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

This document has been electronically approved and signed.

DATE: June 30, 2015

BALLOT VOTE SHEET

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Patricia H. Adkins, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
David M. DiMatteo, Attorney, OGC

SUBJECT: Draft Direct Final Rule and Notice of Proposed Rulemaking: Toys; Determination Regarding Heavy Elements Limits for Unfinished and Untreated Wood

BALLOT VOTE DUE: July 7, 2015

The Office of the General Counsel is providing for Commission consideration the attached direct final rule and notice of proposed rulemaking for a determination for unfinished and untreated wood for the ASTM heavy elements limits in ASTM F963-11.

A. *Federal Register* Notice for Direct Final Rule

Please indicate your vote on the following options:

I. Approve publication of the attached direct final rule in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

II. Approve publication of the attached direct final rule in the *Federal Register*, with changes. (Please specify.)

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_____ _____

(Signature) (Date)

III. Do not approve publication of the attached direct final rule in the *Federal Register*.

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

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_____ _____

(Signature) (Date)

B. *Federal Register* Notice for Proposed Rulemaking

Please indicate your vote on the following options:

I. Approve publication of the attached notice of proposed rulemaking in the *Federal Register*, as drafted.

_____ _____

(Signature) (Date)

II. Approve publication of the attached notice of proposed rulemaking in the *Federal Register*, with changes. (Please specify.)

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(Signature) (Date)

III. Do not approve publication of the attached notice of proposed rulemaking in the *Federal Register*.

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

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_____ _____

(Signature) (Date)

Attachments: Draft *Federal Register* Notices for Direct Final Rule: Toys; Determination Regarding Heavy Elements Limits for Unfinished and Untreated Wood; and Notice of Proposed Rulemaking: Toys; Determination Regarding Heavy Elements Limits for Unfinished and Untreated Wood.

[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1251

[Docket No. CPSC-2011-0081]

Toys; Determination Regarding Heavy Elements Limits for Unfinished and Untreated Wood

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: The Consumer Product Safety Commission ("Commission," or "CPSC") is issuing a direct final rule determining that unfinished and untreated trunk wood does not contain heavy elements that would exceed the limits specified in the Commission's toy standard, ASTM F963-11. Based on this determination, unfinished and untreated wood in toys does not require third party testing for the heavy element limits in ASTM F963.

DATES: The rule is effective on [**insert date 60 days after publication in the FEDERAL REGISTER**], unless we receive a significant adverse comment by [**insert date 30 days after publication in the FEDERAL REGISTER**]. If we receive a timely significant adverse comment, we will publish notification in the *Federal Register***,** withdrawing this direct final rule before its effective date.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2011-0081, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: http://www.regulations.gov, and insert the docket number CPSC-2011-0081, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Randy Butturini, Project Manager, Office of Hazard Identification and Reduction U.S. Consumer Product Safety Commission, 4330 East West Hwy, Room 814, Bethesda, MD 20814; 301-504-7562: email; rbutturini@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. *Third Party Testing*

Section 14(a) of the Consumer Product Safety Act, ("CPSA"), as amended by the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), requires that manufacturers of products subject to a consumer product safety rule or similar rule, ban, standard or regulation enforced by the CPSC must certify that the product complies with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). For children's products, certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* Pub. L. No. 112-28 (August 12, 2011), directed the CPSC to seek comment on "opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation." In response to Pub. L. No. 112-28, the Commission published in the *Federal Register* a Request for Comment ("RFC"). *See* http://www.cpsc.gov//PageFiles/103251/3ptreduce.pdf. As directed by the Commission, staff submitted a briefing package to the Commission that described opportunities that the Commission could pursue to potentially reduce the third party testing costs consistent with assuring compliance. *See* http://www.cpsc.gov/PageFiles/129398/reduce3pt.pdf.

In addition to soliciting and reviewing comments as required by Pub. L. No. 112-28, the Commission published in the *Federal Register* on April 16, 2013 a Request for Information ("RFI") on four potential opportunities to reduce testing burdens. *See* http://www.gpo.gov/fdsys/pkg/FR-2013-04-16/pdf/2013-08858.pdf. In February 2014, the Commission also published a notice in the *Federal Register* of a CPSC workshop on

potential ways to reduce third party testing costs through determinations consistent with assuring compliance. *See* http://www.gpo.gov/fdsys/pkg/FR-2014-02-27/pdf/2014-04265.pdf. The workshop was held on April 3, 2014.

As discussed further in this preamble, if the Commission determines that, due to the nature of a particular material, children's products made of that material will comply with CPSC's requirements with a high degree of assurance, manufacturers do not need to have those materials tested by a third party conformity assessment body.

2. *CPSC's Toy Standard*

Section 106 of the CPSIA states that the provisions of ASTM International ("ASTM"), *Consumer Safety Specifications for Toy Safety* ("ASTM F963" or "toy standard"), "shall be considered to be consumer product safety standards issued by the Commission under section 9 of the CPSA (15 U.S.C. 2058)."[1] Thus, toys subject to ASTM F963-11, the current mandatory version of the standard, must be tested by a CPSC-accepted third party conformity assessment body and demonstrate compliance with all applicable CPSC requirements for the manufacturer to issue a Children's Product Certificate ("CPC") before the toys can be entered into commerce.

The toy standard has numerous requirements. Among them, section 4.3.5 requires that surface coating materials and accessible substrates of toys[2] that can be

[1] ASTM F963-11 is a consumer product safety standard, except for section 4.2 and Annex 4, or any provision that restates or incorporates an existing mandatory standard or ban promulgated by the Commission or by statute.

[2] ASTM F963-11 contains the following note regarding the scope of the solubility requirement:

> NOTE 3—For the purposes of this requirement, the following criteria are considered reasonably appropriate for the classification of toys or parts likely to be sucked, mouthed or ingested: *(1)* All toy parts intended to be mouthed or contact food or drink, components of toys which are cosmetics, and components of writing instruments categorized as toys; *(2)* Toys intended for

sucked, mouthed, or ingested, comply with the solubility limits on eight heavy elements. (We refer to these elements as the "ASTM heavy elements.") One of the eight ASTM heavy elements is lead. The Commission previously determined that certain materials do not exceed lead content limits, and therefore, those materials do not require third party testing when used in children's products (including toys). 16 CFR 1500.91. Thus, CPSC staff focused its work on the remaining seven ASTM heavy elements. The eight ASTM heavy elements and their solubility limits are shown below.

Element	**Solubility Limit, parts per million, ("ppm")**[3]
Antimony, ("Sb")	60
Arsenic, ("As")	25
Barium, ("Ba")	1000
Cadmium, ("Cd")	75
Chromium, ("Cr")	60
Lead, ("Pb")	90
Mercury, ("Hg")	60
Selenium, ("Se")	500

TABLE 1: Maximum Soluble Migrated Element in Parts-Per-Million for Surface Coatings and Substrates Included as Part of a Toy

children less than 6 years of age, that is, all accessible parts and components where there is a probability that those parts and components may come into contact with the mouth.

[3] The method to assess the solubility of a listed element is detailed in section 8.3.2, *Method to Dissolve Soluble Matter for Surface Coatings*, of ASTM F963-11. Modeling clays included as part of a toy have different solubility limits for several of the elements.

3. *Possible Determinations Regarding the ASTM Heavy Elements*

For some materials, the concentrations of all the listed heavy elements might always be below their respective solubility limits due to biological, manufacturing, or other constraints. For example, one of the specified elements may be sequestered in a portion of a plant, such as the roots, that is not used in textile manufacturing. Additionally, a manufacturing process step may remove a specified element, if the element is present, from the material being processed. For these materials, compliance with the limits stated in section 4.3.5 of ASTM F963-11 is assured without requiring third party testing because the material is intrinsically compliant.

The third party testing burden could only be reduced if all heavy elements listed in section 4.3.5 have concentrations below their solubility limits. Because third party conformity assessment bodies typically run one test for all of the ASTM heavy elements, no testing burden reduction would be achieved if any one of the heavy elements requires testing.

B. Contractor's Research

1. *Overview*

CPSC hired a contractor to conduct a literature search to assess whether the Commission potentially could determine that wood and other natural materials do not contain any of the seven specified heavy elements in concentrations above the ASTM F963-11 maximum solubility limits (excluding the eighth element, lead which is already subject to a determination). The contractor researched the following materials:

- Unfinished and untreated wood (ash, beech, birch, cherry, maple, oak, pine, poplar, and walnut);

- Bamboo;
- Beeswax;
- Undyed and untreated fibers and textiles (cotton, wool, linen, and silk); and
- Uncoated or coated paper (wood or other cellulosic fiber).

Staff chose these materials for research because they met two criteria:

- Materials the Commission previously determined not to contain lead in concentrations above 100 ppm; and
- Materials more likely to be used in toys subject to the ASTM F963-11 solubility limits.

The contractor's report is available on the Commission's website at: http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Toys/TERAReportASTMElements.pdf. CPSC staff reviewed the contractor's report and prepared a briefing package providing recommendations to the Commission. The staff's briefing package is also available on the Commission's website. [INSERT link].

In conducting this research, the contractor considered the following factors:

- The concentrations of the seven heavy elements in the material under study;
- The presence and concentrations of the elements in the environmental media (*e.g.*, soil, water, air), and in the base materials for the textiles and paper;
- Whether processing has the potential to introduce any of the seven heavy elements into the material under study; and
- The potential for contamination after production, such as through packaging.

The contractor examined secondary sources and reviewed articles to identify the available data regarding the elements' concentrations in the materials listed above. The contractor summarized the relevant data on bioavailability and presence/concentrations in environmental media (*i.e.*, soil, air, and water) from the most recent Agency for Toxic Substances and Disease Registry ("ATSDR")[4] toxicological profile, supplemented with more recent authoritative reviews. The contractor conducted a literature search for data on concentrations of the chemical elements in each of the specific materials. Potentially relevant papers for information on concentrations of chemical elements in each product were identified and reviewed. The contractor used the references from reviewed articles to identify other articles to examine and used the references in those articles to find other sources recursively, to uncover relevant cited references.[5] The literature screening was to examine whether there is a potential for an ASTM heavy element to be present in the natural material at levels above its solubility limit. When the contractor determined there was sufficient information to indicate the potential for an ASTM heavy element to be present, the contractor stopped that particular line of inquiry and reported the results.

As discussed in the staff's briefing package, the contractor's report does not support a Commission determination for any material other than unfinished and untreated wood. The literature reviewed by the contractor did not provide sufficient information to determine that any of the reviewed materials, other than unfinished and untreated wood, do not contain the heavy elements in concentrations above the limits stated in the toy standard.

[4] The congressionally mandated Agency for Toxic Substances and Disease Registry produces toxicological profiles for hazardous substances found at National Priorities List sites.
[5] "This method is often referred to as "tree searching."

2. *Findings Regarding Wood*

Of the materials reviewed, the contractor identified the most studies for wood. Although the contractor could not examine every study concerning wood, the contractor reported that the studies examined constitute a representative sample of studies. The contractor studied measurements taken from trees in natural settings, samples from trees grown on contaminated soils, hydroponically grown[6] seedlings, experimental studies with seedlings grown in pots in which the soil had some of the elements intentionally added, and seedlings soaked in solutions containing one or more of the ASTM heavy elements.

The contractor examined measurements on roots, shoots, bark, trunks, branches, and leaves (or needles, for evergreens). Not every study conducted measurements on each part of the tree. Many studies showed concentrations of the ASTM heavy elements at levels below their solubility limits.

Antimony. For antimony, the studies examined showed that roots, shoots, branches, and leaves contained antimony in concentrations greater than the ASTM solubility limit of 60 ppm. No tree trunks showed antimony concentrations above the ASTM solubility limit. One study's measurements of tree trunks showed that the trunks were nearly free of antimony.

Arsenic. For arsenic, trunks, roots shoots, leaves, stems, bark, and branches of trees were characterized. An experimental study showed roots with more than 25 ppm arsenic. A study at a contaminated mining site showed roots, branches, leaves/needles,

[6] Hydroponics is a subset of hydroculture and is a method of growing plants using mineral nutrient solutions, in water, without soil.

and shoots with arsenic concentrations above the ASTM solubility limit. However, no tree trunk measurement showed arsenic in concentrations above 25 ppm. In the two tested cases, tree trunks contained only trace levels of arsenic (levels well below the solubility limit).

One study measured levels of arsenic in sawdust sampled from 15 sawmill locations in the Sapele metropolis (a port city in Nigeria). The highest arsenic concentration measured was 93.0 ppm. The study's authors did not specify what types of trees or wood were processed at the sawmills. However, the authors noted that a major industry in the study area is Africa Timber Plywood Industry and mentioned that arsenic and chromium are used as wood preservatives. Plywood is a manufactured wood and could contain materials not found in natural wood. The authors did not report what woods these sawmills were processing. Therefore, we cannot draw any conclusions from this study.

Barium. For barium, measurements of leaves, leaf litter, wood, and sawdust all showed barium concentrations below the ASTM solubility limit of 1,000 ppm.

Cadmium. For cadmium, the studies examined showed cadmium in tree core samples and wood at levels below the ASTM solubility limit of 75 ppm. Studies that measured cadmium in hydroponic samples showed cadmium levels in root, stem bark, stem wood, and leaf parts above 75 ppm. In a similar manner, shoots grown in pots containing varying amounts of cadmium added, showed cadmium concentrations above the ASTM solubility limit in leaves, stems, and roots.

Chromium. For chromium, one study at a chromate-contaminated site found chromium concentrations above the ASTM solubility limit of 60 ppm in roots, but

measurements were below the detection limit for leaves, wood, and bark. Hydroponic studies by the same researcher showed that tree roots can concentrate chromium, but translocation (the movement of a material from one place to another) of chromium from the roots to other parts of the tree, is very low.

Mercury. For mercury, the contractor reviewed studies that measured mercury uptake in the roots, shoots, leaves, bark, trunks, limbs, fruits, branches, stems, and nuts of trees. The studies included both experimental tests and trees sampled from natural areas. Only an experimental study with seedlings grown in pots, to which either mercuric nitrate, methyl mercury chloride, or both, had been added, showed mercury in concentrations above the ASTM solubility limit in shoots and leaves of sycamore seedlings. The other studies did not show mercury levels above the ASTM solubility limit of 60 ppm in samples, even at contaminated sites.

Selenium. For selenium, one study showed measured concentrations of 1.4 ppm selenium in tree rings growing in contaminated soil. Other studies showed selenium at concentrations of 10 ppm or less, well below the ASTM solubility limit of 500 ppm. Only an experimental study with tree cuttings grown hydroponically in either sodium selenate or sodium selenite for 6 days, showed root concentrations above the ASTM solubility limit. All other parts of the cuttings had selenium levels below the ASTM solubility limit.

Conclusions. The contractor's report provides sufficient information for the Commission to determine that unfinished and untreated wood from tree trunks does not contain the ASTM heavy elements in concentrations above their respective solubility limits, and are, therefore, not required to be third party tested to assure compliance with

the ASTM F963-11 solubility test. The studies examined multiple species of trees grown on several continents. No study examined by the contractor found any of the ASTM heavy elements in tree trunks at concentrations beyond the element's solubility limit.

The contractor's report indicates that heavy elements could be present in wood from other portions of the tree: the roots, bark, leaves, or fruit. The studies examined by the contractor showed high levels of one or more of the ASTM heavy elements in portions of trees other than trunks. However, commercial timber harvesting involves the process of "delimbing" the tree to create logs that can be transported and cut at a sawmill or lumberyard.[7] Often, the sawmill creates uniform-length planks from the delivered logs. These planks are sold to wood wholesalers or retailers, and are bought by wooden toy and other manufacturers. Because commercial practice creates logs from only the trunks of harvested trees, the wood available for use in toys and other wooden objects is sourced from these logs, or trunks of trees, and not the other parts of trees that could contain the ASTM elements above the limits in the toy standard.[8]

C. Determination for Unfinished and Untreated Wood for ASTM F963 Limits for Heavy Elements

1. *Legal Requirements for a Determination*

[7] A succinct description of timber logging can be found at http://en.wikipedia.org/w/index.php?title=Logging&redirect=no. A more comprehensive review of timber harvesting can be found at http://www.amazon.com/Tree-Harvesting-Techniques-Forestry-Sciences/dp/9048182824/ref=sr_1_1?s=books&ie=UTF8&qid=1433193105&sr=1-1&keywords=tree+harvesting+techniques%2C+wiksten.

[8] Often, the sawmill creates uniform-length planks from the delivered logs. These planks are sold to wood wholesalers or retailers, and are bought by wooden toy and other manufacturers. Two references to the woods used in toys are: http://www.ehow.com/list_6896897_kinds-wood-toys-made-from_.html, and http://www.woodtoyz.com/WTCat/LearnMaterials.html.

As noted above, section 14(a)(2) of the CPSA requires third party testing for children's products that are subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Toys must comply with the toy standard, including the specified limits on heavy elements. 15 U.S.C. 2056b. In response to statutory direction, the Commission has investigated approaches that would reduce the burden of third party testing while also assuring compliance with CPSC requirements. As part of that endeavor, the Commission has considered whether certain materials used in toys would not require third party testing.

To issue a determination that a material does not require third party testing, the Commission must have sufficient evidence to conclude that the material would consistently comply with the CPSC requirement that the material is subject to so that third party testing is unnecessary to provide a high degree of assurance of compliance. 16 CFR Part 1107. Section 1107.2, defines "a high degree of assurance" as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture."

For a material determination, a high degree of assurance of compliance means that the material will comply with the specified chemical limits due to the nature of the material, or due to a processing technique (*e.g.*, harvesting, smelting, cleaning, filtering, sorting) that reduces the chemical concentration below its limit. For materials determined to comply with a chemical limit, the material must continue to comply with that limit if it is used in a children's product subject to that requirement. A material on which a determination has been made cannot be altered or adulterated to render it noncompliant and then used in a children's product.

Based on the information discussed in section B of this preamble, the Commission determines that unfinished and untreated trunk wood complies with the solubility requirements for the heavy elements in section 4.3.5 of ASTM F963-11 with a high degree of assurance. This determination means that third party testing for compliance to the solubility requirements is not required for certification purposes for unfinished and untreated trunk wood. The Commission makes this determination to reduce the third party testing burden on children's product certifiers while continuing to ensure compliance.

2. *Potential for Third Party Testing Burden Reduction*

CPSC staff assessed the burden reduction that could result from a determination that unfinished and untreated trunk wood does not require third party testing for compliance with the limits on heavy elements in the toy standards. Testing the soluble concentration of the ASTM heavy elements requires placing the toy (or component part of the toy) in a solution of hydrochloric acid for 2 hours. After 2 hours, the solids are separated from the solution, and the solution is analyzed for the presence of any of the ASTM F963-11 heavy elements using atomic spectroscopy. The cost of this testing can vary by factors such as geography and the volume of testing that a manufacturer obtains from a testing laboratory. Based on published invoices and price lists, the cost of a third party test for the ASTM heavy elements ranges from around $60 in China, up to around $190 in the United States.

Staff cannot estimate with any certainty what the total potential burden reduction would be from a determination that unfinished and untreated wood will not contain concentrations of antimony, arsenic, barium, cadmium, mercury, and selenium in excess

of the limits in ASTM F963-11. Most of the approximately 80,000 kinds of toys on the market[9] probably do not contain any wood components. If we assume that 10 percent of the approximately 80,000 different kinds of toys on the market have at least one wood component that requires third party testing, and we also assume that the average cost of a third party test is about $125 (representing the approximate midpoint of the range for the test's cost), then the potential total burden reduction from a determination for unfinished and untreated wood from tree trunks would be about $1 million annually. This estimate assumes that only one type of wood was used in a product so that the manufacturer would not have to test each individual unfinished and untreated wood component part in a product, as allowed by the component part testing rule (16 CFR Part 1109). The estimated benefits could be lower if some manufacturers certify that their wood components comply with the ASTM F963-11 heavy elements requirements, based on third party tests of their raw materials instead of the finished product, as allowed by the component part testing rule. Moreover, the assumption that 10 percent of the toys have wood components is intended only to illustrate the potential benefits; the assumption is not based on any formal study of the toy market.

3. *Statutory Authority*

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. Public Law No. 110-314, § 3, Aug. 14, 2008. As noted previously, section 14 of the CPSA, which was amended by the

[9]The estimate that there are 80,000 different kinds of toys is based on the number of toys listed on the Amazon.com website on June 2, 2015, for which Amazon.com was listed as the seller and recommended for children 13 years old or younger. Examples of toys that might include wood components include building blocks, various wood pull toys, some toy cars and trucks, train sets, some games and puzzles, some toy figures, and some toys for toddlers and infants.

CPSIA, requires third party testing for children's products that are subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Section 14(d)(3)(B) of the CPSA, as amended by Public Law No. 112-28, gives the Commission the authority to "prescribe new or revised third party testing regulations if it determines that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." *Id.* 2063(d)(3)(B). These statutory provisions authorize the Commission to issue this rule determining that unfinished and untreated trunk wood will not exceed the limits for heavy elements stated in the toy standard, and therefore, unfinished and untreated trunk wood does not require third party conformity assessment body testing to assure compliance with the heavy elements limits stated in the toy standard.

This determination relieves unfinished and untreated trunk wood from the third party testing requirement of section 14 of the CPSA for purposes of supporting the required certification. However, if the unfinished and untreated wood is altered so that the material exceeds the heavy elements limits of ASTM F963, the determination is not applicable to that material. The changed or altered material or product must then be tested and meet the heavy element requirements of ASTM F963.

The determination only lifts the obligation to have unfinished and untreated trunk wood tested by a third party conformity assessment body. The underlying requirement that products subject to the toy standard must comply with the toy standard's limits on heavy elements remains in place.

4. *Description of the Rule*

This rule creates a new Part 1251 for "Toys; Determination Regarding Heavy Elements Limits for Unfinished and Untreated Wood." Section 1251.1 of the rule explains the statutorily-created requirements for toys under ASTM F963 and the third party testing requirements for children's products.

Section 1251.2(a) of the rule establishes the Commission's determination that unfinished and untreated trunk wood does not exceed the limits for the heavy elements established in section 4.3.5 of the toy standard with a high degree of assurance as that term is defined in 16 CFR Part 1107. The determination only applies if the material has not been treated or adulterated with the addition of any materials that could result in the addition of any of the heavy elements listed in the toy standard at levels above their respective solubility limits. In section 1251.2(b) of the rule, unfinished and untreated trunk wood means wood harvested from trees with no added surface coatings (*e.g.*, varnish, paint, shellac, polyurethane) and no materials added to the wood substrate (*e.g.*, stains, dyes, preservatives, antifungals, insecticides). Because commercial practice creates wood from only the trunks of harvested trees, unfinished and untreated wood as used in the rule means wood that is generally commercially available. Unfinished and untreated wood does not include manufactured or engineered woods such as pressed wood, plywood, particle board, or fiberboard.

D. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule ("DFR"). The Administrative Procedure Act ("APA") generally requires notice and comment rulemaking 5 U.S.C. 553(b). In Recommendation 95-4, the Administrative Conference of the United States ("ACUS") endorsed direct final rulemaking as an appropriate

procedure to expedite promulgation of rules that are noncontroversial and that are not expected to generate significant adverse comment. *See* 60 FR 43108 (August 18, 1995). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule because we believe the determination will not be controversial. The rule will not impose any new obligations, but will relieve companies from the requirement of having toys (or materials that are component parts of toys) tested by a third party conformity assessment body if the toys or materials are made of unfinished and untreated wood. We expect that the determination will be supported by stakeholders. The determination responds to the desire expressed by numerous stakeholders and Congress that the Commission provide relief from the burdens of third party testing while also ensuring that products will comply with all applicable children's product safety rules. The rule establishes a discrete determination that a specific material (unfinished and untreated wood) in a particular type of product (toys) will always comply with the toy standard's limits on heavy elements. We expect that this focused action will not engender any significant adverse comments.

Unless we receive a significant adverse comment within 30 days, the rule will become effective on [**insert date 60 days after publication in the FEDERAL REGISTER**]. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be one where the commenter explains why the rule would be inappropriate, including an assertion challenging the rule's underlying premise or approach, or a claim that the rule would be ineffective or unacceptable without change.

Should the Commission receive a significant adverse comment, the Commission will withdraw this direct final rule. A notice of proposed rulemaking ("NPR"), providing

an opportunity for public comment, is also being published in this same issue of the *Federal Register*.

E. Effective Date

The APA generally requires that a substantive rule must be published not less than 30 days before its effective date. 5 U.S.C. 553(d)(1). Because the final rule provides relief from existing testing requirements under the CPSIA, the effective date is [**insert date 60 days after publication in the FEDERAL REGISTER**]. However, as discussed in section D of the preamble, if the Commission receives a significant adverse comment the Commission will withdraw the DFR and proceed with the NPR published in this same issue of the *Federal Register.*

F. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA") generally requires that agencies review proposed and final rules for the rules' potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603 and 604.

The rule would relieve toy manufacturers and importers of the responsibility of obtaining third party tests for compliance with the limits on the ASTM elements for components of toys consisting of unfinished and untreated wood. Although the impact will be to reduce testing costs, we expect that the rule would have only limited impact on toy manufacturers and importers for two reasons. First, the rule will affect only those companies that manufacture or import toys that contain unfinished and untreated wood components. We expect that relatively few of the approximately 80,000 toys on the market contain any unfinished and untreated wood components. Therefore this rule

would be expected to impact only a small number of manufacturers and importers or at most, a small portion of the toys in the market.

Second, manufacturers of toys containing unfinished and untreated wood components still would be required to test to other aspects of the ASTM toy standard, so the impact of this rule relative to production costs for most firms should be small. Due to the small number of entities affected and the limited scope of the impact, the Commission certifies that this rule will not have a significant impact on a substantial number of small entities pursuant to section 605(b) of the RFA, 5 U.S.C. 605(b).

G. Environmental Considerations

The Commission's regulations provide a categorical exclusion for Commission rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required. The Commission's regulations state that safety standards for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this rule alters that expectation.

List of Subjects

Business and industry, Infants and children, Consumer protection, Imports, Product testing and certification, Toys.

Accordingly, 16 CFR part 1251 is added to read as follows:

PART 1251—Toys; Determinations Regarding Heavy Elements Limits for Certain Materials

Sec.

Part 1251 Toys; Determinations Regarding Heavy Elements Limits for Certain Materials

§ 1251.1 The toy standard and testing requirements.

The Consumer Product Safety Improvement Act of 2008 ("CPSIA") made provisions of ASTM F963, Consumer Product Safety Specifications for Toy Safety ("toy standard"), a mandatory consumer product safety standard. Among the mandated provisions is section 4.3.5 of ASTM F963 which requires that surface coating materials and accessible substrates of toys that can be sucked, mouthed, or ingested, must comply with solubility limits that the toy standard establishes for eight heavy elements. Materials used in toys subject to section 4.3.5 of the toy standard must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act ("CPSA"), unless listed in § 1251.2.

§ 1251.2 Wood.

(a) Unfinished and untreated wood does not exceed the limits for the heavy elements established in section 4.3.5 of the toy standard with a high degree of assurance as that term is defined in 16 CFR Part 1107, provided that the material has been neither treated nor adulterated with materials that could result in the addition of any of the heavy elements listed in the toy standard at levels above their respective solubility limits.

(b) For purposes of this section, unfinished and untreated wood means wood harvested from the trunks of trees with no added surface coatings (such as, varnish, paint, shellac, or polyurethane) and no materials added to the wood substrate (such as, stains, dyes, preservatives, antifungals, or insecticides). Unfinished and untreated wood does not include manufactured or engineered woods (such as pressed wood, plywood, particle board, or fiberboard).

Dated: _____

_____

Todd A. Stevenson, Secretary,
Consumer Product Safety Commission

[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1251

[Docket No. CPSC-2011-0081]

Toys; Determination Regarding Heavy Elements Limits for Unfinished and Untreated Wood

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission ("Commission" or "CPSC") is proposing to determine that unfinished and untreated trunk wood does not contain heavy elements that would exceed the limits specified in the Commission's toy standard, ASTM F963-11. Based on this proposed determination, unfinished and untreated trunk wood in toys would not require third party testing. In the "Rules and Regulations" section of this *Federal Register*, the Commission is issuing this determination as a direct final rule. If we receive no significant adverse comment in response to the direct final rule, we will not take further action on this proposed rule.

DATES: Submit comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]**.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2011-0081, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments.

The Commission does not accept comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: http://www.regulations.gov, and insert the docket number CPSC-2011-0081, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Randy Butturini, Project Manager, Office of Hazard Identification and Reduction U.S. Consumer Product Safety Commission, 4330 East West Hwy, Room 814, Bethesda, MD 20814; 301-504-7562: email; rbutturini@cpsc.gov.

SUPPLEMENTARY INFORMATION: Along with this proposed rule, CPSC is publishing a direct final rule in the "Rules and Regulations" section of this issue of the

Federal Register. This direct final rule establishes a determination that unfinished and untreated trunk wood does not contain heavy elements that would exceed the heavy elements limits specified in the Commission's mandatory toy standard, ASTM F963-11. Based on this determination, unfinished and untreated trunk wood in toys does not require third party testing. CPSC did not issue a proposed rule before today because CPSC believes that this action is not controversial and CPSC does not expect significant adverse comment. CPSC has explained the reasons for the determination in the direct final rule. Unless CPSC receives significant adverse comment regarding the determination during the comment period, the direct final rule in this issue of the *Federal Register* will become effective [INSERT DATE 60 DAYS AFTER PUBLICATION], and CPSC will not take further action on this proposal. If CPSC receives a significant adverse comment, CPSC will publish a notice in the *Federal Register* withdrawing the direct final rule, and the rule will not take effect. CPSC will then respond to public comments in a later final rule, based on this proposed rule. CPSC does not intend to institute a second comment period on this action. Parties interested in commenting on this determination must do so at this time. For additional information, please see the direct final rule published in the "Rules and Regulations" section of this issue of the *Federal Register*.

Dated: _____

_____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission

Briefing Package

Recommendation for Determinations on the ASTM Elements in Unfinished and Untreated Woods and Other Natural Materials

June 30, 2015

The views expressed in this report are those of the CPSC staff, and they have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

CPSC Hotline: 1-800-638-CPSC (2772) ★CPSC's Web Site: http://www.cpsc.gov

This document has been electronically
approved and signed.

Date: June 30, 2015

TO : The Commission

THROUGH: Stephanie Tsacoumis, General Counsel
Patricia H. Adkins, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM : George A. Borlase, Ph.D., P.E., Assistant Executive Director
Office of Hazard Identification and Reduction

Randy Butturini
Lead General Engineer
Office of Hazard Identification and Reduction

SUBJECT : **Recommendation for Determinations on the ASTM Elements in Unfinished and Untreated Woods and Other Natural Materials**

Executive Summary

The U.S. Consumer Product Safety Commission ("CPSC") contracted with Toxicology Excellence for Risk Assessment ("TERA") to conduct a literature review of the presence of seven elements whose maximum solubility in toys is specified in ASTM F963-11. The materials studied are unfinished and untreated woods, cotton, wool, linen, silk, bamboo, and beeswax. TERA reviewed more than 200 studies identified by TERA's search method, which TERA believes is representative of the relevant studies available. CPSC staff recommends that the Commission determine that unfinished and untreated wood from tree trunks do not contain any of the elements in ASTM F963-11 in concentrations above the elements' respective solubility limit. If the Commission makes this determination, unfinished and untreated wood made from tree trunks in toys subject to the solubility limit would not require third party testing for certification purposes. CPSC staff has provided the Commission with a Direct Final Rule Federal Register Notice and a Notice of Proposed Rulemaking Federal Register Notice as directed by the Commission in the Fiscal Year 2015 Operating Plan Midyear Manager's Amendment.

1. Introduction

Section 14 of the Consumer Product Safety Act ("CPSA"),[1] as amended by the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), requires third party testing of children's products subject to an applicable rule, ban, standard or regulation. Section 106 of the CPSIA states that the provisions of ASTM International ("ASTM"), *Consumer Safety Specifications for Toy Safety* ("ASTM F963," "toy standard"), "shall be considered to be consumer product safety standards issued by the Commission under section 9 of the CPSA (15 U.S.C. 2058)."[2] Thus, toys subject to the currently accepted version of ASTM F963[3] require passing third party testing results for all applicable tests for the manufacturer to issue a Children's Product Certificate ("CPC") before the toys can be entered into commerce.

Section 4.3.5 of ASTM F963-11 requires that surface coating materials and accessible substrates of toys[4] that can be sucked, mouthed, or ingested, comply with the solubility limits of eight elements stated in Table 1 of the toy standard. The materials and their solubility limits are shown below.

Element	**Solubility Limit, parts per million, ("ppm")[5]**
Antimony, ("Sb")	60
Arsenic, ("As")	25
Barium, ("Ba")	1000
Cadmium, ("Cd")	75
Chromium, ("Cr")	60
Lead, ("Pb")	90
Mercury, ("Hg")	60
Selenium, ("Se")	500

TABLE 1: Maximum Soluble Migrated Element in Parts-Per-Million for Surface Coatings and Substrates Included as Part of a Toy

[1] http://www.cpsc.gov/PageFiles/129663/cpsia.pdf.

[2] ASTM F963-11 is a consumer product safety standard, except for section 4.2 and Annex 4, or any provision that restates or incorporates an existing mandatory standard or ban promulgated by the Commission or by statute.

[3] The currently-accepted version is ASTM F963-11.

[4] ASTM F963-11 contains the following note regarding the scope of the solubility requirement:

> NOTE 3—For the purposes of this requirement, the following criteria are considered reasonably appropriate for the classification of toys or parts likely to be sucked, mouthed or ingested: *(1)* All toy parts intended to be mouthed or contact food or drink, components of toys which are cosmetics, and components of writing instruments categorized as toys; *(2)* Toys intended for children less than 6 years of age, that is, all accessible parts and components where there is a probability that those parts and components may come into contact with the mouth.

[5] The method to assess the solubility of a listed element is detailed in section 8.3.2, *Method to Dissolve Soluble Matter for Surface Coatings*, of ASTM F963-11. Modeling clays included as part of a toy have different solubility limits for several of the elements.

For some materials, the concentrations of all eight elements will always be below their respective solubility limits due to biological, manufacturing, or other constraints. For example, one of the specified elements may be sequestered in a portion of a plant that is not used in textile manufacturing, such as the roots. Additionally, a manufacturing process step may remove a specified element, if it is present, from the material being processed. For these materials, compliance with the requirements of Table 1 of ASTM F963-11 is assured without requiring third party testing; the material is intrinsically compliant.

To reduce the third party testing burden on children's product certifiers while continuing to ensure compliance, the CPSC could determine that such materials comply with the solubility requirements for the eight elements in Table 1 of ASTM F963-11. This determination would mean that third party testing for compliance to the solubility requirements would not be required for certification purposes. The third party testing burden can be reduced only if all eight elements in Table 1 have concentrations below their solubility limits. Because laboratories typically run one test for all of the ASTM elements, no testing burden reduction is achieved if any one of the eight elements requires compliance testing.

2. Research Conducted

The CPSC contracted with TERA[6] to conduct a literature search on whether wood and other natural materials could be determined not to contain any of seven specified elements in concentrations above the ASTM F963-11 solubility limits.[7] The materials researched were:

- Unfinished and untreated woods (ash, beech, birch, cherry, maple, oak, pine, poplar, and walnut);
- Bamboo;
- Beeswax;
- Undyed and unfinished fibers and textiles (cotton, wool, linen, and silk); and
- Uncoated or coated paper (wood or other cellulosic fiber).

Unfinished and untreated wood means wood harvested from trees with no added surface coatings (*e.g.*, varnish, paint, shellac, polyurethane) and no materials added to the wood substrate (*e.g.*, stains, dyes, preservatives, antifungals, insecticides). Unfinished and untreated wood does not include manufactured or engineered woods such as plywood, particle board, or fiberboard.

The Commission has previously determined that lead is not present in the specified materials in concentrations above 100 ppm.[8] Because of this determination, TERA was directed to research only the remaining seven elements. We chose these materials for research from materials previously determined not to contain lead in concentrations above 100 ppm and were more likely to be used in toys subject to the ASTM F963-11 solubility limits.

TERA's research included the following factors:

[6] http://www.tera.org/.
[7] The task order for the contract is CPSC-D-12-0001-0009.
[8] See 16 C.F.R. §1500.91.

- The concentrations of the seven elements in the material under study;
- The presence and concentrations of the elements in the environmental media (*e.g.*, soil, water, air), and in the base materials for the textiles and paper;
- Whether processing has the potential to introduce any of the seven elements into the material under study; and
- The potential for contamination after production, such as through packaging.

TERA examined secondary sources and review articles to identify the available data regarding the elements' concentrations in the materials listed above. TERA summarized the relevant data on bioavailability and presence/concentrations in environmental media (*i.e.*, soil, air, and water) from the most recent Agency for Toxic Substances and Disease Registry ("ATSDR")[9] toxicological profile, supplemented with more recent authoritative reviews. TERA conducted a literature search for data on concentrations of the chemical elements in each of the specific materials. Potentially relevant papers for information on concentrations of chemical elements in each product were identified and reviewed. TERA used the references from reviewed articles to identify other articles to examine and used the references in those articles to find other sources recursively, to uncover relevant cited references.[10] The literature screening was to examine whether there is a potential for an ASTM element to be present in the natural material at levels above its solubility limit. When TERA determined there was sufficient information to indicate the potential for an ASTM element to be present, TERA stopped that particular line of inquiry and reported the results.

3. Contractor's Findings & Staff Evaluation

Once the contract work was underway, CPSC staff directed the contractor to prioritize their work after the initial literature search and document reviews. Currently, the ASTM F963-11 toy safety standard does not require testing of paper for the seven elements and does not include methods for conducting that testing. Given the amount of information identified and the limited contract resources, staff asked that the contractor allocate priority to researching wood and fibers/textiles over paper. Evaluation of paper, in part, can rely on the research on wood and other fibers because those materials are used in paper production.

The contractor report, *Concentrations of Selected Elements in Unfinished Wood and Other Natural Materials*,[11] is organized into a Final Report with two appendices. The Final Report presents the results of the literature study. Appendix I of the Final Report contains data tables for studies showing concentrations below the ASTM solubility limit for each element investigated. Appendix II of the Final Report details the contractor's literature search methods for data on the elements and each of the specific materials.

[9] The congressionally mandated Agency for Toxic Substances and Disease Registry produces toxicological profiles for hazardous substances found at National Priorities List sites.
[10] 'This method is often referred to as "tree searching."
[11] The report can be found on the CPSC website at: http://www.cpsc.gov/Global/Research-and-Statistics/Technical-Reports/Toys/TERAReportASTMElements.pdf.

Table 2 summarizes the findings of the TERA report and the staff evaluation of the results.

	Antimony	Arsenic	Barium	Cadmium	Chromium	Mercury	Selenium
Wood (trunk)	Does not Exceed	Does not Exceed	Does not Exceed	Does not Exceed	Does not Exceed	Does not Exceed	Does not Exceed
Bamboo	No data found	Does not Exceed	No data found	Does not Exceed	No data found	No data found	No data found
Beeswax	No data found	No data found	No data found	Does not Exceed	Does not Exceed	Does not Exceed	No data found
Cotton	No data found	Exceeds	No data found	Does not Exceed	Exceeds	Does not Exceed	No data found
Wool	Does not Exceed	Exceeds	No data found	Does not Exceed	Does not Exceed	Does not Exceed	Does not Exceed
Linen (Flax)	No data found	No data found	No data found	Does not Exceed	Does not Exceed	Does not Exceed	Does not Exceed
Silk	No data found	Does not Exceed	No data found	No data found	No data found	Does not Exceed	No data found

Table 2: Concentrations of the Selected Elements Relative to the ASTM Solubility Limits

3.1 Wood

By far, wood had the most studies identified by the contractor's search methods. Due to the constraints of the contract, TERA did not examine every study, but the contractor reported that the studies constitute a representative sample of the population of studies. The contractor studied measurements taken from trees in natural settings, samples from trees grown on contaminated soils, hydroponically grown[12] seedlings, experimental studies with seedlings grown in pots in which the soil had some of the elements intentionally added, and seedlings soaked in solutions containing one or more of the ASTM elements.

The contractor examined measurements on roots, shoots, bark, trunks, branches, and leaves (or needles, for evergreens). Not every study conducted measurements on each part of the tree. Many studies showed concentrations of the ASTM elements at levels below their solubility limits. The contractors' report contains references to those studies in Appendix I.

For antimony, the studies examined showed that roots, shoots, branches, and leaves contained antimony in concentrations greater than the ASTM solubility limit of 60 ppm.[13] No tree trunks showed antimony concentrations above the ASTM solubility limit. One study's measurements of tree trunks showed that the trunks were nearly free of antimony.

For arsenic, trunks, roots shoots, leaves, stems, bark, and branches of trees were characterized. An experimental study[14] showed roots with more than 25 ppm arsenic. A study at a contaminated

[12] Hydroponics is a subset of hydroculture and is a method of growing plants using mineral nutrient solutions, in water, without soil.
[13] Wanat et al., 2014, and Jana et al., 2012.
[14] Castillo-Michel et al., 2011.

mining site[15] showed roots, branches, leaves/needles, and shoots with arsenic concentrations above the ASTM solubility limit. However, no tree trunk measurement showed arsenic in concentrations above 25 ppm. In the two tested cases, tree trunks contained only trace levels of arsenic (levels well below the solubility limit).

One study measured levels of arsenic in sawdust sampled from 15 sawmill locations in the Sapele metropolis (a port city in Nigeria).[16] The highest arsenic concentration measured was 93.0 ppm. The study's authors did not specify what types of trees or wood were processed at the sawmills. However, the authors noted that a major industry in the study area is Africa Timber Plywood Industry and mentioned that arsenic and chromium are used as wood preservatives. Plywood is a manufactured wood and could contain materials not found in natural wood. The authors did not report what woods these sawmills were processing. Therefore, we cannot draw any conclusions from this study.

For barium, measurements of leaves, leaf litter, wood, and sawdust all showed barium concentrations below the ASTM solubility limit of 1,000 ppm.

For cadmium, the studies examined showed cadmium in tree core samples and wood at levels below the ASTM solubility limit of 75 ppm.[17] Studies that measured cadmium in hydroponic samples showed cadmium levels in root, stem bark, stem wood, and leaf parts above 75 ppm. In a similar manner, shoots grown in pots containing varying amounts of cadmium added, showed cadmium concentrations above the ASTM solubility limit in leaves, stems, and roots.

For chromium, one study at a chromate-contaminated site found chromium concentrations above the ASTM solubility limit of 60 ppm in roots, but measurements were below the detection limit for leaves, wood, and bark.[18] Hydroponic studies by the same researcher showed that tree roots can concentrate chromium, but translocation (the movement of a material from one place to another) of chromium from the roots to other parts of the tree, is very low.

For mercury, the contractor reviewed studies that measured mercury uptake in the roots, shoots, leaves, bark, trunks, limbs, fruits, branches, stems, and nuts of trees. The studies included both experimental tests and trees sampled from natural areas. Only an experimental study with seedlings grown in pots, to which either mercuric nitrate, methyl mercury chloride, or both, had been added, showed mercury in concentrations above the ASTM solubility limit in shoots and leaves of sycamore seedlings.[19] The other studies did not show mercury levels above the ASTM solubility limit of 60 ppm in samples, even at contaminated sites.

For selenium, one study showed measured concentrations of 1.4 ppm selenium in tree rings growing in contaminated soil.[20] Other studies showed selenium at concentrations of 10 ppm or

[15] Jana et al., 2012.
[16] Nwajei and Iwegbue, 2007.
[17] Algreen et al., 2012, 2014.
[18] Pulford et al., 2001.
[19] Jean-Philippe et al., 2011a,b.
[20] Liu et al., 2007.

less, well below the ASTM solubility limit of 500 ppm. Only an experimental study with tree cuttings grown hydroponically in either sodium selenate or sodium selenite for 6 days, showed root concentrations above the ASTM solubility limit. All other parts of the cuttings had selenium levels below the ASTM solubility limit.

3.2 Bamboo

The data on bamboo were extremely limited, with only two studies found by the contractor. One market study[21] showed concentrations of arsenic in bamboo shoots to be less than 0.1 ppm.[22] The second study showed concentrations of cadmium in bamboo wine (fermented bamboo sap) to be less than 0.5 ppm.[23]

The contractor's searches did not locate any studies for five of the ASTM elements (antimony, barium, chromium, mercury, and selenium) in bamboo.

3.3 Beeswax

The data on beeswax were very limited. One review and five studies showed concentrations of cadmium in beeswax to be less than 1 ppm.[24] One study showed concentrations of chromium in beeswax to be less than 0.1 ppm.[25] One review showed concentrations of mercury in beeswax to be less than 0.1 ppm.[26]

The contractor's searches did not locate any studies for four of the ASTM elements (antimony, arsenic, barium, and selenium) in beeswax.

3.4 Cotton

The contractor identified 24 studies using the search methods described above. The research studies included measurements taken from cotton fiber, leaves, wax, seeds, and shoots containing one or more of the ASTM elements. Not every study conducted measurements on each part of the cotton plant. Appendix 1 of the contractor's report contains references to those studies.

The contractor's searches did not locate any studies for four of the ASTM elements (antimony, barium, mercury, and selenium) in raw cotton fiber. One study[27] was identified that measured mercury levels of absorbent sterile cotton at less than the ASTM solubility levels.

Studies on arsenic content of cotton fiber and yarns, as well as seed, leaves, wax, and shoots, were reviewed. According to the studies, arsenic can be present in chemicals used to defoliate cotton plants in preparation for harvesting. One study[28] showed cotton fiber and yarn with more than 285 and 366 ppm arsenic, respectively. Additionally, the study reported that the arsenic is completely removed from yarn during the scouring process if the water used in processing is at

[21] The bamboo shoots studied were collected from various regions of China.
[22] Zhao et al., 2006.
[23] Mosha et al., 1996.
[24] Bogdanov 2006, Formicki et al., 2013, Zhelyazkova et al., 2001, Conti and Botre 2001, Veleminsky et al., 1990
[25] Conti and Botre, 2001.
[26] Madras-Majevska et al., 2002 (as cited by Bogdanov 2006).
[27] Tkachuk, 1983.
[28] Perkins and Brushwood, 1991.

least 100° C.[29] Another study[30] characterized cotton leaves, showing concentrations up to 41.1 ppm.

Studies on cadmium content of cotton plants were reviewed. According to the studies, cadmium may be present in the plant at levels above the ASTM solubility limit, but no studies showed cadmium present in the fiber at levels above the solubility limit. An experimental study[31] showed cotton fiber with a bioconcentration factor from soil to fiber of up to 0.033, meaning that the fiber does not efficiently take up the element. The study reported cotton fiber cadmium concentrations at 1.5 ppm on average. Another study reported that cotton grown at a contaminated site (near a nonferrous metal works with soil concentrations at 12.2 ppm) resulted in fiber concentrations of up to 0.154 ppm.[32] These studies and others showed higher concentrations in other parts of the plant, some above the ASTM solubility limits for cadmium.

One study[33] on chromium content of cotton fiber was reported. According to the study, cotton fiber ginned[34] using Chrome Composite Leather-Clad ("CCLC") rollers can result in chromium levels above the ASTM solubility limit. The authors reported cotton fiber chromium concentrations ranging from 17 to 1,990 ppm.

3.5 Wool

The contractor's review was limited to studies on natural animal-sourced wool; studies on synthetic wools were not included. The contractor located three studies on concentrations of the ASTM elements in natural wool. Although studies have detected antimony, arsenic, cadmium, chromium, mercury and selenium in wool, only arsenic was measured at concentrations greater than the soluble limits. The contractor did not locate any studies that examined the barium content of natural wool.

Arsenic has been measured in wool at concentrations greater than the solubility limit of 25 mg/kg. One study measured concentrations up to 3,765.4 ppm in wool of sheep dipped in arsenical pesticides.[35] After scouring the wool with carbon tetrachloride (a strong solvent), arsenic concentrations remained as high as 1601.8 ppm. This result indicates that arsenic binds tightly to the wool fibers. While arsenic-based pesticides are no longer used in most developed countries, arsenic has still been detected in wool from sheep living in areas of high arsenic contamination. One study reported concentrations of arsenic in wool up to 3,264 ppm from sheep grazing in an area surrounding a copper mine that was reported to have high concentrations of arsenic in the water and plants.[36] Another study also measured concentrations of arsenic in wool

[29] A wet treatment using a slightly basic hot water bath to prepare the yarn for further finishing.
[30] Wilkinson and Hardcastle, 1969.
[31] Li *et al.*, 2012.
[32] Angelova *et al.*, 2004.
[33] Iyer and Mastorakis, 2007.
[34] A processing technique that separates the cotton lint (fiber) from the seed.
[35] Hoffman *et al*., 1963.
[36] Rezazadeh *et al*., 2013.

up to 364 ppm from wool taken from sheep in an area around a gold mine smelting plant and dump with high arsenic concentrations in the topsoil.[37]

3.6 Linen

The contractor located very few studies on concentrations of the ASTM elements in unfinished linen fiber and unfinished linen fabric/textile. Given the lack of data on unfinished linen fiber and unfinished linen fabric/textile, the contractor also searched for data about these elements in the flax plant and its parts (including its shoots, roots, stems, and leaves).

The contractor's searches did not locate any studies for three of the ASTM elements (antimony, arsenic, and barium) in the flax plant and its parts. However, TERA did identify five studies that provided concentrations of cadmium, four studies that provided concentrations of chromium, one study on the concentration of mercury, and one study on the concentration of selenium. These studies showed concentrations that were less than the ASTM F963-11 solubility limits for these four elements.

The identified studies show concentrations of cadmium, chromium, mercury, and selenium below their respective ASTM solubility limits in the flax plant and its parts.

3.7 Silk

The contractor located very few studies on concentrations of the ASTM elements in silk. Given the lack of data on silk fibers or textiles, the contractor also searched for data about these elements in silkworms, the source of silk. The contractor reviewed five publications concerning silk or silkworms.

One study searched for and did not detect arsenic in silk fabric.[38] Another study did not detect arsenic or mercury in wild silk proteins.[39] Although available data show low concentrations of arsenic and mercury in silk, data are limited and may not be generalizable to other silkworm populations.

The contractor's searches did not locate any studies for five of the ASTM elements (antimony, barium, cadmium, chromium, and selenium) in silk fibers or textiles.

In silkworms, one study[40] found low levels of selenium in some tissues. Two separate laboratory-based studies investigated uptake of specific elements from the silkworms' diet. One study[41] found uptake of cadmium into silkworm tissues after exposure to an artificial diet containing specified concentrations of cadmium. Another study[42] found uptake of chromium by silkworms after feeding on plants grown in chromium-treated irrigation water. The latter study

[37] Rezazadeh *et al*., 2014.
[38] Saravanan and Chandramohan, 2011.
[39] Lee *et al.*, 2011.
[40] Benţea *et al.*, 2012.
[41] Suzuki *et al.*, 1984.
[42] Shoukat *et al.*, 2014.

showed significant toxicity to the silkworms, including death, associated with the chromium exposure. These studies did not provide corresponding information on the element concentrations in silk produced by the exposed animals.

Although laboratory studies on silkworms show uptake of cadmium and chromium from the diet, toxicity was observed with the chromium exposure. The contractor did not identify any information about whether such exposures occur in silk-producing areas, or if silk can be commercially harvested from silkworms experiencing toxicity.

4. Staff Recommendation

Children's products subject to a children's product safety rule are required to be third party tested and certified with a high degree of assurance that the product is compliant with those rules, per 16 C.F.R. part 1107. Any staff recommendation for a determination regarding a specific material would be based on a high degree of assurance that the material being recommended for a determination would consistently comply with the requirements, such that third party testing of that material is unnecessary to provide that high degree of assurance of conformity. The Commission has defined "a high degree of assurance" as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture."[43]

For a material, a high degree of assurance of compliance means that the material will comply with the specified chemical limits due to the nature of the material, or due to a processing technique (*e.g.*, harvesting, smelting, cleaning, filtering, sorting) that reduces the chemical concentration below its limit. For materials determined to comply with a chemical limit, the material must continue to comply with that limit if it is used in a children's product subject to that requirement. A material on which a determination has been made cannot be altered or adulterated to render it noncompliant and then used in a children's product.

CPSC staff required data showing that the concentrations of all of the selected elements were consistently below the ASTM solubility limits to recommend that the Commission make a determination for that material. If there were no data for the solubility limits for one or more of the selected elements for that material, staff did not recommend the Commission make a determination. The contractor has located no information that explains the lack of data on the concentration of one or more of the elements in a material of interest. One hypothesis is that chemical content of a material is not of interest to producers, consumers, or regulators of that material, or to researchers. Another hypothesis is that no study has shown particularly high concentrations of an element in a material, and, therefore, no reports have been published.

4.1 Wood

CPSC staff recommends that the Commission issue a direct final rule (along with a notice of proposed rulemaking) to determine that unfinished and untreated wood from tree trunks do not to

[43] 16 C.F.R. § 1107.2, See http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=b1c430defe23657e1f12d1ceeb593794&ty=HTML&h=L&r=PART&n=pt16.2.1107#se16.2.1107_12.

contain the ASTM elements in concentrations above their respective solubility limits and are therefore, not required to be third party tested to assure compliance with the ASTM F963-11solubility test. The studies examined multiple species of trees grown on several continents. No study examined by the contractor found any of the ASTM elements in tree trunks at concentrations beyond the element's solubility limit.

This recommendation does not extend to other portions of the tree, the roots, bark, leaves, or fruit. The studies examined by the contractor showed high levels of one or more of the ASTM elements in portions of trees other than trunks. However, timber harvesting worldwide involves "delimbing" the tree to create logs for transport to a sawmill or lumber yard.[44] Because commercial practice creates logs from harvested trees, the wood available for use in toys and other wooden objects is sourced from these logs, or trunks of trees.[45]

The literature search did not investigate individual tree species in sufficient depth to warrant a recommendation for a specific tree part of a given species (*e.g.*, pine bark).

4.2 Cotton and Wool

Staff does not recommend that the Commission determine that cotton or wool do not contain the ASTM elements in concentrations above their respective solubility limits. For cotton, arsenic and chromium were found to be present in concentrations above the ASTM solubility limits of 25 and 60 ppm, respectively. For wool, arsenic was found to be present in concentrations above the ASTM solubility limit of 25 ppm.

4.3 Bamboo, Beeswax, Linen, and Silk

Staff is unable to recommend that the Commission determine that bamboo, beeswax, linen, or silk do not contain the ASTM elements in concentrations above their respective solubility limits. For these materials, no data were located by the contractor for one or more of the ASTM elements. The lack of data on the concentration of the ASTM elements in a material is insufficient, by itself, to provide a high degree of assurance of the material's compliance to the ASTM solubility limits.

5. Potential for Third Party Testing Burden Reduction

Testing the soluble concentration of the ASTM elements requires placing the toy or component (or piece thereof) in a solution of hydrochloric acid for 2 hours. After 2 hours, the solids are

[44] There are many references to commercial timber harvesting, which include removing the limbs of a felled tree to create a log that can be transported. Limbs left on a tree are potentially dangerous because they may snap violently as the tree is dragged, posing a hazard to loggers. Furthermore, sawmills are designed to handle limbless logs. Lastly, the limbs and crown are used for pulp and fuel, rather than for wood pieces. A succinct description of timber logging can be found at: http://en.wikipedia.org/w/index.php?title=Logging&redirect=no. A more comprehensive review of timber harvesting can be found at: http://www.amazon.com/Tree-Harvesting-Techniques-Forestry-Sciences/dp/9048182824/ref=sr_1_1?s=books&ie=UTF8&qid=1433193105&sr=1-1&keywords=tree+harvesting+techniques%2C+wiksten.

[45] Often, the sawmill creates uniform-length planks from the delivered logs. These planks are sold to wood wholesalers or retailers, and are bought by wooden toy and other manufacturers. Two references to the woods used in toys are: http://www.ehow.com/list_6896897_kinds-wood-toys-made-from_.html, and http://www.woodtoyz.com/WTCat/LearnMaterials.html.

separated from the solution, and the solution is analyzed for the presence of any of the ASTM F963-11 elements using atomic spectroscopy. The cost of this testing can vary by factors such as geography and the volume of testing that a manufacturer obtains from a laboratory. Based on published invoices and price lists, the cost of a third party test for the ASTM elements ranges from around $60 in China, up to around $190in the United States.
Staff cannot estimate with any certainty what the total potential burden reduction would be from a determination that unfinished and untreated wood from tree trunks will not contain concentrations of antimony, arsenic, barium, cadmium, mercury, and selenium in excess of the limits in ASTM F963-11. Most of the approximately 80,000 toys on the market probably do not contain any wood components. Examples of toys that might have unfinished and untreated wood components include many building blocks, various wood pull toys, some toy cars and trucks, train sets, some games and puzzles, some toy figures, and some toys for toddlers.

If we assume that 10 percent of the approximately 80,000 different toys on the market[46] had at least one wood component that required third party testing, and we also assume that the average cost of a third party test is about $125 representing the approximate midpoint of the range for the test's cost, then the potential total burden reduction from a determination for unfinished and untreated wood from tree trunks would be about $1 million annually. This estimate assumes that only one type of wood was used in a product so that manufacturer would not have to test each individual unfinished and untreated wood component part in a product, as allowed by the component part testing rule (16 C.F.R. part 1109). The estimated benefits could be lower if some manufacturers certify that their wood components comply with the ASTM F963-11 elements requirements, based on third party tests of their raw materials instead of the finished product, also as allowed by the component part testing rule. Moreover, the assumption that 10 percent of the toys have wood components is intended only to illustrate the potential benefits; the assumption is not based on any formal study of the toy market.

6. Impact on Small Businesses

The proposed rule would relieve toy manufacturers and importers of the responsibility of obtaining third party tests for compliance with the limits on the ASTM elements for unfinished and untreated wooden component parts of toys. While the impact will be to reduce testing costs, we expect that the rule would have only limited impact on toy manufacturers and importers. Appendix A details the expected impact on small businesses.

7. Conclusions

CPSC contracted with TERA to conduct a literature review of the presence of the ASTM elements in unfinished and untreated woods and other specified natural materials. TERA reviewed more than 200 studies identified by their search method, which TERA believes is

[46] The estimate that there are 80,000 different kinds of toys is based on the number of toys listed on the Amazon.com website on June 2, 2015, for which Amazon.com was listed as the seller and recommended for children 13 years old or younger.

representative of the relevant studies available. CPSC staff reviewed the information provided in the contractor report and formulated recommendations for Commission consideration.

CPSC staff recommends that the Commission determine that unfinished and untreated woods made from tree trunks do not contain any of the elements in ASTM F963-11 in concentrations above the elements' respective solubility limit. CPSC staff has provided the Commission with a Direct Final Rule Federal Register Notice and a Notice of Proposed Rulemaking Federal Register Notice as directed by the Commission in the Fiscal Year 2015 Operating Plan Midyear Manager's Amendment. CPSC staff recommends an effective date of 60 days after publication of the Federal Register Notice, unless the Commission receives a significant adverse comment within 30 days of publication.

Appendix A: Small Business Impacts of a Rule Determining that Unfinished and Untreated Wood Will Not Have Concentrations of Certain Elements Above the Limits in ASTM F963

United States
Consumer Product Safety Commission
Washington, DC 20207

Memorandum

Date: June 9, 2015

TO : Randy Butturini, Project Manager
Third Party Testing Burden Reduction Project

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 : Small Business Impacts of a Rule Determining that Unfinished and Untreated Wood Will Not Have Concentrations of Certain Elements Above the Limits in ASTM F963

The Commission is considering whether to issue a direct final rule declaring that unfinished, untreated wood from tree trunks does not, and will not, contain antimony, arsenic, barium, cadmium, chromium, mercury, or selenium (hereafter referred to as "the ASTM elements") in excess of the limits established by ASTM F963.[47] The rule would reduce the third party testing burden on manufacturers and importers of toys. If the Commission promulgates this rule, toy manufacturers will no longer be required to obtain third party testing on toys or components of toys made from unfinished and untreated wood to certify that the toy or component does not contain any of the ASTM elements. The rule would apply to toys or components that consist of unfinished and untreated wood from the trunks of trees. The rule

[47] Lead is also a heavy element that is limited by ASTM F963. However, lead is covered by other children's product safety rules, and the Commission has already made a determination that wood does not contain lead at concentrations above the regulated level.

would not apply to manufactured wood, plywood, or particle board; nor would the rule apply to any paints or coatings that might be used on a wood component.

Impact on Small Businesses

The rule would relieve toy manufacturers and importers of the responsibility of obtaining third party tests to confirm compliance with the limits on the ASTM elements for components of toys consisting of unfinished wood. Although the impact will be to reduce testing costs, we expect that the rule would have only limited impact on toy manufacturers and importers for two reasons. First, the rule will only affect companies that manufacture or import toys that contain unfinished and untreated wood components. We expect that relatively few of the approximately 80,000 kinds of toys on the market contain any unfinished and untreated wood components.[48] Therefore, this rule would be expected to impact only a small number of manufacturers and importers, or at most, impact a small portion of the toys in the market. Second, manufacturers of toys containing unfinished and untreated wood components would still be required to test to other aspects of the ASTM toy standard. Accordingly, the impact of this rule, relative to production costs for most firms, should be small. Due to the small number of entities affected and the limited scope of the impact, the rule should not have a significant impact on a substantial number of small businesses, and the Commission could certify this.

[48] The estimate that there are 80,000 different kinds of toys is based on the number of toys listed on the Amazon.com website on June 2, 2015, for which Amazon.com was listed as the seller of toys sold on the site and recommended for children 13 years old or younger. Examples of toys that might have wood components are building blocks, various wood pull toys, some toy cars and trucks, train sets, some games and puzzles, some toy figures, and some toys for toddlers and infants.