

established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the High and Low offshore airspace areas located off the east coast of the United States.

#### ICAO Considerations

As part of this proposal relates to navigable airspace outside the United States, this proposal is submitted in accordance with the International Civil Aviation Organization (ICAO) International Standards and Recommended Practices.

The application of International Standards and Recommended Practices by the FAA, Office of System Operations Airspace and AIM, Airspace & Rules Group, in areas outside the United States domestic airspace, is governed by the Convention on International Civil Aviation. Specifically, the FAA is governed by Article 12 and Annex 11, which pertain to the establishment of necessary air navigational facilities and services to promote the safe, orderly, and expeditious flow of civil air traffic. The purpose of Article 12 and Annex 11 is to ensure that civil aircraft operations on international air routes are performed under uniform conditions.

The International Standards and Recommended Practices in Annex 11 apply to airspace under the jurisdiction of a contracting state, derived from ICAO. Annex 11 provisions apply when air traffic services are provided and a contracting state accepts the responsibility of providing air traffic services over high seas or in airspace of undetermined sovereignty. A contracting state accepting this responsibility may apply the International Standards and Recommended Practices that are consistent with standards and practices utilized in its domestic jurisdiction.

In accordance with Article 3 of the Convention, state-owned aircraft are exempt from the Standards and Recommended Practices of Annex 11. The United States is a contracting state to the Convention. Article 3(d) of the Convention provides that participating state aircraft will be operated in international airspace with due regard for the safety of civil aircraft. Since this action involves, in part, the designation of navigable airspace outside the United States, the Administrator is consulting with the Secretary of State and the Secretary of Defense in accordance with the provisions of Executive Order 10854.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

#### **PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS**

1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

##### **§ 71.1 [Amended]**

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9S, Airspace Designations and Reporting Points, signed October 3, 2008 and effective October 31, 2008, is amended as follows:

*Paragraph 2003—Offshore Airspace Areas.*

\* \* \* \* \*

##### **Atlantic High [Amended]**

That airspace extending upward from 18,000 feet MSL to and including FL 600 within the area bounded on the east from north to south by the Moncton FIR, New

York Oceanic CTA/FIR, and the San Juan Oceanic CTA/FIR; to the point where the San Juan Oceanic CTA/FIR boundary turns southwest at lat. 21°14'21" N., long. 67°39'02" W., thence from that point southeast via a straight line to intersect a 100-mile radius of the Fernando Luis Ribas Dominicci Airport at lat. 19°47'28" N., long. 67°09'37" W., thence counter-clockwise via a 100-mile radius of the Fernando Luis Ribas Dominicci Airport to lat. 18°53'05" N., long. 67°47'43" W., thence from that point northwest via a straight line to intersect the point where the Santo Domingo FIR turns northwest at lat. 19°39'00" N., long. 69°09'00" W., thence from that point the area is bounded on the south from east to west by the Santo Domingo FIR, Port-Au-Prince CTA/FIR, and the Havana CTA/FIR; bounded on the west from south to north by the Houston Oceanic CTA/FIR, southern boundary of the Jacksonville Air Route Traffic Control Center and a line 12 miles offshore and parallel to the U.S. shoreline.

\* \* \* \* \*

*Paragraph 6007—Offshore Airspace Areas.*

\* \* \* \* \*

#### **San Juan Low, PR [Amended]**

That airspace extending upward from 5,500 feet MSL from the point of intersection of the San Juan Oceanic CTA/FIR and Miami Oceanic CTA/FIR boundary at lat. 21°14'21" N., long. 67°39'02" W., thence from that point southeast via a straight line to intersect a 100-mile radius of the Fernando Luis Ribas Dominicci Airport at lat. 19°47'28" N., long. 67°09'37" W., thence clockwise via a 100-mile radius of the Fernando Luis Ribas Dominicci Airport to lat. 18°53'05" N., long. 67°47'43" W., thence from that point northwest via a straight line to intersect the point where the Santo Domingo FIR turns northwest at lat. 19°39'00" N., long. 69°09'00" W., thence from that point northeast along the San Juan CTA/FIR and Miami CTA/FIR boundary to the point of beginning.

\* \* \* \* \*

Issued in Washington, DC, on January 5, 2009.

**Edith V. Parish,**

*Manager, Airspace and Rules Group.*

[FR Doc. E9–501 Filed 1–14–09; 8:45 am]

**BILLING CODE 4910–13–P**

## **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: 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 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.

**DATES:** Written comments and submissions in response to this notice must be received by February 17, 2009.

**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, PhD, M.P.H., Directorate for Health Sciences, Consumer Product Safety Commission,

4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504–7254; 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.<sup>1</sup> 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 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.<sup>2</sup>

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

<sup>1</sup> The Supreme Court has held that paper hearing procedures are adequate where, in the total context of the 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).

<sup>2</sup> 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.

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 CFR 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 ( $\$60 \times 40$ ). 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 ( $\$56 \times 24$ ). 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**.

#### J. List of Relevant Documents

(1) Memorandum from Kristina M. Hatlelid, PhD, 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.

#### List of Subjects in 16 CFR Part 1500

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

#### K. 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 §§ 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 lead levels that exceed 600 ppm, 300 ppm or 100 ppm.

(c) To request a determination under paragraph (b) of this section, the request must:

(1) Be e-mailed to *cpssc-os@cpssc.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 e-mail 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) 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) 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:

(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 *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 e-mail 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) 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) 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.

Dated: January 9, 2009.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

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## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1500

#### Children's Products Containing Lead; Proposed Determinations Regarding Lead Content Limits on Certain Materials or Products; Notice of Proposed Rulemaking

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314, 122 Stat. 3016. This notice of proposed rulemaking (NPR) initiates a proceeding under section 3 of the CPSIA authorizing the Commission to issue regulations, as necessary, to implement the CPSIA. In this document, the Commission solicits written comments concerning preliminary determinations on certain natural, untreated and unadulterated materials and metals that have not been

found to exceed the lead content limits prescribed under section 101(a) of the CPSIA.

**DATES:** Written comments and submissions in response to this notice must be received by February 17, 2009.

**ADDRESSES:** Comments should be e-mailed to

*Sec101Determinations@cpsc.gov.*

Comments should be captioned "Section 101 Determinations of Certain Materials or Products NPR." 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.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:**

#### A. Background

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, these products and materials 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, on and after February 10, 2009, general conformity certificates certifying that they comply with the applicable lead content limit are required for children's products. 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 laboratory whose accreditation to perform the testing has been accepted by the Commission.

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. There may be certain products or

materials that inherently do not contain lead or contain lead at levels that do not exceed the lead content limits under section 101(a) of the CPSIA. To the extent that such materials or products exist, the Commission, of its own initiative, is proposing to exercise its section 3 authority to make preliminary determinations that certain commodities or classes of materials or products do not exceed the lead limits prescribed in section 101(a) of the CPSIA. The effect of such a Commission finding would be to relieve the material or product from the testing requirement of section 102 of the CPSIA for purposes of supporting the required certification. 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.

#### B. Proposed Determinations on Certain Products and Materials

The Commission staff identified a number of commodities or classes of materials that do not inherently contain lead or contain lead that does not exceed the CPSIA lead limits of 600 ppm or 300 ppm.

##### *Certain Natural Materials*

Based on the staff's review, the Commission preliminarily determines that the following natural materials do not exceed the 600 ppm or 300 ppm lead content limits under section 101(a) of the CPSIA. These preliminary determinations are based on materials that are untreated and unadulterated with respect to the addition of materials or chemicals, including pigments, dyes, coatings, finishes or any other substance, and that do not undergo any processing that could result in the addition of lead into the product or material:

1. Precious gemstones: Diamond, ruby, sapphire, emerald
2. Certain semiprecious gemstones provided that the mineral or material is not based on lead or lead compounds and is not associated in nature with any mineral that is based on lead or lead compounds (minerals that contain lead or are associated in nature with minerals that contain lead include, but are not limited to, the following: Aragonite, bayldonite, boleite, cerussite, crocoite, linarite, mimetite, phosgenite, vanadinite, and wulfenite)
3. Natural or cultured pearls
4. Wood