Consumer Product Safety Commission

§ 1500.90 Procedures and requirements 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 years of age or younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or

(viii) 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

(ix) Any data or information that is unfavorable to the request that is reasonably available to the requestor.

(e) Where a submission fails to meet all of the requirements of paragraph (d) of this section, 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.

(f) Upon receipt of a complete request for a determination, the Office of Hazard Identification and Reduction (EXHR) will assess the request to determine whether the product or material is one that does not contain lead in excess of the limits as provided under paragraph (a) of this section. EXHR will make an initial recommendation within thirty (30) calendar days, to the extent practicable. EXHR may request an extension from the Executive Director of the CPSC, if necessary, to make its initial determination. A complete request is one that does not require additional information from the requestor for EXHR to make an initial recommendation to the Commission.

(g) Where the Office of Hazard Identification and Reduction’s (EXHR) initial recommendation is to deny the request for a lead content determination, it will provide, in a staff memorandum to the Commission, submitted to the Commission for ballot vote, the basis for the denial with sufficient detail for the Commission to make an informed decision that reasonable grounds for a determination are not presented. The filing of a request for a determination does not have the effect of 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, unless the testing requirement is otherwise stayed by the Commission.

(h) Where the Office of Hazard Identification and Reduction’s (EXHR) initial recommendation is to grant the request for a lead content determination, it will submit the basis for that recommendation to the Commission in a memorandum to be voted on by ballot, with sufficient detail for the Commission to make an informed decision that reasonable grounds for a determination are presented. If the notice of proposed rulemaking (NPR) is published, it will invite public comment in the Federal Register. EXHR will review and evaluate any comments and supporting documentation before making its final recommendation to the Commission for final agency action, by staff memorandum submitted to the Commission. If the Commission, after review of the staff’s final recommendation, determines that a material or product does not and would not exceed the lead content limits, it will decide by ballot vote, on whether to publish a final rule in the Federal Register.

(i) The filing of a request for a determination does not have the effect of 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, unless the testing requirement is otherwise stayed by the Commission.

[74 FR 10480, Mar. 11, 2009]
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.

(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:

(1) 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

(2) Have any other adverse impact on public health or safety.

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

(1) Be e-mailed to cpsc-os@cpsc.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 e-mail address or telephone number, of the requestor.

(4) Provide documentation including:

(i) A detailed description of the product or material and how it is used by a child;

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

(iii) All relevant 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 demonstrating that 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 public health or safety. This literature should support a request for 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 request that is reasonably available to the requestor.

(d) Where a submission fails to meet all of the requirements of paragraph (c) of this section, 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) Upon receipt of a complete 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, that 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.
EXHR will make an initial recommendation within thirty (30) calendar days to the extent practicable. EXHR may request an extension from the Executive Director of the CPSC, if necessary, to make its initial recommendation. A complete request is one that does not require additional information from the requestor for EXHR to make an initial recommendation to the Commission.

(f) Where the Office of Hazard Identification and Reduction’s (EXHR) initial recommendation is to deny the request for an exclusion, it will provide in a staff memorandum to the Commission, submitted to the Commission for ballot vote, the basis for denial with sufficient detail for the Commission to make an informed decision that reasonable grounds for an exclusion are not presented. The Commission, by ballot vote, will render a decision on the staff’s recommendation. The ballot vote and the staff memorandum will be posted on the CPSC Web site. Any determination by the Commission to grant a request will be published in the FEDERAL REGISTER for comment. If the Commission concludes that the request shall be denied, the requestor shall be notified in writing of the denial from the Office of the Secretary along with the official ballot results and the EXHR’s staff’s memorandum of recommendation.

(g) Where the Office of Hazard Identification and Reduction’s (EXHR) initial recommendation is to grant the exclusion, it will submit the basis for that recommendation to the Commission in a memorandum to be voted on by ballot, with sufficient detail for the Commission to make an informed decision that reasonable grounds for a determination are presented. If the notice of proposed rulemaking (NPR) is published, it will invite public comment in the FEDERAL REGISTER. EXHR will review and evaluate the comments and supporting documentation before making its final recommendation to the Commission, by staff memorandum submitted to the Commission, for final agency action. If the Commission, after review of the staff’s final recommendation, determines that an exclusion is supported by the evidence, it will decide by ballot vote, on whether to publish a final rule in the FEDERAL REGISTER.

(b) The filing of a request for exclusion does not have the effect of 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 as provided under paragraph (a) of this section.

[74 FR 10480, Mar. 11, 2009]