

Product Responsibility Best Practices	SUBJECT		LAST UPDATE
	Lead and Other Heavy Metals		July 2019
	APPLIES TO	FOCUS ON	
	<ul style="list-style-type: none"><li>• Suppliers</li><li>• Distributors</li></ul>	Laws that regulate heavy metals in your products and how they affect our industry and consumers.	
	QUICK LINKS		Intended for beginner compliance programs
	<ul style="list-style-type: none"><li>• PPAI Corporate Responsibility: <a href="http://ppai.org/corporate-responsibility">http://ppai.org/corporate-responsibility</a></li><li>• UL: <a href="http://industries.ul.com/premiums-promotional-and-licensed-goods">industries.ul.com/premiums-promotional-and-licensed-goods</a></li><li>• Consumer Product Safety Commission: <a href="http://www.cpsc.gov">www.cpsc.gov</a></li></ul>		

*Italic grey text indicates a hyperlink listed in the Online Resources section of this document.*

## What Are Heavy Metals?

Heavy metals are naturally occurring metallic elements that may be used in the production of many consumer products. Also referred to as toxic metals and toxic chemicals, heavy metals are known to cause harm to the environment in addition to adversely affecting human health based on a number of toxicity factors, including dose, age, gender, type of exposure, and more.

The most well-known and commonly regulated heavy metals in the consumer product market are antimony, barium, cadmium, chromium, lead, and mercury. Methods of exposure to these chemicals can include oral consumption, inhalation, transdermal, and hand-to-mouth.

## Regulations That Address Heavy Metal Hazards

There are several agencies on both federal and state levels that are responsible for enforcement of regulations related to heavy metals. Among these regulations are, but not limited to, the *Consumer Product Safety Act (CPSA)*, *Consumer Product Safety Improvement Act (CPSIA)*, *Federal Hazardous Substances Act (FHSA)*, *California Proposition 65*, *California Safer Consumer Products Act (SCP) (Green Chemistry Law)*, *Illinois Lead Poisoning Prevention Act*, *Massachusetts Toxics Use Reduction Act*, *Washington Children's Safe Products Act*, *Maine Toxic Chemicals in Children's Products Law*.

## Antimony And Barium

The *American Society for Testing and Materials (ASTM)* is one of the oldest standards developing organizations and is a globally recognized leader in the development and delivery of international voluntary consensus standards. *ASTM standard F963* prohibits pacifiers from containing any of the following heavy metals in surface coatings or substrate materials in excess of the limits listed in the standard: antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium. In addition, there are

federal proposals to restrict antimony under the *Safe Kids' Jewelry Act* and *Children's Toxic Metals Act*.

There are several forms of antimony which can be found throughout the environment at low levels and exposure to a specific type of antimony is difficult to determine. Exposure can occur through a variety of sources including drinking water, skin contact, inhalation, and consuming foods containing the chemical. Adverse effects on human health include irritation to eyes, skin, and lungs resulting in pneumoconiosis, heart problems, joint and muscle pain, anemia, diarrhea, stomach pain, vomiting, and stomach ulcers. At this point it is unknown as to whether antimony causes cancer, birth defects or other reproductive harm.

## Cadmium

The *ASTM F963* addresses a limit on cadmium in substrates and surface coatings for toys; in addition to specific requirements for soluble cadmium in small metal parts. However, there are no federal restrictions on cadmium in all children's products as the CPSC terminated a petition in October 2012 that would have further regulated cadmium in children's products.

ASTM released a standard for children's jewelry (*ASTM F2923*) and adult jewelry (*ASTM F2999*). *ASTM F2923* defines jewelry as items intended to be worn as an ornament and designed for or primarily intended for children under the age of 12. Although this ASTM standard is voluntary, retailers and consumers may require or expect compliance. Voluntary standards are considered industry best practices or "industry-consensus" standards, and the CPSC considers them to be the starting point from which to design your product. Federal agencies can use statutory authority to enforce voluntary standards the same as mandatory standards, even if a voluntary standard is not incorporated by reference into a federal law.

*CPSC F963-11 Section 4.3.5.2(1)* states that the accessible

substrates in toys (including accessible glass, metal, and ceramic toys or small parts of toys) are subject to the limits set forth in (*Table 1 of F963-11*), which specifies, among other requirements, a limit of 75 ppm of soluble cadmium content (or 50 ppm for modeling clays that are part of toys).

If the product is not covered by a current regulation but an end buyer insists on tests for cadmium, a supplier or distributor could test the product according to the European standard, which limits total cadmium to 100 ppm.

Some individual states have passed laws regarding the use of cadmium, primarily in children's jewelry. Rhode Island has passed legislation that makes *ASTM F2923* mandatory in the state. Minnesota has enacted a law that limits soluble cadmium content in surface coatings and substrate materials of children's jewelry at 75 ppm. Under the Minnesota law children's jewelry exceeding the 75 ppm limit cannot be sold or offered for sale.

Connecticut and Washington have also enacted laws restricting cadmium in children's jewelry for total amounts of cadmium rather than soluble amounts. States continue to consider additional product safety requirements.

You should always check with your state to make sure you have current information. Some of the proposed legislation is specific to children's jewelry while others include all children's products. The ages of children's jewelry range from six to 13 years, and proposed limits can be soluble or total cadmium.

## Chromium

Chromium exposure has been linked to cancer, male reproductive issues, and respiratory problems. Exposure to chromium is most common in the manufacturing environment, however it can be found in some consumer products made of leather or stainless steel. Currently, chromium levels are not regulated by the federal government. *ASTM F963* includes chromium as a regulated heavy metal in surface coatings and substrates of toys.

## Lead

Because lead is a potent neurotoxin and can cause brain disorders, as well as damage to the nervous system, the CPSC has regulated lead in paint and in similar surface coatings since the 1970s. In 2008, CPSIA introduced a lead content limit on accessible materials of children's products. The CPSC recognizes the two categories of materials, lead in paint and lead content in substrate materials, and maintains separate regulations for each.

**Lead content in paint and surface coatings:** In

August 2009, the lead in paint limit per the Code of Federal Regulations (CFR), chapter 16, section 1303 was dramatically reduced from 600 to 90 parts-per-million (ppm). Section 101 of the CPSIA regulates lead in children's products, items that include clothing, backpacks, toys, furniture, jewelry, electronics, tableware and other items. Third-party testing of lead in paint has been mandatory for children's products since December 2008.

**Lead content in substrate materials:** The CPSIA introduced a lead content limit on accessible substrate materials of children's products. Prior to the CPSIA, only the surface coatings required lead compliance. As of February 10, 2009, the lead content limit was 600 ppm, and it applied to existing inventory. On August 14, 2011, that level was further reduced to 100ppm, and it applies to all children's products manufactured after that date.

In response to public comments and consideration, the CPSC granted some relief on the lead content provision—the lead limit only applies to accessible substrate materials. A material is considered to be accessible if it can be touched using the existing accessibility probes from the sharp point and sharp edge regulations. Accessibility is evaluated both before and after standard use and abuse testing per the Federal Hazardous Substances Act, with the upper age extended to 12 years. Barriers such as paint, coatings or electroplating do not make the substrate inaccessible.

**Electronic components:** Certain electronic components may be exempt from the CPSIA lead content requirement when the component cannot be covered and made inaccessible, when there is a lack of technologically feasible substitutions and/or when lead is required for proper function. In these cases, compliance to the European RoHS directive may be allowed.

**Case-by-case product exclusion:** There is a provision for exclusion of certain products or materials, if the CPSC determines, based on scientific evidence, that lead in such product or material would not result in the absorption of any lead into the human body or have any other adverse impact on public health or safety.

**Material exemptions:** The CPSC has determined that certain materials and classes of materials do not exceed the lead content limits, and while compliance is required, testing these identified materials is not. These materials include precious and semi-precious gemstones, wood, paper and paperboard (and their coatings that soak into the paper and

cannot be scraped off), CMYK process printing inks, dyed and undyed textiles (excluding after-treatment applications such as screen prints, transfer, and decals as well as leather and vinyl), plant or animal derived materials, such as beeswax, seeds, bone and feathers, surgical steel, and precious metals.

Based on CPSC's Statement of Policy regarding testing and certification of lead content in children's products, lead testing is not required on products or components that are made entirely of exempt materials, and no testing is required to prove that an item is made of an exempted material (for example, you don't have to test a cotton shirt to prove that it is cotton). When products contain components made of both exempted and non-exempted materials, only the non-exempted materials need to be tested, but the entire finished product must be certified for compliance. A screen printed children's t-shirt would require lead testing of the screen print only, not the shirt itself, but a certificate of compliance would need to be issued for the finished product—the printed children's shirt.

**California's Metal Containing Jewelry Law:** Restricts lead content in jewelry for all consumers. It includes the definition of jewelry watches as well as detachable shoe and clothing ornaments and hair accessories. The law was enacted in 2006 as the result of a 2004 Proposition 65 consent judgment with a number of jewelry manufacturers, distributors and retailers. The law classifies materials as Class 1, 2 or 3 and sets limits on the amount of allowable lead for each class.

- **Class 1 Materials** are materials that are not likely to contain lead. All Class 1 Materials are acceptable for use if the jewelry is made entirely of the material. The Class 1 Material list includes but is not limited to stainless steel, sterling silver, gold, and natural materials including coral, feathers and shells.

- **Class 2 Materials** are more specific to the lead levels present in the materials. Electroplated metal must have less than 6 percent lead by weight. Unplated metal must have less than 1.5 percent lead. Plastic and rubber materials must have less than 200 ppm of lead by weight. And, a dye or surface coating is considered a Class 2 Material if it has less than 600 ppm of lead by weight.

- **Class 3 Materials** are materials that are not Class 1 or Class 2 materials. All Class 3 materials must contain less than 600 ppm of lead by weight.

In order to comply with the California Lead Containing Jewelry

Law, a manufacturer or supplier of jewelry must provide certification that the jewelry is in compliance. This certification should be provided to the person who is distributing the jewelry or the certification can be displayed prominently on the shipping container or on the jewelry's packaging. Additionally, the manufacturer or supplier must, upon request from the DTSC (and within 28 days) provide to DTSC technical documentation or other information showing that the jewelry is in compliance with the law.

Individual persons who violate the law may be subject to civil penalties up to \$2,500 per day per violation. The fines are higher for manufacturers, suppliers and distributors who "knowingly and intentionally manufactures, ships, sells, offers for sale, or offers for promotion jewelry in violation of the law." In these instances, fines may be between \$5,000 and \$100,000, or imprisoned up to a year, or both. Businesses that "knowingly and with intent to deceive falsifies any document or certificate required by the law" could receive fines up to \$50,000, or imprisoned up to a year, or both.

The test methods required by the Metal-Containing Jewelry law require specific sample preparation and testing procedures for certain materials as outlined in sections 25214.4 and 25214.1 of the *California Health and Safety Code*. Test methods found in *EPA Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, SW-846 (Third Edition)* are required to determine compliance.

This law is completely separate from Proposition 65 and is not pre-empted by the CPSC. Compliance with Prop 65 and the Metal Containing Jewelry Law is required. Under the Metal Containing Jewelry Law manufacturers have two options for providing certification of their jewelry's compliance:

1. Upon request, provide certification to the entity selling/distributing the manufacturer's jewelry; or
2. Displaying the certification in a prominent location on the shipping container or the jewelry packaging.

## Mercury

The federal *Mercury Containing Battery Management Act* limits mercury in batteries to 25 mg per cell. Some state legislation further restricts mercury, particularly in batteries and battery-operated novelties. The limit is typically considered to be less than 5 mg per cell, which is expected to reduce the likelihood of mercury having been added intentionally. There are a number of states that have passed mercury in batteries and novelties laws. These laws cover products that are intended for personal or household enjoyment, including but not limited to: toys, figurines, adornments, games, cards, ornaments, yard statues and

figurines, candles, jewelry, holiday decorations and footwear and other apparel items.

States with these battery restrictions include California, Connecticut, Illinois, Maine, Michigan, New Hampshire, Ohio, Oregon and Texas. There is proposed legislation in certain states for further mercury restrictions. States continue to consider additional product safety requirements. You should always check with your state to make sure you have current information.

## Additional Requirements For Toys

The Consumer Product Safety Commission (CPSC) notes on their website that, “for toys, *ASTM F963-11*, Standard Consumer Safety Specification for Toy Safety, places additional limits on the amount of antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium based on the soluble portion of that material using a specified extraction methodology given in the standard.”

It is necessary to conduct ASTM F963-11 solubility testing on applicable toys for antimony, arsenic, barium, cadmium, chromium, mercury, and selenium because those are not covered by *16 CFR § 1303.1*. For lead, however, testing for the soluble limit is not necessary for products subject to *16 CFR § 1303.1* because the maximum total lead content in paint is 90 ppm in *16 CFR § 1303.1*, which is a more stringent requirement in all cases.”

The CPSC addresses the testing referred to here and other requirements specifically for toys in their *frequently asked questions (FAQs)* on toys and the mandatory toy standards.

**California Proposition 65:** This legislation is also known as the Safe Drinking Water and Toxic Enforcement Act of 1986, with the initial purpose to protect California citizens from chemicals known to cause cancer, birth defects or other reproductive harm. The list has grown to more than 900 chemicals and new chemicals continue to be added. Prop 65 is essentially a labeling requirement—if your product contains a chemical on the list, a warning statement is required to alert consumers of its presence so that consumers can then make informed purchasing decisions. *Proposed changes to Prop 65* are even more stringent and expected to be implemented in the near future. PPAI has created a Prop 65 Best Practices guide for our members.

## Product Concept and Sourcing Considerations

When selecting a product and a production partner, it is not enough to simply understand regulations and how they apply to your product. It is essential that you evaluate your production partners to ensure they have proper chemical controls in their facilities. Consider asking:

- How are chemicals sourced?
- How are chemicals stored?
- How are chemicals mixed? What controls do you have in place?
- How do you label chemicals? What languages do you include on those labels?
- Do you have SDS on-site for all chemicals in use?
- Is your team trained to handle chemical spills / human exposure?
- Do you regularly inspect your facility to ensure compliance with chemical management procedures? When you find non-conformities, how do you put CAPs in place?

**Online Resources:****U.S. National Library of Medicine - Heavy Metals Toxicity and the Environment:**

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4144270/>

**Agency for Toxic Substances & Disease Registry:** <http://www.atsdr.cdc.gov/csem/csem.asp?csem=1&po=11>

**ASTM F963-11:** <http://www.astm.org/Standards/F963.htm>

**ASTM F963 Quick Facts:** <http://www.astm.org/toys.html>

**ASTM F2923-14:** <http://www.astm.org/Standards/F2923.htm>

**ASTM F2999-14:** <http://www.astm.org/Standards/F2999.htm>

**FHSA 16 CFR 1500:** <https://www.govinfo.gov/app/details/CFR-2012-title16-vol2/CFR-2012-title16-vol2-part1500>

**Code of Federal Regulations (CFR):** <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>

**CPSC Toy Safety FAQs:** <http://www.cpsc.gov/Business--Manufacturing/Business-Education/Toy-Safety/>

**CPSC Study on XRF Technology:**

<http://www.cpsc.gov/en/Regulations-Laws--Standards/Federal-Register-Notices/2013/Requirements-Pertaining-to-Third-Party-Conformity-Assessment-Bodies/>

**Consumer Product Safety Act (CPSA):** <http://www.cpsc.gov/PageFiles/105435/cpsa.pdf?epslanguage=en>

**Consumer Product Safety Improvement Act (CPSIA):**

<https://www.cpsc.gov/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act>

**CPSIA ASTM F963:** <http://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Toy-Safety/ASTM-F-963-11-Chart/>

**Child Safety Protection Act (CSPA):** <http://www.cpsc.gov/PageFiles/105423/cspa.pdf>

**Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint:**

<https://www.gpo.gov/fdsys/granule/CFR-2011-title16-vol2/CFR-2011-title16-vol2-sec1303-1/content-detail.html>

**California Proposition 65:** <http://oehha.ca.gov/prop65.html>

**PPAI Prop 65 Best Practice:**

<https://leginfo.ca.gov/faces/codesTOCSelected.xhtml?tocCode=HSC&tocTitle=+Health+and+Safety+Code+-+HSC>

**Prop 65 Impending Changes – New Article 6:** [http://oehha.ca.gov/prop65/CRNR\\_notices/WarningWeb/NPR\\_Article6.html](http://oehha.ca.gov/prop65/CRNR_notices/WarningWeb/NPR_Article6.html)

**California Safer Consumer Products Act (SCP):** <https://www.dtsc.ca.gov/SCP/SaferConsumerProductsProgram.cfm>

**California Lead in Jewelry: Metal-Containing Jewelry Law:** <https://dtsc.ca.gov/toxics-in-products/metal-containing-jewelry-law/>

**Illinois Lead Poisoning Act:** <http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1523&ChapterID=35>

**Massachusetts Toxics Use Reduction Act:** <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleII/Chapter21I>

**Maine Toxic Chemicals in Children's Products Law:** <http://www.maine.gov/dep/safechem/>

**Washington Children's Safe Products Act:** <http://www.ecy.wa.gov/programs/hwtr/RTT/cspa/index.html>

**PPAI State Regulations Best Practices:** <http://www.ppai.org/media/1819/pr-bp-state-regulations.pdf>

**PPAI State Regulations Summary:** <http://www.ppai.org/media/1845/pr-guide-state-regulations-chart.pdf>

**PPAI Jewelry Product Responsibility Best Practice:** <http://www.ppai.org/media/1810/pr-bp-jewelry.pdf>

**Safe Kids' Jewelry Act:** <http://thomas.loc.gov/cgi-bin/query/z?c111:S.2975.IS>:

**Children's Toxic Metals Act:** <https://www.govtrack.us/congress/bills/111/hr4428/text>

**European RoHS Directive:** [http://ec.europa.eu/environment/waste/rohs\\_eee/legis\\_en.htm](http://ec.europa.eu/environment/waste/rohs_eee/legis_en.htm)

**Mercury Containing Battery Management Act:** <https://www.epa.gov/sites/production/files/2016-03/documents/p1104.pdf>

**Safer States Network:** <http://www.saferstates.com/>

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