



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

BALLOT VOTE SHEET

DATE: **APR - 1 2009**

TO: The Commission
 Todd A. Stevenson, Secretary

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

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

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

Ballot Vote Due: APR - 8 2009

Attached are the staff memoranda and initial recommendation on the requests from Specialty Vehicle Institute of America; Polaris Industries, Inc., American Suzuki Motor Corporation, Arctic Cat Inc., Bombardier Recreational Products Inc., Kawasaki Motors Corp., USA, American Honda Motor Co, Inc., and Yamaha Motor Corporation, USA; and the Motorcycle Industry Council (collectively ATV companies) 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 ATV companies' request for exclusion.

 (Signature)

 (Date)

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

 (Signature)

 (Date)

III. 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 Motorized Recreational Vehicle Firms and Associations dated April 1, 2009.

Human Factors Response to Request for Motorized Recreational Vehicles Group Request for Exclusion from Lead Limits under Section 101(b)(1)) of the Consumer Product Safety Improvement Act dated March 31, 2009.



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

Memorandum

Date: APR - 1 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 Sciences *KM*

SUBJECT : Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from Motorized Recreational Vehicle Firms and Associations

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.

Note: This document has not been reviewed or accepted by the Commission.
 Initials RH Date 4/1/09

CPSIA 6(b)(1) CLEARED for PUBLIC
 4/1/09
 NO FRMS PRIVILEGES OR PRODUCTS IDENTIFIED
 EXCEPTED BY: PETITION RULEMAKING ADMIN. PROCDG
 WITH PORTIONS REMOVED:

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 three groups of motorized recreational vehicle firms and associations, including the Specialty Vehicle Institute of America (SVIA); Polaris Industries, Inc., American Suzuki Motor Corporation, Arctic Cat Inc., Bombardier Recreational Products Inc., Kawasaki Motors Corp., USA, American Honda Motor Co, Inc., and Yamaha Motor Corporation, USA; and the Motorcycle Industry Council in their requests for exclusion of certain parts of youth all-terrain vehicles (ATVs), motorcycles, and snowmobiles.

Product

The groups request that certain parts of youth recreational vehicles be excluded from the lead content limits of the CPSIA, specifically, battery terminals containing up to 100 percent lead, and 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.

Specified components include: tire valve stems, fittings and connectors made with copper (and brass) alloys; brake and clutch levers and other brake components, throttle controls, engine housings, and carburetors made with aluminum alloys; and fasteners, frames, and structural or engine components made with steel alloys, among other components.

Assessment

The groups included in their requests 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 motorized recreational vehicle, and copper (brass) tire valve stems because of the anticipated relatively high lead content of the brass. The authors assumed that the products are for use by children aged 6-12 years.

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 motorized

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.

recreational vehicles, 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 motorized recreational vehicle 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.

The authors concluded that for most parts of a motorized recreational vehicle, 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 motorized recreational vehicles would be well below background intake from food and water (*i.e.*, for a 6 year old, about 2.2 $\mu\text{g}/\text{day}$ from food and 0.6 $\mu\text{g}/\text{day}$ from water).

The authors stated that the statute would be reasonably interpreted by the scientific community to mean no measurable impact on blood lead. 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 motorized recreational vehicle component parts. The authors relied on data concerning metal jewelry and plumbing fixtures—materials that may or may not be sufficiently similar to motorized recreational vehicle 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 requestors' evaluation of lead exposure from motorized recreational vehicle 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 requestors' evaluation, relying in part on sampling of electroplated jewelry could underestimate the possible transfer of lead from the motorized recreational vehicle components to children using the products.

The requestors' supporting report indicated that children's use of motorized recreational vehicles could result in exposure to lead of approximately 0.015-0.05 $\mu\text{g}/\text{day}$, 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 ($\mu\text{g}/\text{dL}$). 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 $\mu\text{g}/\text{dL}$ (*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 $\mu\text{g}/\text{dL}$ and 2.6 $\mu\text{g}/\text{dL}$. The software would not discern smaller differences, however; for example, 2.50 $\mu\text{g}/\text{dL}$ and 2.54 $\mu\text{g}/\text{dL}$ will both be reported in the text file output as 2.5 $\mu\text{g}/\text{dL}$. On the other hand, both 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 $\mu\text{g}/\text{day}$ 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.

One of the requested exclusions is battery terminals, although battery terminals were not specifically assessed in the evaluation. Given that physical contact with bare lead would likely result in transfer of some lead to the skin, which could then be transferred to a child’s mouth either directly or indirectly, such as during eating, if a child occasionally came into contact with battery terminals, however infrequent, some exposure to lead could occur.

While the evaluation may be considered a reasonable attempt at assessing children’s lead exposure from motorized recreational vehicle 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 staff 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 staff agrees that exposure to lead from motorized recreational vehicles 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 guidance⁴ providing a recommended maximum lead level of 0.1 ppm in candy (equivalent to 0.1 $\mu\text{g}/\text{g}$). 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 motorized recreational vehicles would be well below intakes from food and water sources.

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

⁴ 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>).

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 requestors, the staff likely would have concluded that the estimated exposure to lead from children's use of motorized recreational vehicles would have little impact on the blood lead level. 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 requestors' report indicated that children's use of motorized recreational vehicles 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 on the grounds that the statutory standard has not been met.



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Memorandum

Date: March 31, 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 *HMM*

FROM : Celestine T. Kiss, Engineering Psychologist, Division of Human Factors, Directorate for Engineering Sciences *CK*
Sarah B. Brown, Engineering Psychologist, Division of Human Factors, Directorate for Engineering Sciences *SB*

SUBJECT : Human Factors Response to Request for Motorized Recreational Vehicles Group Request 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 for certain metal parts on motorized recreational vehicles to be excluded from lead limits submitted by three groups of motorized recreational vehicle firms and associations, including the Specialty Vehicle Institute of America (SVIA); Polaris Industries, Inc., American Suzuki Motor Corporation, Arctic Cat Inc., Bombardier Recreational Products Inc., Kawasaki Motors Corp., USA, American Honda Motor Co, Inc., and Yamaha Motor Corporation, USA; and the Motorcycle Industry Council.

Product

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Specified components include: tire valve stems, fittings and connectors made with copper (and brass) alloys; brake and clutch levers and other brake components, throttle controls, engine housings, and carburetors made with aluminum alloys; and fasteners, frames, and structural or engine components made with steel alloys, among other components.

CPSA 6(b)(1) CLEARED for PUBLIC
NO MFRS/PRVTBLRS OR PRODUCTS IDENTIFIED *6/1/09*

EXCEPTED BY: PETITION
RULEMAKING ADMIN. PRCDG

WITH PORTIONS REMOVED: _____

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.

Human Factors staff looked at the reasonably foreseeable use and abuse of metal parts specifically mentioned in the request for exclusion to assess the likely interaction of the youth user and the parts. First and foremost, in the regular use of the product, users will have to touch the brake and clutch levers and the throttle controls. It is reasonable to assume that children will not be washing their hands immediately after touching these parts. Average users (6 – 12 year olds) do not typically engage in hand-to-mouth behavior, however, it is not unreasonable to assume they may wipe their mouth or face with their hands while using or right after using the recreational vehicle.

Some instruction manuals and training classes recommend that children not engage in vehicle maintenance; rather this should be done by an adult or trained mechanic. Therefore, the likelihood of youths interacting with the other metal parts specifically mentioned in the request is more likely to be on an incidental basis. While the youths may attach a pump to the tire valve stem to inflate a tire, specifically touching the tire valve stem fittings and connectors made with copper (and brass) alloy is not really necessary or very likely for the maintenance of the tire. Human Factors staff is not aware of any scientific data that measured how many times a child using a motorized recreational vehicle will contact the various metal parts of the vehicle, but, it is reasonable to assume that on occasion they may come in contact with them.

The CPSIA required that all youth All-Terrain Vehicle (ATV) sales be discontinued due to the lead content of some component parts. However, youth ATVs were introduced to encourage parents to purchase and children to ride appropriately sized ATVs. The CPSC staff has previously stated that the risk of injury increases when a child rides an adult ATV as opposed to a non-adult ATV (Levenson, 2004)¹. The elimination of youth ATV sales will most likely increase the number of adult ATVs purchased to be used by younger children; therefore increasing their risk of injury and death.

Staff Conclusion

It is Human Factors staff opinion that during normal use, youth recreational vehicle users will interact with the metal brake and clutch levers and the throttle controls. On a less frequent basis it is also likely youth users will interact with the tire valve stem, but not necessarily the valve stem fittings and connectors made with copper (and brass) alloys. The other component parts (i.e., engine housings, carburetors made with aluminum alloys, fasteners, frames, and structural

¹ Levenson, M. S. (2004). *ATV Risk Estimates for Youths*. Washington DC: US Consumer Product Safety Commission.

or engine components made with steel alloys, among other components) may not be routinely touched, but when the youth is riding the vehicle they have access to those parts.

A bigger safety concern than lead exposure is that the elimination of youth ATV sales will most likely increase the number of adult ATVs purchased to be used by younger children; therefore increasing their risk of injury and death.