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

**BALLOT VOTE SHEET**

**DATE:** MAY 2 2 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 HSK

**SUBJECT:** Request from the Writing Instrument Manufacturers Association for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act (CPSIA)

**Ballot Vote Due:** JUN - 2 2009

Attached are the staff memoranda on the Writing Instrument Manufacturers Association (WIMA) request for an exclusion of ball point pen tips under section 101(b)(1) of the CPSIA.

Please indicate your vote on the following options.

A. Request for Exclusion

I. Deny WIMA's request for exclusion.

_____ _____
(Signature) (Date)

II. Grant WIMA's request for exclusion.

_____ _____
(Signature) (Date)

CPSA 6(b)(1) CLEARED for PUBLIC RL 5/22/09
NO MFRS/PRVTLBLRS OR PRODUCTS IDENTIFIED
EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCDG
WITH PORTIONS REMOVED: _____



Note: This document has not been reviewed or accepted by the Commission.
Initials RF Date 5/22/09

B. Stay of Enforcement

I. If vote is to deny WIMA's request for exclusion or the vote results in no action due to a one-one tie, direct the staff to draft a stay of enforcement of the section 101(b)(1) lead limits for ball point pens that are children's products.

_____ _____

(Signature) (Date)

II. If vote is to deny WIMA's request for exclusion or the vote results in no action due to a one-one tie, do not direct the staff to draft a stay of enforcement of the section 101(b)(1) lead limits for ball point pens that are children's products.

_____ _____

(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 the Writing Instrument Manufacturers Association.

Human Factors Response to Request from the Writing Instrument Manufacturers Association for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act.

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

**Memorandum**

Date: MAY 22 2009

TO : The Commission
Todd A. Stevenson, Secretary

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

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

SUBJECT : Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from the Writing Instrument Manufacturers 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 absorption[1] 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 term exposure is 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) CLEARED for PUBLIC 5/22/09
__NO MFRS/PRVTLBLRS OR PRODUCTS IDENTIFIED
X
__EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCDG
__WITH PORTIONS REMOVED: _____

Note: This document has not been reviewed or accepted by the Commission.
Initials KH Date 5/22/09

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

By rule[2], 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 Writing Instrument Manufacturers Association in its request for exclusion of a part of ball point pens.

Product

The Association requests that the tip of a ball point pen that holds the ball be excluded from the lead content limits of the CPSIA. Brass tips contain 2.5 to 5 percent lead; the more expensive stainless steel or nickel silver tips contain 0.1 to 2 percent lead. The Association indicates that there is no available substitute for this part of a pen and that it would take two or more years to develop possible substitutes. The request indicates that retractable and stick ball point pens are about 95 percent of the pens sold for use in schools or by children, and about 85 percent of all pens.

Assessment

The Association included in its request a peer-reviewed evaluation prepared by Woodhall Stopford, MD, MSPH and Danielle Cappellini, B.Sc., MHA. The report presented an analysis of the amount of lead released from the part and the potential for exposure and absorption by a child.

The assessment consisted of measuring leaching of lead from ball point pen tips into sweat or saliva simulants, which would be relevant to skin contact with the product and mouthing of the pen tip. Most of the measurements were below the limit of detection for the method and instrumentation. Based on results of detectable leaching of lead from some pen samples, and applying other assumptions, the authors estimated that skin contact with the exposed portion of a pen tip for one minute would amount to absorption through the skin of less than 0.00000004 micrograms (μg) of lead; similarly, the authors estimated that mouthing a pen tip for one minute would result in absorption of less than 0.012 μg of lead.

The authors conclude that because contact with pen tips is expected to be incidental the actual absorption of lead would be much less than the estimates, and would, in fact, not be detectable. Thus, they assert that ball point pens would not pose a public health risk.

[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.

Staff Conclusion and Recommendation

The staff believes that the assessment approach is generally sound. However, the authors did not assess exposure that may occur from handling the product with subsequent hand-to-mouth transfer of lead. The authors' simulated sweat leaching and dermal absorption assessment does not account for lead that could be removed from the surface of the part from touching or rubbing. On the other hand, exposure estimates for this route of exposure might not have substantially altered the report's conclusion given the small amount of lead that would likely be available on the surface of the pen tip.

The authors also misreported the results of an observational mouthing study[3], by claiming that "from the age of 5-12 no mouthing of objects could be detected in any hour." Table 4 of this study showed that for the age groups including 5-12 year olds the *median* rate of mouthing of objects was zero, but the *mean* activity rate was one object-to-mouth contact per hour.

Despite its shortcomings, the evaluation may be considered a reasonable attempt at assessing children's lead exposure from ball point pen tips. However, it leaves unresolved whether absorption of any lead into the body would occur from children's contact with the pens. The staff agrees with the report's conclusion that contact with the lead-containing part would not be extensive, but the staff[4] also believes that such contact is not inconceivable.

Although the requestor's supporting analysis did not attempt to quantify what they think would be expected exposures to lead from children's use of ball point pens, the report indicated that absorption of lead from children's use of pens would be less than 0.00000004 - 0.012 μg of lead from skin contact and mouthing, explaining that this level of potential exposure would be undetectable. While the staff agrees that absorption of lead from ball point pen tips would likely be low, as estimated by the report's authors, the data indicate that lead may leach from the product, and that children may be exposed to the lead, and consequently that absorption of some lead could occur.

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 guidance[5] 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 Association's report did not refer to any specific example of regulations or guidance concerning lead exposure, the evaluation concluded that children's exposure to lead from pens would not be detectable and would not be a public health risk.

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

---

[3] Freeman NC, Jimenez M, Reed KJ, Gurunathan S, Edwards RD, Roy A, Adgate JL, Pellizzari ED, Quackenboss J, Sexton K, Lioy PJ. 2001. Quantitative analysis of children's microactivity patterns: The Minnesota Children's Pesticide Exposure Study. J Expo Anal Environ Epidemiol 6: 501-509.

[4] Memorandum from Celestine T. Kiss to Kristina M. Hatlelid, "Human Factors Response to Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from the Writing Instrument Manufacturers Association," 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).

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 pens 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 requestor's report indicated that children's use of ball point pens could result in absorption of lead, 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.

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

**Memorandum**

Date: MAY 22 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
Hugh M. McLaurin, Associate Executive Director, Directorate for Engineering Sciences

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

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

Introduction

This memorandum provides the Human Factors staff response to the request by the Writing Instrument Manufacturers Association Product for exclusion of a part of ball point pens.

Product

The Association requests that the tip of a ball point pen that holds the ball be excluded from the lead content limits of the CPSIA. Brass tips contain 2.5 to 5 percent lead; the more expensive stainless steel or nickel silver tips contain 0.1 to 2 percent lead. The Association indicates that there is no available substitute for this part of a pen and that it would take two or more years to develop possible substitutes. The request indicates that retractable and stick ball point pens are about 95 percent of the pens sold for use in schools or by children, and about 85 percent of all pens.

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 the tip of a ball point pen that holds the ball mentioned in the request for exclusion to assess the likely interaction of children users and pens.

*Age of user*

According to the AGE DETERMINATION GUIDELINES: Relating Children's Ages to Toy Characteristics and Play Behavior (2002)[1], around 12 months of age, children are expansively exploring the world through all of their senses: seeing, hearing, touching, tasting, and smelling. They scribble either by imitation or spontaneously, and can make circular marks. Suitable materials are appropriately sized to children's grips, and are lightweight but sturdy. Large easy-to-grip crayons and markers are appropriate for these children. By 2 years of age, their fine-motor movements are becoming more skillful, and they are still using large easy-to-grip crayons and markers. It is not until children are around 5 years of age when thinner-diameter, adult-sized crayons and color pencils begin to be usable.

While ballpoint pens are not specifically mentioned in the age determination guidelines, it is reasonable to assume that children will be exposed to pens in addition to crayons and markers. Since pens are not typically considered "washable," they are not generally the first choice when giving a young child a writing instrument.

Anecdotal evidence suggests that children around 4$^{th}$ grade (9 and 10 years of age) begin using pens for final school work, but that is dependent on the teachers' preferences and discretion.

*Pen design/appeal*

Pens come in all shapes, sizes, and decorations, making it difficult to distinguish which ones would be primarily intended for children 12 years of age and younger. However, there are some features that could be evaluated to make initial assessments.

The advertising and marketing of products with themes that correspond to obvious children's interests, e.g., preschool characters, will greatly influence the purchase for preschool children. While researching this issue, Human Factors staff observed pens that were clearly marketed to young children. Those pens had cartoon characters associated with preschool programs, fat barrels, and were brightly colored. There were also pens with plush animals on top and animal-shaped notebooks sold with a matching stick pen with a fuzzy top. Both of these would appeal to young children.

Staff also found pens that would likely appeal to pre-teenage children. For example, there were a wide variety of pens decorated with characters from a very popular pre-teen movie. In those cases, the pens were clearly targeted to children 12 years of age and younger.

However, there were also "novelty" pens that could appeal to children 12 years and younger as well as older children and adults. For example, a simple ball point stick pen with the name of an

[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.

elementary school embossed on it without any other decorations. This would likely appeal to anyone (e.g., students, teachers, parents) connected with the school. A pen with a silly head on the top, not associated with any particular mass media, would have just as much appeal to adults as it would to children. Pens with puzzle features that allow the user to take it apart and reconfigure the design are also likely to appeal to children and adults alike.

*Pen grip/behavior*

In addition to determining if a pen is "primarily intended" for children 12 years of age and younger, how children hold a pen is important for assessing exposure. According to occupational therapist Jan Z. Olsen, founder and developer of the Handwriting Without Tears® program[2], children should be taught to hold a pencil using a small crayon or pencil. This teaches the child to hold the writing instrument close to the tip in order to have better control and proper grasp. Documents on this website show the users' fingers posed approximately one-half-inch away from the tip of the pencil. Assuming the average consumer uses this type of grip, the likelihood of actually contacting the tip of a ballpoint pen that holds the ball during normal writing is probably low. The most likely scenario in which children would actually touch the tip of the ball is when they are actually writing on themselves, either on purpose or by mistake. For young children learning to write, experimenting with writing instruments most certainly will include writing on themselves. It is not unlikely that these children will put pens in their mouths also, but, parents are likely to teach them not to put the writing end in their mouth if children are observed doing so. School age children and adults have also been known to write reminders on themselves and their friends.

Staff Conclusion

It is Human Factors staff opinion that during normal and reasonably foreseeable use, children 12 years of age and younger will have access to, and likely use ball point pens. However, it is difficult to distinguish pens that are primarily intended for children 12 years of age and younger from adult pens. The marketing and advertising of pens must be taken into consideration when making such a determination. Themes that are associated with preschool and elementary age children's interests are likely to be purchased for and used by those children. Pens that have unique and generic themes, e.g., silly faces, hair, puzzles, are likely to appeal to children and adults.

During normal and reasonably foreseeable use, chances of children actually touching the tip of the ball of the pen are low unless they are writing on themselves.

[2] Handwriting Without Tears® website: www.hwtears.com