FDC date	State	City	Airport	FDC No.	Subject
02/18/09	IA	ANKENY	ANKENY REGIONAL	9/6097	RNAV (GPS) RWY 22, ORIG.
02/18/09	IA	ANKENY	ANKENY REGIONAL	9/6100	RNAV (GPS) RWY 18, ORIG.
02/18/09	UT	OGDEN	OGDEN-HINCKLEY	9/6135	ILS OR LOC RWY 3, AMDT 4A.
02/18/09	AK	DILLINGHAM	DILLINGHAM	9/6173	LOC/DME RWY 19, AMDT 6.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Children's Products Containing Lead; Final Rule; Procedures and Requirements for a Commission Determination or Exclusion

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) is issuing a final rule on procedures and requirements on requests 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 Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110–314; or an exclusion of a commodity or class of materials or a specific material or product under section 101(b)(1) of the CPSIA, that exceeds the lead content limits under section 101(a) of the CPSIA, 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.

DATES: *Effective Date:* This regulation becomes effective on March 11, 2009.

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; e-mail *khatlelid@cpsc.gov;* telephone 301–504–7254.

SUPPLEMENTARY INFORMATION:

A. Background

The CPSIA establishes specific limits on lead in children's products. Section 101(a) of the CPSIA provides that after 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 by weight for any part of the product. After August 14, 2009, products designed or intended primarily for children 12 years of age or younger cannot contain more than 300 ppm of lead by weight for any part of the product. On August 14, 2011, the limit will 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 or prevent the absorption of any lead in the human body through normal and reasonably foreseeable use and abuse of the product.

Consumer products designed or intended primarily for children 12 years of age or younger that do not contain more than 600 ppm or 300 ppm total lead by weight (as of August 14, 2009), are not considered to be banned hazardous substances under the Federal Hazardous Substances Act (FHSA). Children's products that meet the lead limits however, are still subject to the testing requirements of section 102 of the CPSIA (codified at section 14 of the Consumer Product Safety Act (CPSA)), unless specifically relieved of those requirements through Commission lead content determinations.[1]

Children's products that contain more than 600 ppm or 300 ppm lead in any component part (as of August 14, 2009) are considered to be banned hazardous substances under the FHSA. However, 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) of 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.'' Children's products that have lead containing accessible parts that are specifically excluded under this section would generally not be subject to the testing and certification requirements of section 102 of the CPSIA for lead content.

[1] On February 9, 2009, the Commission published a stay of enforcement of testing and certification requirements of certain provisions of subsection 14(a) of the CPSA as amended by section 102(a) of the CPSIA until February 10, 2010. 74 FR 6396. However, absent 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 CPSIA, such products will be subject to the testing requirements under section 102 of the CPSIA after February 10, 2010.

B. Statutory Authority

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. Accordingly, the Commission will exercise its authority under section 3 of the CPSIA to make determinations regarding such commodities or classes of material or products that do not and would not exceed the lead limits of section 101(a) of the CPSIA.

In addition, the Commission may exercise its authority under section 101(b)(1) of the CPSIA to issue any regulations on a specific product or material that exceeds the lead limits established for children's products under section 101(a) of 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. Notice of Proposed Rulemaking

On January 15, 2009, the Commission published a notice of proposed rulemaking on procedures and requirements in the **Federal Register** (74 FR 2428) for future Commission determinations regarding certain materials or products that do not and would not exceed the lead limits. In the

same issue of the **Federal Register** (74 FR 2433), the Commission published another notice of proposed rulemaking describing preliminary determinations that specific materials including certain natural materials and certain metal and alloys do not and would not exceed the lead limits.

For materials or products 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, the Commission proposed procedures and requirements by which requests for determinations on materials or products will be reviewed. The Commission emphasized that it 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 and that review of individual products of a single manufacturer would be assigned a low priority.

For materials or products that exceed the lead content limits in section 101(a) of the CPSIA, section 101(b) of the CPSIA requires the Commission to provide notice and a hearing to consider and evaluate the best-available, objective, peer-reviewed, scientific data before promulgating a rule on exclusions. Given the highly technical nature of the information sought—peer-reviewed, scientific data—the Commission stated its intention to provide notice and comment procedures based on written submissions, rather than an oral hearing. 74 FR 2430. Accordingly, the Commission proposed procedures and requirements which required that a request for exclusion must be supported by the best-available, objective, peer-reviewed, scientific evidence, 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.

D. Discussion of Comments to the Proposed Rule

Several comments were received in response to the proposed rule.[2] All of the commenters generally express support for the proposed procedures and requirements. Additional comments are addressed below.

Standard for Exclusions

The ATV Companies[3] question the Commission's statement regarding the difficult standard that needs to be met for exclusions under section 101(b)(1) of the CPSIA, suggesting that possibly no petition might qualify for an exclusion and citing recent statements from a Senate conferee suggesting that the exclusion is appropriate for use in this context. They assert that exclusions provided for by Congress should not be rendered meaningless and that Congress must have intended to provide relief for some accessible components when evaluated in the context of a child's reasonably foreseeable use and abuse of a product, and that certain ATV components fall within the scope of such an exclusion.

The Commission believes that the clear language of the statute which provides that it must determine, 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 human body * * *'' (emphasis added) does not allow the Commission any discretion to consider materials or products whereby exposure to the lead-containing elements under reasonably foreseeable use and abuse conditions would result in any absorption of lead, including through swallowing, mouthing, breaking, and the aging of the product. While Congress focused on ingestion by using the words ''swallowing, mouthing, and breaking,'' the use or abuse of a children's product containing lead in excess of the lead limits could lead to the absorption of lead from hand to mouth contact, as the Commission has recognized for many years. Had Congress not included the use of the word ''any'', the Commission, relying, *inter alia,* on the advice of its toxicologists, engineers and human factors experts, would have had the authority to have considered whether the requirement could be met if there were some low amount of absorption of lead, resulting in ''no meaningful increase'' in children's blood lead levels, thereby constituting a negligible risk. While there is no established threshold for adverse effects of lead, peer-reviewed scientific literature suggests ways of assessing the risk to children given child-specific exposure routes, and taking into account the current knowledge of lead toxicology. Models for such assessments have been advanced recently by other federal and state agencies. *See e.g., Development of Health Criteria for School Site Risk Assessment Pursuant To Health and Safety Code Section 901(G): Child-Specific Benchmark Change in Blood Lead Concentration for School Site Risk Assessment, Final Report April 2007, Integrated Risk Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency.* Physiologically, if there is absorption of lead into the human body, blood lead levels will increase, but whether that has significance from a health standpoint remains a question. However, the addition of the word ''any'' made it explicit that Congress had already made this risk assessment and legislated that any absorption of lead from products or materials containing lead above the content limits established by Congress, no matter how insignificant, would be deemed unacceptable. The exclusion is not rendered meaningless, as conceivably some product could be over the lead limit but designed in a way to avoid hand to mouth exposure or some other absorption pathway in children of a certain age. Accordingly, the Commission must follow the clear language of the statute and cannot grant any exclusion that does not meet this requirement.

Other Considerations for Exclusion Requests

The United States Association of Importers of Textiles and Apparel (USA–ITA) supports the proposed procedures for requesting exclusions or determinations for other materials that may be included in apparel, such as rhinestone beads. The Fashion Jewelry Trade Association (FJTA) agrees that an oral hearing is not required for the Commission to act on exclusions and requests expedited action on crystals. For proposed exclusions, it states that only relevant exposure conditions should be considered, including consideration of the child's age. The American Apparel & Footwear Association (AAFA) *et al.* assert that the Commission should rely on an extractable lead test rather than the total lead content in its evaluations for proposed exclusions and requirements.

FJTA requests that, in the absence of published best-available, objective, peer-reviewed scientific evidence, test data using accepted published test methods should be considered reliable information. It also opposes the requirement that a request for exclusion should include evidence that may be unfavorable to the requestor, because it claimed that the purpose of the public

[2] There were other comments that were submitted but that did not address any issues related to this rule. Accordingly, they will not be addressed here.

[3] The ATV Companies are American Honda Motor Co., American Suzuki Motor Corp., Arctic Cat Inc., Bombardier Recreational Products Inc., Kawasaki Motors Corp., U.S.A., Polaris Industries Inc., and Yamaha Motor Corp., U.S.A.

comment process is to elicit countervailing information.

The standard for lead established by the CPSIA is based on total lead content of component parts of children's products. However, section 101(b)(1) of the CPSIA provides that the Commission may exclude a specific product or material from the lead content limits if the Commission determines 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 based on factors specific to the product or material and to the children using the product. Therefore, under this section, exclusion of a product or material from the lead content limits would necessarily be based on factors other than the total lead content. A request should contain as much credible scientific evidence as is available, including any test data using established test methods particularly if the requestor is asking the Commission to consider estimates of extractable lead in reaching conclusions about the absorption of lead in the child's body. However, such a submission will be reviewed by staff to determine the veracity and applicability of the studies to the product or material in question and whether, in consideration with other available evidence, it supports a showing that lead in such product or material would not result in the absorption of any lead into the body.

The Commission will continue to require that a request for exclusion be accompanied by information unfavorable to the request, if reasonably available. In addition, the Commission will require that a request for a determination be accompanied by information unfavorable to the request, if reasonably available and if it accurately reflects the product's lead content. Therefore, this final rule requires the production of ''representative'' data to ensure that the Commission has relevant data reflecting the actual likely lead content of the product or class of products. To the extent that such information is reasonably available to the requestor, particularly if the information was produced by or presented to the requestor, it must be provided to the Commission to ensure that all available information and data is reviewed in determining whether an exclusion or determination is appropriate based on the totality of the evidence.

Process Timeline and Treatment of Confidential Information

AAFA requests that the Commission articulate a timeline for the process, indicate how requests for exclusion will be disclosed, and provide guidelines on how business-confidential information will be protected. The Office of the California Attorney General (CA AG) also requests that the Commission continue to post applications and supporting documents and, where materials are withheld from the public, provide the reasons for withholding the information.

As part of this rulemaking, the Commission has specified a timeline for processing requests for determinations and exclusions. The Commission will continue its practice of providing public access to requests and supporting materials received from the requestors as well as comments from the public. With respect to confidential materials, the Commission will note in the public docket where such materials are withheld from the public docket. Section 6(a)(2) of the CPSA, 15 U.S.C. 2055(a)(2), and the regulations promulgated under 16 CFR 1015.18 and 1015.19 govern requests for confidential treatment of information and requests for disclosure of such information. These procedures are applicable to any such requests received in these proceedings.

Additional Requirements for Determinations

The CA AG states that the Commission should be explicit in the regulation, not just the preamble, that a determination that the lead content of a material or product is below the lead limits does not relieve the material or product from complying with the applicable lead limits. In addition, the CA AG suggests additional information to be obtained from applicants including: (1) Data or information on the facilities and manufacturing processes used to manufacture the material or product, and any materials used in the product; and (2) an assessment of the likelihood or lack thereof that the use of leaded materials in a facility will result in lead contamination of a material or product that ordinarily does not contain lead. Consumers Union, *et al.*[4] state that products from the market should be tested with reasonable frequency to act as an effective deterrent.

The Commission has already indicated that all children's products subject to a determination must comply with the lead limit in its Statement of Commission Enforcement Policy on Section 101 Lead Limits, dated February 6, 2009, and includes in the regulation the requirement for compliance with the CPSIA lead limits. The Commission had also indicated that a request for a determination would need to include information on ''manufacturing processes through which lead may be introduced in to the product * * * and why the assessment of the manufacturing processes strongly supports a conclusion that they would not be a source of lead contamination.'' However, in response to these comments, the Commission will also clarify that the procedures and requirements for determinations will include a request for an evaluation of facilities and manufacturing processes as well as a request for an assessment of whether lead uses in manufacturing facilities could possibly result in lead contamination of a material or product. With respect to market testing, compliance and enforcement activities, including market testing, have always been and continue to be essential to the Commission's mission. Moreover, even when a particular product or material has been relieved of the requirement to undergo testing and certification under section 102 of the CPSIA, manufacturers and importers continue to be responsible for verifying that the material or product has not been altered or modified, or experienced any change in the processing, facility or supplier conditions that could impart lead into the material or product to ensure that it meets the statutory lead levels at all times.

E. Procedures and Requirements

1. § 1500.89—Lead Content Level Determinations

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 and how it is used by the child;

[4] Consumers Union, Consumer Federation of America, Kids in Danger, Public Citizen, and the U.S. Public Interest Research Group filed joint comments. In their comments, they expressed satisfaction with the Commission's process for determining exclusions based on best available, objective, peer reviewed, scientific evidence that the product or material cannot result in the absorption of any lead in the human body as discussed above.

- Representative data on the lead content of parts of the product or the materials used in the production of a product;
- All relevant data or information on manufacturing processes through which lead may be introduced into the product or material;
- An assessment of the likelihood or lack thereof that the manufacturing processes will result in lead contamination of a material or product that ordinarily does not contain lead;
- All relevant data or information on the facilities used to manufacture the material or product, and any other materials used in the product;
- An assessment of the likelihood or lack thereof that the use of leaded materials in a facility will result in lead contamination of a material or product that ordinarily does not contain lead;
- 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;
- Detailed information on the relied upon test methods for measuring lead content of products or materials, including the type of equipment used and 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
- Any data or information that is unfavorable to the request that is reasonably available to the requestor.

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 a determination must be based on objectively reasonable and representative testing of the material or product.

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 of section 101 of the CPSIA. 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. If a request is submitted that is not complete, 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. If EXHR's initial recommendation is to deny the request for a lead content determination, it will provide, in a staff memorandum 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 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 staff's memorandum of recommendations.

If the staff's initial recommendation is to grant the 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**. Although such materials or products would be relieved of the testing and certification requirements in section 102 of the CPSIA, manufacturers and importers would continue to be responsible for verifying that the material or product has not been altered or modified, or experienced any change in the processing, facility or supplier conditions that could impart lead into the material or product. These materials or products must still meet the statutory lead level requirements at all times. 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 and could take additional regulatory action if repeated enforcement actions call into question the original determination. In addition, all materials or products must still meet any other applicable consumer product safety rules as defined in the CPSA or similar rules, bans standards, or regulations under any other Act enforced by the Commission.

2. § 1500.90—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, any requests seeking an exclusion must submit documentation 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 reasonably foreseeable use and abuse by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product, nor have any other adverse impact on health or safety. This is the standard by which the Commission will review such requests for exclusions. A justification submitted by an interested party for an exclusion should provide:

- A detailed description of the product or material and how it is used by a child;
- Representative data on the lead content of parts of the product or materials used in the production of a product;
- All relevant 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 that is reasonably available to the requestor;
- 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;
- 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;
- Best-available, objective, peer-reviewed, scientific evidence to support a request for an exclusion that demonstrates 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 body, nor have any other adverse impact on 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; and

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

Upon receipt of a complete request for an exclusion, the Office of Hazard Identification and Reduction (EXHR) will assess the request 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 public health or safety, and 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. If a request is submitted that is not complete, 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.

If EXHR's 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 staff's memorandum of recommendation.

If the staff's 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 any 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 by ballot vote decide on whether to publish a final rule in the **Federal Register**.

F. Effect of Filing a Lead Content Determination or Exclusion Request

Under section 101(e) of the CPSIA, 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 would remain in full force and effect. However, the Commission's ability to exercise its enforcement discretion is not eliminated nor diminished.

G. 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. The Commission preliminarily found that the proposed rule would not have a significant impact on a substantial number of small entities. The procedures and requirements would allow certain businesses, including small businesses, the ability to seek determinations and exclusions which would allow these entities to continue to manufacture their products without the continuing cost of testing the materials for the presence of lead. Based on the foregoing assessment, the Commission certifies that the rule issued today on procedures and requirements would not have a significant impact on a substantial number of small entities.

H. 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(a)). The rule on procedures and requirements is not expected to have an adverse impact on the environment, thus, the Commission concludes that no environment assessment or environmental impact statement is required in this proceeding.

I. 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.

J. Paperwork Reduction Act

The rule would require manufacturers to provide certain information along with any request for a Commission determination or exclusion. For this reason, the rule contains ''collection of information requirements'' as that term is used in the Paperwork Reduction Act, 44 U.S.C. 3501–3520. Therefore, the preamble to the proposed rule discussed the paperwork burden that may be incurred and specifically requested comments on the paper burden of the proposal. The agency has applied to OMB for a control number for this information collection, and it will publish a notice in the **Federal Register** providing the number when the agency receives approval from the Office of Management and Budget (OMB).

K. Effective Date

The Administrative Procedure Act 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 and requirements for Commission determinations and exclusions expeditiously, for good cause

shown, the effective date is March 11, 2009.

List of Subjects in 16 CFR Part 1500

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

L. Conclusion

■ For the reasons stated above, the Commission amends chapter II of title 16 of the Code of Federal Regulations as follows:

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES: ADMINISTRATION AND ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1500 is revised 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 and requirements 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 years of age or younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 years of age or younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that this lower limit is not technologically feasible. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child or prevent the absorption of any lead in the human body through normal and reasonably foreseeable use and abuse of the product.

(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, as applicable.

(c) A determination by the Commission under paragraph (b) of this section that a material or product does not contain lead levels that exceed 600 ppm, 300 ppm, or 100 ppm, as applicable does not relieve the material or product from complying with the applicable lead limit as provided under paragraph(a) of this section.

(d) To request a determination under paragraph (b) of this section, 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 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 material or product;

(iv) An assessment of the likelihood or lack thereof that the manufacturing processes will result in lead contamination of a material or product that ordinarily does not contain lead;

(v) All relevant data or information on the facilities used to manufacture the material or product, and any other materials used in the product;

(vi) An assessment of the likelihood or lack thereof that the use of leaded materials in a facility will result in lead contamination of a material or product that ordinarily does not contain lead;

(vii) Any other information relevant to the potential for 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;

(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 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 staff's memorandum of recommendation.

(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.

§ 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 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 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**.

(h) 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.

Dated: March 5, 2009.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E9–5075 Filed 3–10–09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 09–05]

RIN 1505–AC11

Extension of Import Restrictions Imposed on Archaeological Material From Honduras

AGENCIES: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends Customs and Border Protection (CBP) regulations to reflect the extension of import restrictions on certain categories of archaeological material from the Pre-Columbian cultures of the Republic of Honduras (Honduras) that were imposed by CBP Decision (Dec.) 04–08 and expire on March 12, 2009. The Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has determined that conditions continue to warrant the imposition of import restrictions. Accordingly, these import restrictions will remain in effect for an additional 5 years, and the CBP regulations are being amended to reflect this extension until March 12, 2013. These restrictions are being extended pursuant to determinations of the United States Department of State made under the terms of the Convention on Cultural Property Implementation Act in accordance with the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property. CBP Dec. 04–08 contains the Designated List of archaeological material that describes the articles to which the restrictions apply.

DATES: *Effective Date:* March 11, 2009.

FOR FURTHER INFORMATION CONTACT: For legal aspects, George Frederick McCray, Esq., Chief, Intellectual Property Rights and Restricted Merchandise Branch, Regulations and Rulings, Office of International Trade, (202) 325–0082. For operational aspects, Michael Craig, Chief, Interagency Requirements Branch, Trade Policy and Programs, Office of International Trade, (202) 863–6558.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the provisions of the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention, codified into U.S. law as the Convention on Cultural Property Implementation Act (Pub. L. 97–446, 19 U.S.C. 2601 *et seq.*), the United States entered into a bilateral agreement with the Republic of Honduras (Honduras) on March 12, 2004, concerning the imposition of import restrictions on certain categories of archaeological material from Honduras. The archaeological materials subject to the bilateral agreement represent the Pre-Columbian cultures of Honduras and range in date from approximately 1200 B.C. to 1500 A.D. On March 16, 2004, CBP published CBP Decision (Dec.) 04–08 in the **Federal Register** (69 FR 12267), which amended 19 CFR 12.104g(a) to reflect the imposition of these restrictions and included a list designating the types of archaeological material covered by the restrictions.

Import restrictions listed in 19 CFR 12.104g(a) are ''effective for no more than five years beginning on the date on which the agreement enters into force with respect to the United States. This period can be extended for additional periods not to exceed five years if it is determined that the factors which justified the initial agreement still pertain and no cause for suspension of the agreement exists'' (19 CFR 12.104g(a)).

After reviewing the findings and recommendations of the Cultural Property Advisory Committee, the Assistant Secretary for Educational and Cultural Affairs, United States Department of State, concluding that the cultural heritage of Honduras continues to be in jeopardy from pillage of certain archaeological materials, made the necessary determinations to extend the import restrictions for an additional five years on December 4, 2008. Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of the import restrictions. The Designated List of Pre-Columbian Archaeological Material from Honduras covered by these import restrictions is set forth in CBP Dec. 04–08. The Designated List and accompanying image database may also be accessed from the following Internet Web site address: *http://exchanges.state.gov/heritage/culprop.html*. The restrictions on the importation of these archaeological materials from Honduras are to continue in effect for an additional five years. Importation of such material continues to be restricted unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure (5 U.S.C. 553(a)(1)). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

Because this rule involves a foreign affairs function of the United States, it is not subject to Executive Order 12866.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1).

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise.

Amendment to CBP Regulations

■ For the reasons set forth above, part 12 of Title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

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