Fashion Jewelry and Accessories Trade Association
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Analyzing ASTM F2923–14, the Standard Specification for Consumer Product Safety for Children's Jewelry, and the underpinning analyses conducted by the U.S. Consumer Product Safety Commission (CPSC) and others. ASTM F2923 is well-supported by rigorous tests of actual samples of children's metal jewelry, and was developed at the request of the federal agency with jurisdiction in connection with this question.

Frequently asked questions:

> *1) Both industry and the Department of Ecology, the agency responsible for implementing present statute, prefer to use X-ray fluorescence (XRF) analyzers when determining content of cadmium in jewelry. Existing data (CPSC, 2010; Weidenhamer et al., 2011) indicate that this technique provides for cadmium measurements with much greater error and the measurements provide for cadmium content that is 2- to 3- fold below actual content when compared to techniques using atomic absorption or inductively coupled plasma spectrometry. As XRF will be used in the future, attempts to define a standard needs to incorporate the shortcomings of results obtained using technique.*

Response: ASTM F2923–14 asserts that XRF is a viable screening method for screening for cadmium content and is determined to be a rigorous, stringent test method. Testing of samples of children's jewelry by CPSC indicated that at low cadmium levels, XRF measurements were in close correlation with ICP methods that involve complete dissolution. The relative error between the two methods was found to increase at a cadmium content greater than 1.35%, much higher than the CPSC recommended screening limit of 300 ppm (0.03% cadmium) that requires migration testing. The Weidenhamer study results show the same trend as the CPSC results where the cadmium levels are underestimated by XRF with pieces of jewelry that contain higher levels of cadmium *several orders of magnitude greater than the screening limit*. Based on

CPSC's results, XRF is a viable method to use for screening for cadmium at level of 0.03%, a level at which XRF can accurately measure the total cadmium contest of a piece of jewelry. As with any analytical method, it is important that the XRF instrument be compared to standards to introduce correction factors, if any, needed for the analysis.

> *2) Surface coating-cadmium testing occurs under certain circumstances and levels measured cannot exceed the amount identified as maximum within the ASTM document (75 mg/kg). This value comes from a cited national toy standard (Consumer Safety Specification F963) and from a cited European toy safety standard (BS EN 71-3). The cited document, BS EN 71-3, was recently updated in 2013 and provides for a different maximum value in surface coatings (17 ppm). The 2014 ASTM document did not reflect this change made in 2013. As part of the process to identify a standard this disparity between the two values will need to be addressed and explained, with a scientific determination made for which surface coating concentration is appropriate for protection of children.*

Response: Jewelry components need to comply with the 75 ppm *soluble* limit on paint and surface coatings in order to be compliant with F2923–14, which aligns with requirements for cadmium in surface coatings under the mandatory federal Toy Standard, ASTM F963, currently in force. This standard was based in part on the 1994 version of EN 71–3 and associated tests. As you note, the European standard was recently revised; those changes have been considered by the ASTM toy committee and rejected as not correctly assessing the risk of exposure from toy materials. The children's jewelry safety standard aligns with this federally-mandated toy safety standard with respect to surface coatings and members of the F15.24 subcommittee reached the same conclusion in reviewing and updating ASTM F2923.

Importantly, the Toy Safety Directive, which EN 71–3 implements, specifically exempts "[f]ashion accessories for children which are not for use in play" from the regulation. Jewelry, not being for play (otherwise it would be toy jewelry and thus subject to ASTM F963 in the U.S.), would not come under the requirements – or the logical basis – of EN 71–3. Likewise, children's jewelry, because they are not toys, are not subject to ASTM F963, although efforts to harmonize the mandatory U.S. toy safety standard, ASTM F963, with the children's jewelry standard, ASTM F2923, result in adoption of very similar requirements and test methods.

> *3) For the sub-surface material, the ASTM standard provides for a screening level of permissible total cadmium content (300 ppm). This screening level will result in less than 200 μg of cadmium migrating from the material. However, the derivation of this screening level takes into account neither the available evidence pertaining to observed differences in cadmium that can leach out from one identical new piece of jewelry to*

another, nor does the derivation of the value take into account the cadmium that can leach out from a piece once it has been played with and damaged versus just a new undamaged piece. The impact of these variables must be incorporated into the derivation of a standard deemed to be protective of children's health.

Response: ASTM F2923–14 requires compliance with the migration testing that cannot yield more than 200 µg cadmium. To simplify the testing protocol the standard allows for a "screening level" limit of 300 ppm total content. In its review of the data from the tests it conducted on children's jewelry components, CPSC determined that if the cadmium content of a piece of jewelry was not greater than 1.35%, migration of cadmium was not detectable or resulted in a low migration level less than the limit of 200 µg. These tests were conducted on pieces of jewelry where cadmium was directly exposed on the surface of the article, as would be the case for broken or worn jewelry. This level is considered small enough so that dangerous amounts of cadmium will not leach out. Notably, CPSC observed another important difference in tested samples: zinc substrates released approximately an order of magnitude less cadmium than tin substrates. Zinc is commonly used as a result of CPSIA because it is typically a low-lead material.

CPSC's recommended limit was based on both a toxicological evaluation, and testing of actual jewelry samples. CPSC staff considered the Weidenhamer study and compared it to their research and determined that increasing the heated acid extraction testing time to 24 hours and subjecting samples to constant agitation would be sufficiently corrosive to simulate damage to the surface and degrade platings, yielding the greatest exposure to the substrate.

FJATA commissioned testing of jewelry samples from an independent, third party testing laboratory, which was further analyzed by Exponent, a worldwide scientific engineering company,[1] and supported the CPSC's findings. Cadmium is a soft metal with a low melting point that is easily homogenized in the alloy; it is unlikely to be released from an item merely at a scratch of surface coating. To correctly analyze exposure, tests were conducted on castings with both a surface coating and without to obtain the maximum exposure to the substrate; results from this supported the CPSC's data and conclusions. Moreover, the dramatic increase in migration of cadmium from damaged jewelry shown in the Weidenhamer study is dependent on using high cadmium content pieces; as the CPSC and other sources have revealed, such items are not present in the market. CPSC applies ASTM F2923 in its import surveillance and enforcement and compliance activities related to children's jewelry.

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[1] *See* About, http://www.exponent.com/about/.

4) The ASTM standard document indicates that if the screening level is exceeded, the item may still be sold if it can be shown that the piece of sub-surface material does not result in more than 200 μg of cadmium migrating from the jewelry item. Available data pertaining to metal leaching from children's jewelry indicates that there is a great deal of variability in the amounts that can leach out between and within jewelry pieces (CPSC, 2010). Accordingly, this step within the testing procedure needs to be eliminated as it could result in widely variable cadmium levels to be made available for children to be exposed to, especially in pieces that have undergone normal wear and have become damaged.

Response: The standard, like the ASTM F963 mandatory toy safety standard, relies on solubility extractability testing for surface coatings, and the more aggressive CPSC method for metal jewelry components. Again, ASTM F963 also adopts a screening level. In both instances, the screening level is only used to determine that cadmium concentration is minimal and therefore that the component does not require migration testing, which is the only precise measure of exposure according to CPSC's report. It should be noted that CPSC's tests demonstrated that even at significantly higher levels of approximately 1.35%, migratable cadmium levels were negligible and never came close to the extractable limit of 200 μg. Thus, although variability in extraction levels associated with differing cadmium level may occur, with a screening level of 300 ppm (or 0.03%) level of cadmium in the piece of jewelry, the safe acute exposure limit of 200 μg will not be exceeded.

Further, "a direct correlation between the extent of migration and cadmium content has not been established – although when cadmium content is very low, migration is generally also low."[2] This is precisely the reason that ASTM F963 and ASTM F2923 use a migration standard in coordination with an optional total content screening threshold to determine the safety of a component part with respect to cadmium. Solubility testing has undergone peer review and is firmly established as the only true representation of a given material's potential hazard from exposure.

5) Any derived standard should include a description of the shortcomings associated with the allowable acute exposure level (200 μg/day). This description should include the lack of available in vivo studies on the accessibility of metals which would greatly enhance exposure analysis (Guney and Zagury, 2012), and should acknowledge that as new

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[2] Final Report, *Socio-Economic Impact of a Potential Update of the Restrictions on the Marketing and Use of Cadmium* 103 (2010), http://bookshop.europa.eu/en/socio-economic-impact-of-a-potential-update-of-the-restrictions-on-the-marketing-and-use-of-cadmium-pbNB0114207/ (prepared for the European Commission Directorate-General for Enterprise and Industry).

experimental animal results or human data become available, the acute exposure level and any standard derived based on the acute exposure level should be re-evaluated.

Response: The Guney and Zagury (2012) report studied various trace metals in various metal items that could accidently be swallowed by children under 6. ASTM F2923–14 and the CPSIA both regulate products designed and expressly marketed to children 12 and younger. The report correctly states that, "bioaccessibility measurement may provide more accurate risk characterization," establishing the author's agreement with the proposition advanced by CPSC that migration testing is the best measure of the potential risk of cadmium. The CPSC has concluded that 200 µg acute exposure level is safe, and this is the level which is a required benchmark for toys and for jewelry. Furthermore, ASTM F2923–14 establishes rigorous safety standards and testing methods to assess the potential hazard from cadmium in children's jewelry, applying CPSC's risk assessment methodology regarding the acute cadmium exposure limit, and CPSC's recommended bioaccessibility test method to determine when such limit is met. The standard does not require bioaccessibility testing where cadmium content is 300 mg/kg or less because available data establishes that components at this level will not yield soluble cadmium. If that screening limit is exceeded, it certainly does not mean that the component poses a hazard. However, to establish safety, additional extraction testing involving a 24 hour test in a heated 0.07 hydrochloric acid (HCl) solution with agitation is required under the standard to determine that the bioaccessibility of cadmium from a swallowed metal jewelry item is less than 200 µg. These testing conditions or extraction conditions required by the CPSC test are more rigorous and severe than the other test methods reported in Guney and Zagury (2012) that require an acid extraction of only 2 hours.

b) The questions we have relevant to the methodology mentioned in the standard are as follows:

When conducting surface coating tests, are solubility tests conducted? Or has a method been identified that allows this test to be conducted using an XRF analyzer? Are there any other conditions under which surface coatings are not tested outside of there not being a coating or if the coating weighs less than 10 mg?

Response: Surface coating solubility (extraction) tests are performed to support a 75 ppm migratable limit. Both ASTM F2923-14 and EN 71-3 require soluble migration testing. It is generally agreed that nothing would migrate 100% in this pathway of exposure so if a piece tested at 75 ppm total cadmium content or lower with an XRF analyzer, then it would certainly not migrate over 75 ppm and would therefore be considered compliant. The CPSC has indicated that it will sometimes use XRF to determine whether further solubility testing is required in the

case of another heavy metal, lead;[3] similar screening tests could apply here, but F2923 does require solubility testing to assure compliance.

> *When conducting the sub-surface test using an XRF analyzer, is the surface coating (when present) first removed? Or is the entire piece being examined, tested in its entirety with the surface coating intact?*

Response: The surface coating is removed as a component part and tested separately. Importantly, ASTM F2923-14 requires testing of each individual component of children's jewelry. This often results in 8, 10, or even more tests for each item.

> *c) Neither the ASTM F2923-11 nor -14 document (from 2011 and 2014) reflect our present day knowledge base for cadmium leaching from children's jewelry and neither addresses the uncertainties associated with determining a permissible cadmium concentration for children's jewelry. A standard for cadmium in children's jewelry should address the above described issues, and to achieve a standard the Department of Health proposes two possibilities that provide for a process by which a standard can be determined.*
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> *The first would be to assemble a group of experts in the fields of cadmium toxicity and metal migration (from children's jewelry) that do not have any financial or non-financial competing interests. This panel could then be convened, but at no small cost, and mandated to answer a set of questions or issues, including if sufficient information is available to determine a standard, and if so, what would that standard be.*
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> *The second possibility is for the Department to seek a smaller sum of funds to conduct some testing of children's jewelry so as to address a few issues that could benefit the Department of Health in developing a standard. The Department could then use these additional data to derive a standard that would be scientifically sound and peer reviewed prior to publication. The Department of Ecology has indicated that they have funds available for conducting testing of children's jewelry and may be able to incur most, but not all, of the costs of this type of endeavor.*

Response: On the contrary, CPSC's report and recommendations were subjected to peer review. The basic toxicology of cadmium has not been shown to change since that report was issued. Groups of experts have been convened via the ASTM F15.22 Toy Safety Subcommittee, and the ASTM F15.24 Jewelry Subcommittee. The latter is made up of 60 members including laboratories, consumer groups, retailers, trade associations, university scholars, manufacturers, international stakeholders and, most importantly, representatives of the CPSC. As the standard underwent the update process during 2014, stakeholders agreed that no changes in the standard,

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[3] *See* CPSC-CH-E1003-09, https://www.cpsc.gov/PageFiles/128129/CPSC-CH-E1003-09.pdf.

and particularly no revisions to the acute solubility limit for either surface coatings or for metal components, was warranted based on the available data.

> *Along with industry, we support the need for a national standard as it allows all to work from the same page and allows all children across the United States to be equally protected. Presently the ASTM F2923-14 document does not provide a sound foundation properly reflecting presently available knowledge from which to adequately protect those children who have the misfortune of mouthing or swallowing children's jewelry. However, with the implementation of either process presented, the Department considers the determination of a standard feasible.*

Response: We respectfully urge that you consider that Congress has mandated toy requirements for lead and phthalate content as well as over toy safety compliance with ASTM F963. ASTM F963 adopts a 75 ppm limit for soluble cadmium in surface coatings, and a 200 µg acute limit using an acid extraction test for cadmium in metal components. ASTM F2923–14 standard uses the same solubility limits for surface coatings and metal substrates, references the same test methods, and was produced by a diverse group of stakeholders, in the same manner as ASTM F963. The CPSC – by providing data to the subcommittees, participating on the panels, considering and denying a Sierra Club petition to create its own rules on cadmium, and by adopting and approving ASTM F963 and issuing statements in support of the health-protective nature of ASTM F2923 – has made it very clear that both the ASTM toy safety standard and the children's jewelry standard sufficiently protect children from numerous hazards, among them cadmium exposure. By adopting ASTM F2923–14, the State of Washington would adopt not just a cadmium standard that has been proven to be health-protective and is applied by CPSC in the field when evaluating the safety of cadmium in children's jewelry, but a comprehensive checklist of potential hazards to evaluate in children's jewelry. Further, adopting ASTM F2923 would make the State of Washington the second state in the nation (after Rhode Island) to have any requirement at all for nickel in children's jewelry.

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We respectfully disagree with the Department's current position. A wealth of science supports the children's jewelry standard as reasonable and health-protective. We urge the Department to reconsider and support the State's adoption of F2923. ASTM F2923–14 is based on actual testing of actual jewelry components, and reflects the CPSC's considered recommendations that industry incorporate its test method and findings into a jewelry safety standard, just as CPSC recommended that the toy industry adopt the same requirements. ASTM F963 is a federally required standard; it makes no sense for the State to pursue yet another initiative on children's jewelry when the children's jewelry safety standard incorporates similar requirements as the toy safety standard. We urge the State to conserve taxpayer resources and recognize the ASTM F2923–14 standard as health-protective, just as CPSC has.

Sincerely,

/s/ Brent Cleaveland

Brent Cleaveland
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