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Issued in Seattle, Washington, on August 14, 2009.

H. Steve Karnes,

*Team Manager, Operations Support Group,
Western Service Center.*

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Children's Products Containing Lead; Determinations Regarding Lead Content Limits on Certain Materials or Products; Final Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (Commission) is issuing a final rule on determinations that certain materials do not exceed the lead content limits specified under section 101(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA).

DATE: *Effective Date:* This regulation becomes effective on August 26, 2009.

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SUPPLEMENTARY INFORMATION:

A. Background

Under section 101(a) of CPSIA, consumer products designed or intended primarily for children 12 years old and younger that contain more than 600 ppm of lead (as of February 10, 2009); 300 ppm of lead (as of August 14, 2009); and 100 ppm after three years (as of August 14, 2011), unless the Commission determines that it is not technologically feasible to have this lower limit, are considered to be banned hazardous substances under the Federal Hazardous Substances Act (FHSA). Products below these lead content limits are not banned; however, in the absence of Commission action, these products and materials used to make children's products remain subject to the lead limits and consequently, the testing requirements of certain provisions of

section 14(a) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the CPSIA.¹ By this rule, the products and materials determined by the Commission to fall under the lead content limits, are no longer subject to section 101(a) of the CPSIA and no testing of these products and materials is required under section 102(a) of the CPSIA.

B. Statutory Authority

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. The Commission has the authority under section 3 of the CPSIA to make determinations that certain commodities or classes of materials or products do not, and, by their nature, will not exceed the lead limits prescribed in section 101(a) of the CPSIA. Accordingly, in this rule, the Commission has determined that certain products or materials inherently do not contain lead or contain lead at levels that do not exceed the lead content limits under section 101(a) of the CPSIA. The effect of such a Commission determination would be to relieve the material or product from the testing requirement of section 102 of the CPSIA for purposes of supporting the required certification. However, if the material or product changes such that it exceeds the lead limits of section 101(a) of the CPSIA, then the determination is not applicable to that material or product. The changed or altered material or product must then meet the statutory lead level requirements. The Commission intends to obtain and test products in the marketplace to assure that products comply with the CPSIA lead limits and will take appropriate enforcement action if it finds a product to have lead levels exceeding those allowed by law.

C. Notice of Proposed Rulemaking

In the **Federal Register** of January 15, 2009 (74 FR 2433), the Commission

¹ Currently, there is 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 (see 74 FR 6936 (February 9, 2009)). The stay does not cover those requirements where testing and certification was required by subsection 14(a) of the CPSA before the CPSIA's enactment, and third party testing and certification requirements for lead paint, full-size and non-full size cribs and pacifiers, small parts, metal components of children's metal jewelry, certifications expressly required by CPSC regulations, certifications required under the Virginia Graeme Baker Pool and Spa Safety Act, certifications of compliance required for All-Terrain Vehicles in section 42(a)(2) of the CPSA, and any voluntary guarantees provided for in the Flammable Fabrics Act.

issued a notice of proposed rulemaking on preliminary determinations that certain natural materials do not exceed the lead content limits under section 101(a) of the CPSIA. The preliminary determinations were based on materials that are untreated and unadulterated with respect to the addition of materials or chemicals, including pigments, dyes, coatings, finishes or any other substance, and that did not undergo any processing that could result in the addition of lead into the product or material. These materials included:

- Precious gemstones (diamond, ruby, sapphire, emerald);
- 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);
- Natural or cultured pearls;
- Wood;
- Natural fibers (such as cotton, silk, wool, hemp, flax, linen); and
- Other natural materials including coral, amber, feathers, fur, untreated leather.

See 74 FR at 2435.

In addition, in the proposed rule, the Commission preliminarily determined that certain metals and alloys did not exceed the lead content limits under section 101(a) of the CPSIA provided that no lead or lead-containing metal is intentionally added. The metals and alloys considered included surgical steel, precious metals such as gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium. (See 74 FR at 2435). The preliminary determinations did not extend to the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications.

D. Discussion of Comments to the Proposed Rule

The proposed rule generated several hundred comments from a diverse range of interests, including advocacy groups, consumer groups, a State's attorney general's office, and small businesses including crafters. No comment opposed the proposed determinations, and, therefore, the final rule retains those determinations. The proposed rule considered those initial determinations in the context of whether the lead limits

of such materials would exceed 600 ppm and 300 ppm.

After reviewing the comments and additional data submitted, the Commission further evaluated those materials in the context of whether these materials would exceed 100 ppm, and finds that, for the reasons discussed in the preamble, that such materials would not exceed 100 ppm.

Accordingly, the final rule revises the language in former §§ 1500.91(c) and (d) (renumbered as §§ 1500.91(d) and (e)) to remove references to 600 ppm and 300 ppm, and includes a reference to “lead content limits” to reflect that the determinations made in the final rule also fall below 100 ppm for such materials. Most comments sought to add to the list of materials; accordingly, the preamble to this final rule will focus on those comments suggesting additions to the list and also describe the changes made to the final rule as a result of those comments. After review of the comments and data, including test results, if any, submitted, the Commission has determined that some materials that fall below the lead content limits may be manufactured or man-made. Accordingly, we have revised proposed § 1500.91(c) (renumbered as § 1500.91(d)) to remove the word “natural” before “materials.” We note that in the final rule on procedures and requirements for a Commission determination (procedures rule), the Commission explicitly stated that any request for a determination that a specific material or product contains no lead or a lead level below the applicable statutory limit must show that the product or material does not, and would not, exceed the lead limit specified in the request. (74 FR 10475, 10477 (March 11, 2009)). Accordingly, the manufactured materials that the Commission has determined to be below the lead content limits in this rule are limited only to those materials that we could verify do not, and would not contain lead because either their composition or formulation does not contain lead or the use of lead would interfere with or compromise the material or the product on which it is used, and there is no possibility that the product or material can be contaminated with lead or otherwise adulterated. Given the well documented dangers to children for exposure to lead paint, the Commission will not consider any determinations for paints or similar surface-coating materials that are subject to the lead paint ban under the Commission’s regulations at 16 CFR part 1303.

For metal (except for the determinations made for certain metals

in this rule) and plastic components, the Commission has found that these materials do sometimes contain lead. For example, the Commission previously examined metal and plastic components in the context of children’s jewelry. The CPSC Directorate for Laboratory Sciences, Division of Chemistry analyzed 466 children’s metal jewelry items from 156 compliance samples since 1996. Nearly 270 items tested had total lead of 600 ppm or more. Numerous metal components including pendants, charms, chains, links, hooks, clasps, and beads contained lead content exceeding 300 ppm, and some components were composed of almost 100 percent lead. In addition, several plastic components such as beads and cords had lead contents ranging from 540 ppm to 5,020 ppm. See CPSC Memorandum from David Cobb to Kristina M. Hatlelid, “Summary of Test Results for Lead in Children’s Metal Jewelry,” November 29, 2006. Tab B of Briefing Package for Petition Requesting Ban of Lead in Toy Jewelry (Petition No. HP 06–1), December 4, 2006.) The Commission also has found lead in other children’s items made of plastic. An analysis of 81 polyvinyl chloride (PVC) bib samples in May 2007 showed samples with total lead content of up to 6,880 ppm. (See CPSC Staff Analysis of Lead Content and Accessible Lead in Vinyl Baby Bibs, May 5, 2007; <http://www.cpsc.gov/CPSCPUB/PREREL/prhtml07/07175.pdf>.) In November, 1997, the CPSC staff also analyzed the lead content for numerous vinyl children’s products and found that several children’s products, such as an umbrella and toy telephone, showed lead content up to 6,300 ppm. (See CPSC Staff Report on Lead and Cadmium in Children’s Polyvinylchloride (PVC) Products, November 21, 2007; <http://www.cpsc.gov/CPSCPUB/PUBS/pbcdtoys.html>.) The Commission has found lead in other products as well. For example, in May 2001, the Commission found that vinyl miniblinds that had lead added to stabilize the plastic in the blinds presented a lead poisoning hazard for young children. The Commission found that over time, the plastic deteriorates from exposure to sunlight and heat to form lead dust on the surface of the blind. In homes where young children were present, children could ingest the lead by wiping their hands on the blinds and then put their hands in their mouths. (See Report on lead in vinyl miniblinds Part 1–Part 3 (May 2, 2001); <http://www.cpsc.gov/library/foia/foia97/os/bp971.pdf>.) In 2003, the Commission

banned candles made with metal-cored wicks with lead content exceeding 600 ppm. The Commission found that, as a lead-cored wick candle burns, some of the lead may vaporize and be released into the air. (See Metal-Cored Candlewicks Containing Lead and Candles With Such Wicks, 68 FR 19142 (April 18, 2009).) The Commission stated, “[s]ome of this lead may deposit onto floors, furniture and other surfaces in the room where children may be exposed to it. One cannot tell by looking at the wick core if it is made of lead, and there is no simple way for a consumer to determine its lead content. The presence of lead in a wick can be determined only by laboratory analysis.” *Id.* at 19143.

Given the Commission’s past experience with lead in plastic and metal, we cannot make a determination that these materials do not or would not contain lead in an amount that does not exceed the lead content limits without a demonstration that the material or product does not and would not contain lead because the inclusion of lead would either interfere with or compromise the manufacture of the material or product, or interfere with or compromise the use of the material or product. Such materials or products must also demonstrate that lead contamination cannot occur during the manufacturing process or be otherwise adulterated. The CPSIA was enacted, in part, to ensure that any material used in any part of a children’s product that could contain lead would be tested by a third-party conformity assessment body (laboratory) so that lead-containing materials would not be used, either deliberately, or inadvertently, to make such products. The determinations excluding metal, plastic, and painted components used in children’s products will ensure that the materials that do contain lead or could contain lead will continue to be tested consistent with section 102 of the CPSIA.

Most comments requested that the Commission add other materials to the list of materials that the Commission determines are not expected to contain lead above the lead limits prescribed under section 101(a) of the CPSIA. [Ref. 2]. However, most comments were not supported by specific data or other information relevant to the determinations of lead content of the materials, and so we did not have a sufficient evidentiary basis to determine whether those materials would not be expected to contain lead above the statutory limits. For determinations on a specific material or product, a party must submit an application that provides the information requested

under the procedures rule (see 74 FR 10475), including objectively reasonable and representative test results and other evidence showing that the product or material does not and would not exceed the lead content limits. The list of determinations made in this rule is not exhaustive; the Commission will continue to evaluate other requests on materials or products submitted under the procedures rule, and consider whether to re-evaluate a material if new evidence indicates that a re-evaluation is warranted or the Commission receives data or information demonstrating that a particular material does not and would not contain lead. In such circumstances, the Commission will amend the rule, if appropriate.

In other cases, the comments did provide test data and other information relevant to this proceeding, and those comments are addressed in parts D.1 through D.15 of this preamble below.

1. Compliance With Section 101(a) of the CPSIA

Several commenters generally supported the reduction of potentially repetitive and wasteful testing of products and materials that are not expected to contain lead, but they stressed that the Commission should proceed carefully to ensure that the requirements of the law are met. The commenters asserted that the Commission should not only request data from firms, but should test children's products itself, especially those products that have not, to date, been subject to lead content requirements or testing for lead content. One commenter also stated that the final rule should make clear that materials that the Commission determines do not contain excess lead levels must still comply with the statutory lead content standard.

The Commission has already indicated that it intends that all children's products subject to a determination must still comply with the lead limit in its "Statement of Commission Enforcement Policy on Section 101 Lead Limits," dated February 6, 2009 (available on the CPSC's Web site at <http://www.cpsc.gov/about/cpsia/101lead.pdf>). However, the Commission agrees with the comments that the final rule should remind interested parties of their obligation to comply with the lead limits even if their products are the subject of a determination, and so we have amended the final rule to create a new § 1500.91(c) (and renumbering the remaining paragraphs accordingly) stating that:

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 if the product or material is changed or altered so that it exceeds the lead content limits.

In addition, the Commission has in place procedures and requirements for a Commission determination that a specific material or product contains no lead or a lead level below the applicable statutory limit (see 74 FR 10475). Among other things, any request must be supported by objectively reasonable and representative test results or other evidence showing that the product or materials does not, and would not, exceed the lead limit specified in the request. 74 FR at 10477.

As for compliance with the statutory limits, 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 testing and certification requirements under section 102 of the CPSIA, manufacturers and importers remain 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.

2. Plant and Animal Based Materials

Many commenters asserted that there are many natural, plant or animal-based materials that likely do not contain appreciable lead content and should be suitable for use in children's products without testing for lead content. Materials mentioned include plants in general, and specifically bark, leaves, flowers and flower petals, seeds, cones, loofa, rattan, wicker, bamboo, bamboo fiber, plant-based dyes, nut shells, buckwheat hulls, essential plant oils, lavender, witch hazel, jute, kapok, kenaf, ramie, sisal, hemp, agave, coconut, soy, moss, straw, jojoba oil, and tung oil. Animal-based materials that were mentioned included yak, angora, mohair, llama, alpaca, bison, camel, guanaco, cashmere, horse hair, claws, horn, seashells, bone, animal glue, shellac.

Our review showed that plant and animal-based materials generally do not contain lead at levels that exceed the CPSIA lead limits. [Ref. 1]. However, we find that any determinations made

regarding plant and animal-based materials must be confined to those materials that are unadulterated by the addition of chemicals and materials (such as paints and similar surface-coating materials, as discussed further in part D.7 of this preamble) since such treatments or additions may not comply with the lead limits without further testing. Although most materials identified in the comments were not specifically included in the proposed rule, the proposed determinations included three categories of natural materials with examples that are similar to many of these items (*i.e.*, wood; natural fibers, including cotton, silk, wool, hemp, flax, and linen; other natural materials including coral, amber, feathers, fur, and untreated leather). Accordingly, the final rule includes other materials, such as plant and animal-based materials that have not been adulterated or modified as a new § 1500.91(d)(8). Specifically, the new provision covers "other plant-derived and animal-derived materials, including, but not limited to, animal glue, beeswax, seeds, nut shells, flowers, bone, sea shell, coral, amber, feathers, fur, leather." Leather is discussed further in part D.13(c) of this preamble.

3. Foodstuffs

Some commenters stated that foodstuffs or materials suitable in food uses may be used in making children's products and should be determined to comply with lead limits given that they are largely natural plant or animal based materials and are considered edible or safe for use by consumers. Some materials mentioned included vegetable and nut oils, medicinal-grade mineral oil, table salt, flax seed, food coloring, food preservatives, cream of tartar, grain flours, dried beans, dried corn, millet, herbs, cherry pits, rice, seeds, milk, honey, beeswax, candelilla wax, and carnauba wax.

In general, articles that fall within the statutory definition of "food" under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321 et seq.) are excluded from the definition of "consumer product" under the Consumer Product Safety Act (CPSA). 15 U.S.C. 2052(a)(5)(I). Section 321(f) of the FFDCA defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Section 402(a)(1) of the FFDCA provides that a food is deemed to be adulterated if it contains any poisonous or deleterious substances, such as chemical contaminants, which may or ordinarily render it harmful to

health. Under this provision and other provisions in the FFDCA, the Food and Drug Administration (FDA) oversees the safety of much of the food supply. Accordingly, the Commission will not make determinations on lead content limits for foods used in consumer products. However, to the extent that there are materials available to manufacturers, such as beeswax, that are sometimes sold as food, but that are not always sold in a form intended for consumption, the Commission will treat such products as other natural materials if they are unadulterated and have not been treated with lead-containing material, and new § 1500.91(d)(8) specifically identifies some of those products, such as beeswax.

4. Cosmetics

A few commenters suggested that determinations be made for soaps, lotions and dental floss.

In general, articles that fall within the statutory definition of “cosmetic” or “device” under the FFDCA (21 U.S.C. 321 *et seq.*) are excluded from the definition of “consumer product.” 15 U.S.C. 2052(a)(5)(H). Soaps and lotions are considered cosmetics under the FFDCA as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance.” 21 U.S.C. 321(i). Dental floss is considered a “device” under the FFDCA because it is “an instrument, apparatus, implement, machine, contrivance, implant * * * intended to affect the structure or any function of the body of man * * *” or, alternatively, is intended for use in the mitigation or prevention of disease. 21 U.S.C. 321(h). Products and materials that are not consumer products under the Commission’s jurisdiction are not subject to section 101(a) of the CPSIA, and testing of these products and materials are not required under section 102(a) of the CPSIA. Such cosmetics and devices would, instead, be subject to the requirements of the FFDCA.

5. Glues and Adhesives

A number of commenters sought determinations for glues and adhesives. Certain glues are made entirely from natural materials, such as animal glue. Accordingly, animal glue has been added under new § 1500.91(d)(8). However, we did not receive specific data regarding specific formulations of individual glues and adhesives; therefore we cannot make determination regarding the entire category of glues and adhesives that may be available in

the marketplace. However, we believe that in most instances, glues and adhesives will be inaccessible to children.

The Commission has issued a final interpretative rule on inaccessible component parts (inaccessibility rule) which finds 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. (74 FR 39535 (August 7, 2009)). In the inaccessibility rule, the Commission provided that accessibility probes specified for sharp points or edges at 16 CFR 1500.48 through 1500.49 should be used to determine whether a lead-containing component can be contacted by a child. In addition, the inaccessibility rule provides that the use and abuse tests specified in 16 CFR 1500.50 through 1500.53 should be used to assess the accessibility of lead-component parts during normal and reasonably foreseeable use and abuse of a product by a child. However, paint, coatings or electroplating may not be considered a barrier that would render lead in the substrate to be inaccessible to a child.

Most glues and adhesive are used to affix decorations and ornamentation to products or to secure sections of fabric, leather, wood, paper and other materials. In most instances, the glue or adhesive is usually not physically exposed because the materials covering the glue or adhesive serve as barrier to the underlying glue or adhesive. For instance, a children’s book is bound with adhesives, but the adhesive is not accessible because the spine is covered with paper, cloth, leather, or other materials, and would not become physically exposed through reasonably foreseeable use and abuse of the product. As set forth in the inaccessibility rule, manufacturers of children’s products should use the Commission accessibility probes specified for sharp points or edges at 16 CFR 1500.48 through 1500.49, and the use and abuse tests specified in 16 CFR 1500.50 through 1500.53 to determine whether glue or adhesives, or other components, would be accessible to children.

6. Composite Wood Products

Several commenters stated that wood is not expected to contain lead while other commenters asked us to expand the determination to include related products, such as composite wood

constructed of wood, adhesives, and other materials.

The commenters did not provide sufficient test data or other information to enable us to assess whether the lead content of manufactured wood products that contain various non-wood materials would fall under the lead content limits prescribed by the CPSIA. A request for a Commission determination for materials that fall under the lead content limits of the CPSIA must provide data and other information requested under the procedures rule. Accordingly, although the final rule does not include composite wood products, a request for a specific materials determination may be submitted to the Commission, consistent with those requirements.

7. Certain Finishes

Several commenters requested that water based paints, acrylic paints, water based clear finishes, varnishes, lacquers, and milk paint be determined to comply with the lead content limits.

We decline to revise the rule as suggested by the comments. The Commission has long-standing regulations on paint and similar surface coatings at 16 CFR part 1303. Section 101(f) of the CPSIA imposed an even stricter lead limit for paint and similar surface coatings from 600 ppm total lead by weight to 90 ppm total lead by weight as of August 14, 2009. Because of the well-documented danger to children from contact with lead-containing paints and similar surface coatings and past instances of children’s products bearing lead-containing paints or coatings despite regulations prohibiting the practice, such materials must be tested to show their compliance with the regulations, and we have revised proposed § 1500.91(a) to include the following: “Materials used in products intended primarily for children 12 and younger that are treated or coated with paint or similar surface-coating materials that are subject to 16 CFR part 1303, must comply with the requirements for lead paint under section 14(a) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the CPSIA.”

8. Other Metals Including Titanium, Aluminum, Pewter, Copper

Some commenters requested that certain other metals, including stainless steel, titanium, aluminum, pewter and copper be added to the list of determinations.

We agree, in part, with the commenters that stainless steel (with the exception of one stainless steel alloy) and titanium should be added to

the list of determinations. [Ref. 6]. Stainless steel is a generic name for corrosion-resistant steel alloys. Typically, the manufacturing process for stainless steel uses recycled scrap as well as “virgin” (newly refined) steel, yet the manufacturing process heats the steel to temperatures high enough to vaporize any lead and lead oxide present. Once the steel melts, the mix is subjected to a vacuum, and the lead/lead oxide gases are drawn off for condensation and recycling.

Consequently, the manufacture of stainless steels results in alloys with lead concentrations less than 100 ppm.

However, we found that one stainless steel alloy, designated as 303Pb, does contain lead. The concentration of lead in 303Pb stainless steel is between 0.12% and 0.30% (1200 to 3000 ppm). The Unified Numbering System designation for 303Pb steel is S30360. Thus, 303Pb stainless steel is excluded from any determination for stainless steel. The Commission has revised proposed § 1500.91(d)(1) (now renumbered as § 1500.91(e)(1)) to add “other stainless steel within the designations of Unified Numbering System, UNS S13800–S66286, not including the stainless steel designated as 303Pb (UNS S30360).”

Titanium (both α - and β -phase) uses elements such as aluminum, gallium, oxygen, nitrogen, molybdenum, vanadium, tungsten, tantalum, and silicon as alloying materials. Lead is considered an undesired impurity and is not found in titanium alloys. In all of the titanium alloys examined, we did not find an instance where lead was a constituent. Consequently, the Commission has revised proposed § 1500.91(d)(2) (now renumbered as § 1500.91(e)(2)) to add “titanium” to the list of determinations on precious metals.

As for other metals and alloys, including aluminum, copper and pewter, such metals and alloys may contain significant amounts of lead, and we cannot verify that the specific products containing such metals or alloys comply with the lead content limits without testing. (See *e.g.*, American Society for Metals: *Metals Handbook, Properties and Selection: Nonferrous Alloys and Pure Metals*, 9th ed., v.2 (1979).) Accordingly, these other metals and alloys continue to be subject to the testing and certification requirements of section 102 of the CPSIA.

9. Other Minerals and Items Found in the Earth

Several commenters stated that, in addition to certain precious and

semiprecious gems, other minerals and items found in the earth, such as rocks or fossils, should be determined to contain lead below the lead content limits.

As with the precious gemstones and certain semi-precious stones that the Commission determines do not contain lead at levels that exceed the CPSIA lead content limits, other rocks and stones may comply with lead limits provided that they are not based on lead or lead compounds and are not associated in nature with any mineral that is based on lead or lead compounds. [Ref. 4]. In general, we agree that most minerals do not contain lead.

However, some minerals are known to contain lead or are associated in nature with minerals that contain lead. We have previously identified minerals that can contain lead, such as aragonite, bayldonite, boleite, cerussite, crorocite, linarite, mimetite, phosgenite, vanadinite, and wufenite. We have also identified galena, and will add this mineral to the list of lead-containing minerals under section 1500.91(d)(2). Accordingly, these minerals are specifically excluded from the determinations regarding minerals generally, and would require testing if they are used in any children’s products to assess whether they are under the lead content limits.

10. Ceramic Glaze and Clay

A few commenters claimed that ceramic glazes and clays comply with lead limits.

We are aware that some products or materials used in ceramics production do not contain lead or use lead-free glazes, but others are known to contain lead at levels that exceed the CPSIA limits for lead content. Lead in ceramic ware typically comes from the varnish or glaze applied to give a shiny finish to the product. In addition, certain colorants used in decoration may contain lead pigments. Without the required testing of ceramic glazes and other materials, compliance with the lead content limits of the CPSIA cannot be verified for the myriad of products that are available. Moreover, in the Joint Conference Report, H.R. Rep. No. 110–787, the conferees stated under the section titled *Special Issues* that they “believe the Commission should take appropriate action with respect to lead included in any ceramic product within its jurisdiction.” Conference Report on H.R. 4040, Consumer Product Safety Improvement Act of 2008, 154 Cong. Rec. H7214 (daily ed. July 29, 2008). Accordingly, for children’s ceramic ware, until the Commission receives

detailed information and test data regarding lead in ceramic ware, the Commission will continue to require the testing and certification requirements under section 102 of the CPSIA.

11. Glass, Crystals, and Rhinestones

Several commenters listed glass, glass beads, rhinestones, leaded glass crystals, and porcelain enamel as items that should be exempted from compliance with the CPSIA requirements for lead content or testing.

While not all glass or glass products, crystals, or rhinestones contain lead at levels that exceed the CPSIA lead limits, in the absence of tests or other data on these products, we cannot verify that such products meet the CPSIA’s lead content limits. Further, many leaded glass crystals and other glass-based products contain lead at levels exceeding the statutory limits and, therefore, cannot be included in a determination that they do not and would not contain lead. We also note that, on July 17, 2009, the Commission voted 2–1 to deny a request to exclude crystal and glass beads, including rhinestones and cubic zirconium, from the lead content limits. The Commissioners’ statements accompanying that decision can be found at: <http://www.cpsc.gov/about/cpsia/sec101.html#statements>.

12. Pencils, Crayons, Other Materials Regulated as Art Materials

Some commenters requested that certain art materials be determined to not contain lead at levels that exceed the CPSIA lead limits.

The CPSIA’s requirements for lead content are in addition to other statutory and regulatory requirements for children’s art materials. Compliance under the Labeling of Hazardous Art Materials Act (LHAMA) (15 U.S.C. 1277) requires the submission of art material product formulations to a toxicologist for review to assess chronic adverse health effects through customary or reasonably foreseeable use. If the toxicologist determines that the art material has this potential, the producer or repackager must use cautionary labeling on the product in accordance with the requirements set forth at 16 CFR 1400.14(b)(8), and section 2(p) of the FHSA, 15 U.S.C. 1261(p). Any art material intended for children that is or contains a hazardous substance (by reason either of chronic or acute toxicity) would be a banned hazardous substance under section 2(q)(1)(A) of the FHSA, 15 U.S.C. 1261(q)(1)(A). Art supplies that are intended primarily for use by children must also comply with the lead content

limits under section 101(a) of the CPSIA. Accordingly, without receiving more information and data regarding the lead content of specific art materials intended primarily for children, we are unable to make any determinations in this proceeding.

13. *Fabrics, Dyes and Similar Materials*

Numerous commenters claimed that many fabrics, yarns, batting, fill, and similar materials (such as ribbon), and related materials (such as elastic), including those that are dyed or similarly processed, do not contain lead. In addition, some commenters requested a determination that fabric dyes comply with the lead content limits. The commenters provided data and other information to support their claims. Additionally, during a public meeting held on January 22, 2009, industry representatives, test laboratories, and stakeholders met with CPSC staff and presented materials and test data on lead levels in textile and apparel products. Several hundred test reports and analyses were submitted. The tests analyzed lead levels in various textile and apparel products, including a range of daywear, sleepwear, and outerwear garments. Tests for lead were also conducted on the many functional and decorative components used on apparel items. These items include adornments (rhinestones and beads), closures and findings (buttons, snaps, and zippers), trims, and fasteners.

Information on the dye industry was also submitted by the Ecological Association of Dye and Organic Pigment Manufacturers (ETAD). ETAD states that it represents about 80% of worldwide dye manufacturers. According to ETAD, 80% or more of dyes used in commercial processing are organic carbon compounds and do not contain lead. Dyes used for cotton, other cellulose, and polyester, the most commonly used fibers for apparel, account for 70% of total dye consumption. According to ETAD, these fibers use specific dye classes (e.g., disperse, direct, reactive) that would not contain lead. ETAD also recommends that its member companies follow lead limits of 100 ppm using a sampling and testing procedure that ensures the recommended limits.

a. *Textiles*

We reviewed the data pertaining to textile products intended for children and the general practices used in the textile industry and the modern production and coloration of textiles and apparel. [Refs. 1 and 3]. We conclude that most textile products are manufactured using processes that do

not introduce lead or result in an end product that would not exceed the CPSIA's lead limits. Modern textile and apparel production practices are recognized and well-characterized. With a few uncommon exceptions, modern production practices do not involve lead or lead-based chemicals.

In general, textile materials and products do not contain lead and have not undergone any processing or treatment that imparts lead resulting in a total lead content that exceeds the CPSIA total lead limits. Accordingly, new § 1500.91(d)(7) adds "Textiles" to the list of determinations. Additionally, with respect to fibers from natural sources, we find that natural fibers are natural materials and do not contain lead, whether they are dyed or undyed. [Ref. 3]. Examples of plant based fibers, from the seed, stem, or leaves of plants, include, but are not limited to, cotton, kapok, flax, linen, jute, ramie, hemp, kenaf, bamboo, coir, and sisal. Animal fibers, or natural protein fibers, include but are not limited to silk, wool (sheep), and hair fibers from alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, and guanaco. The final rule thus adds these natural fibers to § 1500.91(d)(7)(a) (formerly proposed § 1500.91(c)(5)).

We also reviewed information pertaining to fibers that are not obtained from natural sources and are classified as manufactured or man-made. [Ref. 3]. Manufactured fibers are created by technology and are classified as regenerated, inorganic, or synthetic. Regenerated fibers are made from natural materials that are reformed into usable fibers. These fibers include, but are not limited to, rayon, azlon, lyocell, acetate, triacetate, and rubber. Synthetic fibers are polymers created through a chemical process and include, but are not limited to, polyester, olefin, nylon, acrylic, modacrylic, aramid, and spandex. The information we have indicates that manufactured fibers are produced in controlled environments by processes that do not use lead or incorporate lead at any time during their production, whether they are dyed or undyed. Consequently, we have added these manufactured fibers as a new § 1500.91(d)(7)(b); specifically, the new provision refers to "Manufactured fibers (dyed or undyed) including, but not limited to, rayon, azlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex."

b. *Dyes*

We also examined the dyes used on textiles. [Refs. 1 and 3]. Dyes are organic chemicals that can be dissolved and

made soluble in water or another carrier so they can penetrate into the fiber. Dyes can be used in solutions or as a paste for printing. Commercial dyes are classified by chemical composition or method of application. Many dyes are fiber specific. For example, disperse dyes are used for dyeing polyester, and direct dyes are used for cellulosic fibers. Dyes can be applied to textiles at the fiber, yarn, fabric, or finished product stage. Dye colorants are not lead based. Although not typical, some dye baths may contain lead. However, even if the dye bath contains lead, the colorant that is retained by the finished textile after the rinsing process would not contain lead above a non-detectable lead level.

In contrast to dyes, pigments are either organic or inorganic. Pigments are insoluble in water, are applied to the surface of textile materials, and are held there by a resinous binder. Binders used with pigments for textiles are non-lead based. Processes that are lead-based are used for some industrial textiles that require a greater level of colorfastness or durability, but are not typically intended for apparel textiles. Although most pigments do not contain lead, there may be some lead based paints and pigments on non-textile materials that may be directly incorporated into textile products or added to the surface of textiles, such as decals, transfers, and screen printing. All such non-textile components must be tested for lead content under section 102 of the CPSIA unless they are made entirely from materials that the Commission has determined would not contain lead in excess of the CPSIA lead limits. Since we are allowing the use of dyes and pigments on textile materials, we have revised proposed § 1500.91(c) (now renumbered as § 1500.91(d)) to remove "or chemicals such as pigments, dyes, coatings, finishes or any other substance, nor undergone any processing." However, we have excluded from "Textiles" under new paragraph § 1500.91(d)(7), any textiles that are "after-treatment applications, including screen prints, transfers, decals, or other prints."

c. *Leather*

Although leather is not made from fibers like most textiles, it may be used to produce apparel and coverings or may be used along with textile products. Leather begins as natural products, but they undergo processing (e.g., tanning) to convert the natural skin into a usable, durable product. Similar to most textile products, leather products are often colored with dyes or pigments during their processing. Many of the same dyes used in the textile industry also are used

for dyeing leather. According to information submitted by the Leather Industries of America, many processes used to process and finish leather do not use lead or lead-based chemicals.

However, many leather products may be finished with pigment-based coatings, including some that are colored using lead-based pigments. [Refs. 1 and 3]. Currently, any children's leather product that has paint or a similar surface-coating material is subject to the lead paint ban at 16 CFR part 1303. Products that are finished with such coatings are subject to the testing and certification for lead paint under section 102 of the CPSIA. Section 1303.2 (Definitions) specifically provides that paint or other similar surface coating includes application on wood, stone, paper, leather, cloth, plastic or other surface. The treatment that could potentially impart lead onto leather is the application of leaded pigment onto the surface of the leather product. We deleted the term "untreated" before the word "leather" from former § 1500.91(c)(6) (now renumbered as § 1500.91(d)(8)) because, as discussed in part D.7 of this preamble, § 1500.91(a) makes explicit that the determinations do not cover any material in a children's product that has paint or similar surface-coating materials subject to 16 CFR part 1303. Such materials and products must comply with the testing and certification requirements for lead paint under section 102 of the CPSIA.

d. Other Comments

Several commenters, including the Organic Trade Association, stated that certifications based on standards such as the Global Organic Textile Standard (GOTS) and Oeko-Tex® should be allowed in place of testing for compliance with the CPSIA lead content requirements.

Because the Commission has determined that textiles fall under the lead content limits, the Commission will not require testing on textiles under section 102 of the CPSIA. However, 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 are 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 and ensure that the material or product meets the statutory lead levels at all times. With respect to the GOTS and Oeko-Tex® standards, we believe that certifications

from GOTS and Oeko-Tex® would serve to provide such verifications for textiles. Both GOTS and Oeko-Tex® standards limit lead content in certain textile products to no more than 100 ppm lead.

14. Book Components

Several commenters, such as associations for the publishing, printing, and paper industries, and libraries, asked us to determine that "ordinary books" are within the CPSIA's lead content limits. The Association of American Publishers (AAP) defined "ordinary books" to mean paper-based, printed books that are designed or intended primarily for 12 years and younger. AAP states that it does not intend the term to include so-called "novelty" products such as, for example, plastic-based bath toys or teething products that are made to resemble books in shape and form, or books that have plastic, metal or electronic parts that are not part of the binding and with which children may be expected to interact. According to the commenters, ordinary books generally consist of papers, inks, coatings, adhesives, and bindings. We held three public meetings with representatives of these industries on January 22, 2009, June 9, 2009, and August 11, 2009, in Bethesda, Maryland.

Under section 101(a) of the CPSIA, the Commission is required to evaluate the lead content limit for any *part* of a product. Accordingly, we must assess whether each part of a children's book would contain lead over the lead content limits. Therefore, we reviewed comments, data, and other information regarding papers, inks, coatings, adhesives, and bindings to assess whether those components could contain lead over the lead content limits.

a. Paper

Several commenters stated that paper is derived from natural wood, which inherently has a *de minimis* level of total lead content, and that the primary components in the production of paper are wood fiber and water. They stated that lead-based chemicals are not introduced in the major phases of the paper manufacturing process (*i.e.*, wood preparation/pulping; bleaching/refining; running of the paper machine; and finishing processes, including coating).

After review of the test data and other information submitted by the commenters, we have determined that paper and similar cellulosic materials do not contain lead in excess of the CPSIA's lead content limits. [Refs. 1 and 5]. Paper products include paper, paperboard, linerboard and medium,

and pulp. Paper is predominantly made from wood, but also may be made with other cellulosic fibers. For tinting and coloring of fibers, dyes are most commonly used. Dyes, especially basic dyes and direct dyes, are relatively inexpensive and widely available and used in easily processed forms which are highly substantive to fiber and produce a uniform color or shade and which can be varied easily to achieve whatever shades are needed.

Pigments, particularly inorganic pigments, are comparatively expensive and difficult to use due to their density. Complex chemistry must be added to get the pigments to retain the pigments with the fibers and not have them drain out. The comparative expense and difficulty involved in the use of inorganic pigments for coloration limits their use to highly-specialized grades of paper, such as for laminate countertop and flooring applications where the decorative layer must be lightfast, durable, and be able to withstand the heat and chemical conditions of the resin-impregnation stage to convert layers of paper into a countertop, such as Formica®. Such specialty papers are not expected to be used for ordinary printing and writing purposes. As with the fibers and textiles, paper and similar cellulosic materials, including the dyes and treatments used to make them, are not expected to contain lead above the CPSIA lead limits. Accordingly, we have added paper and similar materials made from wood or other cellulosic fiber, including, but not limited to, paperboard, linerboard, and medium to a new § 1500.91(d)(5).

b. Printing Inks and Coatings

With respect to inks, the commenters noted that, in theory, lead pigments can be used in any printing process; however, in practice, lead has been eliminated from all but a few limited applications such as outdoor signage, labels used in harsh environments, or other applications where the product's ability to withstand the weather is a critical factor. The commenters stated that, as a practical matter, lead-based or lead-containing inks are not used in modern printing processes. They explained that the regulations promulgated under the Resource Conservation and Recovery Act of 1976 (RCRA) (40 CFR part 261.24) require that any waste, include printing ink, which contains lead in an amount exceeding five (5) ppm must be treated as hazardous waste. They also pointed to regulations promulgated under the Occupational Safety and Health Act (OSHA) (29 CFR 1910.1025) which requires workplaces in which lead is

used to maintain five (5) micrograms/cubic meter or less permissible exposure limits in workplace air environments, as well as the Coalition of Northeastern Governors (CONEG) standard, known as the Model Toxics in Packaging Legislation which has been adopted as packaging regulations by 19 states and the European Union, as factors discouraging the use of lead-based and lead-containing inks in “ordinary” books. Specifically, they stated that the CONEG standard was designed to phase out the use and presence of mercury, lead, cadmium, and hexavalent chromium in packaging and packaging materials and prescribes combined limits for all four of these heavy metals that are lower than the CPSIA’s lead content limits. According to the commenters, the CONEG standard has been widely adopted by the children’s book publishing industry.

The commenters also stated that lead-based pigments are not compatible with the four-color process. This process, commonly called CMYK, uses transparent cyan (C), magenta (M), and yellow (Y) inks, in addition to black ink, to create a wide range of colors. The comments indicated that lead could be used in “spot colors” and described several lead-based pigments, but claimed that the use of the lead pigments is not current practice because of safety and environmental concerns. The commenters also explained that the types of printing inks that might contain lead, such as for screen-printing and for certain processes for printing on plastic or other non-paper materials, are specifically designed for those purposes and cannot be used for printing children’s paper-based books and similar paper-based materials because different printing processes require different ink systems.

We evaluated printing inks, which are distinct from the dyes used to color paper and textiles. Data and information provided in response to the notice of proposed rulemaking, at CPSC public meetings with members of the publishing and printing industries (January 22, 2009, June 9, 2009, August 11, 2009), and in written materials following those public meetings indicate that the use of lead in printing inks has largely been eliminated, except for certain inks formulated for use in printing on materials such as plastic or fabric, including screen printing. Lead-based pigments are not compatible with the four-color process (and variations of this process, such as those that add colors or diluted colors to the system to improve the quality of images printed using CMYK). Lead would not be found in paper or similar paper-based

materials printed using only the CMYK processes. We confirmed that transparent pigments or dyes are used in CMYK process inks and that leaded pigments, which are opaque, are not compatible with “process inks.” Accordingly, we added to the list of determinations CMYK process printing inks under a new § 1500.91(d)(6). [Ref. 1].

On the other hand, lead-based inks could be used for spot colors, including spot colors used in conjunction with the CMYK process (sometimes referred to as CMYK plus spot). Spot colors are only used when a specific color cannot be reproduced with the CMYK process colors; however, unlike CMYK process colors, spot colors could contain leaded pigments. [Ref. 1]. Although the commenters state that, “[s]pot colors, which could use lead chromate pigments, have been phased out due to safety and environmental concerns” (Letter from American Publishers Association to Kristina M. Hatlelid, Consumer Product Safety Commission, July 1, 2009), the Commission can only verify that such leaded pigments were not used through additional testing. Accordingly, new § 1500.91(d)(6) specifies that spot colors, other inks that are not used in the CMYK process, and inks that do not become part of the substrate under 16 CFR part 1303 are excluded from the determinations. Inks that do not become part of the substrate are considered to be paints or similar surface-coating material under 16 CFR part 1303 and currently require certification based on third-party testing by an accredited laboratory.

In addition, as discussed in part D.13 of this preamble, we have found that certain after-treatments, including screen printing, may use leaded pigments. The commenters state that screen printing inks use four major types of ink systems: UV inks, water-based ink, plastisols, and the solvent-based ink systems. The Commission cannot determine that all screen printing inks do not contain lead below the lead content limits. Plastisol inks are made with PVC, and, as stated earlier in part D of this preamble, PVC may contain lead. As discussed in part D of this preamble, the Commission will not make determinations for any materials that have been found to contain lead. The Commission recognizes that not all products made of PVC contain lead, but to verify that a component part does not contain lead, we would have to test such plastic parts to assess whether it was over the lead content limits. Such products will continue to require testing under section 102 of the CPSIA. Accordingly, except for CMYK process

inks, inks used in any after-treatments, such as screen prints, decals, transfers, and other prints will be excluded from the determinations under new § 1500.91(d)(6).

Transparent or other coatings which soak into the substrate are not considered to be a surface coating for the purpose of 16 CFR part 1303 because they become part of the substrate (16 CFR 1303.3(b)(1)). As discussed in part D.14(a) of this preamble, the comparative expense and difficulty of using inorganic pigments for coloration is a deterrent for ordinary printing and writing purposes. Similarly, paper coatings that use leaded pigments for coloring would not be found for ordinary grades of paper. [Ref. 5]. Because such coatings do not contain lead, insofar as printing is concerned, they do not require testing under section 102 of the CPSIA. Accordingly, we added to the list of determinations on paper under new § 1500.91(d)(5), “and coatings on such paper which become part of the substrate.”

Other additional treatments such as laminates, including plastic sheet or film, or other coatings, such as foils, that do not become part of the substrate also would continue to require testing and certification under section 102 of the CPSIA. Although commenters sought determinations for these materials, their test data indicates that some of these coating materials contain PVC. As discussed in part D of this preamble, the Commission has found that some products made of PVC can contain lead. In addition, the commenters have described foils to be made primarily of aluminum. Part D.8 of this preamble discusses other metals, including aluminum, which can contain lead. Because the lead content of such items cannot be verified without testing, the Commission cannot make a determination that all laminates and other surface coatings would not contain lead below the lead content limits, and thus, such materials must be tested under section 102 of the CPSIA.

c. Adhesives and Binding Materials

Some commenters stated that the post-press step involves folding, cutting and binding of collated sections into a finished product. According to the commenters, the binding can be done either mechanically or chemically with hot-melt or cold glue adhesives, sewing them with polyester or cotton threads, saddle stitching them with wire or stapling, or punching holes for use with spiral wires.

As discussed in part D.5 of this preamble, we find that most adhesives

in books would not require testing and certification under section 102 of the CPSIA. We have determined that animal glues and threads would not contain lead above the lead content limits. In addition, most adhesives used in children's products, including children's books, would not be accessible under the guidance provided by the Commission in the inaccessibility rule. To the extent that any such adhesive is not covered in the determinations and is accessible, (*i.e.* not covered by any other material), it, too, would be subject to the testing and certification requirements of section 102 of the CPSIA.

Certain binding materials also may be inaccessible if they are enclosed or encased by material which does not permit physical contact with that component part. However, for binding materials that are accessible and contain plastic or metal parts (for which a determination has not been made), the Commission will continue to require testing and certification under section 102 of the CPSIA. Although AAP sought determinations on plastic and metal wire binding, it did not explain why the plastic or metal in those products are distinct or unique from what they describe as "novelty books that have plastic, metal or electronic parts with which children may be expected to interact." Although the commenters claim that all of their materials are CONEG compliant, the certification of compliance under CONEG is currently based on self-certification by the supplier or manufacturer and not based on a third-party certification by a CPSC accredited laboratory as required under section 102 of the CPSIA. Accordingly, the Commission cannot adopt those certifications in lieu of the certifications required under the CPSIA.

Although the commenters seek determinations for metal wire saddlestitch and spiral binding as well as plastic spiral binding, as discussed in part D of this preamble, the Commission has found that certain plastic components have contained lead due to the addition of certain additives or colorants. In addition, the Commission has found that many metals can contain lead and has even banned certain metal components, such as metal-cored wicks over 600 ppm. Although commenters state that their metal components are lead-free because, among other things, they are made of carbon steel and galvanized zinc, carbon steel components often have lead added to it to improve machinability and impart other properties. In addition, there are zinc plating processes that add lead to improve its surface tension and increase

its fluidity which would result in a more uniform coating. The added lead could be as high as 16,000 ppm or as low as 100 ppm. Although there are lead-free galvanizing techniques that require more refinement (washing, prefluxing, preheating, *etc.*), the Commission cannot tell which processes are being used without testing the components. Because these metals could contain lead, the Commission cannot make determinations that they fall below the lead content limits. Accordingly, the Commission will continue to require testing and certification on the components parts that have been found to or may contain lead including plastic parts, metal parts, and paints and similar surface-coating materials subject to 16 CFR part 1303.

d. Older Books

Comments were received from the American Library Association (ALA) requesting that books available in libraries not be subject to the CPSIA lead content requirements. In general, ALA claimed that children's books fall outside of the scope of the CPSIA because they are not distributed in interstate commerce. ALA also stated that libraries should not be required to test books that are on the shelf, even new books, given libraries' limited resources.

We disagree with the commenters regarding libraries and the CPSIA. Although ALA requested an exemption from the testing requirements for lead content, ALA may have misinterpreted the testing requirements. Currently, only manufacturers and importers of children's products are required to obtain testing showing compliance with CPSIA lead limits. (See Final Rule on Certificates of Compliance, 74 FR 68328 (November 18, 2008)). A library is neither a manufacturer nor an importer, so it is not required to test products before their sale or distribution.

ALA also argues that library books are not "distributed" in interstate commerce. ALA suggests that because children's library books are not sold, therefore, they are not distributed. As explained in the House Report No. 92-1153 accompanying the Consumer Product Safety Act of 1972, the definition of "consumer product" was not limited to the sale of a product to a consumer. "It is not necessary that a product be actually sold to a consumer, but only that it be produced or distributed for his use. Thus products which are manufactured for lease and products distributed without charge (for promotional purposes or otherwise) are included within the definition and would be subject to regulation under

this bill." H.R. 92-1153, 92nd Cong. (2d Sess. 1972). The Commission's authority, therefore, applies to consumer products, including children's products, that are distributed in commerce, whether or not such books are sold or lent, if they are for the use of a child.

According to ALA, library books should not become a "hazardous substance" unless they are "reintroduced" into interstate commerce after the effective dates of the lead limits. Children's products are consumer products that are distributed in interstate commerce regardless of when they are introduced, and the FHSA does not limit the definition of a banned hazardous substance to new products or to the product's first introduction of such a product into interstate commerce. Under section 2(q)(1) of the FHSA, 15 U.S.C. 1261(2)(q)(1), a "banned hazardous substance" is any toy, or other article intend for use by children, which is a banned hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted. Section 4(b) of the FHSA explicitly prohibits "[t]he alteration, mutilation * * * with respect to, a hazardous substance, if such act is done while the substance is in interstate commerce, or while the substance is held for sale (*whether or not the first sale*)" (emphasis added). In addition, section 4(c) of the FHSA further prohibits "[t]he receipt in interstate commerce of any misbranded hazardous substance or banned hazardous substance and the delivery or proffered delivery thereof for pay or otherwise" (emphasis added.) Under section 101(a) of the CPSIA, Congress has deemed that children's products that do not meet the lead content limits within the specified dates "to be banned hazardous substances." Accordingly, the Commission may not provide relief from the lead content limits except under the specific exclusions provided under section 101(b) of the CPSIA. Absent a finding that all used children's books fall within the scope of an exclusion, the Commission is bound by the statutory language of the CPSIA. Unfortunately, the Commission is unable to make such a determination in this proceeding. Because older books have not been manufactured using modern printing processes, such as the CMYK color process, and have been found, in some circumstances, to contain leaded ink or components, the Commission is unable to make a determination that the components of

all older children's books fall under the lead content limits.

For older used children's books that are sold, many of these books may be collector's items that are sold to adults. Such books would not be considered to be intended primarily for children, and accordingly, may continue to be sold to adults. For older used children's books that are lent out, ALA has requested additional guidance regarding the treatment of these products. Accordingly, the Commission intends to issue a separate Statement of Policy addressing the treatment of older children's books.

15. Issues Related to Component Part Testing

a. Material Safety Data Sheet (MSDS)

Some commenters indicated that the materials they use should not require testing because the material safety data sheets (MSDS) already show that the materials do not contain lead.

As the Commission stated in the procedures rule, material safety data sheets are insufficient for purposes of demonstrating compliance with the lead limits under the CPSIA (74 FR at 10478). Since regulations concerning MSDS require reporting only for chemicals with content levels that exceed 1000 ppm, the MSDS sheets cannot be used to show that a product complies with the lead limits of the CPSIA, which are 600 ppm for products sold after February 10, 2009, 300 ppm for products sold after August 14, 2009, and 100 ppm for products sold after August 14, 2011 (if deemed to be technologically feasible).

b. Metal, Plastic and Painted Components

Many commenters requested a testing exemption for certain metal and plastic items, such as buttons, zippers, snaps, grommets, eyelets, head bands, hair combs and clips, and barrettes. Other commenters mentioned products such as plastic hangers, dolls and doll accessories (such as shoes and eyeglasses), pipe-stem cleaners, brass or other metal bells, beading wire, and certain construction materials such as Plexiglas and aluminum screening. Some commenters listed fasteners, such as nails, screws, or plastic fasteners, as items that should be exempted from compliance with CPSIA requirements. Most commenters did not provide test data or other information about the lead content of these types of products. However, some commenters from the apparel industry acknowledged that lead has been found sometimes in

apparel accessories, such as zippers, buttons, snaps, and grommets.

In general, plastic, metal, and painted materials and products (for which determinations have not been made) have been found, in certain instances, to contain lead at levels that exceed the CPSIA lead limits. Data provided in response to the proposed rule and at the CPSC public meeting with members of the textile industry showed that some items, such as zippers, buttons, and other applied decorations, currently contain lead levels that exceed the CPSIA's lead content levels. In addition, based on the Commission's past experience with other children's products that have been found to contain lead, the Commission cannot make a determination that any component parts made out of plastic or metal (with the exception of metal determinations made in this rule) are below the lead content limits. Accordingly, these products and materials continue to be subject to the lead content limits of section 101(a) of the CPSIA, as well the testing and certification requirements of section 102 of the CPSIA.

The Commission is aware that there are many questions regarding component part testing and certification for lead content given that any children's product may be made with a number of materials and component parts. The questions regarding testing and certification are significant because not all component parts may need to be tested if they fall under the scope of the exclusions approved by the Commission. For example, component parts would not need to be tested if they: (1) Are inaccessible, as set forth under the Commission's regulations at 16 CFR 1500.87; (2) are or contain an electronic device exempt under the Commission's regulations at 16 CFR 1500.88; or (3) are made of material determined by the Commission to fall under lead content limits in this rule (to be codified as 16 CFR 1500.91(a)–(e)(2)). However, all other component parts will need to be tested and certified under section 102 of the CPSIA. The Commission intends to address component part testing and the establishment of protocols and standards for ensuring that children's products are tested for compliance with applicable children's products safety rules, as well as products that fall within an exemption, in an upcoming rulemaking.

E. Impact on Small Businesses

A few commenters stated that the new rule would have a significant impact on small businesses. These commenters

stated that the CPSIA would have devastating economic consequences for small businesses that cannot afford to test their products.

These commenters have misinterpreted the Regulatory Flexibility Act (RFA) section of the proposed rule. That section did not address the impact of the CPSIA on small businesses; that section addressed what impact the proposed rule on the determinations would have on small businesses. The Commission does not have the authority to change the CPSIA. However, under the general rulemaking authority vested to the Commission under section 3 of the CPSIA, the Commission has the authority to promulgate a rule to determine that certain products or materials would not exceed the lead content limits. When an agency issues a proposed rule, it 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 if they were found to be inherently under the lead content limits prescribed. [Ref. 7]. The number of small businesses that will be directly affected by the rule is unknown, but could be considerable. However, the final rule 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 materials under section 102 of the CPSIA. Based on the foregoing assessment, the Commission certifies that the rule would not have significant impact on a substantial number of small entities.

F. Environmental Considerations

Generally, CPSC rules are considered to "have little or no potential for affecting the human environment," and environmental assessments are not usually prepared for these rules (see 16 CFR 1021.5(c)(1)). The determinations rule 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.

G. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of regulations such as this proposal is stated in section 18 of the FHSA. 15 U.S.C. 1261n.

H. Effective Date

The Administrative Procedure Act requires that a substantive rule must be published not less than 30 days before its effective date, unless the rule relieves a restriction. 5 U.S.C. 553(d)(1). Because the final rule provides relief from existing testing requirements under the CPSIA, the effective date is August 26, 2009.

I. References

The following references are available from the Commission's Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone 301-504-7923; or e-mail: cpssc-os@cpssc.gov or from the Commission's Web site (<http://www.cpsc.gov/library/foia/foia09/brief/leadfinalrule.pdf>).

1. Memorandum from Kristina M. Hatlelid and Robert J. Howell, "Consumer Product Safety Improvement Act of 2008 (CPSIA)—Determination of Lead Content for Certain Products and Materials," August 6, 2009.
2. Memorandum from Kristina M. Hatlelid to Mary Ann Danello, "Response to Public Comments: Determinations," August 6, 2009.
3. Memorandum from Allyson Tenney to Kristina Hatlelid, "Textiles and Apparel Subject to the CPSIA," June 5, 2009.
4. Memorandum from Mark F. Gill to Kristina M. Hatlelid, "Results of Research on Lead Content in Slate," July 22, 2009.
5. Memorandum from Joel Recht to Kristina Hatlelid, "Lead in Paper," July 15, 2009.
6. Memorandum from Randy Butturini to Kristina M. Hatlelid, "Lead in Stainless Steel and Titanium Alloys," June 3, 2009.
7. Memorandum from Robert Franklin to Kristina Hatlelid, "Final regulatory analysis of a rule making determinations that certain materials or products do not have lead contents that exceed the limits established in section 101(a) of the CPSIA," July 17, 2009.

List of Subjects in 16 CFR Part 1500

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

J. Conclusion

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

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

■ 1. The authority for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261–1278, 122 Stat. 3016.

■ 2. Add a new § 1500.91 to read as follows:

§ 1500.91 Determinations regarding lead content for certain materials or products under section 101 of the Consumer Product Safety Improvement Act.

(a) The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to have this lower limit. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child. Materials used in products intended primarily for children 12 and younger that are treated or coated with paint or similar surface-coating materials that are subject to 16 CFR part 1303, must comply with the requirements for lead paint under section 14(a) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the CPSIA.

(b) Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, either on its own initiative or upon the request of any interested person, to make a determination that a material or product does not exceed the lead limits as provided under paragraph (a) of this section.

(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 if the product or material is changed or altered so that it exceeds the lead content limits.

(d) The following materials do not exceed the lead content limits under

section 101(a) of the CPSIA provided that these materials have neither been treated or adulterated with the addition of materials that could result in the addition of lead into the product or material:

- (1) Precious gemstones: diamond, ruby, sapphire, emerald.
- (2) Semiprecious gemstones and other minerals, provided that the mineral or material is not based on lead or lead compounds and is not associated in nature with any mineral based on lead or lead compounds (excluding any mineral that is based on lead or lead compounds including, but not limited to, the following: aragonite, bayldonite, boleite, cerussite, crocoite, galena, linarite, mimetite, phosgenite, vanadinite, and wulfenite).
- (3) Natural or cultured pearls.
- (4) Wood.

(5) Paper and similar materials made from wood or other cellulosic fiber, including, but not limited to, paperboard, linerboard and medium, and coatings on such paper which become part of the substrate.

(6) CMYK process printing inks (excluding spot colors, other inks that are not used in CMYK process, inks that do not become part of the substrate under 16 CFR part 1303, and inks used in after-treatment applications, including screen prints, transfers, decals, or other prints).

(7) Textiles (excluding after-treatment applications, including screen prints, transfers, decals, or other prints) consisting of:

(i) Natural fibers (dyed or undyed) including, but not limited to, cotton, kapok, flax, linen, jute, ramie, hemp, kenaf, bamboo, coir, sisal, silk, wool (sheep), alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, guanaco;

(ii) Manufactured fibers (dyed or undyed) including, but not limited to, rayon, azlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex.

(8) Other plant-derived and animal-derived materials including, but not limited to, animal glue, bee's wax, seeds, nut shells, flowers, bone, sea shell, coral, amber, feathers, fur, leather.

(e) The following metals and alloys do not exceed the lead content limits under section 101(a) of the CPSIA, provided that no lead or lead-containing metal is intentionally added but does not include the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications:

(1) Surgical steel and other stainless steel within the designations of Unified Numbering System, UNS S13800–

S66286, not including the stainless steel designated as 303Pb (UNS S30360).

(2) Precious metals: Gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium, titanium.

Dated: August 19, 2009.

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. E9-20589 Filed 8-25-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2009-N-0381]

Advisory Committee; Tobacco Products Scientific Advisory Committee; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Establishment of the Tobacco Products Scientific Advisory Committee. These actions are needed to implement the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act. Elsewhere in this issue of the **Federal Register**, FDA is publishing two separate documents requesting nominations for voting and non-voting membership on this committee. This document also amends the agency's regulations to add the Tobacco Products Scientific Advisory Committee (the committee) to the agency's list of standing advisory committees.

DATES: This rule is effective August 26, 2009. The committee is being established and this charter will remain in effect until amended or terminated by the Commissioner of Food and Drugs (the Commissioner).

FOR FURTHER INFORMATION CONTACT: Erik P. Mettler, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4324, Silver Spring, MD 20993-0002, 301-796-4711, FAX: 301-847-3541, e-mail: erik.mettler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The committee was established under 21 U.S.C. 387q, as added by section 917 of the Family Smoking Prevention and Tobacco Control Act (Public Law 111-31). The committee is also governed by part 14 (21 CFR part 14), Public Law 92-

463 (5 U.S.C. app.), and the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The committee advises the Commissioner or designee in discharging responsibilities as they relate to the regulation of tobacco products.

The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

Specifically, the committee will submit reports and recommendations on tobacco-related topics, including the following:

- The impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other racial and ethnic minorities;
- The nature and impact of the use of dissolvable tobacco products on the public health, including such use on children;
- The effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not product dependence on the tobacco product involved; and
- Any application submitted by a manufacturer for a modified risk tobacco product.

The committee may provide recommendations to the Secretary of Health and Human Services regarding any regulations to be issued under the Federal Food, Drug, and Cosmetic Act and may review any applications for new tobacco products or petitions for exemption under section 906(e) of the Family Smoking Prevention and Tobacco Control Act. The committee may consider and provide recommendations on any other matter as provided in the Family Smoking Prevention and Tobacco Control Act.

The committee shall consist of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The committee shall include nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members shall be physicians, dentists, scientists, or health care professionals practicing in the area of

oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty. One member shall be an officer or employee of a State or local government or of the Federal Government. The final voting member shall be a representative of the general public. In addition to the voting members, the committee shall include three nonvoting members who are identified with industry interests. These members shall include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. This final position can be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the committee.

The Commissioner or designee shall designate one of the voting members of the committee to serve as chairperson.

As added by section 917 of the Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. 387q(d)(3) provides that section 14 of the Federal Advisory Committee Act does not apply to this committee.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely amends the information in § 14.100 to reflect the establishment of the committee.

Therefore the agency is amending § 14.100(a) as set forth in the regulatory text of this document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended to read as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451-1461, 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107-109; Pub. L. 108-155.