



**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: August 30, 2011

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: Philip L. Chao, Assistant General Counsel
Hyun S. Kim, Attorney

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

BALLOT VOTE Due: September 6, 2011

Attached is CPSC staff's update on the petition submitted by the Empire State Consumer Project, the Sierra Club, the Center for Environmental Health, and the Rochesterians Against the Misuse of Pesticides regarding cadmium in toy metal jewelry. Previously, on February 9, 2011, CPSC staff submitted a briefing package for Commission consideration. The Commission voted to defer its decision for 6 months and directed staff to participate in the ASTM subcommittees that develop standards for children's metal jewelry and for toy jewelry. The attached report updates the Commission on the status of these efforts.

CPSC staff recommends that the Commission defer its decision on the petition an additional 6 months and direct staff to continue its participation in the ASTM F15.24 subcommittee to develop a voluntary standard addressing accessible cadmium from children's metal jewelry, as well as continue its participation in the ASTM F15.22 subcommittee to amend the ASTM F963 toy safety standard (Defer Option II). If the Commission votes to defer its decision for 6 months, then at the end of the 6-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 pursue other Commission action as discussed in the February 9, 2011 briefing package.

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)

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

(Signature)

(Date)

II. Defer the petition for an additional 6 months and direct staff to continue its participation in the ASTM F15.24 subcommittee to develop a voluntary standard addressing accessible cadmium from children’s metal jewelry, as well as continue its participation in the ASTM F15.22 subcommittee to amend the ASTM F963 toy safety standard.

(Signature)

(Date)

III. Deny the petition.

(Signature)

(Date)

IV. Take other action (Please specify).

(Signature)

(Date)

Attachment:

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



UNITED STATES
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Memorandum

Date: August 30, 2011

TO : The Commission
Todd A. Stevenson, Secretary

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

FROM : DeWane Ray, Acting 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.

The petitioners also asserted 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 processors to test toy metal jewelry for cadmium.

II. Previous Staff Conclusions and Recommendation

Staff prepared a briefing package for Commission consideration, which was transmitted to the Commission on February 9, 2011. In its consideration of Petition No. HP 10-2, Requesting Restriction of Cadmium in Toy Jewelry, staff assessed the information 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 supported a conclusion that children may sometimes swallow jewelry; and testing of cadmium-containing children's

metal jewelry and other metal items by CPSC staff indicated that cadmium can migrate from products in amounts that could be associated with adverse health effects in children. Based upon the potential for exposure to cadmium from cadmium-containing metal jewelry and the known hazards of ingestion of cadmium, 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 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 Consumer Safety Specification for Toy Safety (ASTM F 963) for 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.

III. Commission Action

On February 16, 2011, the Commission voted unanimously to defer its decision and directed staff to participate in the ASTM subcommittees.

IV. Other Standards

Other Standards

Previously, staff described several mandatory standards that have been established for cadmium in jewelry and reiterates those descriptions below. Since the February 9, 2011, staff briefing package, two new standards—in Maryland and in the European Union—were published. As indicated below, these new standards, as well as two standards already implemented (California and Connecticut) will take effect in the coming months and years. Two standards, in Illinois and Minnesota, are already in effect. The standards are described below and summarized in Table 1. In addition, a number of other states are considering or have considered legislation related to cadmium in children's jewelry. To date, however, no legislation has been enacted other than in the states listed herein and in the European Union.

California¹

Legislation signed into law on September 25, 2010 (Senate Bill 929 of 2010), amends California's Health and Safety Code to restrict cadmium in children's jewelry to no more than 0.03 percent cadmium (300 parts per million) by weight. The restriction takes effect on January 1, 2012. "Children" are defined as 6 years of age and younger; "children's jewelry" means

¹ State of California. Health and Safety Code Sections 25214.1-25214.4.2. Available at <http://www.leginfo.ca.gov/calaw.html>. Last accessed 7/21/2011.

jewelry that is made for, marketed for use by, or marketed to, children, and the definition includes, broadly, 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 (CPSIA).

Connecticut²

Connecticut Public Act 10-113, signed into law on June 4, 2010, restricts cadmium in children's jewelry to 0.0075 percent (75 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 specifically address toy jewelry.

Illinois³

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 ASTM 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.

Maryland⁴

In 2011, the state of Maryland enacted a requirement for the total amount of cadmium in children's jewelry, limiting cadmium to no more than 0.0075 percent (75 ppm) by weight. The requirement applies to the manufacture, sale, offer for sale, or distribution of products as of July 1, 2012. "Children's jewelry" includes: any charm, bracelet, pendant, necklace, earring, or ring, and any component of jewelry for children younger than 13 years of age. The law excludes toy jewelry regulated under the CPSIA.

Minnesota⁵

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 6 years and younger). The restriction is for soluble cadmium, at 75 ppm, based on ASTM F 963. The law became effective on January 1, 2011, for manufacturers and wholesalers and on March 1, 2011, for retailers. The legislation does not apply to toys regulated for cadmium exposure by ASTM F 963.

² State of Connecticut. Available at: <http://www.cga.ct.gov/2010/ACT/PA/2010PA-00113-R00HB-05314-PA.htm>. Last accessed 7/21/2011.

³ 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 7/21/2011.

⁴ State of Maryland. Article-Environment. Title 6. Subtitle 14: Cadmium in Children's Jewelry. Annotated Code of Maryland. Available at: http://www.mlis.state.md.us/2011rs/chapters_noln/Ch_578_hb0145E.pdf. Last accessed 7/20/2011.

⁵ 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 7/21/2011.

European Union⁶

On May 20, 2011, the European Union, with Commission Regulation (EU) No 494/2011, amended Annex XVII to Regulation (EC) No 1907/2006, restricting the marketing and use of cadmium. The amendment restricts cadmium content of metal jewelry parts to 0.01 percent (100 ppm) by weight. The amendment does not specifically address toy jewelry or children's jewelry. In addition to metal jewelry items, the amendment restricts cadmium in plastics to 100 ppm, with the exception of PVC recovered for certain construction purposes. The restrictions take effect on December 10, 2011.

Jurisdiction	Scope	Standard	Effective Date
California	Children's jewelry; 6 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: 0.0075 percent cadmium (75 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
Maryland	Children's jewelry; under 13 years of age; does not apply to toys	Total content: 0.0075 percent (75 ppm) by weight	July 1, 2012
Minnesota	Surface coating or accessible substrate material of metal or plastic components of children's jewelry; age 6 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 parts; plastic	Total content: 0.01 percent (100 ppm) cadmium by weight	December 10, 2011

⁶Commission Regulation (EU) No 494/2011 Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:134:0002:0005:en:PDF>; corrigendum at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:136:0105:0105:EN:PDF>. Last accessed 7/21/2011.

V. Update

Previously, staff indicated that a new voluntary standard that would include limits for migration of cadmium from children's jewelry items was under development and was expected to be completed in 2011.

Staff also indicated that 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 items. 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 has focused on metal jewelry because the available data indicated 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 may assess additional types of products when data become available.

Staff brought this knowledge to the ASTM subcommittees, and contributed to discussions about the types of products that should be included in a standard and the form of the limits (*e.g.*, total content or extractable) on cadmium in children's products.

ASTM F15.24 Children's Jewelry Subcommittee

The ASTM F15.24 subcommittee was charged with developing a voluntary standard addressing cadmium in children's metal jewelry. Because children's jewelry has not previously been subject to a safety standard—unless products were also considered to be a children's toy—this subcommittee chose to develop a standard for children's jewelry that addressed a number of other potential hazards, such as hazardous magnets, certain chemicals in surface coatings, and contact with nickel.

Scope

"Children's jewelry" is defined in the voluntary standard as jewelry designed or intended primarily for use by children 12 years of age or under, which is consistent with the statutory definition of a children's product. "Jewelry" is defined broadly as a product principally designed and intended as an ornament worn by a person, with a number of specific examples provided, including bracelets, chains, necklaces, and earrings.

Cadmium Standard

The children's jewelry standard includes several restrictions for cadmium.

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 ppm), based on the weight of the dried paint film, using a specified laboratory test.

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 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 will be 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, 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, in which staff concluded that a result for the 24-hour acid extraction test 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 based on acute toxicity.

Plastic components will be subject to cadmium migration testing as is currently done for 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 will be 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, 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.

Staff, as well as some participants in the voluntary standards development process, believes that firms will tend to avoid the use of cadmium or cadmium-containing alloys in manufacturing children’s jewelry, because intentional uses of cadmium or cadmium-containing materials would likely result in cadmium content greater than 300 ppm. Because conformance with the ASTM voluntary standard may be demonstrated through testing products for total cadmium content, which can be done concurrently with mandatory testing for lead content, a firm can avoid the additional solubility testing for products with cadmium content less than 300 ppm. In addition, other standards exist that restrict the cadmium content of jewelry to less than 300 ppm, such as the EU regulation that limits cadmium in jewelry to no more than 100 ppm.

Table 2. Children’s Jewelry Cadmium Requirements		
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
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

Timeline

In spring 2011, the ASTM F15.24 subcommittee completed development of the draft standard and began the review and approval process. The draft standard was balloted to the main ASTM F15 committee in June 2011, with voting completed in July 2011. Two negative votes were cast, which addressed issues of the scope, style, and format of the draft standard, definitions, and the basis of the cadmium restriction (solubility rather than total content). Negative votes must be addressed through procedures established by ASTM. Accordingly, the subcommittee chair prepared responses to each issue in two new F 15 ballot items. The ballot opened August 11, 2011 and closes September 10, 2011. If these items are found “not persuasive,” then the draft will be reviewed through the internal ASTM International processes and prepared for publication. With publication of the standard, firms could then test and confirm conformance to the standard.

Discussion

The benefits of developing a safety standard 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. While the standard would allow the use of cadmium at concentrations greater than 300 ppm—with the condition that the cadmium does not migrate out of the product—staff believes that, based on available data 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. 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 done with little change in testing costs. While the standard development process is not yet complete, staff expects the draft standard to be finalized in 2011.

ASTM F15.22 Toy Safety Subcommittee

While the definition of “children’s jewelry” may encompass a variety of products, including toy jewelry, staff believes that most products considered to be “children’s jewelry” are not toy jewelry, and therefore, would be subject to the ASTM children’s jewelry standard. However, any jewelry products intended for children that are not subject to the children’s jewelry standard, and which are considered to be toys, would be subject to the ASTM F 963 toy safety standard, which was made a mandatory standard by section 106 of the CPSIA.

Previously, staff indicated that 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. Currently, only paints and surface coatings are subject to the requirements for cadmium and other chemicals. Amendments to the standard would apply restrictions to the non-paint materials in toys, such as plastics and metal.

The ASTM F15.22 subcommittee established a working group charged with developing an amendment to the ASTM F 963 toy safety standard addressing cadmium in toy jewelry and other toy products.

Scope

The standard establishes certain requirements for cadmium in toys, as well as the other chemical elements that had previously been restricted only for paints and surface coatings.⁷ In addition to paints and surface coatings, the standard would limit cadmium and several other chemicals in plastics, 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 those toys and toy parts that are accessible. Toys and parts of toys which, 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 the following criteria are reasonably appropriate for the classification of toys or parts likely to be sucked, mouthed, or ingested:

- All toy parts intended to be mouthed or come in contact with food or drink, components of toys that are cosmetics, and components of writing instruments categorized as toys;
- Toys intended for children under 6 years of age (*i.e.*, 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 toy safety standard, as amended, will include several restrictions for cadmium.

Currently, the standard covers paints and surface coatings, restricting the solubility or migration of cadmium and other chemical elements from surface coatings. 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 amendments to the standard would also restrict 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 would be subject to additional testing to determine the migration of cadmium using a laboratory test specific to such products. This test, in which the item to be tested is placed in a heated acid solution and agitated for 24 hours, is based on work by CPSC staff that showed 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 parts subject to this test is 200 µg cadmium per component part.

The 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), the solubility testing may be omitted.

⁷ Antimony, arsenic, lead, barium, cadmium, chromium, mercury, and selenium.

Table 3. Toys Cadmium Requirements		
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	75ppm (50 ppm for modeling clay toys)	Total cadmium content (may replace solubility tests)
Metal small parts	200 µg	Solubility; specified acid solution and procedure

Timeline

In spring 2011, the working group under the ASTM F15.22 subcommittee completed development of the draft standard, presented it to the subcommittee membership at the May 17, 2011, subcommittee meeting, and began the review and approval process. The draft standard was balloted to the main ASTM F15 committee in June 2011, with voting completed in July 2011. Several negative votes were cast and must be addressed through procedures established by ASTM. Accordingly, the working group chair will attempt to resolve the issues, and another committee ballot may be required. The draft will then be reviewed through the internal ASTM International processes and prepared for publication. With publication of the standard, firms could then test and confirm conformance to the standard.

Discussion

The ASTM F 963 toy safety standard is a mandatory standard as established by the CPSIA. As with the jewelry standard, the benefits of developing a safety standard through the ASTM voluntary standards process include quick implementation of the standard, a built-in process to relatively quickly modify and amend the standard based on new information or technologies, and multiple stakeholder involvement in the consensus process.

While the standard would allow the use of cadmium at concentrations greater than 75 ppm, on 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 choose to produce products without cadmium or with cadmium content no more 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 done with little change in testing costs. While the standard development process is not yet complete, staff expects the draft standard to be finalized in 2011.

VI. Inter-Laboratory Study

During the children's jewelry standard development process, some participants in the ASTM F15.24 subcommittee expressed that the analytical method used to measure the migration of cadmium from small metal parts had not been evaluated for inter-laboratory variation. This method involves subjecting the product or component to a heated and agitated acid solution for

24 hours to evaluate potential exposure to cadmium from items that may be swallowed by a child.

CPSC's Directorate for Laboratory Sciences Chemistry Division staff is participating in a round-robin inter-laboratory study (#0688, administered by ASTM), to evaluate the test method. The goal of this study is to determine inter-laboratory variation in a documented and statistically valid way. Participants include more than 30 laboratories on at least two continents. The study materials include five wire samples with varying cadmium concentrations. Each participating laboratory will conduct the specified tests and submit analytical results through an ASTM administered web portal for statistical analysis. To date, the study materials have been prepared and packaged for shipping, awaiting confirmation of participants' shipping addresses. Participants have met, via conference call, to discuss questions or concerns prior to initiating the analyses. The study is expected to be completed by fall 2011.

VII. 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, which said that 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 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, or in person, to collaborate and discuss each agency's ongoing efforts to address the potential hazards of cadmium in consumer products. By letter dated May 2, 2011 (Appendix A), CPSC staff requested assistance in obtaining data and other information related to the use or presence of cadmium and cadmium compounds in children's products and other consumer products. Staff indicated that the information will be used to identify the extent of cadmium use in consumer products and help focus staff's work on identifying products for testing and evaluation, conducting exposure and risk assessments for cadmium from products, and developing recommendations for further Commission action regarding cadmium in products. After receiving the letter, EPA staff agreed to initiate 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 to the EPA unpublished health and safety studies. EPA staff expects this work to be completed in fall 2011, and they anticipate that data submissions would start in early calendar year 2012. EPA staff also described a rulemaking process that would require unpublished health and safety studies from processors and distributors. The date for completion of a proposed rule, which would include review by the Office of Management and Budget (OMB), is less clear; however, EPA staff indicated that it could be early 2012.

In a separate action, EPA's TSCA Interagency Testing Committee (ITC) transmitted its Sixty-Eighth Report to the EPA Administrator on June 14, 2011.⁸ The report added cadmium and 103 cadmium compounds to TSCA section 4(e) Priority Testing List. 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.

VIII. 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 to assessing product hazards. Staff has considered children's behaviors, the toxicology of cadmium, product characteristics, and approaches to testing and evaluation of products.

Staff believes that the new children's jewelry standard and the amended toy safety standard, when finalized, will be appropriate measures for reducing the risk of harm from exposure to cadmium in children's jewelry. Staff expects the draft standards to be finalized in 2011.

IX. Recommendation

Staff recommends that the Commission defer its decision on the petition from the Empire State Consumer Project, the Sierra Club, the Center for Environmental Health, and the Rochesterians Against the Misuse of Pesticides for an additional 6 months. Staff further requests that the Commission direct staff to continue its participation in the ASTM F15.24 subcommittee toward the development of a voluntary standard addressing accessible cadmium from children's metal jewelry. Likewise, staff suggests that the Commission allow staff to continue their participation in the ASTM F15.22 subcommittee in developing amendments to the ASTM F 963 toy safety standard. If the Commission votes to defer its decision for 6 months, then at the end of the 6-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 and to assess the effectiveness of the voluntary standards once they are implemented, or decide instead to pursue other Commission action.

⁸ 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.

APPENDIX A



U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY, BETHESDA, MD 20814

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

Tel: 301-504-7254
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Email: khatlelid@cpsc.gov

Via e-mail

May 2, 2011

Maria J. Doa, Ph.D.
Director, Chemical Control Division
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, DC 20460
Doa.Maria@epa.gov

Re: Use of cadmium in consumer products and related health and safety information

Dear Dr. Doa:

The U.S. Consumer Product Safety Commission (Commission or 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. We docketed the request as a petition under the Federal Hazardous Substances Act (FHSA). CPSC staff prepared a briefing package containing technical analysis and recommendations for the Commission. On February 16, 2011, the Commission voted unanimously (5-0) to defer the decision on the petition for regulations on cadmium 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 toy safety standard for toy jewelry. By mid-August 2011, staff will update the Commission on progress made on the voluntary standards and address whether any information concerning industry compliance with the standards is available.

The petitioners also directed their request to the U.S. Environmental Protection Agency (EPA). The EPA responded to the petitioners by letter dated August 30, 2010, stating that the EPA would use its Toxic Substances Control Act (TSCA) section 8(d) authority to request submission of unpublished health and safety studies relevant to the determination of whether a potential hazard exists and whether a product may be a banned hazardous substance under CPSC guidelines. The EPA's letter further stated that it would work closely with the CPSC to determine the most effective means of addressing cadmium in toy metal jewelry, in addition to considering additional rulemaking, if necessary.

Through this letter, CPSC staff requests assistance in obtaining data and other information related to the use or presence of cadmium and cadmium compounds in children's products and

other consumer products. This information will be used to identify the extent of cadmium use in consumer products and help focus staff's work on identifying products for testing and evaluation, conducting exposure and risk assessments for cadmium from products, and developing recommendations for further Commission action regarding cadmium in products.

CPSC staff seeks data and information related to consumer products or materials and components that may be used in the manufacture of consumer products (both domestic and foreign production), including:

- Descriptions of the use of cadmium or cadmium compounds in a product, material, or component, including typical and maximum concentration;
- Identification of cadmium alloys or cadmium compounds used in a product, material, or component;
- Function of the cadmium or cadmium compounds in the product, material, or component;
- Data on volume of production of the product, material, or component;
- Data on human exposure to the product, material, or component;
- Data on bioavailability and bioaccessibility of cadmium from the product, material, or component;
- Toxicity data on the cadmium-containing alloy or cadmium compound, including *in vitro*, *in vivo*, epidemiological, computational, or other studies on effects of exposure to or use of the cadmium-containing product, material, or component.

CPSC staff requests that CPSC and EPA staff meet no later than June 15, 2011 to discuss the EPA activities related to developing and collecting the data and information, and the projected timeline for completion of EPA work and transmission of the collected information to the CPSC. We look forward to your response and continued collaboration on this important issue.

Sincerely,

/s/

Kris Hatlelid, Ph.D., M.P.H.

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