

“shall ensure that each of the fees * * * is reasonably related to the Administration’s costs, as determined by the Administrator, of providing the service rendered * * *.” Section 119(d) of the Aviation and Transportation Security Act of 2001, Public Law 107–71.

4. Objective. The Administrator deems it appropriate to create the Overflight Fees Aviation Rulemaking Committee to obtain advice and recommendations on the appropriate amounts for future Overflight Fees.

5. Duties. The Committee is to evaluate information regarding the services rendered to overflights by the FAA and the costs of providing those services to overflights, and, based on that evaluation, to make recommendations regarding future overflight fee increases. The Committee shall provide its recommendations to the Administrator by a deadline to be determined by the Chair, which may be modified by the Administrator.

6. Organization and Administration.

a. The Committee shall be led by the Chair, who shall be a full-time employee of the FAA appointed by the Assistant Administrator for Financial Services. The Chair may designate a Vice Chair, who shall not be employed by the FAA and who shall be a representative of foreign air carriers or trade associations of those carriers, or other system users who are subject to Overflight Fees.

b. In addition to the Chair and Vice Chair, the Committee shall be comprised of not more than 15 members, who shall be employees or other representatives of the foreign air carriers (or trade associations of those carriers) or other system users that are subject to the FAA’s Overflight Fees. The members shall be selected by the Associate Administrator for Financial Services and, to the extent possible, the membership also shall be geographically diverse and include representatives that conduct primarily enroute overflights and primarily oceanic overflights. Each member may designate one representative and one alternate to serve on the Committee. Each member of the Committee shall have one vote.

c. Members may permit their employees and consultants (including financial, technical and legal professionals) to attend any Committee meeting and review Committee documents.

d. Additional FAA personnel may participate, as directed by the Chair, as adjunct non-members of the Committee.

e. The Assistant Administrator for Financial Services is the sponsor of the Committee. The Associate Administrator for Financial Services

shall receive all Committee recommendations and reports. The Associate Administrator shall also be responsible for providing administrative support for the Committee and shall provide a secretariat. The Chair shall be responsible for establishment of the procedures, consistent with this charter, under which the Committee shall operate.

f. Meetings shall be held as frequently as needed, as determined solely by the Chair.

g. The Chair shall arrange notification to all members of the time, place and agenda for any meeting through the secretariat and shall ensure that, to the extent practicable, any materials to be considered at the meeting are distributed to Committee members in advance. The Committee is not required to keep minutes, but the Chair may elect to do so. Committee recommendations to the Administrator must be approved by at least a two-thirds vote of the members. The Chair shall have the right to submit a separate report or recommendation to the Administrator.

7. Compensation. All non-government Committee members shall serve without compensation from the U.S. government, and shall bear all costs related to their participation on the Committee.

8. Public Participation. Unless otherwise decided by the Chair, all meetings of the Committee shall be closed. Interested persons wishing to attend a meeting who are not members of the Committee (or employees or consultants invited by a member) must request and receive approval in advance of the meeting from the Chair.

9. Availability of Records. Subject to the provisions of the Freedom of Information Act, Title 5 U.S.C. 522, records, reports, agendas, working papers, and other documents that are made available to, prepared by, or prepared for the Committee shall be available for public inspection and copying at the FAA Office of Rulemaking, 800 Independence Avenue, SW., Washington, DC 20591. Fees shall be charged for the information furnished to the public in accordance with the fee schedule published in part 7 of title 49, Code of Federal Regulations.

10. Public Interest. The formation of the Committee is determined to be in the public interest in connection with the performance of duties imposed on the FAA by law.

11. Effective Date and Duration. This order is effective immediately. The Committee shall remain in existence for two years after the effective date of this Order unless sooner terminated or extended by the Administrator.

Dated: December 17, 2008.

Robert A. Sturgell,

Acting Administrator.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Children’s Products Containing Lead; Exemptions for Certain Electronic Devices; Interim Final Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Interim final rule.

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) is issuing an interim final rule concerning certain electronic devices for which it is not technologically feasible to meet the lead limits as required under section 101 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110–314, 122 Stat. 3016. By notice published elsewhere in today’s **Federal Register**, the Commission is withdrawing the proposed rule on exemptions for certain electronic devices published in the **Federal Register** on January 15, 2009, 74 FR 2435.

DATES: This interim final rule is effective February 10, 2009. Comments must be in writing and should be submitted by March 16, 2009.

ADDRESSES: Comments should be e-mailed to

Sec101ElectronicDevices@cpsc.gov.

Comments should be captioned “Section 101 Electronic Devices Interim Rule.” 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:

Kristina Hatlelid, PhD., M.P.H., Director 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 Lead Content Limits

The CPSIA 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. The limit may be further reduced to 100 ppm after three years, or August 14, 2011, unless the Commission determines that it is not technologically feasible to have this lower limit. A children's product is defined in section 235(a) of the CPSIA as a consumer product designed or intended primarily for children 12 years of age or younger.

Section 101(b)(2) of the CPSIA provides that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children's activities, and the aging of the product, as determined by the Commission. Paint, coatings, or electroplating may not be considered to be a barrier that would render lead in the substrate to be inaccessible to a child. Section 101(b)(2)(B) further provides that the Commission must promulgate a rule providing guidance with respect to what product components or classes of components will be considered to be inaccessible. A proposed interpretative rule providing guidance on inaccessibility was published in the *Federal Register* on January 15, 2009, 74 FR 2439.

In addition, if the Commission determines that it is not technologically feasible for certain electronic devices to comply with the lead limits, section 101(b)(4) of the CPSIA provides that the Commission may issue requirements by regulation to eliminate or minimize the potential for exposure to and accessibility of lead in such electronic devices, and establish a schedule for achieving full compliance unless the Commission determines that full compliance with the lead limits is not technologically feasible within such a schedule. Technological feasibility is based on the commercial availability of products, technology, or other practices that will allow compliance with the lead limits.

On January 15, 2009, the Commission issued a notice of proposed rulemaking on requirements for certain electronic devices that could not comply with the lead limits due to technologically infeasibility. 74 FR 2435. The comment

period ends on February 17, 2009. As discussed below, and by notice published elsewhere in today's *Federal Register*, the Commission is withdrawing that notice of proposed rulemaking.

Stay of Enforcement

Due to substantial confusion by the public and affected businesses regarding implementation of the CPSIA, and as to which testing and certification requirements of the CPSIA apply to which products under the Commission's jurisdiction, and what sort of testing is required where the provisions do apply, on February 2, 2009, the Commission announced a stay of enforcement of testing and certification requirements of certain provisions of subsection 14(a) of the Consumer Product Safety Act (CPSA) as amended by section 102(a) of the CPSIA until February 10, 2010. Although the testing and certification requirements are stayed for manufacturers or importers of children's products, including electronic devices until February 10, 2010, the stay of enforcement did not provide any meaningful relief to manufacturers or importers of children's electronic devices that contain component parts that exceed the lead content limits due to technological infeasibility. Absent issuance of an immediate interim final rule, such manufacturers and importers would not be able to sell children's electronic devices containing component parts that exceed lead content limits due to technological infeasibility until the issuance of a final rule granting exemptions, and yet such a final rule would necessarily issue after the comment period closes for the notice of proposed rulemaking on February 17, 2009. Because the first lead content limit will go into effect on February 10, 2009, manufacturers, importers, retailers and distributors would not know how to address these electronic products between the February 10, 2009 date and the date of any final rule based on the proposed rule. Therefore, by notice published elsewhere in today's *Federal Register*, the Commission is withdrawing the proposed rulemaking and is issuing this interim final rule to provide certainty regarding exemptions for certain children's electronic devices that are in the stream of commerce and fall within the scope of the exemptions provided in this interim final rule.

B. Discussion

The Interim Final Rule

The CPSIA provides authority for the Commission under section 101(b)(4), to

issue regulations concerning certain electronic devices to eliminate or minimize the potential for exposure to and accessibility of lead in such electronic devices if it is not technologically feasible to comply with the lead limits set by the CPSIA. The Commission recognizes that it is currently not technologically feasible for certain parts of electronic devices to comply with the CPSIA lead limits. Accordingly, the Commission is issuing an interim final rule providing exemptions for certain electronic devices.

1. Inaccessible Electronic Devices

Some lead-containing component parts of electronic devices are, by design, not accessible to children because the lead is fully enclosed within a component that is itself within the electronic device. Accessibility of the lead-containing component part may be evaluated through application of the accessibility probes described in 16 CFR 1500.48 and 1500.49, before and after use and abuse tests at 16 CFR 1500.50 through 1500.53 (excluding the bite tests of 1500.51(c) and 1500.52(c)). If a lead-containing component part is not accessible to a child, it is not subject to the lead limits under the CPSIA.

2. Accessible Electronic Devices That Are Exempt

Certain component parts in children's electronic devices cannot be produced without lead due to the lack of technologically feasible substitutions or may require lead for the proper functioning of the component part. However, these component parts may not be able to be made physically inaccessible. An example is a cathode ray tube, in which the lead in the glass protects users from the x-ray radiation generated by the device during normal operation. However, other components could be made to be inaccessible, taking account of normal and reasonably foreseeable use and abuse by children. The Commission expects that manufacturers will continue to assess the technological feasibility of making electronic devices that have accessible component parts which contain lead above the lead content limits inaccessible, and make such component parts inaccessible whenever possible.

To the extent that certain electronic component parts cannot be made inaccessible, the staff has reviewed the exemptions granted under other directives including European Union Directive 2002/95/EC (EU RoHS), and Korea Act for Resource Recycling of Electrical and Electronic Equipment and Vehicles (Korea RoHS), to evaluate

possible exemptions when substitution for lead was not possible due to scientific and technical considerations.¹ These measures are broader, containing limits on allowable lead concentrations, generally 1,000 ppm for lead content, in electronic components and products, without regard to the intended age range of the users. However, the measures also provide for certain exemptions to the allowable lead concentrations for some components.

Staff's review of the use of lead in children's electronic devices showed that in general, lead is added to components in electronic products to take advantage of the unique material properties that lead and lead compounds exhibit including improved ability of the material to be machined and improved corrosion resistance of an alloy. For example, lead is added to copper alloys to adjust its mechanical strength and modulus of elasticity. Lead is added to glass to adjust its index of refraction. Lead also serves to mechanically strengthen glass and in the case of cathode-ray tubes, improve its ability to absorb x-rays. Lead added to bushing and bearing materials acts as a dry lubricant to lower friction in the components during use. Lead is also used to adjust the mechanical properties of electronic connectors.

As a result of these unique properties for lead, the staff determined that it is not technologically feasible for certain components in electronic devices to meet the lead content limits under the CPSIA because the presence of the lead is necessary for proper functioning of certain component parts in electronic devices and substitution of the lead is not yet technologically feasible. Based on staff's review, the Commission has determined that the following exemptions for lead as used in certain components parts in children's electronic devices that do not meet the lead content limits under the CPSIA are currently necessary:

1. Lead blended into the glass of cathode ray tubes, electronic components and fluorescent tubes.
2. Lead used as an alloying element in steel. The maximum amount of lead shall be less than 0.35% by weight (3500 ppm).
3. Lead used in the manufacture of aluminum. The maximum amount of

lead shall be less than 0.4% by weight (4000 ppm).

4. Lead used in copper-based alloys. The maximum amount of lead shall be less than 4% by weight (40,000 ppm).

5. Lead used in lead-bronze bearing shells and bushings.

6. Lead used in compliant pin connector systems.

7. Lead used in optical and filter glass.

8. Lead oxide in plasma display panels (PDP) and surface conduction electron emitter displays (SED) used in structural elements; notably in the front and rear glass dielectric layer, the bus electrode, the black stripe, the address electrode, the barrier ribs, the seal frit and frit ring as well as in print pastes.

9. Lead oxide in the glass envelope of Black Light Blue (BLB) lamps.

3. Removable or Replaceable Component Parts

Some components of children's electronic devices may be removable or replaceable. For example, battery packs and light bulbs may be provided as spare or replacement parts. Until such components are installed in the product, lead-containing parts may be accessible to a child. However, the Commission finds that spare parts or other removable components shall 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 exemptions provided herein.

4. Accessible Electronic Devices Which Are Not Exempt

All component parts of children's electronic devices that exceed the CPSIA's specified lead limits which cannot be made inaccessible and that are not exempted on the basis of exemptions adopted by the Commission must comply with the lead limits specified in the CPSIA. The Commission's expectation is that, with the exception of a few particular applications such as cathode ray tubes, many electronic devices will be in compliance with the CPSIA lead provisions either because they already meet the lead content limits or through the exception for inaccessibility of lead-containing component parts. However, to the extent that an accessible component part does not qualify for an exemption, it must continue to meet the CPSIA lead limits.

5. Periodic Review

The Commission will consider all comments received during the comment period as discussed below. In addition, because of the changing state of technology and continuing progress in replacing lead with other substances, and consistent with the mandate to conduct periodic reviews under section 101(b)(5) of the CPSIA, staff will reevaluate the technological feasibility of compliance with the lead limits for children's electronic devices, including the technological feasibility of making accessible component parts inaccessible, and the status of the exemptions, no less than every five years as required by the CPSIA.

C. 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 determined that the exemption for certain specified materials from the requirements of section 101(a) of the CPSIA will not result in any increase in the costs of production for any firm. Its only effect on businesses, including small businesses, will be to reduce the costs that would have been associated with testing the exempted materials. Accordingly, the Commission finds that the proposed rule would not have a significant impact on a substantial number of small entities.

D. 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 interim final rule will not result in any additional use of lead over what is occurring at the present time. Accordingly, the Commission does not expect the proposal to have any negative environmental impact.

E. 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

¹ European Union Directive 2002/95/EC and amendments to the directive are available at <http://eur-lex.europa.eu/en/index.htm>. The Korea RoHS is available at <http://www.kece.eu/rohs/kr.htm>. The consideration and application of these limited exemptions from such directives in this interim final rule do not imply that the Commission endorses or supports those directives in any way.

the Federal Hazardous Substances Act, 15 U.S.C. 1261n.

F. Effective Date

The Administrative Procedure Act (APA) requires that a substantive rule must be published not less than 30 days before its effective date, unless it grants an exemption. 5 U.S.C. 553(d)(1). Because this interim final rule grants exemptions from the existing requirements, the effective date is February 10, 2009.

G. Request for Comments

The interim final rule will become effective without prior notice and comment. Notice and comment procedures are not required under the APA when the agency for good cause finds that notice and comment is impracticable, unnecessary or contrary to the public interest. 5 U.S.C. 553(b)(B). The Commission finds that the public notice and comment before the issuance of this interim final rule would have been impracticable given the statutory requirement imposed in the CPSIA that the lead limits go into effect on February 10, 2009, six months after the enactment of the CPSIA, and the inapplicability of the Commission's stay of certain testing certification requirements to lead content limits imposed on these products.

Interested persons are invited to submit comment on the interim final rule. The Commission will consider these comments before issuing final regulations. In addition, comments previously submitted in response to the notice of proposed rulemaking will be considered along with the comments to the interim final rule in this proceeding. Comments should be submitted by March 16, 2009. Comments should be e-mailed to

Sec101ElectronicDevices@cpsc.gov.

Comments should be captioned "Section 101 Electronic Devices Interim Rule." 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.

List of Subjects in 16 CFR Part 1500

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

■ For the reasons stated above, the Commission amends 16 CFR part 1500 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 a new § 1500.88 to read as follows:

§ 1500.88 Exemptions from lead limits under section 101 of the Consumer Product Safety Improvement Act for Certain Electronic Devices.

(a) The Consumer Product Safety Improvement Act (CPSIA) 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)(4) of the CPSIA provides that if the Commission determines that it is not technologically feasible for certain electronic devices to comply with the lead limits, the Commission must issue requirements by regulation to eliminate or minimize the potential for exposure to and accessibility of lead in such electronic devices and establish a compliance schedule unless the Commission determines that full compliance is not technologically feasible.

(c) Certain lead-containing component parts in children's electronic devices unable to meet the lead limits set forth in paragraph (a) of this section due to technological infeasibility are granted the exemptions that follow in paragraph (d) of this section, provided that use of lead is necessary for the proper functioning of the component part and it is not technologically feasible for the component part to meet the lead content limits set forth in paragraph (a) of this section.

(d) Exemptions for lead as used in certain component parts in children's electronic devices include:

(1) Lead blended into the glass of cathode ray tubes, electronic components and fluorescent tubes.

(2) Lead used as an alloying element in steel. The maximum amount of lead shall be less than 0.35% by weight (3500 ppm).

(3) Lead used in the manufacture of aluminum. The maximum amount of lead shall be less than 0.4% by weight (4,000 ppm).

(4) Lead used in copper-based alloys. The maximum amount of lead shall be less than 4% by weight (40,000 ppm).

(5) Lead used in lead-bronze bearing shells and bushings.

(6) Lead used in compliant pin connector systems.

(7) Lead used in optical and filter glass.

(8) Lead oxide in plasma display panels (PDP) and surface conduction electron emitter displays (SED) used in structural elements; notably in the front and rear glass dielectric layer, the bus electrode, the black stripe, the address electrode, the barrier ribs, the seal frit and frit ring as well as in print pastes.

(9) Lead oxide in the glass envelope of Black Light Blue (BLB) lamps.

(e) Components of electronic devices that are removable or replaceable such as battery packs and light bulbs that are inaccessible when the product is assembled in functional form or are otherwise granted an exemption are not subject to the lead limits in paragraph (a) of this section.

(f) Commission staff is directed to reevaluate and report to the Commission on the technological feasibility of compliance with the lead limits in paragraph (a) of this section for children's electronic devices, including the technological feasibility of making accessible component parts inaccessible, and the status of the exemptions, no less than every five years after publication of a final rule in the **Federal Register** on children's electronic devices.

Dated: February 9, 2009.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E9-3025 Filed 2-11-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2008-N-0039]

Implantation or Injectable Dosage Form New Animal Drugs; Flunixin

AGENCY: Food and Drug Administration, HHS.