UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

This document has been electronically approved and signed.

Memorandum

Date:
6/29/2011

TO : The Commission
Todd A. Stevenson

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

FROM : Marc J. Schoem, Deputy Director, Office of Compliance and Field Operations
Mary F. Toro, Director, Regulatory Enforcement, Office of Compliance and Field Operations
Howard N. Tarnoff, Special Assistant to the Acting Assistant Executive Director, Office of Compliance and Field Operations
John W. Boja, Ph.D., Lead Compliance Officer, Regulatory Enforcement, Office of Compliance and Field Operations

SUBJECT : The Technological Feasibility of Reducing Lead Content to 100 ppm: Compliance Data

I. Introduction

Section 101(a)(2) of the Consumer Product Safety Improvement Act of 2008, (hereinafter referred to as the "Act" or "CPSIA"), Pub. L. 110-314 (August 14, 2008), provides that for products designed or intended primarily for children 12 years old and younger, the total lead content limit by weight in any part of a children's product is limited to 300 parts per million (ppm) 1 year after the date of enactment of the Act (August 14, 2009), and 100 ppm of lead 3 years after the date of enactment of the Act (August 14, 2011), unless the Commission determines that it is not technologically feasible to have this lower limit for a particular product or product category. The Commission may make such a determination only after notice and a hearing and after analyzing the public health protections associated with substantially reducing lead in children's products. If the Commission determines that the 100 ppm lead content limit is not technologically feasible for a product or product category, the Commission shall, by regulation, establish the lowest amount of lead content below 300 ppm that it determines is technologically feasible.

Staff of the Office of Compliance is responsible for enforcing the regulations under the authority of the U.S. Consumer Product Safety Commission (CPSC or Commission). Staff is also responsible for providing advice and guidance to the regulated industry on how to comply with the regulations. Prior to implementation of the CPSIA, the Office of Compliance issued guidance for regulating the lead content in children's products in two separate documents under the Federal Hazardous Substances Act (FHSA, 15 U.S.C. § 1261–1278). The first guidance document addressed lead content in children's products and presented the factors Commission staff uses to determine when lead content in a children's product meets the definition of a hazardous substance under the FHSA. This interpretation is codified at 16 CFR § 1500.230. The second guidance document on lead in children's products addresses children's metal jewelry containing lead. The guidance states that an article of children's metal jewelry is deemed a "hazardous substance" if it contains toxic quantities of lead sufficient to cause substantial illness as a result of reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children (15 U.S.C. § 1261(f)(1)(A)). The jewelry constitutes a "banned hazardous substance" under the FHSA, 15 U.S.C. § 1261(q)(1)(A), if it is intended for use by children and its toxic lead content is accessible by a child. In addition to regulating lead content in children's products under the FHSA, the Commission has regulated the lead content in paint and certain consumer products bearing lead-containing paint since 1978.

The guidelines on children's metal jewelry specify a procedure for CPSC staff to follow in determining whether to pursue enforcement under the FHSA. If the total lead concentration in an article of children's metal jewelry is less than or equal to 0.06 percent by weight (600 ppm), staff will not seek corrective action. If however, the screening test shows that the total lead content in a product exceeds 600 ppm, then staff will conduct additional testing using an acid extraction test. If the acid extraction test yields an accessible level of lead that is less than or equal to 175µg of lead, then the Office of Compliance will not seek corrective action. On the other hand, if the total lead concentration exceeds 175µg of lead, staff will decide, on a case-by-case basis, whether to pursue corrective action. Staff considers factors such as the size of the object, the number of violative components, and the likelihood of exposure or ingestion in deciding whether to pursue corrective action.

Under the CPSIA, Congress initially mandated that the total lead content of products not exceed 600 ppm. The statute specifies that after one year, the lead level must be reduced to 300 ppm. In addition, the CPSIA specifies that the total lead content in a product will be considered as opposed to the extractable amount of lead in a product. This mandate effectively eliminates any determination of risk of harm, which prior enforcement policy took into consideration.

II. Discussion

A. Current Compliance at 300 ppm

Under Section 101(a)(2)(B) of the CPSIA, the total lead content allowable in a children's product is 300 ppm by weight for any part of the product, effective August 14, 2009. Accordingly, under the statute, no product that is intended primarily for children ages 12 and under can be offered for sale if the total lead content exceeds 300 ppm. As of October 1, 2009, all products collected for inspection at manufacture, retail, or import must demonstrate a total lead content level below 300 ppm. From October 1, 2009 to the present, CPSC staff found 812 violations of the lead content limit in children's products.

To examine compliance with the CPSIA's total lead content limit in greater detail, we selected a specific children's product category: children's shoes. We selected children's shoes for several reasons: (1) Currently, there is no program specifically targeting children's shoes; therefore, we chose samples with no prior knowledge of the lead content levels in the products. (2) The product code for shoes is well-defined. This means that the collected samples will not be listed under multiple codes. (3) Finally, most, if not all, children's shoe samples analyzed at the CPSC lab were collected at import. This later factor provides two benefits. First, all import samples are logged into an import log book that notes not only the samples collected, but also the number of samples screened but not collected. Second, import samples turnaround faster than domestically collected samples at the laboratory. This is due to the 30-day detention period imposed on import samples.

From FY 2010 to the present, we collected records of 279 shoe samples. The samples are of shoes primarily intended for children ages 12 and under, culled from the Compliance Integrated Field System (IFS) and Section 15 databases. This number includes 271 samples collected at import to examine for lead content or small parts compliance determinations. The number also includes eight Section 15(b) reports of potential violations. The majority of the shoe samples originated from China (268), with smaller numbers of shoe samples originating from Taiwan (5), the United States (2), Mexico (1), and Thailand (1). We have not determined the country of origin for two samples.

Section 15(b) reports are self-reported and the products associated with these cases were not tested by the CPSC laboratory. Additionally, some Section 15 reports pertain to issues other than lead content. Therefore, we excluded Section 15(b) reports from the data set; this included all of the samples from the United States, Mexico, and Thailand, plus four samples from China. From FY 2010 to the present, 559 pairs of shoes intended primarily for children ages 12 and under were screened preliminarily for lead content with a hand-held X-ray fluorescence (XRF) spectrometer. Of those 559 pairs of shoes, 289 had lead concentrations or other hazards, which warranted sending them to the CPSC laboratory for testing; an additional 270 pairs of sampled shoes from 68 manufacturers were sent to the CPSC laboratory for a more complete analysis. Laboratory analysis revealed that in 257 samples from 66 different manufacturers, the total lead content exceeded 300 ppm; another 12 samples (among those which were pre-screened as having potentially excessive lead content) had a lead content level below 300 ppm. Laboratory analysis is pending for one sample. In two cases, however, the manufacturer is unknown. The majority of the samples originated in China (265); however, five samples were imported from Taiwan.

The violative components of the shoes included various polymer components (sole, uppers, and decorations), metal parts, and crystal decorations. In some cases, lead levels found in components, especially crystals, exceeded the 300 ppm level by several orders of magnitude. In six cases (1.1 percent of the 559 pairs of shoes sampled at the ports), the level of lead detected in the shoes was close to the 300 ppm level limit.

While the lead content we have observed in children's shoes may or may not be representative of the entire state of compliance with the current 300 ppm lead content limit for all shoes, or for just children's products, this observation certainly suggests that some manufacturers of children's products are having difficulty complying with the current limit. It would be easy to dismiss some of the violations for crystals[1] and vinyl by stating that it is well known that these materials contain lead and acknowledging that reduced lead or lead-free substitutes are available. However, the fact remains that manufacturers, for some reason, used violative components to make these children's products, but it is beyond the scope of this memorandum to investigate or even postulate about the reason(s) for the noncompliance. As noted above, 289 pairs of shoes screened at the ports were found not to have sufficient lead content to warrant testing; and of those found to have lead content that exceeded 300 ppm, some of those demonstrated excessive lead in crystals, while others demonstrated excessive lead content in the soles, uppers, or decorations on the shoes sampled. Therefore, the makers of violative shoes still used compliant materials for other parts of the product, and no single material was uniformly found to be the cause of failures. The laboratory screens all of the different accessible parts of each sample.

As noted previously, during FY 2010, and part of FY 2011, 559 pairs of shoes from 68 manufacturers were examined at import. Of that number, 270 pairs of shoes from 66 manufacturers were collected for lead analysis. Most of the shoes were imported from China, with a very small number of samples imported from Taiwan and at least three other countries. Laboratory analysis revealed that the total lead content exceeded 300 ppm in 257 samples, indicating that 46 percent of the total number of shoes that were examined at the ports was determined to contain excessive lead.[2] The shoe shipments were typically recommended for seizure, and therefore, ultimately were not distributed in commerce.

B. Sample-to-Sample Variability of Total Lead Content Within CSPC Samples

1. Variability Within a Given Class of Samples

When determining if a sample contains a violative amount of lead, one major difficulty is the variability in lead content that may occur between samples. It is very important to draw a distinction between testing variability and material variability. Staff of the Directorate for Laboratory Sciences has analyzed materials known to contain lead to clarify that testing variability at levels below 100 ppm is reasonable. Laboratory staff found that uncertainty in the results overlap with uncertainty in the materials themselves.

Staff determined total lead content in 270 samples of shoes that were intended primarily for children ages 12 and under. In most of the samples, at least two subsamples of each product were tested. The laboratory commonly found material differences between subsamples, such that both screening by XRF and additional testing by other methods showed the presence of different levels of lead in the materials.

---

[1] Only 23 of the 257 lead content violations were for crystals.

[2] It is worth noting that this sample set is overly representative of smaller importers or distributors. Many large, well-known brands are not represented in the data, which renders the data biased to some extent because smaller manufacturers and importers may not have the sophistication to test the raw material frequently or undertake the quality control testing of the finished product that larger manufacturers or importers would complete.

2. Specific Examples of Variability in Lead Content

In some cases, the sample-to-sample variability within a specific collected sample resulted in one subsample having a lead content greater than the current CPSIA limit of 300 ppm, while another subsample had a lead content less than 300 ppm. This variability has been observed in all materials, including metal and plastic. Laboratory analysis of a metal rivet on a pair of children's shoes found a total lead content of 213 ppm in one subsample and 321 ppm in another. This variability most likely represents material differences between the subsamples. While the total lead content measured in one subsample was below the current CPSIA 300 ppm limit for lead content, the other subsample demonstrated lead content above the limit. In many cases, a "sample" consisted of 8 to 10 subsamples. At times, investigators included different colors or styles within the same sample; thus, sometimes, only one or two "green" or "blue" shoes were present, and testing demonstrated that one part on one style of shoe (obviously made of different materials than the shoe of a different color) exceeded 300 ppm while the other sample of the same part on the same color shoe did not exceed 300 ppm.

Testing revealed that the total lead content of a metal button on another pair of shoes was 170 ppm in one subsample and 30 ppm in another. The sample was released to the firm because the current limit for lead content is 300 ppm. However, if this sample were tested to the proposed limit of 100 ppm, additional subsamples of the item would need to be tested due to the high variability of the lead content within the subsamples. It should be noted that for samples that are far below the current regulatory limit, the laboratory may have reported screening results only, without completing full testing because of the low levels of lead found in the sample.

In addition to the sample-to-sample variation observed within metal components of the shoes, sample-to-sample variations are also observed among plastic components. The rear wheel of a ride-on toy intended for children ages 12 years and younger demonstrated a total lead content of 265 ppm in one subsample, and 362 ppm in another subsample. Other plastic components of the toy also demonstrated sample-to-sample variability. For example, the total lead content of the seat was determined to be 423 ppm in one subsample and 287 ppm in another. However, not all components of these two particular samples displayed this degree of subsample-to-subsample variability. The plastic front wheel connector was determined to contain 458 ppm of total lead in one subsample and 452 ppm of lead in the other. Due to the high total lead content in many of the components of this product, the firm requested permission to recondition the product by replacing the violative components with components that met the total lead requirements under the CPSIA.

In another example, the total lead content of the plastic substrate of a toy helicopter was determined to be 281 ppm in one subsample and 193 ppm in a second subsample of the toy. The total lead content was below 300 ppm, and the sample was released.

Laboratory analysis of the yellow plastic used in two of the molded plastic figurines in a set of toy wrestlers indicated a lead content in one subsample of 312 ppm and 298 ppm in another subsample. The product was released, and the importer was notified that because the lead content of the toys was close to the current 300 ppm limit for lead under the CPSIA, slight variations in the manufacturing process or the raw materials could result in the presence of violative levels. We asked the manufacturer to identify potential sources of lead contamination and to ensure that these and any related products imported into the United States in the future contain no more than the regulated amount of lead.

Several products that exhibited sample-to-sample variability appear to be well below the current 300 ppm limits and near the impending 100 ppm limit. Compliance staff knows that some manufacturers and importers anticipate that a total lead content limit of 100 ppm will be adopted and that the limit will be retroactive. As a result, many of these firms already require their products to be tested to a total lead content limit of 100 ppm. From the 28,000 items tested for lead content since October 1, 2009, it is possible to find examples in which different subsamples might straddle a higher or lower limit, regardless of whether a 300 ppm limit or a 100 ppm limit is chosen.

As another example of a product apparently manufactured to meet the proposed new lower total lead limit, a portion of the silver plastic undercarriage of a remote control toy car was determined to be 67 ppm in one subsample, 111 ppm in another sub-sample, and 77 ppm in a third subsample. The mean total lead content in these subsamples was 85 ppm. While this sample did exhibit a large variation in total lead content, it would meet the proposed 100 ppm total lead content limit.

A handlebar pad constructed of sheet plastic was determined to have a total lead content of 127 ppm in one subsample and 78 ppm in a second subsample. Under the proposed 100 ppm total lead content limit, staff would request that the manufacturer identify potential sources of lead contamination and ensure that these and any related items imported into the United States contain no more than the regulated amount of lead.

A toy set consisting of a plastic garage, plastic track, and various plastic vehicles also demonstrated a degree of variability near the 100 ppm level. The plastic track component of the toy was determined to have a total lead content of 108 ppm in one subsample and 160 ppm in a second subsample. A gray plastic trailer in the set was determined to have a total lead content of 111 ppm in one subsample and 99 ppm in the second subsample. One subsample of the red plastic tanker truck was determined to have a total lead content of 100 ppm, while the second subsample was determined to have a total lead content of 92 ppm. The current regulated level of lead is 300 ppm, and the sample was released.

In this example, under the proposed limit of 100 ppm, staff would request additional testing due to the high sample-to-sample variability observed in the plastic track. If the mean total lead content of the track sample remained high, CPSC staff would request that the item be reconditioned by removing or replacing the track within the set. If the track could not be removed because it was an integral part of the set, or the track could not be replaced, CPSC staff would request that CBP seize the toy set. If the toy could be reconditioned, staff would also notify the firm that the lead content of the plastic trailer was close to the 100 ppm limit for lead under the CPSIA and slight variations in the manufacturing process or the raw materials could result in violative levels being present. We would ask the manufacturer to identify potential sources of lead contamination and to ensure that these and any related items imported into the United States contain no more than the regulated amount of lead.

In addition to the examples of sample-to-sample variability in total lead content analysis observed with testing by the CPSC laboratory, outside laboratories have also experienced the same findings of material differences. A firm supplied data showing a high degree of sample-to-sample variability with items made of plastic. This firm produces an educational item that contains plastic chips that are used as counters. Three different samples of a yellow plastic counter that originated from the same lot were digested in acid, and the total lead content for each sample was determined using inductively coupled argon plasma spectrometry. The total lead content in the three counters was determined to be 23, 88, and 139 ppm. The limit for lead content at the time of testing was 600 ppm; however, if the proposed limit of 100 ppm were in effect, then one of the three counters would be considered violative, even though the plastic counters originated from the same lot.

When determining compliance with the lead content limit of the CPSIA, at 100 or 300 ppm, the sample-to-sample variability presents several problems. The first decision that needs to be made is the selection of the proper number of samples. The decision on the number of samples to be tested is up to the manufacturer of the product; however, the proposed text of 16 CFR part 1107 states that the number of samples selected must be sufficient to provide a high degree of assurance that the tests conducted demonstrate accurately the ability of the children's product to meet all applicable children's product safety rules. If a given number of samples are selected and then tested, the question becomes, if one sample is determined to contain an excessive amount of lead, should the entire lot or batch be considered violative?

When a data point appears to deviate markedly from several other data points the anomalous data point can be called an "outlier." An outlier may indicate bad data that was due to experimental error, which could be due to a host of causes. Alternately, outliers may be due to random variation within the sample. No matter the cause, outliers cannot simply be deleted without good reason. There are statistical techniques that can be used to determine if an outlier is due to experimental error or arises from a random variation within the sample.

While larger firms may be able to employ these statistical methods, smaller companies may not have the sophistication to employ these statistical techniques. As a result, they would need to consult with an outside party or rely on the testing laboratory to conduct the statistical tests. If neither option was available to them, they may simply accept the test results, assume that the sample indeed was violative, and as a result, scrap the tested material.

In order to reduce the effect of outliers, manufacturers can reduce the total amount of lead within a sample or use methods to reduce sample-to-sample variability. Reducing the total amount of lead within a product would have the effect of decreasing the number of violations due to sample-to-sample variability. However to use this approach effectively, the manufacturer would need to know how much sample-to-sample variability exists. For example, if a manufacturer knew that the sample-to-sample variability was 40 ppm, it could specify that the product would never contain more than 60 ppm of lead so that sample would never exceed the regulated amount. Unfortunately, it is difficult to predict with certainty the amount of expected variability, unless the source of the variability is identified and the source is tightly controlled. If the source of variability is unknown, then it would be impossible to predict the degree of variability expected to occur. Of course, this is also the case with a limit of 300 ppm or any other defined boundary.

Another method that could be employed to reduce the effect of outliers is to reduce the number of outliers. This can be accomplished by reducing the source(s) of variability. The Staff Briefing Package on the Technological Feasibility of 100 ppm Lead states that lead is only present in many materials because it is intentionally added. Thus, with the manufacture of raw metals or plastics, the manufacturer must take care to avoid the addition of lead. However, lead could also be added unintentionally when recycled material that contains lead is introduced into the manufacturing process. This source of lead could be eliminated by no longer using recycled materials in the manufacturing process or by testing the recycled material extensively prior to its addition into the manufacturing process. Each method would have the effect of reducing the amount of potential variability in lead levels and would also beneficially reduce the overall amount of lead within the sample.

C. Reports of Lead Variability Within the Same Sample

The lead content has not only been demonstrated to vary between samples, but it also can vary within the same sample. Recently, a firm submitted a laboratory report to the staff of the Office of Compliance. The report pertained to a test for total lead content in a single piece of aluminum alloy casting that was a component of a larger item Ten different areas of the casting were sampled. Each area sampled was digested in acid, and the total lead content was determined for each area using inductively coupled argon plasma spectrometry. The results of the analysis for total lead content from the 10 areas on the aluminum alloy casting are shown in the table below.

Area	1	2	3	4	5	6	7	8	9	10
Lead (ppm)	119	126	113	98	99	82	94	99	100	102

Here, the existence of a larger sample set (10), reportedly extracted from a single material, makes an analysis of mean and standard deviation relevant. This data set has an average of 103 ppm with a standard deviation of 12.8 ppm, which is 12 percent of the mean. This data represents the compliance dilemma surrounding any regulatory lead limit, impact resistance, or other measurable limit given the fact that the measurements from four areas of the single casting exceeded the proposed 100 ppm limit, and the remaining six areas fell below the 100 ppm limit. Good laboratory practice should include ensuring that a representative aliquot from the entire part is analyzed, as discussed in CPSC Method CPSC-CH-E1001-08.1: “When preparing a sample, the laboratory shall make every effort to assure that the aliquot removed from a component part of a sample is representative of the component to be tested, and is free of contamination.”

A firm presented data that also shows lead content variability in material other than metal. A string from a mesh bag that holds dominoes was cut into 10 pieces. Each piece was then digested in acid, and the total lead content for each piece was determined using inductively coupled argon plasma spectrometry. The results of the analysis for total lead content from the 10 pieces of string are shown in the table below.

Specimen	1	2	3	4	5	6	7	8	9	10
Lead (ppm)	255	239	271	241	265	259	275	255	254	254

The lead content varied from 239 ppm to 271 ppm in the 10 pieces of string that were cut from a single piece of longer string. The mean lead content of the 10 pieces of string was 257 ppm, with a standard deviation of 12, which is 4.5 percent of the mean. In each case, the sampled areas would pass the test for the current limit of 300 ppm; however this example illustrates that materials other than metals show some degree of variability within the same sample, albeit an example with low variability.

Section 101(a)(2) of the CPSIA limits the total lead content limit by weight in any part of a children's product to 300 ppm. While the word "part" could be interpreted to mean "component," it could also denote "part" or, in other words, a piece of the whole. Because part of the casting contains excessive lead, the entire casting could be considered violative, although this is not how CPSC staff has interpreted lead content in materials.

III. Conclusion

Section 101(a)(2) of the CPSIA states that in products designed or intended primarily for children 12 years of age and under, the total lead content limit by weight in any part will be limited to 100 ppm three years after the date of enactment of the Act (August 14, 2011), unless the Commission determines that it is not technologically feasible to have this lower limit for a product or product category. The fact that some products have been able to reach total lead content levels of 100 ppm, demonstrates that it is technologically feasible to produce products to a total lead limit of 100 ppm. However, as observed with children's shoes, some manufacturers are not producing compliant products.

The testing variability and material variability discussed above mean that ensuring compliance with the 100 ppm limit may require that lead in components or products is sufficiently below the limit to account for expected quality control variability. Due to the reported variations in lead distribution within a single component item cast with a lead-containing metal alloy, metal alloys used to make the components will need to contain substitutes for lead, or the metal alloy will need to have very low levels of lead. Firms should ensure that they test with appropriate, representative aliquots of alloyed component parts.