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Via email to C&F@hc-sc.gc.ca

Consumer Product Safety Directorate
Health Canada
123 Slater Street, 4th floor
Address Locator: 3504D
Ottawa, Ontario
K1A 0K9

Re: Comments on Draft Proposal for Cadmium Guideline in Children's Jewelry

Dear Sir or Madam:

On behalf of the members of the Fashion Jewelry and Accessories Trade Association ("FJATA"), we appreciate this opportunity to submit comments in response to the *Draft Proposal for Cadmium Guideline in Children's Jewelry* ("Proposal").[1] FJATA is the voice of the jewelry and accessories industries in the United States, representing over 225 manufacturers, suppliers, and retailers, from small independent businesses to large multi-national corporations. Many of our members and their customers distribute children's jewelry in Canada and thus are vitally interested in assuring that these requirements reflect the best available technical data and are consistent between our important trading markets. We are pleased to comment on the Proposal and also to share important information on our efforts to promote science-based standards for safe children's jewelry.

FJATA members have a strong commitment to consumer safety, supporting science-based standards for cadmium in children's jewelry. As Chair of the ASTM International F15.24 Subcommittee on Children's Jewelry, we are pleased to inform you of the approval by the ASTM International membership of the Children's Jewelry Safety Standard. This will be the first comprehensive international standard on children's jewelry.[2] The standard addresses cadmium, lead, heavy metals in surface coatings, nickel, and physical hazards posed by batteries

[1] Draft Proposal for Cadmium Guideline in Children's Jewelry, Document for Public Comment, Health Canada, Consumer Product Safety Directorate (July 2011).

[2] Consistent with the U.S. Consumer Product Safety Improvement Act of 2008 ("CPSIA"), the standard applies to children's jewelry, defined as jewelry designed and intended primarily for children 12 and younger.

and magnets, among other issues. A diverse group of stakeholders, including consumer representatives, testing laboratories, industry groups, retailers, many members of the U.S. Consumer Product Safety Commission ("CPSC") staff, and Sarah Sheffield of Health Canada, were involved in the development of the standard.

At the request of the CPSC, Subcommittee members carefully examined CPSC data, and also evaluated industry data on the range of total cadmium and potential for cadmium to be released from metal and plastic components of children's jewelry in developing the recommended limits for cadmium. The ASTM Children's Jewelry Safety Standard includes a 300 ppm total cadmium content screening limit for metal and plastic components of jewelry, coupled with migration standards for plastic or metal components that exceed the screening limit. The migration tests vary depending on whether potential exposures relate to possible ingestion (in which case acid extraction tests are required), or to mouthing (in which case a simulated saliva test is required).

Exemptions apply to all other materials (*e.g.*, crystal, glass, gemstones, natural materials, etc.) based on the absence of any data suggesting that levels of cadmium pose a risk to children in these materials.

CPSC staff has concluded that the approach taken by the ASTM Children's Jewelry Safety Standard is health protective in a recent briefing provided to the CPSC Commissioners.[3] In fact, the 300 ppm total content screen and CPSC's decision to support the ASTM Children's Jewelry Safety Standard were based on CPSC's toxicology assessment for cadmium exposure which yielded much more conservative exposure rates than those derived by Health Canada. CPSC concluded that for a product that may be mouthed by a child, but is not likely to be ingested, migration tests should not yield more than 18 µg in a 6-hour saline extraction test.[4] For a metal product or part of a product that may be swallowed by a child, the CPSC staff concluded that a 24-hour acid extraction test should not yield more than 200 µg.[5] The CPSC has developed a new 24 hour test method, which is now undergoing a round robin inter-laboratory study to evaluate its methods.[6] Both of CPSC's recommended exposure limits are significantly *lower* than the exposure rate used by Health Canada in establishing a 130 ppm total content limit, which was 0.9516 mg or about 952 µg. Expressed another way, Health Canada's recommended exposure limit is 4.75 times greater than CPSC's recommended acute exposure limit of 200 µg, and more than 52 times greater than CPSC's chronic exposure limit of 18 µg.

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[3] *See* Memorandum from DeWayne Ray and Kristina M. Hatlelid, Staff Update re: Petition HP 10-2, Requesting Restriction of Cadmium in Toy Jewelry, August 30, 2011, p. 11, *available at http://www.cpsc.gov/library/foia/foia11/brief/cadmiumpetupd.pdf* ("August 30, 2011 Cadmium Briefing").

[4] Consumer Product Safety Commission Staff Report: Cadmium in Children's Metal Jewelry, October, 2010, p. 9, *available at* http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf ("Cadmium Staff Report").

[5] Cadmium Staff Report at 9.

[6] *See* August 30, 2011 Cadmium Briefing, at p. 10 ("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 [24 hour] 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.").

In addition to the health protective nature of the ASTM Children's Jewelry Safety Standard, the value of a preliminary screening level based on sound science, such as 300 ppm, is that members of the supply chain will seek conformity to the screening limit as migration testing may be more expensive.[7]

A 130 ppm total cadmium limit without exemptions, however, could result in an outright ban on many safe products and prove unmanageable in practice due to the well-established issue of inter-laboratory variability in even total content test results, and the inherent variability in component sourcing. The failure to exempt specific materials known not to pose a risk also will pose problems to the supply chain without enhancing actual consumer safety.

Therefore, as explained in more detail below, FJATA opposes the Health Canada proposal and urges Health Canada to adopt the requirements for cadmium reflected in the ASTM Children's Jewelry Safety Standard, which is based on extensive and controlled testing of metal jewelry samples by an independent third party testing laboratory accredited by CPSC, Mutual Cornell ("Mutual Cornell").[8] Both of these reports are enclosed as they represent important technical data that we urge Health Canada to carefully review.

FJATA provides below an overview of cadmium use, and a summary of the available data on which the ASTM Children's Jewelry Safety Standard's cadmium limits were based. FJATA has also reviewed the data Health Canada relied on in the Proposal and illustrates below that Health Canada's data further supports the health protective nature of adoption of limits consistent with the ASTM Children's Jewelry Safety Standard. FJATA therefore urges Health Canada to review the enclosed data and to adopt an approach, similar to the ASTM Children's Jewelry Safety Standard that ensures any restrictions are based on sound science and are in harmony with the best available current scientific data on the behavior of cadmium in children's jewelry.

Cadmium: Where and Why Is It Present in Jewelry?

Cadmium has been used for decades in both fashion and fine jewelry products without reports of adverse health effects in adults or children at levels historically used.[9] A wide variety of different materials may be used in jewelry, including base metals like zinc or tin; plating metals, such as copper, nickel, sterling silver, or karat gold; glass and crystal; plastic; wood; solder; filament; textiles; epoxies; enamelwork; paint and surface coatings; natural elements like seeds; and more. Thus, cadmium may be present in substrate materials used to make jewelry, such as metal, as well as in paint and surface coatings, and may be present in components such as plastics or crystal, where it is typically used to impart color.

The principal danger of cadmium has long been associated with inhalation exposure. This is not a route of exposure that consumers, including children, face from wearing, mouthing or even

[7] *See* August 30, 2011 Cadmium Briefing, at p. 6.

[8] Exponent Technical Report, *Evaluation of Cadmium in Metal Jewelry*, November, 2010.

[9] *See* Proposal at 3 ("no reported incidents of cadmium poisoning were found following ingestion of jewelry.").

accidentally ingesting jewelry.[10] In talking with experts and stakeholders, including U.S. and Canadian health officials, there is general agreement that the primary exposure route involves accidental ingestion, a very unique, occasional situation involving an acute potential hazard, normally associated with levels higher than those associated with chronic (daily) exposures.

While we understand that there are no reports of actual injury, our industry shares concerns that children who may accidentally ingest a jewelry component should not be exposed to dangerous levels of cadmium. That is why our industry strongly supported the ASTM International approach to restricting cadmium by applying a screening limit that is well below levels that could actually be supported based on the available technical data.

Cadmium is a heavy metal found in nature. It is in soil and in rocks, so is found with ores used in metals to make jewelry. Cadmium is therefore often present, typically in trace amounts, in metal components, such as zinc or tin, used to make children's jewelry. Through the alloying process, where a metal such as tin may be combined with other metals, like antimony, bismuth and copper, additional trace amounts of cadmium may also be combined into the alloy. Cadmium may also be incorporated into the final plated product through low, trace amounts that are present in plating materials. As a result, even "low cadmium" metals widely used in the fashion jewelry industry, when alloyed into an appropriate casting alloy and electroplated, will not be free of cadmium because naturally occurring amounts of cadmium may be present in the alloying and plating process.

Precise control of these levels is not always possible. Small amounts of cadmium may be added to metals used to make jewelry to impart specific technical and functional attributes to the metals, especially for adult jewelry. Cadmium may be alloyed with tin to improve melt and flow, resulting in an ability to obtain filigree effects often seen in adult jewelry, and may also improve strength since tin is an inherently brittle material.

In precious metal jewelry, including karat gold jewelry and sterling silver jewelry, and in fashion jewelry, one of the principal longstanding uses of cadmium in jewelry is as a component in solders used in joining jewelry components, typically at an *average* level of about 300 ppm. These solders melt and flow better at a lower temperature than non-cadmium solders. Cadmium solder is also used in gold and silver solder-filled wire, where levels can vary widely. Cadmium-based solders are being reformulated to reduce cadmium levels, but in setting limits Health Canada should be mindful of recycling practices, especially in the fine jewelry sector.

Many new karat gold and sterling silver alloy melts begin with using what the industry calls clean scrap material, important with the implementation of green initiatives in the industry. This material is typically created from general jewelry fabrication and is reusable material free of oil, grease and contaminants. With the introduction and use of both clean scrap material and other general jewelry scrap, there exists in the normal course of alloying some amount of cadmium in precious metals used to make jewelry. While levels are generally low, (levels are below 300 ppm over 95% of the time), cadmium may be present at levels of 1000 ppm or higher in gold or

[10] *See* U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Cadmium*, pp. 3-4 (Sep. 2008) *available at* http://www.atsdr.cdc.gov/ToxProfiles/tp5.pdf .

silver alloys through these recycling practices; occasional reports of content in the 2,000 ppm range have been noted. Again, precise control of total content is not possible where recycling is concerned.

In addition to use in metals, solder, and solder-filled jewelry, cadmium is used as a stabilizer in certain plastics and may be used as a pigment in crystal, glass, ceramics, enamel or plastics, or in paint and surface coatings. Cadmium in crystal and glass, like lead, will not easily migrate because it becomes part of the matrix of the crystal. In some applications, like ceramics or enameling, the manufacturing process results in a strong bond of the elements and the other material, also resulting in limited bioavailability of the element.

Toxicological Assessments

Health Canada and CPSC reviewed available data and developed suggested limits for cadmium exposure. The approaches are different in several ways. For a product that may be mouthed by a child, but is not likely to be ingested, the CSPC staff concluded that migration tests should not yield more than 18 µg of cadmium in a 6-hour saline extraction test.[11] This extraction limit protects children from the effects of long-term mouthing, based on an ADI of 1.8 µg Cd/kg bw/day derived from an epidemiological study.[12] For a metal product or part of a product that may be swallowed by a child, the CPSC staff concluded that a 24-hour acid extraction test should not yield more than 200 µg of cadmium.[13] An extraction limit of 200 µg cadmium protects children from accidental swallowing of the article, based on an ADI of 11 µg Cd/kg bw/day derived from a 10-day drinking water study.[14]

CPSC's approach for acute exposures could be criticized as being overly conservative because it was derived from a study involving exposure over 10 days. Health Canada, in contrast, determined than an acceptable acute and chronic exposure rate is about 952 µg total cadmium for a single exposure. Thus, Health Canada's acute exposure limit of 952 µg of cadmium is 4.75 times greater than CPSC's 200 µg acute exposure rate, and more than 52 times greater than CPSC's 18 µg chronic exposure rate. However, as discussed in more detail in Section IV below, a 300 ppm screening level results, at most, in a chronic exposure rate to cadmium of 0.002 µg/kg bw, which is much lower than the chronic oral exposure limits of 0.1 to 1 µg/kg bw/day cited in the Proposal.[15]

The ASTM Children's Jewelry Safety Standard is designed to assure that exposure to cadmium in children's jewelry will be well within the more conservative exposure limits recommended by

[11] Cadmium Staff Report at 9.

[12] Suwazono Y, 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.

[13] Cadmium Staff Report at 9.

[14] 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.

[15] *See* Proposal at 10.

the CPSC, and they also fall well within the exposure limits relied on in the Proposal applying reasonable assumptions about migration drawn from available data.

Total Versus Soluble Cadmium Content

Experts who have studied the issue have agreed that it is not presently possible to establish a total content limit on cadmium. Health Canada acknowledges that total cadmium content is not proportional to migratable content, stating in the Proposal that the "results show no clear correlation between the total amount of cadmium in a jewelry sample, and the amount that might migrate out of the sample in the acidic environment of the stomach over time." Proposal at 8.

That conclusion is similar to conclusions reached by CPSC in a report issued last year. The CPSC report also concluded that "soluble cadmium migration is not generally proportional to cadmium content" and that "product composition factors such as element content and coatings have a larger effect on cadmium migration than does total cadmium content."[16] Moreover, according to a European Union report on cadmium, "there is no direct relation between the level of cadmium migration and the cadmium content; hence, it is not possible to assume that a high concentration of the metal in jewelry leads to high migration, although where the cadmium content is very low, a very low migration is common."[17]

While the absence of a supportable relationship between total and migratable heavy metals has not stopped regulators from proposing such limits, as Health Canada has done here, there is a better approach. History tells us that total content limits or "bans" often prove too restrictive, resulting in bans of safe products that impose costs and burdens on businesses without enhancing the safety for consumers. That has been the experience in the U.S. in the wake of adoption of lower lead limits under CPSIA, since unintentional contamination, variability in both materials and in laboratory test results, and other factors have notably resulted in instances where actual levels exceed total content limits while the products remain entirely safe. European authorities experienced the unanticipated adverse consequences resulting from adoption of total content limits on nickel for piercings several years ago, and subsequently revised the piercing standard to adopt migration limits because the total content limit resulted in a ban on stainless steel, which is recognized as extremely safe for piercings.[18]

This is why the ASTM Children's Jewelry Subcommittee ultimately recommended a combined approach: a total content screening limit coupled with migration testing where the total content was exceeded. The basis for developing the screening limit was actual test data and an analysis of the relationship, if any, between total and migratable cadmium.

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[16] Memorandum to Kristina Hatlelid from Ian A. Elder, Assessment of Cadmium Migration from Materials, June 3, 2010, contained in Cadmium Staff Report.

[17] European Commission Office of Directorate-General Enterprise and Industry, Socio-Economic Impact of a Potential Update of the Restrictions on the Marketing and Use of Cadmium, p. vii (April 2010).

[18] *See* Commission Directive 2004/96/EC (Sep. 2004) *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:301:0051:0052:EN:PDF.

Table 1 provides a short overview of the relevant limits on cadmium in children's jewelry based on the ASTM International requirements:

Table 1: ASTM International Children's Jewelry Safety Standard Cadmium Requirements

Product or Component	**Limit/Requirement**
Paints and surface coatings	75 mg/kg soluble cadmium (EN-71/ASTM F963)
Metal or plastic component parts of children's jewelry	300 ppm total cadmium content (using suitable method)
Metal small parts with content >300 ppm	200 µg soluble cadmium (CPSC 24-hour acid extraction test)
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 soluble cadmium (saline extraction test)

We provide below a summary of the industry tests and CPSC tests, and explain how this data informed the ultimate adoption of the screening level and migration test requirements outlined herein. We urge Health Canada to adopt a similar approach.

Mutual Cornell Tests and Exponent Analysis

Three tin alloys containing cadmium at levels of 1%, 5% and 10%, and a zinc alloy with 1% cadmium were prepared for an assessment of total and migratable cadmium by Mutual Cornell. The alloy supplier had difficulty with the preparation of such small batches as the cadmium levels were difficult to quantify. Therefore, higher concentrations than what would normally be found in children's jewelry products were generated in the samples to ensure accurate cadmium quantification across multiple content levels. Once the alloys were generated, samples were cast into a disc wafer, heart, and winged circle. The zinc alloy was molded into a cone shape.

"Economy" and "quality" plating finishes were then applied to the raw metal (unplated) sample products. The "quality plate" started with a vibratory finishing step to prepare the surface to accept the plating process. Then the process continued with an acid copper flash, 5-7 mills palladium, and 10 mills gold. The "economy plate" also started with the vibratory process, then the acid copper flash, an imitation rhodium flash, and then 2-3 mills gold.

Samples were tested for total cadmium, and for migratable cadmium using four different test methods: EN-71-3, the CPSC's 6-hour test, a static 24-hour test, and a 24 hour test using constant agitation.

FJATA then commissioned Exponent, an internationally recognized scientific research company, to explore the relationship, if any, between migratable and total cadmium. Exponent concluded that the data from these tests, while based on limited samples, suggested that an initial correlation between total and migratable cadmium could potentially be developed on plated metals containing cadmium at lower levels more typical in children's jewelry using a regression analysis. In fact, very little cadmium migrates from the plated samples, even under worst-case

24-hour test conditions using constant agitation at higher total content levels. Results of the approximate 1%, 5% and 10% added cadmium samples for the 24-hour agitated test were plotted against the associated total content concentration, in Figure 1 (winged circle), Figure 2 (heart), and Figure 3 (disc wafer). Each of these samples used tin as the starting material.

The data below is offered to provide useful information on possible relationships between total and migratable content.

The fitted linear models indicate significant slopes with high R^2 values for both of these sample types, which supports use of these linear models to potentially predict the 24-hour agitated cadmium results for lower total content cadmium concentrations in the lower amounts more typical of children's jewelry. To provide for an ability to evaluate a total content versus migratable content per gram of test materials, values were converted to μg/g (ppm) in the chart below.

Figure 1: Regression Analysis for Plated Winged Circle

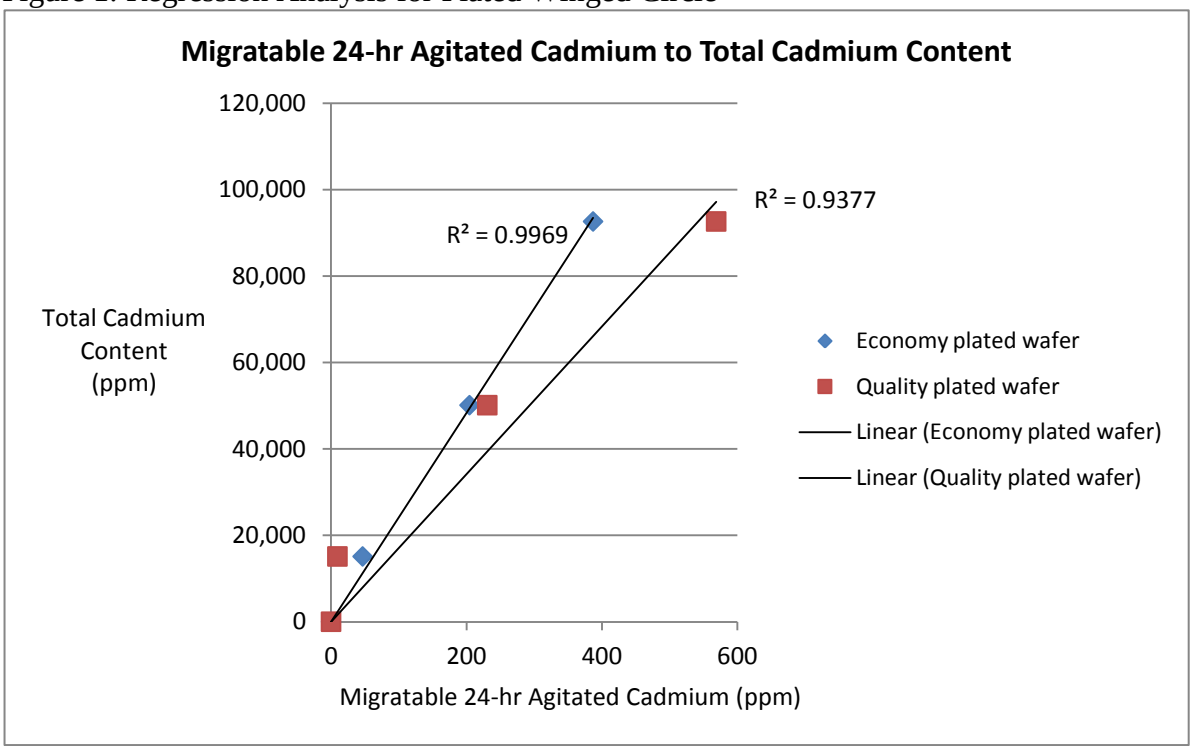


Figure 2: Regression Analysis for Plated Heart

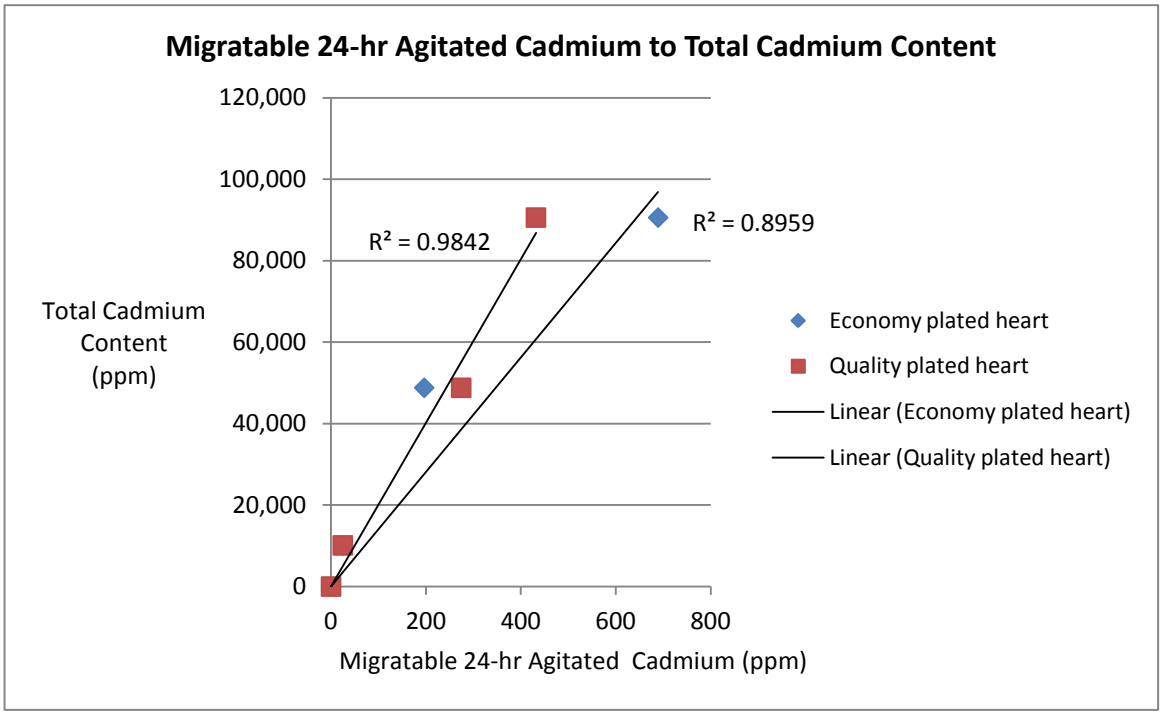
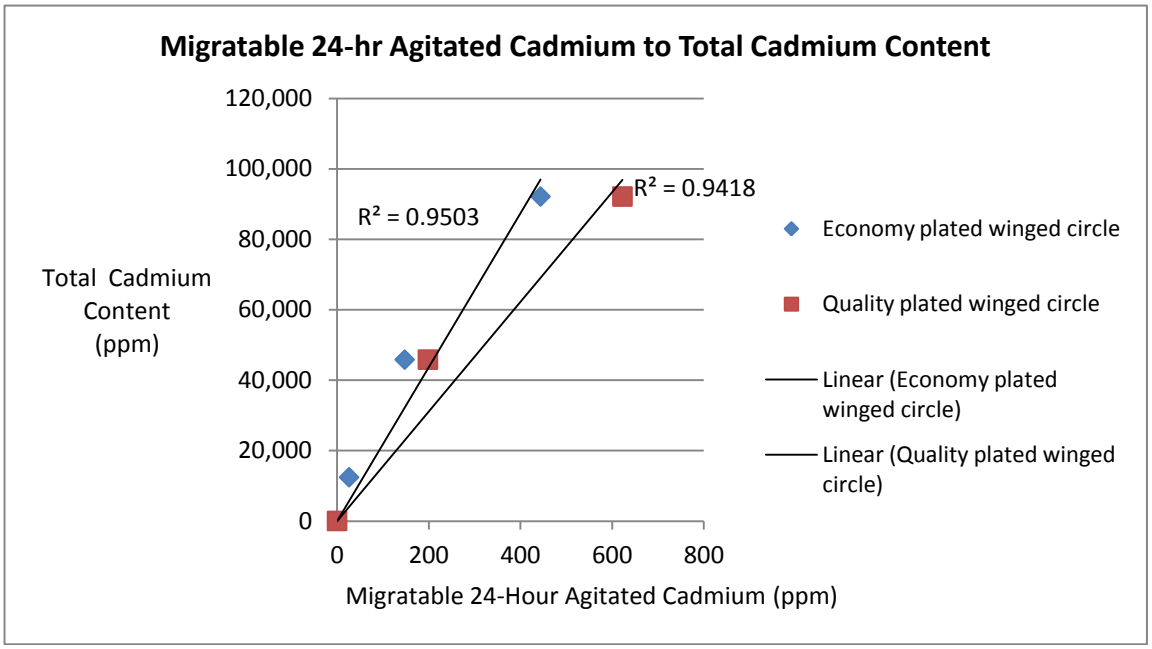


Figure 3: Regression Analysis for Plated Wafer Sample



The percentage of cadmium dissolved from the tin-based samples tested under an unrealistic worst-case 24-hour agitation condition ranged on average from approximately 0.03% - 0.44% of the total. More limited testing of the plated zinc sample suggests that cadmium may be more tightly bound in zinc, as migration rates were significantly lower. The data suggests that use of an assumed 0.5% rate could provide a very conservative approach to calculating migratable cadmium for plated metal jewelry components that contain 10% or less cadmium. Using this type of regression analysis it is expected that migratable cadmium in items that contain 1,000 ppm cadmium or less should result in negligible exposures even if the item were accidentally ingested and unrealistic, worst-case test conditions (24-hour constant agitation) are used.

This data was available to the ASTM International F15.24 Subcommittee, which subsequently received CPSC's data and report with a request that the Subcommittee review that information. In examining CPSC's data, the Subcommittee determined that actual migration rates were strikingly similar to the rates seen in the Mutual Cornell tests.

CPSC Tests in Developing the ASTM Children's Jewelry Safety Standard

The CPSC staff analyzed hundreds of samples in its Cadmium Staff Report, considerably more than the limited samples examined in the Mutual Cornell study. Available CPSC data suggests that the mass loss of metal in even an aggressive acid test where test items are subjected to constant agitation for 24 hours in a 0.07 N hydrochloric (HCl) acid solution is quite low. CPSC data on cadmium migration from metal jewelry components with total cadmium content ranging from 285 ppm to 99% suggest that migration of cadmium is, on average, 0.38%.[19] This average migration rate was found to be similar in the Mutual Cornell tests of samples containing 1%, 5% and 10% cadmium. In both these tests and the CPSC tests, jewelry components containing around 1.35% cadmium or less generally resulted in non-detectible or low migratable cadmium.[20]

Thus, for purposes of developing a screening level, an average migration rate of 0.5% was considered a very conservative assumption, recognizing that cadmium migrates from certain alloys (*e.g.*, zinc) at an even lower migration rate (typically an order of magnitude less) than others, such as tin. However, the highest rate of migration identified in the CPSC and Mutual Cornell tests was considered to develop a screening limit for the ASTM Children's Jewelry Safety Standard. In tests of samples conducted by Mutual Cornell, the highest rate of migration (for an unplated sample) was 1.1%. The highest rate of migration in CPSC's 24-hour tests was 2.349% (information was not available as to whether samples were plated or unplated, or the relative quality of the plating). For purposes of developing a screening level, based on the available technical data, a worst-case assumed migration rate of 3% was selected. Based on this data, a very conservative level for screening purposes to assure that under actual ingestion scenarios exposure to cadmium would not exceed CPSC's recommended 200 μg limit (which is

[19] Memorandum to Kristina Hatlelid from Ian A. Elder, Assessment of Cadmium Migration from Materials, June 3, 2010, contained in Cadmium Staff Report.

[20] A wafer sample unrepresentative of typical jewelry shapes yielded higher cadmium results, but was tested principally to assess migration rate in comparison to other types of components. Migration rates were similar.

far below the 952 µg limit established by Health Canada) was determined to be 300 ppm. We describe the approach used to develop that screening limit below.

Weight of jewelry components in children's jewelry can range from approximately 0.1 g to a maximum of 10 grams, with children's jewelry components at the high end extremely rare. The Proposal, for example, identified a sample slightly above 7 grams as the highest weight sample in its review. Jewelry components weighing 20 grams are unknown in children's jewelry. More typically, in children's jewelry a charm or pendant weighs between 2 – 4 g, with a 3 g item often used as an average weight.

This is consistent with information reflected in the Proposal, which indicates that the mean weight for the 94 samples collected by Health Canada was 2.8 g. Proposal at 14.

Using the 300 ppm screening level, and an assumed 3% migration rate (which is an order of magnitude above the average migration rate, and above the highest migration levels reported by CPSC), the chart below provides an overview of maximum anticipated cadmium exposure demonstrating that exposure to harmful levels of cadmium is not anticipated to exceed CPSC's acute exposure limit of 200 µg, recognizing that actual migration data on jewelry components do not suggest that migratable cadmium will approach these worst-case assumed migration levels.

Table 2 reflects the calculated exposures to cadmium in an acute exposure situation from the ASTM International F15.24 Children's Jewelry Safety Standard.

Table 2: Calculated Assumed Migration of Cadmium from Plated Metal Jewelry Components Containing 300 ppm Cadmium Using Worst-Case Assumptions.

Component Weight (g)	Total Cadmium Content (ppm)	Assumed Migration Rate (%)	Estimated Exposure (µg) (must be less than 200 µg)
.1	300	3	0.9
3	300	3	27
5	300	3	45
10	300	3	90
20	300	3	180

This chart demonstrates the health-protective nature of a 300 ppm total cadmium content screening level, applying worst-case assumed migration standards and using as a limit CPSC's proposed 200 µg limit for acute exposure (which is almost 5 times lower than Health Canada's recommended 952 µg exposure limit). Calculated exposure in even the heaviest sample representative of a typical weight metal jewelry component (10 g) assumed for purposes of the analysis is less than half of the CPSC's toxic endpoint for acute exposure.

Table 2 above also shows that, extrapolated to an unrepresentative weight of 20 g, a weight that is almost 7 times higher than the average or mean weight of a typical component in children's jewelry, results universally are predicted to fall well below the CPSC's conservative toxic endpoint for acute exposure. Migration rates of polymeric materials are expected to be lower due to the nature of the material and its behavior in simulated stomach acid. Consequently, 300

ppm was agreed by the ASTM International F15.24 Subcommittee to represent a reasonable screening limit based on conservative migration assumptions derived from testing of jewelry samples.

Given the available information on cadmium toxicity and the assumptions about children's interactions with cadmium-containing metal jewelry products, the ASTM Children's Jewelry Safety Standard incorporates migration limits for testing for exposure when evaluating metal or plastic components of children's jewelry that exceed the screening limit: For a product that may be mouthed by a child, but is not likely to be ingested, tests should not yield more than 18 µg in a 6-hour saline extraction test; and for a metal product or part of a product that may be swallowed by a child, a 24-hour acid extraction test should not yield more than 200 µg. Thus, small parts, as defined in 16 C.F.R. 1501.4, that exceed the 300 ppm screening level are compliant under the ASTM Children's Jewelry Safety Standard if tests for migratable cadmium by acid extraction yield less than 200 µg cadmium for metal components or 75 ppm cadmium for plastic or polymeric components. Metal or plastic/polymeric components which are not small parts (as defined in CPSC regulations at 16 C.F.R. 1501.4) that exceed this screening level are compliant if tests for migratable cadmium conducted by a simulated saliva test yield less than 18 µg cadmium.

The approach reflected in the ASTM Standard – a total content screening limit for accessible metal or plastic components, coupled with migration testing based on available exposure rates – provides a common-sense risk-based approach to addressing potential risks from metal or plastic components of children's jewelry while avoiding bans on safe products. Note that the ASTM International Children's Jewelry Safety Standard does not impose restrictions on cadmium in crystal or other materials based on the absence of any information that the presence of cadmium is likely to pose a potential risk to children from these materials.

Health Canada's Data Supports the Health Protective Nature of the ASTM Children's Jewelry Safety Standard

Despite concluding that migratable cadmium is not proportional to total content, Health Canada proposes to establish a maximum total cadmium content level of 130 ppm for children's jewelry. There are no apparent material exclusions to this limit. This proposed level was based on a provisional minimum risk level of 0.0732 mg/kg bw for cadmium. Assuming 13 kg is an average body weight for children 7 months to 4 years, Health Canada concluded in the Proposal that this results in a safe level of incidental intake of 0.9516 mg (or about or 952 µg) of cadmium,[21] and the apparent, but unwarranted assumption that 100% of cadmium will be released from an ingested component. Again, a 952 µg exposure limit is far above that utilized by the ASTM Children's Jewelry Safety Standard.

Under an accidental ingestion scenario, it is highly implausible that 100% of a given element in an item will be released and available for uptake in the body, nor is a 100% migration assumption supported by available data, including Health Canada's data, CPSC data or industry data. In fact, available extraction and migration studies have demonstrated that only a small

[21] 0.0732 mg/kg bw x 13 kg bw = 0.9516 mg.

fraction, usually less than 1%, of the total cadmium content will migrate, therefore demonstrating that the 3% rate of migration used in developing the 300 ppm screen is highly conservative.

Moreover, a 300 ppm screen is health protective as *more than 43% of the available cadmium would have to migrate* to exceed Health Canada's health protective cadmium intake level of 0.9516 mg for children (300 mg-Cd/kg-jewelry x 43% (accessible Cadmium) x 0.0073 kg-jewelry = 0.9417 mg-Cd). Of course, no available data suggests that migration rates approach 5% much less 43%.

Assuming, however, that the migratable rate of cadmium is doubled from the worst-case 3% scenario used to develop the ASTM Children's Jewelry Safety Standard's 300 ppm screening limit, to 6%, a 300 ppm (mg/kg) total cadmium level will continue to fall within Health Canada's acceptable exposure rate of 0.9516 mg for small children, using Health Canada's weight of 7.31g to represent the heaviest piece of jewelry that might be ingested by a small child: 300 mg-Cd/kg-jewelry x 6% (accessible Cadmium) x 0.0073 kg-jewelry = 0.131 mg-Cd. Of course, 0.131 mg cadmium is far below Health Canada's provisional minimum risk level of 0.9516 mg.

Table 3 further demonstrates that, by using Health Canada's assumptions that the heaviest piece of jewelry that a child will be exposed to weighs 7.3 g, and when an exposure rate as high as 43% is considered - a level not seen in any of the available data - total migratable cadmium would still fall within Health Canada's provisional minimum risk level of 0.9516 mg.

Table 3: Calculated Assumed Migration of Cadmium from Plated Metal Jewelry Components Containing 300 ppm Cadmium Using Worst-Case Assumptions Fall Below Health Canada's Assumed Exposure Limits

Component Weight (g)	**Total Cadmium Content (ppm)**	**Assumed Migration Rate (%)**	**Estimated Exposure (mg) (must be less than 0.9516 mg)**
7.3	300	3	0.066
7.3	300	6	0.131
7.3	300	43	0.9417

Thus, a 300 ppm total cadmium content screen for children's jewelry is health-protective applying Health Canada's toxicity considerations.

As for chronic exposure and risks associated with a child licking or sucking jewelry, if the total content screening level of cadmium is 300 ppm, and assuming all of the cadmium content is ingested, using the hypothetical scenario presented in Section 12 of the Proposal, a maximum exposure to cadmium would be 2.2 mg (300 mg/kg x 0.0073 kg = 2.2 mg). Applying the factor of 0.0000135, as was used by Health Canada, the theoretical maximum amount of cadmium that could migrate is calculated to be 0.03 μg (2.2 mg x 0.0000135 = 3 x 10^{-5} = 0.03 μg). For children aged 7 months to 4 years old with an average body weight of 13 kg, this is equivalent to 0.002 μg/kg bw (0.03 μg/13 kg = 0.002 μg/kg bw). A 0.002 μg/kg bw exposure to cadmium is much lower than the chronic oral exposure limits of 0.1 to 1 μg/kg bw/day cited in the

Proposal.[22] Thus, a 300 ppm total cadmium content screening level for metal and plastic components of children's jewelry is health conservative, and where these limits are exceeded the product may not be sold unless suitable migration testing can establish that exposure will not exceed recommended limits.

Conclusion

FJATA members are strongly committed to protecting the safety of its customers, especially children. Our industry has always supported risk-based standards for safe children's jewelry based on the view that science and facts should form the basis for product safety standards. The ASTM Children's Jewelry Safety Standard reflects the best available science on cadmium in jewelry and enjoys strong stakeholder support. We therefore urge Health Canada to consider the 300 ppm screening level, coupled with migration testing, utilized in the ASTM Children's Jewelry Safety Standard as an appropriate, health-protective approach to regulating cadmium content in children's jewelry, and also urge that children's jewelry be defined in a manner consistent with the ASTM International F15.24 Children's Jewelry Safety Standard to include jewelry designed and intended primarily for children 12 and younger.

Free trade between our two countries is best served through harmonization of standards.

FJATA appreciates the opportunity to submit these comments. Please contact me, or our outside counsel, Sheila A. Millar (202-434-4143) with any questions.

Sincerely,

Brent Cleaveland
Executive Director

Enclosures

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[22] *See* Proposal at 10.