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January 28, 2009

BY E-MAIL & HAND DELIVERY

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East-West Highway, Room 502
Bethesda, MD 20814-4408

Re: Petition for a Temporary Final Rule to Exclude a Class of Materials Under Section 101(b) of the Consumer Product Safety Improvement Act

Dear Mr. Stevenson:

Enclosed please find an original and five copies of a petition for a temporary final rule to exclude a class of materials under Section 101(b) of the Consumer Product Safety Improvement Act. This petition is being submitted on behalf of the Bicycle Product Suppliers Association.

Sincerely,

Erika Z. Jones /ACS

Erika Z. Jones

PETITION FOR TEMPORARY FINAL RULE TO EXCLUDE A CLASS OF MATERIALS UNDER SECTION 101(b) OF THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT

INTRODUCTION

Because some bicycles (including used bicycles), jogger strollers, and bicycle trailers (hereinafter, "bicycles and related products") are or have been intended primarily for use by children ages 12 and younger, they are subject to the lead content limits specified in Section 101 of the Consumer Product Safety Improvement Act ("CPSIA"), Pub. L. No. 110-314. Some components of such bicycles and related products contain small quantities of lead in excess of the CPSIA limits—although not in excess of the lead limits set forth in various European Union Directives for electronic devices and motorized vehicles and motorcycles. The manufacturers of bicycles and related products are making efforts to identify alternative materials for these components that would be compliant with the lead content limits, but the alternatives are not yet fully proven as suitable for the intended applications. In the meantime, therefore, lead in these components may be present either because small amounts of lead are needed for safety and functionality (such as machining the deep grooves on tire valves, which is needed for air retention) or because lead cannot feasibly be removed from recycled materials. Therefore, because these small quantities of lead in certain components are unavoidable, the members of the Bicycle Product Suppliers Association ("BPSA") which is an association of suppliers of bicycles, parts, accessories and services who serve the specialty bicycle retailer, will need relief from the CPSIA requirements in order to continue to sell their products on or after February 10, 2009.

PETITION FOR A TEMPORARY FINAL RULE

Pursuant to Sections 3 and 101(b)(1) of the Consumer Product Safety Improvement Act ("CPSIA"), Pub. L. No. 110-314, and this agency's proposed implementing regulations, the

Bicycle Product Suppliers Association ("BPSA") hereby petitions for a temporary final rule excluding from the lead limits established for children's products under the CPSIA the class of materials consisting of steel, aluminum, brass and copper alloys that are used in bicycles (including used bicycles), jogger strollers, and bicycle trailers that are primarily intended for use by children ages 12 and younger (hereinafter, "bicycles and related products") and that contain lead in amounts not greater than those permitted by European standards for lead in automobile and electronic components and that are not otherwise inaccessible to children (and therefore exempt from the CPSIA). The grounds for this request are that the lead in such materials will not result in the absorption of any measurable lead into the human body—taking into account normal and reasonably foreseeable use and abuse of such products by a child, as well as the aging of the products—nor have any other adverse impact on public health and safety. A proposed regulatory provision is attached at the end of this petition.[1]

The BPSA is an association of suppliers of bicycles, parts, accessories and services who serve the specialty bicycle retailer. BPSA provides a networking and educational forum for

[1] This petition relates only to *accessible* lead in bicycles, jogger strollers, and bicycle trailers. As the Commission has noted in its proposed interpretative rule on inaccessible component parts, "Section 101(b)(2) of the CPSIA provides that the lead limits will not apply to any component part of a children's product that is not accessible to a child through normal and reasonably foreseeable use and abuse." *See* Children's Products Containing Lead; Interpretative Rule on Inaccessible Component Parts, 74 Fed. Reg. 2439, 2439 (Jan. 15, 2009). In the proposed interpretative rule, the Commission has preliminarily determined that "an accessible component part of a children's product is one that a child may touch, and an inaccessible component part is one that is located inside the product and not capable of being touched by [a] child, whether or not such part is visible to a user of the product." *Id.* at 2440. For example, the air valves inside the valve stems are inaccessible to children through normal and reasonably foreseeable use and abuse under this proposed standard, and, therefore, are excluded from compliance with the CPSIA's specified limits on lead levels. In addition, components of the BPSA's members' products that contain lead in amounts below the CPSIA's limits (and, therefore, that are in compliance with the CPSIA) are not addressed in this petition.

members, spearheads industry initiatives in regulatory and safety issues, and is the leading resource for bicycle statistical data.

Because the Commission has recently published proposed procedures for exclusion determinations, and comments on those procedures are not due until February 17, 2009 (*see* 74 Fed. Reg. 2428, 2429 (Jan. 15, 2009)), there is no reasonable prospect that a petition for a final exclusion could be acted upon by the Commission prior to February 10, 2009, when the requirements of the CPSIA go into effect. As set forth below, the CPSIA's restrictions on lead in products intended for use by children 12 or younger may preclude the BPSA's members from selling certain bicycles and related products.[2]

A temporary Final Rule, however, will allow the CPSC's staff the time it needs for a thorough review of the public comments filed in response to its now-pending CPSIA regulatory proposals, resulting in an orderly completion of the rulemakings, consistent with the Administrative Procedure Act. It also will allow the BPSA's members to continue selling their products (while, at the same time, posing none of the risks to children that the CPSIA was enacted to prevent) pending completion of a proceeding addressing a subsequent petition that the BPSA anticipates filing for a permanent exclusion for its members' products.

The CPSIA's lead limits would not only deprive American children and youth of the health benefits and convenience of certain ***new*** youth bicycles and related products, but it also would deprive needy children of certain ***used*** bicycles. For instance, Trek Bicycles was a

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[2] BPSA has separately asked the Commission staff for guidance on how to define "children's product" in the context of bicycles. One possibility is to define it in terms of the wheel size, presumptively categorizing a bicycle with a wheel size of 24" or less as a children's product. While this approach has the advantage of being easy to administer, it also has the disadvantage that it also may capture certain sectors, such as the BMX segment, which uses small wheels on products intended for use by adults, including professional riders and Olympic contestants. Specialty designs intended for small stature adults would also be included as "children's products" if a definition based solely on wheel size were to be adopted.

founding contributor to a non-profit used bicycle store in Madison, Wisconsin, called "DreamBikes." In partnership with the Boys and Girls Club of Dane County, the store provides job training for disadvantaged youth and makes used and donated bicycles available to disadvantaged youngsters at affordable prices. DreamBikes is about to open a new location in Milwaukee, and is hoping to take the concept nationwide in the future. DreamBikes likely cannot continue its mission if used bicycles are subject to the new lead standards without exemption, because these used bicycles are likely to exceed the lead standard, at least with respect to their valve stems and spoke nipples. See more information about DreamBikes at www.dream-bikes.org.

The Administrative Procedure Act confers authority on agencies to issue interim and temporary final rules without prior notice and comment "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b). Here, the imminent compliance date for the lead limits in the CPSIA effectively precludes an opportunity for notice and comment on exclusion requests prior to the effective date of the CPSIA's lead content provisions. In similar circumstances, the Commission has previously exercised its authority to issue an immediately effective final rule under the CPSIA. *See* Final Rule, Certificates of Compliance, 73 Fed. Reg. 68328 (Nov. 18, 2008). In this matter, the need for immediately effective regulatory action is at least as compelling as it was with regard to certificates of compliance. Accordingly, the Commission should issue an immediately effective temporary final rule, granting the BPSA's request on an interim basis, until August 14, 2009, or for such period of time as the Commission requires to complete the procedural rule on exclusion petitions and process a petition for permanent exclusion through a final decision, whichever is later. At this time, the BPSA anticipates that it will file a petition for a permanent exclusion promptly after the Commission adopts a final rule specifying the procedures and requirements for seeking such exclusions.

The BPSA's requests are amply supported by the best-available, objective scientific evidence. The class of materials for which an exclusion is being sought are components made with copper (or brass), aluminum, and steel alloys—such as tire valve stems, spoke nipples, brake levers, and brake lever bushings—that contain lead in amounts not greater than those permitted under the European Union's RoHS and End-of-Life Vehicles ("ELV") Directives.[3]

The RoHS Directive (EU Directive 2002/95/EC (Jan. 27, 2003)) addresses "the restriction of the use of certain hazardous substances in electrical and electronic equipment." In its proposed exemptions for certain electronic devices, the CPSC has recognized that the RoHS Directive's functionality-based exemptions from the RoHS lead prohibitions are sufficiently protective of children to comply with CPSIA. The lead limits and exemptions in the RoHS Directive were derived from the ELV Directive, EU Directive 2000/53/EC (Sept. 18, 2000). Both directives stem from the EU's ongoing efforts to establish an "Integrated Product Policy" to address environmental issues over the life cycle of products. *See generally* Communication from the Commission to the Council and the European Parliament: Integrated Product Policy: Building on Environmental Life-Cycle Thinking.

In connection with a review of exemptions mandated by Annex II of the ELV Directive, the European Union has recently engaged in an exhaustive reexamination of the bases for exempting the various alloys and components, including those for which the BPSA seeks an

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[3] In this petition, following the practice in the RoHS and ELV Directives, the BPSA uses the term "copper alloys" to refer generically to copper and brass alloys. The requested exclusion for copper alloys should, therefore, be construed to cover brass alloys, as well.

exclusion here. That reexamination was conducted by an independent institute and involved a transparent process marked by extensive stakeholder participation and a thorough review of the state-of-the-art in materials properties, substitutability, and functionality. *See* Öko-Institut e.V., Final Report: Adaptation to Scientific and Technical Progress of Annex II, Directive 2000/53/EC (Jan. 16, 2008) ("Final ELV Report") (http://147.67.243.36/Public/irc/env/elv/library?l=/ stakeholder _consultation/evaluation_procedure/reports/final_report/report_revision/ _EN_1.0_&a=d).

The Final ELV Report recommended the retention of exemptions for lead in steel, aluminum, and copper alloys, noting the current lack of acceptable substitutes that do not contain lead. As set forth in greater detail below, the Final ELV Report exhaustively examined the uses of those alloys and components, the contribution that lead makes to such features as machinability, strength, and corrosion resistance; and the availability (or lack thereof) of substitute materials that do not contain lead. The Final ELV Report concluded that, at the present time, there are no adequate replacements for the class of materials at issue in this petition, although potentially acceptable replacement alloys may become available in the future. This conclusion comports with the CPSC's proposed exemption for certain electronic devices, in which the CPSC tentatively concludes that there are, at present, no suitable substitutes for these particular lead-containing alloys.

The lack of available substitutes for steel, aluminum, and copper alloys used by the BPSA's members in their youth bicycles and related products supports the reasonableness of the relief requested in the BPSA's instant request, which seeks only limited exclusions for lead in certain alloys at levels not in excess of those permitted under the RoHS and ELV Directives.

In addition, the BPSA is attaching a report prepared by Dr Barbara D. Beck, Ph.D., DABT, an expert in toxicology and health risk assessment for environmental chemicals, especially metals and air pollutants; former Fellow in the Interdisciplinary Programs in Health at the Harvard School of Public Health; current Lecturer in Toxicology at Harvard; and principal of Gradient Corporation. *See* Attachment A. In that report, which is based on a thorough literature review and analysis of existing data concerning the alloys at issue in this petition, Dr. Beck explains her conclusion that the lead content in brass, aluminum, and steel alloys in certain components of bicycles and related products does not present an exposure concern for children and that an exclusion is appropriate for such components. She bases this conclusion on an analysis showing that—even in worst-case scenarios and using projected intakes of lead greater than those expected to result from exposure to the BPSA's members' products—no measurable increase in the blood lead levels of children can be expected to result from their exposure to and contact with the materials for which this petition seeks an exemption.

Dr. Beck's focus on exposure effects on blood lead levels is consistent with the overall purposes of the lead level requirements of the CPSIA. As the House Report on the Act explained in connection with the exception to the lead standards for inaccessible parts, the legislation's focus was on ensuring "that any products granted an exception has no meaningful ability to expose a child to lead *in such a way that could raise blood lead level.*" H.R. Rep. 110-501, at 30 (2007) (emphasis added).

Finally, the relief requested here also is amply supported by available scientific evidence that, while extremely young children may occasionally attempt to mouth a variety of objects, children of the ages likely to use bicycles and related products do not typically engage in mouthing behaviors that are likely to involve the affected components of the BPSA's members' products. *See generally, e.g.*, B. Norris & S. Smith, *Research Into Mouthing Behaviour of Children Up To 5 Years Old* (London: Department of Trade and Industry 2002), available at http://www.berr.gov.uk/files/file21800.pdf. Nor, as we explain below, are children likely to engage in hand-to-mouth activities, such as nail biting, while using bicycles and related products. Therefore, the exclusion sought in these requests should be granted.

In accordance with the Commission's proposed procedures and requirements for a Commission determination or exclusion, we are submitting the following information.

1. Requester's Identifying Information.

Bicycle Product Suppliers Association
P.O. Box 187
Montgomeryville, PA, 18936
Tel. (215) 393-3144
Fax (215) 893-4872.

2. Description of Class of Materials

The class of materials for which this petition seeks an exclusion are steel, aluminum, and copper alloys containing lead in amounts up to those permitted under the RoHS and ELV Directives' exemptions.[4] Such alloys are used in various components, including, but not limited to, tire valve stems, spoke nipples, brake levers, and brake lever bushings.

3. Lead Content

The lead content of the alloys for which an exclusion is being sought alloys varies because the diverse applications of the alloys in the BPSA's members' products may require different lead levels for machinability, corrosion resistance, or other functional reasons. In addition, the lead content of the alloys also necessarily varies because, in some cases, the lead

[4] As noted above (at note 3), in this petition, following the practice in the RoHS and ELV Directives, the BPSA uses the term "copper alloys" to refer generically to copper and brass alloys.

content results from the use of recycled materials. In no case, however, does the lead content exceed the permissible lead content permitted under the exemptions set forth in the pertinent annexes to the RoHS and ELV Directives – that is, 0.35% lead by weight for steel alloys, 0.4% lead by weight for aluminum alloys, and 4% lead by weight for copper alloys.

4. Introduction of Lead in the Manufacturing Process

Lead is deliberately introduced into some members of the class of materials for which an exclusion is being sought in this petition in the process of preparing them according to precise standards and specifications that set forth the amounts of lead to be used for various applications and performance requirements. Lead also appears as an unavoidable result of the use of recycled materials. Lead, however, is ***not*** introduced by the BPSA's members either deliberately or as a by-product of their own manufacturing processes.

5. Other Information Relevant to Lead Content

The Final ELV Report contains exhaustive discussions establishing that, in the current state of the art, lead is necessary in the alloys for which an exclusion is being sought in order to assure safety, durability, and machinability.

Thus, for lead in steel, the report explains, "[l]ead is used in steel for improved machinability. By the addition of lead better chip fracturing, automation of the productive process, high cutting speed (low cycle times), longer tool life, better surface finish and more accurate dimension control can be achieved." Final ELV Report at 11. In galvanized steel, lead "has important functions in the galvanizing process" itself. *Id.* at 12.

As the report also makes clear, although attempts have been made to develop alternatives to lead as a machinability enhancer in steel, none of the possible substitutes has performed as well as leaded steel. Thus, for instance, leaded steels have been shown to outperform bismuth, increased sulfur, tin, phosphorous, and calcium as additives to steel. *Id.* at 14. These "non-leaded alternative grades generally gave poorer chip form and surface finish."

Bismuth provides some substitutability for lead under certain circumstances, but "the hot workability of bismuth steels is reduced compared to leaded steels. Hot workability is a fundamental requirement for steel production." *Id.* As a result, "it is significantly harder for a steel roller to produce a bar with the same machining properties and surface integrity if the steel obtains its machining properties through bismuth rather than lead." *Id.*

Calcium also showed significant drawbacks as compared to lead (*id.* at 15), and "[s]teels containing tin generally did not show good performance in the machinability tests and thus, [were] not considered as a suitable replacement for lead in steel." *Id.*

Similarly, although there are ongoing efforts to develop alternatives to lead for galvanized steel, there is currently a lack of adequate supplies of potential alternatives (for instance, bismuth), and technical problems with regard to drainage of excess zinc from the galvanized product and the quality of the surface finish remain. *Id.* at 16-17.

As a result the Final ELV Report concludes that because of the lack of available alternatives, "the use of lead in steel for machining purposes and in galvanized steel at the current state of the art is unavoidable." *Id.* at 18.

With regard to aluminum, the Final ELV Report explains that lead is found in aluminum either because it has been deliberately added for improved machinability or because the aluminum alloys contain lead as an impurity as a result of the production of the alloys from scrap. *Id* at 21. With regard to lead that is deliberately added, lead in aluminum alloys increases corrosion and wear resistance.

As for recycled aluminum alloys—that is, "[a]luminum produced from recycled scrap metal" (*see id.*)—the Final ELV Report concludes that the removal or dilution of lead impurities in aluminum is not technically feasible on the scale needed for industrial purposes. *See id.* at 24-25.

With regard to copper alloys, the Final ELV Report notes that "[t]he lead that is embedded as tiny nodules in the matrix of these alloys has the function of a chip breaker and machinability enhancer. The formation of small chips, which can be removed automatically, is facilitated." *Id.* at 26; *see also id.* at 28. The Final ELV Report notes, however, that there are potential substitutes for leaded copper alloys. At present, however, these alternatives to lead have a number of drawbacks. Thus, bismuth alloys are more susceptible to stress corrosion cracking, unfavorable chip form, and missing self-lubricating effects that result in higher tool wear. *Id.* at 29. As a result, the enhanced machinability of leaded copper alloys, which, for instance, permits the creation of deep grooves in threaded parts such as valve stems that are needed to ensure secure cap and air valve fitment for safety reasons, supports an exclusion for leaded copper alloys, in accordance with the conclusion of the Final ELV Report.

The Final ELV Report's conclusions strongly support the relief sought by the BPSA here. Although technological feasibility is not the statutory touchstone for exclusions of the class of materials for which the BPSA is petitioning, it is clear that Congress intended the Commission to consider issues of technological feasibility in implementing the CPSIA. Thus, in explaining Section 101, the Conference Report on the CPSIA states that the CPSC is ultimately required to "lower the permissible lead level in children's products to the lowest amount that is *technologically feasible.*" H.R. Rep. 110-787, at 66 (2008) (Conf. Rep.) (emphasis added), *as reprinted in* 2008 U.S.C.C.A.N. 1112, 1113. The Final ELV Report establishes that, at the present time, feasible alternative materials are not available to substitute for the class of materials for which this petition seeks an exclusion.

BPSA's members are interested in substituting adequate, equally safe, functional, and machinable non-leaded alternatives for these components if and when they become available. But in the present state of the art, if the petition were denied, the safety of the BPSA's members' products could be compromised, and the BPSA's members could be forced to suspend or terminate their production and sale of such products.

In this regard, BPSA notes that if its members were required to stop selling bicycles intended for use by children ages 12 or younger, which are generally smaller and more appropriate for children's physical stature, parents could be forced to purchase adult-sized bicycles for their children. This situation would expose children to the increased risks associated with riding bicycles that do not and cannot be properly fitted to their statures.

6. Methods for Testing Lead Content

Standards-setting organization, such as ASTM International and the International Standards Organization, set forth precise standards for the composition of metallic alloys for various purposes, as well as methods for determining the content of such alloys. These standards are used by the suppliers of alloys used by the BPSA's members and their component suppliers. Materials engineers use highly sophisticated preparation and quality control procedures to assure uniformity and consistency in the preparation of alloys for industrial and commercial uses. The BPSA's members and their suppliers source the alloys used in their products and components from reputable companies that employ advanced metallurgical methods to produce the alloys used in their products.

7. Assessment of Manufacturing Processes

The BPSA's members' manufacturing processes do not introduce lead into their products either deliberately or as a manufacturing by-product. Rather, as noted above, lead is introduced into the products through the use of steel, copper, and aluminum alloys into which lead is introduced deliberately according to precise specifications by the suppliers of the alloys, or through the use of recycled materials. Accordingly, this category is not applicable to this petition.

8. Lead In The Product, Lead Coming Out of the Product, Conditions Under Which Lead Comes Out of the Product, and Information Relating to a Child's Interaction With the Product.

A. Lead in the Product

As noted above, the BPSA seeks an exclusion for lead in steel, aluminum, and copper alloys only up to the amount permitted by the RoHS and ELV Directives. Their products do not contain lead in excess of those amounts.

B. Lead Coming Out of the Products: Amounts and Conditions

In her report (Attachment A), toxicology and health risk assessment expert, Dr. Barbara D. Beck, provides a comprehensive analysis of the amounts of lead that can be dislodged from the pertinent components of the products via direct contact, which is the only relevant condition for lead to emanate from the BPSA's members' products. *See* Attachment A at 3-9. Dr. Beck and her team focused principally on two components—the brake lever and the tire valve stem. The former was selected for analysis because it is the component with which children would have the most frequent and prolonged contact. The valve stem was selected not because contact is likely, but because it is a copper (or brass) component that, under the RoHS and ELV directives, is permitted higher concentrations of lead than are aluminum or steel alloys.

Dr. Beck's analysis concluded that the "estimated lead intake from brake levers and valve stems ranges from 0.015 to 0.050 μg/day." *Id.* at 8. As Dr. Beck points out, "the default lead intake for diet used in the US EPA's Integrated Uptake Biokinetic Model (IEUBK) . . . is 2.22 μg/day for a 6 year old, and the default lead intake from water is 0.6 μg/day. The estimated intake from the [BPSA's members'] components is well below these background exposures to lead in food and soil." *Id.* Dr. Beck goes on to show that a lead intake of "***ten times higher*** than the maximum estimated intake from motorized recreational vehicle components"—that is, 0.5 μg/day—"would have no discernable impact on blood levels in children." *Id.* at 9 (emphasis added); *see also id.* ("estimated lead intakes from motorized recreational vehicle components are well below background intakes of lead from food and water" and "will not result in a measurable impact on blood levels in children"). In short, the impact on blood lead levels of the *de minimis* intake of lead that could foreseeably result from contact with the Companies' products is simply *not detectable*. *See id.*

C. Children's Interactions With the Products

The best available scientific evidence indicates that youth bicycles and related products are not the kind of objects that children typically mouth. *See generally, e.g.*, B. Norris & S. Smith, *Research Into Mouthing Behaviour of Children Up To 5 Years Old* (London: Department of Trade and Industry 2002), available at http://www.berr.gov.uk/files/file21800.pdf.

Other contacts by children with the class of materials for which an exclusion is sought in this petition are possible, however. Such contacts may include touching with bare hands, and subsequent hand-to-mouth contacts. Such hand-to-mouth behaviors, however, are highly unlikely. The hand-to-mouth behaviors—such as nail biting—typically observed in children of the ages expected to come into contact with bicycles and related products seldom occur when children are engaged in the kind of physical activities associated with these use of these products. *See*, *e.g.*, D.W. Woods, *et al.*, *Understanding Habits: A Preliminary Investigation of Nail Biting in Children*, 24 Educ. & Treatment of Children 199 (2001); N.C.G. Freeman, *et al.*, *Quantitative Analysis of Children's Microactivity Patterns: The Minnesota Children's Pesticide Exposure Study*, 11 J. Exposure Analysis, 501, 507 (2001), available at http://www.nature.com/jes/journal /v11/n6/full/7500193a.html ("Most hand-to-mouth and object-to-mouth activities were observed during the children's inactive periods, particularly when watching television.").

In addition, as noted above, Dr. Beck's toxicological analysis demonstrates that any contacts foreseeably resulting from children's interactions with the BPSA's members' products would result in no detectable increases in blood level levels.

9. Best Available Evidence Unfavorable to the Petition

The BPSA is not aware of any objective, peer-reviewed, scientific evidence that is unfavorable to the request.

PROPOSED REGULATORY PROVISION

Part 1500 – HAZARDOUS SUBSTANCES AND ARTICLES: ADMINISTRATION AND ENFORCEMENT REGULATIONS

Add a new section 1500.__ to read as follows:

§ 1500.__ Exemptions from Lead Limits under section 101 of the Consumer Product Safety Improvement Act for certain alloys used in bicycles and related products.

(a) Section 101(b)(1) of the Consumer Product Safety Improvement Act (CPSIA) provides that "[t]he Commission may, by regulation, exclude a specific product or material from the prohibition in subsection (a) if the Commission, after notice and hearing, determines on the basis of the best-available, objective, peer-reviewed, scientific evidence that lead in such product or material will neither (A) result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor (B) have any other adverse impact on public health."

(b) The CPSIA provisions on lead limits in products designed or intended primarily for children 12 and younger go into effect no later on February 10, 2009. The Commission will not complete the promulgation of a final rule setting forth procedures for requesting exclusions under Section 101(b) of the CPSIA prior to that date. The Bicycle Product Suppliers Association, whose members are suppliers of bicycles, parts, accessories, and services, have established that the CPSIA's restrictions on lead in products intended for use by children may preclude them from selling certain bicycles, jogger strollers, and bicycle trailers (collectively, "bicycles and related products"). They also have shown that the imminent compliance date for the CPSIA's lead limits effectively precludes an opportunity for notice and comment on their request for the issuance of a final rule excluding a certain class of materials used in their products from those lead limits. For this reason, as well as for the other reasons shown in their petition for a temporary final rule to exclude a class of materials under Section 101(b) of the CPSIA, the Commission finds "that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest," 5 U.S.C. § 553(b), and that, therefore, good cause exists to promulgate a temporary final rule without prior notice and comment.

(c) The following class of materials used in bicycles and related products are hereby temporarily excluded from the prohibitions of Section 101(a) of the CPSIA: steel, aluminum, and copper alloys that contain lead in amounts not greater than the amounts that are granted exemptions published in the Annex to the European Union Directive 2002/95/EC, as amended through European Union Decision on January 24, 2008, provided that the exemption is based on a functional requirement both for the use of a lead-containing component and for the use of the lead in such component, and does not include an exemption for decorative or non-functional uses of lead.

(d) This exclusion shall remain in effect until August 14, 2009 or until a final determination is made with respect to the excluded class of materials on a petition submitted pursuant to the procedures adopted by the Commission for exclusion petitions, whichever is later.

ATTACHMENT A

Exposure Evaluation of Manufactured Components in Consideration for Exclusion from the Consumer Product Safety Improvement Act (CPSIA)

Prepared for
Mayer Brown, LLP
1909 K Street, NW
Washington, DC 20006

Prepared by
Gradient Corporation
20 University Road
Cambridge, MA 02138

January 26, 2009

1 Introduction

This report presents a scientific evaluation of certain youth bicycle, jogger stroller, and bicycle trailer components, manufactured from certain lead-containing alloys in consideration of possible exclusion from the Consumer Product Safety Improvement Act of 2008 (CPSIA). Using scientifically accepted exposure assessment procedures and reasonable and foreseeable exposure scenarios, we have determined that the lead content in brass, aluminum, and steel alloys in certain components of these products does not present any risk of a measurable increase in blood lead levels in children and that an exclusion is therefore appropriate for such components. Our detailed analysis follows.

2 Background

The Consumer Product Safety Improvement Act (CPSIA) of 2008 stipulates that, by February 10, 2009, children's products that contain more than 600 ppm (mg/kg) lead may no longer be sold in the United States (US Congress 2008, Pub. L. No. 110-314, § 101(a)(2)). The limit will be reduced to 300 ppm after August 14, 2009 and then to 100 ppm on August 14, 2011 unless the Commission determines that this lower limit is not technically feasible. Section 101(b) of the Act also allows for an exclusion for certain products or materials that exceed this limit, based on evidence that reasonably foreseeable use and abuse of the product will not "result in the absorption of any lead into the human body". In addition, a recent rulemaking notice has proposed procedures and guidance as to how an exclusion may be formally considered by the Consumer Product Safety Commission (CPSC) (74 Fed. Reg. 2428, 2429 (Jan. 15, 2009)).

In this analysis, we provide technical evidence that certain lead-containing components of bicycles, jogger strollers, and bicycle trailers primarily intended for use by children ages 12 and under should be considered for exclusions under the language of the CPSIA statute.

3 Metal Alloys and Bicycle (and Related Product) Components

Certain components of bicycles, jogger strollers, and bicycle trailers are made of metal alloys, which, as part of their functionality, contain lead. The alloys are:

- Copper brass alloys that may contain up to 4% lead (40,000 ppm)
- Aluminum alloys that may contain up to 0.4% lead (4000 ppm)
- Steel alloys that may contain up to 0.35% lead (3500 ppm)

In addition, exposed battery terminals contain unalloyed lead.

For the purpose of this analysis we have focused on specific components; however, this should not be taken to indicate that other alloys exceeding the CPSIA limits may not also merit exemptions. Rather, timing constraints prevent an analysis of all components individually. We have, as an upper bound case, focused on components where the concentrations of lead are relatively high and/or the exposure potential appears to be greatest.

The components of interest and their alloys (or lead composition) are:

- Valve stem (copper brass)
- Brake lever (aluminum)
- Spoke nipples (copper brass)

In our analysis, we will focus only on the brake lever and valve stem, as, together, these are believed to present the worst-case scenario – brake levers are the components with which a child will likely have the most contact in an exposure scenario, and the valve stem, while unlikely to be contacted by a child on a regular basis, has the highest permissible lead concentration of the components of interest that are foreseeably likely to be contacted by children.

4 Methodology

Our approach is based on generally accepted principles and approaches of exposure assessment, as applied to lead-containing materials (US EPA, 1994; 1997). There are three main components of the analysis:

- Estimation of amount of lead released from the component, leading to a potential for contact by a child
- Estimation of the amount of lead potentially taken up into the body by a child, considering reasonable use and abuse of the component
- Interpretation of the amount potentially taken up into the body, in the context of the statutory language

Details on each of these components is provided in the subsequent sections.

4.1 Estimation of Amount of Lead Released from the Component, Leading to a Potential for Contact by a Child

We employed two methods to quantify the potential amount of lead released from the component. While the preferred data would be actual lead measurements from wipe methods mimicking hand contact, such data are not available. Therefore, we extrapolated from the best-available existing data, using conservative assumptions where appropriate. For example, we assumed that lead released from copper brass products into water reflected the amount of lead on the surface of a component and that all of this lead could be transferred to fingers and hands; however, it is more plausible that only some lead on the surface of a product would be transferred to hands and fingers.

The two methods to estimate release of lead from bicycle and related product components are:

- Extrapolation from studies of lead release from jewelry onto fingers by direct contact
- Extrapolation from studies of release of lead from brass faucets into water, normalizing to mass of lead released as a function of surface area

We focused our modeling effort on the brake lever and the valve stem. Our approach was to use worst case examples, either in terms of the nature of the contact or in terms of lead concentrations. Thus, the results of the analysis would be applicable to other components, which involve lesser contact or have lower lead concentrations. For example, the lead content in steel components (0.35%, or 3500 μg/g) is more or less comparable to that of the brake lever (0.4% lead, or 4000 μg/g), and it is reasonable to assume that a bicycle rider will have more frequent contact with the brake levers than with any other components made of an alloy covered by this analysis. Likewise, the spoke nipple is composed of the same brass alloy (4% or 40000 μg/g lead content) as the valve stem. An older child is more likely to make adjustments to tire pressure using the valve stem than to touch the spoke nipple. Additionally, it is highly unlikely that a younger child (*i.e.* less than 6-years old, the population of greater concern for lead exposure) would ever adjust tire pressure at all. Therefore, estimating lead released from these components will result in a worst-case estimate of lead intake for the infrequently contacted components.

Details on the specific estimation methods are as follows.

4.1.1 Literature Review

We reviewed the literature for relevant, peer-reviewed studies that quantitatively evaluate the amount of lead that can be dislodged *via* direct contact with metallic surfaces. A study by

Druhan (2004) of metallic jewelry is the only study that we identified that measured direct contact between hands and metallic surfaces; because the type of metal used in the jewelry was nonspecific, this study was used to evaluate both aluminum brake levers and brass valve stems. We also reviewed several faucet leaching studies. A study performed by Maas *et al.* (1997) was selected to evaluate brass components because of the large sample size (22 faucets), and because the size of each faucet tested was reported, which allowed us to estimate surface area.

In order to extrapolate the results of the jewelry and brass faucet studies to bicycles and related product components, we developed a value called the Handling Transfer Coefficient (HTC). For both studies, we determined the amount of lead removed per surface area of test material, then divided this value by the lead concentration in the test material:

$$HTC\left[\frac{g}{cm^2}\right] = \frac{\dfrac{lead\ removed\ from\ test\ material\ [\mu g]}{surface\ area\ of\ test\ material\ [cm^2]}}{lead\ concentration\ in\ test\ material\ \left[\dfrac{\mu g}{g}\right]}$$

The HTC is an estimate of the amount of test material removed per surface area handled. Using this information, we derived average HTCs for both the jewelry study and the faucet study. Our approach is described in detail below.

4.1.2 Druhan (2004)

The jewelry study performed by Druhan (2004) involved volunteers briefly handling (with a portion of two fingers and the thumb) 20 pieces of metal jewelry. Following handling of each piece of jewelry, the fingers and thumb of the volunteers were rinsed with water, and the rinsate was then analyzed to determine the mass of lead (μg) transferred from the jewelry to the hand.[5]

For each piece of jewelry, Druhan reported the associated lead concentration (range of 11,000 μg/g to 893,700 μg/g), as well as the amount of lead removed from each piece of jewelry per square centimeter of surface area (range of 0.0028 $\mu g/cm^2$ to 0.80 $\mu g/cm^2$, excluding one outlier that was over 20 times greater than the next highest value). We calculated the HTC for each piece of jewelry, and the 95% upper confidence limit on the mean (UCLM) of all jewelry samples (excluding the outlier) is 1×10^{-6} g/cm^2. Because the lead concentration in the majority of the jewelry pieces was much higher than that of bicycle and related product components, we chose to average the HTC for a total of three jewelry pieces containing less than 100,000 μg/g of lead; the concentrations in these three samples more closely resembled the concentrations in the bicycle and related product components and are thus considered more representative. The

[5] Note that it appears Druhan (2004) may not have adequately controlled for cutting or scraping of individual jewelry pieces during an earlier analysis for total lead content. This would result in a bias towards overpredicting the amount of lead transferred to the hand.

maximum HTC for these samples is 2×10^{-6} g/cm^2 (the maximum value was used in this case because there were not enough samples to calculate a UCLM).

4.1.3 Maas *et al.* (1997)

Maas *et al.* (1997) conducted a study of 22 faucets that were connected to a pressurized supply of a leaching solution prepared according to the NSF 61 protocol for faucet evaluation (pH of 8, 0 mg/L available chlorine, and 100 mg/L hardness) (NSF, 2000). Over the course of the study, faucets were "aged" by periodically flushing them with 100 mL of test solution. Prior to taking 200 mL leachate samples, each faucet was flushed, then allowed to stand for 30 minutes. Faucets were sampled three times at one-week intervals and analyzed for lead. Maas *et al.* reported the volume (cm^3) of each faucet tested and the concentration of lead in the associated leachate samples (μg/L). Using this volume, we were able to estimate the surface area (SA) of each faucet by assuming a uniform radius (r) of 1 cm for all faucets where:

$$SA = 2\pi r^2 + 2\frac{Volume}{r}$$

We determined the mass of lead removed from the faucet in the leaching test by multiplying the lead concentration (average of three samples) by the volume of leachate collected. We estimated the lead concentration of the brass faucets by assuming that faucets were composed of a brass alloy with 60,000 μg/g lead (6 % lead).[6] Using the mass of lead removed after 30 minutes of leaching, the estimated surface area of the faucet, and the estimated lead content in brass, we calculated the HTC for each faucet. The 95% UCLM of the HTC over all faucets is 6×10^{-7} g/cm^2.

4.2 Estimation of Amount of Lead Released from the Component and Subsequently Taken into the Body

There are several factors involved in transferring lead from the surface of the component into the body of the child. These include the surface area of the hand/fingers touching the component, the transfer of that amount of lead to the hand/fingers, the frequency and duration of the contact, the transfer of lead from hand/fingers to mouth, and subsequent intake of the lead into the body. This may be represented as the following equation:

$$Intake\left(\frac{ug}{day}\right) = HTC \times CA \times PbC \times TE \times \frac{EF}{7\ days/week}$$

where:

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[6] According to a study by Dresher (1992), the two most common brass alloys used in plumbing contain between 5.57% and 7% lead. We selected 6% as a value in the middle of this range. Use of this percentage is considered to be conservative since the brass components in bicycles and related product contain less than 6% lead (brass bicycle and related product components contain up to 4% lead).

HTC	= Handling transfer coefficient, g/(cm^2 ride)
CA	= Area of component contacted, cm^2
PbC	= Lead concentration in component, µg/g (ppm)
THE	= Hand transfer efficiency, unitless
EF	= Exposure frequency, rides/week

Each of these parameters is explained in more detail below, and the exposure assumptions used for the component scenarios are provided in Table 1.

Table 1
Lead Intake Exposure Assumptions

Component	Material	HTC g/(cm^2 ride)	HTC basis[1]	CA cm^2	PbC µg/g	HTE unitless	EF rides/week
brake lever	aluminum alloy	1×10^{-6}	jewelry	56	4,000	0.25	2
valve stem	brass alloy	4×10^{-7}	jewelry	2.2	40,000	1	2
valve stem	brass alloy	6×10^{-7}	faucet study	2.2	40,000	1	2

Notes:
1. The Druhan (2004) jewelry study did not identify the metallic composition of the jewelry pieces; therefore, we applied the results to both aluminum and brass components. The Maas (1997) faucet study was specific to brass components; therefore, we have applied the results only to the brass valve stem.

Area of Component Contact (CA): This parameter represents the area of contact between a child's hand and the specific bicycle and related product component (brake lever or valve stem).

The area of contact between the brake lever and hand is based on a brake lever with a 1.5 cm diameter (based on a reasonable approximation). We assume that the full perimeter of the lever is contacted across the width of a child's hand. We made a conservative assumption that a child's hand is 6 cm, which is an overestimate for younger children, but yields a larger contact area and therefore a higher, more conservative estimate of lead intake. With these assumptions, the contact area for each hand is 28 cm^2, and the total for two hands is 56 cm^2.

The area of contact between the valve stem and hand is equal to the exposed brass on the valve stem, which has a diameter of 0.7 cm and a length of 1 cm, for a total area of 2.2 cm^2 (based on measurement of a valve on a typical bicycle tube). We conservatively assume that one valve is handled per ride, which overstates exposure since a child is unlikely to touch the valve stem each time he or she rides a bicycle, bicycle trailer, or jogger stroller.

Lead Concentration in Component (PbC): This parameter is the concentration of lead in the bicycle or related product component in µg/g (ppm).

The brake lever is made of an aluminum alloy that may contain up to 4,000 μg/g (0.4%) lead. Valve stems are made of a copper brass alloy that may contain up to 40,000 μg/g (4%) lead.

Hand Transfer Efficiency (HTE): The hand transfer efficiency parameter, or HTE, describes the fraction of soil on the hands that might be subsequently ingested via hand-to-mouth contact.

We used soil HTE factors developed by Dubé *et al.* (2004) to estimate HTE for the components. To develop the HTE factor, Dubé *et al.* (2004) reviewed data regarding children's incidental ingestion of soil, adherence of soil to the hands, and the skin surface area of the hands. The estimate of soil loading on the hands was combined with an estimated soil ingestion rate to derive the HTE factor, which is an estimate of the proportion of the mass of soil adhering to the hands that would need to be ingested to yield the estimated soil ingestion rate. Dubé *et al.* (2004) calculated a HTE factor of 0.25 for a child (ages 2-6 years), meaning that, on average, incidental ingestion of approximately one-fourth of the soil adhering to the palmar surface of a child's hands yields the typical estimated daily soil ingestion rate. For a child ages 7-12 years, Dubé *et al.* (2004) estimated the HTE would be approximately half of the HTE for a child (*i.e.*, 0.13), because available data indicates that, for older children and adults, incidental soil ingestion is less than that in younger children (less than 7 years old), and hand-to-mouth contacts are less frequent. For example, standard default soil ingestion rates for adults are typically about half of those for children ages of 2–6 years old (US EPA, 1997).

For scenarios involving contact with bicycle and related product components, we extrapolated Dubé *et al.*'s soil HTE factors and have made the conservative assumptions that 1) one-fourth of all material that adheres to a child's hands from touching the brake lever is ingested (a lower value may be appropriate for older children) and 2) all of the material that adheres to a child's fingers from touching a valve stem is ingested.

Exposure Frequency (EF): The exposure frequency is the number of days per week that a child is expected to ride a bicycle, bicycle trailer, or jogger stroller.

We estimated an exposure frequency of 2 days/week for typical bicycle and related product use.

4.3 Interpretation of Amount of Lead Taken into the Body

We recognize that the statute refers to no lead absorption in the body; however, we believe that, as a scientific matter, the concept of "no lead absorption" would be reasonably interpreted by the scientific community to mean no measurable impact on blood lead. This is consistent with the fact that, even at the permitted concentrations of lead in products, *i.e.*, 600 ppm at the first threshold, one cannot assume that the impact on lead intake is zero. Hence we have interpreted the intake and absorption of lead from the products in terms of an impact on blood lead, which would be so slight as to have no detectable impact in an individual). The specific intakes associated with these comparison points are described as follows in the results section.

5 Results

The results of our analyses were calculated using the above equations and assumptions, and are presented in Table 2. One can observe that the estimated lead intake from brake levers and valve stems ranges from 0.015 to 0.050 μg/day.

To place these values into context, the default lead intake for diet used in the US EPA's Integrated Exposure Uptake Biokinetic Model (IEUBK) (US EPA, 1994; 2001; 2009) is 2.22 μg/day for a 6 year old, and the default lead intake from water is 0.6 μg/day. The estimated intake from the components is well below these background exposures to lead in food and soil.

The IEUBK model will not register a detectable incremental increase to blood lead when modeling lead intakes as low as 0.015 to 0.050 μg/day for a child 6 years of age. Thus, in order to further evaluate the significance of intakes of 0.015 to 0.050 μg/day, we modeled the effect of an intake of 0.5 μg/day, which is ten times higher than the maximum estimated intake from bicycle and related product components. We ran the IEUBK model with the assumption that the 6 year old child would be exposed to 0.5 μg of lead each day for a full year (US EPA, 1994; 2001; 2009).

With conservative default inputs for all exposure routes and without consideration of any lead intake from bicycle and related product use, the IEUBK model predicts a blood lead level of 1.9 μg/dL for a 6-year-old child. Adding 0.50 μg/day of lead intake (which is higher than the intake amounts resulting from the modeling) starting at age 6 does not change the predicted blood lead level, yielding the same predicted blood lead level of 1.9 μg/dL. Thus, it is clear that an intake of 0.015 to 0.050 μg/day would have no discernable impact on blood lead levels. In other words, the predicted blood level would be 1.9 μg/dL even with an additional intake of 0.015 to 0.050 μg/day.

Table 2
Lead Intake Results

Component	Material	Basis of HTC	Lead Intake μg/day
brake lever	aluminum alloy	jewelry	0.032
valve stem	brass alloy	jewelry	0.050
valve stem	brass alloy	faucet	0.015

In conclusion, because estimated lead intakes from bicycle and related product components are well below background intakes of lead from food and water, and because such intake will not result in a measurable impact on blood lead levels in children, we believe that exclusions are merited for the components noted.

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