Staff Responses to Commissioners' Questions

July 8, 2011

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Commissioner Moore’s Questions

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

This document has been electronically approved and signed.

Memorandum

Date: July 8, 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 Williams, Toxicologist, Directorate for Health Sciences

SUBJECT : CPSC Staff Response to Commissioner Moore's Questions: Technological Feasibility of 100 Parts Per Million Total Lead Content Limit

Introduction

The following is staff's response to Commissioner Moore's questions received on July 1, 2011, regarding the 100 ppm lead technological feasibility staff briefing package. The questions all relate to comment No. 5 on page 40 of the staff briefing package.

Responses

1. *Do we know how much lead the decals contain before they are applied to the glassware?*

Response: No. The commenter did not provide data or a quantitative estimate of the lead content, and staff has not obtained samples for testing.

2. *The commenter states: "Any small amounts of lead that may be present are not free to be released from the substrate as they are vitrified in the firing process." Later the commenter states: "Products that are decorated with ceramic decals have very little potential for any lead release." Do these statements mean that the lead is not accessible to a child who touches it?*

Response: Staff interprets the commenter's statements to indicate that the lead is not accessible to a child who touches the product. Staff's experience with testing for potential exposure to lead, from handling glass or ceramic products containing lead, shows that small amounts of lead can be detected in wipes of products' surfaces.

3. *Have we not recalled glasses in the past that have etchings on them that contained lead? How do they differ from these products?*

Response: Yes, the CPSC has taken action, including product recalls, against glass and ceramic products that contained lead in surface decorations after the products were tested for potential exposure to the lead and evaluation of product showed that excess lead exposure could result from children's use of the product. Such actions were based on the authority of the Federal Hazardous Substances Act, after case-by-case testing and evaluation. Whether or not a similar product would also face such action by the Commission would depend on testing and evaluation.

4. *When does an accessible component that contains lead in excess of the lead limits cease to be a component and become part of a larger product such that the weight of the* <u>*product*</u> *is the relevant measure, as opposed to the weight of the component? Would welding accomplish that? Would cementing/gluing such that the product would have to be destroyed to separate the components do that?*

Response: A component, such as a surface decoration on a glass or ceramic item, may become bonded to the substrate through vitrification. Vitrification is the process using high heat and subsequent cooling that creates "glass" from the components of a decoration or glaze (*e.g.*, silicate compounds). This process establishes bonds within the applied decoration and also with the surface of the substrate of the product. When vitrification occurs, the component is considered to be part of the substrate of the product—as one whole part—for testing purposes.

Practically, whether a decoration has become part of the substrate may be determined by using a razor blade or other tool to assess whether it can be separated from the surface. If it can be separated from the surface, it is considered to be a separate component part (*i.e.*, a paint or similar surface coating) and would be tested for lead content separately from the other components of the products. Currently, the limit for lead in a paint or similar surface coating is 0.009 percent (equivalent to 90 ppm) by weight of the total nonvolatile content of the dried paint or the weight of the dried paint film. 16 CFR part1303.

Electroplating and certain inks that become bonded to the substrate are additional examples of materials that would not be considered to be paints or similar surface coatings, as defined in 16 CFR part 1303. These materials are also considered to become a part of the substrate of the product—as one whole part—for testing purposes.

Other types of bonds between component parts would be considered on a case-by-case basis, with some more susceptible to separation using tools in the laboratory. For example, a screwdriver could be used to separate parts that had been mechanically joined, or a solvent could be used to dissolve adhesive.

5. *Please explain the scientific and legal rationale that distinguishes this type of component from other components that contain excessive amounts of accessible lead but that would be prohibited under the CPSIA when the relevant statutory language relates to "total lead content by weight for any part of the product"?*

Response: The scientific rationale is based on the nature of the construction of the product and its components and the practical ability to separate and test each component. Certain processes, such as vitrification, alter materials in such a way that individual component parts are no longer distinguishable, except, for example, for differences in color. Also, the definitions for "paint and similar surface-coating materials," found in 16 CFR part 1303, expressly identifies ceramic glazing (vitrification) and electroplating as processes that cause the surface material to become part of the substrate. Staff has considered this as an indication that such a material is not to be treated as a surface coating of a product component, but rather, that the material and the surface to which it is applied are to be treated as a single part of the product.

Commissioner Nord's Questions

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

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Memorandum

Date: July 8, 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
William W. Zamula, Directorate for Economic Analysis
Deborah V. Aiken, Ph.D., Senior Staff Coordinator, Directorate for Economic Analysis
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences
Dominique Williams, Toxicologist, Directorate for Health Sciences

SUBJECT : CPSC Staff Response to Commissioner Nord's Questions: Technological Feasibility of 100 Parts Per Million Total Lead Content Limit

Introduction

The following is staff's response to Commissioner Nord's questions received on July 1, 2011, regarding the 100 ppm lead technological feasibility staff briefing package.

Responses

1. *Page 27 of the Staff Briefing Package states, "[t]he large number of diverse products affected by the lead limits makes it difficult to estimate aggregate costs associated with the lead content limitation." Additionally, on page 29 of the Staff Briefing Package it states, "on the basis of current information, it is not possible to quantify the aggregate economic impacts of imposing the 100 ppm lead content limit." What additional information would be needed to quantify the economic impacts? How would such information be obtained?*

Response: A detailed estimate of the aggregate economic impacts of the 100 ppm lead content limit would require, among other things, information on the number of manufacturers of children's products; information on the number and types of children's products they produce (*e.g.*, toys, clothing); an understanding of how the production processes will change for each of these products when the requirement for lead content changes from 300 ppm to 100 ppm; and the amount and costs of the types of low-lead inputs that would need to be substituted into these children's products. This type of detail is currently unavailable in existing sources of data. One way to get some of this information would be to conduct a national survey of manufacturers to find out how many produce children's products, how many and what types of children's products they produce, and how each of the manufacturers is addressing the 100 ppm lead content limit. Conducting such a survey, however, would be time-consuming and expensive. After the development of survey instrument, OMB review and clearance would be required. Under the best circumstances, the process would require more than a year for completion, and more likely, much more than a year.

While aggregate cost information would be very difficult to collect, such information could have been submitted in response to staff's notices and at the hearing held by the Commission, and to a limited extent, was provided in regard to certain products. The Bicycle Products Suppliers Association (whose products are made almost entirely out of metals, alloys, and plastic parts) estimated that achieving a 100 ppm lead content limit would raise their costs by about 25 percent. Additionally, Learning Resources, Inc., which produces educational products for children, expects that the 100 ppm lead content limit would increase their costs of production by about 10 percent to 20 percent. Both of these estimates should only be considered a rough approximation. However, as rough estimates, they do not seem unreasonable.

2. *Pages 6 of the Staff Briefing Package states, "[i]n 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 . ... 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." Does staff believe that the statute requires costs to be considered in determining whether a reduction in the permissible lead limit to 100 ppm for a product or product category is not technologically feasible? Did the recommendation that the Commission not find that the lead content limit of 100 ppm is not technologically feasible for a product or product category take into consideration cost information? If so, how? If not, why not? Is there any cost information that would lead staff to a different recommendation as to the technological feasibility of the 100 ppm lead limit? If so, describe this information.*

Response: Staff's analysis included cost information, to the extent that such information was available. Cost issues were raised by the comments and responded to by the staff at pages 45-46 of the staff briefing package. However, if the low-lead materials were available, but only at higher prices, staff assumed that it was still technologically feasible to produce the low-lead children's products. Staff made this assumption because there is no economic basis for determining at what point a cost increase would make production not technologically feasible. However, the Commission may decide to interpret the definition of "technological feasibility" differently than staff, and provide direction on how to consider the contribution of cost.

3. *Staff states in response to Comment 10 that "[b]ased on 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." Does the data referred to include the data submitted by Sanjeev Ghandi of SGS North America, Inc.? To what other specific datasets does the response refer? Does the statement at page 5 of the Briefing Package that "the datasets do not offer details about the materials or products tested" apply to the datasets upon which you base your 99% figure in the response to Comment 10? If so, explain the basis for staff's use of that data as representative of the current market for children's products?*

Response: The data referred to includes all of the data submitted by the public, including the data provided by Mr. Gandhi. Other data included the set of results submitted by the Hong Kong American Chamber of Commerce of more than 13,000 tests of metallic parts used in the toy industry; screening testing of more than 2,000 items by the Center for Environmental Health; and product testing by the State of Missouri. In addition, one commenter, representing an accredited third party laboratory in Mexico, concluded from analysis of the results of testing products from more than 150 manufacturers of footwear and footwear materials, that the 100 ppm level is technologically feasible (although the data itself was not submitted with the comment).

Toys R Us/Babies R Us submitted data to demonstrate lead content measurements greater than 100 ppm; the dataset also showed many products and components that had lead content less than 100 ppm. The Bicycle Products Suppliers Association provided screening data using an x-ray fluorescence instrument for component parts of a single bicycle, which showed that most parts would conform to a 100 ppm limit.

The largest datasets from SGS North America and the Hong Kong American Chamber of Commerce identify the products as toys, and indicated the general material (*i.e.*, metal, plastics, glass), but did not specifically identify the material or the product.

Staff did not assume that any of the submitted data was statistically representative of the children's product market. Staff considered that it was information about a relatively large number of lead content measurements for a variety of children's products and component parts of children's products manufactured in several different countries and sold, or held potentially for sale, in the United States. Staff believes that many common types of products, as well as a variety of materials and component parts of products, are represented in the data.

4. *In response to Comment 11, staff states "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." What if anything did staff do to obtain the more specific data necessary, on a product basis or otherwise, to determine whether or not an alternative that meets the lead limit is commercially available?*

Response: Staff analyzed all of the information submitted by public commenters, researched general categories of materials, such as metals and metal alloys, as well as some specific products, and contacted manufacturers and suppliers of certain materials. There are thousands of children's products currently on the market, each with its own purpose, characteristics, and functionality. Public commenters, representing broad industry sectors, such as juvenile products, or more specific products, such as bicycles, largely made general remarks concerning the ability or inability of manufacturers to produce products to the 100 ppm limit. In particular, commenters generally identified some materials that sometimes contain lead, but they did not identify specific components or products for which the only available or useful components necessarily contain lead in excess of the 100 ppm limit. With respect to metals and metal alloys, staff generally assessed whether materials containing less than 100 ppm are available that could substitute for lead-containing materials. That assessment concluded that for metals and metal alloys, substitutes exist for metals with intentionally added lead and for metals whose trace amounts of lead may exceed 100 ppm.

Commissioner Northup's Questions

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

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Memorandum

Date: July 8, 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 Williams, Toxicologist, Directorate for Health Sciences
William W. Zamula, Directorate for Economic Analysis
Deborah V. Aiken, Ph.D., Senior Staff Coordinator, Directorate for Economic Analysis
Thomas Caton, Directorate for Engineering Sciences
Randy Butturini, Office of Hazard Identification and Reduction

SUBJECT : CPSC Staff's Response to Commissioner Northup's Questions: Technological Feasibility of 100 Parts Per Million Total Lead Content Limit

Introduction

The following is staff's response to Commissioner Northup's questions received on June 30, 2011, regarding the 100 ppm lead technological feasible staff briefing package. The responses are separated into two groups, based upon whether the questions were directed to Randy Butturini and Thomas Caton, or posed to William Zamula and Deborah Aiken.

Responses to Questions for Randy Butturini and Thomas Caton

1. *Pages 14–15 of your memorandum explains that you considered a low lead substitute alloy to be commercially available if, among other reasons, the substitute alloy uses another element that is sufficiently available to "meet production demand."* ***Upon what did you base your estimate of the scope of "production demand"? Was it based on current demand, or was it based on a projection of potential future demand after a reduction in the lawful lead limit to 100 ppm? If it is the latter, what was the basis for your estimate of potential future demand?***

Response: Staff did not make an estimate of the demand for metals with intentionally added lead (*i.e.*, machine steels, free machining aluminum, and some brasses). The research into substituting other elements for lead in machine steels and free machining aluminum included both commonly available elements, such as tin or sulfur, and elements that are currently not being produced in as large a quantity, such as bismuth and indium. If bismuth or indium were the only materials that could be substituted for lead in leaded metals, then their current low volume of production would be a legitimate concern regarding the availability of substitute metals for leaded metals used in children's products. However, other, widely available materials demonstrated acceptable performance as lead substitutes for machine steels and free machining aluminum. Thus, the statement highlighted a potential, but unlikely circumstance, regarding the substitution of lead in leaded metals used for accessible parts of children's products.

Staff notes that the amount of lead in machine steels, free machining aluminum, and leaded brasses is typically in the thousands of parts per million. Therefore, this potential situation exists with either the 300 or 100 ppm limit on lead content in children's products. Currently, accessible component parts of children's products with lead content exceeding 300 ppm are treated as banned hazardous substances.

2. *At page 15 of your memorandum, you explain that CPSC staff interpreted the phrase "technology to comply with the limit being commercially available" to mean that "noncommercialized processes . . . have been developed."* ***Please explain the reasoning that supports interpreting "commercially available" to mean a "noncommercialized process."***

Response: In this context, a noncommercialized process is a process that has been demonstrated in the laboratory or in small-scale commercial production but has not yet been implemented on an industrial production scale. The second of the four factors defining technological feasibility refers to technology being commercially available. A noncommercialized process consists of technology that has been developed and is available for implementation as further explained on page 5 of the staff briefing package which states that "there are no obvious impediments to the production of that substitute material."

3. *Pages 16–18 of your memorandum state that various metals such as steel, zinc, copper alloys/brass, aluminum, and "some metal alloys" are available with a guaranteed lead content below the proposed 100ppm from several sources.* ***Please explain the extent to which accredited labs have verified any of the claims reported by these suppliers.***

Response: Our research into the availability of metals and metal alloys with less than 100 ppm lead did not include inquiries into whether the metals manufacturers used third party testing laboratories accredited to ISO/IEC 17025:2005 or any other standard. Our information indicated that the metals manufacturers used first party production testing in manufacturing metals to meet a customer specification of less than 100 ppm lead. However, independently, the accredited lab SGS did provide data on 13,000 tests of metallic parts used in the toy industry which suggests that the products that passed those tests were able to find compliant metals.

4. ***Please explain again your position regarding the relationship between the price differential of 300 ppm and 100 ppm of a metal and the "market flux" for the metal. Please also explain how that point comports with the statements at pages 16 and 17 of your memorandum that in moving from 300 ppm to 100 ppm there would be quantifiable price increases for at least Zinc and Copper Alloys****.*

Response: We did not investigate the price differential between metals with 300 ppm and 100 ppm. In researching the availability of a common brass alloy with the extra requirement of less than 100 ppm lead, we obtained a price quote. When we compared that quote to the advertised prices of the same brass alloy—with no extra requirement for less than 100 ppm lead (the nominal specification is less than 500 ppm lead)—different vendors had widely varying prices. Frequently, the quoted price for low-lead material was lower than the advertised prices for the similar material without any extra requirements on a per-cubic-inch price.

Over the last year, prices for copper on the London Metal Exchange were shown to vary between around $6,000 per metric ton to nearly $10,000 per metric ton. Steel prices over the same period varied from less than $300 per metric ton to nearly $600 per metric ton. Thus, the volatility of metal prices makes comparisons more difficult. (Note: a metric ton, also called a tonne, is 1000 Kg, or 2,200 lbs.)

The production of metals guaranteed to meet the 100 ppm requirement will require more effort (*e.g.*, testing, materials sourcing, paperwork) and may require that less expensive recycled materials are reduced, as a percentage of the melt, or not used at all. All of these factors will tend to increase the price for metals meeting the requirement. For some metals, the price increases could be small enough to be masked by the natural price volatility.

5. *At page 17 of your memorandum, you state that zinc meeting the 100 ppm limit can be purchased for a 3% premium over zinc that does not.* ***Is that price quote dependent on a minimum order amount, or subject to change based on the amount of low lead zinc ordered?***

Response: The three percent premium stated in the memorandum was for an Internet-advertised price of one grade of zinc (special high grade, or SHG), with a specified lead content of less than 30 ppm, compared to high grade, or HG zinc with a specified lead content of less than 300 ppm. The price quote depended upon a standard minimum order size. Special high-grade zinc appears to be widely available from numerous sources.

6. *Randy also stated during his testimony that there appeared to be multiple manufacturers of "most popular materials" and that he identified no limits in the amount available at 100 ppm.* ***Was any consideration given to the impact on availability of a rule requiring all children's products manufacturers to meet a 100 ppm lead limit? If so, what was done to determine that impact?***

Response: Lead is not a natural constituent of the ores of aluminum and steel, and few alloys of those metals have lead intentionally added for a functional purpose. When added, the lead is in concentrations of thousands of ppm. Aluminum alloys typically have no lead in them, so the impact on availability is expected to be none. Many steels have no lead listed (not even as "other") in their chemical composition. A major steel manufacturer stated that it is routine for customers to add extra specifications to a standard type of steel. The impact on the availability of steels at 100 ppm is expected to be similar to, if not identical to, the impact of the availability of steels at 300 ppm.

Copper alloys (mostly brass alloys with zinc) in which lead was not intentionally added, typically specify maximum lead concentrations of 500, 700, or 1,500 ppm. The prevalence of leaded brasses in the recycling pool means that extra care must be taken to produce copper alloys with less than 300 ppm or 100 ppm lead. Similar to steels, the impact on the availability of copper alloys at 100 ppm is expected to be similar to, if not identical to, the impact of the availability of the alloys at 300 ppm because the same care and testing is needed to produce alloys at both limits.

Again, the intentional use of lead in metals and other materials for functional purposes results in lead content in the thousands of parts per million. Therefore, currently, such materials may not be used to make children's products, if the component part is accessible to a child.

7. ***Are there materials that are not "popular" within your meaning of the term, but that are used in children's products? If so, state what they are and describe what you or other staff members have learned regarding the extent of their current and potential future availability at 100 ppm of lead.***

Response: Other metals that are found in some children's products include stainless steel and titanium. Both of these materials have been determined by the Commission not to contain lead in concentrations exceeding 100 ppm, and are excluded from lead testing (16 CFR § 1500.91).

Among other metal materials, it is possible that gold, silver, tin, or iron might be used in children's products. In the case of tin, the lead content generally exceeds 300 ppm and is, therefore, currently not appropriate for use in manufacturing accessible component parts for children's products. Iron (*e.g.*, cast iron), while not expected to be used in a significant number of children's products, generally has a maximum limit of 0.003 percent lead (30 ppm).

8. *At pages 17–18 of your memorandum, you recount a telephone conversation with a brass alloy producer who stated that he could produce brass alloys with less than 100 ppm lead.* ***Please provide any information you obtained from him or any other source concerning the market price (taking into account, if a factor in the price, the volume purchased) for that low lead brass alloy, how that cost compares to brass alloys meeting the current 300 ppm lead limit, and whether there would be a sufficient supply of 100 ppm lead brass to meet the volume of 300 ppm lead brass currently used in children's products.***

Response: The brass manufacturer contacted by phone declined to provide a price for the brass his company was making with less than 100 ppm lead. The price quote staff received from a metals supplier by e-mail for C260 brass with less than 100 ppm lead was $207/sheet for 1,000 sheets at 0.25 in. x 12 in. x 36 in. Our research into the availability of brasses with less than 100 ppm lead did not include price comparisons for the same material with less than 300 ppm lead. Our research indicates that there appear to be multiple metals manufacturers capable of making products with less than 100 ppm lead using current technology.

The technological or natural resource constraints on the world's ability to produce low lead metals should be similar to the constraints on their higher lead counterparts. If capacity constraints exist, these would tend to be in the short term, as an increase in demand for low lead metals will tend to increase prices, which will serve as a signal to producers to increase capacity and production.

9. *At page 18 of your memorandum, you state that Kobe Steel Group manufactures aluminum with additives such as bismuth and indium, in place of lead.* ***Is the CPSC aware of any data concerning whether bismuth, indium, or any other materials used as a substitute for lead in aluminum are harmful to children?***

Response: To date, staff has not identified children's products with aluminum components containing lead, or bismuth, indium, or other substitutes for lead, to which children would be expected to have significant exposure to the component.

As with any chemical substance, the toxicity of bismuth, indium, or their compounds is dependent on the chemical form of the substance, the route of exposure, and the dose or level of exposure. The extent of use of bismuth or indium in children's products, or the possible applications of bismuth or indium in children's products, is unknown. Some bismuth and indium compounds (such as bismuth subsalicylate) have pharmaceutical, cosmetic, dental, or medical applications, for which some exposure to the chemicals is expected and is tolerated well. However, at this time, staff cannot evaluate whether bismuth, indium, or other materials are used in aluminum parts of children's products, or whether such uses are potentially harmful.

10. *At page 19 of your memorandum, you suggest that the problem of large minimum order requirements could be overcome through pooling arrangements among smaller businesses or long-term contracts.* ***Do you have any information concerning whether suppliers would be willing to enter into either type of agreement?***

Response: No, we did not investigate whether metals suppliers would be willing to enter into the agreements mentioned above. Small manufacturers, relative to large manufacturers, have always been disadvantaged on materials procurement. The techniques small manufacturers use to overcome access to limited component parts (such as a new integrated circuit with limited initial production), might be applicable to metals with less than 100 ppm lead. We note that we have not seen any evidence of materials shortages with lead content of less than 300 ppm since that requirement went into effect.

11. *At page 19, you posit circumstances where a manufacturer may need to "investigate the use of alternative methods to avoid the use of leaded materials," including materials substitution, redesign, or other techniques.* ***Did you seek or obtain any information from which a conclusion could be reached as to the likelihood that those methods would be effective for any product or class of products? If so, please describe the information you obtained. If not, why not?***

Response: With the variety of children's products produced, and the number of alternatives to the use of metals with greater than 100 ppm lead, it is unlikely that a conclusion can be reached regarding the likelihood that every children's product needing to address lead in metals can make use of an alternative. Instead, our limited research determined that:

- For metals into which lead has not been added intentionally for a functional purpose, there appear to be multiple suppliers who can produce the same metals with less than 100 ppm lead. There appears to be no technological barrier to their production. It is possible that, for any given children's product, a different metal (such as aluminum substituting for brass, or one type of low-lead steel substituting for another steel with an allowable concentration above 100 ppm) could be used.

- For many applications where lead serves a functional purpose in a metal, those metals greatly exceed the current 300 ppm limit, and alternative metals without lead in concentrations greater than 100 ppm, currently exist that can be substituted for the leaded metals.
- Depending on the children's product, other methods, such as rendering the accessible metals with greater than 100 ppm lead inaccessible, or replacing the metal component part with a nonmetal component part, may be attempted. These methods necessarily depend upon the individual children's product under consideration. What may be effective and economical for one children's product may not be the case for another children's product.

12. ***In testing materials to determine if they meet a 100 ppm lead limit, what are the sources of testing variability (i.e., laboratory error, technician variation, materials variation, sample variation) and the percentages of variability that they cause. Taking all of the sources of variability into account, what is the total percentage variability that can be expected? Given that total, how many ppm of lead would a product or material need to contain in order to assure consistent and reliable testing at 100 ppm or below? If your answers to the above questions depend on the particular product or material at issue, please provide answers for each product or material for which you have responsive information.***

Response: Lead in steel is found as microscopic elemental lead clustered at the boundaries of steel crystals. Subsequent metals processing (*e.g.*, rolling, milling, forming) may "smear" the lead at the surface of the metal without changing the total lead content. Care must be taken to avoid sampling a nonhomogeneous section of the metal and overestimating or underestimating the lead content. CPSC test methods state that the laboratory shall make every effort to ensure that the sample removed from a component part of a product for testing is representative of the component and is free of contamination.

Further, product testing strategies can account for material variability or heterogeneity. For example, analysts may obtain a larger sample of the material to be tested by grinding or milling a component, which would tend to result in a homogeneous sample representative of the item. Analysts may also test multiple samples 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.

In general, random variability in testing is expected to be within about 10 percent of the nominal lead content value. Interlaboratory error may result in an additional five percent variability. These variations come, in general, from weighing, measuring volumes, and diluting samples; from variations in pumping rates on Inductively Coupled Plasma Spectrometers; from instrumental fluctuations in response to temperature and humidity variations, and so forth. The use of known concentration quality control samples and standard reference materials helps laboratories identify and minimize variations and ensure that experiments are within normal variations. While material variability (nonhomogeneity) may exist, staff does not know of any source of information that describes quantitatively the variability, generally or specifically, for any particular material or product. A manufacturer's experience with the materials it uses and the vendors that supply its materials is likely to be the best information for that manufacturer to determine the steps required to ensure conformance with a 100 ppm limit.

For example, consider a manufacturer that has purchased a material from a particular supplier. Certificates of analysis and third party testing showed that the last 20 batches of the material contained 20±10 ppm lead. For this example, even assuming 15 percent or more testing variation, the manufacturer would have a high degree of assurance of compliance with a 100 ppm limit.

In another case in which the procured product contains lead at a higher concentration or with more shipment-to-shipment variability, the manufacturer may need to search for another supplier or conduct more quality assurance testing prior to accepting shipments to obtain a high degree of assurance of meeting a limit of 100 ppm.

13. ***Did you undertake to ascertain the availability of materials guaranteed to be at 85 ppm? What about at 90 ppm? What about at any other level below 100 ppm? If so, what did you learn? If not, why not?***

Response: No, we did not try to ascertain the availability of materials at concentrations below 100 ppm. For the market for metals without lead intentionally added, the actual lead content is typically far below the highest level allowed. The upper limit is a guaranteed specification. Occasionally, one would expect the lead concentration to approach the upper limit.

We did not attempt to ascertain the availability of materials at limits below 100 ppm because our task was to ascertain whether a limit of 100 ppm for component parts of children's products was technologically feasible.

14. *I understand that one method of reducing the risk that testing multiple areas of a single sample will yield materially different results, is to change the metals processing (e.g., rolling, forging, casting, milling), to achieve a higher degree of homogeneity of any lead contained in the alloy.* ***Did you seek or obtain any information concerning the cost differentials between processing techniques more likely and less likely to achieve the required degree of homogeneity? If so, please describe the information you obtained. If not, why not?***

Response: Material homogeneity in a component part is not a requirement of section 101 of the CPSIA. Thus, there is no need to examine means to increase a component part's homogeneity. Standard methods for determining the lead content of a component part include measures to minimize the effects of any material nonhomogeneity in the sample selected for analysis. Notwithstanding the possibility of nonhomogeneity on a small scale, such as microscopically at the boundaries of steel crystals, each component part, as a whole, still would need to conform to lead content requirements either at the 300 ppm or 100 ppm limits.

15. *You conclude at page 20 that the third alternative for establishing technological feasibility is established by the facts that "research continues, and patents have been issued to address removing lead from metal alloys." But the third alternative states that "industrial strategies or devices" must now be capable or "will be capable of achieving such a limit by the effective date of the limit." And you interpreted that at page 15 to mean "actions taken or planned by metals manufacturers to develop industrial capacity to create lower lead substitute materials."* ***Does the existence of a patent for a process necessarily mean that the strategy or device will be capable of achieving the lower limit, or that the industrial capacity to do so will be available, by mid-August of this year? If not, please explain what evidence supports your conclusion that the third alternative is satisfied.***

Response: The existence of a patent for a process does not necessarily mean that the process to which the patent refers has been implemented.[1] The existence of a patent is more indicative of the second of the four factors listed for technological feasibility in section 101 of the CPSIA:

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

Namely, technology to comply is commercially available to manufacturers.

Our conclusion that the third factor, which is:

- 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;

is satisfied, is based on our research indicating that commercial manufacturers have already developed strategies or devices that can produce metals with less than 100 ppm lead. Aluminum alloys currently conform to a 100 ppm limit. Steel and copper alloy manufacturers, using current technology and techniques, are producing those metals for their customers who specify a lead content of less than 100 ppm.

16. ***Please point to the specific language contained in 75 FR 43942, 76 FR 4641, and/or 76 FR 12944 from which you believe a reader should have concluded that the CPSC sought information concerning the costs associated with meeting the lower lead limit.***

Response: In the notice announcing the public hearing (76 FR 4641 (January 26, 2011)), the Commission sought additional information on specific issues. Two questions were worded broadly to invite public input on the terms "commercially available" and "otherwise available within the common meaning of the term." Specifically, with respect to products or product categories that already comply with the 100 ppm, and the extent to which such product(s) or product categories are commercially available in the United States, question (1)(d) asked:

> What factors or considerations should we evaluate in deciding whether a product complying with the limit is "commercially available?"

[1] We interpret the question's reference to a "patent for a process" to mean a patent pertaining to a method of manufacturing a product. Generally speaking, one cannot obtain a patent for an abstract idea (so a strategy might not be patentable). This also should be distinguished from a patent for a product. To illustrate the distinction, there may be several ways to make a widget, and the process for making the widget may be patentable. A patent for the product—the widget itself—could exist.

With respect to technologies that would enable manufacturers to comply with the 100 ppm limit, question (2)(b) asked:

> Section 101(d)(2) of the CPSIA states that the technology to comply with the limit is “commercially available to manufacturers or is otherwise available within the common meaning of the term.” What factors or considerations should we evaluate in deciding whether a technology is “commercially available” or “otherwise available within the common meaning of the term?” See 76 FR at 4642.

Although these questions did not focus on “costs associated with meeting the lower lead limit,” they did invite the public to comment on *any* factor or consideration that the public thought we should consider in interpreting “commercially available” and “otherwise available within the common meaning of the term.”

In response to the notices, many commenters provided market and economic information because some of them indicated that the term “commercial availability” may be construed to include such factors. Further, some commenters addressed the concept of “feasibility” in economic terms.

Responses to Questions for William Zamula and Deborah Aiken

1. *You state at page 24 that commenters provided information on products that already achieved compliance with the 100ppm limit, but did not provide information regarding whether product modifications were necessary, the cost of finding substitute materials, or the costs of redesigning products to meet the standard.* ***Did we follow up with any of them to try and obtain this information? If so what did we find out? If not, why not?***

Response: We did not follow up with these commenters about whether they were required to modify their products that already comply with the 100 ppm lead content limit to achieve that limit. Most of the comments were general and did not provide specific company or detailed product information. We focused our analysis on situations where compliance may be more difficult or costly. If a company's products already meet the 100 ppm lead limit, the marginal costs associated with the standard, if any, should be small.

2. *You state at page 24 that it should not be "too difficult" to achieve 100 ppm for plastic, as long as virgin plastic is used. You also state that virgin plastic costs 50-100% more than recycled plastic, that no data was presented on the lead levels in recycled plastic, and that it is not known how much recycled plastic in the market does not meet 100 ppm.* ***Do you have a basis, under these circumstances, to estimate the economic impact of requiring all plastic used in children's toys to have no more than 100 ppm of lead? If so, what is that basis and what is your conclusion? If not, are you aware of any effort that was made to obtain this data?***

Response: As described in our analysis, <u>if</u> manufacturers need to use virgin plastics to meet the 100 ppm lead content limit, as opposed to the recycled products they may already use, their production costs will rise. The extent of the cost increase associated with substituting virgin plastic for recycled plastic will depend upon the amount of virgin plastic used, as well as the proportion of the cost of plastic in the total cost of production. If, for example, plastic constitutes a minor input into the production of a children's product, the increased plastic cost, per product produced, may be small. Alternatively, if an entire product is made out of plastic, the relative cost increase will be more significant.

However, we cannot estimate the aggregate economic impact of requiring all plastic used in children's products to have no more than 100 ppm lead. To do so would require that we know how many children's products are produced, how much plastic is used in each products, and whether and how much virgin plastic would be needed to substitute for the recycled plastics. Such data is not available.

3. *Page 25 states that a U.S. steel manufacturer reported that steel guaranteed to be below 100 ppm is "substantially more expensive" than general use steel, but that the manufacturer did not more precisely define the phrase in the comment.* ***Was any effort made to determine the price differential? If so, what was learned? If no effort was made, why not?***

Response: We did attempt to follow up with this manufacturer to obtain this price differential information, but we were unable to obtain it. However, the primary goal of our analysis was to describe, in general terms, the likely impact of the 100 ppm lead content limit on the costs of producing children's products. In the case of steel, we showed that the 100 ppm content limit, in fact, will tend to increase the costs of producing children's products that contain steel. This was unclear from some of the comments the Commission received, which seemed to suggest that "all" lead would evaporate from the metal in the steelmaking process. Our discussion indicates that trace levels of lead in excess of 100 ppm may remain, even though lead tends to evaporate in the steelmaking process. Thus, if manufacturers of children's products require their steel suppliers to guarantee that the steel they provide has a content of less than 100 ppm lead, that requirement will, in fact, tend to increase the costs of steel components

4. *You state at page 25 that a manufacturer reported that getting brass below 100 ppm requires a higher proportion of virgin brass and a 5% to 10% rework of brass that fails. You also state that the manufacturer did not provide any cost estimate, but that "it is probable that brass with a lead level below 100ppm will cost manufacturers at least 10 percent more than other brass alloys."* ***How did you arrive at the 10 percent figure? If 10% is the least, what is the range?***

Response: The 10 percent figure was an estimate based on the increased use of virgin brass in conjunction with the 5 to 10 percent rework estimate provided by a manufacturer. It was meant to serve as an estimate of the minimum cost impact. It is not possible to predict an upper boundary or a range, given available information.

5. *According to footnote 16 of your memo, "much of the information CPSC has been able to compile on materials complying with the 100ppm lead requirements is from U.S. sources," which "may not be informative on the Asian market."* ***Given that a large % of toys are made in China, of what value is the US data, and to what extent may the absence of Chinese data make our analysis of the costs inaccurate? Did we try to get data on the Asian market? If so, what data did we obtain? If not, why not?***

Response: The manufacturing processes for materials used in the production of children's products (such as metals and plastics) in the Asian market are similar to the processes in the United States. However, because the cost of inputs may vary from those in the U.S. market (*i.e*., the costs of labor, raw materials) the price premium for low-lead materials may also vary from the price premium in the U.S. market. This footnote simply highlights this point. Staff did not directly contact any Asian manufacturers who might produce low-lead materials. However, staff did contact U.S. manufacturers with Asian operations and made use of readily available information from Asian manufacturers, including information indicating that Chinese manufacturers are developing low-lead zinc alloys for use in children's jewelry.

6. *You state at page 26 of your memorandum that 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.* ***How does this fact impact on the analysis of what is "commercially available"? Do you consider a material to be "commercially available" if it is available only to large manufacturers?***

Response: While the evidence indicates that low-lead materials appear to be generally available in the marketplace, and hence meets Staff's definition of commercial availability, it is possible that some manufacturers may not be able to obtain the materials due to the lack of available distribution channels. For example, it is possible that microbusinesses might be too small to purchase low-lead plastic or metal parts from manufacturers or wholesalers directly, but will typically purchase them from retail outlets. However, these retail outlets are not required to provide materials that have been certified as low-lead compliant. Additionally, some small manufacturers of children's products, in contrast to large manufacturers, may be at a cost disadvantage and have to pay a premium to obtain small quantities of low-lead materials that might cost less if purchased in larger quantities. (Of course, this may be true generally; small manufacturers may also have to pay a premium for non-low-lead materials because of the smaller quantities they purchase.)

7. *You state at page 27 that manufacturers reported that complying with a 100 ppm lead standard will involve "additional costs", including: more expensive materials (like virgin steel or plastic); and, the costs of redesigning or reengineering the product to make use of new materials (as when substituting plastic for metal). You also state that most of the comments addressing these costs described the "types" of costs, but did not provide "quantitative cost information." You further state that in other cases, cost increases were provided in percentages for a component, without specifying the contribution of the component to the overall cost of manufacturing the product.* ***Did anyone follow up with any of these manufacturers to try to obtain quantitative cost information or to understand how percentage increases in the costs of particular components impacted the overall cost of manufacturing a product? If so, what additional information did they provide? If not, why not?***

Response: The primary purpose of our economic analysis was to summarize the public comments received by the Commission and to describe, to the extent possible, the economic effects of the 100 ppm lead content limit. Given time constraints, and the fact that manufacturers are not always forthcoming with cost information, we did not follow up with these manufacturers to try to obtain quantitative cost information or to determine specifically how the percentage increases in the costs of particular components might impact the overall cost of manufacturing children's products. However, with the millions of children's products produced every year and the numerous components that each product potentially may contain, such an effort (which might have provided information on a small number of products or components) would have provided little additional information supporting our general conclusion that the 100 ppm lead content limit will increase the costs of producing children's products, and that in some cases, these cost increases will be significant.

8. *You state at page 27 of your memorandum that when the lead limit went from 600 ppm to 300 ppm, 10 out of 40 manufacturers stopped producing youth bicycles. You further observe that a commenter predicted that the remaining small manufacturers would stop producing youth bicycles if the standard goes to 100 ppm. While you state that may be an extreme prediction, you also acknowledge a likely further contraction in the market.* ***Does the analysis of whether reducing the lead limit to 100 ppm is "technologically feasible" for a product or product category take into account the number or percentage of manufacturers of a product or product category that will stop producing the product if the lead limit is reduced to 100 ppm? If so, explain the impact of that factor on the analysis. If not, explain why it is not relevant.***

Response: The economic analysis assumes that if low-lead materials are available and are being used currently, then it is technologically feasible to produce children's products with these low-lead materials, even though the low-lead materials are more costly and, in some cases, may make the production process somewhat more difficult. This does not mean that no manufacturers will choose to exit the market. If low-lead materials are available, but only at a higher cost, the costs of production will rise. Increased production costs will result in increased prices for children's products (if the costs can be pushed forward to consumers) or a reduction in manufacturer's profits (if the costs cannot be pushed forward). Either possibility (*i.e*., an increase in the retail price of a children's product that will lead to a reduction in the quantity of the products demanded by consumers, or a reduction in a firm's expected profits) can result in manufacturers exiting the market for these children's products. In some cases, it is possible that a large proportion of firms might exit the market or market segment. In the case of bicycles, for example, some manufacturers might decide that the expected profits from the production of children's models, with the added constraint of the lead limits, are simply too small to justify continued production.

Consequently, while producing the more costly products with low-lead materials may be "technologically feasible," such production may not always be "economically feasible." That is, a determination of technological feasibility does not necessarily mean that manufacturers will remain in the market.

9. *At page 28, you appear to cite the availability of adult versions of products as a potential substitute for the children's versions that will no longer be made after the lead limit is dropped (small "general use" ATVs).* ***Is the potential availability of such substitute "general use" products considered a relevant factor in determining whether it is technologically feasible to reduce the lead limit for any children's product? If not, what is the relevance of the point?***

Response: The availability of substitute adult versions of a product is not a relevant factor in determining whether it is technologically feasible to produce a low-lead version of the children's product. We used this example only to describe the possible market impact of the 100 ppm lead content limit on the production of children's products when close, general-use adult substitutes are available. In such cases, and when there has been a relative increase of the price of a children's product due to the increased stringency of the lead limit, there is a likelihood that some parents will substitute a relatively less expensive adult version of the product.

10. *Page 28 of the memo recounts that "relatively little information was provided on compliance costs for toys and juvenile products."* ***Did we affirmatively seek additional information regarding the compliance costs for those products? If so, what additional information did we learn? If not, why not?***

Response: We did not seek additional information regarding the compliance costs for specific toys and juvenile products. As noted earlier, the primary goal of our analysis was to summarize the public comments received by the Commission, and to the extent possible, describe the general economic effects of the 100 ppm lead content limit. Moreover, given the millions of children's products sold every year, contacting a few manufacturers about their products would have provided little additional information supporting our general conclusion that the 100 ppm lead content limit will tend to increase the costs of producing children's products and that, in some cases, the cost increases may be substantial.

11. *In a summary of the potential economic impacts at page 29, the memorandum states that "[o]n 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.” ***Why is “current information” limited in that way? Other than considering solicited comments and hearing testimony, did staff proactively seek evidence that would allow us to make a more informed decision? If not, why not?***

Response: A detailed estimate of the aggregate economic impact of the 100 ppm lead content limit would require, among other things, information on the number of children’s products produced; a detailed understanding of how the production processes will change for each of these products; and the amount and costs of low-lead inputs that would need to be substituted into these children’s products. This type of detail currently is unavailable in existing sources of data. One way to obtain some of this information would be to conduct a national (or quite possibly international) survey of manufacturers to find out how many produce children’s products; how many and what types of children's products they produce; and how each of the manufacturers is addressing the 100 ppm lead content limit. Conducting such a survey, however, would be time-consuming and expensive, and it would not necessarily provide all the desired information.

12. ***Please state the price differential between aluminum with 100 ppm lead and aluminum with 300 ppm lead. If you do not have this information, please state whether you sought to obtain it, and if not, why not?***

Response: A price premium for aluminum guaranteed to have less than 100 ppm of lead content was not determined. As reported in our analysis, an aluminum manufacturer to ES staff that low-lead aluminum under 100 ppm is available. However, a representative of a testing lab for bicycles was unable to obtain a price quote for low-lead aluminum.

Aluminum is one of a number of metals and alloys that may be used in the production of children’s products. As with the other metals that we discussed, it is possible that an added constraint on the production process—that the aluminum contain less than 100 ppm of lead—would tend to increase the cost that manufacturers of children’s products must pay to obtain it.

13. ***Does your understanding of a product’s commercial availability take into account the extent to which there are businesses willing to manufacture and sell the product? Is there a point at which the reduction in the available quantity of a product renders the product not commercially available? If so, what is that point? Did you undertake to determine for any product or products the degree to which total production would likely be reduced if the lead limit went to 100 ppm? If so, please explain what you learned. If not, why not?***

Response: Our understanding of commercial availability, in general, would take into account the extent to which manufacturers of low-lead materials are willing to manufacture and sell the product. Consequently, there would be a point at which a reduction in available quantity would render a product not commercially available. However, we have not been provided any information to suggest that the technical processes needed to make low-lead materials are particularly difficult; rather, our information suggests only that the processes simply are more expensive.

You also ask whether we determined for every product or products, the degree to which total production would likely be reduced if the lead content limit went to 100 ppm. It is not clear from the question whether you are asking about the low-lead materials that would be used to produce the children’s products, or referring to the children's products themselves. In the case of low-lead materials, the effect of the 100 ppm requirement would be to increase demand, resulting in higher prices and an increase in the quantity supplied (*i.e*., the quantity produced). For children's products themselves, the effect of the 100 ppm requirement would be to increase the costs of production and reduce supply (*i.e*., in a simple supply-demand diagram, the higher costs of production would be represented as a shift in the supply curve to the left), thereby resulting in a reduction in the quantity demanded by consumers. In summary, even though we expect the production of children's products to decrease due to the increased costs of production, we expect the production of low-lead inputs to increase due to an increase in demand. This is intuitive because, by regulation, low-lead inputs must be substituted for higher lead inputs. Consequently, we do not anticipate that the 100 ppm limit will render any low lead input commercially unavailable.

14. ***In determining whether materials substitution would allow a "product or product category" to meet the 100 ppm lead limit, did you consider whether, for any product or products, there is a point at which the degree and/or nature of substitution of materials changes the product into a different product or product category? If so, please explain your reasoning, generally, and with respect to any particular product for which you considered the question.***

Response: No. We did not consider whether, for any product or groups of products, there was a point at which the degree or nature of the substitution of materials would change the product into a different product. It is not clear how such a determination could be made. Additionally, such cases (if they exist) would probably be rare. We assume that if low-lead materials are available, then it is technologically feasible for low-lead children's products to be produced, although these products likely would be produced at higher costs.

15. *The Briefing Package at pages 8–9 identifies each of the following as "economic impacts that are likely to occur": the need to use more expensive low-lead materials rather than the nonconforming materials used today; the costs associated with reengineering products to make use of new materials; the costs of making leaded components inaccessible; increased testing costs; increased consumer prices; reductions in the types and quantity of children's products available to consumers; businesses exiting the children's product market; manufacturers going out of business; reduction in the utility of products due to the substitution of materials; reduction in the durability of products due to the substitution of materials; and, the loss of the value of all inventory not satisfying the new standard.* ***Did staff consider these economic impacts, either separately or together, in its determination whether it is not technologically feasible to reduce any particular product or product category to 100 ppm of lead? If so, please explain staff's reasoning with respect to each such product and product category. Did staff ever formulate a position as to what quantity and/or quality of evidence of these economic impacts would warrant a finding that the reduction to 100 ppm of lead for any product or product category would not be technologically feasible? If so, please describe that position? Please explain how any one or more of these factors, in the absence of quantifiable data, could result in a finding that it is not technologically feasible to reduce any particular product or product category to 100 ppm of lead.***

Response: The economic impacts mentioned in your question are the types of impacts that might result from the 100 ppm content limit, which will primarily affect the costs of producing children's products. If the low-lead materials are available, but are available only at higher prices, then staff assumes that it is still technologically feasible to produce the low-lead children's products. Staff made this assumption because there is no economic basis for determining at what point a cost increase would make production not technologically feasible. However, the Commission may decide to interpret the definition of "technological feasibility" differently than staff, and provide direction on how to consider the contribution of cost.