

PAH for new parts that will be installed in articles for which a dual airworthiness release is to be issued. In order to serve European customers many U.S. repair stations will be required to possess parts documentation that U.S. PAHs cannot currently issue and which can only be obtained from the FAA or its designees.

Although the FAA and EASA have agreed to delay the implementation of Change 5 to the MAG until March 29, 2016, correcting the effective date of § 21.137(o) will provide PAHs with the ability to establish a system for the issuance of authorized release documents to meet EASA requirements without increasing staff in the form of Organization Designation Authority (ODA) unit members or Designated Manufacturing Inspection Representatives (DMIRs), or incurring the cost of hiring additional Designated Airworthiness Representatives (DARs).

Additionally, correcting the effective date of §§ 21.142, 21.147, and 45.11(c) will alleviate the current need for PAHs to request new exemptions or renew current exemptions to manufacture and install interface components and appropriately mark wooden propellers.

The remaining sections of the final rule become effective on March 29, 2016, its originally published effective date.

#### Correction

In FR Doc. 2015–24950, beginning on page 59021 in the **Federal Register** of October 1, 2015, in the second column, correct the **DATES** section to read as follows:

**DATES:** This final rule is effective March 29, 2016, except for §§ 21.1(b)(1), 21.1(b)(5) through (9), 21.137(o), 21.142, 21.147 and 45.11(c), which are effective on January 4, 2016.

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on December 11, 2015.

**Lirio Liu,**

*Director, Office of Rulemaking.*

[FR Doc. 2015–31639 Filed 12–16–15; 8:45 am]

**BILLING CODE P**

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## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### 15 CFR Part 762

#### Recordkeeping

##### *CFR Correction*

In Title 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of January 1, 2015, on pages 657 and

658, in § 762.1, in paragraph (b), remove “§ 762.7” and add “§ 762.2” in its place, and remove “§ 762.6” and add “§ 762.7” in its place.

[FR Doc. 2015–31733 Filed 12–16–15; 8:45 am]

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## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### 15 CFR Part 772

#### Definitions of Terms

##### *CFR Correction*

In Title 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of January 1, 2015, on pages 723, 727, and 733, in § 772.1, remove the definitions of “fault tolerance”, “laser duration” and “positioning accuracy”.

[FR Doc. 2015–31737 Filed 12–16–15; 8:45 am]

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## 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:** Final rule.

**SUMMARY:** The Consumer Product Safety Commission (“Commission,” or “CPSC”) is issuing a 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 trunk wood in toys does not require third party testing for the heavy element limits in ASTM F963.

**DATES:** The rule is effective on January 19, 2016.

**FOR FURTHER INFORMATION CONTACT:** John W. Boja, Lead Compliance Officer, Office of Compliance, U.S. Consumer Product Safety Commission, 4330 East West Hwy., Room 610M, Bethesda, MD 20814; 301–504–7300; email: [jboja@cpsc.gov](mailto:jboja@cpsc.gov).

**SUPPLEMENTARY INFORMATION:**

#### A. Background

##### 1. Third Party Testing and Burden Reduction

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.* Public Law 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.” Public Law 112–28 also authorized the Commission to issue new or revised third party testing regulations if the Commission 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).

##### 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 sucked, mouthed, or

<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:

Continued

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 the lead content limit, 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.

TABLE 1—MAXIMUM SOLUBLE MIGRATED ELEMENT IN PARTS-PER-MILLION FOR SURFACE COATINGS AND SUBSTRATES INCLUDED AS PART OF A TOY

Element	Solubility limit, parts per million, (“ppm”) <sup>3</sup>
Antimony, (“Sb”) .....	60
Arsenic, (“As”) .....	25
Barium, (“Ba”) .....	1000
Cadmium, (“Cd”) .....	75
Chromium, (“Cr”) .....	60
Lead, (“Pb”) .....	90
Mercury, (“Hg”) .....	60
Selenium, (“Se”) .....	500

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 subsequent 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

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.

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.

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.

4. Direct Final Rule and Notice of Proposed Rulemaking

On July 17, 2015, the Commission published a direct final rule (“DFR”) and a companion notice of proposed rulemaking (“NPR”) for the ASTM wood determination that is the subject of this final rule in the same issue of the **Federal Register**. (DFR, 80 FR 42376; NPR, 80 FR 42438). Because the Commission received significant adverse comment to the DFR, the Commission withdrew the DFR and is proceeding with the rulemaking under the NPR that was published simultaneously with the DFR. 80 FR 54417 (Sept. 10, 2015). The comments to the DFR/NPR are addressed in section C of this preamble.

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 Web site 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 Web site: <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

<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.

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 trunk 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 trunk 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 the population 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.

**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 requirements. 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

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

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

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>

### C. Discussion of Comments to the DFR/ NPR

The CPSC received six comments in response to the DFR and NPR published in the **Federal Register** on July 17, 2015 (80 FR 42376). Summaries of each comment and our responses are provided below.

Three comments express support for the proposed determination that unfinished and untreated wood from tree trunks does not require testing for the ASTM elements. Two comments raise questions and requested clarification about the rule. One comment expresses opposition to exempting wood toys from testing.

*Comment 1:* One commenter asks what safety measures would be implemented to prevent manufacturers from using treated wood instead of untreated wood in toys, and asks what would be classified as untreated wood. For example, the commenter asks if a clear sealant could be used to protect the wood from water and saliva and still be considered untreated wood.

The commenter also asks what penalties would be incurred if treated wood was used in children's toys.

*Response 1:* The proposed rule does not prohibit the use of wood finishes or treatments in children's products. There is no penalty for using treated woods in children's toys as long as the treatment does not violate an applicable children's product safety rule. The purpose of the rule is for the Commission to determine that unfinished and untreated wood does not contain the chemical elements that are restricted in toys under the mandatory toy standard, and thus unfinished and untreated wood does not require third party testing to ensure compliance to the toy standard's chemical solubility requirement. The effect of the rule would be to relieve manufacturers and importers of the third party testing requirement for

children's products for unfinished and untreated wood toys or wood component parts of toys.

A surface coating, such as a clear sealant applied to unfinished wood, is subject to the requirements of 16 CFR part 1303 and the toy standard's chemical solubility requirement. The manufacturer would need to third party test the finished product or could use component part testing to test only the surface coating pursuant to 16 CFR part 1109.

*Comment 2:* A commenter asserts that testing still should be required for untreated wood because "so many toys are filled with other chemicals which will be inserted into the mouths of millions of children." The commenter asserts that much of the wood from outside the United States could be contaminated by heavy metals during processing or before shipping. This commenter also states that the required testing is a simple step to ensure the safety of toys.

*Response 2:* The commenter does not provide any data or specific information about toys "filled with other chemicals" that would support a testing requirement for unfinished and untreated wood subject to the ASTM elements restrictions. Nor does the commenter dispute the data and information relied upon by the Commission. The determination for unfinished and untreated wood is based on data and information about the chemical content of wood from all over the world that demonstrated that unfinished and untreated wood does not contain the chemical elements that are restricted in toys under the toy standard. We note that the only chemicals specifically prohibited in toys by ASTM F963 are lead and the seven other ASTM elements; in addition, the CPSIA prohibited specified phthalates.

Although the commenter refers to the "simple step" of testing, mandatory third party testing can be costly, especially for small or low-volume suppliers. The determination responds to the statutory requirement to consider new or revised third party testing requirements that will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

*Comment 3:* A commenter states that his or her understanding of the proposed rule is that "any untreated wooden toy [could] be tested at any 3rd party lab, not [only those] accredited by the CPSC." Based on this commenter's understanding of the rule, the commenter asks whether other required ASTM F963 tests on natural wood toys,

such as for accessible edges and small parts, could be performed at any third party laboratory, not just laboratories accredited by the CPSC.

*Response 3:* The rule affects only the testing requirement for compliance to the ASTM F963 chemical solubility limits. If a toy is subject to other ASTM F963 requirements, such as the mechanical requirements, compliance with those requirements still must be demonstrated through testing by a CPSC-accepted conformity assessment body for the manufacturer to issue a children's product certificate.

*Comment 4:* A commenter asserts that the testing requirements are "overwhelming," and are a factor in reducing the number of specialty "single store, independent 'mom and pop' stores."

The commenter urges passing a law that would establish that federal requirements would preempt state requirements that add to the burden for small companies, and further asserts that only the largest companies are able to meet the requirements.

*Response 4:* The comment is beyond the scope of the current rulemaking. The proposed rule does not address state requirements or testing issues other than the determination for unfinished and untreated wood.

*Comment 5:* One commenter, representing several consumer organizations, expresses support for the CPSC's detailed research and study on this issue and agrees that unfinished and untreated trunk wood can be exempted from compliance testing for the heavy elements of the toy standard without any impact on safety. This commenter also expresses support for the Commission's decision not to include in the proposed rule bamboo, beeswax, cotton, wool, linen, and silk, and states that not enough evidence has been presented for a determination on these materials.

*Response 5:* The rule is based on data and information on the presence of the ASTM elements in unfinished and untreated wood and other natural materials. The information on bamboo, beeswax, linen, and silk was insufficient to make a Commission determination on these materials.

*Comment 6:* A commenter states that the rule would provide limited relief to toy manufacturers because very few toy manufacturers are making products using wood, and wood toys constitute only a small percentage of the toys in the marketplace.

The commenter urges the Commission to continue to find ways to provide meaningful third party testing burden reduction for companies and for

<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>.

products most impacted by the testing requirements. The commenter suggests that one way for the Commission to do this is by reconsidering the parameters used to exclude materials from testing. The commenter states that the Commission's current standard for finding materials that could be exempt from testing is "unreasonably high." In addition, the commenter claims Congress's intent was not for the CPSC to apply a "near zero-risk-tolerance approach." The commenter references other Commission actions that "allow for some level of risk tolerance," such as the component part testing rule at 16 CFR 1109.5(b), which the commenter claims addresses the exercise of due care, and does not require certainty. Additionally, the commenter mentions the lead determination rule at 16 CFR 1500.91(b), pointing to text indicating that the rule is based on a finding that the material or product "does not exceed" the lead limits, not on a more onerous standard of "will never exceed."

The commenter also points to the test procedures of the toy standard (*i.e.*, testing is not conducted if only a small amount of material is present on the product), and urges the Commission to consider this *de minimus* approach, and approaches like it, to provide meaningful third party testing burden relief.

*Response 6:* Public Law 112–28 requires that actions to reduce the costs associated with third party testing must be consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. This requirement establishes the standard for Commission decisions for implementing any actions to reduce the cost associated with third party testing.

The rule on determinations for the ASTM elements in wood for products subject to the toy safety standard represents only one of several completed and ongoing Commission activities to implement, research, and pursue opportunities to reduce the cost of third party testing requirements.

The commenter's recommendation to consider *de minimus* and other approaches to reduce third party testing costs are beyond the scope of this rulemaking.

#### **D. 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 conformity assessment body. 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

<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 Web site 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.

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 110–314, sec. 3, Aug. 14, 2008. As noted previously, section 14 of the CPSIA, 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 CPSIA, as amended by Public Law 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 CPSIA for purposes of supporting the required certification. However, if the unfinished and untreated wood is altered so that the material could exceed 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 § 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.

### 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 January 19, 2016.

### 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 Commission certified 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) in the DFR. 80 FR 42376, 42380. The Commission did not receive any comments that questioned or challenged this certification, nor has CPSC staff received any other

information that would require a change or revision to the Commission’s previous analysis of the impact of the rule on small entities. Therefore, the certification of no significant impact on a substantial number of small entities is still appropriate.

### 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 in 16 CFR Part 1251

Business and industry, Consumer protection, Imports, Infants and children, 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. 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. 15 U.S.C. 2056b. The toy standard 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 the heavy elements limits in 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 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: December 9, 2015.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 2015-31723 Filed 12-16-15; 8:45 am]

BILLING CODE 6355-01-P

**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA-419F]

**Schedules of Controlled Substances: Placement of Eluxadoline Into Schedule IV; Correction**

**AGENCY:** Drug Enforcement Administration, Department of Justice.  
**ACTION:** Final rule; correction.

**SUMMARY:** The Drug Enforcement Administration (DEA) is correcting a final rule that appeared in the **Federal Register** of November 12, 2015 (80 FR 69861). The document issued an action placing the substance 5-[[[(2S)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1S)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act. This document inadvertently included a paragraph in the regulatory text that was not intended for publication, and was unable to be removed before being placed on public inspection. This

document corrects the final rule by removing this paragraph.

**DATES:** Effective December 17, 2015.

**FOR FURTHER INFORMATION CONTACT:** John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2015-28718 appearing on page 69864 in the **Federal Register** of Thursday, November 12, 2015, the following correction is made:

*Administrative Procedure Act [Corrected]*

1. On page 69864, in the preamble, at the bottom of the first and top of the second columns, the section titled *Administrative Procedure Act* is removed entirely.

Dated: December 11, 2015.

**Chuck Rosenberg,**

*Acting Administrator.*

[FR Doc. 2015-31843 Filed 12-16-15; 8:45 am]

BILLING CODE 4410-09-P

**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****30 CFR Part 925**

[SATS No. MO-041-FOR; Docket ID: OSM-2013-0008; S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

**Missouri Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.  
**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving an amendment to the Missouri regulatory program (Missouri program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Missouri proposed revisions to its regulations concerning several topics regarding: Valid Existing Rights; Protection of Hydrologic Balance; Post-mining Land Use; Permit Applications; and Air Resource Protection. Missouri intends to revise its program to be no less effective than the Federal regulations, to clarify ambiguities, and to improve operational efficiency.

**DATES:** *Effective Date:* December 17, 2015.

**FOR FURTHER INFORMATION CONTACT:** Len Meier, Director Alton Field Division,

Office of Surface Mining Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, IL 62002, Telephone: (618) 463-6460, Email: [Lmeier@osmre.gov](mailto:Lmeier@osmre.gov).

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Missouri Program
- II. Submission of the Amendment
- III. OSMRE's Findings
- IV. Summary and Disposition of Comments
- V. OSMRE's Decision
- VI. Procedural Determinations

**I. Background on the Missouri Program**

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, "a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act . . . ; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act." See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Missouri program on November 21, 1980. You can find background information on the Missouri program, including the Secretary's findings, the disposition of comments, and conditions of approval, in the November 21, 1980, **Federal Register** (45 FR 77017). You can find later actions concerning the Missouri program and program amendments at 30 CFR 925.10, 925.12, 925.15, and 925.16.

**II. Submission of the Amendment**

By letter dated August 12, 2013 (Administrative Record No. MO-678), Missouri sent us an amendment to its Program under SMCRA (30 U.S.C. 1201 *et seq.*). Missouri sent the amendment in response to a January 31, 2008, letter (Administrative Record No. MO-669) we sent to Missouri in accordance with 30 CFR 732.17(c) concerning changes to valid existing rights requirements. Missouri also made changes to eliminate required program amendments recorded at 30 CFR 925.16(p)(4), (p)(20) and (v); and program disapprovals at 30 CFR 925.12(d). Missouri revised other sections of its regulations at its own initiative. Missouri proposed revisions to title 10 of its Code of State Regulations (CSR) under Division 40 Land Reclamation Commission. The specific sections of 10 CSR 40 in Missouri's amendment are discussed in Part III OSMRE's Findings. Missouri intends to revise its program to be no less effective than the Federal regulations, to clarify ambiguities, and improve operational efficiency.