

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

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

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed procedures and requirements

SUMMARY: On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. The Commission proposes to establish procedures and requirements for: (1) a Commission determination that a commodity or class of materials or a specific material or product does not exceed the lead content limits specified under section 101(a) of the CPSIA; or (2) an exclusion of a commodity or class of materials or a specific material or product under section 101(b), that exceeds the lead content limits under section 101(a), but which will not result in the absorption of any lead into the human body nor have any other adverse impact on public health or safety. This notice sets out and solicits comments on proposed procedures and requirements and information to be supplied with such requests.

DATE: Written comments and submissions in response to this notice must be received by [insert date that is 30 days after publication].

ADDRESSES: Comments on the proposed procedures and requirements for Commission determinations that specific materials or products do not exceed the lead content limits should be e-mailed to Sec101Determinations@cpsc.gov.

Comments should be captioned "Section 101(a) Determinations." Comments on the proposed procedures and requirements for Commission decisions on requests for exclusions under section 101(b) should be e-mailed to Sec101Exclusions@cpsc.gov. Comments should be captioned "Section 101(b) Exclusions." Comments may also be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814, or delivered to the same address (telephone (301) 504-7923). Comments also may be filed by facsimile to (301)504-0127.

Comments on the Paperwork Reduction Act burdens posed by these proposals should be directed to the Desk Officer for the Consumer Product Safety Commission, Office of Information and Regulatory Affairs, OMB, Washington, DC 20503. The Commission asks commenters to provide copies of such comments to the Commission's Office of the Secretary,

with a caption or cover letter identifying the materials as comments submitted to OMB on the proposed collection of information requirements in the proposed procedures and requirements under sections 101(a) and (b) of the CPSIA.

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The CPSIA establishes specific limits on lead in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm unless the Commission determines that it is not technologically feasible to have this lower limit. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child.

B. Legal Considerations

1. Materials or products that do not exceed the lead limits.

Under section 101(a) of CPSIA, consumer products designed or intended primarily for children 12 years old and younger that do not contain more than 600 ppm of lead (as of February 10, 2009), 300 ppm of lead (as of August 14, 2009); 100 ppm after three years (as of August 14, 2011), unless the Commission determines that it is not technologically feasible to have this lower limit, are not considered to be banned hazardous substances under the Federal Hazardous Substances Act (FHSA). However, in the absence of Commission action, children's products remain subject to the testing requirements of section 102 of the CPSIA (codified at § 14 of the Consumer Product Safety Act (CPSA)).

Under these provisions, for children's products manufactured on and after February 10, 2009, general conformity certificates certifying that they comply with the applicable lead content limit are required. The certification must be based on tests of each product or a reasonable testing program. On and after August 14, 2009, absent Commission action to the contrary, the certificates must be based on testing performed by a third-party laboratory whose accreditation to perform the testing has

been accepted by the Commission. Comments submitted to the Commission suggest that these testing and certification requirements will result in significant expense for products that may be inherently free of lead or dangerous lead levels.

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. There may be certain commodities or classes of products or materials that inherently do not contain lead or contain lead at levels that would not exceed the lead content limits under section 101(a) of the CPSIA. To the extent that such materials or products exist, the Commission, either of its own initiative or upon the request of an interested person, is proposing to exercise its CPSIA section 3 authority to make determinations that certain commodities or classes of material or products do not exceed the lead limits of section 101(a). This rule proposes a procedure by which the Commission will address requests for determinations that these types of materials or products do not and would not exceed the lead limits. The effect of such a Commission finding would be to relieve that material or product from the testing requirement of section 102 for purposes of supporting the required certification.

If this proposal is issued in final form, the Commission would concentrate its efforts on evaluating those materials that are commodity-like, are used across industry in a number of applications, and are subject to detailed consensus standards related to lead content and other pertinent properties. Given the Commission's resources, requests to evaluate individual products of a single manufacturer would be assigned a very low priority.

Of course even where a material or product has been so relieved of the testing requirement, it must still meet the statutory lead level requirements in actual fact. The Commission will obtain and test products in the marketplace to assure that this remains the case and will take appropriate enforcement action in situations where that is not the case.

2. Materials or products that exceed the lead limits.

The Commission is also proposing procedures to address requests for exclusions for certain products or materials that exceed the lead content limits in section 101(a). Section 101(b)(1) of the CPSIA provides that the Commission may, by regulation, exclude a specific product or material that exceeds the lead limits established for children's products under section 101(a) 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.

Under section 101(b) of the CPSIA, the Commission is required to provide notice and a hearing to consider and evaluate the best-available, objective, peer-reviewed, scientific data before promulgating a rule on exclusions. Section 553 of the Administrative Procedure Act (APA), provides that after notice, the agency must give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. 5 U.S.C. 553(c). Section 101(b) does not require a "hearing on the record," which would trigger more extensive procedural requirements under the APA. Accordingly, for this matter the Commission has determined that an oral hearing is not necessary to satisfy the requirements of due process.¹

¹ The Supreme Court has held that paper hearing procedures are adequate where, in the total context of the

Given the highly technical nature of the information sought--peer-reviewed, scientific data--the Commission believes that the APA notice and comment procedures based on written submissions would provide the most efficient process for obtaining the required information as well as provide adequate opportunity for all interested parties to participate in the proceedings.

C. Procedures and Requirements

1. Inherent lead content level determination

Any request for a Commission determination that a specific material or product contains no lead or a lead level below the applicable statutory limit must be supported by objectively reasonable and representative test results or other scientific evidence showing that the product or material does not, and would not, exceed the lead limit specified in the request.

A justification submitted by an interested party for a determination must include a detailed description of the product or material; data on the lead content of parts of the product or the materials used in the production of a product; data or information on manufacturing processes

process, they are deemed to ensure adequate notice and a genuine opportunity to explain one's case. *Mathews v. Eldridge*, 424 U.S. 319, 334-35 (1976). See also *United States v. Florida East Coast Railway Co.*, 410 U.S. 224, 238-41(1973).

through which lead may be introduced into the product or material; any other information relevant to the potential for the lead content of the product or material to exceed the statutory lead limit specified in the request, that is 600 ppm, 300 ppm, or 100 ppm, as applicable; and detailed information on the test methods used to support such data, including the type of equipment used and any other techniques employed, as well as a statement as to why the data is representative of the lead content of such products or materials generally and why the assessment of the manufacturing processes strongly supports a conclusion that they would not be a source of lead contamination of the product or material, if relevant. MSDS sheets will not be sufficient to satisfy the representative testing criteria because they do not show sufficient information regarding lead content. Rather, the showing necessary to obtain an exclusion must be based on objectively reasonable and representative testing of the material or product.

As noted above, given the potential number of requests for determinations that might be submitted to the Commission, the Commission would evaluate industry-wide applications for commodities or classes of materials or products based on technical specifications or other data suggesting that the generic commodity or class of materials

is representative of that used by a number of manufacturers before it will review any brand specific products or proprietary formulas from individual manufacturers. The type of materials or product classes that the Commission considers may fall within the class for priority evaluation might include, but not be limited to, materials such as paper, vegetable dyes, inks, adhesives, fabrics, and the like, provided that adequate documentation of the technical specifications of the materials or products such that they are representative of a broad class and testing data is provided as to those generic products. In time, the Commission would apply the same criteria on a product by product or material by material basis, if necessary, and provided it has the resources to do so.

Upon receipt of a complete request for a determination, the Commission proposes to direct the Office of Hazard Identification and Reduction to assess the request and make an initial determination. If the recommendation is to grant the exclusion, the Commission will publish a notice of proposed rulemaking inviting public comment on whether the determination should be granted in final form, and the Office of Hazard Identification and Reduction will review and evaluate the comments and supporting documentation before making its

recommendation to the Commission for final agency action.

2. Exclusion of a material or product exceeding lead content limit

For products that exceed the lead content limits prescribed in section 101(a) of the CPSIA, the Commission proposes procedures that will allow the Commission to evaluate products or materials for possible exclusions under section 101(b)(1) of the CPSIA. Under this section, such evaluations must be based on the best-available, objective, peer-reviewed, scientific evidence showing that lead in such product or material will not result in the absorption of any lead into the body, taking into account normal and reasonable foreseeable use and abuse by a child, nor have any other adverse impact on health or safety. Therefore, a request for an exclusion must be supported by the best-available, objective, peer-reviewed, scientific evidence that address 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.²

² The Commission notes that the statutory language of section 101(b)(1) makes it difficult to make a showing that would be adequate to exclude any material or product on that basis.

Upon receipt of a complete exclusion request, the Commission proposes to direct the Office of Hazard Identification and Reduction to assess the request and make an initial determination. If the recommendation is to grant the exclusion, the Commission will publish a notice of proposed rulemaking inviting public comment on whether the exclusion should be issued in final form, and the Office of Hazard Identification and Reduction will review and evaluate the comments and supporting documentation before making its recommendation to the Commission for final agency action.

D. Effect of filing a lead content determination or exclusion request

The filing of a request for a lead content determination or for an exclusion would not have the effect of automatically staying the effect of any provision or limit under the statutes and regulations enforced by the Commission. Unless issued in final form by the Commission after notice and comment, all CPSC requirements related to the lead content in the material or product and all applicable testing and certification requirements would remain in full force and effect. CPSIA § 101(e). However, the Commission's ability to exercise its enforcement discretion is not eliminated nor diminished.

E. Impact on Small Businesses

Under the Regulatory Flexibility Act (RFA), when an agency issues a proposed rule, it generally must prepare an initial regulatory flexibility analysis describing the impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of relieving certain materials or products from the testing requirements of section 102 of the CPSIA. That assessment found that the procedures and requirements would only impact those firms that wish to seek a formal Commission determination or exclusion from the requirements. Its only potential effect on businesses, including small businesses, will be to reduce the costs that would have been associated with testing the materials under section 102 of the CPSIA, if the request is granted. Based on the foregoing assessment, the Commission preliminarily finds that the proposed rule would not have a significant impact on a substantial number of small entities.

F. Environmental Considerations

Generally, CPSC rules are considered to "have little or no potential for affecting the human environment," and environmental assessments are not usually prepared for these rules (see 16 C.F.R. 1021.5(c)(1)). The proposed rule will not result in any additional use of lead over what is occurring at the present time. Therefore, the Commission does not expect the proposal to have any negative environmental impact.

G. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of regulations such as this proposal is stated in section 18 of the FHSA. 15 U.S.C. 1261n.

H. Paperwork Reduction Act

Since the proposed rule would require manufacturers to provide certain information along with any request for a Commission determination or exclusion, the proposed rule contains "collection of information requirements" as that term is used in the Paperwork Reduction Act, 44 U.S.C. 3501-3520. Therefore, the proposed rule is being submitted to the Office of Management and Budget (OMB) in accordance with 44 U.S.C. 3507(d) and implementing regulations codified at 5 CFR 1320.11. The estimated costs of these

requirements will depend on the number of requests that are received by the Commission.

The number of manufacturers or importers that might seek a determination that their products or materials do not contain lead or exceed the lead content limits or that might seek an exclusion from the lead-content requirements for their product is not currently known. The requirements for obtaining a determination or exclusion are extensive, which may be a deterrent to some firms; 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 or exclusions could be higher than expected. It would be expected that the firms making such requests would be familiar with the product or material for which the determination or exemption is sought and the required information may already be in the firm's possession or easily obtainable.

Based on comments received on the CPSIA lead content provisions thus far, staff estimates that a minimum of approximately 250 firms may submit requests. The burden to assemble the information and prepare the submission, if performed by a senior level management employee, may take approximately 40 hours. The compensation would be approximately \$60 an hour (U.S. Department of Labor, Bureau

of Labor Statistics), and the average cost of preparing a submission would be about \$2,400 (\$60 x 40). An estimate of the annual burden for the information collection could reach \$600,000.

An estimate of the burden on the federal government to review each submission could be as much as 24 hours at an average hourly wage of \$56, the equivalent of a GS-14 employee, or \$1,344 for each submission (\$56 x 24). If approximately 250 submissions are received, the cost of the annual burden to the federal government will be approximately \$336,000.

I. Effective Date

The APA generally requires that a substantive rule be published not less than 30 days before its effective date, unless the agency finds for good cause shown, that a lesser time period is required. 5 U.S.C. 553(d)(3). Because the Commission recognizes the need for providing procedures for Commission determinations and exclusions expeditiously, for good cause shown, the proposed effective date is the date of publication of a final rule in the *Federal Register*.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, and Toys.

J. Conclusion

For the reasons stated above, the Commission proposes to amend title 16 of the Code of Federal Regulations as follows:

PART 1500 - HAZARDOUS SUBSTANCES AND ARTICLES:

ADMINISTRATION AND ENFORCEMENT REGULATIONS

1. The authority for part 1500 is amended to read as follows:

Authority: 15 U.S.C. 1261-1278, 122 Stat. 3016

2. Add new sections 1500.89 and 1500.90 to read as follows:

§ 1500.89 Procedures for Determinations Regarding Lead Content of Materials or Products under Section 101(a) of the Consumer Product Safety Improvement Act.

(a) 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 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to meet

this lower limit. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child.

(b) The Commission may, either on its own initiative or upon the request of any interested person, make a determination that a material or product does not contain leads levels that exceed 600 ppm, 300 ppm or 100 ppm.

(c) To request a determination under (b), the request must:

1. Be e-mailed to cpsc-os@cpsc.gov. and titled "Section 101 Request for Lead Content Determination." Requests may also be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814, or delivered to the same address.
2. Be written in the English language.
3. Contain the name and address, and email address or telephone number, of the requestor.
4. Provide Documentation including:
 - (i) a detailed description of the product or material;

(ii) data on the lead content of parts of the product or materials used in the production of a product;

(iii) data or information on manufacturing processes through which lead may be introduced into the product or material;

(iv) any other information relevant to the potential for lead content of the product or material to exceed the CPSIA lead limits that is reasonably available to the requestor;

(v) detailed information on the relied upon test methods for measuring lead content of products or materials including the type of equipment used or any other techniques employed and a statement as to why the data is representative of the lead content of such products or materials generally; and

(vi) an assessment of the manufacturing processes which strongly supports a conclusion that they would not be a source of lead contamination of the product or material, if relevant.

(d) Where a submission fails to meet all of the requirements of paragraph (c), the Office of the Secretary shall notify the person submitting it, describe the

deficiency, and explain that the request may be resubmitted when the deficiency is corrected.

(e) Each complete request for a Commission determination will be reviewed by the Office of Hazard Identification and Reduction who will preliminarily recommend granting or denying the request. Where the preliminary determination is to grant, the Commission will publish a notice of proposed rulemaking inviting public comment on whether the preliminary determination should be granted in final form, and the Office of Hazard Identification and Reduction will review and evaluate the comments and supporting documentation before making its recommendation to the Commission for final agency action.

(f) The filing of a request for a determination does not have the effect of automatically staying the effect of any provision or limit under the statutes and regulations enforced by the Commission. Even though a request for a determination has been filed, unless a Commission determination is issued in final form after notice and comment, materials or products subject to the lead limits under section 101 of the CPSIA must be tested in accordance with section 102 of the CPSIA.

**§ 1500.90 Procedures for Exclusions from Lead Limits
under Section 101(b) of the Consumer Product Safety
Improvement Act.**

(a) 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 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to have this lower limit. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child.

(b) 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.

(c) To request an exclusion from the lead limits as provided under (a), the request must:

1. Be e-mailed to cpssc-os@cpssc.gov. and titled "Section 101 Request for Exclusion of a Material or Product." Requests may also be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814, or delivered to the same address.
2. Be written in the English language.
3. Contain the name and address, and email address or telephone number, of the requester.
4. Provide Documentation including:
 - (i) a detailed description of the product or material;

- (ii) data on the lead content of parts of the product or materials used in the production of a product;
- (iii) data or information on manufacturing processes through which lead may be introduced into the product or material;
- (iv) any other information relevant to the potential for lead content of the product or material to exceed the CPSIA lead limits that is reasonably available to the requestor;
- (v) detailed information on the relied upon test methods for measuring lead content of products or materials including the type of equipment used or any other techniques employed and a statement as to why the data is representative of the lead content of such products or materials generally; and
- (vi) an assessment of the manufacturing processes which strongly supports a conclusion that they would not be a source of lead contamination of the product or material, if relevant.

5. Provide best-available, objective, peer-reviewed, scientific evidence to support a request for an exclusion that addresses 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.

6. Provide best-available, objective, peer-reviewed, scientific evidence that is unfavorable to the request that is reasonably available to the requestor.

(d) Where a submission fails to meet all of the requirements of paragraph (c), the Office of the Secretary shall notify the person submitting it, describe the deficiency, and explain that the request may be resubmitted when the deficiency is corrected.

(e) Each complete request for exclusion will be reviewed by the Office of Hazard Identification and Reduction, who will preliminarily recommend granting or denying the request. Where the preliminary determination is to grant, the Commission will publish a notice of proposed rulemaking inviting public comment on whether the proposed exclusion should be issued in final form, and the Office of

Hazard Identification and Reduction will review and evaluate the comments and supporting documentation before making its recommendation to the Commission for final agency action.

(f) The filing of a request for exclusion does not have the effect of automatically staying the effect of any provision or limit under the statutes and regulations enforced by the Commission. Even though a request for an exclusion has been filed, unless an exclusion is issued in final form by the Commission after notice and comment, materials or products subject to the lead limits under section 101 of the CPSIA are considered to be banned hazardous substances if they do not meet the lead limits.

List of relevant documents

(1) Memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences "Consumer Product Safety Improvement Act of 2008 (CPSIA): Exclusions from Compliance with Limits for Lead, Certain Materials of Products: Required Technical Information." December 2008.

(2) Memorandum from Robert Franklin, Economist, Directorate for Economic Analysis, "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." December 2008.

Dated: _____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission