UNITED STATES
CONSUMER **PRODUCT SAFETY COMMISSION**
4330 East West Highway
Bethesda, MD 20814

This document has been electronically approved and signed.

BALLOT VOTE SHEET

Date: June 29, 2012

TO : The Commission
Todd A. Stevenson, Secretary

FROM : Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Hyun S. Kim, Acting Assistant General Counsel
Andrew J. Kameros, Attorney

SUBJECT : Petition HP 10-2; Request for Regulations on Cadmium

BALLOT VOTE: Due July 6, 2012

The Empire State Consumer Project, the Sierra Club, the Center for Environmental Health, and the Rochesterians Against the Misuse of Pesticides submitted a petition to the Commission to promulgate regulations declaring any metal "toy jewelry" containing more than trace amounts of cadmium by weight, which foreseeably could be ingested by children, a banned hazardous substance. On September 6, 2011, the Commission voted to grant the petition and directed staff to begin drafting a notice of proposed rulemaking, unless voluntary standards for cadmium in children's jewelry and toy jewelry were published within 3 months of publication of the notice of that vote in the *Federal Register*. The Commission further directed staff to assess the adequacy of any voluntary standards published and determine whether there is substantial compliance with the voluntary standards, and based on those assessments, make a recommendation on the disposition of the petition within 9 months. Staff recommends that the Commission terminate the petition.

Please indicate your vote on the following options:

I. Issue a rule.

(a) Direct staff to draft an advance notice of proposed rulemaking.

_____ _____
Signature Date

(b) Direct staff to draft a notice of proposed rulemaking.

_____ _____
Signature Date

II. Terminate the proceeding, and direct staff to prepare a letter to the petitioners, notifying them of the termination of the petition.

_____ _____
Signature Date

III. Defer action on the petition.

_____ _____
Signature Date

IV. Take other action (please specify):

_____

_____

_____

_____ _____
Signature Date

Staff Briefing Package

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

June 29, 2012

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Briefing Memo

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

Memorandum

This document has been electronically approved and signed.

Date: June 29, 2012

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

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

SUBJECT : Staff Update re: Petition HP 10-2 Requesting Restriction of Cadmium in Toy Jewelry

I. Petition Background

The CPSC received a request from the Empire State Consumer Project, the Sierra Club, the Center for Environmental Health, and the Rochesterians Against the Misuse of Pesticides, dated May 28, 2010, regarding cadmium in toy jewelry. The request was docketed under the Federal Hazardous Substances Act (FHSA) as Petition No. HP 10-2.

The petition asked the Commission to adopt regulations declaring that any toy metal jewelry that contains more than trace amounts of cadmium by weight that children could ingest constitutes a banned hazardous substance. The petitioners defined "toy jewelry" and offered other suggestions for regulating these products. However, they did not define "trace amounts of cadmium." The petitioners suggested that as an interim step, the CPSC should use the same maximum level that Congress established for lead content for children's products (currently 100 parts per million lead for products manufactured after August 14, 2011).

The petitioners also stated that if the CPSC has insufficient information regarding cadmium, the Commission 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), and include metal jewelry in the scope of reporting under section 8(d) of the TSCA, as well as require importers and processers to test toy metal jewelry for cadmium.

II. Previous Commission Activities

Staff prepared a briefing package for Commission consideration in response to Petition No. HP 10-2, Requesting Restriction of Cadmium in Toy Jewelry, which was transmitted to the

Commission on February 9, 2011.[1] In its briefing package, staff assessed the information available on the toxicity of cadmium, children's behaviors, data on children's metal jewelry, and related economic data. Evaluation of incidents and possible behaviors in children supported the conclusion that sometimes children may swallow jewelry. Furthermore, testing by CPSC staff of cadmium-containing children's metal jewelry and other metal items indicates that cadmium can migrate[2] from products in amounts that could be associated with adverse health effects in children. Staff concluded that children who swallow cadmium-containing metal jewelry could experience excess cadmium exposure that could result in substantial illness.

Staff described two voluntary standards activities under the ASTM International, Inc., standards development process that would address cadmium in children's jewelry and toy jewelry. Staff indicated that the work on those standards was expected to be completed in 2011.

Staff recommended that the Commission defer its decision on the petition for 6 months and direct staff to participate in two ASTM subcommittees: F 15.24 to develop a voluntary standard addressing accessible cadmium from children's metal jewelry, and F 15.22 to consider amendments to the existing ASTM F 963 standard (Standard Consumer Safety Specification for Toy Safety) to address toy jewelry. Staff indicated that if the Commission voted to defer its decision, staff would provide the Commission with an update on the progress of the voluntary standards for children's jewelry and toy jewelry at the end of the 6-month period.

Staff indicated that at the end of the 6 months, the Commission could make a determination to continue to defer its decision on the petition and direct staff to proceed with the voluntary standards process or pursue other Commission action. On February 16, 2011, the Commission voted unanimously to defer its decision and directed staff to participate in the ASTM subcommittees.

On August 30, 2011, staff transmitted to the Commission a briefing package[3] for Commission consideration, providing an update of the status of the two voluntary standards and other information related to restrictions on cadmium in children's jewelry. Staff concluded that the new children's jewelry standard and the amended toy safety standard, when finalized, would be appropriate measures for reducing the risk of harm from exposure to cadmium in children's jewelry. Staff expected the draft standards to be finalized later in 2011.

On September 6, 2011, the Commission granted the petition and directed staff to begin drafting a proposed rule, unless the voluntary standard for cadmium in children's jewelry and the revised toy safety standard were published by ASTM International, Inc., within 3 months after September 16, 2011. 76 *Federal Register* 57682.

In the case that the voluntary standards were published, the Commission directed staff to assess the adequacy of the standards and whether there is substantial compliance with the standards, and based on these assessments, make a recommendation on the disposition of the petition within 9 months after September 16, 2011.

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[1] Available at: http://www.cpsc.gov/library/foia/foia11/brief/cadmiumpet.pdf.

[2] "Migration" of cadmium from a product refers to the "solubility" of cadmium from a product or component part, such as when a part is exposed to saliva or stomach acid, or when a product is analyzed in the laboratory under specified testing conditions. "Extraction" is sometimes used in place of "migration." Staff considers that these terms, and their variants (*i.e.*, migrate, extractable, soluble) refer to the same process.

[3] Available at: http://www.cpsc.gov/library/foia/foia11/brief/cadmiumpetupd.pdf.

III. Update

Both standards under discussion were published in 2011. The standard ASTM F 2923-11, *Standard Specification for Consumer Product Safety for Children's Jewelry*, was published in November 2011. The revised standard ASTM F 963-11, *Standard Consumer Safety Specification for Toy Safety*, was published in December 2011.

With respect to cadmium in children's jewelry and toy jewelry, these two standards restrict the migration of cadmium from surface coatings, metal, and other materials using specified test methods. Both standards allow the option of testing for cadmium content, which can be done during the testing for lead content that is already required for children's products, rather than testing for migration of cadmium.

CPSC staff participated in the development of both standards and contributed to discussions about the types of products that should be included and the form of the limits (*e.g.*, total content or extractable) for cadmium in children's products. During the standards development proceedings, staff provided its own data and analyses for consideration by both the ASTM F 15.24 children's jewelry subcommittee and the ASTM F 15.22 toy safety subcommittee.

Staff previously presented to the Commission that there was no clear relationship between the extractability of cadmium from children's metal jewelry or other metal items and the cadmium content of items.[4] Staff concluded that setting exposure limits and establishing testing methods for soluble cadmium would 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 developed testing methods and exposure limits that could be used to establish standards for testing and evaluation of children's metal jewelry.

Staff also indicated that it focused on metal jewelry because the available data showed that such products could be hazardous due to their cadmium content and potential for exposure. Staff did not have information concerning potential cadmium hazards of nonmetal materials that may be used in jewelry. Staff indicated to the Commission and the ASTM subcommittees that additional types of products may be assessed when data become available. Either standard may be revised through the procedures established by ASTM International, Inc., and staff will continue participation in the subcommittees.

ASTM F 2923-11, *Standard Specification for Consumer Product Safety for Children's Jewelry*

Published in November 2011, ASTM F 2923-11, *Standard Specification for Consumer Product Safety for Children's Jewelry* is the new voluntary standard for children's jewelry. This standard does not include products that are considered to be children's toys.

In addition to the potential hazards associated with cadmium, this standard addresses a number of other potential hazards, such as hazardous magnets, hazardous batteries, certain chemicals in surface coatings, and contact with nickel.

[4] Staff Briefing Package for Petition HP 10-2 Requesting Restriction of Cadmium in Toy Jewelry, February 9, 2011. Available at: http://www.cpsc.gov/library/foia/foia11/brief/cadmiumpet.pdf. Also see Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials, August 2010. Available at: http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf.

Cadmium Standard

The ASTM F 2923-11 voluntary standard for children's jewelry includes several restrictions for cadmium (Table 1).

Table 1. Cadmium Requirements for Children's Jewelry

Product or Component	Limit	Standard
Paints and surface coatings	75 mg/kg	Soluble cadmium
Component parts of children's jewelry	300 ppm	Total cadmium content (optional; may replace solubility testing)
Metal small parts with content >300 ppm	200 µg	Solubility; specified acid solution and procedure
Plastic small parts with content >300 ppm	75 mg/kg	Soluble cadmium
Metal or plastic parts that are NOT small parts with content >300 ppm	18 µg	Solubility; saline solution

The standard covers paints and surface coatings, similar to the ASTM F 963 toy safety standard, restricting the solubility or migration of cadmium and other chemical elements from surface coatings. The solubility of cadmium may not exceed 75 mg/kg (equivalent to 75 parts per million or 75 ppm), based on the weight of the dried paint film, using the laboratory test specified in the standard.

Component parts of children's jewelry are subject to restrictions on cadmium. If the total cadmium content of a component does not exceed 300 ppm, no additional testing for cadmium migration is required. This limit represents a relatively low cadmium concentration that, in staff's experience, is not expected to be associated with excess exposure or subsequent adverse health effects.

If the cadmium content of a component that is a small part (as defined in 16 CFR §1501.4) exceeds 300 ppm, then the part is subject to additional testing to determine the migration of cadmium using specified laboratory tests. Metal components that are "small parts," as defined in CPSC regulations, are subject to a test in which the item is placed in a heated acid solution and agitated for 24 hours. This test is based on work by CPSC staff,[5] which showed that the test conditions are sufficient to identify cadmium-containing items that could result in excess cadmium exposure and subsequent health effects under certain conditions of exposure, such as swallowing by a child. The migration limit for parts subject to this test is 200 µg cadmium per component part. This limit is based on analysis by CPSC staff,[6] in which staff concluded that a result exceeding 200 µg in the 24-hour acid extraction test would indicate that the product may meet the criteria established in the FHSA for a product to be considered a hazardous substance based on acute toxicity.

[5] Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials, August 2010. Available at: http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf.

[6] CPSC Staff Report on Cadmium in Children's Metal Jewelry. October 2010. Available at: http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf.

Plastic components are subject to cadmium migration testing as is currently performed on toys under the European toy safety standard EN 71-3; the migration limit for this test is 75 mg/kg.

Metal or plastic components with cadmium content of more than 300 ppm that are not small parts are subject to a different test for migratable cadmium that uses a heated, agitated saline solution to identify cadmium-containing items that could result in excess cadmium exposure and subsequent health effects under certain conditions of exposures, such as mouthing by a child. The migration limit for parts subject to this test is 18 µg cadmium per component part. This limit is based on an analysis by CPSC staff,[7] in which staff concluded that a result from the specified saline extraction test that exceeds 18 µg would indicate that the product may be considered a hazardous substance based on chronic toxicity.

ASTM F 963-11, *Standard Consumer Safety Specification for Toy Safety*

Published in December 2011, ASTM F 963-11, *Standard Consumer Safety Specification for Toy Safety*, is the latest revision of the toy standard. On February 15, 2012, the Commission voted to accept the revised standard. As provided by section 106 of the Consumer Product Safety Improvement Act of 2008, ASTM 963-11 became a mandatory consumer product safety standard, effective June 12, 2012, replacing the previous mandatory standard ASTM F 963-08.

Staff believes that most products considered "children's jewelry" are not toy jewelry, and therefore, would be subject to the ASTM F 2923 children's jewelry standard. However, any jewelry products intended for children that are not subject to the children's jewelry standard, and are considered toys, would be subject to the ASTM F 963 toy safety standard.

Previously, staff indicated proposed changes to the ASTM F 963-08 toy safety standard that would expand the requirements for cadmium and other chemicals in toys, including toy jewelry. Prior to the latest revision, only paints and surface coatings were subject to the requirements for cadmium and other chemicals. The revised ASTM F 963-11 standard adds restrictions for other materials in toys, such as plastics and metal, in addition to paints and surface coatings.

Scope

The standard establishes certain requirements for cadmium in toys, as well as for the other chemical elements that previously had been restricted only for paints and surface coatings.[8] In addition to paints and surface coatings, the standard sets limits for cadmium and several other chemicals in plastic, metal, glass, and ceramic toys and parts of toys.

Products subject to this section of the standard include toys and parts of toys that are small parts (*i.e.*, that fit into the test fixture specified at 16 CFR part 1501), and toys and toy parts that are accessible. Toys and parts of toys that, due to their inaccessibility, size, mass, function, or other characteristics, cannot be sucked, mouthed, or ingested, are not subject to the requirement.

The standard indicates that the following criteria are reasonably appropriate for the classification of toys or parts that are likely to be sucked, mouthed, or ingested:

(1) "All toy parts intended to be mouthed or contact food or drink, components of toys which are cosmetics, and components of writing instruments categorized as toys;"

[7] CPSC Staff Report on Cadmium in Children's Metal Jewelry. October 2010. Available at: http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf.

[8] Antimony, arsenic, lead, barium, cadmium, chromium, mercury, and selenium.

(2) "Toys intended for children less than 6 years of age, that is, all accessible parts and components where there is a probability that those parts and components may come into contact with the mouth."

Cadmium Standard

The revised toy safety standard includes several restrictions for cadmium (Table 2).

Table 2. Cadmium Requirements for Toys

Product or Component	Limit	Standard
Paints and surface coatings	75 ppm	Soluble cadmium
Accessible component parts, as specified in scope	75 ppm (50 ppm for modeling clay toys)	Soluble cadmium
Accessible component parts, as specified in scope	75 ppm (50 ppm for modeling clay toys)	Total cadmium content (may replace solubility test)
Metal small parts	200 µg	Solubility; specified acid solution and procedure

Previously, the restriction for cadmium and other chemical elements was applied to paints and surface coatings only, based on the solubility or migration of cadmium and other chemical elements from surface coatings. The revised standard retains the requirement that the solubility of cadmium may not exceed 75 ppm (equivalent to 75 mg/kg), based on the weight of the dried paint film, using a specified laboratory test.

The revised standard also restricts cadmium and the other elements in parts of toys, other than paints and surface coatings. For toys within the scope of the standard, the migration limit for cadmium for accessible parts of toys is 75 ppm (the limit for modeling clay toys is 50 ppm), using a specified laboratory test.

Metallic toys, or toy components that are small parts, are subject to additional testing to determine the migration of cadmium using a laboratory test specific to such products. This test, in which the item is placed in a heated acid solution and agitated for 24 hours, is based on work by CPSC staff, which showed that the test conditions are sufficient to identify cadmium-containing items that could result in excess cadmium exposure and subsequent health effects under certain conditions of exposures, such as swallowing by a child. The migration limit for this test is 200 µg cadmium for each component part.

The revised ASTM F 963-11 standard also includes the option of satisfying the standard's requirements by testing for total cadmium content, rather than for cadmium solubility. If the cadmium content of a component does not exceed 75 ppm (50 ppm for modeling clay toys), then solubility testing may be omitted.

IV. Cooperation and Collaboration with U.S. Environmental Protection Agency (EPA)

The request from the Empire State Consumer Project, the Sierra Club, the Center for Environmental Health, and the Rochesterians Against the Misuse of Pesticides 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, stating that it was granting the request and would propose a rule to require submission of

unpublished health and safety studies relevant to the determination on whether a potential hazard exists due to the presence of cadmium 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 would consider initiating additional rulemaking, if necessary.

Since the EPA granted the petitioners' request, EPA staff and CPSC staff have met frequently, by teleconference, videoconference, and in person, to collaborate and discuss each agency's ongoing efforts to address the potential hazards of cadmium in consumer products. EPA staff has initiated work on a direct final rule pursuant to the agency's authority under the Toxic Substances Control Act (TSCA), to require manufacturers and importers to submit unpublished health and safety studies to the EPA. Although EPA staff had previously indicated that this work would be completed in late 2011, as of spring 2012, the work was still ongoing.

EPA staff is also working on a rule that would require unpublished health and safety studies from processors and distributors. This work, which will include review by the Office of Management and Budget, is expected to be completed after the direct final rule described above.

Separately, EPA's TSCA Interagency Testing Committee (ITC) included cadmium and cadmium compounds in its Sixty-Eighth Report to the EPA Administrator.[9] The report added cadmium and 103 cadmium compounds to the TSCA section 4(e) Priority Testing List. Subsequently, the ITC's Sixty-Ninth Report[10] removed the 103 cadmium compounds, but added a category for cadmium compounds including any chemical that contains cadmium as part of the chemical's structure. This was done to provide a more comprehensive approach to assessing the safety of cadmium compounds. Manufacturers (including importers) of chemicals added to the Priority Testing List are required to submit to EPA certain production and exposure information and unpublished health and safety studies.

Additional health and safety studies that might be obtained through these activities will be used to continue CPSC staff's work on children's jewelry and toys and to inform additional work on other possible cadmium hazards in children's or other consumer products.

V. Adequacy of the Standards

On September 6, 2011, the Commission directed staff to assess the adequacy of the standards and whether there is substantial compliance with the standards.

ASTM F 2923-11, *Standard Specification for Consumer Product Safety for Children's Jewelry*

This standard was developed with the participation of CPSC staff, considering data and other information contributed by staff. The data showed that there was no clear relationship between the extractability of cadmium from children's metal jewelry or other metal items and the cadmium content of such items. Staff concluded that setting exposure limits and establishing

[9] Sixty-Eighth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments. 76 Federal Register 46174. August 1, 2011. Available at: http://www.gpo.gov/fdsys/pkg/FR-2011-08-01/pdf/2011-19414.pdf.

[10] Sixty-Ninth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments. 77 Federal Register 30856. May 23, 2012. Available at: http://www.gpo.gov/fdsys/pkg/FR-2012-05-23/pdf/2012-12493.pdf.

testing methods for soluble cadmium would 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 developed testing methods and exposure limits that could be used to establish standards for testing and evaluation of children's metal jewelry. The new standard incorporates the findings and conclusions of CPSC staff, along with data and information contributed by other stakeholders.

Staff believes that the standard's provisions will reduce the risk of harm from exposure to cadmium. Further, staff believes that, based on available data (see Tabs A and B and the summaries of these tabs below) and discussions among subcommittee members, many, if not most, manufacturers will choose to produce products without cadmium, or with cadmium content of no more than 300 ppm, even though the standard allows the use of cadmium at concentrations greater than 300 ppm, with the condition that the cadmium does not migrate out of the product. Cadmium content measurements can be conducted simultaneously with lead content testing. Because testing for total lead content in children's products is already required by statute, measuring total cadmium content can be done with little increase in testing costs.

ASTM F 963-11, *Standard Consumer Safety Specification for Toy Safety*

The specific requirements for cadmium in the toy safety standard, while not identical to the children's jewelry standard, were also developed with contributions from CPSC staff. As in the case of the jewelry standard, staff believes that the toy standard's provisions will reduce the risk of harm from exposure to cadmium.

While the toy standard allows the use of cadmium at concentrations greater than 75 ppm, with the condition that the cadmium does not migrate out of the product, staff believes that, based on available data for products manufactured over the past several years, most manufacturers will continue to produce products without cadmium, or with cadmium content no greater than 75 ppm. Cadmium content measurements can be conducted simultaneously with lead content testing. Because testing for total lead in children's products is already required by statute, measurements for total cadmium content can be performed with little change in testing costs.

VI. Compliance with the Standards

Tab A provides a summary of several activities by the CPSC's Office of Compliance and Field Operations staff to determine compliance with the mandatory lead content limits for children's jewelry products and to assess children's products for the presence of cadmium and possible exposures to cadmium, based on the recommendations of CPSC staff that are now part of the ASTM F 2923-11 children's jewelry voluntary standard. During fiscal years 2011 and 2012,[11] staff screened several hundred items of children's jewelry, or items that were similar to children's jewelry, using portable x-ray fluorescence instruments (XRF), and collected for laboratory testing, items that potentially had high lead or cadmium content. Collected samples were also subject to age determination evaluations by CPSC staff to determine whether the products could be considered children's products.

As described in Tab A, several products were identified as having excess lead and/or cadmium content. Items with excess cadmium were subjected to additional testing for soluble cadmium, based on the test procedure used by CPSC staff and that is incorporated into the voluntary

[11] The federal government fiscal year begins October 1; *i.e.*, fiscal year 2011 began on October 1, 2010.

standard. Three children's products tested in the 2011 and 2012 fiscal years activities were found that exceeded the standard's migration limits for cadmium. These three products were no longer in distribution and staff requested that remaining inventory be destroyed. In addition, several items were found to be in violation of the mandatory lead content limits for children's products and were subjected to enforcement action.

Tab B provides a brief summary of the approach of the CPSC's Office of Import Surveillance and Inspection to address the possible presence of cadmium in imported children's products. Since May 2010, staff has screened thousands of products of interest for cadmium and other substances. Initially, staff focused on products with high levels of cadmium (likely intentional uses of cadmium); subsequently, staff recorded all products with detectable cadmium content for possible further evaluation.

Based on the results of screening, Compliance and Field Operations staff then followed up, as necessary, using the procedures outlined in Tab A, including requesting laboratory analysis and age determinations. From the information presented in Tab B for screening during surveillance of imports in 2010, 2011, and 2012, it appears that high levels of cadmium are detected infrequently.

VII. Conclusions

CPSC staff has brought to the standards development processes its knowledge of the potential hazards associated with cadmium in children's jewelry, as well as its experience in evaluating test methods and approaches for assessing product hazards. Staff considered children's behaviors, the toxicity of cadmium, product characteristics, and approaches to testing and evaluation of products.

CPSC surveillance and enforcement activities show that items of children's jewelry, or jewelry that may be similar to children's jewelry, that were manufactured, imported, or offered for sale from 2010 to 2012, generally do not contain high levels of cadmium and are compliant with the provisions of the children's jewelry voluntary standard. The data show that not all products conform to the optional cadmium content limit, but of those that exceeded the content limit, only three tested products exceeded the soluble cadmium limit. Staff also notes that some of the tested items exceeded the mandatory limit for lead content of children's products and that the presence of both lead and cadmium was detected in a small portion of samples. These findings suggest that whether requirements are mandatory (lead limits) or part of a voluntary standard (cadmium), high levels of conformance with standards can be achieved in these areas. Overall, staff believes that cadmium use in jewelry is not widespread and that the potential exposures to cadmium from children mouthing or swallowing jewelry items appear to be minimal.

While the petitioners requested that cadmium in children's jewelry be limited to no more than "trace amounts," this term was not defined. CPSC staff conducted a human-health risk assessment, which resulted in estimates of acceptable intake levels–exposure levels that should not be exceeded to avoid adverse health effects.[12] As discussed above, CPSC staff shared the results of this human-health risk assessment as part of our participation in the development of both ASTM standards, and staff contributed to discussions about the limits for cadmium in

[12] CPSC Staff Report on Cadmium in Children's Metal Jewelry. October 2010. Available at: http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf.

children's products. These limits are based on scientific analysis, and provide specific quantitative standards for evaluation of products.

Staff believes that the new children's jewelry standard and the amended toy safety standard are appropriate measures for reducing the risk of harm from exposure to cadmium in children's jewelry. The ASTM F 963 toy safety standard is a mandatory standard, as established by the CPSIA.

The benefits of a safety standard developed through the voluntary standards process include: quick implementation of the standard, a built-in process to modify and amend the standard relatively quickly based on new information or technologies, and multiple stakeholder involvement in the consensus process. Staff will continue to evaluate products and test methods, assess the application of the standards, and participate in the ASTM children's jewelry and toy safety subcommittees to ensure the health protectiveness of the standards' provisions. Staff will continue its enforcement activities to ensure a high level of compliance with both the voluntary and mandatory standards that apply to children's jewelry products.

VIII. Recommendation

Staff recommends that the Commission terminate the petition from the Empire State Consumer Project, the Sierra Club, the Center for Environmental Health, and the Rochesterians Against the Misuse of Pesticides.

TAB A: Compliance

TAB A

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

Memorandum

Date: June 5, 2012

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

THROUGH: Marc Schoem, Acting Director,
Office of Compliance and Field Operations
Mary Toro, Director, Division of Regulatory Enforcement,
Office of Compliance and Field Operations

FROM : John W. Boja, Ph.D., Lead Compliance Officer, Division of Regulatory Enforcement, Office of Compliance and Field Operations

SUBJECT : Reported Cadmium Levels in Children's Metal Jewelry

INTRODUCTION

The Office of Hazard Identification and Reduction requested that staff from the Office of Compliance and Field Operations ("Compliance") summarize the results of the Office of Compliance children's jewelry programs for use in a staff briefing package on petition HP 10-2, "Requesting Restriction of Cadmium in Toy Jewelry." Compliance has the responsibility of enforcing the regulations under the authority of the U.S. Consumer Product Safety Commission (CPSC or Commission) and provides advice and guidance to the regulated industry in complying with the regulations. Section 101 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) establishes limits for lead content and lead in paint and specifies that children's products that exceed the limits are banned hazardous substances under Section 2(q)(1) of the Federal Hazardous Substances Act (FHSA), 15 U.S.C. § 1261(q)(1). This limit was formerly 300 ppm; however, beginning on August 14, 2011, any item of children's jewelry that has a lead content in excess of 100 parts per million (ppm) cannot be manufactured, imported, distributed, sold, or offered for sale in the United States (or exported for sale, if previously distributed in the United States).

In addition to lead, cadmium has been detected in a number of children's metal jewelry items. Currently, cadmium is not a regulated substance in children's products; however, staff has recommended an acceptable daily intake (ADI) for acute exposure of 200 µg/day for young children (http://www.cpsc.gov/LIBRARY/FOIA/FOIA11/os/cadmiumjewelry.pdf). CPSC staff recommended that this level of exposure should not be exceeded to avoid adverse health effects. In response, the ASTM subcommittee on children's jewelry developed a voluntary standard (ASTM F-2923) that recommends a total maximal cadmium content and cadmium extraction limit.

Prior to development of the ASTM standard for children's jewelry, Compliance conducted a children's jewelry program in fiscal year (FY) 2011, to specifically determine compliance with mandatory lead limits and to assess the use of cadmium, as well as other metals listed in the ASTMF963-08 toy standard in the manufacturing of children's jewelry. The

FY 2011 program directed field staff to visit retail establishments that sell children's jewelry. Field staff was directed to select items of jewelry and screen them with an x-ray fluorescence (XRF) spectrometer. Staff was directed to collect any item of jewelry if the screening levels met or exceeded the following values:

Antimony (Sb) –	300 ppm
Arsenic (As) –	120 ppm
Barium (Ba) –	2,850 ppm
Cadmium (Cd) –	200 ppm
Lead (Pb) –	250 ppm
Mercury (Hg) –	200 ppm
Selenium (Se) –	2,500 ppm

During this enforcement program, a total of 711 items of children's metal jewelry were screened by XRF in 94 separate stores. As a result of those screenings, 147 items of jewelry were collected: 50 items for elevated lead readings, 20 items for elevated cadmium readings, 7 items for elevated lead and cadmium readings, and 69 items for elevated readings of the other metals listed in the toy standard.

All jewelry items collected were analyzed by CPSC laboratory staff for total lead, cadmium, and other metal content. Extraction tests for the metals, other than lead, were conducted when elevated levels of the metal were found. In addition, all jewelry items collected were age-graded by CPSC staff.

Of the 50 items of jewelry collected by field staff that demonstrated high XRF screening levels for lead, three were determined to have high levels of lead in the metal components by the lab using the methods outlined in CPSCCH-E1001-08.1. One of the three items contained lead in excess of 100 ppm and cadmium in excess of 300 ppm. These three items of jewelry were necklaces attached to children's clothing. These three items were recalled from consumers (Release #11-195, http://www.cpsc.gov/CPSCPUB/PREREL/prhtml11/11195.html). An additional 11 items of children's jewelry were removed from the marketplace or distribution chain, rather than being recalled. These items were not subject to a consumer recall, generally, because the lead was determined to be in a nonmetallic component of the jewelry. An additional 15 items of jewelry also demonstrated high levels of lead; however, CPSC staff determined that these items of jewelry were not primarily designed or intended by the manufacturer for a child 12 years of age or younger, and no action was taken on those items. In a few cases (9), the number of samples that could be collected was too few to be a representative sample. Those manufacturers or importers were scheduled for later inspections so that a full set of samples could be collected. The remaining 12 items of jewelry did not have excess lead according to a laboratory analysis.

Of the 22 items of jewelry that were collected by field staff due to high XRF screening levels of cadmium, eight items were confirmed by the methods outlined in CPSCCH-E1001-08.1 to have more than 300 ppm of cadmium and were subjected to cadmium extraction tests. Two items were determined not to be children's products while four other items did not release more than 200 µg of cadmium. A seventh item did not have sufficient documentation in order to allow for further action. The retailer was requested to destroy any remaining inventory. The last item of jewelry contained cadmium in a painted area of the jewelry; however, there was less than

10 mg of paint present on the item of jewelry, an amount that is less than the minimum level required for analysis in the toy standard; and therefore, no further action was taken.

Seven items of jewelry were collected by the field due to high XRF screening levels for both lead and cadmium; one item was found to contain more than 100 ppm of lead and more than 300 ppm of total cadmium content (see the above recall). Two items were determined not to contain excessive levels of lead or cadmium. CPSC staff determined that the remaining four items of jewelry were not primarily designed or intended by the manufacturer for a child 12 years of age or younger. All four of these items contained lead in excess of 100 ppm, while two of the items also contained cadmium exceeding 300 ppm.

Sixty-nine items of jewelry were collected for metals other than lead or cadmium. Most items were determined to have less than 100 ppm of antimony, arsenic, mercury, and selenium, and less than 200 ppm of barium. One item of jewelry contained 4,270 ppm of barium in a plastic component. Another item of jewelry contained 15,200 ppm of antimony, but less than 0.5 µg of antimony was extracted after 24 hours. A third item of jewelry contained antimony in the crystals in a concentration that ranged from 13,186 to 32,996 ppm.

Three additional items of jewelry were collected from an importer during an annual lead compliance program conducted during FY 2011. These three items of jewelry were collected by field staff due to high XRF cadmium screening levels. The items of jewelry were shown to have more than 300 ppm of cadmium by the methods outlined in CPSCCH-E1001-08.1 and were subjected to cadmium extraction tests. The average extractable amount of cadmium exceeded 200 µg in two cases, while in the third item an average of 150 µg was extracted. The importer stated that these three items of jewelry were no longer being distributed and the importer was requested to destroy any remaining inventory.

Because the FY 2011 children's jewelry program examined large retailers of children's jewelry, the FY 2012 program focused on small retailers with low-cost jewelry. The Compliance program was scheduled to run from February to May of 2012. The FY 2012 Low-Cost Jewelry program directed field staff to visit smaller retail establishments that sold low-cost children's jewelry. Field staff was directed to select items of jewelry and screen them with an XRF spectrometer. Staff was instructed to collect any item of jewelry if the screening levels met or exceeded the following values:

Cadmium (Cd) –	300 ppm
Lead (Pb) –	125 ppm

During this program, 217 items of children's metal jewelry have been screened by XRF from 45 separate stores. As a result of those screenings, 37 items of jewelry were collected; 28 items were collected for elevated lead readings, 5 items were collected for elevated cadmium readings, and 4 items were collected for elevated lead and cadmium readings.

All items of jewelry that were collected were analyzed by CPSC laboratory staff for total lead, cadmium, and other metal content. Extraction tests for metals other than lead were conducted when elevated levels of the metal were found. In addition, all items of collected jewelry were age-graded by CPSC staff.

Only four of the nine items of jewelry that were collected for either elevated cadmium readings or elevated cadmium and lead readings were determined to have more than 300 ppm of

cadmium. A 24-hour cadmium extraction test was conducted on each of those four items. The results of those tests are presented below:

Item	Age (preliminary)	Total Cadmium Content	24-hr Extraction
Earrings	12 and under	6,220 ppm	2.6 µg
Earrings	9 and older	9,160 ppm	1.3 µg
Earrings	13 and older	10,300 ppm	42.0 µg
Ring	12 and under	4,630 ppm	45.0 µg

In addition to containing cadmium, all four items demonstrated a lead content that exceeded 100 ppm. Appropriate action will be taken on those items of jewelry that contain excessive lead. However, no item of jewelry appears to contain extractable cadmium above the recommended 200 µg limit.

On March 13, 2012, HealthyStuff.Org, reported results for 99 jewelry items they had collected and tested (http://www.healthystuff.org/get-stuff.php?report=Low-Cost+Jewelry+Ranks+HIGH+for+Toxic+Chemicals). They reported excessive levels of selected metals, including lead and cadmium, in the products. Compliance staff reviewed the 99 items that were alleged to have lead and/or cadmium in excess of the limits. Of those items, staff identified 14 items that might possibly be considered children's jewelry and Compliance management instructed field investigators to collect those 14 items.

Of those 14 items identified by staff, five items could not be found at retail stores based on the limited information available from HealthyStuff.Org. The remaining nine items were sampled by CPSC staff. Seven items were determined by staff not to be primarily designed or intended by the manufacturer for a child 12 years of age or younger; and the remaining two items of jewelry were tested and evaluated. Neither item was determined to have excessive levels of either metal.

TAB B: Import Surveillance

TAB B

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

Memorandum

May 29, 2012

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

THROUGH: Robert J. Howell, Deputy Executive Director for Safety Operations
Carol Cave, Director, Office of Import Surveillance and Inspection

FROM : Hank Tapy, Supervisory Compliance Investigator, Office of Import Surveillance and Inspection

SUBJECT : Import Surveillance Response to the Cadmium Petition

In accordance with sampling guidance issued by the Office of Compliance and Field Operations, the Office of Import Surveillance and Inspection (EXIS) began recording cadmium content levels in excess of 20,000 parts per million (ppm) in children's metal jewelry starting in May 2010.

In March 2012, EXIS began to record any cadmium content levels screened above the level of detection of the device for all consumer products evaluated.

In addition, EXIS has screened for cadmium in the surface coatings of toys since the adoption of ASTM F963-08 as the mandatory toy standard in August 2009.

In all cases, cadmium content for imported consumer products is screened through the use of a handheld X-Ray Fluorescence (XRF) device.

The voluntary standard for children's jewelry under ASTM F 2923-11 and the mandatory standard for children's toys under ASTM F 963-11 require that solubility testing be performed to determine the migratable cadmium content. The XRF device cannot determine the level of migratable cadmium, only total cadmium content.

The following table displays the number of products examined that would have been sampled and analyzed by the CPSC Laboratory had ASTM F 2923-11 and F 963-11 been enforceable at the time of screening. As the standards were not in place, only a subset of these products that were suspected of violating another standard, such as the ban on lead content, were sampled and analyzed. For violation information for products collected both at importation and domestically, see the memorandum from John W. Boja, Ph.D., Lead Compliance Officer, Division of Regulatory Enforcement, Office of Compliance and Field Operations included as TAB A of this briefing package. It is important to note that, even though products may screen above the threshold, the amount of migratable cadmium may be determined to be within the acceptable level after laboratory analysis is performed. Therefore, just because a product is above the screening threshold, there can be no determination regarding the product's compliance to the applicable standard until the amount of migratable cadmium is determined.

	Products Screened at Import October 1, 2009 through May 17, 2012			
	Products Screened that Indicated Possible Cadmium Content in excess of 90ppm for Surface Coatings or 300ppm for Substrate			Total Screenings Performed
	Children's Jewelry	Toys	Other Products	
FY 2010	12	1	16	7,011
FY 2011	5	1	7	9,923
FY 2012	0	4	6	9,391

In FY2010, there were 12 styles of children's jewelry that screened at or above the cadmium threshold established by ASTM F 2923-11; one toy recorded a cadmium screening at or above the thresholds established by ASTM F 963-11; and, for purposes of comparison, 16 other products screened above 300pppm for cadmium. These other products included six styles of adult jewelry (under CPSC jurisdiction but not regulated), five styles of children's shoes (a regulated product for which there is no cadmium standard), and 5 products either jointly or independently under FDA jurisdiction such as dinnerware, drinking mugs, and cutlery. In FY2010, children's jewelry accounted for approximately 9% of all consumer product screenings; toys accounted for approximately 51% of all screenings; and all other products accounted for the remainder (40%).

In FY2011, there were five styles of children's jewelry that screened at or above the cadmium threshold established by ASTM F 2923-11; one toy recorded a cadmium screening at or above the thresholds established by ASTM F 963-11; and, for purposes of comparison, seven other products screened above 300pppm for cadmium. These other products included three styles of adult jewelry (under CPSC jurisdiction but not regulated), one item of an adult Halloween costume accessory (under CPSC jurisdiction but not regulated), and three products either jointly or independently under FDA jurisdiction such as dinnerware, drinking mugs, and cutlery. In FY2011, children's jewelry accounted for approximately 11% of all consumer product screenings; toys accounted for approximately 49% of all screenings; and all other products accounted for the remainder (40%).

In FY2012 (through May 17, 2012), there were no instances of cadmium in children's jewelry screened at or above the threshold established by ASTM F 2923-11; four toys recorded a cadmium screening at or above the thresholds established by ASTM F 963-11; and, for purposes of comparison, six other products screened above 300pppm for cadmium. These other products included four styles of children's shoes (a regulated product for which there is no cadmium standard), a child's bank (a regulated product for which there is no cadmium standard), and a child's lunchbox (a product under joint CPSC/FDA jurisdiction). In FY2012, children's jewelry accounted for approximately 4% of all consumer product screenings; toys accounted for approximately 48% of all screenings; and all other products accounted for the remainder (48%).