staff chose as the key study, the evaluation of short-term exposure in rats through drinking water by Borzelleca *et al.* (1989).

This study involved groups of male and female rats that were exposed to cadmium chloride in drinking water for 10 days. Cadmium exposure was calculated at 1.1, 7.8, and 11.1 mg/kg/day in males, and 1.1, 8.1, and 13.8 mg/kg/day in females, based on the concentration of cadmium chloride in the water and the animals' water intake. The authors noted a dose-dependent decrease in body weight gain among males. The summary data also appear to show reduced body weight in the highest dose group in males, and dose-related reduced body weight gain in females, but statistical analyses were not presented.

Because of the disagreeable taste of water containing cadmium chloride, reduction in body weight or reduction in body weight gain may be due to the tendency of the animals to reduce their water intake with a concomitant reduction in food intake. However, the same publication (Borzelleca *et al.*, 1989) included a study in which dosing through gavage (*i.e.*, delivery of the dose directly into the stomach through a feeding tube) also resulted in reduced body weight and reduced body weight gain. This latter study suggests that cadmium exposure affects body weight through means other than the effect on the taste of the drinking water, and, therefore, changes in the body weight endpoints should be considered related to the exposure. The results of this study are supported by findings of body weight effects in two other animal studies involving dosing through gavage (Baranksi, 1985; Machemer and Lorke, 1981).

For exposures through both gavage and drinking water, Borzelleca *et al.* (1989) also noted significant changes in certain clinical chemistry measures, suggesting systemic effects in addition to the effects on body weight. Therefore, staff concludes that short-term exposure to cadmium is associated with adverse effects in animals. The lowest dose administered in the drinking water study (1.1 mg/kg/day) (Borzelleca *et al.*, 1989) can be considered the no observed adverse effect level (NOAEL) and is appropriate for extrapolating to an acceptable intake level for humans.

As with the estimation of a longer term ADI, for an acute duration exposure limit, staff identifies the LOAEL or NOAEL and applies up to three uncertainty factors to account for sensitive

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

individuals, the use of a LOAEL instead of a NOAEL if that is the case, and for the use of data from studies in animals instead of in humans if that is also applicable. Consequently, the acute ADI for cadmium is 11 µg/kg/day, based on the NOAEL of 1.1 mg/kg/day, and the use of an uncertainty factor of 10 for the use of data from animals rather than humans, and another factor of 10 to account for sensitive individuals in human populations.

No information was located for human oral exposures of intermediate length duration. However, recent studies in young rats demonstrate dose-related effects on bone metabolism and bone biomechanical properties for exposures up to 12 months (Brzóska and Moniuszko-Jakoniuk 2005). Based on a number of effects reported at the lowest dose tested, the LOAEL for the intermediate duration study is approximately 0.2 mg/kg/day. The intermediate exposure MRL of 0.5 µg/kg/day presented in the recent draft toxicological profile (ATSDR 2008) was derived using a benchmark dose approach to analysis of this data.

In general, the animal studies conducted in acute exposure scenarios and intermediate duration scenarios indicate a very wide range of LOAELs and NOAELs (*i.e.*, orders of magnitude difference between lowest and highest reported values) including, in some cases, adverse effect dose levels that are comparable to the LOAELs and NOAELs reported in longer-term studies (see summary in Table 3.6, ATSDR 2008). As discussed above, ADIs, MRLs, and RfDs derived from chronic and intermediate duration studies range across about one order of magnitude. No acute exposure limits have been derived previously for oral exposure to cadmium.

Because cadmium is found in the environment, in foods, and in tobacco, most people experience some level of exposure to cadmium. Any additional exposure to cadmium from consumer products will add to the overall risk of adverse health effects that might be associated with other sources of cadmium.

Evaluation

Children's jewelry is not a distinct, easily-defined product for a specific group of consumers. Rather, this category of products could encompass a large variety of jewelry products suitable for children of specific ages or for children of all ages. Because exposure to substances is the focus of staff's assessment, the assessment will focus on a group of children likely to participate in the behaviors that could result in excess exposure to the substances, and who are also the most vulnerable to the effect of the possible exposures. In this case, staff has chosen to consider young children ages 2 through 6 years old. Children in this age group still have significant mouthing behaviors, and occasionally may swallow—accidentally or intentionally—small objects. This age group may also be of special concern because of the potential health effects of cadmium exposure in people at early stages of development, similar to the concern about lead exposure in young children. However, data currently do not exist that clearly show adverse health effects specifically associated with exposures in early childhood.

Children are not expected to use certain pieces of jewelry, such as a charm bracelet, throughout their daily life. Some jewelry, such as jewelry with seasonal themes, may be used for a few weeks, and pieces that are especially valued by the child or by their parents, may be worn only occasionally. However, some jewelry, such as inexpensive items, may be used frequently or until the item is no longer favored by the child or is lost. For this evaluation, staff assumes that a child will use a jewelry item frequently over weeks, months, or years.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Exposure to cadmium from metal jewelry items or similar objects could occur during handling or mouthing the product, or from swallowing a pendant, bead, or other small component part of jewelry.

An ingested product could result in an acute or short-term exposure, because ingested objects are usually eliminated from the body within a few days or possibly weeks. Therefore, data on the effects of acute or short-term cadmium exposure would be most relevant for an assessment of swallowed jewelry items.

As discussed above, acute exposure in humans and experimental animals causes a number of adverse effects. Because of the uncertainty regarding the circumstances and quantitative details of human exposure cases, staff has chosen to evaluate short-term exposures using the study in experimental animals by Borzelleca *et al.* (1989) to derive an ADI for acute exposure of 11 μg/kg/day.

To assess children's cadmium-containing jewelry, staff assumes that the vulnerable group of children is 2 to 6 years old, with an average weight of 18.2 kg (40 pounds) (Ogden *et al.* 2004). Given the 11 μg/kg/day acute ADI, **the maximum allowable acute exposure for a young child is about 200 μg/day**.

Handling or mouthing a product could result in a longer-term exposure because use of the product could occur over many weeks, months, or years. In contrast to acute exposure, long-term exposure to cadmium has been studied extensively and is well characterized. Given data from multiple studies, staff prefers to use studies in humans for characterization of human risks. Thus, because of the strength of the evidence in studies of human populations, staff has chosen to use epidemiological information (Suwazono *et al.* 2006) in the assessment of exposure to cadmium from children's jewelry. As discussed above, staff derived an acceptable daily intake level (ADI) for cadmium of 0.1 μg/kg/day for chronic exposure. Given the 18.2 kg body weight for children ages 2 to 6 years, and the 0.1 μg/kg/day ADI, **the maximum allowable chronic exposure for young children is about 1.8 μg/day**.

Ingestion of foreign bodies

As discussed in the staff's briefing package on lead-containing children's metal jewelry, several cases show that excessive exposure to lead resulted from children swallowing lead-containing metal jewelry items (CPSC 2006a).

Further, as documented in the briefing package, jewelry items are among the most commonly ingested items by young children (CPSC 2006b). 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. For 2000–2005, the staff estimated 302,587 emergency room-treated injuries, nearly 80 percent of which were children under age 7 years. The objects most commonly swallowed were coins (accounting for nearly half of ingestions); jewelry; toys not elsewhere classified; and nails, screws, tacks, or bolts.

Additional data on ingestion of objects are found in a 1998 study that evaluated 100 children ages 9 months to 13 years, who ingested various foreign bodies, including coins, ball bearings, pins, marbles, screws, buttons, a light bulb, a novelty nail file, and a clothespin (Macgregor and Ferguson, 1998). This study evaluated how long an ingested object might remain within the gastrointestinal tract. The total transit time for passage (from ingestion to elimination through

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

the rectum) of the items ranged from 1 to 46 days. The peak time of passage was 2 days, with a median time of 6 days. The authors noted that the mean transit time for an ingested object increased with age; it was greater than 15 days for 13 year olds, while it was typically 5 days for 4 through 10 year olds.

Thus, the available information shows that children may swallow items such as jewelry, and that ingested items can cause excessive exposure to chemicals from the swallowed items.

Assessment

Exposure to cadmium from children's metal jewelry could occur as children use and interact with a product. This exposure might occur from activities such as mouthing a product or handling the product with subsequent hand-to-mouth transfer of cadmium that might be removed from the surface of the product. This exposure could occur over the many days or months that a child uses a product such as metal jewelry. Exposure to cadmium also might occur if a child swallows a small item or a part of an item. In the case of ingestion of a product, the exposure would occur during the usually short time that the item remains in the gastrointestinal tract, notwithstanding the possibility that an ingested object sometimes is retained in the body for several weeks.

Staff evaluates possible exposures to cadmium or other chemicals from children's products by measuring leaching of the cadmium from the item using a saline solution to mimic the effects of mouthing, and a dilute hydrochloric acid solution to simulate the gastric effects on a swallowed item. The staff's standard laboratory procedure is to immerse an item in the saline solution for a period of six hours. Because of the data showing that ingested items sometimes remain in the stomach for several days, for products such as metal jewelry, staff conducts the dilute acid leaching test for 24 hours. Data generated by the staff indicates that 24 hours is generally sufficient time to identify products that could leach large amounts of chemicals.

Mouthed object

For the case of mouthing, staff assumes that each minute of extraction in the saline solution represents a minute of mouthing of the object by a child. A CPSC study of mouthing behaviors of young children estimated an average daily mouthing time of 37 minutes for all objects (excluding pacifiers) for children ages 24–36 months (CPSC 2001).

Using the saline extraction to simulate the effects of mouthing a jewelry item, with the assumption that mouthing a children's product for 37 minutes per day represents an excess exposure, and that the ADI for chronic exposure to cadmium is 1.8 micrograms per day for a young child, the ADI would be exceeded if the results of the saline extraction of the item exceeds 18 micrograms total cadmium extracted during the 6-hour saline extraction (Eq. 1).

$$(1.8\ \mu g/day)/(37\ min/day) \times (6\ hours \times 60\ min/hour) = 18\ \mu g \qquad \text{(Eq.1)}$$

where

1.8 μg/day is the chronic acceptable daily intake level (ADI) for children 2–6 years old,
37 min/day represents the daily mouthing time of jewelry, and
6 hours x 60 min/hour is the number of minutes each jewelry item is tested for leaching of cadmium into the saline solution in the laboratory evaluation.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Therefore, a test result for saline extraction of a mouthable product that exceeds 18 μg indicates that the product may meet the criteria established in the FHSA for a product to be considered a hazardous substance.

Swallowed object

Swallowing a cadmium-containing object is an acute exposure situation, for which the available toxicology database is limited. However, the need to evaluate products for the potential for acute exposure to cadmium prompted staff to choose data from acute studies in experimental animals to derive an acute exposure limit of 200 μg/day.

In contrast to repeated exposures to small amounts of a chemical over time, ingestion of an item results in the total exposure from the item occurring within a short time (*i.e.*, an acute exposure). The acute ADI would be exceeded if the result of the acid extraction of the item exceeds 200 micrograms total cadmium extracted during the 24-hour acid extraction.

Therefore, based on the available data on acute exposures, a test result for acid extraction of a swallowable product that exceeds 200 μg would indicate that the product may meet the criteria established in the FHSA for a product to be considered a hazardous substance.

Conclusion

Given the available information on cadmium toxicity and the assumptions about children's interactions with cadmium-containing products, staff has estimated limits for testing that may be used for evaluating children's jewelry under the FHSA. For a product that may be mouthed by a child, staff concludes that a result from the 6-hour saline extraction test that exceeds 18 μg would indicate that the product may meet the criteria established in the FHSA for a product to be considered a hazardous substance based on chronic toxicity. For a product or part of a product that may be swallowed by a child, the staff concludes that a result for the 24-hour acid extraction test that exceeds 200 μg would indicate that the product may be considered a hazardous substance based on acute toxicity.

In order for a substance to be considered a hazard under the FHSA, both exposure and the risk of adverse health effects associated with handling and use of the substance must be taken into account. Therefore, the characteristics of the product and a child's behaviors and interactions with the product must be considered along with the information on toxicity.

Discussion

This evaluation provides an approach to assessing cadmium-containing children's metal jewelry that takes into account both acute exposure (*e.g.* from swallowing) and longer term exposures (*e.g.* from repeated mouthing behaviors over time).

A key consideration in the toxicology of cadmium is that once absorption of cadmium occurs, it remains in the body, particularly in the kidneys and liver, for many years. Given the very long half-life of cadmium in the body, exposures that occur from swallowing an object or from mouthing an object over time could have significant impacts on the overall exposure to cadmium from all sources and contribute to the risk of adverse health effects from cadmium exposures.

The evaluation is based on a number of assumptions about children's behaviors, product characteristics, and relevant testing methods, and the existing knowledge base for cadmium toxicology. Because of the known hazards associated with human exposure to cadmium, staff has taken a conservative approach by using an estimated acceptable daily intake level (ADI) for

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

chronic exposure and assuming a relatively high level of mouthing activity. The acute exposure scenario was evaluated using data on adverse health effects from short-term exposure to cadmium in animals because that data is most relevant to the possible scenario in which a child swallows a cadmium-containing item.

The approach in this assessment to longer term exposure from mouthing items is conservative, largely because of the assumptions about the behaviors expected in very young children. Staff used data from an observation study for mouthing of all objects during a day, which would overestimate exposure that might occur from a particular product. Furthermore, the staff's assessment of mouthing behaviors that occur over time is based on an acceptable daily intake level that is not expected to cause adverse effects if the exposure occurred over many years.

While staff has taken a conservative approach, exposure to cadmium is associated with significant health effects, and any exposure from consumer products, such as jewelry, is in addition to exposures that most people experience from food, water, and other sources.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

References

ATSDR (2008) Toxicological Profile for Cadmium (Draft). Agency for Toxic Substances and Disease Registry. U.S. Department of Health and Human Services. http://www.atsdr.cdc.gov/toxprofiles/tp5.html.

Baranski B (1985) Effect of exposure of pregnant rats to cadmium on prenatal and postnatal development of the young. J Hyg Epidemiol Microbiol Immunol 29:253–262.

Brzóska MM, Moniuszko-Jakoniuk J (2005) Disorders in bone metabolism of female rats chronically exposed to cadmium. Toxicol Appl Pharmacol 202(1):68–83.

Council Directive 2009/48/EC of 18 June 2009 on the safety of toys. Official Journal L 170, 30.6.2009, pp. 1–36.

CPSC (1992) Labeling requirements for art materials presenting chronic hazards; guidelines for determining chronic toxicity of products subject to the FHSA; supplementary definition of "toxic" under the Federal Hazardous Substances Act; final rules. 57 Fed. Reg.: 46626–46674 (9 October 1992).

CPSC (2001). A mouthing observation study of children under 6 years. CT Kiss.

CPSC (2006a) Memorandum from Kristina M. Hatlelid and Jacqueline Elder to the Commission, Todd A. Stevenson, Secretary. "Petition HP 06-1 Requesting Ban of Lead in Toy Jewelry," dated December 4, 2006. In: Briefing Package for Petition Requesting Ban of Lead in Toy Jewelry (Petition No. HP 06-1). December 4, 2006.

CPSC (2006b) Memorandum from Craig O'Brien to Kristina M. Hatlelid. "Analysis of Data on Child Ingestions," dated November 30, 2006. In: Briefing Package for Petition Requesting Ban of Lead in Toy Jewelry (Petition No. HP 06-1). December 4, 2006.

EPA (1994) Integrated Risk Information System, Cadmium (CASRN 7440-43-9). http://www.epa.gov/iris/subst/0141.htm.

European Standard EN 71-3 (1994) Safety of Toys—Part 3: Migration of certain elements.

Järup L, Hellstrom L, Alfven T, Carlsson MD, Grubb A, Persson B, Pettersson C, Spang G, Schutz A and Elinder CG (2000) Low level exposure to cadmium and early kidney damage: The OSCAR study. Occup Environ Med 57(10):668-672.

JECFA (2010) Summary and conclusions of the seventy-third meeting, Geneva, 8–17 June 2010. Geneva, World Health Organization, Joint FAO/WHO Expert Committee on Food Additives.

Macgregor D, Ferguson J (1998) Foreign body ingestion in children: an audit of transit time. J Accid Emerg Med 15: 371–373.

Machemer L and Lorke D (1981) Embryotoxic effect of cadmium on rats upon oral administration. Toxicol Appl Pharmacol 58:438–443.

Nordberg G, Slorach S, Steinstrom T (1973) [Cadmium poisoning caused by a cooled-soft-drink machine.] Lakartidningen 70: 601–604.

Ogden CL, Fryar CD, Carroll MD, Flegal KM (2004) Mean bodyweight, height, and body mass index, United States 1960–2002. Advance data from vital and health statistics; no 347. Hyattsville, Maryland: National Center for Health Statistics.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Ruiz P, Mumtaz M, Osterloh J, Fisher J, Fowler BA (2010) Interpreting NHANES biomonitoring data, cadmium. Toxicol Lett 198(1):44–48.

Suwazono Y, Sand S, Vahter M, Filipsson AF, Skerfving S, Lidfeldt J, Akesson A (2006) Benchmark dose for cadmium-induced renal effects in humans. Environ Health Perspect 114:1072–1076.

Uno T, Kobayashi E, Suwazono Y, Okubo Y, Miura K, Sakata K, Okayama A, Ueshima H, Nakagawa H and Nogawa K (2005). Health effects of cadmium exposure in the general environment in Japan with special reference to the lower limit of the benchmark dose as the threshold level of urinary cadmium. Scand J Work Environ Health 31(4): 307–315.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB A: Staff Responses to Peer Review Comments

T
A
B

A

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

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

Memorandum

Date: October 14, 2010

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

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

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

SUBJECT : Staff Responses to Peer Review Comments on "Children's Cadmium–Containing Metal Jewelry" [1]

In June 2010, Consumer Product Safety Commission (CPSC) staff sought external scientific peer review of staff's draft document, "Children's Cadmium-Containing Metal Jewelry." Comments from the three reviewers were received by staff in July 2010. Staff revised the draft document based on the peer reviewers' comments and provides brief responses to the comments here. Similar comments or comments pertaining to specific topics are grouped and addressed together.

Comment

There were several specific observations related to sentence structure, wording, or clarity of the text, and a general comment that the document should contain more background on the purpose of the document and the regulatory approach.

Response: Staff revised the text accordingly to address both the specific and general comments about the document.

Comment

Among the three reviewers' comments were somewhat conflicting conclusions that the ADI approaches and data used are appropriate, or that there are deficiencies in the approach and discussion.

Response: The staff carefully considered each comment and revised the draft document to best address the comments and present an appropriate evaluation of the available data and information.

[1] The responses to the peer review comments are those of the CPSC staff and have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Comment

A comment concluded that the review is incomplete, specifying that the form of cadmium and dose route in the toxicology studies should be included, as well as the form of cadmium expected from exposure to children's products. The review should include discussion of the renal cortex concentration threshold concept and database.

Response: The staff document was revised to include additional material and a greater level of detail to address the reviewers' concerns, although this document is not intended to be a standalone toxicity review. Staff's toxicity review of cadmium, a document produced separately from the reviewed evaluation, also addresses some of the reviewers' comments.

Comment

Consider the bone effects in the derivation of the ADI.

Response: While adverse effects on bone are important outcomes from exposure to cadmium, published analyses of epidemiological data show that for long-term exposure, effects in kidney are more sensitive endpoints. Thus, staff chose the study of effects in kidney for the dose-response analysis and derivation of the chronic duration ADI.

Comment

If long-term and intermediate-term LOAELs and NOAELs are similar, what does this mean for the minimum exposure period needed to produce a long-term effect?

Response: The available information indicates that the relationship between cadmium exposure and adverse health effects is complex, with considerable variability in responses, depending on dose, route of administration or exposure, and species or strain of animal or human population. Further, there are a variety of endpoints for cadmium toxicity, each with its own dose-response relationship. Many effects of cadmium are observed only at relatively high exposure levels, regardless of duration of exposure. Other effects have been seen following longer term exposures at lower levels, such as the adverse effects in kidney and bone that are the most significant and most sensitive endpoints for chronic exposures. The results of studies in experimental animals that show, in some cases, similar LOAELs and NOAELs in intermediate or longer term studies may be due to the specific endpoints considered in the studies, or the specific conditions of the studies, such as choice of species. However, the data do not provide for a clear conclusion to be made about the minimum exposure period needed to produce a long-term effect.

Comment

The application of the default uncertainty factor in the derivation of the chronic ADI could be reconsidered. Based on the large size of the populations included in the epidemiological studies, a factor of 3 would be appropriate. However, some remaining uncertainty, such as the possibility of effects of childhood exposure to cadmium, should be discussed.

Response: Staff agrees that the database for chronic exposure to cadmium is robust, and that uncertainty can be characterized using a factor of 3, rather than the default value of 10, to account for effects in sensitive subpopulations. Although children have not been specifically studied with respect to adverse effects from long-term exposure to cadmium, the epidemiological studies included populations with general environmental exposures to cadmium that likely occurred throughout their lives, including during childhood. Therefore, the results of those studies would, in part, reflect childhood exposure.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Comment

CPSC staff should model short-term exposure and derive ADI based on effects on cadmium concentration in the kidney.

Response: At this time, the staff does not believe that such an analysis, using available information, would significantly reduce the uncertainties related to data on short-term exposures. However, staff agrees that the approach to the short-term exposure data in the draft document is inadequate, and has revised the evaluation using information from published studies of acute exposure in experimental animals.

Comment

The approach to the swallowing scenario does not make sense and is not appropriate.

Response: Staff's approach to evaluating the acute exposure scenario was developed because of the lack of data specific to acute exposure to cadmium, particularly from foreign body ingestion, such as swallowing jewelry. Staff has reconsidered this approach and made appropriate changes to the report. Staff is now using published studies of acute exposure in experimental animals for the swallowing scenario assessment.

Comment

An acute exposure limit is needed. Reevaluate the available acute data or use an intermediate duration limit. Provide more details about the acute exposure data, including GI effects.

Response: Staff agrees that an acute exposure limit is needed. While staff still considers the available database on effects from acute exposures to be limited, this section of the report was revised to include information from published acute exposure studies in experimental animals.

Comment

How might the acute and chronic mechanisms of action differ?

Response: The toxicological effects of cadmium are many, and depend on dose, form, and route of exposure, whether the effect is observed in humans, and the species and strain of animal used in experimental studies. Systemic effects (multiple organs and tissues) are observed from both acute and chronic exposures. Acute exposures often involve higher exposure levels, which may result in effects that are not observed with lower dose, longer term exposures (*e.g.*, effects directly on gastrointestinal tissue that are related to high doses). Some actions of cadmium would be expected to occur regardless of the duration of exposure; some effects involving certain biological systems or processes may occur only after longer term exposures because repeated exposures over time are required to perturb the systems. Thus, acute and chronic toxicity may share certain mechanisms, depending on dose and other factors of exposure, while some mechanisms are relevant only with longer-duration exposure.

Comment

A commenter suggested that staff consider recent data that show increased urinary excretion of cadmium in children ages 6 through 11 years, as well as for females, which could indicate important differences in exposure and uptake of cadmium in these populations.

Response: Staff added discussion to the report, but because staff's analysis is based on a study in women who likely also had been exposed in childhood, the conclusions have not changed.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Although uncertainty remains on the implications of possible differences among various groups of people, the relatively large body of literature concerning long-term exposure and effects of cadmium supports the approach taken by staff.

Comment

It appears that the CPSC is deriving a different (higher) ADI than the ATSDR chronic MRL or USEPA RfD.

Response: As described in the draft document, CPSC staff derived an oral, chronic ADI that is lower than either the existing or draft MRL derived by the ATSDR, or the existing RfD derived by the EPA. The difference between the CPSC staff's draft ADI and the EPA's RfD stems from using different epidemiological studies as the basis for the analysis. Similar data were used to estimate the ADI in CPSC staff's draft analysis and the ATSDR's draft, but CPSC staff applied an uncertainty factor of 10 to account for sensitive members of the population, while the ATSDR used a factor of 3. ADI estimates are divided by uncertainty factors, so that using a factor of 10 results in a lower estimated ADI. Based on the peer review comments and additional consideration of this issue, the revised CPSC staff analysis includes an uncertainty factor of 3 rather than the default value of 10 (to account for effects in sensitive subpopulations) because of the strength of the numerous epidemiological studies. Therefore, staff's revised ADI is the same as the ATSDR's draft chronic MRL.

Comment

Are there data specifically on ingestion of jewelry regarding GI transit time?

Response: The CPSC databases allow estimates of the number of cases involving ingestion of jewelry, but few cases, if any, provide details about the incidents, such as GI transit time. The scientific literature discusses cases of foreign body ingestions, but jewelry ingestions have not been considered specifically, and the cases that have been reported are not well-described.

Comment

The dose associated with emesis should not be normalized to body weight; volume of stomach contents would be a more appropriate measure for extrapolation to different ages.

Response: The staff agrees with this comment, and revised the description of the data accordingly.

Comment

For the mouthing scenario, an intermediate duration exposure limit would be more appropriate.

Response: The staff used data from studies in humans to derive the exposure limit for longer term exposures. An intermediate duration study, conducted in animals, was not chosen for use in the assessment because data in humans, when available, is preferable to animal studies. In addition, in this case, the numerous, well-conducted studies in humans, lead to a higher level of confidence in the results than would occur using the study in animals.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB B: Toxicity Review of Cadmium

T
A
B

B

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: October 14, 2010

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

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

FROM : Dominique J. Williams, Toxicologist, Division of Health Sciences
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

SUBJECT : Toxicity Review of Cadmium[1]

This memorandum provides the U.S. Consumer Product Safety Commission's (CPSC) Health Sciences staff assessment of the potential toxicity associated with cadmium and cadmium-containing compounds.

CPSC staff assesses a product's potential health effects to consumers under the Federal Hazardous Substances Act (FHSA). The FHSA is risk-based. To be considered a "hazardous substance" under the FHSA, a consumer product must satisfy a two-part definition. 15 U.S.C. §1262 (f)(1)(A). First, it must be toxic under the FHSA, or present one of the other hazards enumerated in the statute. Second, it must have the potential to cause "substantial illness or injury during or as a result of reasonably foreseeable handling or use." Therefore, exposure and risk must be considered in addition to toxicity when assessing potential hazards under the FHSA (CPSC, 1992; summarized at 16 C.F.R. §1500.135).

The FHSA addresses both acute and chronic hazards. While the FHSA does not require manufacturers to perform any specific battery of toxicological tests to assess the potential risk of chronic health hazards, the manufacturer is required to label a product appropriately according to the requirements of the FHSA. The first step in the risk assessment process is hazard identification, that is, a review of the available toxicity data for the chemical under consideration and a determination of whether the chemical is considered "toxic" under the FHSA. Chronic toxicity data (including carcinogenicity, neurotoxicity, and reproductive and developmental toxicity) are assessed by CPSC staff using guidelines issued by the Commission (CPSC, 1992). If it is concluded that a substance is toxic under the FHSA due to chronic toxicity, then a quantitative assessment of exposure and risk is performed to evaluate whether the chemical may be considered a "hazardous substance" under the FHSA.

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

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

This memo represents the first parts of the risk assessment process, that is, the hazard identification and dose-response steps.

Staff's conclusion is that the data concerning the toxicity of cadmium, discussed below, are sufficient for cadmium to be considered toxic under the FHSA due to effects on multiple organ systems and toxic endpoints, including kidney dysfunction.

Staff has developed an acceptable daily intake level (ADI) for chronic exposure to cadmium by the oral route of 0.1 micrograms cadmium per kilogram body weight per day (0.1 μg/kg/day) based on studies in human populations. This is the level of chronic exposure that should not be exceeded in order to avoid health effects.

Introduction

Cadmium is a metal found in the earth's crust, and is known to be associated with zinc, lead, and copper ores. Pure cadmium is a soft, silvery-white metal that is insoluble in water; soluble forms include cadmium chloride and cadmium sulfate. Most cadmium used in the United States comes from the processing of other metals, such as lead, as well as recycling of nickel-cadmium batteries. According to Agency for Toxic Substances and disease Registry's Draft Toxicological Profile for Cadmium (ATSDR, 2008), approximately 83 percent of cadmium is used in batteries.

For nonsmokers, the primary source of cadmium is food. Those regularly consuming shellfish and organ meat have higher exposures. Leafy vegetables also contain high levels of cadmium. Tobacco leaves accumulate cadmium from the soil, leading to increased cadmium exposure among smokers (ATSDR, 2008).

Blood cadmium concentrations reflect recent and cumulative exposures; urinary cadmium levels reflect both cadmium exposure and the concentration of cadmium in the kidneys. As part of its National Health and Nutrition Examination Survey (NHANES), the Centers for Disease Control and Prevention (CDC) measured cadmium in the blood and urine of a representative sample of the U.S. population. From the 2003–2004 survey (CDC, 2009), the geometric mean blood and urine cadmium levels for the group 20 years of age and older was 0.378 micrograms per liter (μg/L) in blood and 0.260 μg/L in urine. Females (0.326 μg/L, blood; 0.216 μg/L, urine) had slightly higher levels than males (0.283 μg/L, blood; 0.206 μg/L, urine).

Several agencies have established recommendations or regulations for cadmium. The U.S. Environmental Protection Agency (EPA) developed an oral reference dose (RfD[2]) of 1 μg/kg/day for food intake and 0.5 μg/kg/day for cadmium in drinking water (different levels of absorption of cadmium from food or from water account for the different RfD values) (EPA, 1994) and has established limits for cadmium concentration in drinking water of 0.04 mg/L for exposures up to 10 days, or 0.005 mg/L for lifetime exposures (EPA, 2003). The U.S. Food and Drug Administration (FDA) established the limit for cadmium in bottled water at 0.005 mg/L (FDA, 2009). For exposure through inhalation in the workplace, the Occupational Safety and Health Administration (OSHA) established a limit of 5 micrograms per cubic meter of air (5 $\mu g/m^3$) for an 8-hour workday (OSHA, 2009).

[2] The EPA's RfD is defined as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

The ATSDR's 2008 draft toxicological profile includes a minimal risk level (MRL[3]) for chronic[4] oral exposure of 0.1 μg/kg/day, based on kidney effects in humans (ATSDR, 2008). The draft toxicological profile also includes an MRL for intermediate length exposure of 0.5 μg/kg/day based on effects on bone in experimental animals. Due to inadequacies in the acute oral exposure database, ATSDR has not derived an acute duration MRL.

Toxicokinetics

Cadmium is not well absorbed into the body, especially after ingestion or through the skin. After absorption, cadmium is widely distributed throughout the body, but is predominantly found in the liver and kidney. Excretion is very slow, with approximately 0.007 and 0.009 percent of the body burden being excreted in the urine and feces, respectively, per day (ATSDR, 2008).

Absorption

Based on a number of studies, the ATSDR (2008) reported that absorption from oral exposure likely ranges between 1 and 10 percent. While exposures through inhalation are important in the workplace, inhalation exposures are less likely from consumer products than exposures through ingestion of cadmium-containing substances and products.

All of the studies reviewed suggest that the absorption of cadmium via the dermal route is slow. Less than 1 percent of the administered dose is absorbed through the skin during dermal exposures. Dermal absorption generally would be a concern when solutions come into contact with the skin for several hours or more, such as in an occupational setting (ATSDR, 2008).

Distribution

Cadmium can be detected in all tissues, with the largest concentrations in the liver and the kidneys. Kjellström (1979) presented data from an international investigation of cadmium exposure. In this study, analysis of tissues from hundreds of people in Japan, Sweden, and the United States showed geometric mean concentrations in the kidneys and liver increased from less than 1 microgram per gram tissue weight (1 μg/g) in early childhood to a peak of 40–50 μg/g in the kidney, and 3–4 μg/g in the liver that occurs at around 50 to 60 years of age. After about age 60, tissue cadmium concentrations decrease over time.

Metabolism

After absorption, cadmium does not undergo direct metabolic conversion such as oxidation, reduction, or alkylation. However, the cadmium ion binds to proteins and other molecules, especially the proteins albumin and metallothionein (Nordberg, 1984). Cadmium in the blood is found primarily in protein complexes.

Elimination

Kjellström and Nordberg (1978, 1985) studied the available data and developed a human toxicokinetic model for cadmium to describe cadmium absorption, distribution, and excretion. Based on the available data, cadmium excreted from the body in feces is largely unabsorbed material from the gastrointestinal tract. Most of the cadmium that is absorbed into the body is

[3] The ATSDR's MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure.

[4] As defined in the ATSDR toxicological profiles, chronic exposure is exposure to a chemical for 365 days or more; intermediate exposure is 15 through 364 days; acute exposure is through 14 days.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

excreted slowly, with urinary and fecal excretion being approximately equal. Urinary excretion is dependent on blood and kidney concentrations, and the total excretion is assumed to be equal to the daily intake of cadmium at steady state.

From the model, these authors estimated that daily excretion in feces and urine is approximately 0.007 and 0.009 percent of body burden, respectively. The model also predicts that the half-life for cadmium in human tissue is in the range of 6 to 38 years in the kidney and 4 to 19 years in the liver.

Acute Toxicity

Investigation of suicide involving cadmium ingestion found that death occurred due to massive fluid loss, edema, and widespread organ destruction. Buckler *et al.* (1986) described a case of an estimated exposure of 1,840 mg/kg cadmium chloride that resulted in death within 33 hours. Wisniewska-Knypl *et al.* (1971) reported death within 7 days of ingestion of 25 mg/kg cadmium iodide.

In a less severe case of acute toxicity, Nordberg *et al.* (1973) reported gastrointestinal effects in children who ingested 16 mg/L cadmium from soft drinks. This case involved gastrointestinal symptoms in boys 13 to15 years old following ingestion of a beverage containing 16 milligrams cadmium per liter of beverage (16 mg/L). Based on information collected from the boys about five months after the incident, symptoms began within 15 minutes of consumption of the drink, and included headache, nausea, vomiting, abdominal pain, and diarrhea. All symptoms resolved within seven hours, and most of the boys returned to school when classes resumed three days later. The children reported consuming 0.5 to 2.5 glasses of the drink, with an average of about one glass. Although the volume of beverage consumed was not reported, information in the publication's discussion suggests that the investigators considered a glass to be about 0.15 L.

Studies in experimental animals show that the oral LD_{50}[5] ranges from approximately 100 to 300 mg/kg in rats and mice (Baer and Benson, 1987; Kostial *et al.*, 1978; Kostial *et al.*, 1979). The lowest dose of cadmium found to cause death (2 of 20 animals) was 15.3 mg/kg administered as cadmium chloride in water in a single dose by gavage in Sprague-Dawley rats (Borzelleca *et al.*, 1989). Other adverse effects from acute oral exposure include: reduced body weight or reduced body weight gain (cadmium doses greater than about 2 mg/kg/day); hemorrhages, ulcers, and reddening of the stomach and intestinal tract (61 mg/kg/day); testicular atrophy (66 mg/kg/day); and necrotic changes in the kidney (15.3 mg/kg/day) and liver (138 mg/kg/day) (Baranski, 1985; Borzelleca *et al.*, 1989; Machemer and Lorke, 1981).

Systemic Toxicity

Ingestion of cadmium is associated with numerous effects, primarily in the kidney and bone. The main effects and key studies are summarized below.

Kidney

The adverse effects of cadmium in the kidney are related to the concentration of cadmium within the kidney, particularly within the kidney cortex. Studies have been conducted using kidney cortex cadmium concentration as the measure of exposure. Because the concentration of cadmium in the kidney is associated with the concentration of cadmium in the urine, the latter

[5] LD_{50}, or lethal dose-50, is the dose that produces death in half of the group of test animals under specified conditions and test duration.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

metric has been used in studies of living humans, in which kidney levels of cadmium cannot be directly measured.

Tubular dysfunction is considered one of the first signs of kidney damage, characterized by an increase in urinary, low-molecular-weight protein excretion, such as β2-microglobulin (β2M), human complex-forming glycoprotein (pHC) (also known as α1-microglobulin(α1M)), and retinol binding protein; or increased levels of intracellular enzymes, such as N-acetyl-β-glucosaminidase (NAG) in the urine (European Chemicals Bureau, 2007; Järup *et al.*, 1998).

Exposure at higher levels is associated with excretion of high-molecular-weight proteins, such as albumin, as demonstrated in studies of workers with exposure by inhalation (Bernard *et al.*, 1979, 1990; Chen *et al.*, 2006a, 2006b; Elinder *et al.*, 1985; Roels *et al.*, 1989, 1993; Thun *et al.*, 1989).

In workers exposed to high levels of cadmium, ending exposure does not usually lead to the reversal of the damage affecting the kidney. The increases in urinary levels of β2M, retinol binding protein, or total protein, or the decreases in glomerular filtration rate (GFR) have been seen years after the cadmium exposure in workers ended (Elinder *et al.*, 1985; Järup *et al.*, 1993; Mason *et al.*, 1999; Piscator, 1984; Roels *et al.*, 1989; Thun *et al.*, 1989). For workers with low exposure levels of cadmium, decreases or no change in urinary β2M levels were seen after exposure ended (McDiarmid *et al.*, 1997; van Sittert *et al.*, 1993). Roels *et al.* (1997) and Trzcinka-Ochocka *et al.* (2002) found that reversibility of cadmium-induced tubular dysfunction was dependent on the cadmium body burden and the severity of microproteinuria at the time cadmium exposure was reduced or stopped.

A number of large epidemiological studies have examined the effects of cadmium exposure on the kidney. A few such studies are summarized here.

Järup *et al.* (2000) examined 1,021 individuals living near a nickel-cadmium battery plant in Sweden for at least five years (n=799) or employed as battery workers (n=222). The mean urinary cadmium levels were 0.81 and 0.65 μg/g creatinine[6] in males and females, respectively. Urinary cadmium levels were significantly associated with urinary pHC levels, after adjustment for age, in the whole study population, or with the workers removed from the analysis. The prevalence of abnormal pHC values (defined as exceeding the 95th percentile in a Swedish reference population) was estimated to increase by 10 percent at urinary cadmium levels of 1 μg/g creatinine.

The European Chemicals Bureau (2007) recalculated the probability of pHC proteinuria (using the raw data from Järup *et al.*, 2000) to account for the differences in age of the reference population (mean of 40 years) and study population (mean of 53 years). Based on these recalculations, the urinary cadmium level associated with a 10 percent increased probability of abnormal pHC values (20 percent total probability) was 2.62 μg/g creatinine for the total population. In the nonworker subgroup, a urinary cadmium level of 0.5 μg/g creatinine was associated with a 13 percent probability (representing a doubling of the probability for the reference population) of abnormal pHC values.

[6] Measurement of creatinine levels in the urine or blood is used to evaluate kidney function. Urinary protein measurements are often normalized to creatinine to account for the variations in excretion of urine and allow comparison of urinary measurements over time, between subjects, or from different studies.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Noonan *et al.* (2002) examined 361 residents in Pennsylvania living near an old zinc smelting facility (geometric mean urinary cadmium level of 0.14 μg/g creatinine) and a reference community (without an identified exposure source) located 10 miles from the facility (geometric mean urinary cadmium levels of 0.12 μg/g creatinine). The data from the two communities were pooled because there were no differences in urinary cadmium levels between them. β2M, NAG, alanine aminopeptidase (AAP), and albumin (ALB) levels were measured as biomarkers of renal dysfunction. The geometric mean urinary cadmium levels were 0.07 and 0.08 μg/g creatinine in 88 males and 71 females ages 6 to17 years old, and 0.24 and 0.23 μg/g creatinine in 71 males and 80 females aged ≥18 years. No significant correlations between urinary cadmium levels and renal biomarkers were observed in the children, after adjustment for creatinine, age, and gender. In adults, significant correlations (after adjustment for creatinine, age, gender, smoking, and self-reported diabetes or thyroid disease) between urinary cadmium and NAG (partial correlation coefficient of 0.20, 95% CI of 0.05–0.36) and AAP (partial correlation coefficient of 0.21 and 95% CI of 0.05–0.36) were observed. Significant dose-effect relationships also were found for these two biomarkers. Urinary cadmium levels were not significantly associated with elevated levels of β2M or ALB.

Jin *et al.* (2002) examined three populations living various distances from a nonferrous metal smelter. The geometric mean levels of urinary cadmium were 11.18 and 12.86 μg/g creatinine in males (n=294) and females (n=171) in the highly polluted area, 3.55 and 4.45 μg/g creatinine in males (n=243) and females (n=162) in the moderately polluted area, and 1.83 and 1.79 μg/g creatinine in males (n=253) and females (n=155) in the control area. Significant correlations were found between urinary (and blood) cadmium levels and renal biomarkers (β2M, retinol binding protein, and ALB).

Dose-Response Relationships for Effects in Kidney

Several dose-response analyses have been done using a number of studies, including those summarized above, investigating the relationship between adverse effects in the kidney and urinary cadmium levels as a biomarker of cadmium concentration in the kidney.

Investigators analyzed data involving hundreds of people from studies in Europe (Järup *et al.*, 2000; Suwazono *et al.*, 2006), Japan (Kobayashi *et al.*, 2006; Shimizu *et al.*, 2006; Uno *et al.*,, 2005), and China (Jin *et al.*, 2004). The study populations lived in cadmium-polluted areas or had no particular source of cadmium exposure. Several studies used benchmark dose[7] approaches to estimate critical exposure levels. Most of these studies considered urinary excretion of pHC, NAG, β2M, retinol binding protein, ALB, or other proteins, and markers for changes in GFR as biomarkers of kidney injury. The analyses differed in choice of study population and also in the choice of model and parameters resulting in estimates of critical urinary cadmium concentrations (*i.e.*, the cadmium concentration associated with a specified level of risk for kidney dysfunction) ranging from about 0.3 to 15 micrograms cadmium excreted in urine per gram creatinine in urine (μg/g creat). These studies are summarized below.

In a population of workers and environmentally exposed people in Europe, Järup *et al.* (2000) found a 10 percent excess in urinary pHC at a cadmium concentration 1.0 μg/g creat.

Jin *et al.* (2004) examined a population living in a cadmium-contaminated area of China. Using a benchmark dose approach and cutoff value for defining abnormality for excretion of β2M of

[7] A benchmark dose approach uses mathematical modeling to characterize exposure-response relationships.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

0.8 mg/g creat., these researchers estimated a critical cadmium concentration of about 4 to 15 μg/g creat. for a 5 percent excess risk.

In an analysis of data collected in a region of Japan without a source of cadmium pollution, Kobayashi *et al.* (2006) estimated a critical cadmium concentration for a 5 percent excess risk of about 2-4 μg/g creat.

Shimizu *et al.* (2006) analyzed people living in a cadmium-contaminated area of Japan. Using a benchmark dose approach and cutoff value for defining abnormality for excretion of β2M of 1 mg/g creat., these researchers estimated a critical concentration between 1 μg/g creat. and 4 μg/g creat.

Suwazono *et al.* (2006) used data from a study of Swedish women who had no particular environmental or occupational exposure to cadmium. Using a benchmark dose approach, and a cutoff based on the 95th percentile for urinary protein excretion estimated for a person with no cadmium exposure, the critical concentration was estimated at 0.6-1 μg cadmium/g creat. for a 5 percent excess risk based on excretion of NAG and pHC.

Another study in Japanese populations not exposed to a known source of cadmium resulted in an estimated critical concentration of 0.3-3 μg cadmium/g creat. (Uno *et al., 2005*).

Another analysis of several studies conducted mostly in Japanese populations was conducted by Gamo *et al.* (2006), with a focus on studying the effects of age and sex. Urinary cadmium was used as a biomarker of exposure and the prevalence of abnormal levels of β2M as an indicator of kidney dysfunction. The authors concluded that a significant increase in the prevalence of abnormal β2M levels would not result if the geometric mean urinary cadmium level in a nationwide population does not exceed 2 μg/g creat.

Diamond *et al.* (2003) considered data from 15 different epidemiological studies. These authors developed a pharmacokinetic/pharmacodynamic (PK/PD) model to determine the relationship of low molecular weight (LMW) proteinuria with cadmium exposure. The authors estimated tissue cadmium concentrations, rather than using cadmium excretion in the urine as a marker of dose, and estimated intake levels corresponding to the specified probabilities of observing LMW proteinuria in a model of a 55-year-old person. The analysis resulted in an estimate for 10 percent risk for LMW proteinuria with a median kidney cortex concentration of 153 μg cadmium per gram tissue, corresponding to a cadmium intake of 2 μg/kg/day in females and 4.3 μg/kg/day in males.

Liver

While liver tends to accumulate cadmium, it does not appear to be as sensitive to cadmium effects as the kidney.

The two cases involving death in humans discussed above (Buckler *et al.*, 1986; Wisniewska-Knypl *et al.*, 1971) included liver injury; but studies of lower doses in human have not shown significant liver-specific effects (Ikeda *et al.*, 1997, 2000).

In experimental animals, exposure in rats for 10 days to drinking water containing 13.9 mg/kg/day was not associated with liver effects, while a dose of 138 mg/kg/day caused severe effects, including necrosis of hepatocytes (Borzelleca *et al.*, 1989). Longer term studies have shown liver effects at lower doses. A 10-week study in male Rhesus monkeys at a dose of 4 mg/kg/day by gavage found decreased glutathione peroxidase and glutathione *S*-transferase

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

(GST) activity in the liver and other tissues (Sidhu *et al.*, 1993). A number of other studies have noted histopathologic changes in the liver and changes in liver-associated enzymes in other laboratory animals at doses as low as about 2 mg/kg/day (Groten *et al.*, 1990; Müller and Stacey, 1988; Schroeder *et al.*, 1965; Steibert *et al.*, 1984; Stowe *et al.*, 1972). Other studies with similar doses did not observe liver effects (Loeser and Lorke, 1977a; Kotsonis and Klaassen, 1978).

Musculoskeletal Toxicity

Cadmium effects on the bone in humans are evident in a cadmium-contaminated area in Japan, where some residents suffer from a disease known as *Itai-Itai* or "ouch-ouch" disease involving osteoporosis and osteomalacia.

In a study of a population of Swedish men and women living in an area with past sources of cadmium pollution, significant decreases in bone mineral density were observed in the group more than 60 years of age with the highest blood cadmium levels compared to lowest exposed group (Alfvén *et al.*, 2002). Åkesson *et al.* (2006), in a study of Swedish women without a particular exposure to cadmium, reported a significant negative relationship between urinary cadmium levels and bone mineral density. The median urinary cadmium concentration was 0.67 μg/g creat. in this population. These two study populations also were used to examine the relationship between cadmium exposure and kidney toxicity (see above).

A study in a group of Flemish women (Schutte *et al.*, 2008) showed effects on several measures of bone health in the absence of evidence of kidney dysfunction in most of the subjects.

In an analysis of women in the United States, Gallagher *et al.* (2008) used data from the Third U.S. National Health and Nutrition Examination Survey (NHANES) 1988—1994, as well as NHANES 1999—2004, to evaluate the association of urinary cadmium levels and osteoporosis. These researchers reported that women who were at least 50 years of age with urinary cadmium levels between 0.50 and 1.00 μg/g creat., were at 43 percent greater risk for osteoporosis, relative to those with levels less than or equal to 0.50 μg/g creat. Because smokers did not show a statistically increased risk, the authors concluded that dietary sources of cadmium, rather than cigarette smoke, are related to the osteoporosis risk. These authors also concluded that perhaps 21 percent of osteoporosis prevalence among women at least 50 years of age may be attributed to cadmium.

Recently, Suwazono *et al.* (2010), following their analysis of kidney effects in a population of Swedish women, looked at cadmium-induced bone effects. Using the benchmark dose approach, these researchers estimated the critical cadmium concentration of 1.8-3.7 μg/g creat. for a 5 percent excess risk of low bone mineral density. The lower confidence limit of the critical cadmium concentration (BMDL) is 1.0-2.1 μg/g creat.

Brzóska and colleagues published a series of studies demonstrating effects of cadmium on bone in experimental animals (Brzóska and Moniuszko-Jakoniuk, 2004a, 2004b, 2005a, 2005b, 2005c, 2005d; Brzóska *et al.*, 2004, 2005a, 2005b, 2005c). Osteopenia and osteoporosis were noted in male rats exposed for 12 months to cadmium at 0.5 mg/kg/day and 4 mg/kg/day, respectively. In female rates, osteopenia was reported after exposure at 0.08 mg/kg/day for 12 or 18 months, and osteoporosis was observed with exposed at 0.08 mg/kg/day for 24 months. Altered mechanical properties of bone also were observed by these researchers and others (Ogoshi *et al.*, 1989). A number of studies reported decreased bone calcium and increased urinary excretion of calcium in intermediate- and chronic-duration studies with doses of 0.2–8 mg/kg/day (Brzóska and

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Moniuszko-Jakoniuk, 2005d; Kawamura *et al.*, 1978; Nogawa *et al.*, 1981; Pleasants *et al.*, 1992; Watanabe *et al.*, 1986).

Reproductive Toxicity

Several studies investigated the relationships between cadmium in blood, serum, or semen and hormone levels (testosterone, follicle stimulating hormone, luteinizing hormone, prolactin, estradiol) and measures of fertility. In a study of Eastern European men, Jurasović *et al.* (2004) reported a number of significant associations between reproductive health endpoints and cadmium blood concentrations, after adjusting for smoking status. Akinloye *et al.* (2006) also reported significant relationships between physical measures of decreased fertility and blood serum cadmium measurements. Seminal plasma cadmium concentration was not associated with the fertility outcomes. For hormone measurements, only seminal plasma cadmium concentration had a significant effect, and only for follicle stimulating hormone levels. In a study of men in the United States, using data from the third National Health and Nutrition Examination Survey (NHANES III), Menke *et al.* (2008) reported no association between urinary cadmium levels and serum testosterone and estradiol levels, after adjusting for smoking status.

No studies were found on reproductive effects in women after oral exposure to cadmium.

Several studies in experimental animals considered reproductive effects of cadmium exposure. Borzelleca *et al.* (1989) noted testicular atrophy in rats after exposure to 66 mg/kg/day by gavage for 10 days. A single dose of up to 25 mg/kg in rats had no effect (Dixon et al., 1976). Longer term studies (up to 17 weeks) in rats showed testicular effects with doses of about 5–12 mg/kg/day (Pleasants *et al.*, 1992; Pleasants *et al.*, 1993; Saxena *et al.*, 1989).

In studies of female animals, no effects on reproductive organs were noted in rats after exposure up to 138 mg/kg/day by gavage for 10 days (Borzelleca *et al.*, 1989). Baranski and Sitarek (1987) observed a significant increase in the duration of the estrous cycle in rats administered 40 mg/kg by gavage 5 days/week for 14 weeks.

A two-generation study involving male and female rats exposed to 2.5 mg/kg/day in drinking water for 180 days showed decreased litter size and increased interval between litters, and failure to breed in three of five second-generation pairs (Schroeder and Mitchener, 1971).

Developmental Toxicity

Several studies have considered the possible effects of cadmium exposure on pregnancy and offspring in humans. Salpietro *et al.* (2002) reported a significant association between cord blood cadmium levels and decreased newborn birth weight in a small study of women with relatively low cadmium exposures. Nishijo *et al.* (2002) reported decreased birth weight, probably secondary to early delivery, associated with maternal urinary cadmium levels. Zhang *et al.* (2004) reported an association between cord blood cadmium level and infant height, but not weight, or other pregnancy outcomes. These and other similar studies involved small numbers of participants, and did not control for confounding factors that might also be related to pregnancy outcomes, resulting in limited evidence of a causal relationship between cadmium exposure and pregnancy outcomes.

Numerous studies in experimental animals provide clearer evidence for developmental toxicity. Several studies reported reduced fetal or pup weight and increased incidence of skeletal malformations, missing internal organs or tissue, failure of testes to descend, and cleft palate in

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

offspring of mothers exposed to cadmium at doses of about 1–20 mg/kg/day (Ali *et al.*, 1986; Baranski, 1985; Baranski, 1987; Machemer and Lorke, 1981; Schroeder and Mitchener, 1971).

In multigenerational studies of rats, Nagymajtenyi and colleagues reported that cadmium administration of 7–14 mg/kg by gavage during pregnancy, lactation, and after weaning resulted in significant behavioral and electrophysiological effects in the offspring (Nagymajtenyi *et al.*, 1997; Desi *et al.*, 1998).

In a study in rats, Saxena *et al.* (1986) reported no developmental effects from exposure to either cadmium acetate (21 mg/kg/day as cadmium in drinking water) or lindane (20 mg lindane/kg by gavage), when administered alone during gestation. Coexposure to cadmium and lindane resulted in maternal toxicity and developmental toxicity. Effects in the dams included decreased weight gain; developmental effects included decreased fetal body weight, increased intrauterine death, and skeletal anomalies.

Neurologic Toxicity

A few studies have evaluated neurological effects from cadmium exposure. Based on analysis of metal content of hair, Thatcher *et al.* (1982) and Marlowe *et al.* (1985) reported associations between cadmium exposure and measures of intelligence or behavior. Because of shortcomings, including lack of control for confounding factors, such as exposure to lead, and inadequate assessment of cadmium exposure, the significance of these studies is unclear.

In studies in experimental animals, in both short-term and long-term studies with doses ranging from about 1 to 50 mg/kg/day, a number of neurologic endpoints, including decreased motor activity, weakness and muscle atrophy, increased aggressive behavior, increased passive avoidance behavior, and other changes in certain cells and enzyme levels have been observed (Baranski and Sitarek, 1987; Kotsonis and Klaassen, 1977; Kotsonis and Klaassen, 1978; Murthy *et al.*, 1989; Nation *et al.*, 1984; Nation *et al.*, 1990; Sato *et al.*, 1978; Valois and Webster, 1989).

Carcinogenicity

The carcinogenicity of cadmium and cadmium compounds has been evaluated largely in populations exposed through inhalation in workplace settings. Although deficiencies exist in the available information, the evidence supports the relationship between inhalation of cadmium and cancer (see ATSDR, 2008 for review of inhalation exposure studies). Cadmium and cadmium compounds are listed as "known to be human carcinogens" in the Report on Carcinogens, largely based on studies in workers (NTP, 2005).

A few investigations also have considered the relationship between cancer and oral exposure to cadmium in humans. Studies of populations in areas with known cadmium sources have not found significant associations with cancer (Bako *et al.*, 1982; Hardell *et al.*, 1994; Inskip *et al.*, 1982; Lauwerys and De Wals, 1981; Nakagawa *et al.*, 1987; Shigematsu, 1984). Some of these studies had methodological shortcomings or lacked statistical power to show effects, if such effects exist.

Studies in experimental animals and in vitro studies show that cadmium may have effects that could be associated with cancer. Kurokawa *et al.* (1989), in a study investigating whether certain metal compounds act as promoters of tumors initiated by other chemicals, reported that cadmium exposure at 61 ppm in drinking water did not affect the incidence of renal cell tumors, but was

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

associated with increased numbers of dysplastic foci in the kidney. These authors also reported that cadmium chloride did not act to increase tumors in the liver, stomach, pancreas, or skin.

In a study investigating cadmium carcinogenesis and dietary zinc deficiency in rats, Waalkes and Rehm (1992) reported a number of effects of exposure to cadmium in the diet at 0, 25, 50, 100, or 200 ppm for 77 weeks. The incidence of prostate tumors was slightly increased compared to controls at 50 ppm, but not the other dose groups. An increase in testicular tumors was noted only in the highest dose group that also received adequate levels of zinc, but not in groups that were fed the zinc-deficient diet. Leukemia incidence also was increased in the cadmium-exposed groups. The authors conclude that cadmium is associated with the incidence of tumors in exposed animals, and that dietary zinc deficiency has a complex, inhibitory relationship in cadmium carcinogenesis.

Although cadmium exposure carcinogenesis is not clearly shown in the human and animal studies, recent work *in vitro* provides evidence that cadmium exposure could be related to cancer. Benbrahim-Tallaa *et al.* (2009) showed that cadmium transformed normal human breast cells into cells that displayed characteristics of basal-like breast carcinoma. These cells, when injected into mice, produced invasive, metastatic cancer.

In a study of effects of cadmium on kidney cells, Chakraborty *et al.* (2010) reported that cadmium exposure caused changes in the cells related to proliferation and survival of preneoplastic cells, possibly providing a mechanism for cadmium-induced carcinogenicity.

Discussion

Cadmium is poorly absorbed in the body following exposure by inhalation (about 25 percent) or ingestion (about 1–10 percent). Cadmium that is absorbed can be found largely in the liver and kidney. Cadmium is excreted slowly; estimated half-lives of cadmium in tissues are 6–-38 years for the human kidney and 4–19 years for the human liver.

Cadmium has effects on numerous organ systems and cells within the body, principally the kidney and bone. Although cadmium exposure through inhalation in workers is associated with lung cancer, there is insufficient evidence in humans or experimental animals to determine whether cadmium is carcinogenic from oral exposure. CPSC staff concludes that the data are sufficient for cadmium to be considered toxic under the FHSA.

Based on a review of the data, the effects in the kidney can be considered the most sensitive endpoint. Cadmium exposure is associated with increased excretion of biomarkers for kidney dysfunction, including urinary N-acetyl-β-D-glucosaminidase (NAG), human complex-forming protein (pHC), β_2-microglobulin (β2M), and total protein, and decreased glomerular filtration rates (GFR).

CPSC staff identified the analysis of Suwazono *et al.* (2006) as the key study for an exposure-response analysis because this analysis was based on a large, well-characterized population of women who had no particular environmental or occupational exposure to cadmium; the study population excluded individuals such as those with diabetes, kidney cancer, or those who used certain medications; the analysis controlled for other potential confounders; and the estimated critical effect level was among the lowest estimated from the many published analyses.

Suwazono *et al.* (2006) used a benchmark dose approach to analyze the data from the study of 820 Swedish women. The analysis estimated the concentration of cadmium in urine associated with urinary protein markers (NAG and pHC) for adverse effects in the kidney. These

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

researchers reported a benchmark dose (BMD) for a 5 percent excess risk for each of the proteins excreted in the urine of 0.6 micrograms cadmium per gram creatinine in the urine (0.6 μg/g creat.). The lower confidence limit of the cadmium concentration BMD (*i.e.*, BMDL) was 0.5 μg/g creat. Similar results were reported by Uno *et al.* (2005) and Järup *et al.* (2000).

Because the BMDL is a measure of cadmium excreted in urine, additional analysis is required to estimate the corresponding level of cadmium intake into the body. This can be done using modeling techniques. The derivation of the MRL presented in the draft ATSDR Toxicological Profile for Cadmium (ATSDR, 2008) has applied such an analysis using the results of several studies of European populations, including Suwazono *et al.* (2006). For a 0.5 μg/g creat. urinary concentration, the analysis published by ATSDR (2008) estimated a level of cadmium intake of 0.33 μg/kg/day. This is the intake level chosen by CPSC staff as the critical exposure level.

The scientific community generally addresses uncertainty in the understanding of toxicology and dose-response through the use of uncertainty factors. CPSC staff also uses an uncertainty factor approach in evaluating exposure levels to account for a lack of robust data from animal studies, or a lack of information from human exposures (CPSC, 1992). CPSC staff may apply up to three uncertainty factors, depending on the completeness and relevance of the available data. An uncertainty factor may be used if data are available only in studies of animals and not in humans. An uncertainty factor is applied if the available studies do not identify a dose or exposure level that is not associated with an adverse effect (no observed adverse effect level or NOAEL). When a benchmark dose approach is used, the BMDL is treated as a NOAEL. The third type of uncertainty factor is applied to account for sensitive populations if the available studies do not adequately address such concerns.

In this case, only one uncertainty factor is needed, which is intended to account for the possibility of sensitive members of the population. Staff has chosen to apply a reduced uncertainty factor of 3, rather than the factor of 10 that is more typically used because of lack of knowledge of effects throughout a population. The reduced uncertainty factor is appropriate in this case because of the strength of the data that supports the identified critical exposure level, based on multiple studies of large numbers of people in different parts of the world. Therefore, an uncertainly factor of 3 applied to the intake level of 0.33 μg/kg/day results in an acceptable daily intake (ADI) of 0.1 μg/kg/day. This is the level of chronic exposure that should not be exceeded in order to avoid health effects.

Conclusion

The data concerning the toxicity of cadmium is sufficient for cadmium to be considered toxic under the FHSA due to effects on multiple organ systems and toxic endpoints, including kidney dysfunction. CPSC staff has developed an ADI for chronic exposure to cadmium by the oral route of 0.1 μg/kg/day, based on studies in human populations. Chronic exposures above the ADI of 0.1 μg/kg/day could cause adverse health effects.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

References

ATSDR (2008) Toxicological Profile for Cadmium (Draft). Agency for Toxic Substances and Disease Registry. U.S. Department of Health and Human Services. http://www.atsdr.cdc.gov/toxprofiles/tp5.html.

Åkesson A, Bjellerup P, Lundh T, Lidfeldt J, Nerbrand C, Samsioe G, Skerfving S, Vahter M (2006) Cadmium-induced effects on bone in a population-based study of women. Environ Health Perspect 114(6):830-4.

Akinloye O, Arowojolu AO, Shittu OB, Anetor JI (2006) Cadmium toxicity: A possible cause of male infertility in Nigeria. Reprod Biol 6(1):17–30.

Alfvén T, Järup L, Elinder C (2002) Cadmium and lead in blood in relation to low bone mineral density and tubular proteinuria. (Erratum in: Environ Health Perspect 110(9):A505). Environ Health Perspect 110(7):699–702.

Ali MM, Murthy RC, Chandra SV (1986) Developmental and long term neurobehavioral toxicity of low level *in utero* cadmium exposure in rats. Neurobehav Toxicol Teratol 8:463–468.

Baer K, and Benson W (1987) Influence of chemical and environmental stressors on acute cadmium toxicity. J Toxicol Environ Health 22(1):35–44.

Bako G, Smith ES, Hanson J, Dewar R (1982) The geographical distribution of high cadmium concentrations in the environment and prostate cancer in Alberta. Can J Public Health 73:92––94. (As cited in ATSDR, 2008).

Baranski B (1985) Effect of exposure of pregnant rats to cadmium on prenatal and postnatal development of the young. J Hyg Epidemiol Microbiol Immunol 29:253–262.

Baranski B (1987) Effect of cadmium on prenatal development and on tissue cadmium, copper and zinc concentrations in rats. Environ Res 42:54–62.

Baranski B, Sitarek K (1987) Effect of oral and inhalation exposure to cadmium on the oestrous cycle in rats. Toxicol Lett 36:267–273. (As cited in ATSDR, 2008).

Benbrahim-Tallaa L, Tokar EJ, Diwan BA, Dill AL, Coppin JF, Waalkes MP (2009) Cadmium malignantly transforms normal human breast epithelial cells into a basal-like phenotype. Environ Health Perspect 117(12):1847–52.

Bernard A, Buchet J, Roels H, Masson P, Lauwerys R (1979) Renal excretion of proteins and enzymes in workers exposed to cadmium. Eur J Clin Invest 9(1):11–22. (As cited in ATSDR, 2008).

Bernard A, Roels H, Cardenas A, Lauwerys R (1990) Assessment of urinary protein 1 and transferrin as early markers of cadmium nephrotoxicity. Br J Ind Med 47(8):559–565.

Borzelleca J, Clarke E, and Condcie L (1989) Short-term toxicity (1 and 10 days) of cadmium chloride in male and female rats: Gavage and drinking water. J Am Coll Toxicol 8:377-404.

Brzóska MM, Moniuszko-Jakoniuk J (2004a) Low-level exposure to cadmium during the lifetime increases the risk of osteoporosis and fractures of the lumbar spine in the elderly: Studies on a rat model of human environmental exposure. Toxicol Sci 82:468–477.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Brzóska MM, Moniuszko-Jakoniuk J (2004b) Low-level lifetime exposure to cadmium decreases skeletal mineralization and enhances bone loss in aged rats. Bone 35(5):1180–1191.

Brzóska MM, Moniuszko-Jakoniuk J (2005a) Bone metabolism of male rats chronically exposed to cadmium. Toxicol Appl Pharmacol 207(3):195-211.

Brzóska MM, Moniuszko-Jakoniuk J (2005b) Effect of chronic exposure to cadmium on the mineral status and mechanical properties of lumbar spine of male rats. Toxicol Lett 157(2):161–172.

Brzóska MM, Moniuszko-Jakoniuk J (2005c) Effect of low-level lifetime exposure to cadmium on calciotropic hormones in aged female rats. Arch Toxicol 79(11):636–646.

Brzóska MM, Moniuszko-Jakoniuk J (2005d) Disorders in bone metabolism of female rats chronically exposed to cadmium. Toxicol Appl Pharmacol 202(1):68–83.

Brzóska MM, Majewska K, Moniuszko-Jakoniuk J (2004) Mineral status and mechanical properties of lumbar spine of female rats chronically exposed to various levels of cadmium. Bone 34(3):517–526.

Brzóska MM, Majewska K, Moniuszko-Jakoniuk J (2005a) Bone mineral density, chemical composition and biomechanical properties of the tibia of female rats exposed to cadmium since weaning up to skeletal maturity. Food Chem Toxicol 43(10):1507–1519.

Brzóska MM, Majewska K, Moniuszko-Jakoniuk J (2005b) Mechanical properties of femoral diaphysis and femoral neck of female rats chronically exposed to various levels of cadmium. Calcif Tissue Int 76(4):287–298.

Brzóska MM, Majewska K, Moniuszko-Jakoniuk J (2005c) Weakness in the mechanical properties of the femur of growing female rats exposed to cadmium. Arch Toxicol 79(5):277–288.

Buckler H, Smith W, and Rees W (1986) Self poisoning with oral cadmium chloride. Br Med J 292:1559-1560.

CDC (2009) Fourth National Report on Human Exposure to Environmental Chemicals. Centers for Disease Control and Prevention. U.S. Department of Health and Human Services. http://www.cdc.gov/exposurereport/.

Chakraborty PK, Lee WK, Molitor M, Wolff NA, Thévenod F (2010) Cadmium induces Wnt signaling to upregulate proliferation and survival genes in sub-confluent kidney proximal tubule cells. Mol Cancer 9:102.

Chen L, Jin T, Huang B, Chang X, Lei L, Nordberg GF, Nordberg M (2006a) Plasma metallothionein antibody and cadmium-induced renal dysfunction in an occupation population in China. Toxicol Sci 91(1):104–112.

Chen L, Jin T, Huang B, Nordberg G, Nordberg M (2006b) Critical exposure level of cadmium for elevated urinary metallothionein: An occupational population study in China. Toxicol Appl Pharmacol 215(1):93–99.

CPSC (1992) Labeling requirements for art materials presenting chronic hazards; guidelines for determining chronic toxicity of products subject to the FHSA; supplementary definition of

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

"toxic" under the Federal Hazardous Substances Act; final rules. 57 Fed. Reg.: 46626–46674 (9 October 1992).

Desi I, Nagymajtenyi L, Schulz H (1998) Behavioral and neurotoxicological changes caused by cadmium treatment of rats during development. J Appl Toxicol 18(1):63–70.

Diamond G, Thayer W, and Choudhury H (2003) Pharmacokinetics/pharmacodynamics (PK/PD) modeling of risks of kidney toxicity from exposure to cadmium: Estimates of dietary risks in the U.S. population. J Toxicol Environ Health A 66:2141–2164.

Dixon RL, Lee IP, Sherins RJ (1976) Methods to assess reproductive effects of environmental chemicals: Studies of cadmium and boron administered orally. Environ Health Perspect 13:59–67.

Elinder CG, Edling C, Lindberg E, Kågedal B, Vesterberg O (1985) β2-Microglobulinuria among workers previously exposed to cadmium: Follow-up and dose-response analyses. Am J Ind Med 8:553–564.

EPA (1994) Integrated Risk Information System, Cadmium (CASRN 7440-43-9). U.S. Environmental Protection Agency. http://www.epa.gov/iris/subst/0141.htm.

EPA (2003) National primary drinking warter standards. U.S. Environmental Protection Agency. Washington, DC.

European Chemicals Bureau (2007) European Union risk assessment report. Cadmium metal and cadmium oxide. Luxembourg: European Chemicals Bureau, Institute for Health and Consumer Protection.

FDA (2009) Beverages: Bottled Water. U.S. Food and Drug Administration. Rockville, MD.

Foulkes E (1985) Interactions between metals in rat jejunum: Implications on the nature of cadmium uptake. Toxicology 37:117–125.

Gallagher C, Kovach J, Meliker J (2008) Urinary cadmium and osteoporosis in U.S. women ≥ 50 years of age: NHANES 1988–1994 and 1999–2004. Environmental Health Perspectives 116(10):1338–1343.

Gamo M, Ono K, and Nakanishi J (2006) Meta-analysis for deriving age- and gender-specific dose-response relationships between urinary cadmium concentration and β2-microglobulinuria under environmental exposure. Environ Res 101(1):104–112.

Groten JP, Sinkeldam EJ, Luten JB, van Bladeren PJ (1990) Comparison of the toxicity of inorganic and liver incorporated cadmium: A 4-week feeding study in rats. Food Chem Toxicol 28:435–441.

Hardell L, Wing MA, Ljungberg B, Dreifaldt AC, Degerman A, Halmans G (1994) Levels of cadmium, zinc and copper in renal cell carcinoma and normal kidney. Eur J Cancer Prev 3:45-48.

Ikeda M, Watanabe T, Zhang ZW, Moon CS, Shimbo S (1997) The integrity of the liver among people environmentally exposed to cadmium at various levels. Int Arch Occup Environ Health 69(6):379–385.

Ikeda M, Zhang ZW, Moon CS, Shimbo S, Watanabe T, Nakatsuka H, Matsuda-Inoguchi N, Higashikawa K (2000) Normal liver function in women in the general Japanese population

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

subjected to environmental exposure to cadmium at various levels. Int Arch Occup Environ Health 73(2):86-90.

Inskip H, Beral V, McDowall M (1982) Mortality of Shipham residents: 40-year follow-up. Lancet 319:896–899.

Järup L, Persson B, Edling C, Elinder CG (1993) Renal function impairment in workers previously exposed to cadmium. Nephron 64:75–81.

Järup L, Berglund M, Elinder CG, Nordberg G, Vahter M (1998) Health effects of cadmium exposure - a review of the literature and a risk estimate. Scand J Work Environ Health 24 Suppl 1:1-52.

Järup L, Hellström L, Alfvén T, Carlsson MD, Grubb A, Persson B, Pettersson C, Spång G, Schütz A, Elinder CG (2000) Low level exposure to cadmium and early kidney damage: The OSCAR study. Occup Environ Med 57(10):688–672.

Jin T, Nordberg M, Frech W, Dumont X, Bernard A, Ye TT, Kong Q, Wang Z, Li P, Lundström NG, Li Y, Nordberg GF (2002) Cadmium biomonitoring and renal dysfunction among a population environmentally exposed to cadmium from smelting in China. Biometals 15:397-410.

Jin T, Wu X, Tang Y, Nordberg M, Bernard A, Ye T, Kong Q, Lundström NG, Nordberg GF (2004) Environmental epidemiological study and estimation of benchmark dose for renal dysfunction in a cadmium-polluted area in China. Biometals 17(5):525–530.

Jurasović J, Cvitkovic P, Pizent A, Colak B, Telisman S (2004) Semen quality and reproductive endocrine function with regard to blood cadmium in Croatian male subjects. Biometals 17(6):735–743.

Kawamura J, Yoshida O, Nishino K, Itokawa Y (1978) Disturbances in kidney functions and calcium and phosphate metabolism in cadmium-poisoned rats. Nephron 20:101–110.

Kjellström T (1979) Exposure and accumulation of cadmium in populations from Japan, the United States, and Sweden. Environ Health Perspect 28:169-97.

Kjellström T and Nordberg G (1978) A kinetic model of cadmium metabolism in the human being. Environ Res 16:248–269. (As cited in ATSDR, 2008).

Kjellström T and Nordberg G (1985) Kinetic model of cadmium metabolism. In L. Friberg, C. Elinder, T. Kjellström, et al., Cadmium and health: A toxicological and epidemiological appraisal. Vol. I. Exposure, dose and metabolism (pp. 179–197). Boca Raton, FL: CRC Press. (As cited in ATSDR, 2008).

Kobayashi E, Suwazono Y, Uetani M, Inaba T, Oishi M, Kido T, Nishijo M, Nakagawa H, Nogawa K (2006) Estimation of benchmark dose as the threshold levels of urinary cadmium, based on excretion of total protein, β2-microglobulin and N-acetyl-β-D-glucosaminidase. Environ Res 101(3):401–406.

Kostial K, Kello D, Jugo S, Rabar I, Maljković T (1978) Influence of age on metal metabolism and toxicity. Environ Health Perspect 25:81–86.

Kostial K, Kello D, Blanusa M, Maljković T, Rabar I (1979) Influence of some factors on cadmium pharmacokinetics and toxicity. Environ Health Perspect 28:89–95.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Kotsonis FN and Klaassen CD. (1977) Toxicity and distribution of cadmium administered to rats at sublethal doses. Toxicol Appl Pharmacol 41:667–680. (As cited in ATSDR, 2008).

Kotsonis F and Klaassen C (1978) The relationship of metallothionein to the toxicity of cadmium after prolonged administration to rats. Toxicol Appl Phamacol 46:39–54. (As cited in ATSDR, 2008).

Kurokawa Y, Takahashi M, Maekawa A, Hayashi Y (1989) Promoting effect of metal compounds on liver, stomach, kidney, pancreas, and skin carcinogenesis. Int J Toxicol 8:1235–1239.

Lauwerys R, De Wals PH (1981) Environmental pollution by cadmium and mortality from renal diseases. Lancet 1(8216):383. (As cited in ATSDR, 2008).

Loeser E and Lorke D (1977a) Semichronic oral toxicity of cadmium. I. Studies on rats. Toxicology 7:215–224.

Loeser E and Lorke D (1977b) Semichronic oral toxicity of cadmium. II. Studies on dogs. Toxicology 7:225–232.

Machemer L and Lorke D (1981) Embryotoxic effect of cadmium on rats upon oral administration. Toxicol Appl Pharmacol 58:438–443.

Marlowe M, Cossairt A, Moon C, Errera J, MacNeel A, Peak R, Ray J, Schroeder C (1985) Main and interaction effects of metallic toxins on classroom behavior. J Abnorm Child Psychol 13:185–198.

Mason H, Williams N, Armitage S, Morgan M, Green S, Perrin B, Morgan WD (1999) Follow up of workers previously exposed to silver solder containing cadmium. Occup Environ Med 56(8):553–558.

McDiarmid MA, Freeman CS, Grossman EA, Martonik J (1997) Follow-up of biologic monitoring results in cadmium workers removed from exposure. Am J Ind Med 32:261–267.

Menke A, Guallar E, Shiels MS, Rohrmann S, Basaria S, Rifai N, Nelson WG, Platz EA (2008) The association of urinary cadmium with sex steroid hormone concentrations in a general population sample of U.S. adult men. BMC Publ Health 8:72–79.

Miller M, Murthy L, Basom C, Petering HG (1974) Alteration in hepatocytes after manipulation of the diet: Copper, zinc and cadmium interactions. Am J Anat 141:23-40. (As cited in ATSDR, 2008).

Müller L and Stacey NH (1988) Subcellular toxicity of low level cadmium in rats: Effect on cytochrome C oxidase. Toxicology 51:25–34.

Murthy RC, Saxena DK, Lal B, Chandra SV (1989) Chronic cadmium-ethanol administration alters metal distribution and some biochemicals in rat brain. Biochem Int 19:135–143.

Nation JR, Bourgeois AE, Clark DE, Baker DM, Hare MF (1984) The effects of oral cadmium exposure on passive avoidance performance in the adult rat. Toxicol Lett 20:41–47.

Nation JR, Grover CA, Bratton GR, Salinas JA (1990) Behavioral antagonism between lead and cadmium. Neurotoxicol Teratol 12:99–104.

Nagymajtenyi L, Schulz H, Desi I (1997) Behavioural and functional neurotoxicological changes caused by cadmium in a three-generational study in rats. Hum Exp Toxicol 16(12):691–699.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Nakagawa H, Sawano S, Okumura Y, Fujita T, Nishi M (1987) Mortality study of inhabitants in a cadmium polluted area. Bull Environ Contam Toxicol 38:553–560. (As cited in ATSDR, 2008).

Nishijo M, Nakagawa H, Honda R, Tanebe K, Saito S, Teranishi H, Tawara K (2002) Effects of maternal exposure to cadmium on pregnancy outcome and breast milk. Occup Environ Med 59(6): 394–397.

Nogawa K, Kobayashi E, Konishi F (1981) Comparison of bone lesions in chronic cadmium intoxication and vitamin D deficiency. Environ Res 23:233–249. (As cited in ATSDR, 2008).

Noonan C, Sarasua S, Campagna D, Kathman SJ, Lybarger JA, Mueller PW (2002) Effects of exposure to low levels of environmental cadmium on renal biomarkers. Environ Health Perspect 110(2):151–155.

Nordberg G, Slorach S, Steinstrom T (1973) Cadmium poisoning caused by cooled soft drink machine. Lakartidingen 70:601-604.

Nordberg M (1984) General aspects of cadmium: transport, uptake and metabolism by the kidney. Environ Health Perspect 54:13–20.

NTP (2005) National Toxicology Program. Cadmium (CAS No. 7440-43-9) and Cadmium Compounds. Report on Carcinogens (RoC). US Department of Health and Human Services. http://ntp.niehs.nih.gov/index.cfm.

Ogoshi K, Moriyama T, Nanzai Y. (1989) Decrease in the mechanical strength of bones of rats administered cadmium. Arch Toxicol 63:320–324.

OSHA (2009) Cadmium. Toxic and hazardous substances. Occupational Safety and Health Administration. http://www.osha.gov/SLTC/cadmium/index.html.

Piscator M (1984) Long-term observations on tubular and glomerula function in cadmium-exposed persons. Environ Health Perspect 54:175–179.

Pleasants EW, Sandow ME, DeCandido S, Waslien , Naughton BA (1992) The effect of vitamin D3 and 1,25dihydroxyvitamin D3 on the toxic symptoms of cadmium exposed rats. Nutr Res 12:1393–1403.

Pleasants EW, Waslien C, Naughton BA (1993) Dietary modulation of the symptoms of cadmium toxicity in rats: Effects of vitamins A, C, D, D hormone and fluoride. Nutr Res 13:839–850.

Roels H, Bernard A, Cardenas A, Buchet JP, Lauwerys RR, Hotter G, Ramis I, Mutti A, Franchini I, Bundschuh I (1993) Markers of early renal changes induced by industrial pollutants. III. Application to workers exposed to cadmium. Brit J Ind Med 50:37–48.

Roels HA, Lauwerys RR, Buchet JP, Bernard AM, Vos A, Oversteyns M (1989) Health significance of cadmium induced renal dysfunction: A five year follow-up. Br J Ind Med 46:755–764.

Roels H, Van Assche F, Oversteyns M, De Groof M, Lauwerys RR, Lison D (1997) Reversibility of microproteinuria in cadmium workers with incipient tubular dysfunction after reduction of exposure. Am J Ind Med 31(5):645–652.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Salpietro CD, Gangemi S, Minciullo PL, Briuglia S, Merlino MV, Stelitano A, Cristani M, Trombetta D, Saija A (2002) Cadmium concentration in maternal and cord blood and infant birth weight: A study in healthy non-smoking women. J Perinat Med 30 (5):395–399.

Sato K, Iwamasa T, Tsuru T, Takeuchi T (1978) An ultrastructural study of chronic cadmium chloride induced neuropathy. Acta Neuropathol 41:185–190.

Saxena DK, Murthy RC, Chandra SV (1986) Embryotoxic and teratogenic effects of interaction of cadmium and lindane in rats. Acta Pharmacol Toxicol 59:175–178.

Saxena DK, Murthy RC, Singh C, Chandra SV (1989) Zinc protects testicular injury induced by concurrent exposure to cadmium and lead in rats. Res Commun Chem Pathol Pharmacol 64:317–329.

Schroeder H, Balassa J, Vinton W (1965) Chromium, cadmium, and lead in rats: Effects on life span, tumors, and tissue levels. J Nutr 86:51–66.

Schroeder HA, Mitchener M (1971) Toxic effects of trace elements on the reproduction of mice and rats. Arch Environ Health 23:102–106. (As cited in ATSDR, 2008).

Schutte R, Nawrot TS, Richart T, Thijs L, Vanderschueren D, Kuznetsova T, Van Hecke E, Roels HA, Staessen JA (2008) Bone resorption and environmental exposure to cadmium in women: A population study. Environ Health Perspect 116:777–783.

Shigematsu I (1984) The epidemiological approach to cadmium pollution in Japan. Ann Acad Med Singapore 13:231–236.

Shimizu A, Kobayashi E, Suwazono Y, Uetani M, Oishi M, Inaba T, Kido T, Nogawa K (2006) Estimation of benchmark doses for urinary cadmium based on β2 -microglobulin excretion in cadmium-polluted regions of the Kakehashi River basin, Japan. Int J Environ Health Res 16(5):329–337.

Sidhu M, Sharma M, Bhatia M, Awasthi YC, Nath R (1993) Effect of chronic cadmium exposure on glutathione S-transferaseand glutathione peroxidase activities in Rhesus monkey the role of selenium. Toxicology 83:203–213.

Steibert E, Krol B, Sowa B, Gralewska K, Kamiński M, Kamińska O, Kusz E (1984) Cadmium-induced changes in the histoenzymatic activity in liver, kidney and duodenum of pregnant rats. Toxicol Lett 20:127–132.

Stowe H, Wilson M, Goyer R (1972) Clinical and morphological effects of oral cadmium toxicity in rabbits. Arch Pathol 94:389–405. (As cited in ATSDR, 2008).

Suwazono Y, Sand S, Vahter M, Filipsson AF, Skerfving S, Lidfeldt J, Akesson A (2006) Benchmark dose for cadmium-induced renal effects in humans. Environ Health Perspect 114:1072–1076.

Suwazono Y, Sand S, Vahter M, Skerfving S, Lidfeldt J and Åkesson A (2010) Benchmark dose for cadmium-induced osteoporosis in women. Toxicol Lett 197(2):123–127.

Thatcher RW, Lester ML, McAlaster R, Horst R (1982) Effects of low levels of cadmium in lead on cognitive functioning in children. Arch Environ Health 37:159–166.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Thun M, Osorio A, Schober S, Hannon WH, Lewis B, Halperin W (1989) Nephropathy in cadmium workers: Assessment of risk from airborne occupational exposure to cadmium. Br J Ind Med 46:689–697.

Trzcinka-Ochocka M, Jakubowski M, Halatek T, Razniewska G (2002) Reversibility of microproteinuria in nickel-cadmium battery workers after removal from exposure. Int Arch Occup Environ Health 75(Suppl):S101–S106.

Uno T, Kobayashi E, Suwazono Y, Okubo Y, Miura K, Sakata K, Okayama A, Ueshima H, Nakagawa H, Nogawa K (2005) Health effects of cadmium exposure in the general environment in Japan with special reference to the lower limit of the benchmark dose as the threshold level of urinary cadmium. Scand J Work Environ Health 31(4):307–315.

Valois AA, Webster WS (1989) The choroid plexus as a target site for cadmium toxicity following chronic exposure in the adult mouse: an ultrastructural study. Toxicology 55(1-2):193–205.

van Sittert N, Ribbens P, Huisman B, Lugtenburg D (1993) A nine year follow-up study of renal effects in workers exposed to cadmium in a zinc ore refinery. Br J Ind Med 50:603–612.

Waalkes MP and Rehm S (1992) Carcinogenicity of oral cadmium in the male Wistar (WF/NCr) rat: effect of chronic dietary zinc deficiency. Fundam Appl Toxicol 19(4):512–20.

Watanabe M, Shiroishi K, Nishino H, Shinmura T, Murase H, Shoji T, Naruse Y, Kagamimori S (1986) An experimental study on the long-term effect of cadmium in mice fed cadmium-polluted rice with special reference to the effect of repeated reproductive cycles. Environ Res 40:25–46.

Wisniewska-Knypl JM, Jablonska J, Myslak Z (1971). Binding of cadmium on metallothionein in man: An analysis of a fatal poisoning by cadmium iodide. Arch Toxicol 28:46-55. (As cited in ATSDR, 2008).

Zhang YL, Zhao YC, Wang JX, Zhu HD, Liu QF, Fan YG, Wang NF, Zhao JH, Liu HS, Ou-Yang L, Liu AP, Fan TQ (2004) Effect of environmental exposure to cadmium on pregnancy outcome and fetal growth: A study on healthy pregnant women in China. J Environ Sci Health A 39(9):2507–2515.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB C: Injury Data Analysis

T
A
B

C

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

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

Memorandum

Date: November 23, 2010

TO : Kristina Hatlelid, Toxicologist
Directorate for Health Sciences

THROUGH: Greg Rodgers, Acting Associate Executive Director
Directorate for Epidemiology

Kathleen Stralka, Division Director
Hazard Analysis Division

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

SUBJECT : Analysis of Data on Child Ingestions, 2000–2009[17]

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 U.S. 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 May 2010, the Sierra Club, the Center for Environmental Health, and other organizations petitioned the CPSC to regulate the cadmium content in children's metal jewelry (Sierra Club, 2010).

III. Injury Data

A. Methodology

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 then the data is transmitted electronically to the 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 United States. Different hospitals carry different weights based on stratification by their annual number of emergency room visits (Schroeder and Ault, 2001).

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

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Hazard Analysis staff searched NEISS for all cases with diagnosis code 41 (Ingested Foreign Object) and patients 18 years of age or younger. Staff 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 expressed generally as a percent. A C.V. of 10 percent 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. Often this is due to a small sample size.[18] 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 percent.

B. Results

1. Overall

From 2000 to 2009, staff found 22,143 NEISS cases involving ingestion of a foreign object and a child age 18 years or younger. Based on these 22,143 cases, staff found that there were an estimated 557,791 emergency room-treated injuries from 2000 to 2009 involving children 18 years old or younger who ingested a foreign object. The 95 percent confidence interval about the number of emergency room-treated injuries from 2000 to 2009 for children 18 years of age or younger is 470,818 to 644,764. Table 1 provides a breakdown of the incidents by age group. 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, 2000–2009

Age Range	Estimate	Percent of Total	Sample Size	C.V.	95% Confidence Interval
0–20 months	136,549	24.5%	5,789	9.46%	111,234–161,865
21 months–3 years	178,283	32.0%	7,118	8.50%	148,580–207,986
4–5 years	106,158	19.0%	4,185	8.00%	89,521–122,795
6–18 years	136,802	24.5%	5,051	7.06%	117,865–155,738
Total	557,791	100.0%	22,143	7.96%	470,818–644,764

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, November 2010
Columns may not sum to totals due to rounding

Staff also categorized the cases by the product associated with the ingestion injury. The 10 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 22,143 incidents analyzed, 1,194 incidents had two associated products. There are several situations where two products may be coded for an ingestion case. Both products may have 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 also may be associated

[18] For a more detailed discussion of measures of variation associated with NEISS estimates, see Schroeder and Ault, 2001.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

with the incident but not swallowed, such as a toddler swallowing a coin found on the floor, with both the coin and the floor coded.

Table 2: Top 10 Products Swallowed by Individuals 18 Years Old and Younger, 2000–2009

Based on Number of Estimated Emergency Room-Treated Injuries

Product Code	Product Code Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	262,242	47.0%	10,892	8.28%
5004	Toys, not elsewhere classified[19]	39,038	7.0%	1,525	8.47%
1616	Jewelry	38,100	6.8%	1,475	8.98%
1819	Nails, screws, tacks, or bolts	30,363	5.4%	1,094	8.42%
0884	Batteries	29,029	5.2%	1,214	11.37%
1354	Marbles	18,754	3.4%	694	11.34%
1650	Desk supplies	10,818	1.9%	395	11.31%
1682	Hair curlers, curling irons, clips, and hair pins	9,944	1.8%	467	10.71%
0428	Kitchen gadgets, not elsewhere classified	8,748	1.6%	334	14.13%
1685	Pens and pencils	7,632	1.4%	264	12.37%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, November 2010

2. Age Groups by Quartile

From 2000 to 2009, staff found 5,789 NEISS cases involving ingestion of foreign objects and children ages 20 months or younger. Based on these 5,789 cases there were an estimated 136,549 emergency-room treated injuries from 2000 to 2009 involving children under the age of 20 months and the ingestion of foreign objects. Staff categorized the cases by the product associated with the ingestion injury. Table 3 shows the 10 product categories with the highest estimates. Of the 5,789 cases analyzed, 433 cases had two associated products.

[19] Toys, not elsewhere classified, is a broad category including all toys that do not have their own NEISS product code, and any case where the type of toy involved was not specified clearly. Most cases involved an unspecified toy or part of a toy, but other common toys from this category that were swallowed include: game pieces, puzzle pieces, doll accessories, small balls, and pieces from building sets.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 3: Top 10 Products Swallowed by Children 20 Months Old and Younger, 2000–2009

Based on Number of Estimated Emergency-Room Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	51,291	37.6%	2,384	10.96%
1819	Nails, screws, tacks, or bolts	9,942	7.3%	345	9.73%
1616	Jewelry	9,454	6.9%	428	12.63%
5004	Toys, not elsewhere classified	8,516	6.2%	338	15.62%
0884	Batteries	8,053	5.9%	343	12.57%
1729	Christmas decorations (nonelectric)	5,227	3.9%	222	13.96%
1682	Hair curlers, curling irons, clips, and hair pins	4,602	3.4%	224	13.34%
1807	Floors or flooring materials[20]	4,302	3.2%	147	17.07%
1137	Paper products	3,566	2.6%	125	14.00%
1650	Desk supplies	3,452	2.5%	129	15.09%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, November 2010

From 2000 to 2009, staff found 7,118 NEISS cases involving ingestion of foreign objects and children ages 21 months through three years old. Based on these 7,118 cases there were an estimated 178,283 emergency-room treated injuries from 2000 to 2009 involving a child between the ages of 21 months and three years and the ingestion of a foreign object. Staff categorized the cases according to the product associated with the ingestion injury. Table 4 shows the 10 product categories with the highest estimates. Note that of the 7,118 cases analyzed, 310 cases had two associated products.

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

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 4: Top 10 Products Swallowed by Children 21 Months through Three Years Old, 2000–2009

Based on Number of Estimated Emergency Room-Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	102,892	57.7%	4,179	8.65%
5004	Toys, not elsewhere classified	12,330	7.2%	506	10.30%
884	Batteries	8,997	5.0%	397	12.14%
1819	Nails, screws, tacks, or bolts	8,976	5.0%	319	12.07%
1616	Jewelry	8,935	5.0%	348	10.48%
1354	Marbles	5,406	3.0%	198	17.44%
1682	Hair curlers, curling irons, clips, and hair pins	2,858	1.6%	133	15.99%
0428	Kitchen gadgets, not elsewhere classified	2,263	1.3%	87	18.16%
1729	Christmas decorations (nonelectric)	1,867	1.0%	75	21.60%
1711	Christmas tree lights	1,393	0.8%	52	17.19%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, November2010

From 2000 to 2009, staff found 4,185 NEISS cases involving ingestion of foreign objects and children ages four through five years old. Based on these 4,185 cases there were an estimated 106,158 emergency room-treated injuries from 2000 to 2009 involving a child between the ages of four and five years and the ingestion of a foreign object. Staff categorized the cases according to the product associated with the ingestion injury. Table 5 shows the seven product categories with the highest estimates. Only seven product categories are shown in Table 5 due to low, and therefore, unreportable estimates for all other product categories. Note that of the 4,185 cases analyzed, 131 cases had two associated products.

Table 5: Top Seven Products Swallowed by Children Four to Five Years Old, 2000–2009

Based on Number of Estimated Emergency Room-Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	60,187	56.7%	2,403	7.45%
5004	Toys, not elsewhere classified	9,470	8.9%	378	10.26%
1354	Marbles	6,111	5.8%	219	15.43%
1616	Jewelry	5,642	5.3%	226	11.47%
0884	Batteries	5,213	4.9%	228	17.51%
1819	Nuts, screws, tacks, or bolts	3,828	3.6%	173	13.17%
0428	Kitchen gadgets, not elsewhere classified	2,782	2.6%	84	19.67%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, November 2010

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

From 2000 to 2009, staff found 5,051 NEISS cases involving ingestion of foreign objects and individuals ages six through 18 years old. Based on these 5,051 cases there were an estimated 136,802 emergency room-treated injuries from 2000 to 2009 involving children between the ages of six and 18 years and the ingestion of a foreign object. Staff categorized the cases according to the product associated with the ingestion injury. Table 6 shows the 10 product categories with the highest estimates. Note that of the 5,051 cases analyzed, 320 cases had two associated products.

Table 6: Top 10 Products Swallowed by Individuals Six through 18 Years Old, 2000–2009

Based on Number of Estimated Emergency Room-Treated Injuries

Product Code	Product Description	Estimate	Percent of Total	Sample Size	C.V.
1686	Coins	47,871	35.0%	1,926	8.33%
1616	Jewelry	14,069	10.3%	473	9.91%
5004	Toys, not elsewhere classified	8,171	6.0%	303	9.48%
1819	Nuts, screws, tacks, or bolts	7,617	5.6%	257	10.48%
0884	Batteries	6,766	4.9%	246	13.19%
1354	Marbles	6,078	4.4%	224	11.27%
1685	Pens and pencils	5,165	3.8%	172	15.68%
1650	Desk supplies	4,902	3.6%	161	13.67%
1103	Self-contained openers[21]	4,595	3.4%	167	12.82%
1669	Pins and needles	3,531	2.6%	131	13.18%

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, November 2010

IV. Summary

By far, coins are 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 21-month- to 3-year-old age group (57.7 percent); and lowest is the 7- to 18-year-old age group (35.0 percent). The next four most commonly ingested product categories are toys, not elsewhere classified; jewelry; nails, screws, tacks, or bolts; and batteries. These four are always in the top five regardless of age category, except for the three- to four-year-old age category, where nuts and bolts rank sixth. The only other product category to make it into the top five in any age category is marbles, which is the third most commonly ingested product in the three- to four-year-old age category.

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

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

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 7: Emergency Room-Treated Jewelry Ingestions by Age Group, 2000–2009

Age Range	Estimate	Percent of Total	Sample Size	C.V.	95% Confidence Interval
0–20 months	9,454	24.8%	428	12.63%	7,113–11,795
21 months–3 years	8,935	23.5%	348	10.48%	7,100–10,770
4–5 years	5,642	14.8%	226	11.47%	4,374–6,910
6–18 years	14,069	36.9%	473	9.91%	11,337–16,801
Total	38,100	100.0%	1,475	8.98%	31,391–44,809

Source: National Electronic Injury Surveillance System
U.S. Consumer Product Safety Commission, November
Columns may not sum to totals due to rounding

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

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 Cadmium in Consumer Products, Especially Toy Metal Jewelry." 28 May 2010.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB D: Human Factors Analysis

T
A
B

D

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

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

Memorandum

Date: December 28, 2010

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

THROUGH: Erlinda Edwards, Acting Associate Executive Director
Directorate for Engineering Sciences
Robert B. Ochsman, Ph.D., Director, Division of Human Factors

FROM : Khalisa H. Phillips, Ph.D.
Psychologist, Directorate for Engineering Sciences,
Division of Human Factors

SUBJECT : Human Factors' Assessment of Cadmium in Children's Jewelry

Background

The Sierra Club, backed by several consumer and environmental protection groups, has petitioned the U.S. Consumer Product Safety Commission (CPSC) and the U.S. Environmental Protection Agency (EPA) to ban the use of cadmium in children's toy metal jewelry under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. § 1261–1278). This memorandum describes key design features that influence the age grading of jewelry items, as well as age differences in the appeal and use of children's jewelry items. Then the memorandum discusses two common risk-conferring behaviors that children participate in that can lead to cadmium exposure, namely, mouthing and swallowing.

The Scope of the Petition

Similar to the lead petition, the petitioners have singled out children's toy metal jewelry as the primary target of their efforts. CPSC Human Factors (ESHF) staff and the ASTM International (ASTM) F15.24 subcommittee on children's jewelry regard toy jewelry as a separate category from jewelry intended for normal wear. However, CPSC staff believes that the petitioners are interested in regulating children's jewelry worn while participating in multiple activities besides play. On page 2 of the petition letter of May 28, 2010, the petitioners define toy jewelry as "any item that serves a decorative but no or minimal functional purpose that is valued at less than $20 per item." For this reason, the term "children's jewelry" will be used to describe items used in play and normal use contexts.

Key Design Features of Children's Jewelry

When making an age determination, ESHF staff (Midgett, October 16, 2006) considers many design features of a jewelry item, including appearance, ease of use, marketing, and cost. However, these features are not weighted equally when assigning an age rating to a jewelry item. Visual characteristics of a jewelry item, such as coloring, extent of detail, and design theme, help

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

differentiate it from an item intended for adults. For instance, young children are more likely to be attracted to jewelry items that are bright, contain graphics, and have few details, while jewelry items containing stylized intricate patterns are more likely to appeal to adults. Ease of use, or the ability to put on and to take off a piece of jewelry, influence the age grading of a particular jewelry item. In general, stretchy items, or items with break-away clasps will receive a lower age rating than items with delicate parts that require intricate manipulation of small clasps. Marketing strategies, such as where and for how much jewelry items are sold, influence the age grading of an item. When an item is cheap and readily available in a place where toys are sold (e.g., a vending machine), it typically receives a lower age grade than other jewelry items.

The petitioners set $20 as a maximum price for jewelry items that they believe should be regulated. However, just because a jewelry item is expensive does not mean that it does not contain cadmium or other hazardous substances. On the converse, cheap jewelry items do not always contain toxic substances; nor are they designated necessarily for children. Human Factors staff knows of several jewelry items that cost upwards of $20 that were recalled because they contained a hazardous substance (Midgett, October 16, 2006). As a result, staff believes that cost should be only one of the features used to assign an age rating to a jewelry item.

Age Appropriateness of Children's Jewelry

A child's age is a major factor influencing interest in and use of jewelry items (Midgett, October 16, 2006). ESHF staff uses the CPSC staff's Age Determination Guidelines (Therell, et al., 2002) to evaluate the age appropriateness of jewelry items. According to the guidelines (p. 95–103), children first become interested in jewelry at approximately 18 months old, particularly colorful items that can be manipulated and removed easily. However, the ASTM Children's Jewelry Safety Standard (in development) suggests that children younger than three years old only wear jewelry under close parental monitoring due to potential choking and strangulation hazards. As their development progresses, children incorporate jewelry into pretend play episodes regularly. By age six, children are attracted to more realistic jewelry containing small parts and intricate design elements, and they can wear necklaces with small clasps safely.

The Consumer Product Safety Act of 1972, as amended by the Consumer Product Safety Improvement Act (CPSIA) of 2008, defines products intended for children 12 years of age or younger as children's products. However, children nine years and older often place a premium on authentic adult-like jewelry items with metallic components. Various risk-conferring behaviors also ultimately influence the age ratings assigned to particular jewelry items. Taken together, ESHF staff considers many factors when assigning an age grade to a jewelry item.

Behaviors Influencing Cadmium Exposure in Children

Children run the risk of becoming exposed to cadmium by mouthing repeatedly or ingesting accidentally small jewelry items. To understand these risks better, it is important to review the latest research on mouthing and ingestion behavior in children.

Mouthing Studies

While mouthing is a common activity across all age groups, mouthing is most likely to be observed in young children, especially those under three years old. Most mouthing studies report their findings as frequencies of contact (events/hour) or in duration of exposure (minutes) values. The length of oral contact with objects is very brief generally, averaging around one to two seconds (AuYueng, 2004). Typically, studies include mouthing of fingers; however, given the

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

present interest in risks associated with jewelry, this memorandum focuses on object mouthing behavior. Another reason to exclude mouthing of fingers is that children who mouth objects often are not the same children who mouth fingers and hands, making it difficult to extrapolate to mouthing events involving jewelry items (Xue et al., 2010). Most studies summarize their findings by the types of objects mouthed. Interestingly, the great majority of objects that are placed in the mouth are small objects not intended for mouthing (Smith, & Norris, 2003). Given the focus on jewelry, the findings described below will focus on the mouthing of non-toy objects.

Xue et al. (2010) recently published the first meta-analysis of object-mouthing behavior, performing in-depth analyses of data from seven separate studies. Across the studies, they found that frequency of mouthing objects is much more common in indoor as opposed to outdoor settings. The meta-analysis also found no gender differences in mouthing behavior between boys and girls.

Focusing on the indoor data, Xue et al. (2010) reported that children under age two engage in the highest frequency of object mouthing, with 15.25 events per hour (+/- 10.91 events); while children two to three years old engage in approximately 9.89 mouthing events per hour (+/- 7.04 events). Children between the ages of three to six years displayed fewer object mouthing events per hour at an average of 10.12 events (+/- 14.77 events). Children over six years displayed the lowest levels of object mouthing at an average of 1.12 events per hour (+/- 1.05 events). Similar to studies that included finger and hand mouthing events (Greene, 2001; Kiss, 2001; Smith, & Norris, 2003; Tulve, 2002), the meta-analysis found a decline in object mouthing events across development, particularly after a child's second birthday.

Researchers have found that object-mouthing activities consume a substantial amount of children's waking time each day. For instance, Norris and Smith (2002) conducted a study on behalf of the Department of Trade and Industry (DTI)[1], and found that children five years and younger spent approximately one hour per day mouthing objects. Juberg (2001) reported a slightly lower figure of 36 minutes of object mouthing per day. However, when the type of object is considered, time spent mouthing non-toy objects is a much lower two to 10 minutes per day (Kiss, 2001). These averages are also inflated by higher values reported for younger ages. For instance, Norris and Smith (2002) found that two-year-olds spend approximately 21 minutes; three-year-olds spend only 15 minutes per day; and four- to five-year-olds spend approximately 10 minutes per day on object-mouthing activities.

These studies provide an overview of the complexities involved in estimating object-mouthing behavior in children. Thus far, the focus has been on describing group-level differences in mouthing behavior for age and gender categories. However, it bears mentioning that children vary considerably in the extent of mouthing behavior, ranging from a low of two to more than 200 events (Kiss, 2001). Furthermore, the same children engaging in a high frequency of object mouthing also might be expected to ingest objects accidentally.

Ingestion Studies

Children ingest a variety of small items not intended for swallowing, including coins, buttons, marbles, and jewelry (Norris, & Smith, 2002). An analysis of data from the CPSC's National Electronic Injury Surveillance System (NEISS) database spanning the years 2000 to 2009,

[1] In 2007, the U.K. Department of Trade and Industry (DTI) was disbanded and subsumed by the Department for Business Innovation and Skills (DBIS).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

revealed that small jewelry items were some of the most commonly ingested items across all age groups of children (O'Brien, November 23, 2010). When these data were broken down by age group, jewelry remained the second most frequently ingested category of products. Once swallowed, items typically remain inside the digestive tract of a child's body for an average of two to five days before elimination is complete (Macgregor, & Ferguson, 1998). Therefore, these data demonstrate that a child's risk of cadmium exposure due to jewelry ingestions continues to present a hazard throughout childhood.

Conclusions

Children's interests in jewelry begin during the toddler years, and its appeal varies based on the design elements of a product. In order to differentiate jewelry intended for children versus adults, key design features, such as appearance, ease of use, marketing, and cost need to be considered. It is only in the preteen years that children begin to choose adult-like jewelry. Mouthing and ingestion of non-toy objects are frequent activities during infancy and childhood. Both behaviors increase the potential for chronic and acute exposure to cadmium in metal jewelry.

References

AuYeung, W., Canales, R.A., Beamer, P., Ferguson, A.C., & Leckie, J.O. (2004). Young children's mouthing behavior: An observational study via videotaping in a primarily outdoor residential setting. *Journal of Children's Health, 2(3-4)*, 271-295.

Greene, M.A. (2001). Mouthing times among young children from observational data. U.S. CPSC report. October.

Hatlelid, K.M. (2010). Children's Cadmium-Containing Metal Jewelry. U.S. CPSC report. October.

Juberg, D.R., Alfano, K., Coughlin, R.J., & Thompson, K.M. (2001). An observational study of object mouthing behavior by young children. *Pediatrics, 107(1),* 135-142.

Kiss, C. (2001). Mouthing observational study of children under 3 years of age. U.S. CPSC report. October.

Macgregor, D. & Ferguson, J. (1998). Foreign body ingestion in children: an audit of transit time. *Journal of Accident & Emergency Medicine, 15(6),* 371-3.

Midgett, J.D. (2006). Age determinations for children's jewelry. U.S. CPSC report. October.

Norris, B., & Smith, S. (2002). Executive Summary: Research into the mouthing behavior of children up to 5 years old. London. U.K. Department of Trade and Industry (DTI). Available at http://www.berr.gov.uk/files/file21800.pdf. Last accessed on 22 November, 2010.

O'Brien, C. (2010). Analysis of data on child ingestions, 2000 to 2009. U.S. CPSC report. November.

Smith, S.A. & Norris, B. (2003). Reducing the risks of choking hazards: Mouthing behavior of children aged 1 month to 5 years. *Injury Control and Safety Promotion, 10*, 3, 145-154.

Therrell, J. A., Brown, P. S., Sutterby, J. A., & Thornton, C. D. (2002). *Age determination guidelines: Relating children's ages to toy characteristics and play behavior* (T. P. Smith, Ed.).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Washington, DC: U.S. Consumer Product Safety Commission. Available at *http://www.cpsc.gov/BUSINFO/adg.pdf*

Tulve, N.S., Suggs, J.C., McCurdy, T., Cohen Hubal, E.A., & Moya, J. (2002). Frequency of mouthing behavior in young children. *Journal of Exposure Analysis and Environmental Epidemiology, 12*, 259-264.

Xue, J., Zartarian, V., Tulve, N., Moya, J., Freeman, N., AuYeung, W., & Beamer, P. (2010). A meta-analysis of children's object-to-mouth frequency data for estimating non-dietary ingestion exposure. *Journal of Exposure Science and Environmental Epidemiology, 20,* 536-545.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB E: Economic Information

TAB E

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

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

Memorandum

Date: January 6, 2011

TO : Kristina M. Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, Project Manager, Cadmium Petition

FROM : Charles L. Smith, Economist, Directorate for Economic Analysis
Gregory B. Rodgers, Ph.D., Associate Executive Director, Directorate for Economic Analysis

SUBJECT : A Market and Economic Evaluation of the Cadmium Petition

In a letter dated May 28, 2010, representatives of four organizations, the Empire State Consumer project, the Sierra Club, the Center for Environmental Health, and Rochesterians Against the Misuse of Pesticides, petitioned the U.S. Consumer Product Safety Commission (CPSC) to issue regulations specifying that any toy metal jewelry containing more than trace amounts of cadmium be declared a banned hazardous substance under the requirements of the Federal Hazardous Substances Act (CPSC, 2010a).[1] The petitioners asserted that toy metal jewelry (hereafter referred to as "children's jewelry") is "any item that serves a decorative but no or minimal functional purpose that is valued at less than $20 per item."

The purpose of this memo is to describe the markets for cadmium and children's jewelry, and to provide a preliminary discussion of the benefits and costs that might result from issuing a rule banning the use of cadmium in children's jewelry.

Cadmium Production

Cadmium is a soft, malleable, ductile, bluish-white metal that is refined as a byproduct of the zinc ore refining process. According to the U.S. Geological Survey (USGS), global primary production of cadmium was 19,600 metric tons in 2008 (Tolcin, 2009). A little more than half of primary cadmium is produced in Asia and the Pacific (primarily China, Japan, and the Republic of Korea), followed by Central Europe and Eurasia (19 percent), North America (19 percent), and Western Europe (6 percent). Cadmium is also produced from recycling operations for cadmium-containing products, mainly from the recycling of rechargeable nickel-cadmium batteries. Secondary cadmium production from recycling of cadmium-containing products accounts for about 20 percent of all cadmium metal production, and this is expected to grow in importance (Tolcin, 2009).

Major Markets for Cadmium

Based on information available from the International Cadmium Association and USGS, the major end-use for cadmium in recent years has been the production of nickel-cadmium (NiCd)

[1] The petition is available at http://www.cpsc.gov/library/foia/foia10/petition/cadmium.pdf.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

rechargeable batteries, which has accounted for more than 80 percent of total cadmium consumption in recent years. NiCd batteries are used commonly in portable power tools, portable telephones, and other consumer electronics because of their lower costs compared to other rechargeable battery technologies. Lithium-ion batteries and other battery chemistries have supplanted NiCd for use in cellular telephones and laptop computers because they provide higher energy densities and other desirable characteristics. Recent information indicates that lithium-ion and other technologies also are eroding NiCd's share in lower cost consumer appliances and electronics (Venteputte, 2008).

Cadmium used in the production of pigments is a distant second in the list of major end-uses, accounting for about 11 percent of cadmium consumption. According to the Cadmium Association, cadmium pigments can be produced in a range of shades of yellow, orange, red, and maroon. Reportedly, their greatest use is in plastics, but they also have significant application in ceramics, glasses, and specialist paints (such as artists' paints and coatings for high-temperature pipes). The USGS reports that cadmium pigments are used mainly to provide color to plastics that are processed at higher temperatures. Cadmium pigments are often preferred in these applications because they can withstand higher temperatures without degrading.

About six percent of cadmium is used for corrosion-resistant coatings for steel, aluminum, and some other nonferrous metal fasteners and moving parts, especially parts exposed to salty or alkaline environments. About 1.5 percent of cadmium is used as stabilizers in the production of polyvinylchloride (PVC). Cadmium-based stabilizers reportedly contain organic cadmium salts, such as cadmium laurate or cadmium stearate, which retard the degradation processes that can occur when PVC is exposed to heat and ultraviolet light.

Reportedly, the remaining minor uses account for about 0.5 percent of all cadmium use. These minor uses include cadmium telluride and cadmium sulfide in the production of photovoltaic cells for solar panels; semiconducting cadmium compounds used in a variety of electronic applications; and alloys used in white metal castings for jewelry and other products. This information indicates that cadmium's use in the production of jewelry, including children's jewelry, comprises a minuscule share of the total use of cadmium.

The Market for Fashion/Costume Jewelry, including Children's Jewelry

Costume jewelry (also called "fashion jewelry") is the least expensive jewelry of the three primary jewelry market segments (i.e., costume jewelry, fine jewelry, and bridge jewelry), with items retailing frequently for only a few dollars. Typically, costume jewelry consists of a base metal that is plated with copper, nickel, and often a finish coat of gold or silver. The base metal is usually a tin-based alloy. Rhinestones, plastics, and acrylics also are used in costume jewelry. Most costume jewelry is sold in specialty stores (*e.g.*, stores specializing in clothing or fashion accessories), mass-market retailers, and department stores (Accessories Magazine, 2010). Bridge jewelry is a middle segment between costume jewelry and fine jewelry. Bridge jewelry is more likely to use semi-precious stones instead of gemstones. Instead of tin-based or lead-based metals, bridge jewelry frequently uses metals such as copper, brass, or silver. These metals are often plated with a precious metal.

Retail sales of costume and bridge jewelry totaled $9.3 billion in 2009, according to a market report published by *Accessories Magazine* (2010). An estimated 736.6 million items of costume and bridge jewelry were sold, with an average unit retail price of $13. Most of these sales probably are costume jewelry. According to the consumer sales tracking data that the report was

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

based upon, 55 percent of the total value and 91 percent of total estimated unit sales of costume/bridge jewelry in 2009 were items that sold for under $25. If the items sold for less than $25 are assumed to be costume jewelry, about 670 million costume jewelry items with a total retail value of $5.1 billion were purchased by U.S. consumers in 2009.

Costume jewelry is purchased and worn by people of all ages. Knowledgeable industry officials estimate that jewelry intended for children age 12 years and younger comprises about five percent of the total value of fashion jewelry sales.[2] On this basis, fashion/costume jewelry purchased for children could have an annual retail value of about $250 million. The total number of items purchased for children probably would exceed five percent of units because these are more likely to be less expensive items. Perhaps 70 million items of children's jewelry are sold annually, if children's jewelry is assumed to account for 10 percent of fashion/costume jewelry unit sales.

The Use of Cadmium in Fashion/Costume Jewelry

When cadmium is used in the production of jewelry, it reportedly is used primarily as a minor component of the base metal alloy for jewelry pieces that are cast in rubber molds.[3] Cadmium is said to be useful particularly in the production of jewelry with filigree styles that require the molten alloy to fill small cavities in intricate molds.[4] When cadmium is included in alloys used in the production of costume jewelry, it lowers the melting point of the alloy and allows it to flow into casting molds more readily. The owner of a firm that supplies metal to fashion jewelry and accessories manufacturers reported that these alloys are between 0.5 percent and 4.0 percent cadmium, with cadmium content of 1.5 percent the most common.[5] He estimated that cadmium-containing alloys (i.e., those containing 0.5 percent to 4.0 percent cadmium) once comprised 60 percent to 70 percent of alloys sold, but that currently, they comprise less than 15 percent. This metal supplier did not know if cadmium-containing alloys were still being used in the production of fashion jewelry because they also are used to make novelties and figurines. A review of alloys marketed by other metal suppliers for jewelry casting indicated that cadmium is listed rarely as a component, and when it is listed, the metal usually comprises three percent or less of the alloys, by weight.[6] All of the cadmium-containing alloys listed also had lead as a component. The metal supplier also said that, to his knowledge, U.S. metal suppliers to the fashion jewelry industry have never added cadmium to lead-free casting metal.[7]

---

[2] Brent Cleaveland, Executive Director of the Fashion Jewelry and Accessories Trade Association (FJATA), comments made in an email communication with Charles Smith, Directorate for Economic Analysis, CPSC, November 23, 2010.

[3] While cadmium reportedly is used primarily as a minor component in base metal alloys, CPSC staff has obtained for testing some items of children's jewelry with high levels of cadmium, including some with cadmium content of more than 90 percent. As described below, these items were obtained for testing after being captured by surveillance at U.S. ports and from U.S. retailers, who suspected that the jewelry items contained cadmium.

[4] Brent Cleaveland, Executive Director of the Fashion Jewelry and Accessories Trade Association (FJATA), comments made during a telephone conversation with Charles Smith, Directorate for Economic Analysis, CPSC, November 19, 2010.

[5] Steven Kaplan, Hallmark Metals, email correspondence with Charles Smith, Directorate for Economic Analysis, CPSC, December 20, 2010.

[6] Based on a review of online catalogs of jewelry alloys marketed by Alchemy Castings, Inc. (http://www.alchemycastings.com/lead-products/jewelry.htm), and Hirsch Metals (http://hirschmetals.com/buy/jewelry-pewter-alloys).

[7] Steven Kaplan, *op.cit.*

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Alternatives to cadmium-containing alloys reportedly are available to fashion jewelry manufacturers that want to produce jewelry items with filigree. Alloys that are mainly tin (92 percent to 98 percent) can be formulated with bismuth and silver to produce filigree styles. The metal supplier we contacted noted that these alloys require different materials for molds, additional clean-up work for castings, and 15 percent to 18 percent higher alloy costs than cadmium-containing alloys.[8]

Domestic Production of Costume/Fashion Jewelry

According to the 2007 Census of Manufactures, 551 U.S. establishments were engaged primarily in the production of costume jewelry and novelty manufacturing (NAICS Code 339914). These establishments had a total value of shipments of about $729 million in 2007 (Census Bureau, 2009). Manufacturers located in Rhode Island, the leading area traditionally for the domestic jewelry industry, accounted for 107 of the establishments (19 percent) and $285 million in value of shipments (39 percent) (Census Bureau, 2010). In recent years, the production of fashion/costume jewelry (including children's jewelry) has shifted largely to foreign sources.

Imports of Fashion/Costume Jewelry

Table 1 (at the end of this report) presents import data for "Costume jewelry and novelty manufacturing" (NAICS Code 339914) from the U.S. International Trade Commission (ITC) (ITC, 2010). As this table shows, China is far and away the leading source of imported costume jewelry, accounting for 75 percent of the total value of imports in 2009. Although unit data for costume jewelry are not available, China likely holds an even greater share of the total number of imported costume jewelry items.

Import data for jewelry items that are more likely to include jewelry intended for children is available by harmonized tariff system (HTS) codes (ITC, 2010). Imports of products in several of the more relevant jewelry HTS codes are shown in Table 2. Table 3 shows the percentage of imports for each HTS jewelry product code that is from China and Hong Kong. These data reaffirm the importance of China as a source of inexpensive jewelry for the U.S. market.

Industry Policies Regarding Cadmium in Children's Jewelry

According to the Fashion Jewelry and Accessories Trade Association (which represents more than 225 U.S.-based manufacturers, suppliers, and retailers of costume jewelry and accessories), major manufacturers and retailers have taken steps in 2010 to further curtail the limited use of cadmium in costume jewelry alloys.[9] According to one jewelry manufacturer/importer contacted by the Directorate for Economic Analysis (EC) staff, other materials have been substituted for cadmium. This firm requires Chinese contract factories to perform testing to verify that cadmium metal content is no more than 10 parts per million.[10] The firm reportedly has broadened this restriction to apply to its adult costume jewelry. A major retailer of costume jewelry, Claire's Stores, Inc., announced on May 10, 2010, that it was requiring all of its suppliers of children's jewelry to test for the presence of cadmium (in addition to lead and nickel

---

[8] *Ibid.*

[9] Brent Cleaveland, *op.cit.*

[10] Keith Barber, Rainbow Sales, Inc. Telephone conversation with Charles Smith, Directorate for Economic Analysis, CPSC, December 9, 2010.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

content).[11] A Claire's corporate attorney advised EC staff that the company's vendors are expected to limit total cadmium content to no more than 75 parts per million, and that this restriction will apply to children's and adults' jewelry.[12] Other major retailers of children's jewelry, including Walmart,[13] Toys 'R' Us,[14] and Disney[15] also announced in 2010 that they are requiring suppliers to test for the presence of cadmium in children's jewelry and other products.

State Laws Related to Cadmium in Children's Jewelry

We are aware of four states that have adopted laws regarding the use of cadmium in jewelry intended for children: Minnesota, Illinois, California, and Connecticut. The laws are scheduled to go into effect between January 1, 2011, and July 1, 2014. The laws differ in terms of cadmium content allowed, methods of measurement of cadmium in jewelry, and the ages of children who will be affected.

The known state laws are summarized as follows:

Minnesota: The Minnesota law for manufacturers and wholesalers became effective on January 1, 2011, and for retailers, it will become effective on March 1, 2011; it will cover jewelry intended mainly for children ages six and younger. The law limits any part or surface coating or accessible substrate that exceeds 75 ppm, as determined through solubility testing for heavy metals defined in ASTM F 963 (Toy Safety Standard).[16]

Illinois: The Illinois law will apply to products manufactured after July 1, 2011, and will cover jewelry intended mainly for children under age 12. The law limits any part or surface coating or accessible substrate that exceeds 75 ppm, as determined through solubility testing for heavy metals defined in ASTM F 963 (Toy Safety Standard).[17]

California: The California law will become effective on January 1, 2012, and requires that jewelry intended for children ages six and younger shall not have more than 0.03 percent (300 ppm) cadmium by weight. Manufacturers and suppliers are required to provide certification that their jewelry does not contain cadmium in violation of the law.[18]

---

[11] Claire's Stores, Inc., "Claire's Statement Regarding Bracelet Recall," May 10, 2010, retrieved December 14, 2010, from http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NDU1NTJ8Q2hpbGRJRD0tMXxUeXBlPTM=&t=1.

[12] Steve Sernett, attorney for Claire's Stores, Inc., Telephone conversation with Charles Smith, Directorate for Economic Analysis, CPSC, December 15, 2010.

[13] Walmart Stores, Inc., "Walmart Statement on Media Reports Regarding Cadmium in Children's Products," May 20, 2010, retrieved December 14, 2010, from http://walmartstores.com/pressroom/news/9912.aspx.

[14] Toys "R" Us, Inc., "Frequently Asked Questions," retrieved December 14, 2010, from http://www.toysrusinc.com/safety/faq/.

[15] Associated Press, "Walmart Pendants Recalled as Disney Bans Cadmium," retrieved December 15, 2010, from http://abcnews.go.com/Health/wireStory?id=9698836.

[16] Minnesota Office of the Revisor of Statutes, "cadmium in Children's Jewelry," retrieved on December 16, 2010, from https://www.revisor.mn.gov/statutes/?id=325E.3891.

[17] State of Illinois, "Cadmium-Safe Kids Act," retrieved on December 16, 2010, from http://www.ilga.gov/legislation/96/HB/PDF/09600HB5040lv.pdf.

[18] California Department of Toxic Substances Control, "Cadmium in Children's Jewelry," retrieved December 16, 2010, from http://www.dtsc.ca.gov/PollutionPrevention/ToxicsInProducts/Cadmium.cfm.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Connecticut: Effective July 1, 2014, jewelry intended for children 12 years old and younger shall not have more than 0.0075 percent (75 ppm) cadmium by weight.[19]

In the absence of a mandatory rule on cadmium in children's jewelry, most major retailers of jewelry intended for children probably would require manufacturers and suppliers of jewelry to comply with the most stringent state laws based on cadmium solubility and cadmium content, according to the Executive Director of the Fashion Jewelry and Accessories Trade Association.[20]

Voluntary Standard Activity

Currently, a new voluntary standard is under development by the ASTM F-15.24 Subcommittee on Children's Jewelry that includes participation of CPSC technical staff. This standard may include limits for migration of cadmium from jewelry items, as well as a content level that could be used for screening products.

Health Effects of Cadmium[21]

The Directorate for Health Sciences (HS) has concluded that data concerning the toxicity of cadmium is sufficient for cadmium to be considered toxic under the Federal Hazardous Substances Act (FHSA). HS staff has derived acceptable daily intake (ADI) levels for chronic and acute exposure scenarios. Based on the estimated ADI levels, staff has proposed, for children ages two to six years, a maximum exposure level of 1.8 μg/day (i.e., micrograms per day) for chronic exposure, and a maximum exposure level of 200 μg/day for acute exposure.

According to the HS analysis, cadmium is absorbed poorly into the body following ingestion. However, the cadmium that is absorbed accumulates primarily in the liver and kidneys with a long half-life that is measured in decades. While cadmium may affect numerous organ systems and cells within the body, its principle effects are on kidneys and bone, with kidneys being the most sensitive endpoint. Cadmium exposure is associated with increased excretion of biomarkers for kidney dysfunction, and can contribute to chronic renal tubular disease. Cadmium also has been associated with osteoporosis and osteomalacia in epidemiological studies.

While cadmium tends to accumulate in the liver, the liver does not appear to be as sensitive as the kidneys to cadmium effects. HS found two cadmium-related deaths in humans that involved liver injury. However, these deaths were suicides involving massive ingestions of cadmium compounds that resulted in widespread organ destruction.[22] Studies of lower doses in humans have not shown significant liver-specific effects.

Cadmium exposure through inhalation in workers has been associated with lung cancer, but there is insufficient evidence in humans or experimental animal studies to determine whether cadmium

[19] http://www.cga.ct.gov/2010/ACT/PA/2010PA-00113-R00HB-05314-PA.htm.

[20] Brent Cleaveland, Executive Director of the Fashion Jewelry and Accessories Trade Association (FJATA), comments made in an email to Charles Smith, Directorate for Economic Analysis, CPSC, December 8, 2010.

[21] This discussion of health effects, and the discussion of the possible benefits associated with reducing cadmium intake, are drawn from Hatlelid (2010) and Williams (2010).

[22] One of the suicides resulted from the ingestion of cadmium chloride crystals from a bottle (Buckler, Smith, and Rees, 1986); the second resulted from the ingestion of cadmium iodide dissolved in water (Wisniewska-Knypl, Jablonska, and Myslak, 1971).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

is carcinogenic from oral exposure. Studies of populations in areas with known cadmium sources have not found significant associations with cancer.

The possible impacts of cadmium ingestion on children were of special concern in the HS analysis because of the potential health effects of cadmium exposure in children at the early stages of development. However, unlike lead, which has been shown to result in significant impacts on the physical and cognitive development of children, data do not exist currently that clearly show adverse health effects specifically associated with cadmium exposures in early childhood.

The Benefits of Reducing Cadmium Ingestions Involving Children's Jewelry

The benefits associated with reducing cadmium intake from children's jewelry are the reductions in injury and disease that would result. Such benefits would be derived from reducing chronic exposures involving mouthing behaviors or acute exposures that might result from swallowing jewelry items containing a high level of extractable cadmium.

The benefits of reducing cadmium from current levels in children's jewelry, however, are likely to be difficult to quantify and may be small. There are several reasons for this conclusion, as described below.

Chronic Exposures

While HS has proposed a maximum allowable chronic exposure level of about 1.8 µg/day for children ages two to six years,[23] dietary cadmium intake from foods and liquids is the major source of cadmium exposure and is likely to exceed the maximum allowable chronic exposure level proposed by HS.[24] Reducing the cadmium intake from a single source, such as children's jewelry, would result in some reduction in the hazards associated with cadmium exposure. However, even if a regulatory action were to reduce the cadmium intake from the mouthing of children's jewelry, the effect of the reduction would be limited: children's dietary intake would still exceed the chronic exposure level proposed by HS, and could exceed it substantially.

Additionally, while absorbed cadmium may contribute to some level of kidney impairment and osteoporosis even at low levels, the effects of chronic absorption usually are observed in older adults who have absorbed cadmium from dietary and other sources throughout their lives. Therefore, (1) because the effects of cadmium ingestion are cumulative over a lifetime, and (2) because the ingestion of cadmium from dietary sources constitutes the major source of cadmium intake for most children, reducing cadmium intake associated with the mouthing behavior of young children is likely to have a small and probably not quantifiable impact on the injuries and disease that may result from chronic cadmium ingestion much later in life. Efforts to attribute chronic disease to the mouthing of children's jewelry with cadmium would be further confounded by the many other environmental factors associated with these chronic conditions.

---

[23] Based on Suwazono (2006), a study of 820 adult women and modeling techniques described in ATSDR (2008), HS staff calculated a 0.33 µg/kg/day *no observed adverse effect level* (NOAEL) for the population described in Suwazono (2006). The 0.33 µg/kg/day was then divided by an uncertainty factor of three to account for general human variability. The result was an estimated ADI of about 0.1µg/kg/day. Thus, for a two- to six-year-old child weighing 18.2 kg, the ADI would amount to about 1.8 µg/day (0.1 µg/kg/day x 18.2 kg).

[24] One study (Choudhury et al., 2001) suggests that the dietary intake may be several times the allowable chronic exposure level of 1.8 µg/day for children ages two to six years.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Toxicological data gaps also contribute to the difficulties of quantifying the benefits associated with reducing chronic cadmium intake. While the staff risk assessment is useful in determining acceptable cadmium intake levels (i.e., levels expected to do no harm), it is less useful for evaluating the impact of reductions in the level of cadmium intake on risk. The goal of the risk assessment is to determine an acceptable daily intake (ADI) below which appreciable adverse health effects can be avoided.[25] However, due to data gaps, there are frequently uncertainties in the risk assessment process. The scientific community generally addresses these uncertainties through the application of "uncertainty" factors. As described in the HS analysis, uncertainty factors may be applied for a number of reasons (Hatlelid, 2010; Williams, 2010; CPSC, 1992). In the case of the chronic intake of cadmium through ingestion, the HS staff applied an uncertainty factor of three to account for general human variability. That is, the HS staff identified a level of exposure considered to be the "no observed adverse effect level" for a particular population group,[26] and divided it by three to ensure that it would be an acceptable intake level for other population groups, including children. If we consider only the "no observed adverse effect level," the maximum allowable chronic exposure level for cadmium ingestion would have been about 5.4 μg/day. The estimated proposed maximum chronic exposure of 1.8 μg/day (i.e., 5.4 μg/day ÷ 3) for children ages two through six years represents a level below which harm is unlikely, even given the uncertainties. Consequently, given full information on the chronic toxic effects of cadmium, the ADI might be higher than 1.8 μg/day, but how much higher is unknown.

Acute Exposures

HS has also proposed a maximum allowable acute exposure level of 200 μg/day for children ages two to six years. Aside from the two suicides involving massive doses of cadmium compounds described earlier, HS staff found a single case of acute cadmium exposure in humans from contaminated beverages that resulted in relatively short-term headache, nausea, vomiting, abdominal pain, and diarrhea (Nordberg, Slorach, and Stenstrom, 1973). Because of the inadequate documentation in this case, however, HS staff found the study unacceptable for further quantitative analysis or derivation of an exposure limit.

Consequently, HS staff based its acute exposure limit on an animal study that found a *no observed adverse effect level* (NOAEL) of 1100 μg/kg/day (Borzelleca, Clarke, and Condie, 1989). Because this limit was based on an animal study, HS applied an uncertainty factor of 100 (i.e., a factor of 10 because the study was based on animals instead of humans and another factor of 10 to account for sensitive individuals within human populations). Thus, the maximum allowable acute human exposure level was estimated to be 11 μg/kg/day (i.e., 1100 μg/kg/day ÷ 100). Given an average weight of 18.2 kg for children ages two to six years, the maximum acute exposure was estimated at about 200 μg/day (i.e., 11 μg/kg/day x 18.2 kg). The 200 μg/day limit represents an acceptable level of intake below which adverse acute health effects are not expected, even given the uncertainties. If full information on the acute toxic effects of cadmium were available, the estimated acute maximum intake level might have been higher than 200 μg/day, but how much higher is unknown.

[25] According to CPSC (1992, p. 46655), the ADI represents an exposure which leads to or is below an "acceptable risk."

[26] In this case, a study of adult women, described in Suwazono *et al.* (2006).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

An acute child exposure involving children's jewelry would most likely result from swallowing a jewelry item containing cadmium, as opposed to simply mouthing it. The cadmium absorbed by the child who swallowed the item would then depend upon the amount of cadmium that would be leached from the item while in the child's digestive system.[27]

CPSC's Hazard Analysis staff analyzed information on child ingestions from the CPSC's National Electronic Injury Surveillance System (NEISS), a stratified national probability sample of hospital emergency departments (ED) in the United States (Schroeder and Ault, 2001). This analysis presented the data in age ranges defined by incident quartiles (O'Brien, 2010). To focus on children through age six years (i.e., the ages included in the CPSC Health Sciences assessment), and children ages seven through eight years (i.e., an additional two years of children who may also engage in significant mouthing behaviors), Hazard Analysis staff provided additional information on additional age ranges.[28] Based on these estimates, there were (during 2000–2009) an annual average of 2,560 ED-treated jewelry ingestions involving children under age seven years, and an annual average of about 250 ED injuries involving children ages seven through eight years. These estimates do not include medically attended injuries treated outside of hospital EDs (such as in doctors' offices or walk-in clinics), which might double the estimate. On the other hand, they may include many adult jewelry items that would not be affected by a rule for children's jewelry.

We do not know the proportion of children's jewelry that has extractable cadmium of 200 μg/day. If, for example, it amounted to about five percent, there might be about 128 potentially toxic ED injuries involving children under age seven years annually (i.e., 2,560 x 0.05), and another 13 involving children ages seven through eight years (i.e., 250 x 0.05). Of course, the available medical and scientific literature provides no empirical support for these (or any other) estimates. As noted in the acute case mentioned earlier, cadmium ingestion may cause gastrointestinal symptoms. Therefore, it is possible that acute cadmium ingestions may present with symptoms in humans that could be mistaken for other short-term illnesses. Nevertheless, the general lack of documented cases involving jewelry (or other types of consumer products) suggests that a widespread hazard associated with acute exposures involving the ingestion of cadmium-containing objects by children does not exist. Consequently, while the expected benefits associated with preventing acute cadmium ingestions are difficult to estimate, they are probably small.

The Cost of Reducing Cadmium Content in Children's Products

There would be two primary costs associated with reducing the cadmium content in children's jewelry by rule. The first would be the cost of substituting another base metal for the cadmium in children's jewelry. The second would be the costs associated with the testing requirements that would be needed to ensure that children's jewelry products are compliant.

While the amount of cadmium included in children's jewelry has not been fully quantified, it is believed to be small and, based on our earlier discussion of the market for children's jewelry, probably has been declining. Nevertheless, the CPSC Directorate for Laboratory Sciences (LS),

[27] The amount of cadmium leached appears be affected by the alloy in which the cadmium is found. According to CPSC laboratory testing, the presence of zinc reduces cadmium migration. However, the addition of co-alloyed elements such as silver and copper seems to mitigate zinc's effect. (Elder, 2010).

[28] Based on special estimates provided by Craig O'Brien for age categories that differ somewhat from the age categories provided in O'Brien (2010).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Division of Chemistry (LSC) staff has tested a number of children's jewelry samples for cadmium content. These tests have found 84 children's jewelry items that contained varying amounts of cadmium, including some with a cadmium content of more than 90 percent. However, the jewelry samples were not collected randomly. They were obtained because they were believed to contain cadmium. Many were obtained after surveillance at U.S. ports. Others originated from retailers who suspected the jewelry items contained cadmium.[29]

To the extent that cadmium is used in children's jewelry, replacing it with another light-colored base metal alloy that can be casted, polished, and have good flow characteristics would result in some added expense. As noted earlier, alloys that are mainly tin (92 percent to 98 percent) can be formulated with bismuth and silver to produce filigree styles. However, these alloys may require different materials for molds, additional clean-up work associated with the castings, and 15 percent to 18 percent higher alloy costs than cadmium-containing alloys.[30]

Regulating cadmium in children's jewelry would also trigger third-party testing requirements under section 102 of the Consumer Product Safety Improvement Act (CPSIA) (CPSC, 2010b)[31] to ensure that the cadmium in the jewelry cannot be leached out or, alternatively, is below some threshold content level. Staff evaluates possible exposures to cadmium by measuring the leaching of the cadmium from the jewelry item using a saline solution to mimic the possible chronic effects of mouthing and a dilute hydrochloric acid solution to simulate the acute gastric effects of swallowing. The staff's standard laboratory procedure for simulating the effects of mouthing is to immerse an item in the saline solution for a period of six hours; the procedure for simulating an acute ingestion exposure is to immerse an item in the dilute hydrochloric acid solution for 24 hours (Elder, 2010).

The cost of conducting a leaching test for cadmium would probably be similar to the costs of conducting the third-party lead content tests: about $50 to $100 per component tested in the United States (CPSC, 2010b). Sample jewelry items would have to be prepared and left in a saline or acid solution for the requisite time. The resulting solutions then would be evaluated for presence of metals using an analytical technique, such as inductive coupled plasma spectroscopy. However, because two independent leaching tests would be needed (i.e., one for the six hour saline test simulating mouthing and one for the 24 hour acid test simulating swallowing), two components would be needed for each test and the total costs could amount to about $100 to $200 per jewelry component. Consequently, if cadmium tests were required as frequently as lead tests under the CPSIA, the testing costs associated with a mandatory standard could be substantial. However, these costs might be reduced if the leaching test could be limited to a single test on each jewelry component, rather than two tests. This approach might be feasible if, for example, staff could make the determination that when an item passes the acid test it will also always pass the saline solution test.

Testing costs might be further reduced if staff determined that a cadmium content under some specified limit (measured as a percent or parts per million) would not pose an absorption hazard. If this were the case, manufacturers might test for cadmium content at the same time that they

[29] This information was based on unpublished testing results provided by staff from the CPSC's Directorate for Laboratory Sciences (LS), Division of Chemistry (LSC).

[30] Steven Kaplan, *op. cit.*

[31] The CPSIA legislation is available at: http://www.cpsc.gov/about/cpsia/legislation.html

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

test for lead content. Overall testing costs would rise, but because manufacturers might be able to piggyback the cadmium tests on top of the lead content tests (i.e., because they would not have to conduct two independent tests, one for lead and one for cadmium), the incremental costs of testing for cadmium might be reduced. While this approach would be likely to reduce testing costs, CPSC staff has not determined yet the feasibility of developing a safe-harbor cadmium content limit, or considered what the limit would be. Additionally, if this approach is feasible, the testing cost savings associated with a safe-harbor cadmium content limit would depend, to some extent, on the limit chosen.

Conclusions

Staff has determined that cadmium is toxic under the requirements of the FHSA and that ingestion can result in significant health effects. Children's jewelry represents a possible source of cadmium exposure and is the subject of the petition before the Commission.

Sales of children's jewelry may amount to about 70 million pieces annually, with a retail value of about $250 million. The amount of leachable cadmium in children's jewelry is not documented well but is believed to be small and, based on recent market trends, is probably declining. However, to the extent that it is present, it could result in chronic exposures by means of children's mouthing behaviors and acute exposures by means of swallowing the jewelry items.

Cadmium accumulates primarily in the liver and kidneys and has a long half-life in the body. It can affect numerous organ systems and cells within the body, but its principle effects are on kidneys and bone, with kidneys being the most sensitive. Unlike lead, data do not exist currently to clearly show adverse health effects associated with cadmium exposures in early childhood.

Given that most cadmium intake is dietary, and because the effects of cadmium ingestions are cumulative over an individual's lifetime, the incremental benefits of reducing cadmium chronic intake from the mouthing of children's jewelry are difficult to quantify and may be small. While acute cadmium poisonings may result from children swallowing jewelry items, no such poisonings have been identified in the medical or scientific literature, and their frequency is unknown.

The costs of testing for cadmium content in children's jewelry could be substantial under the third-party testing requirements of section 102 of the CPSIA, especially if a regulatory action required tests to determine the cadmium content's leachability. These testing costs might be reduced, however, if an achievable cadmium content limit could be determined that would provide a safe harbor below which conforming products could be assumed not to pose an absorption hazard. If such a limit could be determined, testing costs might be reduced by piggybacking cadmium content tests with lead content tests that manufacturers are required to conduct already by Section 102 of the CPSIA.

A more detailed evaluation of the benefits of possible regulatory actions would require additional information on cadmium exposure from children's jewelry (i.e., the proportion containing cadmium and the cadmium content). This information would allow staff to make more detailed estimates of how much cadmium is likely to be ingested through mouthing and swallowing behaviors. Such exposure information might be obtained by collecting a representative sample of children's jewelry from the marketplace and testing it for cadmium leachability by LSC. Finally, more information on how the requisite testing would be conducted would be needed to provide better estimates of the costs of regulating cadmium content in children's jewelry.

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

References

Accessories Magazine. *Fashion/costume & bridge jewelry.* New York: Accessories Magazine; October 2010. Retrieved from: http://www.accessoriesmagazine.com/uploads/reports/6_pdf.pdf

ATSDR. *Draft toxicological profile for cadmium.* Atlanta: GA: Agency for Toxic Substances and Disease Registry; September 2008. Available at http://www.atsdr.cdc.gov/toxprofiles/tp5.pdf

Borzelleca JF, Clarke EC, Condie LW. Short-term toxicity (1 and 10 days) of cadmium chloride in male and female rats: Gavage and drinking water. *Int J Toxicol.* 1989;8:377-404.

Buckler HM, Smith WDF, Rees WDW. Self poisoning with oral cadmium chloride. *Br Med J.* 1986;292:1559-1560.

Census Bureau. *Manufacturing: Geographic area series: Industry statistics for the states, metropolitan and micropolitan statistical areas, counties, and places: 2007*, 2007 Economic Census, U.S. Department of Commerce, April 27, 2010. Retrieved from http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0731A1&-NAICS2007=339914&-_lang=en

Census Bureau. *Manufacturing: Industry series: Detailed satistics by industry for the United States: 2007*, 2007 Economic Census, U.S. Department of Commerce, October 30, 2009. Retrieved from http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC073111&-NAICS2007=339914&-ib_type=NAICS2007&-industrySel=339914&-geo_id=&-_industry=339914&-_lang=en&-fds_name=EC0700A1

Consumer Product Safety Commission. Labeling requirements for art materials presenting chronic hazards; guidelines for determining chronic toxicity of products subject to the FHSA; supplementary definition of "Toxic" under the Federal Hazardous Substances Act. *Fed Regist.* 1992;57(197):46626-46674. Retrieved from: http://www.cpsc.gov/BUSINFO/chronic.pdf

Consumer Product Safety Commission. Petition requesting regulations restricting cadmium in children's products. *Fed Regist.* 2010a;75(160):51246-51247. Retrieved from: http://www.cpsc.gov/businfo/frnotices/fr10/cadpet.pdf

Consumer Product Safety Commission. Testing and labeling pertaining to product certification. *Fed Regist.* 2010b;75(97):28336-28366. Retrieved from: http://www.cpsc.gov/businfo/frnotices/fr10/testing.pdf

Choudhury H, Harvey T, Thayer WC, Lockwood TF, Stiteler WM, Goodrum PE, Hasset JM, Diamond GL. Urinary cadmium elimination as a biomarker of exposure for evaluating a cadmium dietary exposure—biokinetics model. *J Toxicol Environ Health, Part A.* 2001;63:321-350.

Elder IA. *Assessment of cadmium migration from materials.* Bethesda, MD: US Consumer Product Safety Commission; 3 June 2010. Retrieved from: http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf

Hatlelid KM. *Children's cadmium-containing metal jewelry.* Bethesda, MD: US Consumer Product Safety Commission; 14 October 2010. Retrieved from: http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

International Trade Commission US. Washington, DC: Author. October 2010. Import data retrieved via online search of http://dataweb.usitc.gov/

Nordberg G, Slorach S, Stenstrom T. Cadmium poisoning caused by a cooled-soft-drink machine. *Lakartidningen* 1973;70(7):601-604.

O'Brien C. *Analysis of data on child ingestions*. Bethesda, MD: US Consumer Product Safety Commission; November 2010.

Suwazono Y, Sand S, Vahter M, Filipsson AF, Skerfving S, Lidfeldt J, Akesson A. Benchmark dose for cadmium-induced renal effects in humans. *Environ Health Perspect*. July 2006;114(7):1072-1076.

Schroeder T, Ault K. *The NEISS sample (design and implementation)*. Bethesda, MD: U.S. Consumer Product Safety Commission, 2001. Retrieved from http://www.cpsc.gov/neiss/2001d011-6b6.pdf

Tolcin AC. *2008 minerals yearbook: Cadmium [advance release]*. U.S. Geological Survey, Washington, DC: U.S. Department of the Interior; October 2009. Retrieved from: http://minerals.usgs.gov/minerals/pubs/commodity/cadmium/myb1-2008-cadmi.pdf

Venteputte K. *Li-Ion rechargeable battery materials*. Brussels: Umicore; 2008. Retrieved from: http://www.investorrelations.umicore.com/en/newsPublications/presentations/2008/CMD2008/LiIonTech_CMD.pdf

Williams DJ. *Toxicity review for cadmium*. Bethesda, MD: US Consumer Product Safety Commission; 14 October 2010. Available at http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf

Wisniewska-Knypl JM, Jablonska J, Myslak Z. Binding Cadmium on metallothionein in man: An analysis of a fatal poisoning by cadmium iodide. *Arch Toxikol*. 1971;28:46-55.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 1. Costume Jewelry (NAICS 339914)
U.S. Imports for Consumption

Country	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
	In 1,000,000 Dollars (c.i.f.)									
China (incl. Hong Kong)	**384**	**451**	**581**	**669**	**824**	**1060**	**1163**	**1251**	**1262**	**1260**
% of Total Imports	***46%***	***51%***	***59%***	***64%***	***67%***	***67%***	***67%***	***70%***	***71%***	***75%***
Austria	81	88	67	74	96	133	161	151	133	86
Thailand	20	23	28	27	26	35	59	70	52	51
Taiwan	29	28	19	20	30	38	41	38	41	45
India	35	25	39	35	29	65	56	42	46	42
Korea	145	120	93	71	60	52	41	35	32	33
Italy	9	11	16	17	17	20	20	30	34	27
Czech Republic	36	36	32	34	34	40	38	28	24	17
Japan	14	9	9	11	16	10	11	10	14	17
France	7	8	7	10	12	13	15	20	21	14
All Other:	75	80	85	83	81	117	121	125	117	95
Total	**835**	**879**	**977**	**1,050**	**1,224**	**1,584**	**1,725**	**1,799**	**1,777**	**1,689**

Source: Trade data from the U.S. International Trade Commission.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 2. Costume Jewelry Imports – More Relevant Harmonized Tariff System Codes

HTS Number / Product Description	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
	In 1,000 Dollars (c.i.f.)									
7117199000 OTHER IMITATION JEWELRY OF BASE METAL	396,539	444,894	512,787	538,297	614,185	766,945	840,735	887,780	960,207	938,480
7113205000 JEWELRY NESOI - BASE METAL CLAD WITH PRECIOUS METAL	12,058	13,949	32,942	22,548	15,686	14,187	12,839	20,333	27,914	19,968
7117191500 OTHER BASE METAL ROPE, CURB, CABLE, CHAIN, ETC., NOT MORE THAN 33 CENTS PER METER	2,795	3,300	2,467	4,021	3,100	3,213	4,735	4,659	4,328	4,818
7113202900 NECKLACES AND NECK CHAINS NESOI - BASE METAL CLAD WITH GOLD	1,201	1,226	1,265	2,095	2,841	1,356	1,754	2,734	1,910	3,968
7117192000 ROPE CBL CHAIN ETC. BS MTL INC PREC MTL PLTD SUITBL F MFR ARTS THIS SUBPT VAL OVER $.33 PER METER	5,887	4,116	4,903	4,117	5,259	7,007	7,467	5,201	4,760	3,252
7117196000 OTHER TOY JEWELRY OF BASE METAL, NOT > 8 CENTS EACH	3,160	4,877	4,107	4,977	2,268	3,460	6,120	4,813	4,593	3,204
7113202500 MIXED LINK NECKLACES AND NECK CHAINS - BASE METAL CLAD WITH GOLD	649	332	282	783	900	512	580	677	1,108	2,867
7113203000 CLASPS AND PARTS THEREOF OF BASE METAL CLAD WITH PRECIOUS METAL	450	1,068	3,018	2,363	1,042	554	789	742	1,033	661
7117190500 TOY JEWELRY, BASE METAL ROPE, CURB, CABLE, CHAIN, ETC., NOT MORE THAN 8 CENTS EACH	166	192	756	1,077	668	812	433	1,180	1,088	590
7113201000 CHAINS AND SIMLR ARTLS OF BASE MTL CLAD W PREC MTL PRODCD IN CNTS LNGTHS INCL CUT TO LNGTH IN SET W IMIT PRLS ETC SUITBL F USE IN MFR OF JEWELRY ETC	717	598	304	1,135	1,286	596	871	2,316	859	429
7113202100 ROPE NECKLACES AND NECK CHAINS - BASE METAL CLAD WITH GOLD	58	118	58	418	86	86	197	3,118	202	154
Total	423,678	474,670	562,891	581,831	647,321	798,728	876,520	933,553	1,008,002	978,390

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 3. Harmonized Tariff System Costume Jewelry Codes Percent of Total Imported Value from China & Hong Kong

HTS Number / Product Description	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
	In 1,000 Dollars									
7117199000 OTHER IMITATION JEWELRY OF BASE METAL	51%	60%	68%	72%	77%	78%	79%	80%	78%	79%
7113205000 JEWELRY NESOI OF BASE METAL CLAD WITH PRECIOUS METAL	16%	10%	4%	6%	9%	19%	23%	13%	8%	18%
7117191500 OTHER BASE METAL ROPE, CURB, CABLE, CHAIN, ETC., NOT MORE THAN 33 CENTS PER METER	32%	29%	32%	41%	54%	60%	56%	60%	68%	63%
7113202900 NECKLACES AND NECK CHAINS NESOI OF BASE METAL CLAD WITH GOLD	3%	5%	7%	3%	5%	12%	11%	11%	7%	11%
7117192000 ROPE CBL CHAIN ETC., BS MTL INC PREC MTL PLTD SUITBL F MFR ARTS THIS SUBPT VAL MORE THAN $.33 PER METER	32%	21%	48%	34%	49%	54%	37%	49%	51%	65%
7117196000 OTHER TOY JEWELRY OF BASE METAL, NOT MORE THAN 8 CENTS EACH	18%	38%	16%	19%	40%	67%	64%	71%	78%	83%
7113202500 MIXED LINK NECKLACES & NECK CHAINS OF BASE METAL CLAD WITH GOLD	0%	0%	0%	14%	5%	11%	8%	40%	11%	1%
7113203000 CLASPS AND PARTS THEREOF OF BASE METAL CLAD WITH PRECIOUS METAL	13%	1%	5%	3%	53%	23%	17%	31%	33%	56%
7117190500 TOY JEWELRY, BASE METAL ROPE, CURB, CABLE, CHAIN, ETC., NOT MORE THAN 8 CENTS EACH	53%	49%	25%	38%	81%	78%	77%	83%	88%	98%
7113201000 CHAINS AND SIMLR ARTLS OF BASE MTL CLAD W PREC MTL PRODCD IN CNTS LNGTHS INCL CUT TO LNGTH IN SET W IMIT PRLS ETC SUITBL F USE IN MFR OF JEWELRY ETC.	0%	7%	0%	0%	1%	6%	8%	18%	40%	54%
7113202100 ROPE NECKLACES AND NECK CHAINS OF BASE METAL CLAD WITH GOLD	0%	0%	0%	23%	71%	5%	53%	1%	0%	16%
Total	48%	58%	63%	69%	75%	77%	77%	78%	76%	77%

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB F: Public Comments

T
A
B

F

THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

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

Memorandum

Date: January 6, 2011

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 10-2

Introduction

The U.S. Consumer Product Safety Commission (CPSC) received a request from the Empire State Consumer Project, the Sierra Club, the Center for Environmental Health, and Rochesterians Against the Misuse of Pesticides, dated May 28, 2010, regarding cadmium in toy jewelry. This request was docketed under the Federal Hazardous Substances Act (FHSA) as Petition No. HP 10-2.

The CPSC received public comments from 85 organizations and individuals in response to the notice published in the Federal Register on August 19, 2010 (75 FR 51246). This memo provides a summary of those submissions and the staff's responses to them. Seventy-three comments were form letters from individuals indicating affiliation with the Sierra Club. Comments were received from five organizations: American Academy of Pediatrics (CPSC-2010-0087-0076), Consumer Federation of America (CPSC-2010-0087-0077), Consumers Union (CPSC-2010-0087-0081), Kids in Danger (CPSC-2010-0087-0083), and U.S. Public Interest Research Group (CPSC-2010-0087-0087). Two individuals provided comments, Ada Brewster (CPSC-2010-0087-0003) and Frederick Locker of Locker Greenberg & Brainin (CPSC-2010-0087-0084). Comments were received from one firm, X-Ray Optical Systems, Inc. (CPSC-2010-0087-0079), and from four industry associations, the Coalition for Safe Ceramicware (CPSC-2010-0087-0078), International Cadmium Association (CPSC-2010-0087-0080), Jewelry Safety Coalition (CPSC-2010-0087-0082), and Retail Industry Leaders Association (CPSC-2010-0087-0085).

Most of the commenters supported the petitioners' interest in restricting the potential exposure to cadmium from children's jewelry, although commenters offered differing views about the scope and form of possible Commission actions.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Discussion

Comment 1: Cadmium is toxic and a potential risk to children.

Many commenters expressed concern about cadmium, stating that cadmium is toxic, that children may be exposed to cadmium in products, and that the presence of cadmium poses a risk to children.

Three comments from industry groups did not dispute that cadmium exposure in children is undesirable, but offered opinions about the potential for harm. One of these comments stated that cadmium in ceramicware is inaccessible and that children will not be exposed to cadmium from such products. Another stated that cadmium should not be used in children's jewelry but that the news reports and the petitioners have overstated the health effects. The third comment stated that the principle danger of cadmium is from inhalation, which is not an exposure route for consumers using jewelry, but agreed that accidental ingestion of jewelry should not result in exposure to cadmium.

CPSC Staff Response 1:

The CPSC staff recognizes the toxicity of cadmium and the potential for hazardous exposures from some consumer products, including from ingestion.[1] Staff also recognizes that the mere presence of cadmium in a product does not indicate that a hazard exists because exposure to hazardous amounts of the chemical from use of the product may not be likely for all products. However, exposure testing and risk assessment by staff has identified hazardous products, resulting in Commission action, including recalls. Staff continues to evaluate different types of products for possible hazardous cadmium exposures.

Comment 2: Cadmium is being used as a replacement for lead.

Many commenters, mainly the form letters, stated that cadmium is being used as an inexpensive substitute for lead. One commenter representing the jewelry industry stated that there is no widespread practice of substituting cadmium for lead in children's jewelry.

CPSC Staff Response 2:

Although cadmium has been found in some jewelry products, the staff has no information confirming that it has been chosen intentionally as a replacement for lead. Nonetheless, staff agrees that the presence of cadmium could present a risk to children if use of the product, including ingestion, results in exposure to hazardous quantities of cadmium.

Comment 3: Scope and form of possible requirements

Types of products

Several commenters stated that requirements for cadmium should extend to more categories of children's products, and the focus should be on product categories known to be of risk to children, such as children's jewelry, dinnerware, toys, nursery products, as well as products for children under three years of age.

One commenter indicated that requirements should exclude ceramicware because any cadmium used in the decorations is bonded to substrate, and therefore, is inaccessible to a child.

[1] Staff Report on Cadmium in Children's Metal Jewelry, October 2010.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

One commenter agreed that cadmium should not be used in jewelry, but argued that the risks have been overstated and that there are safe uses of cadmium.

Definition of toy jewelry or children's jewelry

Many commenters used the language of the petition and referred to toy jewelry.

Three commenters indicated that the terms "toy jewelry" and "children's jewelry" need clarification. Two of these commenters stated that jewelry is not a toy and that toys are covered by the ASTM F 963 and EN 71-3 toy safety standards.

Two commenters stated that children's jewelry must be defined. Both indicated that price, as suggested by the petition, does not distinguish children's jewelry from jewelry for adults. One of these comments indicated that manufacturers' statements should be taken as the clearest indication of a children's product.

Cadmium content or soluble cadmium

Most of the comments indicated that a standard should be based on the total cadmium content of the product. One of these commenters explained that the standard must be based on total content because a standard based on accessible cadmium could result in inconsistent test results, could be based on exposure assumptions that may be grossly incorrect, could be difficult to enforce, and does not account for changes in the product over time, such as mechanical wear. One commenter did not offer an opinion about whether to restrict cadmium in jewelry or at what level, but claimed that new technology, known as "HDXRF," can measure the cadmium content in products at low levels. Three commenters supported a standard based on solubility or accessibility of the cadmium in a product. The comment from the ceramicware industry stated that if ceramicware is included in a standard, then such products should be subject to a solubility standard because the cadmium-containing material is bonded to the product substrate and does not come off, and broken pieces likely will not be swallowed. This comment stated that the limits for cadmium leaching that currently are used by the U.S. Food and Drug Administration should serve as the standard for ceramicware articles. Two other comments emphasized that there is no relationship between the cadmium content of a product and the amount of cadmium that might be accessible to a consumer; although both suggested that a screening level based on content, in addition to a solubility standard, would be desirable.

Other heavy metals

Comments from three organizations indicated that CPSC should address other toxic heavy metals to prevent substitution of one harmful substance for another.

CPSC Staff Response 3:

Staff agrees that there are several factors concerning the characteristics and types of products that should be considered in evaluating the potential hazards of children's jewelry.

Types of products

The petition specifically requested Commission action for toy jewelry. CPSC staff is focused on children's jewelry because the available data indicate that such products could be hazardous due to their cadmium content and potential for exposure. For other types of products, there is limited available testing and risk assessment information.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Toys, including toy jewelry, currently are subject to testing for cadmium content in paints and surface coatings through the ASTM F 963 toy safety standard, a voluntary standard that became mandatory under the provisions of the Consumer Product Safety Improvement Act of 2008 (CPSIA). This standard undergoes periodic review and revision by stakeholders, including CPSC staff. Consideration of additional requirements for toy jewelry is an option available to the Commission.

Staff has focusing on metal jewelry because the available data indicate that such products could be hazardous due to their cadmium content and potential for exposure. Staff does not have information concerning potential cadmium hazards of nonmetal materials that may be used in jewelry, but could assess additional types of products when data become available. With respect to ceramicware, in addition to requirements under CPSC statutes and regulations, certain ceramicware articles, including dinnerware, currently are subject to food safety standards under the U.S. Food and Drug Administration.

Definition of toy jewelry or children's jewelry

A children's product, in general, is defined as a consumer product designed or intended primarily for children 12 years of age or younger in the Consumer Product Safety Act (15 U.S.C. 2052(a)), as amended by the CPSIA, and in guidance published by the Commission at 16 C.F.R. Part 1200. In addition, staff has described specifically some of the elements of jewelry products that would distinguish consumer products designed or intended primarily for children from products that are not designed or intended primarily for children (Tab D).

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 staff that all jewelry valued at less than $20 should be considered "children's jewelry," or that a $20 limit includes all currently available children's jewelry.

Cadmium content or soluble cadmium

Regulation of products under the FHSA is based on statutory definitions of a hazardous substance, and requires consideration of the accessibility of the hazardous substance to the consumer. Testing by CPSC staff indicates that there is no clear relationship between the cadmium content of children's metal jewelry or other metal items and the extractability of cadmium from such items. Therefore, at this time, the available data indicate that soluble cadmium may be the most appropriate measure for determining whether a product may be considered a hazardous substance.

Other heavy metals

The Commission may consider evaluating the potential hazards associated with other chemicals.

Comment 4: Mandatory standard or voluntary standard

Several commenters, including the form letters, stated or suggested that a mandatory rule is necessary to address the hazards of cadmium in children's jewelry and indicted that manufacturers and importers must be required to test and certify products, as is the case currently for lead in children's products.

Two commenters stated that a voluntary standard is appropriate. One of these commenters indicated that because the petition addresses toy jewelry, the existing ASTM F 963 toy safety standard, which is now a mandatory standard under provisions of the CPSIA, is the appropriate

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

standard. This commenter indicated that the CPSIA provides a mechanism for quick and efficient establishment and revision of requirements in the toy safety standard, that cadmium is already included in the standard with respect to accessible cadmium from the surface of toys, and that the Toy Industry Association (TIA) is proposing to align F 963 with international standards for accessible soluble heavy metals in toys. The other commenter that preferred a voluntary standard stated that CPSC should not only rely on the now-mandatory ASTM F 963 standard, but also defer to the ASTM children's jewelry standard that currently is in development. The commenter indicated that these standards will address adequately the issue without the Commission needing to expend the resources required to develop a mandatory standard, and would be fully consistent with the congressional mandates regarding ASTM F 963, and deferring to voluntary standards.

Another commenter supported national, risk-based standards, including the ASTM children's jewelry standard under development. The commenter stressed that Commission actions must be consistent with the FHSA, and that proposed rules under FHSA require consideration of accessibility of the hazardous substance, must consider costs and benefits, indicate reasons why a voluntary standard or portion of a standard was not chosen, and include a discussion of reasonable alternatives.

CPSC Staff Response 4:

Currently, toy jewelry is subject to the ASTM F 963 toy safety standard, a mandatory standard under the provisions of the CPSIA. As discussed by one of the public commenters, changes to this standard have been proposed that would expand the requirements for chemicals, including cadmium.

However, not all children's jewelry is covered by the toy standard because not all children's jewelry would be considered a toy. A new voluntary standard for children's jewelry currently is under development by an ASTM subcommittee that includes participation of CPSC technical staff. This standard would include limits for migration of cadmium from jewelry items, as well as a content limit that could be used for screening products.

By statute, the Commission is directed to give preference to voluntary standards over promulgating mandatory standards if it determines that a voluntary standard will eliminate or adequately reduce an injury risk, and that there will be a likelihood of substantial compliance with the standard. 15 U.S.C. 2056(b), 15 U.S.C. 1262(g)(2). However, the Commission may not deny a petition on the basis of a voluntary standard, unless the voluntary standard is in existence at the time of the denial of the petition, the Commission has determined that the voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury identified in the petition, and it is likely that there will be substantial compliance with the standard. 15 U.S.C. 1262(j).

Both voluntary standards and mandatory standards are among the options that may be considered by the Commission.

With respect to testing requirements, provisions of the CPSIA require third party testing of children's products for the standards and rules that apply to such products, including the ASTM F 963 toy safety standard, lead content requirements, and other requirements. Although testing for all potential hazards for all products may not be required necessarily, manufacturers,

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

importers, distributors, and retailers are responsible for ensuring the safety of the products they sell.

Comment 5: Test methods

Many commenters, including the form letters, echoed the petition in calling for revised test methods that would reflect the real scenarios, including children swallowing, chewing, and breaking their toys.

One commenter provided extensive discussion of testing issues. The comment stated that tests must use realistic exposure settings, not unrealistic worst-case conditions involving long extraction times and agitation of samples, and must be subjected to testing to establish inter-laboratory variability and statistical uncertainty. The commenter indicated that the European toy safety standard EN 71-3 meets these criteria. This commenter stated that the draft ASTM jewelry standard will rely on EN 71-3 and include a screening test based on total cadmium content. This commenter is not aware of any adverse health effects associated with toys that comply with EN 71-3, and concluded that the standard appears health protective of children and would be a useful approach for children's jewelry. This comment also asserted that the toy standards are conservative.

CPSC Staff Response 5:

Staff has evaluated data from solubility testing of metal jewelry and other metal items, and analyzed information related to children's ingestion of small objects, including cases of serious adverse effects and death from exposure to the chemical content of some of the items.[2] Staff concluded that the two-hour test specified in the European toy safety standard EN 71-3 may not identify some products that could result in hazardous exposures.

The basis of EN 71-3 is that a child is assumed to have an average daily intake (ingestion) of toy material of 8 milligrams (mg) per day. The standard acknowledges that in certain individual cases, this figure might be exceeded.

CPSC staff believes that the 8 mg/day assumption might be reasonable for paints and coatings, or materials that can be scraped off or that break up into small bits, but has concluded that it does not represent the exposure expected when a child swallows a larger jewelry component. A larger item would contain a far larger amount of a chemical than a smaller item with the same chemical concentration. Furthermore, the data indicate that swallowed items, such as jewelry, may not be eliminated quickly from the body, but can be retained within the digestive tract for an extended period of time. A longer time in the body could result in increased solubility of chemicals such as cadmium that would not be detected using a short test time. In addition, the shorter test might not be appropriate if a product is plated or coated. The staff's testing shows that such coatings weaken eventually and allow the acid to reach the underlying material. In these cases, leaching would be evident only after several hours in the acid solution.

For these reasons, staff has concluded that testing products for the potential for exposure to chemicals in a product if the item is swallowed by a child should be based on a longer, more stringent test to identify products that could result in hazardous exposures. CPSC staff provided

[2] Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials, August 2010.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

this information to the ASTM children's jewelry subcommittee for use in the development of the voluntary standard.[3]

Comment 6: Request EPA adopt requirements

The many form letter comments repeated the petitioners' request that the CPSC ask the EPA, through the Interagency Testing Committee, to adopt testing and reporting requirements to gather information for decision-making.

CPSC Staff Response 6:

If the Commission or staff concludes that additional information is needed, procedures are already in place to facilitate the collection and dissemination of data from other federal agencies such as the EPA.

Comment 7: Evaluate ASTM F 963

One commenter stated that the CPSC should evaluate the ASTM F 963 toy safety standard to ensure that the solubility test methods are representative of the way children use products and address adequately the risk of a child's potential exposure.

CPSC Staff Response 7:

CPSC staff is engaged actively in the review and refinement of the ASTM F 963 standard. Evaluating this standard with respect to toy jewelry, which is currently subject to the standard, is among the options the Commission may consider.

Comment 8: Use of cadmium in jewelry

One commenter representing the jewelry industry described the uses of cadmium in jewelry. This comment indicated that jewelry may consist of a wide variety of materials. Cadmium may be found in metal, either in trace amounts or as part of certain alloys, especially for adult jewelry, in solder for precious metal settings, in paints and surface coatings, and in plastics or crystal. The commenter explained that precious metals usually contain less than 300 parts per million (ppm) cadmium (0.03 percent), but that the cadmium content may be higher in some cases (up to 1000 ppm to 2000 ppm) (0.1-0.2 percent) because of the recycling of scrap precious metal materials.

CPSC Staff Response 8:

CPSC staff analysis of numerous jewelry items, including children's jewelry, shows that cadmium content of jewelry, especially metal items, is sometimes very high, with some items containing more than 99 percent cadmium.[4] Staff recognizes that different materials, used for a variety purposes, may contain a range of cadmium concentrations, whether the cadmium is naturally occurring, intentionally added, or present as a contaminant.

Comment 9: Data on migration of cadmium from metal jewelry

The jewelry industry commenter reported the results of some testing of items for migration of cadmium. Industry members prepared samples for testing that contained three different levels of

[3] Combined Cadmium Package for ASTM F15.24 Children's Jewelry, including: Staff Report - Cadmium in Children's Metal Jewelry, October 2010; and Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials (pdf), August 2010. Available at http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf.

[4] Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials, August 2010.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

cadmium (three samples were based on tin; one sample was zinc-based), with two different plating finishes ("economy" and "quality" plating). These samples were subject to migration testing under different conditions. The results for six tests were provided, along with the conclusion that very little cadmium migrates from plated samples even under worst-case 24-hour test conditions with constant agitation and higher total cadmium content levels. The commenter noted that the zinc alloy showed lower migration than the tin-based alloys. The commenter concluded that a cadmium content level of 1000 ppm (0.1 percent) should result in negligible exposure and may be a useful screening level.

CPSC Staff Response 9:

Although the study described by the commenter is limited by the small number of samples and types of products tested, the information provided contributes to the knowledge about the potential for exposure to cadmium from cadmium-containing metal jewelry items. However, the staff does not agree with the conclusion that the data shows that very little cadmium migrated from the samples. On the contrary, the data show cadmium migration of up to several hundred parts per million (equivalent to several hundred micrograms of cadmium per gram of jewelry) under the test conditions. While the data suggest that 1000 ppm may be a useful screening level, the results of this limited study should be confirmed with testing of additional samples, including actual products that were not specially manufactured for the analysis.

Comment 10: Other jurisdictions' requirements

Two commenters mentioned that because some states have acted to limit cadmium in jewelry, consumers are asking for, and are supportive of, mandatory rules. One of the comments also suggested that the CPSC should look at the other jurisdictions' requirements for guidance on developing mandatory requirements for cadmium in children's products, although the comment pointed out that many of the other requirements are based on solubility and are limited to jewelry instead of applying to a broader group of children's products.

CPSC Staff Response 10:

The staff is reviewing existing cadmium standards, including state standards.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Index of comments

Regulations.gov Document ID	Name	Organization
CPSC-2010-0087-0003	Ada Brewster	
CPSC-2010-0087-0004	William Herzberg	Sierra Club
CPSC-2010-0087-0005	Paul O'Byrne	Sierra Club
CPSC-2010-0087-0006	Jana Miller	Sierra Club
CPSC-2010-0087-0007	Dan Struble	Sierra Club
CPSC-2010-0087-0008	Terra Pascarosa	Sierra Club
CPSC-2010-0087-0009	Heather Gurnow	Sierra Club
CPSC-2010-0087-0010	Carolyn Mullen	Sierra Club
CPSC-2010-0087-0011	Tanya Elo	Sierra Club
CPSC-2010-0087-0012	Nancy Perkins	Sierra Club
CPSC-2010-0087-0013	Gary Bence	Sierra Club
CPSC-2010-0087-0014	Estela Avalos	Sierra Club
CPSC-2010-0087-0015	Zandra Frank	Sierra Club
CPSC-2010-0087-0016	Marcia & Luther Lyle	Sierra Club
CPSC-2010-0087-0017	Mark & Susan Glasser	Sierra Club
CPSC-2010-0087-0018	Angela Poppe	Sierra Club
CPSC-2010-0087-0019	Steven Holzberg	Sierra Club
CPSC-2010-0087-0020	Keith Teeter	Sierra Club
CPSC-2010-0087-0021	Charles Belmont	Sierra Club
CPSC-2010-0087-0022	Richard Skrzynecki	Sierra Club
CPSC-2010-0087-0023	Barbara Fry	Sierra Club
CPSC-2010-0087-0024	Anna Bergalis	Sierra Club
CPSC-2010-0087-0025	Elaine Fischer	Sierra Club
CPSC-2010-0087-0026	Dennis Ledden	Sierra Club
CPSC-2010-0087-0027	Jacqueline Dendy	Sierra Club
CPSC-2010-0087-0028	Todd Richardson	Sierra Club
CPSC-2010-0087-0029	Cynthia Neal	Sierra Club
CPSC-2010-0087-0030	Amanda Sousa	Sierra Club
CPSC-2010-0087-0031	Shirley Napps	Sierra Club

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Regulations.gov Document ID	Name	Organization
CPSC-2010-0087-0032	Jack A. Morlock	Sierra Club
CPSC-2010-0087-0033	J. W. Oman	Sierra Club
CPSC-2010-0087-0034	Ellen Breiling	Sierra Club
CPSC-2010-0087-0035	Angela Rasmussen	Sierra Club
CPSC-2010-0087-0036	James And Ann Ellen Tuomey	Sierra Club
CPSC-2010-0087-0037	Lorraine Mac Artor	Sierra Club
CPSC-2010-0087-0038	De Bush	Sierra Club
CPSC-2010-0087-0039	Harry Hudson	Sierra Club
CPSC-2010-0087-0040	Todd Jacobs	Sierra Club
CPSC-2010-0087-0041	Rhonda Marrone	Sierra Club
CPSC-2010-0087-0042	Leslie Smith	Sierra Club
CPSC-2010-0087-0043	Robert Cepaitis	Sierra Club
CPSC-2010-0087-0044	Mark Pommer	Sierra Club
CPSC-2010-0087-0045	Bill Nierstedt	Sierra Club
CPSC-2010-0087-0046	Sean Tracy	Sierra Club
CPSC-2010-0087-0047	Margaret Davies	Sierra Club
CPSC-2010-0087-0048	Greg Debros	Sierra Club
CPSC-2010-0087-0049	Lauren Verruni	Sierra Club
CPSC-2010-0087-0050	Marta Simmons	Sierra Club
CPSC-2010-0087-0051	Janine Buckley	Sierra Club
CPSC-2010-0087-0052	Anand Parikh	Sierra Club
CPSC-2010-0087-0053	Roselind Heinekamp	Sierra Club
CPSC-2010-0087-0054	Leslie Burpo	Sierra Club
CPSC-2010-0087-0055	Nicole Babyak	Sierra Club
CPSC-2010-0087-0056	Philip Hult	Sierra Club
CPSC-2010-0087-0057	Richard & Chris Hovda	Sierra Club
CPSC-2010-0087-0058	Susan Zeiger	Sierra Club
CPSC-2010-0087-0059	Maria Szokolai	Sierra Club
CPSC-2010-0087-0060	Ronald Sitton	Sierra Club

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Regulations.gov Document ID	Name	Organization
CPSC-2010-0087-0061	Jacqueline Lasahn	Sierra Club
CPSC-2010-0087-0062	Joel Weiss	Sierra Club
CPSC-2010-0087-0063	Angela Poppe	Sierra Club
CPSC-2010-0087-0064	Robert Kessler	Sierra Club
CPSC-2010-0087-0065	Rebecca Mcdonough	Sierra Club
CPSC-2010-0087-0066	Angelo Feldkamp	Sierra Club
CPSC-2010-0087-0067	Cynthia Zahorik	Sierra Club
CPSC-2010-0087-0068	Jean Rodine	Sierra Club
CPSC-2010-0087-0069	Bryna Hoffmeister	Sierra Club
CPSC-2010-0087-0070	Pamela Cramer	Sierra Club
CPSC-2010-0087-0071	Denise Speicher	Sierra Club
CPSC-2010-0087-0072	Tory Ewing	Sierra Club
CPSC-2010-0087-0073	Jim Head	Sierra Club
CPSC-2010-0087-0074	Lawrence Ynesta	Sierra Club
CPSC-2010-0087-0075	Hank Mirsky	Sierra Club
CPSC-2010-0087-0076	O. Marion Burton, MD	American Academy of Pediatrics
CPSC-2010-0087-0077	Rachel Weintraub	Consumer Federation of America
CPSC-2010-0087-0078	Patrick OLeary	Coalition For Safe Ceramicware
CPSC-2010-0087-0079	Satbir Nayar	XOS
CPSC-2010-0087-0080	Hugh Morrow	International Cadmium Association
CPSC-2010-0087-0081	Ioana Rusu	Consumers Union
CPSC-2010-0087-0082	Sheila Millar	Jewelry Safety Coalition
CPSC-2010-0087-0083	Nancy Cowles	Kids In Danger
CPSC-2010-0087-0084	Frederick Locker	Locker Greenberg & Brainin
CPSC-2010-0087-0085	Jim Neill	Retail Industry Leaders Association
CPSC-2010-0087-0086	Deanna Prine	Sierra Club
CPSC-2010-0087-0087	Elizabeth Hitchcock	U.S. Public Interest Research Group

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)