



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

**BALLOT VOTE SHEET**

**DATE: DEC 24 2008**

**TO:** The Commission  
 Todd A. Stevenson, Secretary

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

**FROM:** Hyun S. Kim, Attorney, OGC

**SUBJECT:** Children's Products Containing Lead; Notice of Proposed Procedures and Requirements for a Commission Determination or Exclusion

**Ballot Vote Due:** JAN - 5 2009

Attached is a staff memorandum "Consumer Product Safety Improvement Act of 2008 (CPSIA) Exclusions from Compliance with Limits for Lead, Certain Materials or Products: Required Technical Information," that sets forth the technical information that may be required by staff to evaluate a specific product or material requesting (1) a formal determination from the Commission that the particular material or product does not and would not exceed the applicable lead limit under section 101(a) of the CPSIA, or (2) an exclusion under section 101(b)(1) of the CPSIA. By separate (restricted) memorandum the Office of the General Counsel is providing a draft Federal Register notice of proposed rulemaking on proposed procedures and requirements for a determination or exclusion.

Please indicate your vote on the following options.

- I. Approve publication of the draft proposed rule in the *Federal Register* without change.

\_\_\_\_\_  
 (Signature)

\_\_\_\_\_  
 (Date)

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

NO MFERS/PRVTLBLS OR  
 PRODUCTS IDENTIFIED

EXCEPTED BY: PETITION  
 RULEMAKING ADMIN. PRCDG

WITH PORTIONS REMOVED

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

Note: This document has not been reviewed or accepted by the Commission.  
 Initials *rh* Date *12-24-08*

II. Do not approve publication of the draft proposed rule in the *Federal Register*.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

III. Publish the draft proposed rule in the *Federal Register* with changes.  
(Please specify.)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Attachment: Staff Memorandum: *Consumer Product Safety Improvement Act of 2008 (CPSIA)*  
*Exclusions from Compliance with Limits for Lead, Certain Materials or Products: Required*  
*Technical Information*



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

Memorandum

Date: DEC 23 2008

TO : The Commission  
Todd A. Stevenson, Secretary

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

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

SUBJECT : Consumer Product Safety Improvement Act of 2008 (CPSIA) Exclusions from  
Compliance with Limits for Lead, Certain Materials or Products: Required  
Technical Information

Introduction

Subsection 101(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) establishes, as of February 10, 2009 (180 days after the enactment of the Act), a limit for lead of 600 parts per million (600 ppm) by weight in any part of a children's product<sup>1</sup>. Lead content of any part of a children's product is limited to 300 ppm as of August 14, 2009 (one year after the enactment of the Act), and subsequently to 100 ppm as of August 14, 2011, if technologically feasible.

Subsection 101(b)(1) provides that the Commission may, by regulation, exclude a specific product or material from the lead content limits 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 not result in the absorption of any lead into the body, taking into account normal and reasonably foreseeable use and abuse by a child, nor have any other adverse impact on health or safety.

In addition, under the general rulemaking authority under section 3 of the CPSIA, the Commission could make a formal determination as to the likelihood or lack thereof that a particular material or product does not and would not exceed the applicable lead limit.

This memorandum describes the technical information that may be required for evaluation of a specific product or material on either of these bases.

<sup>1</sup> "Children's product" means a consumer product designed or intended primarily for children 12 years of age or younger as defined in the Consumer Product Safety Act as amended by the CPSIA section 235.

CPSA 6(b)(1) CLEARED for PUBLIC  
NO MFERS/PRVTBLRS OR  
PRODUCTS IDENTIFIED  
12/24/08

EXCEPTED BY: PETITION  
RULEMAKING ADMIN. PRCDG

Note: This document has not been  
reviewed or accepted by the Commission.  
Initials *ra* Date *12-24-08*

## Discussion

### *Products and Materials that Do Not Exceed the Lead Content Limits – Inherent Lead Content Level Determination*

Certain products or materials inherently do not contain lead or contain lead at levels that do not and would not exceed the CPSIA lead limits. Interested parties may wish to seek a formal determination by the Commission to that effect for a specific product or material.

The staff recommends that a request for a determination that a product or material does not and would not exceed the lead limits specified under the CPSIA should be supported by reliable test results or other scientific evidence based on objectively reasonable and representative testing showing that the product or material does not, and would not, under reasonably foreseeable conditions exceed the lead limits. A justification submitted by an interested party for such a determination should include a detailed description of the product or material; data on the lead content of parts of the product or materials used in the production of a product; data or information on manufacturing processes through which lead may be introduced into the product or material; any other information relevant to the potential for lead content of the product or material to exceed the CPSIA lead limits; and detailed information on the relied upon test methods for measuring lead content of products or materials or assessing manufacturing processes.

### *Products and Materials that Exceed the Lead Content Limits*

Subsection 101(b)(1) provides that the Commission may, by regulation, exclude a specific product or material from the lead content limits 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 not result in the absorption of any lead into the body, taking into account normal and reasonably foreseeable use and abuse by a child, nor have any other adverse impact on health or safety. Therefore, a request for an exemption under section 101(b)(1) of the CPSIA of a product or material that contains lead at a level that exceeds the CPSIA lead limits must be accompanied by the best-available, objective, peer-reviewed, scientific evidence that addresses these issues, such as test results indicating how much lead is present in the product, how much lead comes out of the product and the conditions under which that may happen, and information relating to a child's interaction, if any, with the product.

## Staff Recommendation

CPSC staff recommend that the Commission publish in the Federal Register a process by which interested parties may request either 1) a determination that a specific material or product does not and would not contain lead or exceed the lead content limits, or 2) an exemption under section 101(b)(1) of the CPSIA of a product or material that contains lead at a level that exceeds the CPSIA lead limits. Staff recommends that the Commission specify certain data and information that should be submitted that would provide justification for the Commission's determinations.



UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
WASHINGTON, DC 20207

**Memorandum**

Date: 23 December 2008

TO : Kristina Hatlelid, Ph.D. , Project Manager, HS

FROM : Gregory B. Rodgers, Ph.D., AED, EC *GBR*  
Robert Franklin, EC *RF*

SUBJECT : Procedures for Determinations Regarding Lead Limits and Procedures for Exclusions from Lead Limits Under Section 101 of the Consumer Product Safety Improvement: Small Business and Environmental Impacts

On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. Subsection 101(a) of the Act establishes, as of February 10, 2009, a lead limit of 600 parts per million (ppm) by weight for any part of a children's product. Lead content is thereafter limited to 300 ppm as of August 14, 2009, and 100 ppm as of August 14, 2011, if technologically feasible.

The Commission is considering a notice of proposed procedures and requirements that would allow manufacturers to request a formal determination from the Commission that a product or material does not or cannot contain lead in excess of the limits established by the CPSIA. Additionally the procedures and requirements establish means for manufacturers to request that the Commission consider a regulation that would exclude a specific product or material that exceeds the lead limits established by the CPSIA, but which would not result in the absorption of any lead in the human body or result in any other adverse health impacts. A formal determination by the Commission that a product or material does not contain lead in excess of the legal limits or a regulation excluding the product or material from the requirements of Section 101 because it will not result in any absorption of lead would reduce the conformance testing burden on manufacturers and importers that is required under Section 102 of CPSIA.

**Small Business Impacts**

The procedures and requirements would only impact those firms that wish to seek a formal Commission determination that a product or material does not contain lead in excess of the limits established by the CPSIA or that wish to seek an exclusion from the requirements because the lead in the product or material would not result in any absorption into the human body. It would be expected that any manufacturer that takes advantage of these procedures and requirements would be knowledgeable about the characteristics and use of the product or material for which the determination or exclusion was sought and, therefore, could easily obtain the information required to support the request. Moreover, the only firms that would request such a determination or exclusion are those that expected the potential benefits of receiving the

determination or exclusion (i.e., reduced testing costs) would exceed the costs of making the request. Consequently, the Commission could certify that this action will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### **Environmental Considerations**

The National Environmental Policy Act requires that the Commission consider the impact of its actions on the environment. The procedures and requirements under consideration only set out the procedure that companies must follow if they wish to request a formal Commission determination that a product or material does not contain lead in excess of the limits established by the CPSIA or an exclusion from the requirements of Section 101 of the CPSIA and the information and evidence that must be submitted in support of the request. This rule does not fall into the categories of actions described in the CPSC environmental review regulations as having the potential to produce environmental effects (16 CFR 1021.5) and is in fact highly unlikely to produce an environmental effect.

### **Paperwork Reduction Act Considerations**

Since the rule would result in a collection of information from some manufacturers it is subject to the requirements of the paperwork reduction act. The number of manufacturers or importers that might seek a determination that their products or materials do not contain lead or that might seek an exemption from the lead-content requirements for their products is not known and cannot be estimated reliably. Because the requirements for obtaining a determination that a product does not contain lead or would not result in any adverse health consequences are high, it might be expected that the number of firms seeking such determinations would be low. However, because a very broad range of products, materials and components are affected by the lead content limits, the number of firms seeking such determinations could be higher than expected.

It would be expected that the firms that seek a determination would be familiar with the product or material for which the determination is sought and the required information should already be in the firm's possession or easily obtainable. However, it could take several days for the company to assemble the information into the proper format for submitting it to the Commission. This work would probably be performed or overseen by a senior level management employee. If it typically takes about 40 hours to assemble and prepare the submission and the employee compensation is about \$60 an hour,<sup>1</sup> the average cost of preparing a submission would be about \$2,400.

Consumer Product Safety Commission (CPSC) staff will have to review each submission and make a recommendation as to whether the request should be granted or denied. If it takes

---

<sup>1</sup> Based on the median annual earnings of managers specializing in research and development in physical, engineering, and life sciences (Occupational Outlook Handbook, 2008-2009 Edition, U.S. Department of Labor, Bureau of Labor Statistics . Available at <http://www.bls.gov/oco/ocos009htm#earnings> [accessed 23 December 2008].

CPSC staff 40 hours to review and evaluate each submission at an average hourly wage of \$56,<sup>2</sup> then the average cost of the CPSC review of the submissions will be about \$2,240.

As noted above, the number of submissions that will be received cannot be estimated reliably. If 250 submissions are received, the cost of the submissions will be about \$1,160,000. This includes both the cost to the firms submitting the requests and the cost to the CPSC of reviewing the submissions.

---

<sup>2</sup> Based on the hourly wage of a GS-14 step 5 employee in the Washington, DC metropolitan area