



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

BALLOT VOTE SHEET

DATE: MAY - 6 2009

TO: The Commission
 Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel *CAF*
for Patricia Semple, Executive Director *je*

FROM: Philip Chao, Assistant General Counsel *PC*
 Hyun S. Kim, Attorney, OGC *HSK*

SUBJECT: Request from the Bicycle Product Suppliers Association for Exclusion from Lead Content Limits under Section 101(b)(1) of the Consumer Product Safety Improvements Act (CPSIA)

Ballot Vote Due: MAY 12 2009

Attached are the staff memoranda and initial recommendation on the request from the Bicycle Product Suppliers Association (BPSA) for exclusion of certain component parts and materials under section 101(b)(1) of the CPSIA.

Please indicate your vote on the following options.

- I. Accept staff's initial recommendation and deny BPSA's request for exclusion.

 (Signature)

 (Date)

- II. Reject staff's initial recommendation and grant BPSA's request for exclusion.

 (Signature)

 (Date)

~~CPSA 6(b)(1) CLEARED for PUBLIC~~

CPSC Hotline: 1-800-638-CPSC(2772) ★ CPSC's Web Site: <http://www.cpsc.gov>

5/6/09
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 PRODUCTS IDENTIFIED
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 RULEMAKING ADMIN. PRCDG

Note: This document has not been reviewed or accepted by the Commission.
 Initials RT Date 5-6-09

WITH PORTIONS REMOVED:

III. Direct staff to draft and submit to the Commission for ballot vote a Federal Register notice staying enforcement with regard to the specified lead level as it pertains to certain parts of youth bicycles (including related products such as jogger strollers and bicycle trailers) manufactured before February 10, 2009, and to similar products made on or after that date through April 30, 2011, given the safety concerns raised by the industry's Petition for Exclusion.

(Signature)

(Date)

IV. Take other action.
(Please specify.)

(Signature)

(Date)

Attachments:

EXHR Staff Memorandum: Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from the Bicycle Product Suppliers Association dated May, 2009.

Human Factors Response to Request by Bicycle Product Suppliers Association for Exclusion from Lead Limits under Section 101(b)(1)) of the Consumer Product Safety Improvement Act dated May, 2009.



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Memorandum

Date: **MAY - 6 2009**

TO : The Commission
 Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel *CAF*
 Patricia Semple, Executive Director *PS*

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

SUBJECT : Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from the Bicycle Product Suppliers Association

Introduction

The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 years of age or younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 years of age or younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that this lower limit is not technologically feasible. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child or prevent the absorption of any lead in the human body through normal and reasonably foreseeable use and abuse of the product.

Section 101(b)(1) of the CPSIA provides that the Commission may exclude a specific product or material from the lead limits established for children's products under the CPSIA if the Commission, after notice and a 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 absorption¹ 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,

¹ In toxicology, absorption refers to the transfer of a chemical into the systemic circulation from the site of exposure, primarily through the skin, respiratory tract and gastrointestinal tract [Gregus Z. (2008) Mechanisms of Toxicity In: C. Klaassen, (Ed.) Casarett & Doull's Toxicology, The Basic Science of Poisons. (p. 46) New York: McGraw Hill Medical]. In this memorandum, the terms intake and exposure are used to refer to the amount of lead a child comes into contact with, as well as the amount taken into the body through ingestion. A portion of ingested lead will be absorbed into the body, depending on factors such as the child's age, fasting and nutritional status, and chemical and physical form of the lead.

CPSA 6(b)(1) CLEAR
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Note: This document has not been reviewed or accepted by the Commission.
 Initials *RH* Date *5-6-09*

or other children's activities, and the aging of the product; nor (b) have any other adverse impact on public health or safety.

By rule², the Commission has established procedures by which interested people may request an exclusion from the lead limits of section 101 of the CPSIA. This rule states that upon receipt of a request for an exclusion, the Office of Hazard Identification and Reduction (EXHR) will assess the request to determine whether, on the basis of its review of the submitted materials, the normal and reasonably foreseeable use and abuse activity by a child (including swallowing, mouthing, breaking, or other children's activities) and the aging of the material or product for which exclusion is sought, will not result in the absorption of any lead into the human body nor have any other adverse impact on health or safety.

This memorandum provides the EXHR staff review of materials submitted by the Bicycle Product Suppliers Association in its request for exclusion of certain parts of bicycles and related products.

Product

The Association requests that certain parts of bicycles, jogger strollers, and bicycle trailers that are primarily intended for children aged 12 years and younger be excluded from the lead content limits of the CPSIA, specifically, components made with metal alloys, including steel containing up to 0.35 percent lead, aluminum with up to 0.4 percent lead, and copper with up to four percent lead.

Assessment

The Association included in its request an evaluation prepared by Gradient Corporation. The report presented an estimate of the 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; and an interpretation of the amount potentially taken up into the body, in the context of the statutory language.

The authors assessed contact with aluminum brake levers because children may contact that part of a bicycle, and copper (brass) tire valve stems because of the anticipated relatively high lead content of the brass.

The exposure measurement was a hypothetical assessment based on transfer of lead from the product component to the hands and subsequent hand-to-mouth transfers of lead. Because data do not exist specifically regarding children's contact with lead-containing parts of bicycles, the authors used data and information from other studies, including a study of hand contact with metal jewelry and a study of leaching of lead from faucets into a water-based solution. Exposure was estimated assuming specific areas of contact with the components, amounts of transfer of lead from the components to the hands, amounts of transfer of lead from hands to the mouth, and frequency of contact with the bicycle component parts. The calculations resulted in estimated lead intake of 0.015-0.05 micrograms of lead per day ($\mu\text{g}/\text{day}$), where intake means the amount of lead ingested by a child.

² "Children's Products Containing Lead; Final Rule; Procedures and Requirements for a Commission Determination or Exclusion," 74 Federal Register 10475 (11 March 2009), codified at 16 C.F.R. § 1500.90.

The authors concluded that for most parts of a bicycle, even accessible parts, contact by children is infrequent. They concluded that their assessment was based on conservative assumptions that likely overestimated exposure. They reported that intake of lead from bicycles would be well below background intake from food and water (*i.e.*, for a 6 year old, about 2.2 µg/day from food and 0.6 µg/day from water).

The authors stated that the statute would be reasonably interpreted by the scientific community to mean no measurable impact on blood lead level. Using the U.S. Environmental Protection Agency's Integrated Exposure Uptake Biokinetic Model (IEUBK) software, the authors estimated that intake at their estimated levels would not result in changes in blood lead level.

Staff Conclusion and Recommendation

The staff notes that the report is not based on actual measurements or analysis of bicycle component parts. The authors relied on data concerning metal jewelry and plumbing fixtures—materials that may or may not be sufficiently similar to bicycle components to serve as a reasonable basis for the evaluation.

Further, some of the data could be inappropriate for the analysis. Section 101(b)(3) of the CPSIA specifically states that paint, coatings, or electroplating may not be considered to be a barrier that would render lead in the substrate inaccessible to a child, *or to prevent absorption of any lead into the human body*, through normal and reasonably foreseeable use and abuse of the product [emphasis added]. The staff notes that the requestor's evaluation of lead exposure from bicycle components relied, in part, on data from a wipe study of metal jewelry. Electroplating is commonly used to finish jewelry made with lead-containing base metal. In fact, the authors recognized this in a footnote indicating that the investigator in the jewelry study might not have adequately controlled for cutting or scraping of jewelry pieces, which the authors claim would bias the results towards larger amounts of transferred lead to hands. Under section 101(b)(1)(A) of the CPSIA, the law also requires that aging of the product be considered in an evaluation, as well as normal and reasonably foreseeable use and abuse. Because the law does not allow electroplating to serve to prevent absorption of lead into the body, and because both aging and use may remove any benefit that electroplating might offer, the requestor's evaluation, relying in part on sampling of electroplated jewelry could underestimate the possible transfer of lead from the bicycle components to children using the products.

The requestor's supporting report indicated that children's use of bicycles could result in exposure to lead of approximately 0.015-0.05 µg/day, but that there would not be an increase in blood lead level as demonstrated by use of the IEUBK model software. The IEUBK³ software has several options for reporting results of the model computations. The "text file display" reports estimated blood lead levels for any given exposure scenario to the tenth of a microgram of lead per deciliter of blood (µg/dL). Thus, the model will indicate a difference between one exposure scenario and another when the change affects the estimate by at least one tenth of a µg/dL (*i.e.*, the first digit after the decimal point.) For example, one could discern the difference between two exposure scenarios that result in estimated blood lead levels of 2.5 µg/dL and 2.6 µg/dL. The software would not discern smaller differences, however; for example, 2.50 µg/dL and 2.54 µg/dL will both be reported in the text file output as 2.5 µg/dL. On the other hand, both

³ U.S. Environmental Protection Agency. 2007. Integrated Exposure Uptake Biokinetic (IEUBK) Windows 32-Bit Lead Model Version 1.0 Build 264.

the “distribution curve” and the “density curve” outputs of the software report the estimated geometric mean blood lead level to three decimal places. Choosing one of these output options shows that an exposure of an additional 0.05 µg/day results in an increase, albeit a quite small increase, in the estimated blood lead level. The staff notes that documentation included in the software referring to significant figures in inputs and outputs cautions that the “true precision of a calculation can be strongly influenced by the least precise input value.” The staff agrees, but further notes that, physiologically, if ingestion of lead occurs, some portion of the ingested lead will be absorbed into the body, whether or not the absorption results in a significant change in blood lead level as estimated by modeling software.

While the evaluation may be considered a reasonable attempt at assessing children’s lead exposure from bicycle component parts, given the lack of specific data, the strength of the conclusions is unclear. While some assumptions might overestimate lead exposure, other assumptions might underestimate exposure. The staff⁴ agrees with the report’s conclusion that contact with lead-containing parts would not be extensive, but the staff also believes that such contact is not inconceivable.

The request also asked that jogger strollers and bicycle trailers be granted an exclusion from the lead limits for the metal alloys, but did not address children’s foreseeable use and abuse of such products, or provide an assessment of possible lead exposure. Staff analysis of these products indicates that, as with bicycles, children’s use of jogger strollers and bicycle trailers may include contact with metal parts of the products.

The staff agrees that exposure to lead from bicycles and related products would likely be relatively low, *i.e.*, less than other sources of lead exposure, as estimated by the report’s authors.

The staff is aware that regulatory paradigms for lead in other products exist within other federal regulatory agencies. For example, in 2006, the U.S. Food and Drug Administration (FDA) issued guidance⁵ providing a recommended maximum lead level of 0.1 ppm in candy (equivalent to 0.1 µg/g). If, for example, a child consumed a piece of hard candy weighing 5 grams and containing lead at the recommended maximum level, the total intake of lead would be 0.5 µg. Although the requestor’s report did not specifically cite the FDA guidance, the report indicated that potential exposure to lead from use of bicycles would be well below intakes from food and water sources.

Prior to enactment of the CPSIA, the staff’s assessments of lead-containing children’s products, under the Federal Hazardous Substances Act (FHSA), were based on estimates of lead intake and the subsequent effects of the exposure on blood lead level, considering the toxicology of lead and the demonstrated health effects associated with increasing blood lead levels. Regulation of a consumer product as a “hazardous substance” under the FHSA requires assessment of exposure and risk from reasonably foreseeable use and abuse of the product. In this case, given the assessment provided by the requestor, the staff likely would have concluded that the estimated exposure to lead from children’s use of bicycles would have little impact on the blood lead level.

⁴ Memorandum from Celestine T. Kiss to Kristina M. Hattelid, “Human Factors Response to Request by Bicycle Product Suppliers Association for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act,” April, 2009.

⁵ Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), November 2006 (available at <http://www.cfsan.fda.gov/guidance.html>).

Accordingly, based on the staff's assessment, the staff would have recommended that the Commission not consider the product to be a hazardous substance to be regulated under the FHSA.

However, the CPSIA establishes the standard by which the staff evaluates the materials submitted with a request for exclusions. The law states that an exclusion may be granted if 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 or safety.

Because the requestor's report indicated that children's use of bicycles and related products could result in intake of lead, and therefore absorption, however small the absorbed amount, the staff's initial recommendation to the Commission is to not grant the request to exclude metal alloys used in bicycles and related products on the grounds that the statutory standard has not been met.



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Memorandum

Date: **MAY - 6 2009**

TO : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

THROUGH: Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction *RJH*
Hugh M. McLaurin, Associate Executive Director, Directorate for Engineering Sciences *H-M*

FROM : Celestine T. Kiss, Engineering Psychologist, Division of Human Factors, Directorate for Engineering Sciences *CTK*

SUBJECT : Human Factors Response to Request by Bicycle Product Suppliers Association for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act

Introduction

This memorandum provides the Human Factors staff response to the request by the Bicycle Product Suppliers Association in its request for exclusion of certain parts of bicycles and related products.

Product

The Association requests that certain parts of bicycles, jogger strollers, and bicycle trailers that are primarily intended for children aged 12 years and younger be excluded from the lead content limits of the CPSIA, specifically, components made with metal alloys, including steel containing up to 0.35 percent lead, aluminum with up to 0.4 percent lead, and copper with up to four percent lead. Such alloys are used in various components, including, but not limited to tire valve stems, spoke nipples, brake levers, and brake lever bushings.

Assessment

Section 101(b)(1) of the CPSIA provides that the Commission may exclude a specific product or material from the lead limits established for children's products under the CPSIA if the Commission, after notice and a 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 or safety.

CPSIA 6(b)(1) CLEARED for PUBLIC

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PRODUCTS IDENTIFIED~~

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WITH PORTIONS REMOVED:

Human Factors staff looked at the reasonably foreseeable use and abuse of metal parts on bicycles, jogger strollers, and bicycle trailers specifically mentioned in the request for exclusion to assess the likely interaction of the youth user and the parts.

Bicycles

According to the AGE DETERMINATION GUIDELINES: Relating Children's Ages to Toy Characteristics and Play Behavior (2002)¹, around 3 years of age, children develop the ability to pedal, and have the coordination required to use a steering wheel or handlebars. While they have not developed the balance required to operate two-wheeled scooters and bicycles, they can use four-wheeled vehicles (such as a bicycle with training wheels). Most children by the age of 5 years have the balance and coordination to use two-wheeled scooters and bicycles without training wheels. Six-year-olds have developed the coordination to use hand brakes.

Children 3 and 4 years of age are still engaging in some hand-to-mouth behavior and so it can be expected that some of these children will bring their hands to their mouths after touching the metal parts of the handle bar and frame on their bicycle. While children 5 years and older do not typically engage in hand-to-mouth behavior, it is not unreasonable to assume they may wipe their mouth or face with their hands while using or right after using their bicycle.

By 9 years of age, children are more independent and can take care of some of the maintenance required for operating a bicycle. Therefore, it is likely that they may attach a pump to the tire valve stem to inflate a tire. However, specifically touching the tire valve stem fittings and connectors made with copper (and brass) alloy is not really necessary and could occur on a more incidental basis while inflating the tire. However, when releasing tire air pressure, contact may be made with the fittings and connectors, if using the thumb and index finger to depress the tire valve stem. In addition, most bicycles come with caps that cover the top of the tire valve stem. Whether the cap is "child proof" or not, it must be removed to inflate the tire. During the process of removing and replacing the cap, there may be some incidental contact with the top of the valve stem. Typically consumers replace the cap to protect the valve stem, but, if the cap is discarded or lost there is more opportunity for contact.

Human Factors staff is not aware of any scientific data that measured how many times a child using a bicycle will contact the various metal parts of the vehicle, but, it is reasonable to assume that they will come in contact with various parts during the normal riding experience.

Bicycle Trailers

Bicycle trailers are generally intended to be used attached to an adult bicycle and to carry one or two children. Due to the wide variety of styles of trailers available, it is difficult to predict exactly what children who are riding inside will be able or likely to touch or not touch. Some models have exposed metal bars inside the trailer and other models have cloth coverings. Typically, bicycler trailers can hold up to 100 or more pounds, which means they are not intended strictly for infants and toddlers. Taking this into account, it would be reasonable to assume that older children (3 to 5 years) would be able to get in and out of the trailer themselves. If that is the case, it is also reasonable to assume that they will grab the side frame (i.e., metal frame bar) to help support them while getting in and out.

¹ Smith, T.S. (Ed.). (2002). AGE DETERMINATION GUIDELINES: Relating Children's Ages to Toy Characteristics and Play Behavior, U.S. Consumer Product Safety Commission, Bethesda, MD.

Jogger Strollers

Like bicycle trailers, jogger strollers are generally intended to carry one or two children. In addition, the wide variety of styles available makes it difficult to predict exactly what children who are riding inside will be able or likely to touch or not touch. Jogger strollers can also hold up to 100 or more pounds, which means they are not intended strictly for infants and toddlers. Taking this into account, it would be reasonable to assume that older children (3 to 5 years) would be able to get in and out of the stroller themselves. If that is the case, it is also reasonable to assume that they will grab the side frame (i.e., metal frame bar) to help support them while getting in and out. An additional issue with jogger strollers is that as soon as children start walking it is not unusual to see them pushing their own stroller. While they will not be using the brake lever, it is reasonable to assume they will be touching the frame. Because these children run the full spectrum of mouthing behavior, it is also likely they will have hand-to-mouth contact and even direct mouthing contact with accessible parts of the jogger stroller.

Staff Conclusion

It is Human Factors staff opinion that during normal bicycle use children 3 years and older will interact with the metal frame and handle bars of their bicycles. Children 6 years and older will interact with the brake lever. On a less frequent basis it is also likely older children (9 years and older) will interact with the tire valve stem. Therefore, during reasonable foreseeable use and abuse, they may have incidental contact with the valve stem fittings and connectors made with copper (and brass) alloys while inflating the tire. If they have to deflate the tire, they will have direct contact the tire valve stem fittings and connectors.

Bicycle trailers have a wide variety of designs and therefore, it is difficult to predict what children will be able to touch or not touch in the course of riding inside the trailer.

Jogger strollers are similar to bicycle trailers but have the added exposure to the metal handle bar because as children learn to walk they can be expected on occasion to also attempt to push the stroller.