The Fashion Jewelry & Accessories Trade Association
25 Sea Grass Way, Wickford, RI 02852
Phone (401) 667-0520 Fax (401) 267-9096

www.fjata.org

February 13, 2017

Sarah Sheffield
Project Officer
Risk Management Bureau
Consumer Product Safety Directorate
Healthy Environments and Consumer Safety Branch
Health Canada
Address Locator 4908B
269 Laurier Avenue West
Ottawa, Ontario
K1A 0K9
sarah.sheffield@hc-sc.gc.ca

RE: Proposed Consumer Product Regulations Concerning Children's Jewelry

Dear Ms. Sheffield:

On behalf of the members of the Fashion Jewelry and Accessories Trade Association (FJATA, or the Association), we appreciate this opportunity to submit comments in response to the proposed *Children's Jewellery Regulations* (Proposed Regulations).[1] FJATA is the voice of the jewelry and accessories industries in the United States, representing manufacturers, suppliers, and retailers, from small independent businesses to large multi-national corporations. Many of FJATA's members and their customers distribute jewelry to children, teens, and adults in Canada as well as the U.S., and thus are vitally interested in assuring that requirements reflect the best available technical data and are consistent between these important trading markets. FJATA is pleased to share important technical information on the industry's efforts to promote science-based standards for safe children's jewelry.

[1] Proposed *Children's Jewellery Regulations*, *Canada Gazette* (Part I), Vol. 150, No. 49, 3,887 (Dec. 3, 2016).

I. ASTM F2923-14 Addresses All Key Hazards Associated with Children's Jewelry Better than the Proposed Regulations

A. Cadmium Substrate Requirements in ASTM F2923-14

As Health Canada notes in its Proposed Regulations, a voluntary standard, ASTM F2923–14, *Standard Specification for Consumer Product Safety for Children's Jewelry*, addresses the key safety concerns arising with children's jewelry, including exposure to cadmium, lead, and other heavy metals. The standard is based on a cadmium health risk assessment by the U.S. Consumer Product Safety Commission (CPSC), and extensive laboratory testing of metal and plastic jewelry components by both CPSC and industry. It is aimed at addressing the most significant exposure scenarios (*e.g.*, accidental ingestion and mouthing), and thus is tailored to address actual exposure risks given what we know about how heavy metals behave in different substrates and the toxicological profile of cadmium.

CPSC's cadmium risk assessment is based on a customary risk assessment process. The goal was to determine whether a specific total content limit for cadmium in jewelry could be established based on a toxicological assessment of the chemical, its use in products, and the potential bioavailability of the substance in use.[2] The steps in this process include identifying an adverse effect, the relationship between a dose of the chemical and the adverse response, and evaluating scenarios where exposure may occur. Since "the dose makes the poison," an accurate estimate of the likelihood of exposure must be considered. Even if a substance is present in an article, exposure will not necessarily occur at that level, since it is rare that all of the substance will be released. Consequently, the rate of release or migration in materials is a critical point. Lastly, the risk characterization must be conducted to determine what a safe level of exposure is for the population as a whole based on information on the mechanism and uncertainty in the data set. The CPSC employed these standard risk assessment steps in its review of cadmium in metal jewelry.[3]

Based on this framework, CPSC determined a method for conservatively estimating acute and chronic exposure to children's jewelry based on scientific data on biological simulants and children's behavior. As Health Canada acknowledges, there is no strict relationship between cadmium content in metal and cadmium extraction. This is

---

[2] (U.S.) National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (1983); Elaine M. Faustman & Gilbert S. Omenn, "Risk Assessment" *in* C.D. Klaasen, ed. *Casarett & Doull's Essentials of Toxicology* (6th ed. 2001).

[3] CPSC, *Children's Cadmium-Containing Metal Jewelry* (Oct. 14, 2010), *available at* http://www.cpsc.gov/PageFiles/96163/cadmiumjewelry.pdf

exactly the conclusion reached by CPSC and by the jewelry industry in its own tests of extractable cadmium from metal jewelry components. Higher levels of cadmium in substrate materials may yield higher cadmium levels in extraction media, but does not always do so. Nevertheless, data developed by CPSC and by industry did establish support for identifying a content level suitable to use as a *screening* limit. The screening limit is a level below which no or minimal migration will occur, and thus that exposure in actual use is unlikely, making further migration testing unnecessary. The ASTM F2923–14 standard adopts this approach.

The ASTM F2923-14 screening limit is 300 parts per million (ppm) (0.03%) for swallowable components of metal children's jewelry. This screening limit was derived from actual studies of migration in a stringent 24-hour acid extraction test conducted under constant agitation conditions. Children's products (defined as products for children 12 and younger) with metal components below this limit are deemed safe. Children's jewelry components above this limit are subject to further migration testing and may not exceed a migration limit of less than or equal to 200 µg cadmium using acid extraction and inductively-coupled plasma optical emission spectrometer (ICP-OES) or inductively-coupled plasma mass spectrometer (ICP-MS). Larger jewelry components that are not swallowable small parts containing more than 300 ppm cadmium must meet a migration limit of 18 µg cadmium/day in a saline test designed to mimic possible mouthing exposure.

The assumptions regarding possible exposure to ingestible small metal components of jewelry containing cadmium, or mouthing behavior, are extremely conservative. For example, the 24-hour acid extraction test exposes components to harsher conditions than would be experienced in actual 24 hour ingestion conditions (pH is higher in the intestines than in the stomach, reducing bioavailability of cadmium, and constant agitation continuously over 24 hours does not occur since digestion does not occur for that amount of time). Consequently, so the release rate in reality would be substantially lower, and the test conditions likely reflect a longer residence time in the stomach. Indeed, even though an estimated average migration rate of 0.5% is very conservative based on actual data about migration rates from jewelry samples, the ASTM committee utilized the highest migration rate shown (2.349%) and added an additional safety factor to base estimated exposures potentials on a "worst-case migration scenario." Using these highly conservative assumptions, the ASTM Subcommittee calculated the following estimated exposures from components of metal jewelry at different weights:

Calculated Assumed Migration of Cadmium from Plated Metal Jewelry Components Using Worst-Case Assumptions[4]			
Component Weight (g)	Total Cadmium Content (ppm)	Assumed Migration Rate (%)	Estimated Exposure (µg)
0.1	300	3	0.9
3	300	3	27
5	300	3	45
10	300	3	90
20	300	3	180

Most children's jewelry components weigh under 5 grams; metal jewelry components weighing 20 grams are essentially unknown in children's jewelry. Thus, even in the worst-case scenario, with a highly unlikely scenario of a jewelry component weighing 20g (most are much smaller) and containing 300 ppm total cadmium, actual exposure from accidental ingestion of a metal component would be expected to be less than 200 µg, the limit that CPSC staff designated as the maximum allowable daily acute exposure threshold.[5] The limits were approved through the ASTM process, and also received CPSC approval. Importantly, CPSC expressly rejected adoption of a total content limit as such an approach was inconsistent with the available scientific data or its legal framework.[6]

B. Other Safety Provisions of ASTM F2923–14

In addition to addressing cadmium, ASTM F2923–14 incorporates requirements related to a broad range of potential hazards associated with children's jewelry. This includes not only cadmium, but lead in metal and plastic substrates and in surface coatings. Specifically, ASTM F2923–14 adopts a 100 ppm threshold on lead in the substrates of children's jewelry (subject to exclusions for certain materials determined not to contain lead, such as certain stainless/surgical steels, precious metals, etc.), and a 90 ppm threshold on lead in paint or surface coatings. These levels are consistent with requirements adopted by the U.S. Congress in the Consumer Product Safety Improvement Act (CPSIA). Adopting ASTM F2923–14 as a requirement in Canada would address lead content in children's jewelry, and would align with CPSC-enforced

[4] *See* ASTM F2923–14, Appendix, Table X1.1.

[5] *See* CPSC, *Children's Cadmium-Containing Metal Jewelry* at 8 ("To assess children's cadmium-containing jewelry, staff assumes that the vulnerable group of children is 2 to 6 years old, with an average weight of 18.2 kg (40 pounds) (Ogden *et al.* 2004). Given the 11 µg/kg/day acute ADI, **the maximum allowable acute exposure for a young child is about 200 µg/day**.") (emphasis in original).

[6] *See* CPSC, Letter from Todd Stevenson to Center for Environmental Health, *et al.* (Aug. 9, 2012); CPSC Staff, *Staff Updater: Petition 10-2 Request Restriction of Cadmium in Toy Jewelry* June 29, 2012), *available at* https://www.cpsc.gov/s3fs-public/pdfs/foia_cadmium.pdf.

standards.[7] Importantly, since CPSIA was adopted, the CPSC has not found it necessary to lower limits on lead in substrate or paint/surface coatings, since the existing limits are health-protective.

It bears noting that the Proposed Regulations do not seek to address other potential and known hazards with children's jewelry, which *are* addressed by ASTM F2923–14. Namely, these are:

- other heavy metals (including antimony, arsenic, barium, chromium, mercury, and selenium) in paint and surface coatings;
- nickel allergies;
- liquid-filled children's jewelry hazards;
- magnet hazards;
- strangulation and entanglement hazards;
- sharp points and sharp edges;
- small parts and choking hazards; and
- battery hazards.

ASTM F2923–14 is a comprehensive jewelry safety standard, and thus establishes the highest threshold for the safety of children's jewelry in the world. Addressing all known hazards reflects best practice, and would benefit Canadian consumers and children. Therefore, FJATA urges Health Canada to reject the current proposal and align requirements for children's jewelry with ASTM F2923–14.

II. Total Content Limits Are Unsupported by Data

A. The 130 ppm Threshold for Cadmium Is Less Health Protective Than ASTM F2923's Combination of Content Screening and Migration Testing

Having agreed that the migration of cadmium is not always proportionate to total content, the basis for Health Canada's selection of the proposed 130 ppm total content relative to ASTM F2923–14's 300 ppm limit is not apparent. The CPSC staff's conclusion that the ASTM standard is health-protective is based on recommended toxicological endpoints for acute and chronic exposure that are very conservative. Indeed, Health Canada shows agreement with the principle of setting migration limits and testing for heavy metals subject to restriction in its parallel rulemaking on lead. There, Health Canada proposes migration limits as an alternative limit for components of

[7] *See* CPSIA § 101, Pub. L. 110–314, 122 Stat. 3,016 (Aug. 14, 2008); 16 C.F.R. Part 1303.

products not subject to total content limits for lead.[8] Thus, although Health Canada critiques the availability of a migration-testing-and-limit under ASTM F2923 as "costly," it is apparent that the department fundamentally agrees with the principle that ASTM F9293 adopts by using content screening and migration limits. As a practical matter, jewelry companies benchmark compliance with the screening limit to avoid the more expensive 24-hour migration test.

A diverse array of stakeholders participated in the ASTM F15.24 Subcommittee on Jewelry within the F15 Committee on Consumer Products under ASTM International, Inc., to carefully craft a standard that incorporated safety requirements for children's jewelry. The cadmium limits were determined to be health protective and grounded in available scientific data. The cadmium requirements were based laboratory test data assessing actual migration of cadmium from substrate materials and a peer-reviewed toxicological assessment conducted by CPSC. Even as FJATA agrees with Health Canada about the propriety of identifying health-protective thresholds for cadmium in children's jewelry, the Association believes the content-screening and migration thresholds of ASTM F2923–14 are better grounded in science and demonstrably health-protective than Health Canada's proposal.

B. Health Canada's Proposal Fails to Consider How Exposure Patterns Change with Age

ASTM F2923–14 is focused on children's jewelry, defined as children 12 and younger. Children and teens interface with products in an entirely different manner. In particular, teenagers are interested in very different fashions and styles than younger children, and indeed often purchase adult jewelry. The Proposed Regulations cover minors as old as age 15 year. Yet teens are not likely to engage in the same behaviors, such as mouthing and sucking, that children 10 or more years younger engage in. That is simply not consistent with what children's product manufacturers and regulators have known for decades: young children under 3 are most likely to accidentally ingest an item.

III. Health Canada Should Adopt ASTM F2923–14

FJATA supports action to protect the health and safety of consumers. The fashion jewelry industry supports strong, effective, science-based standards to prevent consumers, and particularly young children, from becoming exposed to harmful substances. That is why FJATA lead the initiative, often attended by Health Canada, to develop safety standards for both children's and adult jewelry. It is important to note that

[8] *See* Proposed *Regulations Concerning Lead in Consumer Products*, *Canada Gazette* (Part I), Vol. 150, No. 49, 3,907 (Dec. 3, 2016)

both before and after ASTM F2923–14 was adopted, no reports were received of any consumers suffering any adverse health effects from being exposed to dangerous levels of cadmium through wearing, handling, or even accidentally ingesting jewelry. The most common route of cadmium exposure to consumers is through smoking or consuming food (which in turn is traceable to agricultural practices), not to the presence of trace amounts of cadmium in substrates or surface coatings of children's jewelry.

ASTM F2923–14, the Children's Jewelry Standard, establishes rigorous safety standards and testing methods to address all potential hazards of jewelry intended for consumers 12 and under, including requirements governing cadmium. The standard incorporates – at CPSC's express request – the risk assessment approach described by the CPSC. It therefore incorporated the acute cadmium exposure limit in a migration test advocated by CPSC applying CPSC's recommended bioavailability test method to determine when such limit is met, but only after a science-based screening limit was exceeded. Jewelry that meets the ASTM F2923–14 Children's Jewelry Standard requirements is safe for children, and will not expose them to excess cadmium or lead. It will also meet safety requirements for other risks, such as nickel exposure and exposure to other heavy metals, use of batteries or magnets, and the like.

We recommend that Health Canada adopt ASTM F2923–14 for all children's jewelry products for children 12 and younger, or, alternatively, restrict application of the proposed limit only to jewelry for very young children and adopt ASTM F2923–14 for older children and teens under 15.

Sincerely,

Brent Cleaveland
Executive Director

cc: Sheila A. Millar
Keller and Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001