



[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: [www.regulations.gov](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](http://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: [www.regulations.gov](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: [www.regulations.gov](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

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## **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)."<sup>1</sup> 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<sup>2</sup> that can be

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<sup>1</sup> 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.

<sup>2</sup> ASTM F963-11 contains the following note regarding the scope of the solubility requirement:

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.

<b>Element</b>	<b>Solubility Limit, parts per million, (“ppm”)<sup>3</sup></b>
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**

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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.

<sup>3</sup> 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.

## **Surface Coatings and Substrates Included as Part of a Toy**

### *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-](http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Toys/TERAReportASTMElements.pdf)

[Reports/Toys/TERAReportASTMElements.pdf](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.

[http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2015/DFR  
andNPRDeterminationsontheASTMElementsUnfinishedWoods%20June302015.pdf](http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2015/DFRandNPRDeterminationsontheASTMElementsUnfinishedWoods%20June302015.pdf).

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")<sup>4</sup> 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.<sup>5</sup> 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

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<sup>4</sup> The congressionally mandated Agency for Toxic Substances and Disease Registry produces toxicological profiles for hazardous substances found at National Priorities List sites.

<sup>5</sup> This method is often referred to as "tree searching."



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.

## *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<sup>6</sup> 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.

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<sup>6</sup> Hydroponics is a subset of hydroculture and is a method of growing plants using mineral nutrient solutions, in water, without soil.

*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, 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 “delimiting” the tree to create logs that can be transported and cut at a sawmill or lumberyard.<sup>7</sup> 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.<sup>8</sup>

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<sup>7</sup> 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](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).

<sup>8</sup> 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](http://www.ehow.com/list_6896897_kinds-wood-toys-made-from_.html), and <http://www.woodtoyz.com/WTCat/LearnMaterials.html>.

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

### *1. Legal Requirements for a Determination*

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<sup>9</sup> 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*

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<sup>9</sup>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.

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 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.

1251.1 The toy standard and testing requirements.

1251.2 Wood.

Authority: Sec. 3, Pub. L. No. 110-314, 122 Stat. 3016; 15 U.S.C. 2063(d)(3)(B).

#### **§ 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).

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Todd A. Stevenson, Secretary,  
Consumer Product Safety Commission  
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