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

The contents of this document will be discussed at the Open Commission Meeting scheduled for June 29, 2011.

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: July 13, 2011

June 22, 2011

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: Philip L. Chao, Assistant General Counsel
Hyun S. Kim, Attorney, OGC

SUBJECT: Technological Feasibility of 100 ppm for Lead Content

The Office of the General Counsel is providing for Commission consideration the attached draft *Federal Register* notice on the technological feasibility of the 100 ppm lead content limit in children's products.

Please indicate your vote on the following options.

I. Approve publication of the draft notice in the *Federal Register* without changes.

______________________________ _______________
(Signature) (Date)

II. Approve publication of the draft notice in the *Federal Register* with changes.
(Please specify.)

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(Signature) (Date)

III. Do not approve publication of the draft notice in the *Federal Register*.

______________________________ ________________

(Signature) (Date)

IV. Take other action. (Please specify.)

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(Signature) (Date)

Attachments:

Draft *Federal Register* Notice: Children's Products Containing Lead; Technological Feasibility of 100 ppm for Lead Content; Notice of Effective Date of 100 ppm Lead Content Limit in Children's Products

Staff Briefing Package: Technological Feasibility of 100 Parts Per Million Total Lead Content Limit, June 2011.

BILLING CODE 6355-01-P

U.S. CONSUMER PRODUCT SAFETY COMMISSION

Children's Products Containing Lead; Technological Feasibility of 100 ppm for Lead Content; Notice of Effective Date of 100 ppm Lead Content Limit in Children's Products

[Docket No. CPSC-2010-0080]

AGENCY: U.S. Consumer Product Safety Commission

ACTION: Notice

SUMMARY: Section 101(a) of the Consumer Product Safety Improvement Act ("CPSIA") provides that, as of August 14, 2011, children's products may not contain more than 100 parts per million ("ppm") of lead unless the Consumer Product Safety Commission ("CPSC," "Commission," or "we") determines that such a limit is not technologically feasible. The determination can only be made after notice and a hearing and after analyzing the public health protections associated with substantially reducing lead in children's products. On February 16, 2011, we conducted a public hearing to receive views from all interested parties about the technological feasibility of meeting the 100 ppm lead content limit for children's products and associated public health considerations. Through this notice, we announce that children's products must meet the statutory 100 ppm lead content limit on August 14, 2011, unless otherwise excluded under 16 CFR 1500.87 through 1500.91.

DATES: The 100 ppm lead content limit for children's products is effective on August 14, 2011.

FOR FURTHER INFORMATION CONTACT: Dominique Williams, Directorate for Health Sciences, Consumer Product Safety Commission, Bethesda, MD 20814; telephone: (301) 504–7597; email: dwilliams@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 101(a)(2)(C) of the CPSIA (15 U.S.C. 1278a(a)(2)(C)) provides that, as of August 14, 2011, children's products may not contain more than 100 ppm of lead unless the Commission determines that such a limit is not technologically feasible. The Commission may make this determination only after notice and a hearing and after analyzing the public health protections associated with substantially reducing lead in children's products. Section 101(d) of the CPSIA (15 U.S.C 1278a(d)) provides that a lead limit shall be deemed technologically feasible with regard to a product or product category if:

(1) a product that complies with the limit is commercially available in the product category;

(2) technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;

(3) industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or

(4) alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

On July 27, 2010, we published a notice in the *Federal Register* (75 FR 43942), requesting comment and seeking information concerning the technological feasibility of meeting the 100 ppm lead content limit for children's products that are not otherwise excluded from the lead content limits under 16 CFR 1500.87 through 1500.91. After initial consideration of the comments and information received in response to the July 27, 2010 notice, we published a notice in the *Federal Register* (76 FR 4641) on January 26, 2011, announcing that we would be conducting a public hearing to receive views from all interested parties about the technological feasibility of meeting the 100 ppm lead content limit for children's products and associated public health considerations. The hearing was held on February 16, 2011. On March 9, 2011, we published another notice in the *Federal Register* (76 FR 12944), reopening the hearing record to allow hearing participants to submit relevant studies and supplementary data in response to additional questions from certain Commissioners.

Participants who submitted comments and hearing testimony regarding the technological feasibility of meeting the 100 ppm lead content limit and associated public health considerations included consumers, consumer groups, manufacturers, retailers, associations, and laboratories. Comments submitted in this proceeding are available at http://www.regulations.gov, under Docket No. CPSC-2010-0080. The video webcast of the hearing, as well as the presentations and written comments from the hearing, are available at the CPSC web site: http://www.cpsc.gov/webcast/previous.html. A transcript of the hearing and supplemental information provided by hearing participants are also available at www.regulations.gov, docket CPSC-2010-0080.

II. Technological Feasibility of 100 ppm

We evaluated the technological feasibility of the 100 ppm lead content limit for children's products based on available technical information, written public comments, public hearing oral comments, and other available information. CPSC staff's analysis regarding the technological feasibility of materials and products to meet the 100 ppm lead content limit is contained in the staff briefing package available on the CPSC website at: http://www.__________.

We evaluated the technological feasibility of meeting the 100 ppm lead content limit in materials such as plastics, glass, and metals; reviewed the economic impacts of reducing the lead content limit from 300 ppm to 100 ppm; and considered the public comments received in this proceeding, including comments on public health protectiveness, economic burdens, availability of compliant materials, and variability in test results. Based upon this analysis, the staff could not recommend that the Commission make a determination that it is not technologically feasible for a product or product category to meet the 100 ppm lead content limit for children's products under section 101(d) of the CPSIA. No such determination has been made by the Commission. Therefore, all children's products sold, offered for sale, manufactured for sale, distributed in commerce, or imported for sale in the United States must meet the 100 ppm lead content limit beginning August 14, 2011 as statutorily mandated by the CPSIA unless otherwise excluded under 16 CFR 1500.87 through 1500.91. With respect to bicycles and related products and youth motorized recreational vehicles, a stay of enforcement regarding the lead content in certain parts, including metal components, is currently in effect until December 31, 2011 (76 FR 6765).

Dated:__________

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Todd A. Stevenson, Secretary
Consumer Product Safety Commission

Staff Briefing Package

Technological Feasibility of 100 Parts Per Million Total Lead Content Limit

June 22, 2011

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Briefing Memo

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

This document has been electronically approved and signed.

Memorandum

Date: June 21, 2011

TO : The Commission
Todd A. Stevenson, Secretary

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

FROM : Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences
Dominique J. Williams, Toxicologist, Directorate for Health Sciences

SUBJECT : CPSIA Section 101: 100 parts per million lead content requirement

This briefing package presents staff's analysis of information and public comments related to the technological feasibility of the mandatory lead content requirements for children's products and parts of products that will be effective Aug. 14, 2011.

I. Background

Section 101(a) of the Consumer Product Safety Improvement Act (CPSIA) (15 U.S.C. 1278a(a)) 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) as of Aug. 14, 2009, and 100 ppm of lead as of Aug. 14, 2011, unless the Commission determines that it is not technologically feasible to have this lower limit for a 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 below 300 ppm that it determines is technologically feasible.

Unless granted a specific exclusion or determination under the Commission's regulations at 16 CFR §§1500.87 through 1500.91, children's products, including the component parts of children's products, are subject to the lead limits and also to the testing and certification requirements of section 14(a)(2) of the Consumer Product Safety Act (CPSA). 15 U.S.C. 2063(a)(2).

Section 101(d) of the CPSIA (15 U.S.C 1278a(d)) provides that a lead limit shall be deemed technologically feasible with regard to a product or product category if:

> (1) a product that complies with the limit is commercially available in the product category;
> (2) technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;
> (3) industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or
> (4) alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

On July 27, 2010, the Commission published a notice in the *Federal Register* (75 FR 43942), inviting comment and seeking information concerning the technological feasibility of meeting the 100 ppm lead content limit for children's products that are not otherwise excluded from the lead limits.

After initial consideration of the comments and information received in response to the July 27, 2010 notice, the Commission published a notice in the *Federal Register* (76 FR 4641) on Jan. 26, 2011, announcing that it would be conducting a public hearing to receive views from all interested parties about the technological feasibility of meeting the 100 ppm lead content limit for children's products and associated public health considerations. The hearing was held on Feb. 16, 2011.[1]

On March 9, 2011, the Commission published a notice in the *Federal Register* (76 FR 12944) reopening the hearing record to allow hearing participants to submit relevant studies and additional data in response to further questions from individual Commissioners.

Products and component parts of products, unless exempted from the lead limits, are subject to the 300 ppm lead content limit effective Aug. 14, 2009. Thus, this briefing package addresses products or materials that currently comply with the 300 ppm lead content limit and that will be required to meet the 100 ppm lead content limit effective Aug. 14, 2011. Products or materials that do not meet the 300 ppm requirement are banned from use in children's products, with certain exceptions set forth under the Commission's regulations at 16 CFR §1500.87-1500.91, and are outside the scope of this proceeding.

II. Staff Analysis

Staff's evaluation of the technological feasibility of the 100 ppm lead content limit for children's products is based on published technical information, information from technical experts, written public comments and public hearing oral comments, and other available information. This section presents staff's analysis of the key issues identified by staff and others with respect to lead content of children's products.

The CPSC's Directorate for Engineering Sciences staff provided a detailed analysis of lead content in metals and metal alloys at Tab A and summarized below. The CPSC's Directorate for

[1] The video webcast of the hearing, as well as the presentations and written comments from the hearing, are available at the CPSC website: http://www.cpsc.gov/webcast/previous.html. A transcript of the hearing and supplemental information provided by hearing participants are available at www.regulations.gov, docket CPSC-2010-0080.

Economic Analysis staff provided a detailed analysis of the economic impacts of a 100 ppm lead content limit at Tab B and summarized below. Staff analyzed and summarized the public comments received in response to the request for comments published in the *Federal Register* and given at the public hearing. The comments and staff's responses to them are detailed at Tab C.

a. Materials and Testing

The CPSC received comments from a variety of stakeholders that addressed several key points concerning the hazards of lead exposure and the importance of limiting lead content in children's products, as well as the implications of lead content requirements for products and manufacturers. Commenters discussed test result variability due to material composition, variability in test results between different laboratories, public health protectiveness, economic burden, and available compliant supply. Several commenters concluded that 100 ppm lead is a technologically feasible limit; but other commenters concluded that it is not feasible for certain products to comply with a 100 ppm limit.

Most of the other major issues that have been raised in the comments address factors related to the lead content of specific materials and to the overall challenges of attaining compliance with a 100 ppm lead content limit.

i. Lead in Products

Lead is ubiquitous in our environment, largely due to human activities, such as mining and smelting and the use of lead in gasoline (now banned in the United States). Lead may be found in consumer products because of the intentional use of lead containing materials, such as pigments used for certain colors in paint, ink, or plastics; stabilizers in certain plastics, glass, and crystals; and certain metals and metal alloys. Lead also may be found in consumer products due to the recycling of lead containing materials in the manufacturing of new products. When the intentional use of lead and certain recycled materials are avoided, lead content of most materials and products may be substantially below 100 ppm.

The lead content of household paint and paints and surface coatings on children's products and certain household items has been restricted in the United States for several decades (16 CFR part 1303). For materials other than paint, international standards have restricted lead in children's toys for many years, although the restrictions have not been based on the lead content of products. Nonetheless, alternatives to the use of lead in products are available and have been in wide use for many years.

With respect to lead exposures, staff agrees that children's exposures to lead, including exposures to lead in children's products, should be limited. Implementation of the CPSIA lead content requirements for children's products helps ensure that children's products will not be a significant lead source.

ii. Plastics

Public commenters and participants at the Commission's public hearing asserted that applying the 100 ppm lead content limit to materials such as plastics is not an issue. For example, Erika Jones, representing the Bicycle Product Suppliers Association (BPSA) at the Feb. 16, 2011 public hearing, indicated: "… the bicycle industry does not have an issue with vinyls and plastics." Another participant at the hearing, Richard Locker, who represents several toy and children's product industries, confirmed that plastics are not a concern with respect to meeting the 100 ppm lead content limit. Richard Woldenberg of Learning Resources, Inc., expressed concern that plastic products are still an issue because of the use of recycled materials that could unintentionally introduce small amounts of lead at concentrations exceeding the 100 ppm limit. No commenter provided specific evidence of the amount of lead in recycled plastic as compared to "virgin" plastic.

Plastics are commonly produced without added lead. Manufacturers may need to implement supply chain controls and use diligence during transitions between the manufacture of non-children's products containing lead and the manufacture of children's products on the same equipment, and possibly avoid materials made with recycled products to ensure that lead has not been unintentionally introduced into their products. All of these actions on the part of manufacturers, if required, will tend to increase the costs of producing children's products, but complying with the 100 ppm lead content limit for plastics will not pose an issue.

iii. Lead Crystal

Lead crystal, typically containing more than 20 percent lead, cannot be used in children's products because the lead content exceeds the current 300 ppm limit. In a written comment, Sheila Millar, representing the Fashion Jewelry and Accessories Trade Association, stated that a new crystal product with the quality, sparkle, and shine of leaded crystal has been developed without the use of lead.

iv. Metals and Alloys

Metals and alloys are among the materials mentioned most often as problematic with respect to lead content above the 100 ppm level. In written and oral comments, the BPSA focused on steel and other metals, which are common materials in bicycles. BPSA stated that many metal component parts of bicycles cannot consistently satisfy a 100 ppm standard and indicated that the lower limit might be possible if virgin raw materials were available. BPSA contended that recycled metals added to the variability of lead content but did not substantiate that claim with data suggesting a difference between metal with recycled content versus metal without recycled content. BPSA added that the costs of moving from recycled steel to a different raw source material could result in an increase in the price of children's bicycles of approximately 25 percent and cited a specific example of a part, the inner tube valve stem, where the price would increase up to 28 percent. The concern with metals is not limited to bicycle manufacturers. Mr. Locker stated that similar materials are used in other children's products. A stay of enforcement for lead content in bicycle and ATV metal components is in effect until Dec. 31, 2011.

CPSC staff analysis of metals and metal alloys indicates that alloys with less than 100 ppm lead are available. Comments from the American Iron and Steel Institute suggest that recycled steel is used to produce steel and the lead vaporizes during the process given the high temperatures required in the steel making process. The staff is not aware of any reason why the same would not be true of steelmaking in China and other parts of the world since the same steelmaking processes are utilized. Furthermore, low-lead metal alloys that can replace alloys that would typically contain lead for functional purposes are also available, although access to these materials, especially for smaller businesses, is less certain.

v. Lead Content Data

CPSC received written submissions and oral discussion at the public hearing about results of testing children's products for lead. For example, Sanjeev Gandhi of SGS North America, Inc., presented results of testing thousands of toy samples. The testing data showed that most products or component parts tested for compliance with the current 300 ppm limit met that limit and that most of the products or parts that complied with the 300 ppm limit would comply with a 100 ppm limit as well. The data showed that metal items were somewhat more likely to have more than 100 ppm lead and also more than 300 ppm lead than glass and ceramics or plastics. This dataset showed that overall, 96.2 percent of metal items had less than 40 ppm lead, while 97.4 percent of glass and ceramic items, and 99.3 percent of plastic items had less than 40 ppm lead. For these materials, the percentage of samples with lead content more than 100 ppm and less than 300 ppm is 0.69, 0.34, and 0.06 percent for metals, glass and ceramics, and plastics, respectively. A submission from the Hong Kong American Chamber of Commerce indicated that in more than 13,000 tests of metallic parts used in the toy industry, 99.54 percent of samples had less than 100 ppm lead.

These data indicate that a large proportion of products and component parts recently manufactured and tested meet a 100 ppm limit. However, the datasets do not offer details about the materials or products tested. This is an important consideration if the lead content of a particular material or product component is likely to exceed 100 ppm, while other types of products typically contain less lead.

vi. Test Variability

Another issue raised in both written and oral comments concerned test variability—specifically, the observation that testing a product that complies with the 100 ppm limit may actually provide a result exceeding the 100 ppm limit. Staff expects a certain amount of test variability. However, the reasons for variability in the data discussed by the commenters are not known. A public commenter, representing associations of analytical laboratories, stated that laboratory test methods using inductively coupled plasma technology (ICP) for measuring lead content, when properly performed, achieve precision, reliability and repeatability in testing for levels of 100 ppm or less in the materials used to make consumer products. Further, analytical laboratories are expected to understand and control the sources of excess test variability. Through CPSC in-house testing of NIST-certified lead standard reference materials containing less than 100 ppm lead, Laboratory Science staff concluded that CPSC-published test methods can be applied effectively to samples with less than 100 ppm lead. Materials may also be heterogeneous; that is, different parts of a sample may have different concentrations of lead. However, CPSC staff test methods for lead are designed to determine the overall lead composition, and not reflect microscopic inhomogeneities that may be present in a material. An example of a product testing strategy that could account for material variability or heterogeneity is obtaining a representative homogeneous aliquot of the material by grinding or milling a component.

Staff believes that some of the issues related to testing and material variability may be addressed on a case-by-case basis, considering all available information. For example, the Commission could choose to focus enforcement efforts, at least initially, on products with the most exposure potential, such as products that may be mouthed or swallowed.

vii. Compliance With Lead Content Limit

While the Commission offered multiple opportunities for interested parties to submit data and other information, public commenters provided very little evidence to support their assertions that meeting the 100 ppm lead limit is not possible in all cases. Similarly, commenters offered little information to explain the processes or costs associated with meeting the lower lead limit. On July 27, 2010, the Commission published a notice in the *Federal Register* (75 FR 43942), requesting information on products and materials that currently meet and do not meet a 100 ppm lead content limit. The Commission published a notice in the *Federal Register* (76 FR 4641) on Jan. 26, 2011, announcing that it would be conducting a public hearing to receive views from all interested parties about the ability of products and materials to comply with a 100 ppm limit, laboratory and lot variability, and health effects associated with reducing the lead limit. Additionally, on March 9, 2011, the Commission published a notice in the *Federal Register* (76 FR 12944), reopening the hearing record to allow hearing participants to submit relevant studies and additional data in response to further questions from Commissioners.

In staff's opinion, complying with the CPSIA's lead content and testing requirements for children's products presents certain challenges for manufacturers. Economically, there are costs associated with the current 300 ppm lead content limit, and there will be additional costs for complying with a 100 ppm limit. The costs will vary, depending upon a number of factors, but will include costs related to stricter control of raw materials and components, alternative materials, product redesign, and increased testing.

The lower lead limit may create certain challenges for manufacturers related to identifying and substituting complying materials and components, as well as testing for compliance, and will tend to increase the costs of producing children's products. Given all available information, however, staff is unable to conclude that the 100 ppm limit is not technologically feasible for a product or product category.

b. Engineering Sciences (Tab A)

The CPSC's Directorate for Engineering Sciences staff prepared an evaluation of the lead content of metals and metal alloys. This information is discussed below and detailed at Tab A.

Through review of standards and available technical literature, as well as discussions with metallurgists and metal alloy manufacturers, staff examined production techniques, existing products, and available standards to assess the technological feasibility of producing metal alloys for children's products that contain less than 100 ppm.

Staff concludes that many different metal alloy products (*e.g.*, steel, aluminum, zinc, and copper alloys (brasses and bronzes)) that have lead content less than 100 ppm are currently commercially available, although metals and metal alloys that contain lead for certain functional purposes may also be used to make children's products. Metals with lead added for functional purposes generally require a lead content far in excess of either the 300 ppm or 100 ppm limits specified for children's products. Purchasers of leaded alloys generally specify their lead content requirements when placing an order.

Substitute alloys with less than 100 ppm lead are commercially available for applications currently using leaded alloys. On the other hand, the presence in commerce of low lead metals does not guarantee their continuous availability to manufacturers, particularly small manufacturers. This is, in part, because metal alloy sellers commonly require minimum purchase quantities.

While lead may be intentionally incorporated into alloys for certain functional purposes, such as machining, other metal alloys have no specific lead content requirements. These alloys may have varying "trace" amounts of lead that are not controlled as long as their final lead concentration is below some specified maximum. A commonly used trace level is 0.05 percent, or 500 ppm. Manufacturers also produce other metal products that are controlled for their "trace" lead content and that are certified to specified levels.

Production methods vary, depending on the material and desired composition and properties. However, one of the reasons that steels would have a low concentration of lead is that part of the steel making process is collection and removal of the lead vapor. Consequently, the temperature of the melt should result in vaporizing any lead present, although, in some cases, trace amounts of lead may remain. Stainless steels (with one identified exception, where lead is intentionally added) currently comply with the 100 ppm limit; other steels tend to have a low lead content level as well, and customers may add the additional requirement for low lead content to an order for a standard alloy.

Aluminum, as with steel, may be produced with the addition of lead for certain functional purposes. Several common aluminum alloys, as part of their ordinary production, do not have lead content above the 100 ppm limit.

Through extensive recycling of intentionally leaded brasses and other factors, many copper alloys specify a trace lead level of between 0.05 percent and 0.15 percent (500 ppm to 1,500 ppm). However, a number of standard copper alloys exist that specify lead content less than 100 ppm; and through inventory management and process control, copper alloys can be produced with trace levels of lead guaranteed below 100 ppm.

Zinc ore may naturally contain some lead, and zinc processing results in different lead concentrations. The three commercial grades of zinc are: Special High Grade (with a maximum 30 ppm lead by weight), High Grade (up to 300 ppm lead), and Prime Western (up to 14,000 ppm lead). Special High Grade Zinc is widely available and is best suited for die-casting applications.

For many metal alloys and manufacturing processes, lead is not normally present. Lead must be intentionally added to produce alloys for a functional purpose. CPSC staff has found no intentional application of lead in metals for functional purposes at the 300 ppm or 100 ppm level specified by the CPSIA. Thus, the presence of lead in the lower concentration range is considered a "trace" amount that does not affect the application of the alloy. Purchasers should be aware of the possibility of "trace" lead content in some alloys and specify materials that meet the 100 ppm limit. Alternatively, a purchaser may choose one of the alloys with a lead content less than 100 ppm as part of its nominal specification.

c. Economic Information (Tab B)

The CPSC's Directorate for Economic Analysis staff prepared an evaluation of the possible economic impacts of reducing the lead content limit from 300 ppm to 100 ppm. This information is discussed below and detailed at Tab B.

Based on public comments received by the Commission, low-lead materials that can be used in the production of children's products generally appear to be commercially available in the market place. The use of these materials in products that do not already conform to the 100 ppm lead content limit will require the substitution of the low-lead material into the product. In a few cases in which lead in excess of 100 ppm is required for the functioning of the product, manufacturers may need to reengineer the product to make the leaded component inaccessible.

In either case, bringing products that do not currently comply with the 100 ppm limit into conformance is generally expected to result in increased manufacturing costs.

While detailed cost estimates were not provided by commenters, a representative of the Bicycle Products Supplier Association (BPSA) reported that manufacturers of children's bicycles experienced a 20 to 25 percent increase in the costs of metallic components when the lead content limits were reduced from 600 ppm to 300 ppm. The BPSA representative said manufacturers of children's bicycles expect another 25 percent increase when the lead content limits are reduced to 100 ppm. Similarly, Learning Resources, Inc., a manufacturer of educational materials and learning toys, said it expects a 10 to 20 percent increase in the cost of producing finished goods when the lead content limit is reduced to 100 ppm.

On the basis of existing information, it is not possible to quantify the aggregate economic impacts of reducing the lead content limit from 300 ppm to 100 ppm. However, we can describe in a general way, the economic impacts that are likely to occur. The more stringent lead content limit will tend to increase the costs of producing children's products. Manufacturers of nonconforming products may have to use the more expensive low-lead materials rather than the nonconforming materials they may use today. There may also be costs associated with reengineering some children's products to make use of the materials or to make leaded components inaccessible. Additionally, because a lead content limit of 100 ppm is harder to achieve than the current 300 ppm (in part, because of testing variability described by several commenters), testing costs may rise.

For products not currently conforming, cost increases are likely to be reflected as a combination of price increases and corresponding reductions in the types and quantity of children's products available to consumers. To the extent that manufacturers are able to push the higher costs onto consumers, the retail prices of children's products will increase. However, in many cases, especially when there are close substitutes for children's products, producers may be unable to push these costs forward onto consumers and will have to absorb the higher costs as reductions in profits. Because there are limits to the reduction in profits that firms are willing and able to accept, some manufacturers are likely to reduce their selection of children's products or exit the children's market altogether. Some manufacturers may even go out of business. Based on public comments and testimony at the public hearing, these types of effects to some extent may have happened already in the markets for bicycles and all-terrain vehicles. In general, for cost increases affecting a broad base of industries, there will be a mixture of effects: both increases in the retail prices of children's products and reductions in overall production levels.

In addition to the direct effects on manufacturers, some firms in the retail and wholesale sectors that sell children's products could experience adverse effects if the new standard were to be applied retroactively. To the extent that children's products that do not comply with the 100 ppm standard remain on the shelf or in inventories after the August 14, 2011 effective date, these items would need to be removed prior to sale. The loss of inventory would result in costs which would be higher for retail and wholesale firms that specialize in the sale of children's products and especially for those that specialize in products for which compliance may be more difficult. These costs cannot be quantified but could be substantial for some firms, especially if the firms were not aware that the limits were to be applied retroactively.

The 100 ppm lead limit also may result in some other secondary effects in the production of children's products. The higher costs associated with metal components will probably result in some efforts to substitute lower cost materials. Plastics, for example, might be substituted for metal parts in some products. Some of these types of substitutions may affect the utility of the children's products. The use of plastic instead of metal, for example, may reduce a product's durability in some applications. Alternatively, some manufacturers may need to redesign or reengineer their products. Valve stems for bicycles, for example, may need to be fitted with more secure caps, which will effectively render them inaccessible and potentially more difficult to use. In addition, products may be simplified to reduce the number of components for testing.

III. Public Health Impact

Staff believes that substantial health protections have already been achieved with the implementation of the CPSIA, which required most children's products and components of children's products to comply with lead content limits of 600 ppm as of Feb. 10, 2009, and with the 300 ppm lead content limit as of Aug. 14, 2009.

Based on staff's review of available information and public input during the public hearing and comment periods, the use of lead for functionality, such as casting, machining or forming of metal parts, or for other purposes requires lead concentrations much higher than the 300 ppm lead content limit. Staff has found no intentional uses of lead in materials at concentrations at or near any of the three statutory lead limits (*i.e.*, 100 ppm, 300 ppm, or 600 ppm). Therefore, staff does not believe that children's product manufacturers intentionally design or make products or components with the maximum allowable lead content because lead concentration near the maximum limit would have no benefit or purpose to the product or the manufacturer.

The lead limits, as required by law, appear to have already resulted in changed business practices and implementation of material and supply chain controls to eliminate any intentional uses of lead in products and materials. Without the intentional use of lead in materials or the use of certain recycled materials, the lead content of most materials is substantially below the mandated limits. In addition, increased testing, inspection, and compliance efforts by firms, the CPSC, and others have already contributed to substantially reducing the presence of lead in products.

If the Commission was to determine that the 100 ppm limit is not technologically feasible for some products or materials, staff believes that most products would still comply with the lower limit. Based on testing of products to date, only a small proportion of children's products, and, in fact, only certain component parts of that small proportion of products, have lead content exceeding the 100 ppm level. For example, the written comment from the Hong Kong American Chamber of Commerce included information about more than 13,000 tests of metallic parts used in the toy industry, showing that 99.54 percent of samples had less than 100 ppm lead. Based on available data, staff believes that most products comply with both the current 300 ppm limit and the 100 ppm limit, and will continue to do so.

Further, the types of products or parts of products that might have lead content between 100 ppm and 300 ppm include items that would tend to be associated with a low likelihood of exposure because of infrequent contact by children, and the low likelihood of being mouthed or accidentally swallowed. Such products include: screws, nuts, bushings, rods, and shafts on bicycles and other children's products.

Therefore, while staff does not have data on potential lead exposure from products that have lead content less than 300 ppm, but more than 100 ppm, staff expects that the overall contribution of such products to lead exposure in children is minimal.

IV. Requirements in Individual States and Other Countries

In the United States, the CPSIA provides that the total lead content limit by weight in any part of a children's product is limited to 300 parts per million (ppm) as of Aug. 14, 2009, and 100 ppm of lead as of Aug. 14, 2011, unless the Commission determines that it is not technologically feasible to have this lower limit for a product or product category. A children's product is a product designed or intended primarily for children 12 years old and younger. Under the authority of the CPSIA, the Commission, by rule, has provided exceptions to the lead content requirement for component parts of products that are not accessible to a child, and for certain electronic products, in addition to determinations regarding certain materials that do not, and would not, contain lead.

Several international and state requirements and standards also address lead in children's products, although the types of products covered and the form of the lead restriction varies.

a. Canada

Canada recently published amendments to the Hazardous Products Act,[2] which prescribe new regulations for certain products. As of Nov. 26, 2010, accessible parts of products used in the mouth (other than kitchen utensils, which are considered separately), or by children under 3 years old, may not contain lead in excess of 90 mg/kg (ppm). The law allows exceptions to the lead content requirement if the lead is necessary to produce an essential characteristic of the part, no alternative part containing less lead is available, and the migratable lead is no more than 90 mg/kg (based on the tests specified in the European toy safety standard EN 71-3). The discussion of the new law shows that the Canadian government recognized during development of the restrictions that certain parts of products are not expected to be extensively contacted by children, and therefore, these parts of products do not need to comply with the lead limit. Examples include wheel axles on toy cars/trucks; the heads of nuts, bolts, screws, and other fasteners; and the tips of inner tube valves on tricycle wheels.

b. Illinois

Effective Jan. 1, 2010, the Illinois Lead Poisoning Prevention Act (410 ILCS 45/)[3] requires manufacturers to include warning labels on certain children's products that contain more than 40 parts per million (ppm) lead. Jewelry made for or marketed to children under the age of 12 years; child care products designed for or intended for use by the manufacturer to help the sleep, relaxation, or feeding of children under the age of six; and toys with surface paint that are designed for or intended for use by children under the age of 12 years that contain more than 40 ppm lead must have a label warning of the lead content.

c. European Union

The European Standard Safety of Toys-Part 3: Migration of certain elements (EN 71-3:1994), restricts lead in certain toys on the basis of solubility (or leaching), using specified test methods. The standard applies to toys for children up to age 6 years, and to certain products that may come into contact with the mouth. The standard does not restrict the lead content of toys. The solubility limit is 90 mg/kg, which means that under the conditions of the specified tests, up to 90 milligrams of lead per kilogram of toy material may be extracted from the material. A toy

[2] Available at http://canadagazette.gc.ca/rp-pr/p2/2010/2010-12-08/html/sor-dors273-eng.html.

[3] Available at http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1523&ChapterID=35.

may contain more than 90 mg/kg (ppm) if the lead does not migrate out of the material during the test.

d. International Organization for Standardization

The International Organizations for Standardization's (ISO) Safety of Toys – Part 3: Migration of Certain Elements (ISO 8124-3:1997) is based on the European Union's EN 71-3:1994 Safety of Toys standard, discussed above. Certain countries have adopted this standard as their national standard.

V. Conclusions

Staff reviewed technical information, written public comments and public hearing oral comments, and other available information concerning the presence of lead in products and component parts of products and the technological feasibility of reducing the lead content limit of children's products to 100 ppm.

The CPSC received comments that stressed that the lead content limit must be reduced in order to prevent lead exposure and subsequent adverse health effects in children. Public comments also indicated that children are not likely to be exposed to the small amounts of lead that might be found in some products, especially parts of products that are not frequently contacted by children and that are not likely to be mouthed or accidentally swallowed.

Little specific evidence was provided by commenters to explain the processes or costs involved in meeting the lower limit or to support their contentions that meeting the limit is not possible in all cases, despite numerous opportunities the Commission offered to interested parties to submit data and information. The Bicycle Product Suppliers Association estimated that a 100 ppm limit could increase the costs of the metal parts of bicycles by up to 28 percent. Learning Resources, Inc., indicated that the 100 ppm limit would result in cost increases of up to 20 percent, although this estimate was not attributed to specific products, or materials, or types of product or materials.

Data submitted by several commenters for a variety of children's products show that more than 99 percent of tested products and component parts currently have lead content less than 100 ppm, although the types of products tested were not specifically identified. Some comments argued that for certain materials, such as metals and metal alloys, it is not technologically feasible to reduce lead content below 100 ppm, even if data show that some such products already meet that limit. These commenters also stated that efforts to comply would be prohibitively expensive and result in removal of products from the market.

Staff's evaluation of the available information and the comments show that for most products and materials, lead content is already low. For other products, staff concluded that materials or technologies exist that manufacturers can specify to meet a 100 ppm limit for children's products.

Complying with the lead content and testing requirements for children's products set forth in the CPSIA presents certain challenges to manufacturers. Economically, there are costs associated with the current 300 ppm lead content limit, and there will be additional costs for complying with a 100 ppm limit. The costs will vary, depending upon a number of factors, but will consist of costs related to stricter control of raw materials and components, alternative materials, product redesign, and increased testing.

While some international and state regulations also address lead in products, staff notes some differences between those standards and the CPSIA requirements. For example, some standards specify limits based on solubility of lead, not lead content, which would allow the presence of lead, as long as it does not migrate out of the material during the test; and some standards provide that certain products are exempt from the requirements.

Based on the available information, staff concludes that intentional uses of lead have largely been eliminated from children's products because of the current 300 ppm lead content requirement; products currently exist that comply with a 100 ppm limit; and technologies and other strategies exist that can be used to achieve compliance with the lower limit.

Options

CPSC staff provides three (3) options for the Commission to consider:

1. Do not find that a lead content limit of 100 ppm is not technologically feasible for a product or product category, as defined by the CPSIA.
2. Find that a lead content limit of 100 ppm is not technologically feasible for a product or product category, as defined by the CPSIA.
3. Take other action.

Recommendation

Based on the information available to staff, CPSC staff has found that materials and products that meet a 100 ppm limit are currently available to manufacturers. Therefore, staff is unable to conclude that the 100 ppm limit is not technologically feasible for a product or product category. Accordingly, staff recommends that the Commission not find that the lead content limit of 100 ppm is not technologically feasible, as defined by the CPSIA (Option No. 1).

TAB A: Directorate for Engineering Sciences Analysis

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

Memorandum

Date: May 7, 2011

TO : Dominique J. Williams
Directorate for Health Sciences
Office of Hazard Identification and Reduction

FROM : Randy Butturini
Office of Hazard Identification and Reduction
Thomas Caton
Directorate for Engineering Sciences
Office of Hazard Identification and Reduction

SUBJECT: Technological Feasibility of Reducing the Lead Content Requirement of Metals to 100 Parts Per Million from 300 Parts Per Million

1. Introduction

On Aug. 14, 2008, the Consumer Product Safety Improvement Act of 2008 (CPSIA) was signed into law. Section 101(a)(2)(A) of the CPSIA established a limit of 600 parts per million (ppm) for accessible components of children's products as of Feb. 11, 2009. Section 101 (a)(2)(B) of the CPSIA reduced that limit to 300 ppm on Aug. 14, 2009. On Aug. 14, 2011, the limit will be reduced to 100 ppm, unless the Commission determines that a limit of 100 ppm is not technologically feasible for a product or product category. Section 101(d) of the CPSIA defines technological feasibility as one or more of the following factors:

- a product that complies with the limit is commercially available in the product category;
- technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;
- industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or
- alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

CPSC staff interpreted the commercial availability of products that comply with the lead content limit to mean that a compliant material or component is available in the marketplace, as evidenced by its use or purchase by manufacturers, or a stated willingness or ability of the supplier to make a material or component available. For example, for a given material with a lead content below 300 ppm lead used in a children's product, another material of the same type (say, a lower lead steel material substituted for a higher lead steel material, or a brass material with a guaranteed lead content of less than 100 ppm substituted for a brass material with up to 300 ppm lead) with the same functionality is offered for sale. Further, there are no obvious impediments to the production of that substitute material. For example, if a substitute alloy uses another element in place of lead, there is sufficient availability of that element to meet production demand.

The CPSC staff interpreted the phrase “technology to comply with the limit being commercially available” to mean that noncommercialized processes to create lower lead substitute materials with the same functionality as higher lead materials of the same type have been developed. “Noncommercialized” means manufacturing techniques developed in laboratories that could be scaled up to industrial production volumes. Further, there are no obvious impediments to the production of that substitute material.

The CPSC staff interpreted “industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit” as actions taken or planned by metals manufacturers to develop the industrial capacity to create lower lead substitute materials.

The CPSC staff interpreted “alternative practices, best practices, or other operational changes” to mean that dissimilar substitute materials (*e.g.*, a lower lead silicon-impregnated steel bearing substituting for a higher lead brass bearing), design changes (*e.g.*, developing a cover for a higher-lead component part to render it inaccessible), or manufacturing process changes (*e.g.*, controlling the variability in the lead content of accessible component parts) are available to allow the manufacturer to comply with the limit.

Section 101(a)(2)(D) of the CPSIA states that if the Commission determines that the 100 ppm limit is not technologically feasible for a product or product category, the Commission should establish an amount that is the lowest amount of lead, lower than 300 ppm, that is determined to be technologically feasible for that product or product category. Regardless of the lead content limit, certain materials,[1] inaccessible component parts,[2] and particular electronic devices[3] have been excluded from compliance. Other component parts of children’s products must comply with the 100 ppm limit or the technologically feasible limit established by the Commission.

The CPSC staff examined the uses of lead in metals used in children’s products and the technological feasibility of reducing the lead content limit of metals used in children’s products to 100 ppm from 300 ppm. This memorandum summarizes the staff’s examination.

2. Background

Before passage of the CPSIA, many metals in children’s products had lead added to achieve particular purposes, some of which are described below. Other metal parts had varying amounts of lead in “trace” amounts that were not controlled, as long as the trace amount was below a maximum allowable percentage. With the lead content limits of the CPSIA applying to accessible metal components of children’s products, certifiers of those products must ensure that those limits are met.

Lead is intentionally added to metals to create a desirable functional property. Most often, the lead is added to improve a metal’s ability to be machined. Machining includes ensuring a good

[1] See 16 C.F.R. § 1500.91.

[2] See 16 C.F.R. §1500.87.

[3] See 16 C.F.R. § 1500.88.

surface finish, maintaining tight tolerances, and creating features like holes and parallel surfaces. The added lead helps keep the metals from chipping poorly as they are being cut; reduces cutting tool wear (extending tool life); and lubricates the cut. Metal parts that are not being machined (*e.g.*, castings, stampings) generally don't need the added lead for their formation. Lead is added to copper alloys to create a dry lubricant. Brass parts with lead are used in bearings, bushings, and in applications where metal parts slide against each other. For some metal processing procedures, such as cold rolling, lead is undesirable because the metal may crack. For all the applications where lead is intentionally added to metal alloys, the amount is well in excess of 300 ppm. However, the CPSIA currently does not permit any materials used in children's products to exceed the 300 ppm lead content level, so the products that require lead in excess of 300 ppm for the proper functioning of certain products are outside the scope of this proceeding. While information on metal alloys with greater than 300 ppm lead content is discussed, the memo focuses primarily on the technological feasibility of metals to comply with the reduction of lead content from 300 ppm to 100 ppm.

3. Technological Feasibility for Metals to Comply with Lead Content Limit

3.1. Steels

Typically, steel manufacturing involves temperatures that should vaporize any lead in the melt, although, in some cases, trace amounts of lead may remain. For applications that do not involve machining, there may be no lead present. Lead is intentionally added back into steel during pouring into the ingot stage to improve its ability to be machined. Typically, from 0.20 percent to 0.35 percent lead by weight (2,000 to 3,500 ppm) is added to free machining steels. The lead remains elemental and tends to cluster at the boundaries where the metal crystals meet. In response to the environmental concerns regarding machining chips and recycled steel, several steel manufacturing companies have announced "lead free" machining steel and stainless steel with no lead (< 20 ppm) as a constituent. Commercially available American Iron and Steel Institute (AISI) 1215 carbon steel (also known as UNS G12150 carbon steel) is reported to contain less than 0.01 percent (100 ppm) lead. Patents have been granted for steel alloys that contain no lead.[4, 5, 6, 7]

"Surgical steel" is a loosely used descriptor for stainless steels (stainless steel has chromium added from 12.5 to 25 percent of the composition) used in medical or jewelry applications – applications where the metal contacts the human body. Stainless steels have been determined not to contain lead in concentrations above the CPSIA limits (16 C.F.R. § 1500.91). Other elements added to the iron are carbon, nickel, molybdenum, manganese, silicon, and phosphorus. A common type of "surgical steel" is 316 stainless steel. Other steels in the 300 series (303, 304, and 317) are sometimes called "surgical steel," based on their application. There are several

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[4] Patent 7195736, Iwama, Naoki, Owaki, Susumu, Uchiyama, Masao, Fujii, Isao, Nishimon, Syoji, Tsunekage, Norimasa, Kobayashi, Kazuhiro, Mori, Motohide, Ogo, Kazutaka, Naito, Kunio, *Lead-free steel for machine structural use with excellent machinability and low strength anisotropy*, March 27, 2007.

[5] Patent 7445680, Iwama, Naoki, et al, Lead-*free steel for machine structural use with excellent machinability and low strength anisotropy,* November 4, 2008.

[6] Patent 4786466, Holowaty, Michael O., *Low-sulfur, lead-free free machining steel alloy*, November 22, 1988.

[7] Patent 6200395, *Free-machining steels containing tin antimony and/or arsenic*, Deardo, Anthony J., and Garcia, Isaac C., March 13, 2001.

manufacturers of 300 series stainless steel. None of them list lead as a constituent, down to 0.01 percent (100 ppm).

Based on a March 4, 2011, telephone conversation between CPSC staff and the chief metallurgist at a major U.S. steel manufacturer, staff believes that it is common for customers to specify a standard steel type (*e.g.*, American Iron and Steel Institute (AISI) 4140), then add specific requirements for the customer's particular application. Continuing with the example, the steel customer could specify AISI 4140 steel, with the additional requirement that the lead content as a trace material must be below 0.01 percent, or less than 100 ppm. The AISI submitted a written comment to the public hearing on the technological feasibility of limiting the lead content in children's products to 100 ppm. The AISI concluded that the reduction of lead to levels below 100 ppm in the United States is technologically feasible because the high temperatures in the steel manufacturing processes tend to vaporize lead from the steel mixture. This vaporization occurs with both main steelmaking processes and for both virgin (unrecycled) and recycled steel.

3.2. Zinc

Zinc and lead are often produced together. Thus, lead is frequently a natural contaminant of zinc metal. The Imperial Smelting process generates roughly one ton of lead for every two tons of zinc. ASTM International (formerly the American Society for Testing and Materials) has a standard, ASTM B6-03 *Standard Specification for Zinc*, which contains three grades for lead in zinc. Prime Western grade allows up to 1.4 percent (14,000 ppm) lead by weight; High Grade specifies a maximum of 0.03 percent (300 ppm) lead; and Special High Grade specifies a maximum of 0.003 percent (30 ppm) lead in zinc. Special High Grade is used mainly for zinc-based casting alloys. Using calendar year 2011 zinc prices, Special High Grade currently sells for about 3 percent more per metric ton than High Grade.

3.3. Copper alloys

Copper is alloyed with zinc for brass and with tin for bronze (although many copper-zinc alloys are referred to as bronzes). The range of copper alloys is wide, with varying amounts of many different elements. Lead is intentionally added (up to 6 percent by weight) to make red brass. More typically with other brasses/bronzes, lead is an impurity with a concentration of 0.05 percent, 0.07 percent, or 0.15 percent (500 ppm, 700 ppm, or 1,500 ppm). "Lead-Free" brass may still contain lead. C69300 brass has a maximum lead content of 0.09 percent (900 ppm). "EnviroBrass II" is an alloy with up to 0.25 percent (2500 ppm) lead. Brass alloys with less lead exist; C6801 brass is available from at least two manufacturers and is specified to contain less than 0.01 percent (100 ppm) lead.

Electrical connectors with copper alloys, such as phosphor bronze, contain up to 0.05 percent (500 ppm) lead. The metal components of connectors are made with the intent of meeting the European Union Reduction of Hazardous Substances (EU RoHS) requirements of less than 0.1 percent (1000 ppm) lead by weight. There are lead-free electroplating materials for the copper alloy conductors. "Lead-Free," in this context, usually means complying with the EU RoHS requirements. The plating materials may contain significantly less than 0.1 percent (1000 ppm) lead.

In an April 11, 2011 telephone conversations between staff and a large producer of brass alloys, a technical expert stated that with extra care on selecting source materials and the greater use of virgin brasses, his company could produce brass alloys with less than 100 ppm lead. Additional costs are incurred in more carefully managing the use of recycled brass and in inventory control. Additionally, the processes result in a "fallout," or production of brass with greater than 100 pm lead at around a 5 to 10 percent rate, which would necessitate rejecting the material and recycling it into the next batch produced. Using a greater percentage of virgin brass in the mix adds to the net cost of the material.

3.4. Aluminum

Lead does not naturally occur in aluminum, and it is intentionally added for much the same reasons it is added to steel—to improve its ability to be machined. The added lead reduces the chip size when machined, improves tool wear, and allows a better surface finish after machining. An EU RoHS exception limits lead in aluminum to no more than 0.4 percent (4,000 ppm). Efforts to remove lead from aluminum have been attempted to reduce the potential environmental hazards posed by machining waste. Patents 5522950,[8] 5776269,[9] 6409966,[10] and 5587029[11] provide formulations for machinable aluminum alloys with less lead. Alcoa, Inc., a leading aluminum producer, manufactures UltrAlloy 6020, a machinable aluminum alloy with up to 0.05 percent (500 ppm) lead. Kobe Steel Group manufactures KE2 and KE6 aluminum with additives such as bismuth and indium, in place of lead.

Many alloy designations of aluminum contain no lead in their composition, but list a maximum "other" concentration of 0.05 percent (500 ppm). Some list the maximum "other" concentration at as low as 0.003 percent (30 ppm). When contacted by phone on March 8, 2011, a major aluminum manufacturer said there was no lead in many common alloys, such as aluminum alloy 2024, and that only the aluminum alloys 2011 and 6262 (6262 is no longer in production in the United States) contain lead. The aluminum alloys that list lead in their compositions range from 0.20 percent (2,000 ppm) to as high as 2 percent (20,000 ppm). Aluminum alloys 6351A and 6061A specify a maximum 0.003 percent (30 ppm) lead content.

4. Other Considerations Regarding Low Lead Metal Alloys

4.1. Substitute alloys for high-lead metals

As discussed above, metal alloys that contain lead for a functional purpose greatly exceed the current 300 ppm limit for children's products, and such high lead metals are outside the scope of this proceeding. However, it is worth noting that some metal alloys have been developed to have the same properties as the leaded alloys, without using lead in concentrations greater than 100 ppm. Often this is accomplished by substituting another element for lead. However, the presence in commerce of these lower lead metals does not guarantee their continuous availability to smaller manufacturers under all circumstances (larger manufacturers may be able to leverage their buying power and obtain greater access to these materials.). Alloys with substitute elements for lead may be produced in limited quantities. Access to guaranteed 100 ppm or less metal alloys may require more time or increased costs. Metals companies typically have

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[8] Bartges, Charles W., Klemp, Thomas, J. Scott, Gerald D., and Allyn, Matthew J., "Substantially lead-free 6XXX aluminum alloy," June, 4, 1996.

[9] Farrar, Larry E. Jr., and Coats, Norman LeRoy II, "Lead-free 6000 series aluminum alloy," July 7, 1998.

[10] Sircar, Subhasish, "Free machining aluminum alloy containing bismuth or bismuth-tin for free machining and a method of use," June 25, 2002.

[11] Sircar, Subhasish, "Machinable aluminum alloys containing In and Sn and process for producing the same," December 24, 1996.

minimum order sizes ranging from a few thousand pounds to many tons. Small manufacturers may have difficulty affording or handling quantities of metals that could represent usage of a year or more. Alternate means of acquiring compliant metals may be needed. A potential means of addressing this situation could involve a group of children's products manufacturers pooling their materials requirements into one order for a low lead metals producer. Alternatively, long-term contracts might be developed between a children's product manufacturer and the metals supplier to guarantee delivery of relatively small quantities over the length of the contract period. In some circumstances, a manufacturer may need to investigate the use of alternate methods to avoid the use of leaded metals. This could involve materials substitution (replacing the leaded metal with a dissimilar material that contains no lead), redesign (*e.g.*, making the part inaccessible), or other techniques that result in the elimination of accessible leaded component parts.

4.2. Alloys with trace amounts of lead

For many metal alloys without the intentional addition of lead, lead in concentrations above 100 ppm is considered a trace level that does not affect the metal's material properties. Therefore, many alloys specify lead concentrations up to a maximum amount well in excess of 100 ppm. The cost of those metals with known low levels of lead may be higher than the same alloys with greater than 300 ppm because metal producers may have to take extra steps during manufacturing to assure that the alloy product has lead concentrations below the 100 ppm limit. The metal alloys are considered commercially available, but that availability might require changing current materials procurement processes. Manufacturers of children's products may have to pay more to certify the history of the metals they order and to ensure that their materials' potential contamination is controlled.

Buyers of lower lead materials may need to take additional steps beyond materials specifications to achieve low-lead component parts. Metals processing (*e.g.*, rolling, forging, casting, milling) may affect the distribution and homogeneity of any lead contained in an alloy. When tests are conducted on these materials, sufficient care must be taken to ensure that microscopic conditions do not adversely affect the accuracy of the measurement. Further, care must be taken to avoid unintentional contamination of low-lead metals before their use in children's products.

5. Conclusion

The CPSC staff has found no application of lead in metals where the lead gives the metal some desired function at the 300 ppm or 100 ppm level specified by the CPSIA. Thus, the presence of lead in concentrations in this range is considered a trace element that does not affect the application of the alloy. This lead may come from the use of scrap materials, some of which contain lead, contamination, or other unidentified sources. For many metals and manufacturing processes, lead is not normally present. Lead must be intentionally added to produce alloys that use lead for a functional purpose.

If we examine the four criteria for technological feasibility listed in § 101(d) of the CPSIA, we find that the current metals market meets all four factors:

- Currently, metals and alloys are commercially available with less than 100 ppm lead, especially if specified to the metals supplier.

- For applications where lead has been added to impart some functionality (*e.g.*, machinability, surface finish), substitute alloys with no lead or lead at less than 100 ppm have been developed and are commercially available.
- Research continues, and patents have been issued to address removing lead from metal alloys.
- If manufacturers institute practices to control the sourcing of the metals and metal alloys used in their products, or institute steps to make leaded metal parts inaccessible, then children's products can be made that are compliant with the 100 ppm limit.

Thus, for metals and metal alloys, the CPSC staff is unable to conclude that the 100 ppm limit is not technologically feasible.

TAB B: Economic Information

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

Memorandum

Date: May 9, 2011

TO : Dominique J. Williams, Toxicologist, Directorate for Health Sciences

THROUGH: Gregory B. Rodgers, Ph.D., Directorate for Economic Analysis

FROM : William W. Zamula, Directorate for Economic Analysis

Deborah V. Aiken, Ph.D., Senior Staff Coordinator,
Directorate for Economic Analysis

SUBJECT : Economic Impacts of Reducing Lead in Children's Products to 100 ppm

Introduction

Section 101(a) of the Consumer Product Safety Improvement Act (CPSIA) provides that, as of Aug. 14, 2011, children's products may not contain more than 100 parts per million (ppm) of lead, unless the Consumer Product Safety Commission (CPSC) determines that such a limit is not technologically feasible. Additionally, if such limits were to be applied retroactively, sellers would need to remove merchandise not meeting the new requirements from retail establishment shelves at the Aug. 14 date. Currently, children's products may not contain more 300 ppm of lead, except for certain exemptions and stays of enforcement.

On July 27, 2010, the CPSC published a notice in the *Federal Register* (75 FR 43942), requesting comments and information regarding the technological feasibility of the 100 ppm lead content limit. Twenty-four comments were received from consumer groups, manufacturers, retailers, associations, and laboratories. After initial consideration of these comments, the CPSC published a notice in the *Federal Register* (76 FR 4641) on Jan. 26, 2011, announcing that it would be conducting a public hearing pursuant to section 101(a) to receive additional information. The hearing notice stated, among other things, that the Commission was seeking information on specific issues, such as whether any product or product category already complies with the 100 ppm limit, as well as what factors or considerations should be evaluated in deciding whether a technology is commercially available. The hearing was held on Feb. 16, 2011. At the hearing, certain Commissioners requested that some participants respond to additional questions in writing and submit relevant studies and data.

This memorandum provides information on the industries affected by the 100 ppm requirement, and it summarizes the public comments received in response to the July 2010 notice and the public hearing, as they pertain to the issue of technological feasibility and costs of compliance. Finally, it includes a discussion of the possible economic impacts of reducing the lead content limit from 300 ppm to 100 ppm.

Overview of Affected Industries

The 100 ppm lead requirement will apply to any manufacturer that produces or imports children's products. The definition of a children's product is broad and includes products such as bicycles, books, furniture, apparel, jewelry, televisions, electronic games, toys, and more, if they are intended for children 12 years of age or younger.

Manufacturers

Table 1 (at the end of this memorandum) shows the number of manufacturing firms by the North American Industrial Classification System (NAICS) categories that cover most children's products; it provides information on the number of small firms, based on U.S. Small Business Administration (SBA) criteria. Although there are more than 30,000 manufacturers in these categories, not all of these firms are engaged in manufacturing children's products. It would be expected that most of the firms engaged in the category, *Doll, Toy, and Game* manufacturing, produce some products that are intended for children age 12 and younger. On the other hand, the *Surgical Appliance and Supplies Manufacturing* category includes crash helmets for children, but most of the other products in this category would not be considered children's products.

Wholesalers

Wholesalers would be subject to the 100 ppm requirement if they import any children's products. In addition, if the limits were to be applied retroactivity, wholesalers that sell children's products would no longer be able to sell products that do not meet the standard. Table 2 shows the number of wholesalers by NAICS code, which would cover most children's products, including the number of small firms based on SBA criteria. Although there are close to 80,000 wholesalers in these categories, not all of these firms are engaged in importing or selling children's products. A significant proportion of the firms classified as *Toy and Hobby Goods and Supplies Merchant Wholesalers* probably import or sell at least some children's products. However, the only firms classified as *Motor Vehicle and Motor Vehicle Parts and Suppliers* that are likely to import or sell children's products would be those that import or sell all-terrain vehicles or other off-road vehicles.

Retailers

There are some retailers that manufacture or directly import some products and they would be responsible for ensuring that their products meet the 100 ppm requirement. Also, if the limits were to be applied retroactively, retailers would no longer be able to sell children's products that do not meet the 100 ppm requirement. Table 3 shows the number of retailers by NAICS code that may sell children's products; and it also provides data on the number of small firms, according to SBA criteria. Although there are nearly 129,000 firms in these categories, it is not known how many are engaged in importing, manufacturing, or selling children's products.

Complying with the 100 ppm Lead Limit

The CPSIA specifies that it is technologically feasible for a product or product category to comply with the 100 ppm limit if:

a) a product that complies with the limit is commercially available in the product category;
b) technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;

c) industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or
d) alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

For purposes of this analysis, "commercially available" has been interpreted to mean that a compliant material or component is available in the marketplace, as evidenced by its use or purchase by manufacturers, or a stated willingness or ability of the supplier to make a compliant material or component available.

Several commenters provided information on a large number of products that are already in compliance with the 100 ppm limit. For the most part, the commenters did not provide information regarding the manner in which compliance was achieved, including whether any product modifications were necessary and, to the extent that modifications were necessary, the costs of finding any substitute materials or the costs of redesigning products to comply with the 100 ppm lead content requirement.

For products that are not yet in compliance, the 100 ppm limit could present difficulties and result in higher costs for manufacturers of some children's products. However, complying materials appear to be commercially available for most products and, in those cases in which products do not currently conform, compliance with the 100 ppm lead limit will require the products to be redesigned or reengineered to make use of these materials. Some complying materials may only be available at higher prices, stemming from the higher quality of the substitute material (*i.e.*, virgin versus recycled), the added constraint in the production process needed to ensure that trace lead amounts are less than 100 ppm, and, in some cases, from the limited availability and lack of sufficiently developed distribution channels.

According to comments received, the 100 ppm limit should not be too difficult to achieve for plastic components; although some commenters said they expect costs to rise. One commenter reported 100 ppm was achievable with homogeneous materials like plastic, but only with higher costs.[1] Similarly, the Juvenile Products Manufacturers Association (JPMA) reported that 100 ppm is technologically feasible, provided that virgin plastics are used.[2] Data on the lead levels present in recycled plastics were not presented. Virgin plastic is more expensive and may be somewhat more difficult to obtain than recycled plastic, but it should be available. While many different plastics are used in children's products, comparing prices for some of the more common "commodity" plastics[3] suggests that the prices for virgin plastics are 50 percent to 100 percent higher than recycled plastics, depending upon the form of the plastic and the volume of the purchase.[4] It is not known how much recycled plastic in the market does not meet the 100 ppm limit.

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[1] Rick Locker, p. 154, Transcript of Public Hearing on Children's Products Containing Lead; Technological Feasibility of 100 ppm for Lead Content, February 16, 2011.

[2] Robert Waller and Michael Dwyer, JPMA, Comment CPSC-2010- 0080-0020, p.3, September 27, 2010.

[3] Such as acrylonitrile butadiene styrene (ABS), high density polyethylene (HDPE), polypropylene (PP), and polyvinyl chloride (PVC).

[4] From Resin Pricing – Commodity Thermoplastics and Resin Pricing – Recycled Plastics; from PlasticsNews.com for May, 9, 2011 (accessed May 12, 2011).

In most steel materials and components, lead is a residue of the steelmaking process, rather than an intentional part of steel alloys. According to the ES staff memo,[5] steel manufacturing occurs at temperatures that typically vaporize lead in the melt. The American Iron and Steel Institute (AISI)[6] reported that reductions below 100 ppm of lead are technologically feasible because the high temperatures in the steel manufacturing processes tend to vaporize lead from the steel mixture. A U.S. fastener manufacturer[7] reported that much of the steel they purchase has virtually no lead. Additionally, one ATV manufacturer[8] reported being able to purchase automotive grade steel for ATV frames at the 100 ppm level, although not substantially below that. As suggested by these comments, steel with low levels of lead is available in the marketplace.

However, according to ES staff, even when steel is produced at these high temperatures, some lead may remain in trace amounts, and these trace amounts may exceed 100 ppm. This is consistent with the Toy Industry Association's (TIA) comment that steel can contain 0.015–0.35 percent (150–3,500 ppm) lead, which would fail the 100 ppm limit (although the upper end of this range may be greater than trace levels). Thus, while low-lead steel is available, requiring manufacturers to provide steel with trace amounts of lead lower than 100 ppm (*i.e.,* creating an additional constraint in the production process) will tend to increase its cost. According to a U.S. steel manufacturer,[9] steel with lead guaranteed to be less than 100 ppm is substantially more expensive than general use steel (although "substantially more expensive" was not defined more precisely).

Other types of metal materials and components also appear to be available in low-lead variations, but, at a higher cost, especially if virgin or nonrecycled materials are needed. In some metals, lead is naturally present in the raw ores. For brass, according to one manufacturer,[10] getting even marginally below the 100 ppm limit requires a higher proportion of virgin brass and a 5 percent to 10 percent rework of brass that fails. While the manufacturer did not provide any cost estimate, it is probable that brass with a lead level below 100 ppm will cost manufacturers at least 10 percent more than other brass alloys. Whether an altogether different substitute at a different price might be available for brass would depend on the product and the function of the brass part.

Low-lead metals, such as 40 ppm tin, are available at a 10 percent to 15 percent premium[11] over other tin products. Chinese manufacturers of children's jewelry are using and developing low-

[5] Memorandum from Randy Butturini and Thomas Caton, Engineering Sciences to Dominique Williams, Health Sciences, "Technological Feasibility of Reducing the Lead Content Requirement of Metals to 100 Parts Per Million from 300 Parts Per Million" May 7, 2011.

[6] American Iron and Steel Institute. Comment CPSC-2010-0080-0028, p.2, February 22, 2011

[7] Russ Johansen, Specialty Screw Corporation, Telephone conversation with William Zamula, Directorate for Economic Analysis, April 5, 2011.

[8] Sean Hilbert of Cobra Motorcycle Manufacturing Company, quoted in dealernewsblog.com, March 27, 2009.

[9] Terry Rasmussen, Nucor Steel, Telephone conversation with William Zamula, Directorate for Economic Analysis, March 30, 2011.

[10] Olin Brass representative, Telephone conversation with Randy Butturini, April 8, 2011.

[11] Email from Steven Kaplan, Hallmark Metals Corporation, to Charles Smith, Directorate for Economic Analysis, RE: Feasibility of reducing lead content in fashion jewelry to 100 ppm, May 20, 2011.

lead zinc alloys[12] as substitutes for other metals. The ES staff memo states that Special High Grade zinc (30 ppm) is available at a 3 percent price premium over High Grade (300 ppm).[13] However, manufacturers have expressed concerns about the availability and variability[14] of these alloys, as well as whether they retain the desirable properties of the alloys with higher lead content.

An ES staff conversation with a major aluminum manufacturer[15] indicated that there is virtually no lead in many common aluminum alloys, and that aluminum alloys containing lead are no longer produced in the United States. Nevertheless, during the hearing on Feb. 16, 2011, a representative from ACT lab, a bicycle testing firm, reported having difficulties obtaining price information on low-lead alloys from Alcoa.[16]

Despite the existence of complying materials and components in the marketplace, some manufacturers, especially very small ones, may not be able to readily purchase these materials and components due to the lack of available distribution channels. For example, the Handmade Toy Alliance stated that its members would be unable to consistently obtain materials complying with such a low lead limit because its members do not purchase raw materials, but instead purchase component parts from retail stores.

Additionally, if the lead limits were to be applied retroactively, firms in the retail and wholesale sectors that sell children's products would no longer be able to sell products that do not meet the new requirements. This would affect firms with noncomplying products remaining in stock after August 14, 2011. Any noncompliant products would need to be removed from inventory prior to sale. The costs of lost inventory, which would be transitional and occur in the short run, but could in some cases be substantial, would be higher for firms that specialize in the sale of children's products and especially for those that specialize in products for which compliance may be more difficult.

Costs of Compliance

Materials Substitution and Product Redesign

For products that do not yet meet the new lead content limit, complying with the 100 ppm limit will likely involve additional costs. This includes costs for more expensive materials (as described above), and the costs of redesigning or reengineering the product, when necessary, to make use of the new materials. Some producers will need to obtain substitute materials, and in some cases, they might need to reduce their use of recycled materials for more expensive virgin

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[12] Zheijang Jewelry industry Association quoted in the "CPSC Beijing Office Trip Report for HQ Working Group Members" February 24, 2011.

[13] Butturini and Caton, p.15

[14] Memorandum from Charles L. Smith to William W. Zamula," Information related to Technological Feasibility of Reducing Lead in Children's Jewelry" April 4, 2011.

[15] Butturini and Caton, p.5.

[16] Much of the information CPSC staff has been able to compile on materials complying with the 100 ppm lead requirements is from U.S. sources. The BPSA comment of March 24, 2011, points out that information from U.S. sources on metals and other materials may not be informative on the Asian market, where bicycles and a large proportion of other children's products are manufactured. Also, the availability of a low-lead alloy does not necessarily indicate that it is technically or economically suitable for a particular application.

materials. In other cases, products may need to be redesigned to accommodate the different properties of materials with low lead content, or when that is not possible, to make any component with lead in excess of 100 ppm inaccessible.

Most of the comments discussing the costs associated with the 100 ppm lead limit provided descriptions of the types of costs that will be incurred, rather than quantitative cost information. Cost increases were often cited in percentages for a component, without specifying the contribution of the component to the overall cost of manufacturing the product. For example, bicycle industry comments state that meeting the 100 ppm requirement will add 28 percent to the cost of a bike tire valve stem, without giving the dollar cost increase of the valve stem or the percentage contribution of the valve stem to the cost of producing the bike. The estimate also assumes that compliance will be achieved by changing the lead content of the inner and outer components of the valve stem, rather than using a cap to limit accessibility, as defined in 16 C.F.R. §1500.87.

The large number of diverse products affected by the lead limits makes it difficult to estimate aggregate costs associated with the lead content limitation. However, there are some specific examples of products that illustrate the type and magnitude of costs involved. Children's jewelry is manufactured with many of the materials and processes that may need to be altered to attain the 100 ppm lead content limit. Zinc, copper, tin, and nickel alloys are used in children's jewelry, and (as described in the last section) the more costly low-lead variants will be required. Additional lead may be introduced in casting, electroplating, soldering, recycling, and other processes. Accordingly, the FJATA maintains that "it is not possible to reliably achieve 100 ppm lead in casting alloys, soft solders, alloys used for chains and wires, and certain other materials, like hard enamel (melted glass) and ceramics, used in jewelry." Manufacturers, in some cases, might use alternative processes, such as stamping, which uses less lead than molding or casting.[17] These actions to ensure compliance with the lead limits are likely to increase the costs of producing children's jewelry.

The experiences in the bicycle and all-terrain vehicle (ATV) markets may be useful for examining some of the issues that producers of children's products may encounter when adjusting to the 100 ppm limit. The Bicycle Products Supplier Association (BPSA) provided information on the possible effects on the bicycle market. Their testimony at the February 2011 public hearing estimated that they had experienced a 20 percent to 25 percent cost increase per component when the lead content limits were reduced from 600 ppm to 300 ppm, and indicated that they expect another 25 percent premium when the lead content limit is reduced from 300 ppm to 100 ppm. Given that the typical price range for children's bikes is $50 to $200, a 25 percent cost increase could result in a new price range of $62.50 to $250. According to a representative of a bicycle testing firm (ACT), 10 out of 40 manufacturers stopped producing youth bicycles after the 300 ppm maximum content was imposed. This commenter also predicted that the remaining small manufacturers would stop producing youth bicycles once the 100 ppm standard goes into effect. This prediction may be extreme, but the 100 ppm lead limit is likely to reduce further the number of manufacturers that will produce these children's models. This commenter stated that small manufacturers have little bargaining power with metal and component suppliers and would be priced out of the children's bicycle market.

[17] Keith Barber, Rainbow Sales, Inc. Telephone conversation with Charles Smith, Directorate for Economic Analysis, March 31, 2011

There is some limited information on compliance costs for ATVs. One ATV manufacturer[18] achieved compliance with 300 ppm (but not 100 ppm) by moving the battery and enclosing some parts in plastic, at a cost of $10. Another manufacturer, DRR,[19] found that buying components complying with 100 ppm limit increased the prices of vinyl handgrips from $3 to $5 and plastic body panels from $14 to $28. DRR's products are high-end children's ATVs with prices in the range of $1,900 to $3,800. By comparison, some children's ATVs manufactured by the recent Chinese and Taiwanese entrants to the ATV market have been priced under $500. At these lower prices, the profit margins are reported to be very small, so any additional costs for materials would have a big impact on profits. Additionally, as with bicycle manufacturers, a number of ATV manufacturers have responded to the lower lead limits by no longer producing ATVs for the youth market.[20] There are also reports[21] that some manufacturers of inexpensive ATVs are marketing small ATVs for general use, rather than attempting to meet the 100 ppm requirement for youth ATVs.

Finally, while relatively little information was provided on compliance costs for toys and juvenile products, one producer of educational materials and learning toys (Learning Resources, Inc.[22]) projects that a 10 to 20 percent increase in the cost of finished goods will be needed to comply with the lead content limit of 100 ppm. Staff has not received information from other manufacturers regarding specific costs related to designing products or components to meet the 100 ppm lead content limit.

Testing Costs

Testing costs also might increase due to the more stringent lead limits. A number of commenters expressed concern that commercial labs are unable to measure accurately lead concentrations in the area of 100 ppm. The problem is that materials meeting the requirement frequently fail third party tests due to variability in the testing equipment and procedures across labs. Several commenters refer to data from a zipper/fastener manufacturer, YKK, which showed a large variation in testing results between independent labs for a sample with a known lead concentration of 71 ppm. While we are unable to verify YKK's claims, YKK reported that out of 20 labs, only half tested within a 10 percent margin of error for the known lead level. One lab tested the sample at 331 ppm. Similarly, Learning Resources, Inc., presented testing data on a single piece of white string from a mesh bag for dominoes, showing lead results of 239–275 ppm. For other items, Learning Resources cited variations between 10 ppm (for a tape measure) to 60 ppm (for yellow plastic counters resembling poker chips), which implies that the actual lead content might need to be lower than 40 ppm in order to avoid the additional costs of dealing with and responding to a "false positive" test result. Finally, one FJATA member sent identical samples of a soldering alloy to eight independent facilities between December 2009 and July 2010. The member's in-house test found a lead level of 217 ppm, but the other seven labs found readings from less than 50 ppm to 262 ppm.

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[18] Hilbert, March 27, 2009.

[19] DRR Marketing Manager, Telephone conversation with William Zamula, Directorate for Economic Analysis, April 6, 2011

[20] Letter from Paul Vitrano, SVIA, requesting a further stay of enforcement of the third party testing requirements for youth ATVs, December 30, 2011.

[21] ATV Factory Tour quoted in the "CPSC Beijing Office Trip Report for HQ Working Group Members" February 25, 2011.

[22] Richard Woldenberg, Learning Resources, Inc., Comment CPSC-2010-0023, p.2, September 27, 2010.

The testing variability means that ensuring compliance with the 100 ppm limit may require that lead in components or products are, in fact, significantly below the limit. Levels significantly below 100 ppm may not be technologically feasible for some products. Moreover, the reported variations in testing suggest that fully compliant products or components are likely to fail tests periodically, even though they actually comply with the legal limits. The economic implications of test failures can be quite significant and include needless scrapping of failing materials, as well as the potential for increased recalls.

Number of Components

For products consisting of numerous components, the problem is amplified because of the need to assure compliance for each individual component. The amount of testing that may be needed to ensure compliance with the lead limits is expected to be costly, especially for products with many components.

Even when most individual components can meet the 100 ppm standard, problems with compliance can occur at the final product stage. Some commenters reported high compliance rates for individual components of products, but not for finished products consisting of numerous components. Learning Resources reported 98.3 percent compliance with the 100 ppm standard for its products, but found this compliance level to be unacceptable because of the difficulty in identifying where the noncomplying components would turn up. As the Toy Industry Association notes, the likelihood of product failure increases with the number of underlying components.

A Summary of the Potential Economic Impacts

On the basis of current information, it is not possible to quantify the aggregate economic impacts of imposing the 100 ppm lead content limit. However, we can describe in a general way, the economic impacts that are likely to occur.

For products that are not yet compliant with the 100 ppm lead content limit, the more stringent lead content limit will likely increase the costs of producing children's products. Some manufacturers may have to purchase more expensive low-lead metals or plastics rather than continue with the materials they use today. Additionally, because a lead content limit of 100 ppm is harder to achieve than the current 300 ppm (in part, because of testing variability described by several commenters), products or components are more likely to fail the third party lead content tests that are required by the CPSIA. Thus, the more stringent lead content limits may result in added testing costs, as well as remedial efforts to dispose of the failing component parts.

Cost increases are likely to be reflected in the market for children's products as a combination of price increases and reductions in the types and quantities of children's products available to consumers. To the extent that the demand for children's products is price inelastic,[23] firms may be able to pass a large proportion of increased costs forward to consumers in the form of higher retail prices. In some cases, the price increases could be significant.

[23]Demand is said to be price inelastic if an increase in price would only result in a relatively small reduction in the quantity purchased.

Alternatively, when the demand for children's products is price elastic,[24] firms will be less able to pass the costs forward, and firms will have to absorb the higher costs in the form of reduced profits. Because there are limits to the reduction in profits that firms are willing and able to accept, some firms may reduce the selection of children's products they manufacturer or exit the children's market altogether. In some cases the firms may even go out of business. Based on public comments and testimony at the public hearing, these types of effects, to some extent, may have occurred already in the markets for bicycles and ATVs. Additionally, and as noted in comments from the Handmade Toy Alliance and the Bicycle Product Suppliers Association, it is likely that the costs will have relatively greater consequences for smaller manufacturers and artisans, who have less bargaining power with components suppliers, fewer technical resources, smaller production runs to spread testing costs over, and smaller product lines.

In general, for cost increases affecting a broad base of industries, there will be a mixture of effects: both increases in product prices and reductions in the production of children's products are possible. However, it should be noted that there are many substitutes for children's products, and there is often the option of purchasing adult versions of products for use by children. ATVs represent a prominent example, but there are many types of products not specifically intended for children that could be substituted for children's products. Consequently, because the availability of substitutes affects the price elasticity of demand for a number of children's products, we expect the lead limits to result in some reduction in the production of products for the children's market.

In addition to the direct effects on manufacturers, some firms in the retail and wholesale sectors that sell children's products could experience adverse effects if the new standard were to be applied retroactively. To the extent that children's products that do not comply with the 100 ppm standard remain on the shelf or in inventories after the August 14, 2011 effective date, these items would need to be removed prior to sale. The loss of inventory would result in costs which would be higher for retail and wholesale firms that specialize in the sale of children's products and especially for those that specialize in products for which compliance may be more difficult. These costs cannot be quantified but could be substantial for some firms, especially if firms were not aware that the limits were to be applied retroactively.

The 100 ppm lead limit may also result in other secondary effects in segments of the market for children's products. The higher costs associated with metal components will probably result in efforts to substitute lower cost materials. Plastics, for example, might be substituted for metal parts in some products. Certain substitutions might affect the utility of the products. The use of plastic instead of metal may reduce a product's durability in some applications. Alternatively, some manufacturers may need to redesign or reengineer their products. Valve stems for bicycles, for example, may need to be fitted with more secure caps, which will effectively render them inaccessible and potentially more difficult to use. In addition, products may be simplified to reduce the number of components for testing.

There appear to be few readily available options for mitigating the costs associated with the 100 ppm content limit. However, several comments suggested that it would be helpful if the CPSC were to specify a range or margin of error for acceptable test results to cover the uncertainty of testing at such low lead concentrations. The Commission could direct staff to

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[24] The demand is said to be price elastic if an increase in price would result in a relatively large decrease in the quantity purchased.

develop an acceptable confidence interval reflecting testing variability, which could be used for purposes of enforcement of the standard. If, for example, it were determined that testing variability at low lead levels amounted to plus or minus a certain value, that value could be used to set a tolerance limit. The Commission could inform producers of children's products that because of testing variability, it would not enforce strictly the 100 ppm lead limit, as long as the testing results showed that the lead content was within 100 ppm, plus the tolerance limit. Such a safe harbor would be unlikely to result in any adverse health effects but could provide some relief to manufacturers of children's products.

Table 1. Manufacturers

NAICS Code	Description	Small Firms	Total Firms
315	Apparel Manufacturing	10,073	10,151
316211	Rubber and Plastic Footwear Manufacturing	53	57
316212	House Slipper Manufacturing	2	2
316219	Other Footwear Manufacturing	67	69
336991	Motorcycle, Bicycle, and Parts Manufacturing	465	473
33712	Household and Institutional Furniture Manufacturing	6,264	6,364
33791	Mattress Manufacturing	442	456
339113	Surgical Appliance and Supplies Manufacturing	1,628	1,720
33991	Jewelry and Silverware Manufacturing	2,656	2,672
33992	Sporting and Athletic Goods Manufacturing	1,858	1,900
33993	Doll, Toy and Game Manufacturing	760	770
339999	All Other Miscellaneous Manufacturing	5,881	6,000
	Total Manufacturers	30,149	30,634

Source: U.S. Small Business Administration, Office of Advocacy, based on data provided by the U.S. Census Bureau, Statistics of U.S. Businesses, "Employer Firms and Employment by Employment Size of Firms by NAICS Codes, 2007 (available at http://www.sba.gov/advo/research/us07_n6.pdf, last accessed on 5 April 2011).

Table 2. Wholesalers

NAICS Code	Description	Small Firms	Total Firms
4231	Motor Vehicle and Motor Vehicle Parts and Suppliers	16,947	17,858
4232	Furniture and Home Furnishing Merchant Wholesalers	10,534	10,981
42362	Electrical and Electronic Appliance, Television, and Radio Set Merchant Wholesalers	2,147	2,269
42391	Sporting and Recreational Goods and Supplies Merchant Wholesalers	4,397	4,552
42392	Toy and Hobby Goods and Supplies Merchant Wholesalers	2,170	2,248
42394	Jewelry, Watch, Precious Stone, and Precious Metal Merchant Wholesalers	7,735	7,815
42399	Other Miscellaneous Durable Goods Merchant Wholesalers	10,146	10,367
42432	Men's and Boy's Clothing and Furnishings Merchant Wholesalers	3,235	3,393
42433	Women's, Children's, and Infant's Clothing, and Accessories Merchant Wholesalers	5,965	6,186
42434	Footwear Merchant Wholesalers	1,434	1,493
42499	Other Miscellaneous Nondurable Goods Merchant Wholesalers	12,497	12,753
	Total	77,207	79,915

Source: U.S. Census Bureau, 2006 County Business Patterns

Table 3. Retailers

NAICS Code	Description	Small Firms	Total Firms
441221	Motorcycle, ATV, and Personal Watercraft Dealers	3,969	4,001
4421	Furniture Stores	16,282	17,542
44813	Children's and Infant's Clothing Stores	2,146	2,200
44814	Family Clothing Stores	5,998	6,240
4482103	Children's & juveniles' shoe stores	300	305
4483	Jewelry, luggage, & leather goods stores	16,341	16,778
45111	Sporting goods stores	14,451	14,831
45112	Hobby, toy, & game stores	4,832	4,903
452	General Merchandise Stores	7,387	7,494
45322	Gift, Novelty, and Souvenir Store	21,412	21,637
453998	All Other Misc. Store Retailers (except Tobacco Stores)	11,934	12,228
4542	Vending machine operators	4,081	4,278
45439	Other direct selling establishments	15,938	16,431
	Total	125,071	128,868

Source: U.S. Census Bureau, 2002 Economic Census, Release date November 25, 2005.

TAB C: Public Comments

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

Memorandum

Date: May 11, 2011

TO : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences, Directorate for Health Sciences

FROM : Dominique J. Williams, Toxicologist, Directorate for Health Sciences
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

SUBJECT : Response to Public Comments: Technological Feasibility of 100 ppm Total Lead Content in Children's Products

Introduction

Section 101(a) of the Consumer Product Safety Improvement Act (CPSIA) provides that, as of Aug. 14, 2011, children's products may not contain more than 100 parts per million (ppm) of lead, unless the U.S. Consumer Product Safety Commission (CPSC or Commission) determines that it is not technologically feasible, after notice and a hearing, and after analyzing the public health protections associated with substantially reducing lead in children's products. Section 101(d) of the CPSIA (15 U.S.C 1278a(d)) provides that a lead limit shall be deemed technologically feasible with regard to a product or product category if:

> (1) a product that complies with the limit is commercially available in the product category;
>
> (2) technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;
>
> (3) industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or
>
> (4) alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

On July 27, 2010, a notice was published in the *Federal Register* requesting comments and information regarding the technological feasibility for manufacturers to meet the 100 ppm lead content limits. Twenty-four comments were received from consumer groups, manufacturers, retailers, associations, and laboratories.

After initial consideration of these comments, the Commission published a notice in the *Federal Register* (76 FR 4641) on Jan. 26, 2011, announcing that it would be conducting a public hearing to receive additional information. The hearing was held on Feb. 16, 2011.[1]

On March 9, 2011, the Commission published a notice in the *Federal Register* (76 FR 12944), reopening the hearing record to allow hearing participants to submit relevant studies and supplementary data in response to additional questions from individual Commissioners.

CPSC received comments from a variety of stakeholders that addressed several key points concerning the hazards of lead exposure and the importance of limiting lead content in children's products, and the implications of lead content requirements for products and manufacturers. Specifically, comments addressed: (1) public health protectiveness; (2) test result variability due to material composition and issues related to specific materials; (3) variability in test results between different laboratories; and (4) the challenges related to attaining compliance with a 100 ppm lead content limit, such as the availability of compliant materials and economic burdens.

Several commenters concluded that 100 ppm lead is a technologically feasible limit, but several commenters concluded that it is not feasible for certain products to comply with a 100 ppm limit. The following are summaries of the comments and staff's responses to the comments. Appendix 1 contains the list of comments received in response to the *Federal Register* Notices of July 27, 2010 and Jan. 26, 2011, as well as the comments received at the public hearing on Feb. 16, 2011, and after the hearing record was reopened to allow the hearing participants to submit additional information.

<u>Discussion</u>

Comment 1: Public health protectiveness

As noted by commenters, section 101 of the CPSIA requires the CPSC to assess the public health protectiveness of substantially reducing lead levels in children's products.

Several commenters (Nos. 14, 16, 17, 23, 29, and 33) expressed concern about children's lead exposure. Commenters stated that there is no safe level of lead and that any reduction in allowable lead levels in children's products increases health protectiveness. One of these commenters (No. 14) reported that significant health problems in children have been associated with blood lead concentrations in the 5–10 microgram per deciliter range and that lead exposure has been shown to have neurocognitive effects, even at low levels. Another commenter (No. 23) stated that products should bear labels indicating the lead content.

Several comments disputed claims that the lead content requirements need to be more stringent. Two commenters (Nos.1 and 6) said they believe that the lead in many materials is trapped in the matrix of the product and that no exposure to children would occur. One commenter (No. 6) mentioned that the two main sources of lead are old lead-containing paint in the home, and soil contaminated from the use of leaded gasoline. One commenter (No. 1) stated that the real

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[1] The video webcast of the hearing, as well as the presentations and written comments from the hearing, are available at the CPSC website: http://www.cpsc.gov/webcast/previous.html. A transcript of the hearing and supplemental information provided by hearing participants are available at www.regulations.gov, docket CPSC-2010-0080.

question should be: “[What is] the potential amount of lead that can be released from a children’s product?”

Another commenter (No. 9) stated that a total lead standard was not a reasonable way to evaluate risk of poisoning and that there are no scientific studies directly correlating total lead content to the risk of lead poisoning; therefore, the commenter argued that a total lead standard is not a scientific assessment and asserted that reducing the limit to 100 ppm would “merely be compounding and increasing the side effects of an unscientific principle.”

Some commenters (Nos. 13, 18, and 19) stated that there is an extremely low risk of exposure to lead in their products, with two commenters (Nos. 13 and 19) reporting that wipe sampling and saline extraction test data show that there are no health risks for representative components containing lead concentrations higher than 100 ppm. One commenter (No. 21) claimed that there is no evidence of injury due to lead levels between 100 ppm and 300 ppm in substrate. This commenter, based on a review of CPSC recall data from 1999 to 2010, stated that the one reported death and three unverified lead injuries are so few in number that it is statistically impossible to prove a benefit from the lead content requirements.

Another commenter (No. 22) stated that the current limit of 300 ppm total lead in children’s components represents a high margin of safety and that the exposure scenarios now have been radically reduced compared to the previously unregulated total contents.

CPSC Staff Response 1:

Staff acknowledges that lead exposure in children, including exposure from children’s products, should be limited. However, staff believes that substantial health protections have already been achieved with the implementation of CPSIA requirements that require most children’s products and components of children’s products to comply with the 300 ppm lead content limit as of Aug. 14, 2009. Because of this requirement, staff believes that changes in business practices and implementation of material and supply chain controls, as well as increased testing, inspection, and compliance efforts that eliminate intentional uses of lead, have already resulted in reductions of lead content below the 300 ppm limit, and, in many cases, below the 100 ppm level.

While staff does not have data on potential lead exposure from products with lead content less than 300 ppm but exceeding 100 ppm, staff expects that the overall lead exposure to children from such products is minimal.

Comment 2: Comments from the American Academy of Pediatrics

In response to written questions from Commissioners following the public hearing, the American Academy of Pediatrics (No. 26), provided additional information related to her previous written and oral comments. The additional comments primarily addressed statements concerning the adverse effects of lead, the potential for lead exposure from products, and the costs associated with lead exposure. The additional comment also provided references for some of the information presented in the original comments.

The commenter answered questions about children’s mouthing behaviors and whether lead exposure depends on the product or the materials used in a product, acknowledging that behaviors change as a person gets older. However, the comment indicated that even adults can be exposed to lead if it is on their hands. The Commenter also acknowledged that the characteristics of specific products can influence the level of exposure to lead, such as the composition of the item and whether an item, if swallowed, remains in the stomach for a long time.

This commenter asserted that an object containing 300 ppm, if swallowed, could decrease a child's IQ by almost 4 points and that an object containing 77 ppm lead, if swallowed, could decrease a child's IQ by 1 point.

CPSC Staff Response 2:

In general, the information provided by this commenter relates to children's exposure to significant environmental sources of lead, such as lead-based paint in older housing or products that contained high levels of lead. The studies cited that have estimated the health effects and economic effects of excess lead exposure in children are also based on populations of children with significant environmental sources of lead.

Staff agrees that the scientific literature clearly demonstrates the adverse effects of lead exposure in situations involving housing, children's environments, or certain lead-containing products. However, the literature relating to relatively less significant lead exposure situations is less robust. Indeed, no information or studies were presented by this commenter concerning exposure estimates for children who use specific products containing relatively low concentrations of lead (*i.e.*, up to 300 ppm).

The conclusion that a child would suffer effects of lead exposure measured as loss of IQ after swallowing objects containing 300 ppm or 77 ppm lead is based on an incorrect characterization of a CPSC staff analysis first released in 2005. As discussed in more detail in the 2006 staff briefing package on lead in children's metal jewelry, staff concluded that children who swallow items containing more than 600 ppm lead may experience excess lead exposure, and that the likelihood of excess lead exposure increases with increasing lead content. Staff did not find that an item containing 600 ppm lead would result in excess lead exposure. Further, staff did not conclude that the effect of acute (short-term) lead exposure from swallowing an item would be loss of IQ. Staff concluded that acute lead exposure could result in adverse health effects, but staff did not conclude that reduced IQ would necessarily result after acute exposure. Such a conclusion would require additional information concerning the relationship between lead exposure and IQ, including the level of exposure to lead, the length of the exposure, and the timing of exposure in a child's life.

Staff does not dispute that a child's use of a lead-containing product could result in exposure to lead. Moreover, staff agrees that children's exposures to lead should be limited. The implementation of the CPSIA lead content requirements for children's products helps ensure that children's products will not be a significant lead source. In fact, staff does not have data showing that children's products containing up to 300 ppm will result in excess exposures to lead.

Comment 3: 100 ppm lead in substrate is technologically feasible; most products already comply.

Several commenters (Nos. 2, 17, 20, and 24) referenced data for tested products that indicate the 100 ppm total lead content limit is feasible and that technology exists that would enable manufacturers to reformulate noncompliant products into compliant products. Another commenter (No. 28) presented data from toy testing, which indicated that a large proportion of tested products have lead content below 100 ppm, but the commenter also discussed the types of materials that are more likely to have lead content that exceeds that level. One commenter (No. 8), on behalf of organizations associated with manufacturing of shoes in Mexico, confirmed that it is technologically feasible for footwear to meet a 100 ppm limit.

One commenter (No. 25), representing American iron and steel producers, provided information stating that "the reduction of lead to levels below 100 ppm in U.S. produced steels is technologically feasible and continues to be so simply by the fact that lead has a lower melting and vaporization point than the high temperatures that are required to make steel." In addition, this commenter referenced a 1998 study, "Residuals in Steel," which showed nearly all measurements of lead levels below 100 ppm, with one sample at 100 ppm, and three samples showing no residual lead at all. This commenter also noted that "steel scrap (recycled steel) is one of the major feed stocks for the steel making process," and that "steel is the most recycled material in the United States and contains the highest level of recycled content of any competing material."

However, several manufacturers (Nos. 3, 11, and 21) expressed concern that the 100 ppm lead content limit cannot be met consistently. One commenter (No. 11) said that in general, "products produced to this stricter standard are compliant," but there is still a small, "but statistically relevant percentage," failure rate of 0.46 percent. Another commenter (No. 21) reported that up to 2 percent of items tested indicate lead concentrations between 100 ppm and 300 ppm, and that this rate of failure to meet a 100 ppm standard is not addressable or controllable because they have not been able to determine any pattern to the products whose tests exhibit lead concentration above 100 ppm.

CPSC Staff Response 3:

Staff acknowledges that a majority of products do not contain lead above the 100 ppm level but that a small portion of products manufactured and tested, to date, have been found to exceed the 100 ppm limit (some of the reported test results also show items with lead content exceeding the current 300 ppm requirement, which may indicate the need for additional efforts toward compliance with the standard). The comments and test data indicate that complying products and materials appear to be available for a wide variety of products and uses. Although the data show that some products currently exceed 100 ppm lead, staff does not believe that this constitutes evidence that products cannot meet a 100 ppm limit, in part because currently, manufacturers are not required to comply with a 100 ppm limit.

Comment 4: 100 ppm lead in substrate is technologically feasible for certain non-metal materials.

Several commenters (Nos. 4, 12, 13, 15, and 18) stated that some non-metal materials, such as glass, paper, stone, ink, and plastics may comply consistently with the 100 ppm total lead limit. On the other hand, some of these commenters (Nos. 4, 12, and 15) also stated that enamel-glazed ceramics and glass that are colored, or that require machining, polishing, or specific optical characteristics, would not be able to comply with the limit.

Two commenters (Nos. 12 and 19) noted that although most plastic components can be made to comply with the 100 ppm total lead content limit, virgin materials would be required to do so. One commenter (No. 15) stated that certain materials used in children's jewelry, such as plastic beads, currently meet a 200 ppm lead limit under laws enacted in California and Minnesota.

This commenter also noted that crystal, with properties similar to leaded crystal, is now available that meets the 100 ppm limit.

CPSC Staff Response 4:

Based on staff research and data submitted by public commenters, staff has concluded that certain materials, including some plastics, glass, and ceramics are commonly produced without added lead. Manufacturers may need to implement supply chain controls and perhaps avoid materials made with recycled products to ensure that lead has not been unintentionally introduced into the product. In some cases, a lead-containing material may be used to make a product, but if that material is not completely separable from the product, the lead content of the finished product may be less than 100 ppm, such as the material described in Comment 5 below.

Comment 5: Decals for glass and ceramic

One commenter (No. 1) was concerned that the decals they manufacture for use on glass and ceramic substrates would not be able to comply with the 100 ppm total lead limit; however, the commenter asserted that most decals can be certified at less than 300 ppm. The commenter further explained the process by which the decals are attached to the substrate through vitrification.

CPSC Staff Response 5:

The CPSIA lead limit for content on decorated glass or ceramic children's products applies to the final product not just to the decal that is applied. Once the decal is applied, fired, and vitrified to the glass or ceramic item, the decal would no longer be a separable component part. The lead content would be determined after obtaining a representative sample of the product, or it could be calculated from the known weight of each original component and the known lead concentration of each component. Given the low weight of the decal compared to the final glass or ceramic item, if the lead content of the glass or ceramic item is less than 100 ppm lead, the lead content of the finished product also could be less than 100 ppm, even if the lead content of the decal component is more than 100 ppm.

Comment 6: Testing used products for lead

A commenter (No. 32) expressed concern about the availability of inexpensive used clothing and shoes at thrift stores because of the requirements for lead in children's products, especially product testing requirements. Another commenter (No. 34) expressed similar concerns about books, stating that the CPSC has issued rules requiring that children's books published before 1986 must be tested for lead content. Both commenters indicated that a different approach is warranted, such as requiring used clothing to be washed or exempting books from the lead content requirements.

CPSC Staff Response 6:

With a few exceptions,[2] the requirements for children's products under the CPSIA provide that all children's products in commerce must meet the lead content limit, which is currently 300 ppm and will become 100 ppm on Aug.14, 2011, unless the Commission determines that the lower limit is not technologically feasible for certain products. However, the product testing

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[2] Exceptions to the lead content requirements, including inaccessible parts (16 C.F.R. § 1500.87), and certain electronic devices (16 C.F.R. §1500.88).

requirements do not apply to used or secondhand products, although compliance with the lead limit is still required, and retailers and resellers should take steps to avoid selling products that do not meet the requirements.[3]

Most textile parts of clothing do not contain lead at concentrations above the lead limit[4]; on the other hand, accessories components, such as buttons, snaps, and zippers could contain lead. Washing items that contain buttons or zippers will not remove the lead.

While ordinary books printed after about 1985 do not contain lead above the lead limits, older books may contain lead due to the prior use of lead in inks. Older used books do not have to be tested. In addition, vintage children's books and other children's products sold as collector's items would not be primarily intended for children, do not fall within the definition of children's product, and do not need to comply with the lead limits.

Comment 7: Material Composition Variability

Some commenters (Nos. 1, 3, and 15) expressed concern that due to inherent background levels of lead in some materials, especially metallic materials, 100 percent compliance with a 100 ppm lead limit would be difficult, if not impossible, to achieve. Although some metallic materials will comply, not all metallic materials will comply (No. 4). In addition, those metallic materials that might generally comply, may not comply all the time (No. 3).

Commenters (Nos. 4, 12, and 15) believe that mixing metals to make alloys and using recycled materials to make common alloys (No. 3), such as brass, also make it difficult to fully comply with the reduced lead content limit due to the nature of metals. One commenter in particular (No. 12), mentioned that the inability for some metal components to comply appears to reflect the requirement for high concentrations of lead in materials intended to be cast, machined, and formed.

Another reason commenters said it would be difficult to comply with a 100 ppm lead content is the multistage process of finishing a product, which includes layering other metals or finishes that have trace amounts of lead (No. 15). In addition, two commenters (Nos.13 and 15) stated that there is a limit to which an element can be removed from an alloy; thus, they argued, even lead-free metals can be contaminated.

CPSC Staff Response 7:

CPSC staff recognizes that variability and heterogeneity may exist within certain materials, products, or component parts with respect to lead content, especially metal items. This results in parts of a product that, at the microscopic level, exceed 100 ppm, even though the product, as a whole, contains an overall lead content of less than 100 ppm. Staff has concluded that metals and metal alloys are generally available that would comply with a 100 ppm limit.

CPSC staff test methods for lead are designed to determine the overall lead composition not demonstrate microscopic inhomogeneities that may be present in a material. Test Method: CPSC-CH-E1001-8.1 Standard Operating Procedure for Determining Total Lead (Pb) in Metal Children's Products (including Children's Metal Jewelry), Revision June 21, 2010, states:

[3] The Commission developed guidance for resellers available at http://www.cpsc.gov/about/cpsia/smbus/retailers.html.

[4] 16 C.F.R. § 1500.91 Determinations regarding lead content for certain materials or products under section 101 of the Consumer Product Safety Improvement Act.

"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." The method requires the use of an aliquot of 30 to 100 mg of metal taken representatively from the sample. Product testing strategies can account for material variability or heterogeneity. For example, analysts may obtain a larger aliquot of the material by grinding or milling a component, which would tend to result in a homogeneous sample representative of the item. Analysts may also test multiple aliquots of a ground or milled sample. These approaches ensure that microscopic heterogeneity does not unduly affect the determination of the overall concentration in the material.

Some metal alloys, such as steel and brass, contain intentionally added lead for certain functional purposes; but in general, in these cases, the lead concentrations are significantly in excess of the current lead content limit for lead in children's products (300 ppm). Products or component parts of products manufactured using such materials are banned from use in children's products if the component parts are accessible; thus, these products are not the subject of these proceedings.

Comment 8: Laboratory Testing Variability

Some commenters (Nos. 4, 6, 15, and 19) claim that the degree of variability in the results from lead testing within laboratories and between laboratories indicates that the 100 ppm limit is not technologically feasible. Many submissions (Nos. 4, 6, 13, and 15) commented on data obtained by YKK, a zipper manufacturer, which suggests a high degree of testing variability that could cause inconsistent compliance for some products. In an article published in the *Product Safety Letter* on July 19, 2010, YKK indicated that of 20 testing laboratories receiving samples of a known material, only half returned results that were within 10 percent of the approximate 71 ppm known target lead concentration.

Some commenters (Nos. 15, 21, and 31) reported that their own test data also showed such variability. One of these commenters (No. 21) reported that the laboratory tests indicating noncomplying products made with many different materials shows no pattern for lead content for the type of product or material. In a response to a Commissioner's written question following the public hearing, this commenter further discussed the implications of a lower lead content limit and testing variability, indicating that "success in obtaining passing test reports will apparently depend on LUCK when lead levels are near the 100 ppm concentration."

Two commenters (Nos. 13 and 19) indicated that when mixed metals, such as steel alloys, are tested, there could be difficulties extracting the lead, as well as errors in measuring it. These commenters report that metallurgists and chemists indicate that this is due to the readings from the primary metal interfering with the results of the other metals present.

One commenter (No. 4) stated: "it is vitally important that third party test results be both accurate and consistent" so that inaccurate tests will not create an economic burden on businesses. One commenter (No. 6) stated that a failed result under these conditions would drive the company to solve a "high lead" problem that may not exist and result in an increase in costs and a reduction in trust in the test results. Another commenter (No. 22) stated that laboratory testing variability could cause a component with a true lead level of less than 100 ppm to fail and that a difference among test results of up to 30 percent has been seen in intra-laboratory testing.

Another commenter (No. 30) addressed laboratory accreditation and the proficiency testing framework that must be considered for testing issues related to a 100 ppm standard. This commenter, representing associations of analytical laboratories, stated that laboratory test methods using inductively coupled plasma technology (ICP) for measuring lead content, when properly performed, achieve precision, reliability and repeatability in testing for levels of 100 ppm or less in the materials used to make consumer products.

One commenter (No. 22) suggested that "… averaging of results of a sample or application of a statistical measure like Z-score to the results" could address issues with laboratory variability.

CPSC Staff Response 8:

Staff acknowledges that testing variability can occur in a variety of testing protocols and requirements, including the current 300 ppm lead content requirement. Staff considers a certain amount of test variability to be expected, and agrees with the conclusions by some commenters who note that variability can be greater for some materials than for others. However, standard practices in analytical laboratories include detecting, understanding, and controlling excess test variability. Staff believes it is important to distinguish testing variability from material variability. Testing variability can be determined by testing materials that have been well characterized, such as Standard Reference Materials (SRMs) produced by the National Institutes of Standards and Technology (NIST). Testing materials that are not well characterized may lead to misattribution of material variability to testing variability. NIST SRMs and similar products from other recognized metrology laboratories are available with certified lead content and with certified uncertainty levels for the lead content. Three lead reference materials with certified lead content ranging from 13 ppm to 85.9 ppm were analyzed using applicable CPSC standard test methods by nine chemists in the Directorate for Laboratory Sciences, Division of Chemistry. The results for each reference material are in agreement with the certified value. There are overlapping 95 percent confidence intervals between CPSC staff results and the certified values. CPSC staff believes that the testing conducted indicates that CPSC test methods can be applied effectively to samples with less than 100 parts per million of lead.

Staff also believes that some of the issues related to testing and material variability may be addressable by the Commission on a case-by-case basis, considering all available information, not just a single test report. For example, the Commission could choose initially to focus enforcement efforts on products with the most exposure potential, such as those that may be mouthed or swallowed.

Staff has found that critical information about the testing by YKK is lacking. Without more information on the composition, processing, and homogeneity of the product or material tested, it is not possible to determine whether the reported variability is due to laboratory performance, inconsistencies in the test material, both possible factors, or some other reasons. CPSC staff requested additional information from YKK about this testing, but additional information has not been provided.

Staff understands the importance of the accreditation process and appropriate test methods for standards, such as the lead content limits. These issues are addressed in other Commission actions related to provisions of the CPSIA.[5]

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[5] See information related to CPSIA Section 102 concerning mandatory third party testing for certain children's products available at http://www.cpsc.gov/about/cpsia/sect102.html.

Comment 9: X-Ray Fluorescence Technologies

One commenter (No. 5) indicated that the limit of detection for a handheld x-ray fluorescence (XRF) analyzer is below the 100 ppm for lead. The commenter stated that XRF is cost effective, easy to operate, nondestructive, and provides reliable and quick extensive analyses of a significant number of products and component parts. The commenter provided data to counter concerns that XRF cannot detect 100 ppm lead consistently. This same presenter at the public hearing (No. 5) provided information that handheld XRF could be used for screening products and noted that it is able to detect 100 ppm lead in most matrices. This commenter indicated that the limit of detection for metals is about 100 ppm to 120 ppm. This commenter also addressed written questions from a Commissioner concerning practical applications of XRF testing, such as the size of an area that can be tested and testing multiple materials in a single sample. The commenter also confirmed that the costs of using XRF do not change for measurement of multiple chemical elements at the same time, although multielement analysis can present certain technical difficulties.

In addition, another presenter (No. 27) provided information on laboratory-based "HDXRF," (distinct technology from handheld analyzers), stating that it can detect low ppm lead levels in plastics and glass, with good repeatability reproducibility statistics; the presenter indicated that this technology may also be appropriate for analysis of metals, although perhaps not to the low levels achievable for plastic and glass. In a follow-up response to a written question from a Commissioner concerning the use of this technology for analyzing both paints and substrate materials, the presenter confirmed that the HDXRF can measure paint and substrate during the same analysis and report the concentration of each separately and reliably.

CPSC Staff Response 9:

CPSC staff recognizes the capabilities and limitations of handheld XRF analyzers. While handheld XRF analyzers may be beneficial for screening metal products for the presence of lead, many metallic products are not homogeneous and may have electroplating or coatings that could impact accuracy of test results. CPSC test method CPSC-CH-E1002-08.1 indicates that XRF may be used for determining lead content in homogeneous polymeric materials (such as plastics), following procedures outlined in ASTM F 2617-08.

The written responses to the Commissioners' questions clarify that XRF technologies can be used to measure lead in a number of different materials in different types of products. The responses also indicate that an analyst's knowledge of the instruments' capabilities and proper use is important for obtaining accurate results.

Recently the CPSC addressed accreditation and testing using specific XRF technology. On April 5, 2011, the CPSC published a notice of requirements in the *Federal Register*, detailing the requirements for accreditation of third party conformity assessment bodies for lead paint (76 FR 18645). In that notice of requirements, the use of test method ASTM F2853-10, *Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams*, also known as HDXRF, is allowed for testing lead in paint concentrations.

Comment 10: Current Product Supply Chain

Many commenters (Nos. 1, 9, 13, 18, 19, 21, 22, and 31) claimed that reducing the lead content limit from 300 ppm to 100 ppm is not technologically feasible due to suppliers not manufacturing component parts specifically for children's products and not providing a consistent supply of compliant products; in addition, these commenters asserted that firms, especially small manufacturers, may have difficulty demanding suppliers' compliance with the requirement. One commenter (No. 22) stated that to achieve lead limits below 200 ppm, stricter controls must be implemented in the supply chain, which would likely reduce the number of suppliers and increase the cost of production.

Two commenters (Nos. 13 and 19) stated that test failures occur "because certain metal components comprised of general use fasteners and other metal parts, which may be used in toys, cannot practically be produced in a controlled fashion without a globally sanitized supply chain."

CPSC Staff Response 10:

Staff recognizes that children's manufacturers often use component parts and materials that are not themselves children's products and that do not have to comply with the requirements for children's products. Commenters' general statements do not provide specific information related to manufacturers' procurement procedures or documentation concerning activities to identify complying material. Based upon staff research and the submitted data showing in excess of 99 percent compliance with the 100 ppm lead limit, staff concludes that complying products and the technology to comply with the 100 ppm lead limit are commercially available.

Staff agrees that supply chain improvements and controls may be needed to address the availability of complying parts and materials.

Comment 11: Economic Burden

Several commenters (Nos. 4, 9, 18, and 21) stated that a further reduction in the total lead limit to 100 ppm would increase the cost of production, increase costs for consumers, and impose economic hardship on businesses. One commenter (No. 9) stated that small businesses lack the resources to repeatedly test inventory to make sure that all products meet the 100 ppm limit.

One commenter (No. 4) expressed concern about the impact of the lower lead limit on the costs of promotional products. This commenter reported that in some cases, the incremental cost of compliance with the lower limit could result in an increase in promotional product costs from about $1 to $13 and that this could result in some companies closing. In some instances, according to another commenter (No. 18), compliance can be achieved through the use of virgin raw material, but the cost would increase by as much as 28 percent and lead to a substantial increase in the price of the finished product, which could continue to increase over time due to the limited supply of the raw materials. Additionally, one commenter (No. 21) projected a 10 percent to 20 percent increase in cost for finished goods subject to the new standard and commented that "purer" materials can be used but asserted that they are not practical or economically feasible.

Two commenters (Nos. 13 and 19) mentioned that some metal alloy additives, such as bismuth, can be used instead of lead for machining purposes, but the process for this is proprietary, making it more costly.

Two commenters (Nos. 4 and 21) questioned whether the economic impact of enforcing a 100 ppm limit is justified by the very small benefits associated with the lower limit.

CPSC Staff Response 11:

While staff cannot verify the specific claims of the commenters, staff agrees with some of the general assertions. To the extent that the lead content in children's products currently exceeds 100 ppm, limiting lead content to that level is expected to result in some increase in the costs of producing children's products. In some cases, if manufacturers are able to push these increased costs forward to consumers, the retail prices of these children's products will rise. However, in other cases, especially when there are close substitutes for children's products, manufacturers may be unable to push these costs forward and may have to absorb the higher costs as reductions in profits. Because there are limits to the reduction in profits that firms are willing and able to accept, some manufacturers are likely to reduce their selection of children's products or exit the children's market altogether. Some firms may even go out of business.

In general, for cost increases affecting a broad base of industries, there will be a mixture of effects, including increases in the retail prices of children's products and reductions in overall production levels. Additionally, the adverse economic effects associated with the increasingly stringent lead limit requirements will probably fall more heavily on smaller manufacturers, who have less bargaining power with suppliers, fewer technical resources, and smaller production runs over which to spread costs.

Staff notes that few public commenters estimated costs that might be associated with a lower lead content limit; and, in general, little information was provided by commenters to explain the processes or costs involved in meeting the lower limit or to support a conclusion that meeting the limit is not possible in all cases. Without more specific data on a product basis, the staff cannot determine whether or not an alternative that meets the lead limit is "commercially available."

With respect to the comments about the relationship between the benefits and costs of the lower lead limit, the lead content limit is mandated by law, unless it is not technologically feasible, and it is not contingent on the magnitude of possible benefits.

Comment 12: Stay of Enforcement for Youth Model Motorized Recreational Vehicles

Two commenters (Nos. 7 and 10) noted that any upcoming requests for extensions of the current stay of enforcement for youth model motorized recreational products as far as the inability of certain parts to comply with the current lead content requirement would include information addressing the fact that it is not technologically feasible to comply with the 100 ppm limit.

CPSC Staff Response 12:

Staff recognizes that information related to compliance with a lead content limit greater than 100 ppm would also apply to the lower 100 ppm lead content limit for these products. Staff notes, however, that any difficulties regarding compliance in general, are not the subject of the current proceeding. The stay of enforcement for products such as bicycles and ATVs is addressed in the stay proceeding, and the Commission may continue to address those products separately.

Comment 13: CPSC Enforcement Discretion

Some commenters (Nos. 13, 15, and 19) suggested that the CPSC should use enforcement discretion if the 100 ppm lead content limit goes into effect. Two commenters (Nos. 13 and 19) stated that due to variability in testing products and the potential for environmental contamination of the tested product that might cause a product to exceed 100 ppm, a margin of error in test results should be specified that would be recognized for compliance purposes.

CPSC Staff Response 13:

CPSC technical staff recognizes the practice of specifying acceptable margins of error in some standards. At this time, the CPSC has not issued rules or guidance concerning handling of test data for products that exceeds the lead content limit. However, a determination of conformance or nonconformance generally is not based on a single test result. In each case, CPSC staff makes full use of the available data and information concerning products, including information on testing variability.

Staff acknowledges that testing variability can occur in a variety of testing protocols and requirements, including the current 300 ppm lead content requirement. Staff considers a certain amount of test variability to be expected, and agrees with the conclusions by some commenters that variability can be greater for some materials than others. However, standard practices in analytical laboratories include detecting, understanding, and controlling excess test variability. Staff believes that some of the issues related to testing and material variability may be addressable on a case-by-case basis, considering all available information. For example, the Commission could choose initially to focus enforcement efforts on products with the most exposure potential, such as products that may be mouthed or swallowed.

Comment 14: Effective date

One commenter (No. 22) stated that the Aug. 14, 2011 date for the 100 ppm total lead limit requirement should be the manufacture date, and that the 100 ppm limit should not apply to products currently on shelves.

CPSC Staff Response 14:

The 100 ppm lead content limit goes into effect by statute on August 14, 2011. After that date all products containing more lead than the 100 ppm lead content limit are to be treated as banned hazardous substances and cannot be sold, offered for sale, manufactured for sale, distributed in commerce or imported into the United States.

Comment 15: Global Harmonization

Two commenters (Nos. 9 and 11) expressed a desire to have section 101 of the CPSIA harmonized to the European solubility standard for lead, which evaluates the risk of lead exposure through measuring the bioavailability of soluble lead in a substrate. These commenters stated that because suppliers are already producing products to the European Union's standard, a move toward a global standard would reduce testing costs and the time needed to do multiple tests under different standards.

One commenter (No. 11) recommended that the CPSC retain the 300 ppm lead in the substrate standard and establish a voluntary leachable lead standard.

CPSC Staff Response 15:

The CPSIA does not allow the Commission to test for lead in children's products using a solubility standard; the lead content limits are based on the total lead content by weight for any part of the product. Moreover, the CPSIA section 101(a)(2)(C), requires that the lead content limit be reduced to 100 ppm, unless the Commission determines that such a limit is not technologically feasible for a product or product category.

Comment 16: Other Requirements

Two commenters (Nos. 16 and 20) referred to requirements that products meet a 40 ppm lead limit (*i.e.*, (1) a State of Illinois labeling law for certain products that exceed this level, and (2) a consent judgment in the State of California for Dollar Tree concerning children's ponchos) as evidence that the lead limit should be 100 ppm.

CPSC Staff Response 16:

The CPSIA currently requires that component parts of children's products in interstate commerce contain no more than 300 ppm lead content. Further, staff notes that one of these requirements does not limit lead content of products; it prescribes labeling for certain products. The other requirement is limited to one specific product. Neither of these two actions relate directly to the technological feasibility for products to meet the 100 ppm lead content limit.

Appendix 1: Identification of Commenters

Commenter Number	Public Docket ID	Commenter Name or Organization
	CPSC-2010-0080-0001	*Federal Register* notice
No. 1	CPSC-2010-0080-0002	Heinrich Ceramic Decal, Inc.
No. 2	CPSC-2010-0080-0003	Ricardo Ruiz (Parent)
No. 3	CPSC-2010-0080-0004	Eiichi Ogo (Unnamed Foreign Manufacturer)
No. 4	CPSC-2010-0080-0005	Promotional Products Association International
No. 5	CPSC-2010-0080-0006; Public Hearing Presentation; CPSC-2010-0080-0042	Thermo Fisher Scientific Inc.
No. 6	CPSC-2010-0080-0007	Kolcraft Enterprises, Inc.
No. 7	CPSC-2010-0080-0008	Kawasaki Motors Corp., USA
No. 8	CPSC-2010-0080-0009	CIATEC
No. 9	CPSC-2010-0080-0010; Written Comment to Public Hearing, see CPSC-2010-0080-0044	Handmade Toy Alliance
No. 10	CPSC-2010-0080-0011	Yamaha Motor Corporation, USA
No. 11	CPSC-2010-0080-0012	Hong Kong American Chamber of Commerce
No. 12	CPSC-2010-0080-0013	Toys “R” Us
No. 13	CPSC-2010-0080-0014; Public Hearing Presentation	Toy Industry Association
No. 14	CPSC-2010-0080-0015	Consumer Federation of America
No. 15	CPSC-2010-0080-0016;	Fashion Jewelry and Accessories Trade Association
No. 16	CPSC-2010-0080-0017	Kids in Danger
No. 17	CPSC-2010-0080-0018; Public Hearing Presentation	Consumers Union
No. 18	CPSC-2010-0080-0019; CPSC-2010-0080-0036; Public Hearing Presentation	Bicycle Product Suppliers Association
No. 19	CPSC-2010-0080-0020; Public Hearing Presentation	Juvenile Products Manufacturers Association
No. 20	CPSC-2010-0080-0021; CPSC-2010-0080-0022; CPSC-2010-0080-0024	Center for Environmental Health

No. 21	CPSC-2010-0080-0023; Public Hearing Presentation; CPSC-2010-0080-0038	Learning Resources, Inc.
No. 22	CPSC-2010-0080-0045	Retail Leaders Industry Association
No. 23	Written Comment to Public Hearing, see CPSC-2010-0080-0044	Tina (unknown affiliation)
No. 24	Written Comment to Public Hearing, see CPSC-2010-0080-0044	Office of Attorney General of Missouri
No. 25	CPSC-2010-0080-0026	American Iron and Steel Institute
No. 26	Public Hearing Presentation, CPSC-2010-0080-0039, and CPSC-2010-0080-0041	American Academy of Pediatrics
No. 27	Public Hearing Presentation; CPSC-2010-0080-0040	XOS
No. 28	Public Hearing Presentation	SGS North America, Inc.
No. 29	Public Hearing Presentation	Kleynimals.com
No. 30	Public Hearing Presentation	Milton Bush
No. 31	CPSC-2010-0080-0046	Whimsical Lo
No. 32	CPSC-2010-0080-0033	Katrina Burson
No. 33	CPSC-2010-0080-0034	Jim Reeves
No. 34	CPSC-2010-0080-0037	American Association of University Women

*The public comments may be found in docket CPSC-2010-0080 at: http://www.regulations.gov. The February 16, 2011 public hearing presentations are available at: http://www.cpsc.gov/library/foia/foia11/pubcom/lead100pres.pdf.