

CLIENT ADVISORY

CPSC PROPOSES NEW RULES TO IMPLEMENT LEAD REQUIREMENTS

On January 9, 2009, the US Consumer Product Safety Commission (CPSC) posted on its website proposed rules on the following topics to implement the lead substrate requirements that are scheduled to go into effect on February 10, 2009:

- (A) Specified materials that CPSC proposes to find do not exceed the Consumer Product Safety Improvement Act (CPSIA) lead content limits (Proposed 16 CFR § 1500.91);
- (B) Proposed procedures and requirements for requests for:
 - (a) a Commission determination that a material or product does not exceed the lead content limits in § 101(a) of the CPSIA (Proposed 16 CFR § 1500.89); or
 - (b) an exclusion from the lead content requirements for a material or product that exceeds the limits under § 101(a), but which will neither result in the absorption of any lead into the human body nor have any other adverse impact on public health or safety (Proposed 16 CFR § 1500.90);
- (C) Guidance on how to determine whether a component part is inaccessible, and thus not subject to the CPSIA lead limits (Proposed 16 CFR § 1500.87); and
- (D) Providing exemptions for electronic components for which compliance with lead limits is not technologically feasible (Proposed 16 CFR § 1500.88).

We summarize these proposed rules below. Comments on each proposed rule will be due 30 days after it is published in the Federal Register.

BACKGROUND

The CPSIA establishes new lead limits for children's products, banning as a hazardous substance any children's product that exceeds the established limit:

- 600 parts per million (ppm) for any part of a children's product, effective 180 days after enactment (February 10, 2009).
- 300 ppm for any part of a children's product, effective 1 year after enactment (August 14, 2009).
- 100 ppm for any part of a children's product, effective 3 years after enactment (August 14, 2011) (unless determined not technologically feasible by CPSC).

Further, according to an advisory opinion by the CPSC's General Counsel, those new requirements will apply not only to products manufactured after the effective

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date but also to inventory. The Act allows CPSC to exclude by rulemaking a specific product or material if lead in such product or material (i) will not be absorbed into the body with “normal and reasonably foreseeable use and abuse” of the product by a child, and aging of the product, and (ii) will not “have any other adverse impact on public health or safety.”

The Act also requires CPSC to issue a rule providing guidance on which components or classes of components are considered “inaccessible,” i.e., “not accessible to a child through normal and reasonably foreseeable use and abuse” of the product, and thus exempt from compliance with the lead limits.

Further, if CPSC determines that it is not technologically feasible for certain electronic devices to comply with the lead substrate limits, it must issue regulations that reduce the “potential for exposure to and accessibility of lead in such devices,” such as by requiring a child-resistant cover or casing, and issue a schedule by which such devices shall be in full compliance with the lead standard, unless CPSC “determines that full compliance will not be technologically feasible for such devices within a schedule set by” CPSC.

A. NOTICE OF PROPOSED DETERMINATIONS REGARDING LEAD CONTENT LIMITS ON CERTAIN MATERIALS OR PRODUCTS

CPSC proposes to issue a rule finding that certain natural materials and metal alloys do not contain more than 600 ppm or 300 ppm lead content. The rule would relieve the material or product from the testing requirement in section 102 of the CPSIA. However, the material/product would still need to comply with the lead standard.

Natural Materials

CPSC proposes to find that the following natural materials do not exceed 600 ppm or 300 ppm lead content if they are “untreated and unadulterated with respect to the addition of materials or chemicals, including pigments, dyes, coatings, finishes or any other substance, and...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
- (5) Natural fibers such as cotton, silk, wool, hemp, flax, linen
- (6) Other natural materials including coral, amber, feathers, fur, untreated leather

Metals and Alloys

CPSC proposes to find that the following metals and alloys do not exceed 600 ppm or 300 ppm lead content “provided that no lead is intentionally added.”

- (1) Surgical steel
- (2) Precious metals: gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium

CPSC has requested comments both on these proposed findings and on whether there are any other natural fibers or materials, metals or alloys or any other materials that would not exceed the lead content limits.

B. NOTICE OF PROPOSED PROCEDURES AND REQUIREMENTS FOR A COMMISSION DETERMINATION OR EXCLUSION

CPSC is proposing procedures and requirements for:

- (1) a Commission determination that a commodity or

class of materials or a specific material or product does not exceed the lead content limits specified under § 101(a) of the CPSIA; and

- (2) an exclusion of a commodity or class of materials or a specific material or product under § 101(b), that exceeds the lead content limits under § 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.

With respect to identifying materials or products that do not exceed the lead limits, CPSC intends to “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.” By comparison, CPSC plans to give a low priority to requests to evaluate individual products of a single manufacturer. Further, even when CPSC has determined that a product, material or class of materials does not exceed lead standards, and thus is relieved of the CPSIA testing requirement, the product/material must still meet the lead standards.

Information That Must Be Submitted

Any request for a determination by CPSC that a specific material or product complies with the applicable 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 request for an exclusion for a material or product that contains lead “must be supported by the best-available, objective, peer-reviewed, scientific evidence that address” the potential for “absorption of any lead into the body, taking into account normal and reasonable foreseeable use and abuse by a child” or “any other adverse impact on health or safety.”

Documentation that must be submitted for such requests includes:

- (1) a detailed description of the product or material;

- (2) data on the lead content of parts of the product or materials used in the production of a product;
- (3) data or information on manufacturing processes through which lead may be introduced into the product or material;
- (4) 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;
- (5) 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
- (6) 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.

The following additional information must be submitted to seek an exclusion for a material or product that contains lead:

- (1) the 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; and
- (2) the best-available, objective, peer-reviewed, scientific evidence that is unfavorable to the request that is reasonably available to the requestor.

Review Procedure

The Office of Hazard Identification and Reduction (HIR) will review requests for a CPSC determination or exclusion and preliminarily recommend granting or denying the request. If the preliminary determination

is to grant the request, CPSC will publish a notice of proposed rulemaking inviting public comment on whether the preliminary determination should be granted in final form, and HIR will review and evaluate the comments and supporting documentation before making its recommendation to the Commission for final agency action.

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. However, CPSC has determined that an “oral hearing is not necessary to satisfy the requirements of due process”; rather, “given the highly technical nature of the information sought...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.”

Effect of Request

Filing a request for a determination or exclusion “does not have the effect of automatically staying the effect of any provision or limit under the statutes and regulations enforced by” CPSC. Unless a CPSC determination or exclusion is issued in final form after notice and comment, lead content requirements and all applicable testing and certification requirements would remain in full force and effect. However, CPSC notes in the preamble to the proposed rules that its “ability to exercise its enforcement discretion is not eliminated nor diminished.”

C. NOTICE OF PROPOSED INTERPRETATIVE RULE ON INACCESSIBLE COMPONENTS

The CPSIA lead limits do not apply to components of a product that are inaccessible to a child through normal and reasonably foreseeable use and abuse. The CPSIA further provides that paint, coatings, or electroplating may not be considered to be a barrier that would render

lead in the substrate of a component to be inaccessible. CPSC is issuing a proposed interpretive rule to provide guidance with respect to what product components will be considered to be inaccessible.

Under the proposed rule, CPSC preliminarily finds that “an accessible component part of a children’s product is one that a child may touch, and an inaccessible component part is one that is located inside the product that a child cannot touch.” The Commission does not propose to define accessibility based on whether a child can swallow the product or component, or based on whether lead may leach from the product.

CPSC proposes to assess whether a child can touch a component part based on whether any portion of the component part is contacted by the accessibility probes that are specified in CPSC’s regulations (16 CFR §§ 1500.48 and 1500.49). Currently, those probes are used to evaluate products for sharp points and edges in products for children aged three years or less (Probe A) or for children up to eight years of age (Probe B). CPSC has preliminarily concluded that a different probe is not needed for products intended for use by children from 8–12 years of age.

CPSC further proposes to use its existing use and abuse tests to evaluate whether a product component will be inaccessible through reasonably foreseeable use and abuse. The existing tests are in brackets of 18 months of age or less, over 18 months of age but not over 36 months of age, and over 36 months but not over 96 months of age. For products intended for use by children from 3–12 years of age, CPSC proposes to use the existing use and abuse tests for children aged 37–96 months.

Finally, in evaluating whether a product component is accessible, CPSC proposes not to consider the “intentional disassembly or destruction of products by children older than eight years of age by means or knowledge not generally available to younger children.”

D. NOTICE OF PROPOSED RULEMAKING FOR EXEMPTIONS FOR CERTAIN ELECTRONIC DEVICES

Section 101(b)(4) of the CPSIA provides a process for CPSC to exempt from the lead limits certain electronic devices if CPSC determines that it is not technologically feasible for such devices to comply with those limits.

CPSC has recognized that it is currently not technologically feasible for certain parts of electronic devices to comply with the CPSIA lead limits. CPSC has proposed granting to such lead-containing component parts the exemptions published in the Annex to EU Directive 2002/95/EC, as amended through European Union Commission Decision of January 24, 2008 (the “EU RoHS Directive”), provided that the exemption is based on a functional requirement both for the use of a lead-containing component and for the use of lead in such component. However, CPSC is proposing not to adopt the EU RoHS exemption for crystal glass, or any other exemption for uses of lead that are solely decorative or non-functional. In addition, CPSC staff must reevaluate and report to the CPSC on the technological feasibility of compliance with the lead limits no less than five years after publication of a final rule on electronic devices. See 16 CFR § 1500.88(e).

The EU RoHS Directive exemptions include, among others, lead in certain alloy metals and certain solders, and lead oxide in LCD and plasma display panels. In addition, CPSC “proposes to adopt future exemptions promulgated under EU Directive 2002/95/EC, if consistent with the Commission’s determinations that are issued in a final rule on exemptions for certain electronic devices.” A link to a complete list of the current EU RoHS Directive exemptions is attached. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSL:EG:2002L0095:20080524:EN:PDF>.

The proposed rule addresses “accessible” components—components in any product that are inaccessible to a child are not subject to the CPSIA lead

limits. Further, CPSC proposes “that spare parts or other removable components be considered inaccessible under the provisions of the CPSIA, provided that the lead-containing component is inaccessible when the product is assembled in functional form or if the component itself meets the criteria for exemption, such as under the possible exemptions with respect to EU RoHS.”

CPSC is seeking comments on which components listed in the EU RoHS Directive, other than cathode ray tubes, cannot currently be made inaccessible to a child and why. (CPSC recognizes that cathode ray tubes must be exempted because lead is necessary to protect against x-rays generated during use.)

We hope that you have found this client advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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