UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

BALLOT VOTE SHEET

DATE: AUG - 6 2009

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF
Maruta Budetti, Executive Director MZB

FROM: Philip Chao, Assistant General Counsel PC
Hyun S. Kim, Attorney, OGC HSK

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

Ballot Vote Due: AUG 13 2009

Attached is a draft final rule for publication in the *Federal Register* on determinations regarding certain materials or products that do not exceed the lead content limits under section 101(a) of the Consumer Product Safety Improvement Act (CPSIA) and accompanying staff memoranda.

Please indicate your vote on the following options.

I. Approve publication of the draft final rule in the *Federal Register* without change.

_____ _____
(Signature) (Date)

II. Do not approve publication of the draft final rule in the *Federal Register.*

_____ _____
(Signature) (Date)

CPSA 6(b)(1) CLEARED for PUBLIC 8/6/09
NO MFRS/PRVTLBLRS OR PRODUCTS IDENTIFIED
EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCDG
WITH PORTIONS REMOVED: _____

Note: This document has not been reviewed or accepted by the Commission.
Initials RH Date 8-6-09

III. Publish the draft final rule in the *Federal Register* with changes.
(Please specify.)

_____

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_____ _____

(Signature) (Date)

IV. Take other action.
(Please specify.)

_____

_____

_____

_____ _____

(Signature) (Date)

Attachments:

Draft FR Notice: Children's Product Containing Lead; Determinations Regarding Lead Content Limits on Certain Materials or Products; Final Rule

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 2009.

Memorandum from Kristina M. Hatlelid to Mary Ann Danello, "Response to Public Comments: Determinations," August 2009.

CPSC Memorandum from Allyson Tenney to Kristina Hatlelid, "Textiles and Apparel Subject to the CPSIA," June 5, 2009.

Memorandum from Mark F. Gill to Kristina M. Hatlelid, "Results of Research on Lead Content in Slate," July 22 2009.

Memorandum from Joel Recht to Kristina Hatlelid, "Lead in Paper," July 2009.

Memorandum from Randy Butturini to Kristina M. Hatlelid, "Lead in Stainless Steel and Titanium Alloys," June 3, 2009.

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 2009.

[Billing Code 6335-01]

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), Public Law 110-314.

DATE: *Effective Date:* This regulation becomes effective on [**insert date of publication in the Federal Register**].

FOR FURTHER INFORMATION CONTACT: Kristina Hatlelid, Ph.D., M.P.H., Directorate for Health Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7254, e-mail khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

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 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

[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.

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), 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 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 comments 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."

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. 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 rule on procedures and requirements for a Commission determination or exclusion (see 74 FR 10475 (March 11,

2009)), 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.

In other cases, the comments did provide test data and other information relevant to this proceeding, and those comments are addressed in part 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 website 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. 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, bee's wax, 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, bee's wax, 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. 321et 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 bee's wax, 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 bee's wax.

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. 321et 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 inaccessibility (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. This rule is available at http://www.cpsc.gov/about/cpsia/cpsia.html, and will be published in the FEDERAL REGISTER. 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 product 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 rule on procedures and requirements for a Commission determination or exclusion (see 74 FR 10475). 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. 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 over 300 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. 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. 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 than contain lead. We have previously identified minerals that can contain lead, such as aragonite, bayldonite, boleite, cerussite, croroite, 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/sect101.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 contain 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, 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 cellulosics, 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. 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. 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. 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, axlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex."

b. Dyes

We also examined the dyes used on textiles. 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. 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 two public meetings with representatives of these industries on January 22, 2009 and June 9, 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. 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

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 Occupation 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), 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 printing inks that use the CMYK process under a new § 1500.91(d)(6).

On the other hand, lead-based inks may 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 may contain leaded pigments. 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 C.F.R. 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. Accordingly, inks used in any after-treatments for decals, transfers, and other prints also will be excluded under new § 1500.91(d) (6). Other additional treatments such as or laminators or laminations, including plastic sheet or film, or other coatings, would continue to require testing and certification under section 102 of the CPISA if such products are plastic component parts or a paint or similar surface-coating material under 16 CFR part 1303.

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 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 required 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. Moreover, the Commission is aware of instances where plastic components have contained lead due to the addition of certain additives or colorants and is aware of instances where metal components have contained lead (such as heavy duty staples). The addition of lead-containing paint on plastic and metal parts in children's products has been and continues to be of great concern. 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 or 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 its rule on procedures and requirements for a determination, 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) falls under 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 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 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. 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 issued today on procedures and requirements 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 [**date of publication in the Federal Register**].

List of Subjects in 16 CFR Part 1500

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

I. 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 is amended to read as follows:

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

2. Add a new section 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.

(6) Printing inks that use the CMYK process (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:

(a) 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;

(b) 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: _____

_____
Todd A. Stevenson, Secretary
Consumer Product Safety Commission

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: AUG - 6 2009

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF
Maruta Budetti, Executive Director MZB

FROM : Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction RJH
Kristina M. Hatfield, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences KMH

SUBJECT : Consumer Product Safety Improvement Act of 2008 (CPSIA) -- Determination of Lead Content for Certain Products and Materials

Introduction

Section 101(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) establishes, as of February 10, 2009 (180 days after the enactment of the Act), a limit for lead of 600 parts per million (600 ppm) by weight in any part of a children's product[1]. Lead content of any part of a children's product is limited to 300 ppm as of August 14, 2009 (one year after the enactment of the Act), and subsequently to 100 ppm as of August 14, 2011, if technologically feasible.

On January 15, 2009, the Commission published in the Federal Register a notice of proposed rulemaking (74 FR 2433) containing proposed determinations that certain materials do not exceed the lead content limits in CPSIA section 101(a).

Background

The staff identified a number of materials that do not contain lead or that contain lead at levels that do not exceed the CPSIA lead limits, and recommended that the Commission make such a determination through rulemaking. The Commission agreed and a proposed rule was published in January 2009.

The proposed rule specified the following materials or categories of materials that do not exceed the 600 ppm or 300 ppm lead content limits under section 101(a) of the CPSIA with the provision that the materials have not been treated or adulterated with the addition of materials or chemicals such as pigments, dyes, coatings, finishes or any other substance, nor undergone any processing that could result in the addition of lead into the product or material:

[1] "Children's product" means a consumer product designed or intended primarily for children 12 years of age or younger as defined in the Consumer Product Safety Act as amended by the CPSIA section 235.

Note: This document has not been reviewed or accepted by the Commission.
Initials RH Date 8-6-09

CPSA 6(b)(1) CLEARED for PI 8-6-09
NO MFRS/PRVTLBLRS OR PRODUCTS IDENTIFIED
EXCEPTED BY: PETITION
RULEMAKING ADMIN PROCS

- Precious gemstones: diamond, ruby, sapphire, emerald.
- 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.
- Other natural materials including coral, amber, feathers, fur, untreated leather.

Certain metals and alloys were also included in the proposed determinations as not exceeding the 600 ppm or 300 ppm lead content limits with the provision that no lead or lead-containing metal is intentionally added, and that the determination 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:

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

Public comments[2]

Few of the hundreds of public comments were directed at the proposed determinations published in the notice. No information refuting the Commissions' findings was provided.

Most commenters requested that additional materials be added to the list of materials that the Commission determines are not expected to contain lead at levels that exceed the CPSIA lead limits, but few of these requests included specific data or other information relevant to determinations of lead content of the materials.

Discussion

Based on a review of available information, including data generated by the staff in testing samples of products for lead content, the staff concludes that some of the items and materials mentioned by commenters are known to sometimes contain lead at levels above the prescribed maximum levels in the CPSIA. Since it is not possible to know the lead content of such items without testing, it would be imprudent to eliminate the testing requirement for materials that could contain lead.

On the other hand, based on the public comments, public meetings and investigation by the staff, the staff believes that the previously proposed materials, as well as other materials that are substantially similar to the previously proposed materials, do not contain lead at levels that exceed the CPSIA limits for lead content.

[2] The staff's summary of the public comments and the staff's responses are located in a memorandum from Kristina M. Hatlelid, Ph.D., M.P.H., to Mary Ann Danello, Ph.D., "Response to Public Comments: Determinations," August 2009.

Textiles and Apparel

The staff's review[3] of the available information indicates that the proposed determination for untreated natural fibers is unnecessarily limited and that certain synthetic materials and treatments, such as dyes, are also not expected to contain lead at levels that exceed the CPSIA lead limits. Therefore, many more types of plant- and animal-derived fibers, synthetic fibers, and the textiles and apparel made from such fibers are not expected to contain lead above the CPSIA lead limits. The staff cautions that these conclusions apply only to materials that do not include a lead-containing material and have not been processed in a way that would result in lead being added to the material.

Although leather and related materials are not made from fibers like most textiles, they may be used to produce apparel and coverings or may be used along with textile products. Leather begins as a natural product, but undergoes 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 are also used for dying leather. According to information submitted by the Leather Industries of America, many of the processes used to process and finish leather do not incorporate lead or lead-based chemicals. However, many leather products may be finished with pigment-based coatings, including some leather products that are colored using lead-based pigments. Therefore, leather could be included among materials that are not expected to contain lead at levels that exceed the CPSIA lead limits, but a children's leather product that incorporates pigment-based coatings, like any children's product that includes paint or a similar surface coating, must conform to the requirements of the lead in paint rule (16 C.F.R. part 1303) and is subject to the third-party testing and certification requirements of section 102 of the CPSIA.

Because products may consist of a number of different materials, some not likely to contain lead, along with some materials that might contain lead at levels that exceed the lead limits, the staff suggests that for purposes of testing and evaluation of a product, distinct parts of products should be considered separately. For example, a garment such as a coat might consist of various threads, fabrics, a liner, buttons, zipper, and rivets. The fabric portions made of one or more of the materials included in a Commission determination, for example, cotton and polyester, would not be expected to contain lead at levels that exceed the CPSIA lead limits. On the other hand, the lead content of the plastic, metal, or painted parts of the coat remains uncertain because of the demonstrated presence of lead in some products. Only the latter materials would require testing to verify that the lead concentration does not exceed the lead limits.

Likewise, a blanket or stuffed doll could be constructed with fabrics, thread, and stuffing or fill made of cotton or polyester or other materials that would not be expected to contain lead at levels that exceed the CPSIA lead limits. Buttons or other non-textile parts of such products would have to be tested for lead content before the product that includes them could be introduced into commerce.

In addition to the non-textile items discussed above, such as buttons and zippers, that may be component parts of products, other non-textile materials 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 should be tested for lead content unless they are made entirely from

[3] CPSC Memorandum from Allyson Tenney to Kristina Hatlelid, "Textiles and Apparel Subject to the CPSIA," June 5, 2009.

materials that the Commission has determined would not contain lead in excess of the CPSIA lead limits.

Other Natural Materials

As with the natural fibers, the staff's review indicates that many products and materials, including foodstuffs and plant- and animal-derived materials could fall under the general category of natural materials, which, as proposed, included coral, amber, feathers, fur, and untreated leather. The staff has found no data that indicates that other natural materials, both plant-based and animal-derived, are expected to have lead content exceeding the CPSIA lead limits. Therefore, some additional materials may be considered as not containing lead above the CPSIA lead limits, including, for example, bee's wax, dried flowers, plant-based oils, bone and slate[4]. As stated above, leather that has not been treated with a pigment-containing paint or surface coating could also be included among materials that are not expected to contain lead at levels that exceed the CPSIA lead limits.

Paper, Printing Ink, and Books and Similar Printed Materials

Paper[5] is predominantly made from wood, but may also be made with other cellulosic fibers. As with the fibers, textiles, and apparel discussed above, paper and similar materials, such as paperboard, including the dyes and treatments used to make them, are not expected to contain lead above the CPSIA lead limits. Data and information[6] submitted to CPSC by the American Forest & Paper Association support the staff's conclusion.

The staff also reviewed 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 staff public meetings with members of the publishing and printing industries (January 22, 2009; June 9, 2009), and in written materials following those public meetings indicates 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. In their July 1, 2009 letter, industry members explained 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, in combination to create a wide range of colors. The letter 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 Printing Industries of America followed the July 1, 2009 letter with correspondence[7] providing additional information about four-color process printing to support the previous assertion that lead-based pigments are not compatible with this process. The staff has independently confirmed that lead-based pigments cannot be used in the four-color process, but, while it may not be the current practice, could be used in spot colors.[8]

The industry members' July 1, 2009 letter 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

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[4] CPSC Memorandum from Mark F. Gill to Kristina M. Hatlelid, "Results of Research on Lead Content in Slate," July 22 2009.

[5] CPSC Memorandum from Joel Recht to Kristina Hatlelid, "Lead in Paper," July 15, 2009.

[6] Paul Noe, American Forest & Paper Association, letter to Consumer Product Safety Commission, July 28, 2009.

[7] Julie Busbee Riccio, Printing Industries of America, E-mail correspondence, July 29, 2009.

[8] Scott A. Williams, Ph.D., Rochester Institute of Technology. Personal communication. July 27, 2009.

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.

The staff's review shows that 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) and, therefore, that excess lead would not be found in books or similar paper-based materials printed using only CMYK processes. On the other hand, lead-based inks may be used for spot colors, including spot colors used in conjunction with CMYK processes. Further, printing inks for use on plastic or in screen printing could use lead-containing pigments. Accordingly, the staff recommends that testing continue to be required for inks used in screen printing, inks that are not directly part of a CMYK system, and inks that are used to print on materials other than paper, including plastic and metal. The staff also notes that inks that do not become part of the substrate, such as those applied to plastic and metal surfaces may be regulated as paints or similar surface coatings under 16 C.F.R. part 1303.

As discussed above with respect to apparel, products may consist of a number of different materials, some not likely to contain lead, along with some materials that might contain lead at levels that exceed the lead limits. The staff suggests that for purposes of testing and evaluation of a product, distinct parts of products should be considered separately. For books and similar printed materials, the paper, paperboard and similar materials made with cellulosic fibers, printing using four-color process ink systems, and certain other materials that are included in a Commission determination would not be expected to contain lead at levels that exceed the CPSIA lead limits. On the other hand, the lead content of printed spot colors, printing not based on CMYK processes, including screen printing, plastic or metal parts, and paint or printing on non-paper parts of a product remains uncertain because of the demonstrated presence of lead in some products. The latter materials would require testing to verify that the lead concentration does not exceed the lead limits.

Metals and Alloys

The Commission has previously indicated that surgical steel and certain precious metals are not expected to contain lead above the CPSIA lead limits. Surgical steel is a type of stainless steel. Further review[9] of these alloys indicates that most stainless steels do not contain lead at levels above the CPSIA lead limits. These steels have Unified Numbering System (UNS) designations S13800 – S66286. The exception to this conclusion is 303Pb stainless steel (UNS S30360), which contains lead at levels from 1200 ppm to 3000 ppm. In addition, staff believes that titanium and titanium alloys do not contain lead.

Regulatory Analysis

Staff prepared the regulatory analysis[10] required for Commission regulatory proceedings, including an assessment of the impact on small businesses and an environmental assessment.

[9] CPSC Memorandum from Randy Butturini to Kristina M. Hatlelid, "Lead in Stainless Steel and Titanium Alloys," June 3, 2009.

[10] CPSC 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.

Because the effect of the rule would be to relieve manufacturers and importers of certain products and materials from the testing and certification requirements of section 102 of the CPSIA, the potential costs of the rule consist of the risk that some hazardous exposures to lead could occur that would have been prevented had the materials or products been tested for lead content. However, because the materials and products for which the determinations are being made are those which the staff has concluded inherently do not contain lead in excess of the statutory limits, they are unlikely to pose a risk of injury due to the absorption of lead. Therefore, the costs of the rule, if any, would be negligible. The potential benefits of the rule consist of a reduction in the testing costs that would have been incurred by firms to test materials that inherently do not contain lead in excess of the statutory requirements but would otherwise have to be tested under the requirements of the CPSIA. Given the large number of products or product components that would not need to be tested under this rule, these benefits may be considerable. Because the reduced testing costs represent the benefits of the rule and the costs of the rule (in terms of increased risk of lead absorption) are negligible, the benefits of the rule would exceed the costs.

The number of small businesses that will be directly affected by the rule is unknown but could be considerable. However, because the effect of the rule would be to relieve the manufacturers and importers of the specified materials from the testing and certification requirements the CPSIA, it 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 specified materials.

Finally, the staff concludes that this rule does not fall into one of the categories of actions described in the CPSC environmental review regulations as having the potential to the produce environmental effects (16 CFR 1021.5) and is in fact highly unlikely to produce an environmental effect.

Recommendations

The staff recommends that the Commission issue a final rule determining that certain materials and classes of materials do not exceed the lead content limits in CPSIA section 101(a). The recommendation includes all of the materials included in the proposed rule; additional fibers and textiles; additional plant- and animal-derived materials; and additional metals and alloys.

Other items and materials mentioned by commenters are known to sometimes contain lead at levels above the prescribed maximum levels in the CPSIA. Therefore, the staff believes that it would not be appropriate for the Commission to determine at this time that such products do not exceed the lead limits, and, since it is not possible to know the lead content of such items without testing, it would be imprudent to eliminate the testing requirement for materials that could contain lead. The staff also notes that products often are made of many different materials and components that should be considered separately for testing purposes. Thus, some parts of a product would be subject to the testing requirements, but other components, if part of the Commission's determination that the material would not contain lead in excess of the CPSIA lead limits, would not require testing for lead content.

The Commission has in place a procedure and requirements for a Commission determination that the lead content of a specific material or product does not exceed the CPSIA section 101 limits. 16 C.F.R. § 1500.90. Through this procedure, interested people could provide data and other

information supporting a request for additional materials and products to be considered by the Commission.

CPSC staff recommends that the final rule include the following materials or categories of materials that the staff believes do not exceed the 600 ppm or 300 ppm lead content limits under section 101(a) of the CPSIA, provided that the materials have not been treated or adulterated with the addition of materials or chemicals nor undergone any processing that could result in the addition of lead into the product or material:

- Precious gemstones: diamond, ruby, sapphire, emerald.
- 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 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, galena, linarite, mimetite, phosgenite, vanadinite, and wulfenite).
- Natural or cultured pearls.
- Wood.
- Paper and similar materials made from wood or other cellulosic fiber, including paperboard, linerboard and medium.
- Printing inks in CMYK processes (cyan, magenta, yellow, and black inks used in combination to create a wide range of color).
- Natural fibers including, but not limited to, cotton, kapok, flax, jute, ramie, hemp, kenaf, bamboo, coir, sisal, silk, wool (sheep), alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, guanaco, and the threads, yarns, fabrics, and other textiles made from such fibers, whether dyed or undyed.
- Synthetic fibers including, but not limited to, rayon, azlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex, and the threads, yarns, fabrics, and other textiles made form such fibers, whether dyed or undyed.
- Other plant-derived and animal-derived materials including, but not limited to, bee's wax, seeds, nut shells, flowers, animal glue, bone, sea shell, coral, amber, feathers, fur, and leather.

The following metals and alloys do not exceed the 600 ppm or 300 ppm lead content limits provided that no lead or lead-containing metal is intentionally added, but this conclusion 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:

- Surgical steel and other stainless steels within the designations of the Unified Numbering System, UNS S13800 – S66286, not including the stainless steel designated as 303Pb (UNS S30360).
- Precious metals: gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium; titanium.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: AUG - 6 2009

TO : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences, Directorate for Health Sciences

FROM : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

SUBJECT : Response to Public Comments: Determination of Lead Content for Certain Products and Materials

Introduction

On January 15, 2009, the Commission published in the Federal Register a notice of proposed rulemaking (74 FR 2433) containing proposed determinations that certain materials do not exceed the lead content limits in section 101(a) of the Consumer Products Safety Improvement Act of 2008 (CPSIA). This memorandum summarizes the comments received from the public in response to this notice, and provides the staff's responses to the comments. The index of public comments is in Appendix A.

The Commission received more than 244 comments in response to the notice. Few comments were directed at the proposed determinations published in the notice. Most commenters requested additional materials be added to the list of materials that the Commission determines are not expected to contain lead at levels that exceed the CPSIA lead limits. Few of these requests included specific data or other information relevant to determinations of lead content of the materials.

Discussion

Comment: Determinations process and data requirements.

Comments from advocacy and consumer groups (American Academy of Pediatrics and others, comment no. 221), (Consumers Union and others, comment no. 226), and the State of California Attorney General's office (comment no. 227) indicate support for reducing potentially repetitive and wasteful testing of products and materials that are not expected to contain lead. However, these commenters stressed that the Commission must proceed carefully to ensure that the requirements of the law are met and that children do not face harm from lead content of children's products. The commenters cautioned that the Commission should not only request data from firms, but should also conduct its own testing of children's products, especially products that have not, to date, been subject to lead content requirements or testing for lead content. The California Attorney General's office 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.

CPSC Staff Response:

The Commission has already indicated that all children's products subject to a determination must comply with the lead limit in its Statement of Commission Enforcement Policy on Section 101 Lead Limits, dated February 6, 2009. Further, the Commission's procedures and requirements for a Commission determination that the lead content of a specific material or product does not exceed the CPSIA section 101 limits provides that a request for a Commission determination must be supported by objectively reasonable and representative test results or other scientific evidence showing that the product or materials does not, and would not, exceed the lead limit specified in the request. 16 C.F.R. § 1500.90. Compliance and enforcement activities, including market testing, have always been, and continue to be, essential to the Commission's mission. Moreover, if a particular product or material has been relieved of the requirement to undergo testing and certification under section 102 of the CPSIA, manufacturers and importers continue to be responsible for verifying that the material or product has not been altered or modified, or experienced any change in the processing, facility or supplier conditions that could impart lead into the material or product to ensure that it meets the statutory lead levels at all times.

Comment: Fabrics and similar materials, whether processed or dyed.

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. Results of laboratory testing for lead in textiles and products, as well as other information, were provided in support of such claims by the American Apparel and Footwear Association and affiliated firms and associations.

CPSC Staff Response:

Based on the data provided in response to the notice of proposed rulemaking and at a CPSC staff public meeting with members of the textiles and apparel industries (January 22, 2009), as well as the staff's knowledge and testing of products, staff agrees that common textiles and similar products, such as ribbon, and other materials used to make apparel, such as elastic, are not expected to contain lead at levels that exceed the CPSIA lead limits.

However, non-textile materials that may be added to textile products and apparel, such as decals, transfers, and screen printing, have not been shown to be materials that cannot contain lead. In fact, screen printing inks sometimes do contain lead. Therefore, since it is not possible to know the lead content of such items without testing, it would be imprudent to eliminate the testing requirement for materials that could contain lead.

Comment: Products certified as compliant with the Global Organic Textile Standard (GOTS) or Oeko-Tex® should be excluded from testing for lead.

Commenters, including the Organic Trade Association (comment no. 216), stated that certifications such as the Global Organic Textile Standard (GOTS)[1] and Oeko-Tex®[2] should be allowed in place of testing for compliance with the CPSIA lead content requirements. Both GOTS and Oeko-Tex®

[1] Available at www.global-standard.org.

[2] Available at www.oekotex.com.

standards limit lead content in certain textile and textile-based products to no more than 100 ppm lead.

CPSC Staff Response:

The staff believes that textiles and textile-based products do not contain lead at levels that exceed the CPSIA section 101 limits for lead content, and therefore, should be included in a Commission determination. However, while such products may not be subject to required testing and certification, all children's products subject to a Commission determination must comply with the lead limit of section 101(a) of the CPSIA. Further, manufacturers and importers continue to be responsible for verifying that a 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. The staff believes that certifications from GOTS or Oeko-Tex® could serve to provide such verifications, given that these standards also have testing and compliance requirements.

Comment: Certain components for apparel or other products.

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.

CPSC Staff Response:

Data provided in response to the notice of proposed rulemaking and at a CPSC staff public meeting with members of the textiles and apparel industries (January 22, 2009) showed that some items, such as zippers, buttons, and other applied decorations currently contain lead at levels that exceed the CPSIA section 101 lead limits. In acknowledging this, industry members agreed that testing such parts is necessary, and urged the Commission to consider component level testing or supplier certification acceptable for demonstrating compliance with statutory lead content requirements.

Based on the available data, the staff believes that metal and plastic materials and products sometimes contain significant lead content, such that the lead levels may exceed the maximum levels set by the CPSIA. Therefore, it would not be appropriate for the Commission to determine that such products do not exceed the lead limits, and, since it is not possible to know the lead content of such items without testing, it would be imprudent to eliminate the testing requirement for materials that could contain lead. The Commission will address certification requirements for 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.

Comment: Leather.

Some commenters claimed that leather and similar products should be determined to comply with the lead limits. A comment from the Leather Industries of America (comment no. 213) provided a detailed discussion of the leather treatments and products that do not add lead to the leather, as well as applications that might include lead. This comment indicated that only pigment-based paints, coatings or certain applied decorations might contain lead; all other leather treatments would not.

CPSC Staff Response:

Leather from hide or skin is based on natural products, but must 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 are also used for dying leather. According to information submitted by the Leather Industries of America, most processes used to finish leather do not include lead-based chemicals. However, many leather products may be finished with pigment-based coatings, including some that are colored using lead-based pigments. Accordingly, a children's leather product that incorporates pigment-based coatings, like any children's product that includes paint or a similar surface coating, must conform to the requirements of the lead in paint rule (16 C.F.R. part 1303) and are subject to the third-party testing and certification requirements of section 102 of the CPSIA.

Comment: Plant and animal based materials.

Many commenters indicated that there are a number of 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 included yak, angora, mohair, llama, alpaca, bison, camel, guanaco, cashmere, horse hair, claws, horn, seashells, bone, hide glue, and shellac.

CPSC Staff Response:

The staff agrees that plant and animal-based materials generally do not contain lead at levels that exceed the CPSIA lead limits. However, this conclusion applies only to such materials that are unadulterated by the addition of chemicals and materials such as pigments, paints and similar surface coatings, and metal or plastic materials since such treatments or additions cannot be known to comply with the lead limits without testing. Although most of these materials 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). The staff believes that these three natural materials categories could reasonably encompass the natural items suggested by commenters.

Comment: Foodstuffs.

Some commenters also 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 of the materials mentioned include 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, bee's wax, candelilla wax, and carnauba wax.

CPSC Staff Response:

Foods are under the jurisdiction of the US Food and Drug Administration (FDA), and are therefore not subject to the CPSIA requirements, even when used as components of consumer products. However, there may be materials available to manufacturers, such as bee's wax, that are sometimes foods, but that are not always sold in a form intended for consumption or that complies with FDA regulations. To the extent that such materials are also natural materials that have not been

adulterated or treated with a lead-containing material, the staff believes that the proposed determination for some natural materials could reasonably encompass additional substances.

Comment: Some wood products.

Several commenters confirmed that wood is not expected to contain lead, and also requested that the determination be expanded to include related products, such as composite wood constructed of wood, adhesives, and other materials (comment no. 228).

CPSC Staff Response:

The commenters did not provide test data or other information to enable the staff to properly 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 must provide data and other information requested under the Commission's rule on procedures and requirements for a determination. 16 C.F.R. § 1500.90. Accordingly, a request for a specific materials determination may be submitted to the Commission by an interested person, consistent with those requirements.

Comment: Some paper products.

Several commenters, including the American Forest & Paper Association (comment no. 230), requested that the determination include paper, paperboard, linerboard and medium, and specific paper products, such as cardboard, scrapbooking and embroiderable papers.

CPSC Staff Response:

The staff agrees that manufactured paper products do not necessarily contain lead at levels that exceed the CPSIA lead limits, especially those that contain no other materials (*i.e.*, do not include lead-based paints or similar surface coatings, lead-based pigments, or metal or plastic parts).

Comment: Fabric dyes

Commenters requested that fabric dyes be determined to comply with the CPSIA lead limits.

CPSC Staff Response:

Based on information and data provided in response to the notice of proposed rulemaking and at a CPSC staff public meeting with members of the textiles and apparel industries (January 22, 2009), the staff believes that dyes used in fabrics do not contain lead at levels that exceed the CPSIA lead limits.

Comment: Printing inks

Commenters requested that printing inks be determined to comply with the CPSIA lead limits.

CPSC Staff Response:

Data and information provided in response to the notice of proposed rulemaking, at CPSC staff public meeting with members of the publishing and printing industries (January 22, 2009; June 9, 2009), and in written materials following those public meetings indicates that the use of lead in printing inks has largely been eliminated, but that inks formulated for use in printing on substrates such as plastic or fabric, including screen-printing, may contain lead. In their July 1, 2009 letter, industry members explained 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, in combination to create a wide range of colors. The letter

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 staff has independently confirmed that lead-based pigments cannot be used in the four-color process, but, while it may not be the current practice, could be used in spot colors.[3] The industry members' letter 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.

The staff's review shows that 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) and, therefore, that excess lead would not be found in books or similar paper-based materials printed using only CMYK processes. On the other hand, lead-based inks may be used for spot colors, including spot colors used in conjunction with CMYK processes. Further, printing inks for use on plastic or in screen printing could use lead-containing pigments. Therefore, these materials or the products made with them cannot be known to comply with the lead limits without testing.

Comment: Metals such as titanium, aluminum, pewter, copper.

Some commenters referenced the proposed determination for lead content for surgical steel and certain precious metals and requested other metals, including other stainless steels (Specialty Steel Industry of North America, comment no. 214) be added to the list.

CPSC Staff Response:

Based on staff review of available information, the staff agrees that, like surgical steel, other common stainless steels do not contain excess lead levels. One type of stainless steel, designated as 303Pb steel or S30360, has lead content that exceeds the CPSIA lead limits.

The staff has not found that titanium would contain lead at levels that exceed the CPSIA lead limits. On the other hand, other metals and alloys, including aluminum, copper and pewter may contain significant amounts of lead, and specific products containing such metals or alloys cannot be known to comply with the lead limits without testing.

Comment: Stones, rocks, and earth.

C.M. Paula Company (comment no. 220) and other commenters stated that, in addition to certain precious and semiprecious gems, other minerals and items found in the earth, such as fossils, should be determined as not containing lead above the CPSIA lead limits.

CPSC Staff Response:

As is the case with the precious gemstones and certain semi-precious stones that the Commission proposed do not contain lead at levels that exceed the CPSIA lead limits, other rocks and stones could be considered to comply with lead limits provided that the mineral or material is not based on lead or lead compounds, and is also not associated in nature with any mineral that is based on lead or lead compounds. Staff has researched some materials, and has concluded, for example, that slate would not be expected to exceed the CPSIA lead limits. Although no commenter submitted data on

[3] Scott A. Williams, Ph.D., Rochester Institute of Technology. Personal communication. July 27, 2009.

the numerous minerals and other materials that commenters claimed would be likely to comply with CPSIA lead limits, in general, the staff agrees that many minerals do not contain lead. The staff has previously identified a number of minerals, including semi-precious gemstones, that contain lead. Another important lead-containing mineral is galena.

Comment: Adhesives.

Several commenters requested a determination that glues and adhesives do not contain lead.

CPSC Staff Response:

The staff currently does not have data or other information about the wide range of formulations of glues and adhesives or the lead content of such products. However, animal glues are animal-based materials that the staff does not expect to contain excess lead. Further, the staff believes that in many applications and finished products, adhesives will not be accessible to a child; component parts of products that are not accessible to a child do not need to comply with the lead limits and testing for lead is not required.

Comment: Certain finishes.

Several comments suggested that water based paints, acrylic paints, water based clear finishes, varnishes, lacquers, and milk paint should all be determined to comply with lead limits.

CPSC Staff Response:

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 surface coatings, and past instances of children's products bearing lead-containing paints or coatings despite regulations forbidding the practice, such materials must be tested to show their compliance with the regulations. Currently, paint and surface coatings require third-party testing by an accredited lab under section 14(a) of the CPSA.

Comment: Ceramic glaze and clay.

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

CPSC Staff Response:

While it may be the case that some products or materials used in ceramics production do not contain lead, many products within this product type are known to contain lead at levels that exceed the CPSIA limits for lead content. Without testing of ceramic glazes and other materials, compliance with the lead content limits of the CPSIA cannot be shown.

Comment: Glass.

Several commenters listed glass, glass beads, rhinestones, leaded glass crystals, and porcelain enamel (The Enamelist Society, comment no. 209) as items that should be exempted from compliance with the CPSIA requirements for lead content or testing.

CPSC Staff Response:

The staff recognizes that not all glass or glass products contain lead at levels that exceed the CPSIA lead limits. However, without testing the glass, compliance with the lead content limits of the CPSIA cannot be shown. Further, leaded glass crystals and other glass-based products that contain

lead clearly exceed the lead content limits and cannot be considered in the Commission's rulemaking to determine that certain materials do not contain lead.

Comment: Nails, screws, and other fasteners.

Some commenters listed metal or plastic fasteners as items they use to make children's products and that should be exempted from compliance with CPSIA requirements.

CPSC Staff Response:

Because products such as nails, screws and other fasteners may contain lead at levels that exceed the lead content limits, the staff has concluded that they cannot be considered as products that do not contain lead at levels the exceed the CPSIA section 101 lead limits.

Comment: Pencils, crayons, other materials regulated as art materials and subject to the voluntary standard ASTM D4236.

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

CPSC Staff Response:

The CPSIA requirements for lead content are in addition to other statutory and regulatory requirements for children's art materials. Because these other requirements do not necessarily limit lead content of products, testing of art materials is required to demonstrate compliance with the lead content limits. Compliance under the Labeling of Hazardous Art Materials Act (LHAMA) requires the submission of art material product formulations to a toxicologist for review to assess chronic adverse health effects; the CPSIA requires further testing of children's art materials to assess the total lead content by weight for any part of the product.

Comment: Other items.

Commenters listed many other products and materials that they use in children's products, that they would like exempted from testing requirements. Some of the products mentioned include 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.

CPSC Staff Response:

The staff currently does not have data or other information about the lead content of these many types of products. Because some plastic and metal materials or products contain lead at levels that exceed the CPSIA lead limits, the variety of products mentioned by the commenters cannot be known to comply with the lead limits without testing. A request for a Commission determination must provide the data and other information requested under the Commission's rule on procedures and requirements for a determination. 16 C.F.R. § 1500.90.

Comment: Previously tested items or items with a material safety data sheet (MSDS).

Some commenters indicated that the materials they used should not require testing because they have already been tested. Some commenters refer to material safety data sheets to show that the materials do not contain lead.

CPSC Staff Response:

Previous testing of product components and materials ("component testing") refers to testing by suppliers of components and materials prior to sale to the ultimate manufacturer of the children's product. The Commission will address more specifically testing and certification requirements for children's products in an upcoming rulemaking.

Material safety data sheets may also relate to component testing, but there is an additional issue. Federal regulations concerning material safety data sheets generally require reporting of chemical content of products or materials for chemicals with content levels that exceed 1000 ppm, although smaller concentrations may have to be reported in certain instances. Because material safety data sheets do not necessarily report all chemicals present at any concentration, these 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 technologically feasible).

Comment: Books, including library books.

A number of comments, including the Association of American Publishers, Inc. (comment no. 210), Scholastic, Inc. (comment no. 219), and many printers (collectively comment no. 240) addressed whether children's books contain lead at levels that exceed the CPSIA section 101 limits and requested that ordinary books and other printed materials be excluded from testing requirements.

Some commenters, including the American Library Association (comment no. 169), requested that books available in libraries should not be subject to the CPSIA requirements, or should be determined to not contain lead the exceeds the CPSIA limits, and should not be required to be tested.

CPSC Staff Response:

Based on data and information provided in response to the notice of proposed rulemaking and at CPSC staff public meetings with members of the publishing and printing industries (January 22, 2009; June 9, 2009), the staff believes that some components of books, such as paper and similar materials, are not expected to contain excess levels of lead. Further, some parts of books would be inaccessible to a child, and therefore not subject to the lead content requirements (see the Commission's accessibility guidance rule published in the Federal Register). Other parts of books do not necessarily contain lead, but materials such as plastic and metal may contain lead at levels that exceed the CPSIA lead content limits.

With respect to whether libraries must test books in their collections, only manufacturers and importers of children's products are required to obtain testing showing compliance with CPSIA lead limits. A library is neither a manufacturer nor an importer, and just like a seller of used products, is not required to obtain testing of products prior to sale or distribution.

Children's ordinary books and similar products may be addressed in a separate Commission proceeding to provide specific guidance for these products.

APPENDIX A

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Memorandum

Date: JUL 13 2009

TO : The Commission

FROM : Todd A. Stevenson, Director,
Office of the Secretary

SUBJECT : **Children's Products Containing Lead; Proposed Determination Regarding Lead Content Limits on Certain Materials or Products; NPR:**
Published in the *Federal Register* January 15, 2009
Comments due by February 17, 2009

COMMENT	DATE	SIGNED BY	AFFILIATION
1	12/28/08	Joanne M. Arthur Proprietor	Happy-Girl-Lucky
2	1/03/09	The Handmade Toy Alliance	(144 toy stores)
3	no date	Pam Crowson Stay at home mom	crowsnest5@Surry.net
4	12/28/08	Pam Crowson	" "
5	1/05/09	Laura E. Jones Executive Director	United States Association of Importers of Textiles and Apparel 1140 Connecticut Ave., NW Washington, DC 20036
6	1/08/09	Cynthia Jamin Owner/Designer	TwirlyGirl Girl's Clothing Company (USA)
7	1/09/09	Jennifer Goldston	pumpkinesque725@hotmail.com

COMMENT	DATE	SIGNED BY	AFFILIATION
8	1/09/09	Heidi Joppich	joppich.heidi@gmail.com
9	1/09/09	Sara Sacks	buster.sugar@yahoo.com
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11	1/09/09	Janie Gaffney	jsandkgaffney@hotmail.com
12	1/09/09	Cindy Jordan	CJ's Fine Designs
13	1/09/09	Michele Williams	www.DillyBopDesigns.com Fresh & Funky Loungewear For Little Ones!
14	1/09/09	Sharon Griffin	sgantiques@earthlink.net
15	1/09/09	Marilyn Ketner	MJKetner119@aol.com
16	1/09/09	Ann Whisler	www.creativeworksbyann.com
17	1/09/09	Hilda Scire	Pembroke, ME
18	1/09/09	Liz Fraijo	Sugarplum Creations
19	1/09/09	Laurie Williams	Crawler Covers & More
20	1/09/09	Lindsey Hignite	lhignite@nc.rr.com
21	1/09/09	Judy Elizabeth Reid	reidsranch@3riversdbs.net Box 6, Babb. MT 59411
22	1/09/09	Bridget Ann Parsell	Charbridge Knits & Gifts 6490 Chabot Rd. Lachine, MI 49753
23	1/09/09	Stefanie Rehbein	Hip Kids Tye Dye Madison, WI 53719
24	1/09/09	Suzi Lang	Starbright Baby Giraffes! www.starbrightbaby.etsy.com
25	1/09/09	Christine Harling	bluemoose@cableone.net
26	1/09/09	Laura Farrell	lefarrell@gmail.com

COMMENT	DATE	SIGNED BY	AFFILIATION
27	1/09/09	Stefanie Rehbein (additional clarification)	HipKids Tye Dye Madison, WI 53719
28	1/09/09	Brenda Lovejoy	PO Box 506 Wittmann, AZ 85361
29	1/09/09	Jesi Josten	www.HipViolet.Etsy.com
30	1/09/09	Brenda Lovejoy	PO Box 506 Wittmann, AZ 85361
31	1/09/09	Neeka Norbury	nnorbury@gmail.com
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33	1/09/09	Nicky O'Reilly	ncoreilly@comcast.net
34	1/09/09	Allyson	Timeless Puzzles sales@timelesspuzzles.com
35	1/09/09	Debbie Suess	Lillifee Boutique
36	1/09/09	Rachel Zylstra Owner	Hop Scotch Children's Store 962 Lake Dr. SE Grand Rapids, MI 49506
37	1/09/09	Susan Deady	Susie Dee's
38	1/09/09	Melissa Dunnaway	she-elf-1@hotmail.com
39	1/09/09	Shaylind Standing	www.constantdreamer.etsy.com
40	1/09/09	Elaine Bard	Elaine_Bard@umit.maine.edu
41	1/09/09	Kelly	kstuffings@comcast.net
42	1/09/09	Nick & Sandy	nicks42@frontiernet.net
43	1/09/09	Denise Handwerker	www.craftwerker.etsy.com

COMMENT	DATE	SIGNED BY	AFFILIATION
44	1/09/09	Tammara Alwaked	Garland, TX
45	1/09/09	William L. Martin III	Downs Rachin Martin PLLC
46	1/09/09	Jenn	jlsouth2@insightbb.com
47	1/09/09	Clint and Katie Nelson	cknelsen@iowatelecom.net
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54	1/09/09	Linda Kessler	lkcreation@yahoo.com
55	1/09/09	Amy Nance	www.barenecessities.etsy.com
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58	1/10/09	Candice Mangum	13180 Taylor Wells Rd. Chardon, OH 44024
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60	1/10/09	Sarah B. Natividad	Curious Workmanship
61	1/10/09	Rose Jagt	prairieroses@gmail.com
62	1/10/09	Joyce Tipton	Winchester, KY
63	1/10/09	Heather Akers	creativekiddo@consolidated.net
64	1/10/09	Erin Oeser	erinoeser@yahoo.com

COMMENT	DATE	SIGNED BY	AFFILIATION
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70	1/10/09	May Nunes	Kids~Cottage~Boutique
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73	1/10/09	Tammy Nichols	625 SE Bugle Ct. Blue Springs, MO 64014
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76	1/10/09	June Ballou	garyballou@sbcglobal.net
77	1/10/09	Laura Singer	Lil' Munchkin Boutique
78	1/10/09	Patricia Henning	Stitchin' Tricia Embroidery Works
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85	1/10/09	Betty Hilyer	betsysbows@earthlink.net
86	1/10/09	Valerie Oldemeyer	2115 W. 6th St. Port Angeles, WA 98363
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89	1/10/09	Bretta Gonsalez Owner	Grace Bowtique
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99	1/11/09	Tracy Erger	PBandJ*Creations
100	1/11/09	Lori Jozwiak	lorijoz@netzero.net
101	1/11/09	Sue Lappan Creator and Designer	Ecoleeko
102	1/11/09	Renee Eggleston	candy_stick_lane@yahoo.com
103	1/11/09	Jacquie Barker	barkerebay@yahoo.com

COMMENT	DATE	SIGNED BY	AFFILIATION
104	1/11/09	Cindy	cmyflowers@aol.com
105	1/11/09	Robin Beal	1104 SW 19th St. Blue Springs, MO 64015
106	1/11/09	Melinda Tabacco	mtabacco11@yahoo.com
107	1/11/09	Stephanie Mains	ablushingbride@yahoo.com
108	1/11/09	Kalli Inman	www.KalQuilts.biz Custom Embroidery
109	1/11/09	Francisbel Boutique	francisbelboutique@hotmail.com
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111	1/11/09	Heather Akers	Creative Kiddos
112	1/12/09	Jennifer van Vorst	Turtle Park Tots
113	1/12/09	Joanne Levine	Jodi Levine, Wild Child Tie-Dyes www.wildchildtiedyes.com 33 Amherst Road Pelham, MA 01002
114	1/12/09	Sarah Lee	sarah@sarahssilks.com
115	1/12/09	Wendy Platt Owner	Ruby RedShoes Baby, Inc.
116	1/12/09	Holli Grubb	Hair Sprouts Bowtique
117	1/13/09	Louise Genowitz	lgenowitz@hotmail.com
118	1/13/09	Claudia Garcia-Bouchacourt	Le Petit Boutique Handmade Blythe Clothing 3800 North Mesa Street Suite A2 #219 El Paso, TX 79902
119	1/12/09	Gavin & Laura Smith	Baby Boss 9625 Monticello Drive Granbury, TX 76049

COMMENT	DATE	SIGNED BY	AFFILIATION
120	1/13/09	Suzsh	suzsh@yahoo.com
121	1/13/09	Robin Riggs	Ella Jean Baby Gifts www.ellajeangifts.etsy.com
122	1/13/09	Melanie Tommey	MCC Enterprises Aka...Mel's Country Crafts www.melscountrycrafts.com 1004 N Lincoln Sand Springs, OK 74063
123	1/13/09	Karen Blum Boateng	Little Gems
124	1/13/09	Deborah Lundgren	DebAviary@aol.com
125	1/13/09	Allison Kelly, M.D. Owner/Designer	Little Miss Blooms
126	1/13/09	Sarah Kronland	Mairzey Dotes www.mairzeydotes.com
127	1/13/09	Hilary Lane	TOT Warehouse
128	1/13/09	Brenda Lovejoy	Lovejoy Fabrication
129	1/13/09	Lisa A. Rooney	crescentmoonschool@gmail.com
130	1/14/09	Kathy Anderson	bumpkinpatch@hotmail.com
131	1/14/09	The Crowson Family	crowsnest@surry.net
132	1/14/09	Marsha Stoops Vifquain Vice President	Edco, Inc.
133	1/14/09	Jaminda Springer	Nato Bello Beautiful Baby Slings For the Artful Mother
134 (same text as 131)	1/14/09	The Crowson Family	crowsnest5@surry.net
135	1/14/09	Paula Mair	Paula_sews@comcast.net

COMMENT	DATE	SIGNED BY	AFFILIATION
136	1/14/09	Sherry E. Baber	7704 Lampworth Terrace Richmond, VA 23231
137	1/14/09	Michelle Fei	Hip Girl Boutique
138	1/15/09	Craft Yarn Council of America Caron International Coats & Clark Lion Brand Yarn Co. Spinrite, Inc. TMA Yarn	
139	1/15/09	Christine Ewald	Taxewald@aol.com
140	1/15/09	Lori Wahl Partner/Owner	Mister Judy, LLC
141	1/15/09	Diana Havier	dhawkeyette@yahoo.com
142	1/15/09	Carol Garrett	cr@bjwe.com
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144	1/16/09	Willy Lin SBS JP Vice Chairman	Textile Council of Hong Kong
145	1/16/09	Valerie Hall	lariha53@bellsouth.net
146	1/17/09	Rae LynnGlispin	kidzcomfort@yahoo.com
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149	1/19/09	Joe Williams	AirbrushGypsy@aol.com
150	1/20/09	The Real Diaper Industry Association	
151	1/20/09	April Todd Designer and Mom	www.littlemissprincesstutu.com
152	1/20/09	Julie S	userhc2001@gmail.com

COMMENT	DATE	SIGNED BY	AFFILIATION
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154	1/21/09	Lawerence H. Kloess, III	917 Jones Parkway Brentwood, TN 37027
155	1/21/09	Rachel Shaw	rachelkshaw@gmail.com
156	1/21/09	Tammy	tammyt1957@aol.com
157	1/21/09	Anja Wray	8235 Stafford Mills Rd. Oak Ridge, NC 27310
158	1/21/09	Shelly Meintzer	lil-ladybugs@mi-connection.com
159	1/22/09	Laura Mellberg	162 Ash Street Denver, CO 80220
160	No Date	Laura Mameesh	Oakland, CA
161	1/23/09	Cheryl Kelly	821 East State Street Salem, Oh 44460-2298
162	1/23/09	Rose Kos	roksyworld@yahoo.com
163	1/24/09	Jeanne Stock Knitter	6571 Loud, Dr. Oscode, MI 48750
164	1/25/09	David L. Tucker Linda S. Lagace	6042 Lone Star Lane Riverbank, CA 95367
165	1/25/09	Ivy Tomosawa	ivy@mysweetiebean.com
166	1/25/09	Robert F. Johnessee President	Bunker Hill Public Library PO Box P Bunker Hill, IL 62014
167	3/23/09	Wang Nini Director General	China WTO/TBY National Notification & Enquiry Ctr No. 9 Ma Dian Dong Lu, Hai Dian District, Beijing
168	1/26/09	Phillip Wakelyn PhD	National Cotton Council

COMMENT	DATE	SIGNED BY	AFFILIATION
169	1/26/09	Nathan A. Brown On behalf of American Library Association	Ropes & Gray LLP One Metro Center 700 12th Street, Ste 900 Washington, DC 20005-3948
170	1/26/09	Mindy Harris	mindyharris@yahoo.com
171	1/26/09	Marilyn Chalais	mchalais@earthlink.net
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173	1/27/09	Stacey Kitchen	spacewurx@gmail.com
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179	1/28/09	Susan Weir	Weir Crafts
180	1/28/09	Ellie Peck	1680 NE 8th Ave Oak Harbor, WA 98277
181	1/28/09	Kathy Anderson	bumpkinpatch@hotmail.com
182	1/28/09	Ann Marie Rodgerson	amrodgerson@gmail.com
183	1/28/09	Joyce Deutsch	turtlerejoicing@yahoo.com
184	1/28/09	Richard A. Stewart Mayor	City Hall 14177 Frederick Street PO Box 88005 Moreno Valley, CA 92552
185	1/29/09	Robert E. Reed Board of Directors	Tallassee (Alabama) Community Library 88838 Tallassee Highway Tallassee, AL 36078

COMMENT	DATE	SIGNED BY	AFFILIATION
186	1/23/09	Sara Saxton Youth Services Librarian	Tuzzy Consortium Library Barrow, AK
187	1/23/09	Delane R. James Library Director	Buckham Memorial Library 11 Division Street East Faribault, MN 55021
188	1/24/09	Katie Gatten Children's Librarian Madison Branch	Mansfield/Richland County Mansfield, OH
189	1/28/09	Karen C. Neville	P.O. Box 913 Berlin, MD 21811
190	1/28/09	Meredith Kivi	2411 Weston Avenue Schofield, WI 54476
191	1/30/09	Deborah Poillon Library Director	Cape May County Library 4 Moore Road, DN2030 30 West Mechanic Street Cape May Court House, NJ 08210
192	1/29/09	Robert Carona Membership Chairman	Jax Woodworkers Club
193	1/29/09	Susanna DeFazio Owner	Papa Don's Toys 87805 Walker Creek Road Walton, OR 97490
194	1/29/09	Angela Plagge Assistant Library Director	Cape May County Library 4 Moore Road, DN2030 30 West Mechanic Street Cape May Court House, NJ 08210
195	1/29/09	Alison Orr Young Adult Assistant Manager	Palos Verdes Library District 701 Silver Spur Rd. Rolling Hills Estates, CA 90274
196	1/29/09	Nancy Gold President	Tough Traveler 1012 State Street Schenectady, NY 12307

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199	1/29/09	Julie Rebboah President	Lightning Bug Learning Corp
200	1/29/09	Marion Scott Owner	Close2Me
201	1/30/09	Mary Campbell Director of R&D	Environments, Inc. 501 Carteret Street PO Box 1348 Beaufort, SC 29901-1348
202	1/30/09	Kathleen Geiger	messnerk001@hawaii.rr.com
203	1/30/09	Stephen Lamar Executive Vice President	American Apparel & Footwear Association 1601 N. Kent Street, 12th FL Arlington, VA 22209
204	2/02/09	Barry Evans COO	Covenant Communications, Inc.
205	2/02/09	Alan Bell Managing Director	The Bell Group / Rio Grande
206	2/04/09	J. Michael Smith, Esq. President	HSLDA Advocates for Homeschooling Purcellville, VA 20134
207	2/06/09	Charlotte MacDonald	Wheee! Everyday Play Gear
208	2/09/09	Shan Aithal, Ph.D. Director of Technology	Stuller, Inc. 302 Rue Louis XIV Lafayette, LA 70508

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212	2/12/09	Cecelia L. Gardner President, CEO and General Counsel	Jewelers Vigilance Committee 25 West 45th Street Suite 1406 New York, NY 10036
213	2/13/09	John L. Wittenborn Joseph J. Green Counsel to the Leather Industries of America	Kelley Drye & Warren LLP Washington Harbour, Ste 400 3050 K Street, NW Washington, DC 20007
214	2/13/09	Joseph J. Green Wayne D'Angelo Counsel to the Specialty Steel Industry of North America	Kelley Drye & Warren LLP Washington Harbour, Ste 400 3050 K Street, NW Washington, DC 20007
215	2/16/09	Laura E. Jones Executive Director Submitted by John B. Pellegrini Counsel for	United States Association of Importers of Textiles and Apparel 13 East 16th Street, 6th Floor New York, NY 10003
216	2/17/09	Tom Hutcheson Regulatory and Policy Manager	Organic Trade Association PO Box 547 Greenfield, MA 01302
217	2/18/09	Becky Maggard	Freelance Children's Clothing Design Monogram & Embroidery

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220	2/17/09	Greg Ionna President and CEO	C.M. Paula Company 6049 Hi-Tek Court Mason, OH 45040
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		Rachel Weintraub Director of Product Safety And Senior Counsel	Consumer Federation of America
		Don Mays Senior Director, Product Safety and Technical Public Policy	Consumers Union/ Consumer Reports
		Nancy Cowles Executive Director	Kids in Danger
		Diana Zuckerman, Ph.D. President	National Research Center for Women & Families
		Elizabeth Hitchcock Public Health Advocate	U.S. Public Interest Research Group

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222	2/17/09	Ryan Trainer Executive Vice President & General Counsel	International Sleep Products Association 501 Wythe Street Alexandria, VA 22314-1917
223	2/17/09	Sheila A. Millar On behalf of Fashion Jewelry Trade Association	Keller and Heckman LLP 1001 G Street, NW Suite 500 West Washington, DC 20001
224	2/17/09	Kevin M. Burke President & CEO	American Apparel & Footwear Association 1601 North Kent Street Suite 1200 Arlington, VA 22209
225	2/17/09	Steve Lamar Submitted on behalf of coalition of 30 trade associations	American Apparel & Footwear Association
226	2/17/09	Donald L. Mays Senior Director, Product Safety & Technical Public Policy	Consumers Union
		Janell Mayo Duncan Senior Counsel	Consumer Union
		Rachel Weintraub Director of Product Safety and Senior Counsel	Consumer Federation of America
		Nancy A. Cowles Executive Director	Kids in Danger
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COMMENT	DATE	SIGNED BY	AFFILIATION
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227	2/17/09	Harrison M. Pollak Deputy Attorney General	Edmund G. Brown Jr. Attorney General State of California Department of Justice 1515 Clay Street, 20th FL Oakland, CA 94612
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229	2/17/09	Georgia C. Ravitz	Arent Fox LLP Washington, DC
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231	2/17/09	Keith A. Jenkins Submitted on behalf Gildan Activewear	Sorini, Samet & Associates, LLC Ten G Street, NE, Suite 710 Washington, DC 20002
232	2/17/09	Ryan Trainer Executive Vice President & General Counsel	International Sleep Products Association 501 Wythe Street Alexandria, VA 22314-1917
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236	1/12/09	Becky McMullen	mypewteriscewter@comcast.net
237	3/17/09	Amy Schulz	Happy Magpie LLC
238		form letters (5)	natural and other textile and apparel materials
239		form letters (7)	natural products
240		form letters (57)	book printers
241		form letters (85)	hair ribbon and bows, etc.
242		form letters (29)	ribbon, etc.
243		form letters (24)	Project Linus
244 **CONFIDENTIAL**	2/25/09	Michael S. DeFranks Director of Engineering	Simmons Company

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: June 5, 2009

TO : Kristina Hatlelid, Ph.D., M.P.H., Project Manager
Directorate for Health Sciences

THROUGH: Hugh M. McLaurin, Associate Executive Director
Directorate for Engineering Sciences
Patricia K. Adair, Division Director
Combustion and Fire Sciences

FROM : Allyson Tenney, M.S., Textile Technologist
Directorate for Engineering Sciences

SUBJECT : Textiles and Apparel Subject to the CPSIA

Introduction

Section 101 of the Consumer Product Safety Improvement Act (CPSIA) sets new limits on lead content in any children's product as defined in the Act. Under the Act, by February 10, 2009 products designed or intended primarily for children 12 years of age 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 will be reduced to 100 ppm in 2011 unless the Commission determines that it is not technologically feasible.

Apparel and textile products intended for children are subject to the prescribed lead limits under the Act. This memorandum summarizes the general practices used in the textile industry and in the modern production and coloration of textiles and apparel. Most textile products are manufactured using processes that do not introduce lead or result in an end product that would exceed the lead limits prescribed in the Act.

Segments of the Textile Industry

Textile products are manufactured for a variety of uses including toys and children's products, apparel, home/decorative furnishings, and industrial/technical applications. The major production stages of the textile industry are fibers, yarns (and threads), fabrics, finishing, and coloration (dyeing and printing).

Textile Fibers Fiber production is one major segment of the textile industry. Fibers are the basic element of textile structures and are either natural or manufactured (man-made). Natural fibers are obtained from either plants or animals.[1] Examples of plant based fibers, from the seed, stem, or leaves

[1] Natural fibers are also obtained from mineral sources.

of plants, include but are not limited to cotton, kapok, flax, 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. Natural fibers are natural materials and do not contain lead.

Fibers that are not obtained from natural sources are classified as manufactured or man-made. 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. Manufactured fibers are produced in controlled environments by processes that do not use lead or incorporate lead at any time during their production.

Yarns and Fabric Two other segments of the industry include the production of yarns (and threads) and fabric (textile) formation. Yarns and threads are produced with fibers[2] that are grouped and twisted together in a spinning mill. Yarns and threads are then used to produce fabrics and textile products. Fabrics can broadly mean any woven, knitted, braided, knotted, or non-woven textile structure made of fibers or yarns. Most textile fabrics are made from yarns, although some fabrics are created from solution or fibers, as in the case of non-wovens. Textile fabrics are produced in a wide range of weights, thicknesses, and sizes and are used to produce many types of products. In addition to forming the base fabrics for apparel, textile fabrics used for apparel include underlinings, fillings, interlinings, ribbons, trims (lace, edgings, tapes), elastic, and some closures and findings.

Textile fiber content, yarn construction, and type of fabric are selected based on cost factors, end use, and desired performance of the product. Most apparel products are made from cotton and polyester. These fibers are the two most used fibers for apparel; the industry estimates that they account for about 80% of the fiber used to produce apparel. Fabric for children's products and apparel is selected for its cost, durability, comfort, and ease of care. For these reasons, some materials are rarely used for children's products. For example, silk, metallic threads, specialty fibers, and glass fibers are seldom used for children's products and apparel.

Textile Finishing The finishing segment of the industry includes a number of treatments that are used to aid processing, enhance appearance, improve performance, or achieve a desired surface effect. Finishing processes can be done to fibers, yarns, or fabrics and can be described as either dry or wet finishing. Some examples of finishing treatments may include scouring, bleaching, heat setting, calendaring, embossing, and pressing. Finishing also includes the application of chemical finishes that are applied to enhance performance. Examples include softening, soil release, and durable press finishes. Most wet finishes use inorganic chlorine, peroxide compounds, and organic compounds that would not be expected to introduce lead into the process. Some processes are done before coloration while others are done after coloration.

Textile Coloration Another segment of the industry involves coloration which includes dyeing and printing. Coloration of textile products is achieved by the addition of colorants (dyestuffs) that are either dyes or pigments.

[2] Yarns may also be produced from extruded polymer films for slit film yarns and polyester and nylon foils. These yarns may have a metallic appearance, but do not contain lead, lead based materials, or other metals.

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 contained lead, the colorant that is retained by the finished textile after the rinsing process would not contain lead above the non-detect lead level.

In contrast to dyes, pigments are either organic or inorganic. Pigments are insoluble in water and are applied to the surface of textile materials and are held there by a resinous binder.[3] Most pigments do not contain lead, but there are some lead based paints and pigments that could be used for textile printing, such as a transfer or decal type print. The type of colorant, either pigment or dye, is selected based on fiber type, desired color, coloration process, and required colorfastness. Most commercial coloration processes do not use lead-based processes. 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.

Industry Data

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[4] 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, zippers), trims, and fasteners. The data were reviewed by CPSC staff and showed that many textile and apparel products do not contain lead that would exceed the limits established by the CPSIA.

Information on the dye industry was submitted by the Ecological Association of Dye and Organic Pigment Manufacturers (ETAD). ETAD 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 cellulosics, and polyester, the most commonly used fibers for apparel, account for 70% of total dye consumption. These fibers use specific dye classes (e.g., disperse, direct, reactive) that do not typically contain lead. ETAD recommends that ETAD member companies follow lead limits of 100 ppm using a sampling and testing procedure that ensures the recommended limits. Any lead levels in excess of 100 ppm are reported in a Materials Safety Data Sheet (MSDS).

[3] Binders used with pigments for textiles are non-lead based.
[4] Available from the U.S. CPSC Office of the Secretary.

Other Products

Although leather and fur are not made from fibers like most textiles, they may be used to produce apparel and coverings or may be used along with textile products. Fur and leather begin with natural products, but they must undergo processing (e.g., tanning) to convert the natural skin into a usable, durable product. Similar to most textile products, fur and leather products are often colored with dyes or pigments during their processing. Many of the same dyes used in the textile industry are also used for dying leather. According to information submitted by the Leather Industries of America,[5] many of the processes used to process and finish leather do not incorporate lead or lead-based chemicals. However, some leather products may be colored using lead-based pigments.

Conclusion

Apparel and textile products intended for children are subject to the prescribed lead limits under the Consumer Product Safety Improvement Act (CPSIA). Modern textile and apparel production established practices that are recognized and well-characterized. With a few uncommon exceptions, the modern production practices do not involve lead or lead-based chemicals. There is no indication that any of the production practices introduce lead amounts into textile products and apparel that would exceed the lead limits established by the CPSIA. Textile materials and products that 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 could be included in the exemptions. Appendix A lists some of the possible exemptions.

[5] Available from the U.S. CPSC Office of the Secretary.

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Appendix A: ***Possible Textiles and Apparel Product Exemptions***

Exemptions include materials and products that 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.

Included in the exemptions:
Non-metallic, dyed, undyed (and/or finished) fibers, threads, yarns, fabrics (woven, knit, or non-woven) (base fabrics, underlining fabrics, and fillings), ribbons, trims (lace, edgings, and tapes), closures, and other findings and fasteners (e.g., elastics, hook and loop tape) consisting of:

Natural fibers:

Plant-based seed, bast, and leaf fibers including but not limited to cotton, kapok, flax, jute, ramie, hemp, kenaf, bamboo, coir, sisal

Animal-based fibers including but not limited to silk, wool (sheep), and hair fibers from alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, guanaco

Man-made fibers:

Modified/regenerated and natural polymers including but not limited to rayon, azlon, lyocell, acetate, triacetate, rubber

Synthetic polymers including but not limited to polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex

Other:

Leather

Fur

Feathers and down

- With or without dyes or other finishing treatments, provided that added substances will not result in lead content that exceeds the CPSIA lead limits
- Non-metallic, includes slit film yarns or yarns from extruded polymer films (e.g., polyester and nylon foils)

Not included in the exemptions:
Items that contain lead or have undergone further treatment or processing that may impart lead:

- Plastic or metal fasteners, such as zippers, buttons, grommets, or snaps, with possible lead content
- Transfers, decals, prints, or after-treatments that use lead-based paints or pigments
- Yarns that contain metal cores
- Labels that contain metal components or metallic threads or yarns
- Metallic, plastic, painted, coated components, ornaments, or objects, such as rhinestones, due to lead content of some materials shown to exceed CPSIA lead limits
- Polyvinyl chloride (also called PVC and vinyl), due to use of lead in PVC formulations or coloring additives
- Leather that is finished or colored with lead-based chemicals or pigments

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: July 22, 2009

TO : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

THROUGH: Hugh M. McLaurin, Associate Executive Director, Directorate for Engineering Sciences
Andrew M. Trotta, Director, Division of Electrical Engineering Sciences

FROM : Mark F. Gill, P.E., Electrical Engineer, Division of Electrical Engineering, Directorate for Engineering Sciences

SUBJECT : Results of Research on Lead Content in Slate

Introduction

This memorandum provides the Directorate for Engineering Sciences (ES) response to the request by the Directorate for Health Sciences to determine the compliance of slate with the lead (Pb) limits established by the Consumer Product Safety Improvement Act (CPSIA). The primary uses of slate in children's products, as defined in the CPSIA, are chalkboards. To answer the question, ES staff attempted to define lead content typically found in slate by researching its geological origins. The response was prepared after consultation with geologists from the US Geological Survey (USGS), the agency in the Department of the Interior which has the scientific staff and expertise on the earth and its composition[1].

Slate is classified as a dimension stone, which is defined by the USGS as "natural rock material quarried for the purpose of obtaining blocks or slabs that meet specifications as to size (width, length, and thickness) and shape. Color, grain texture and pattern, and surface finish of the stone are normal requirements. Durability (essentially based on mineral composition and hardness and past performance), strength, and the ability of the stone to take a polish are other important selection criteria." The principal rock types are granite, limestone, marble, sandstone, and slate.[1]

Assessment

The question of the lead content of slate was directed to Mr. Bill Langer, Research Geologist with the USGS based in Denver, Colorado. Mr. Langer cited a research paper[2], "Distribution of the Elements in Some Major Units on the Earth's Crust," that indicated that the concentration of lead in an average or typical shale rock was 20 parts per million (ppm) by weight. Through the

[1] United States Geological Survey website, http://minerals.usgs.gov/minerals/pubs/commodity/stone_dimension/

[2] Turekian, K.K., and Wedepohl, K.H., 1961, "Distribution of the elements in some major units on the Earth's crust: Geological Society of America Bulletin, v. 72, no. 2, pp. 175-192

geological process of metamorphism, shale (a sedimentary rock) is transformed into slate (a metamorphic rock) by heat and pressure. Mr. Langer commented, "Slate is much less permeable than shale, and lead mobilization is apt to be even less," indicating that it would be highly unlikely for lead to migrate into slate rock formations after the geological genesis of the slate.

Mr. Langer indicated that in extremely rare instances, metallic ore bodies (containing lead, zinc, copper, gold, etc.) may be created adjacent to bodies of slate through geological processes, as well as any other type of dimension stone. The process of metallic ore body genesis could raise the levels of lead in any adjacent dimension stone bodies (granite, limestone, marble, sandstone, slate) beyond 600 ppm. However, to re-emphasize, ore bodies are considered to be extremely rare geological structures.

Conclusions

It is the opinion of the Directorate for Engineering Sciences staff, with input from the USGS, that the typical dimension stone known as "slate" has a lead content far less than 100 ppm by weight. The typical slate is therefore compliant with the lead content requirements stated by the CPSIA.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: July 15, 2009

TO : Kristina Hatlelid, Ph.D., M.P.H., Project Manager
Directorate for Health Sciences

THROUGH: Andrew G. Stadnik, Associate Executive Director
Directorate for Laboratory Sciences

FROM : Joel Recht, Ph.D., Division Director, Chemistry Division
Directorate for Laboratory Sciences[1]

SUBJECT : Lead in Paper

Paper is a generic word for many different products, primarily made from wood pulp or other cellulosic fibers, wet-formed, pressed and dried into thin sheets or rolls (webs) and commonly used in thin sheets for printing, writing, packaging and decorative purposes. Many specialty types of paper exist as well, such as roofing paper, friction paper, abrasive paper, insulation, laminate countertop and flooring, and more. Additionally, synthetic products such as polymer sheets and spun-bonded polyolefins (such as Tyvek®), are sometimes referred to as paper. Given the diverse range of paper products existing, and the vast array of specialty additives necessary to produce some specialty papers, the scope of this memorandum is limited to printing, writing and book papers, along with cover stock, newsprint and other similar cellulosic-based papers, such as cardstock, envelope paper, and folder stock. Examples of these paper types include all of the non-synthetic paper grades listed in the Government Paper Specification Standards[2] published by the Government Printing Office. (The only two synthetic grades in the Government Paper Specification Standards are O-90 and V90.)

Even given the limited scope of this memorandum, paper contains many components. Uncoated papers typically consist of cellulosic fiber and potentially other plant matter, fillers, process and functional chemical additives, colorants, and recycled materials of the same varieties. Coated papers are made by applying one or more layers of pigments, binders, colorants, and additives to one or both sides of an uncoated base paper. Papermaking generally consists of the following steps: Cellulosic fiber is obtained through mechanical and/or chemical means from wood or other plants. The fibers are dispersed in water to the point of being a suspension of individual fibers in a furnish (the slurry of water, paper, fillers and additives used to make paper). Fillers, process chemicals and functional chemicals are also added to the papermaking furnish to produce a well-mixed stock that is typically about 99% water. This papermaking furnish is

[1] Dr. Recht worked as a Senior Research Engineer, specializing in papermaking chemistry including fillers, process additives and functional additives to paper for a major pulp, paper and packaging company prior to working for the Government Printing Office as Chief of Testing and Technical Services until he joined the Consumer Product Safety Commission.

[2] Government Paper Specification Standards, No. 11, February 1999, http://www.gpo.gov/customers/vol11.htm

pumped out through a wide slot onto a porous conveyer belt, known as a "Fourdrenier wire" or simply the "wire", at the so-called "wet-end" of the paper machine. The furnish settles on the "wire" with water draining through, and at this point in the process most of the water is removed through gravity and with vacuum. The fibers settle onto the wire into a mat, which is transferred to a series of presses to remove more water and increase the bonding of the fibers which attract each other through hydrogen bonding as the water is removed. The web of paper is then run through heat-dryers, typically in direct contact with heated rolls, to remove most of the remaining water as the paper web progresses to the so-called dry-end of the paper machine. Additional steps in some grades of paper can include application of surface treatments such as sizing, where the paper is run through a size-press to impart starch and other surface treatments, as well as coating to produce papers such as those used in high quality magazine covers, calendars, etc. Each of the papermaking steps will be considered for the possibility of lead introduction into paper.

Cellulosic Fiber

The major component of most paper is cellulosic fiber. The overwhelming majority of paper is made from wood pulp, but a small amount of specialty paper is made with cotton, jute, kenaf, bamboo, and other natural cellulosic fibers. All these natural plant-fibers are inherently free of excessive lead, and would be expected to be well below 100 parts per million lead, regardless of the growing conditions.

There are several significant ways in which wood and other plants are converted into papermaking pulp. Pulp can be classified as chemical pulp, most commonly, through the sulfate (or Kraft) process, where chemical treatments are applied to wood chips to fully remove lignin and other non-cellulose materials, to produce a "wood-free" paper; mechanical or thermo-mechanical pulp, where mechanical grinding forces alone are used to convert nearly 100% of wood chips into a useable, but less durable material, such as the "groundwood" pulp used for newsprint and other less durable products; and semi-chemical pulp, such as chemi-thermo-mechanical pulp, where chemical impregnation of the wood chips precedes the grinding to produce a product with less lignin and properties approaching those of fully chemical pulps. Each of these types of pulps can be bleached by a variety of means. Typical bleaching treatments involve the use of chlorinated compounds, such as chlorine or chlorine dioxide, oxygenated compounds such as ozone, oxygen and hydrogen peroxide, and commonly combinations of the above, along with extractions, washes and other chemical treatments to brighten and whiten pulp and remove impurities that adversely affect durability. Neither bleaching, nor pulping imparts lead to the pulp, so bleached and unbleached mechanical, chemical and semi-chemical pulp are all expected to be below 100 parts per million lead.

The other major source of pulp fiber is reclaimed fiber from pre- and post-consumer recycling as well as in-plant reprocessing. Printed papers are commonly deinked and/or washed prior to introduction into the papermaking process. Evidence presented by the printing industry at a public meeting with CPSC staff and in comments[3] indicates that it is highly unusual for leaded pigments to be present in printing inks. If leaded pigments are present, they are much denser than cellulosic fibers, and their removal during washing and de-inking would be expected to be

[3] http://www.rrd.com/wwwCPSIA/home.asp.

nearly complete. Thus, it is not expected that recycled papers, even 100% recycled papers, would contain in excess of 100 parts per million lead.

Filler

Many materials are added to paper both for functional and economic purposes. The primary fillers used in papermaking are kaolin clay and calcium carbonate – two inexpensive (relative to bleached chemical wood pulp), white, easily processed pigments which are either mined and processed to purify, whiten and otherwise improve processing, or made by synthetic production, such as precipitated calcium carbonate. The next most common filler used is titanium dioxide, a bright white pigment with excellent hiding power used to increase both the brightness and the opacity of paper. Titanium dioxide is typically more expensive than the fibers that it replaces, but its superior opacity allows for the use of lighter weight papers and provides value. Other, less common fillers include talc, alumina, and silica. These fillers are manufactured and sold as purified materials intended to impart brightness and uniformity to paper, and none of these natural materials or synthetic pigments is expected to impart lead into paper.

Process and functional chemical additives

A range of chemical additives are combined with paper, including colloidal additives such as alum, quaternary amines, and charged polymers to assist in the removal of water and the retention of fine particles and fillers in the forming of paper, dry- and wet-strength additives such as starch and epichlorohydrin cross-linking resins, and chemicals to impart water-resistance to paper, such as rosin and alkyl ketene dimers. None of these process chemicals are expected to contain or impart any lead to the papermaking process.

Colorants

Dyes and pigments are also added to paper, including "white" paper which is shaded to various tints based on order specifications. While the use of pigments for coloring of paper is possible, their use is limited, and the use of inorganic pigments is even more limited than organic pigments due to a number of factors. For tinting and coloring of fibers at the wet-end, 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 are comparatively expensive and difficult to use, particularly inorganic pigments, which due to their density tend to produce a pronounced two-sidedness as the pigments will tend to settle in the forming paper mat on the paper machine at a different rate than the fiber and filler suspension. Complex chemistry must be added to get the pigments to retain the pigments with the fibers and not have them drain out through the Fourdrenier wire.

The comparative expense and difficulty involved in the use of inorganic pigments for coloration at the wet-end 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.

Size-press coloring is occasionally added as a means of affecting surface properties, and could be done with pigments, but it is unlikely in this case as well to find lead introduction as lead pigments are an unlikely choice for a size-press color. Most size-press applications of color are applications of white pigments for improved surface properties and the same white pigments used as fillers are the ones used in size-press applications. Additives applied at the size press are typically prepared in batches rather than continuous addition as is the case for wet-end dyes so color tinting is generally preferable to control at the wet-end where there is minimal lag time in changing the paper tint upon finding a need to adjust.

Coating

Paper coatings are applied either directly on a paper machine with an integrated coater, or off-machine on a separate coater. In either case, a coating similar to latex house-paint is applied by a rod or blade to the web of fully formed, dried paper, excess coating is doctored off and the coated paper is dried, typically by hot air, and/or by passing over heated drums. The coatings consist of typically the same range of pigments used in wet-end fillers, plus plastic pigments, binders such as starch and/or latex, colorants and viscosity modifiers. Again, the only case where lead might be introduced would be the use of leaded pigments for coloring. Again, this is not done in practice for "ordinary" grades of paper such as those discussed in this memo and would typically be reserved for specialty grades where there was a specific need. A member of the American Forest and Paper Association (AF&PA) related at a public meeting with the CPSC that no lead was found in any paper tested, and that all member companies have stated that they do not use lead additives.

Summary

Lead is inherently not expected in cellulosic pulp. Other additives to paper include filler, colorants, process chemicals, surface-sizing and coating. While lead pigment colorants are certainly known and used in some industries, such as paint and anti-corrosion coatings,[4] none of these lead pigments are expected to be used in papermaking for the types of paper used for printing writing and ordinary packaging as described in this memo. Paper of these types is not expected to have greater than 100ppm lead.

[4] Buxbaum, Gunter. (1998), *Industrial Inorganic Pigments, Second Edition.* New York: Wiley-VCH.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: 3 June 2009

TO : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

THROUGH: Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction

FROM : Randy Butturini, PE, Program Area Team Leader, Office of Hazard Identification and Reduction

SUBJECT : **Lead in Stainless Steel and Titanium Alloys**

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. However, the stainless steel manufacturing processes (such as Argon Oxygen Decarburization) heat 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 parts-per-million (ppm).

CPSC staff has searched for stainless steel alloy chemical compositions, both in printed literature (*Key to Steel*, Verlag Stahlschlüssel, Wegst GmbH, D7142 Marbach, Germany, 1992), and on the internet (e.g., Google, Matweb, ASTM.org). Only one stainless steel alloy, 303Pb, was found to contain lead. The concentration of lead in 303Pb steel is between 0.12% and 0.30% (1200 to 3000 ppm). The Unified Numbering System designation for 303Pb steel is S30360.

Similarly, 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 over 300 titanium alloys examined, CPSC staff was unable to find an instance where lead was a constituent.

Therefore, the following materials can be considered not to contain lead in concentrations above 100 ppm. Using the Unified Numbering System (UNS):

1) Stainless steel currently manufactured of the following types:
    a. UNS S13800 – S66286.
    b. Exception, UNS S30360 (303Pb stainless steel) contains lead in excess of the CPSIA limits for children's products.
2) Titanium alloys, UNS R5xxxx

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: 17 July 2009

TO : Kristina Hatlelid, Ph.D., Project Manager
Directorate for Health Sciences

THROUGH: Gregory B. Rodgers, Ph.D.
Associate Executive Director
Directorate for Economic Analysis

Deborah V. Aiken, Ph.D.
Senior Staff Coordinator
Directorate for Economic Analysis

FROM Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT : 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

Introduction

On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. Subsection 101(a) of the Act establishes, as of February 10, 2009, a lead limit of 600 parts per million (ppm) by weight for any part of a children's product. Lead content is thereafter limited to 300 ppm as of August 14, 2009, and 100 ppm as of August 14, 2011, if technologically feasible.

On January 15, 2009, the Commission published a notice of proposed rulemaking (NPR) under Section 3 of the CPSIA that made preliminary determinations that certain materials or products inherently do not contain lead in excess of the limits established in subsection 101(a) of the CPSIA. The effect of the determinations would be to relieve manufacturers and importers from the third-party testing and certification requirements established in section 102 of the CPSIA.

The proposed determinations in the NPR were limited to some specific metals or alloys (e.g., surgical steel and precious metals) and some natural materials, including some natural fibers, provided that they had not "been treated or adulterated with the addition of materials or chemicals such as pigments, dyes, coatings, finishings or any other substance, nor undergone any

processing that could result in the addition of lead into the product or material." Based on information supplied during the comment period and additional research by the staff, the CPSC staff is confident that the list of materials for which determinations that the materials do not contain lead in excess of the statutory limits can be expanded. Among the materials for which the staff believes determinations are merited include most fabrics (including dyed fabrics), food-grade materials, paper (including dyed paper), titanium, and slate. In addition the staff believes that a determination can be made that all but one grade of stainless steel do not contain lead in excess of the statutory limits. The final rule contains the full list of materials for which determinations are being made.

Regulatory Analysis

Because the effect of the rule would be to relieve manufacturers and importers of the materials from the testing and certification requirements of Section 102 of the CPSIA, the potential costs of the rule consist of the risk that some hazardous exposures to lead could occur that would have been prevented had the materials or products been tested and certified. However, because the materials and products for which the determinations are being made are those which the staff has concluded inherently do not contain lead in excess of the statutory standards, they are unlikely to pose a risk of injury due to the absorption of lead. Therefore, the costs of the rule, if any, should be negligible.

The potential benefits of the rule consist of the reduced testing costs that would have been incurred by firms to test materials that inherently do not contain lead in excess of the statutory requirements but would have had to be tested anyway under the requirements of the CPSIA. These benefits have not been quantified but are likely to be high. Third-party testing for lead reportedly costs between $50 and $100 per substrate tested. Therefore, the Commission's determination that the lead content of these materials do not exceed the statutory requirements could reduce the cost of obtaining third-party testing of a children's product that contains these materials by at least $50, and possibly more than $100, depending upon the number of materials used in the product. Since most manufacturers or importers of children's products can be expected to offer at least several different items, this determination could reduce the testing cost for each manufacturer or importer of children's products in which these materials are used by at least several hundred dollars. Because the reduced testing costs represent the benefits of the rule and the costs of the rule (in terms of increased risk of lead absorption) are negligible, the benefits of the rule would exceed the costs.

Impact on Small Businesses

Section 605 of the Regulatory Flexibility Act (RFA) requires the Commission to consider the impact of the rule on small businesses. The number of small businesses that will be directly affected by the rule is unknown but could be considerable. However, because the effect of the proposed rule would be to relieve the manufacturers and importers of the specified materials from the testing and certification requirements the CPSIA, it 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 specified materials.

For small manufacturers the reduction in costs provided by the rule could be significant. Small manufacturers typically have small production runs and so the cost of testing each component for lead increases the cost per unit of the final product by more than it does for a large manufacturer.

A few public comments were received that reflected a misunderstanding of the discussion in the NPR of the impact of the rule on small businesses. The commenters mistakenly assumed that the conclusion that the rule would not have a significant impact on a substantial number of small entities referred to the impact on small businesses of the testing required by the CPSIA. However, this analysis covers only the impact of the rulemaking before the Commission - the determination that some materials inherently do not contain lead and, therefore, do not need to be tested.

Environmental Assessment

The National Environmental Policy Act requires that the Commission consider the impact of its actions on the environment. The determinations that are the subject of the rulemaking would only relieve manufacturers and importers of certain materials and products that inherently do not contain lead in excess of the CPSIA limits from testing the materials and products for lead content. This rule does not fall into one of the categories of actions described in the CPSC environmental review regulations as having the potential to the produce environmental effects (16 CFR 1021.5) and is in fact highly unlikely to produce an environmental effect.