

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

SMALL BUSINESS ADMINISTRATION

[Docket No. SBA-2017-0005]

13 CFR Chapter I

Reducing Unnecessary Regulatory Burden

AGENCY: U.S. Small Business Administration.

ACTION: Request for information; extension of comment period.

SUMMARY: On August 15, 2017, the Small Business Administration (SBA or Agency) published in the **Federal Register** a request for information seeking input from the public on identifying which of the Agency's regulations should be repealed, replaced or modified because they are obsolete, unnecessary, ineffective, or burdensome. That request established a 60-day comment period closing on October 16, 2017. SBA is extending the public comment period for 30 days, until November 15, 2017.

DATES: The comment period for the request for information published on August 15, 2017 (82 FR 38617) is extended. Comments are requested on or before November 15, 2017.

ADDRESSES: You may submit comments, identified by Docket Number SBA-2017-0005, using any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Identify comments by "Docket Number SBA-2017-0005, Reducing Regulatory Burden RFI," and follow the instructions for submitting comments.

Mail: Holly Turner, Regulatory Reform Officer, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

SBA will post all comments on <http://www.regulations.gov>. If you wish to submit confidential business information (CBI) as defined in the User Notice at <http://www.regulations.gov>, please submit the information to Holly Turner, 409 Third Street SW., Washington, DC 20416. Highlight the

information that you consider to be CBI, and explain why you believe this information should be held confidential. SBA will review the information and make the final determination as to whether to publish the information.

FOR FURTHER INFORMATION CONTACT:

Holly Turner, (202) 205-6335, 409 Third Street SW., Washington, DC 20416; email address: IGA@sba.gov.

SUPPLEMENTARY INFORMATION: On August 15, 2017, in accordance with Executive Order 13777, "Enforcing the Regulatory Reform Agenda," SBA published a request for information seeking input from the public on identifying which of the Agency's regulations should be repealed, replaced or modified because they are obsolete, unnecessary, ineffective, or burdensome (82 FR 38617). That request established a 60-day comment period, closing on October 16, 2017. To ensure that all interested parties are provided ample time and opportunity to submit comments, SBA is extending the public comment period for an additional 30 days. Comments must be submitted to SBA no later than November 15, 2017.

Authority: 15 U.S.C. 634(b)(6); E.O. 13771; E.O. 13777.

Dated: October 6, 2017.

Holly Turner,

Regulatory Reform Officer.

[FR Doc. 2017-22130 Filed 10-12-17; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1252

[Docket No. CPSC-2017-0038]

Children's Products, Children's Toys, and Child Care Articles: Determinations Regarding Lead, ASTM F963 Elements, and Phthalates for Engineered Wood Products

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (Commission, or CPSC) is proposing a rule to determine that certain untreated and unfinished engineered wood products (EWPs), specifically, particleboard, hardwood plywood, and medium-density

fiberboard, made from virgin wood or pre-consumer waste wood would not contain lead, the ASTM F963 elements, or specified phthalates that exceed the limits set forth under the CPSC's statutes for children's products, children's toys, and child care articles. Based on these proposed determinations, the specified EWPs would not be required to have third party testing for compliance with the requirements for lead, ASTM F963 elements, or phthalates for children's products, children's toys, and child care articles.

DATES: Submit comments by December 27, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2017-0038, 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 (email), except through [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 comments 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. 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 by mail/hand delivery/courier.

FOR FURTHER INFORMATION CONTACT: Jacqueline Campbell, Senior Textile Technologist, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; Telephone 301-987-2024; email: jcampbell@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, children’s toys, and child care articles, 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).

To provide opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulations, the CPSC assessed whether children’s products, children’s toys, and child care articles manufactured with three engineered wood products, specifically, particleboard, hardwood plywood, and medium-density fiberboard (collectively referred to as EWPs), would comply with CPSC’s requirements for lead, ASTM F963 elements or phthalates. If the Commission determines that such materials 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 testing laboratory to issue a Children’s Product Certificate (CPC).

2. CPSC’s Lead Standard

Section 101 of the CPSIA has two requirements associated with lead in children’s products. 15 U.S.C. 1278a. First, no accessible part of a children’s product may contain more than 100 parts per million (ppm) lead content. Second, paint or other surface coatings

on children’s products and furniture intended for consumer use may not contain lead in concentrations greater than 90 ppm. Manufacturers of children’s products must certify, based on third party testing, that their products comply with all relevant children’s product safety rules. Thus, products subject to the lead content or paint/surface coating limits require passing test results from a CPSC-accepted third party laboratory for the manufacturer to issue a CPC, before the products can be entered into commerce.

To alleviate some of the third testing burdens associated with lead in the accessible component parts of children’s products, the Commission determined that certain materials, including gemstones, precious metals, wood, paper, CMYK process printing inks, textiles, and specified stainless steel, do not exceed the 100 ppm lead content limit under section 101 of the CPSIA. Based on this determination, such materials do not require third party testing for the lead content limits. The determinations regarding lead content for certain materials are set forth in 16 CFR 1500.91.

3. ASTM F963 Elements

Section 106 of the CPSIA provides that the provisions of ASTM International, *Consumer Safety Specifications for Toy Safety* (ASTM F963), shall be considered to be consumer product safety standards issued by the Commission.¹ 15 U.S.C. 2056b. The Commission has issued a rule that incorporates by reference the relevant provisions of ASTM F963. 16 CFR part 1250. Thus, children’s toys subject to ASTM F963 must be tested by a CPSC-accepted third party laboratory and demonstrate compliance with all applicable CPSC requirements for the manufacturer to issue a CPC before the children’s toys can be entered into commerce.

Section 4.3.5 of ASTM F963 requires that surface coating materials and accessible substrates of children’s toys that can be sucked, mouthed, or ingested² must comply with the

¹ ASTM F963 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 contains the following note regarding the scope of the solubility requirement: NOTE 4—For the purposes of this requirement, the following criteria are considered reasonably appropriate for the classification of children’s 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 children’s toys which are cosmetics, and components of writing instruments categorized as children’s toys; (2) Children’s toys intended for children less than 6

solubility limits of eight elements given in Table 1 of the toy standard. The materials and their solubility limits are shown in Table 1. We refer to these eight elements as “ASTM F963 elements.”

TABLE 1—MAXIMUM SOLUBLE MIGRATED ELEMENT IN ppm (mg/kg) FOR SURFACE COATINGS AND SUBSTRATES INCLUDED AS PART OF A TOY

Elements	Solubility limit, (ppm) ³
Antimony (Sb)	60
Arsenic (As)	25
Barium (Ba)	1,000
Cadmium (Cd)	75
Chromium (Cr)	60
Lead (Pb)	90
Mercury (Hg)	60
Selenium (Se)	500

The third party testing burden could be reduced only if all 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 F963 elements, no testing burden reduction would be achieved if any one of the elements requires testing.

To alleviate some of the third testing burdens associated with the ASTM F963 elements in the accessible component parts of children’s toys, the Commission determined that certain unfinished and untreated trunk wood does not contain ASTM F963 elements that would exceed the limits specified in section 106 of the CPSIA. Based on this determination, unfinished and untreated trunk wood would not require third party testing for the ASTM F963 elements. The determinations regarding the ASTM F963 elements limits for certain materials is set forth in 16 CFR 1251.2.

4. Phthalates

Section 108(a) of the CPSIA permanently prohibits the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any “children’s toy or child care article” that contains concentrations of more than 0.1 percent of di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or butyl benzyl

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. Modeling clays included as part of a toy have different solubility limits for several of the elements.

phthalate (BBP). 15 U.S.C. 2057c(a). Section 108(b)(1) prohibits on an interim basis (*i.e.*, until the Commission promulgates a final rule), the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of “any children’s toy that can be placed in a child’s mouth” or “child care article” containing concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-*n*-octyl phthalate (DnOP). 15 U.S.C. 2057c(b)(1). Children’s toys and child care articles subject to the content limits in section 108 of the CPSIA require third party testing for compliance with the phthalate content limits before the manufacturer can issue a CPC and enter the children’s toys or child care articles into commerce.

The CPSIA required the Commission to appoint a Chronic Hazard Advisory Panel (CHAP) to “study the effects on children’s health of all phthalates and phthalate alternatives as used in children’s toys and child care articles.” 15 U.S.C. 2057c(b)(2). The CHAP issued its report in July 2014.⁴ Based on the CHAP report, the Commission published a notice of proposed rulemaking (Phthalates NPR),⁵ proposing to permanently prohibit children’s toys and child care articles containing concentrations of more than 0.1 percent of DINP, and proposing to lift the interim statutory prohibitions with respect to DIDP and DnOP. In addition, the Phthalates NPR proposed adding four new phthalates, DIBP, DPENP, DHEXP, and DCHP, to the list of phthalates that cannot exceed 0.1 percent concentration in accessible component parts of children’s toys and child care articles. The Commission has not finalized its proposal on phthalates in children’s toys and child care articles.

Tests for phthalate concentration are among the most expensive certification tests to conduct on a product, and each accessible component part subject to section 108 of the CPSIA must be tested.⁶ Third party testing burden reductions can occur only if each phthalate’s concentration is below 0.1 percent (1000 ppm). Because laboratories typically run one test for all of the specified phthalates, no testing

burden reduction likely is achieved if any one of the phthalates requires compliance testing.

To alleviate some of the third testing burdens associated with plastics in the accessible component parts of children’s toys and child care articles, the Commission determined that products made with general purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), high-impact polystyrene (HIPS), and super high-impact polystyrene (SHIPS) with specified additives do not exceed the phthalates content limits under section 108 of the CPSIA. 82 FR 41163 (August 30, 2017). Based on this determination, materials used in children’s toys and child care articles that use these specified plastics and additives would not require third party testing for the phthalates content limits. The plastics determinations are set forth in the Commission’s regulations at 16 CFR part 1308.

The research that provides the basis for the phthalates determination covers the six phthalates subject to the statutory prohibition and the additional phthalates that the Commission proposed to prohibit from use in children’s toys and child care articles. After the Commission finalizes its phthalates rule, the Commission will revise its phthalate determination rule to reflect the phthalates restricted by the final phthalates rule.

B. Contractor’s Research

CPSC contracted with the Toxicology Excellence for Risk Assessment (TERA)⁷ who authored literature review reports on the content issues related to certain natural materials, plastics, and EWPs. The following reports produced by TERA formed the basis for the proposed EWP determinations: Task 9, *Concentrations of Selected Elements in Unfinished Wood and Other Natural Materials*; Task 11, *Exposure Assessment: Composition, Production, and Use of Phthalates*; and Task 14, *Final Report for CPSC Task 14*, which summarized the available information on the production of the EWPs. Each report is discussed below.

1. TERA Task 9 Report

In the Task 9 Report, TERA conducted a literature search on whether unfinished wood and other natural materials could be determined not to contain any of the ASTM F963 elements in concentrations greater than the

ASTM F963 solubility limits.⁸ The materials researched included unfinished 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).

To assess the presence of the ASTM F963 elements’ concentrations in the materials, TERA looked at several factors. The factors reviewed included 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 ASTM F963 elements into the material under study; and the potential for contamination after production, such as through packaging. From this report, the Commission determined that untreated and unfinished woods from tree trunks do not contain any of the elements in ASTM F963 in concentrations greater than their respective solubility limits, and thus, they are not required to be third party tested to ensure compliance with the specified solubility test.⁹ TERA relied on this information in TERA Task Report 14 to determine that the virgin wood material used in the manufacture of EWPs does not, and will not, contain any of the elements in ASTM F963 in concentrations greater than their respective solubility limits.

2. TERA Task 11 Report

In the Task 11 Report, TERA conducted a literature search on the production and use of 11 specified phthalates in consumer products.¹⁰ The 11 phthalates researched by TERA were based on the recommendations made in the CHAP report. Table 2 lists the phthalates researched by TERA. TERA’s research focused on the following factors:

- The raw materials used in the production of the specified phthalates;
- The manufacturing processes used worldwide to produce the specified phthalates;
- Estimated annual production of the specified phthalates;
- Physical properties of the specified phthalates (*e.g.*, vapor pressure, flashpoint, water solubility, temperature at which chemical breakdown occurs);

⁴ <http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf>.

⁵ <https://www.federalregister.gov/articles/2014/12/30/2014-29967/prohibition-of-children-s-toys-and-child-care-articles-containing-specified-phthalates>.

⁶ Test costs for the content of all the specified phthalates have been reported to range from \$125 to \$350 per component, depending upon where the tests are conducted and any discounts that might apply.

⁷ After conducting the contract reports for the CPSC, TERA reorganized as the Risk Science Center at the University of Cincinnati: <https://med.uc.edu/eh/centers/rsc>.

⁸ <http://www.cpsc.gov/Global/Research-and-Statistics/TechnicalReports/Toys/TERAReportASTMElements.pdf>.

⁹ 80 FR 78651 (Dec. 17, 2015).

¹⁰ <http://www.cpsc.gov/Global/Research-and-Statistics/Technical-Reports/Other%20Technical%20Reports/TERAReportPhthalates.pdf>.

- Applications for phthalates use in materials and consumer and non-consumer products; and

- Other potential routes by which phthalates can be introduced into an otherwise phthalates-free material (e.g.,

migration from packaging, recycling, reuse, product breakdown).

TABLE 2—PHTHALATES RESEARCHED IN THE TASK 11 REPORT

Phthalate	CASRN ¹¹
DEHP: di-(2-ethylhexyl) phthalate	117-81-7
DBP: dibutyl phthalate	84-74-2
BBP: benzyl butyl phthalate	85-68-7
DINP: diisononyl phthalate	28553-12-0, 68515-48-0
DIDP: diisodecyl phthalate	26761-40-0, 68515-49-1
DnOP: di-n-octyl phthalate	117-84-0
DIOP: diisooctyl phthalate	27554-26-3
DIBP: diisobutyl phthalate	84-69-5
DPENP: di-n-pentyl phthalate	131-18-0
DHEXP: di-n-hexyl phthalate	84-75-3
DCHP: dicyclohexyl phthalate	84-61-7

TERA found that phthalates are used generally as plasticizers or softeners of certain plastics, primarily polyvinyl chloride (PVC), as solvents, and as component parts of inks, paints, adhesives, and sealants.

3. TERA Task 14 Report

In the Task 14 Report, TERA conducted a literature search on the production of three EWP: Particleboard, hardwood plywood, and medium-density fiberboard.¹² TERA first researched authoritative sources,

such as reference books and textbooks, along with Internet resources, for general information about EWPs, adhesives, raw materials, manufacturing processes, and the potential use of recycled materials. TERA used this information and consulted technical experts to identify key words for searching the literature. These key words were then used to conduct primary literature searches for research studies and publications. In addition, TERA searched for Safety Data Sheets (SDS) for information on raw materials.

TERA researched the possibility of the raw materials or finished products in the three EWPs to contain:

- Lead in concentrations exceeding 100 ppm;
- Any of the specified elements that are included in the safety standard for children’s toys, ASTM F963, *Standard Consumer Safety Specification for Toy Safety*, in concentrations exceeding specified solubility limits; or
- Any of 10 specified phthalates in concentrations greater than 0.1 percent (1000 ppm), listed in Table 3.¹³

TABLE 3—PHTHALATES RESEARCHED IN THE TASK 14 REPORT¹⁴

Phthalate	CASRN
DEHP: di-(2-ethylhexyl) phthalate	117-81-7
DBP: dibutyl phthalate	84-74-2
BBP: benzyl butyl phthalate	85-68-7
DINP: diisononyl phthalate	28553-12-0, 68515-48-0
DIDP: diisodecyl phthalate	26761-40-0, 68515-49-1
DnOP: di-n-octyl phthalate	117-84-0
DIBP: diisobutyl phthalate	84-69-5
DPENP: di-n-pentyl phthalate	131-18-0
DHEXP: di-n-hexyl phthalate	84-75-3
DCHP: dicyclohexyl phthalate	84-61-7

TERA found that, generally, the processes for manufacturing the three EWPs are similar; wood fibers, chips, layers, or a similar raw wood product are processed with various adhesive formulations (sometimes referred to as binders or resins) along with other additives to create uniform sheets with known characteristics and performance qualities. The main difference among the three types of EWPs relates

primarily to the size and morphology (shape and surface characteristics) of the wood material used in their production.

TERA reviewed the literature to assess whether the specified EWPs might contain lead or one or more of the other elements at levels that exceed the ASTM solubility limits, or any of the specified phthalates in concentrations greater than the specified limits. TERA reported that no studies found lead, the ASTM

F963 elements, or the specified phthalates in concentrations greater than their limits in particleboard, hardwood plywood, or medium-density fiberboard, that are unfinished and untreated, and made from virgin wood or pre-consumer wood waste.

In the Task 14 Report, TERA described an unfinished EWP as one that does not have any surface treatments applied at manufacture, such

¹¹ A CAS Registry Number is assigned to a substance when it enters the CAS REGISTRY database. <https://www.cas.org/content/chemical-substances/faqs>.

¹² <https://www.cpsc.gov/s3fs-public/ManufacturedWoodsTERATask14Report.pdf>.

¹³ The TERA research providing the basis for this determination covers the six phthalates subject to the statutory prohibition, as well as the additional phthalates the Commission proposed to prohibit in children’s toys and child care articles. The phthalates determination lists only the six phthalates subject to the statutory prohibition. However, when the Commission issues a final rule

for the specified phthalates in children’s toys and child care articles, the Commission could revise the phthalates determination, if needed.

¹⁴ While included in the Task 11 Report, DIOP was not included in the Task 14 Report because the ban on DIOP was proposed to be removed in the Phthalates NPR.

as factory-applied coatings. An untreated EWP is one that does not have any additional finishes applied at manufacture such as flame retardants or rot resistant finishes. TERA described virgin wood as wood logs, fibers, chips, or layers that have not been recycled from a previous use. TERA described pre-consumer wood waste as wood materials that have been recycled from an industrial process before being made available for consumer use. Examples of this type of waste include trimmings from EWP panel manufacturing, sawdust from cutting logs, or remaining wood pieces from sawing a log into framing lumber.

The TERA report highlighted the potential for lead, the ASTM F963 elements, or the specified phthalates to be present in concentrations greater than those specified through the use of contaminated recycled material in EWPs made from recycled wood waste or EWPs that have post-manufacturing treatments or finishes. Recycled wood waste may be made from reclaimed or post-consumer wood waste. Post-consumer wood waste is described as wood waste that is comprised of materials that are recovered from their original use and subsequently used in a new product. Examples of this type of waste include recycled demolition wood, packaging materials such as pallets and crates, used wood from landscape care (*i.e.*, from urban and highway trees, hedges, and gardens), discarded furniture, and waste wood from industrial, construction, and commercial activities.

The three types of EWPs reviewed by TERA are discussed below.

a. Particleboard

Particleboard is a composite of wood chips, adhesives, and other additives pressed into a board. Adhesive formulations are used to bond wood chips, which are then formed into mats that are layered to create uniform boards in a range of dimensions. Particleboard is used widely in furniture making and other interior (or nonstructural) uses. The constituent parts of particleboard reported by TERA can include (by weight):

- Wood (60–99+ percent);
- Adhesive formulation (0–17 percent, with 5–11 percent most common)
- May include phenol-formaldehyde (uncommon but potential for use), urea-formaldehyde, melamine-urea-formaldehyde, polymeric methylene-diphenyl-diisocyanate (pMDI);
- Waxes (0.3–1 percent);
- Other additives (up to 2 percent); or

- Scavengers or additional unspecified materials.

TERA researched the possibility of lead, the ASTM F963 elements, or the specified phthalates, in concentrations greater than their specified limits in particleboard. TERA identified little information on measurements of lead and the ASTM F963 elements in particleboard and no studies that measured the specified phthalates. TERA identified two references where particleboard made from both untreated and copper chromate arsenic-(CCA) treated wood chips was tested. Arsenic and chromium were undetected in the particleboards made from virgin wood chips. However, the particleboard composed of 25 percent wood chips from reclaimed CCA-treated wood products contained 895 and 832 ppm of arsenic and chromium, respectively, without adversely affecting the mechanical performance of the board. Another study that discussed “recycled particleboard” was identified as wood waste obtained from a wood recycling plant.

Apart from the studies on particleboard made from wood waste that may contain post-consumer wood waste or post-manufacturing treatments, TERA reported that no studies found lead, the ASTM F963 elements, or the specified phthalates in concentrations greater than the specified limits in untreated and unfinished particleboard.

b. Hardwood Plywood

Plywood is a layered board of wood veneers where the layers have alternating, perpendicular wood grain directions. Less commonly, the board might have a core of other EWPs with wood veneers as the outer layers. Hardwood plywood, addressed in this report, is a type of plywood that is composed of angiosperms (*i.e.*, “hardwoods,” such as oak or maple) and used primarily in furniture and other interior (nonstructural) uses, as well as in playground equipment, sports equipment, and musical instruments. The constituent parts of hardwood plywood reported by TERA can include (by weight):

- Wood (75–99+ percent);
- Adhesive formulation (0.02–20 percent, with 1 percent to 5 percent most common)
- May include phenol-formaldehyde or phenol-resorcinol-formaldehyde (likely for use in structural plywood but potential for application to hardwood plywood), urea-formaldehyde, melamine-formaldehyde, or melamine-urea-formaldehyde, or polyvinyl acetate (PVAc); or

- Other additives (less than 2 percent).

TERA researched the possibility of lead, the ASTM F963 elements, or the specified phthalates in concentrations greater than those specified in hardwood plywood. TERA identified only one study that measured lead and the ASTM F963 elements in plywood and no studies that measured the specified phthalates. Concentrations of cadmium, chromium, and lead, were all less than the solubility limits, in “plain” plywood. In addition, because hardwood plywood is made from sheets of wood veneer, it is less likely to contain recycled wood content, unless it incorporates a core of some other EWP, such as particleboard or medium-density fiberboard.

Aside from the studies on recycled wood waste that may contain post-consumer wood waste or post-manufacturing treatments in a particleboard, medium-density fiberboard, or other EWP core, TERA reported that no studies found lead, the ASTM F963 elements, or the specified phthalates in concentrations greater than the specified limits in untreated and unfinished hardwood plywood. However, TERA identified research which indicated that polyvinyl acetate (PVAc) can be used as an adhesive system for hardwood plywood as discussed in section (d) below.

c. Medium-Density Fiberboard

Medium-density fiberboard (MDF) is a composite of wood fibers, an adhesive formulation, and other additives pressed into a board. MDF is a similar product to particleboard, differing mostly due to the use of fiber rather than chips. It is used primarily in furniture and other interior (nonstructural) uses. The constituent parts of MDF reported by TERA can include (by weight):

- Wood (73–99+ percent);
- Adhesive formulation (0–25 percent with most common 5–12 percent);
- May include phenol-formaldehyde (uncommon, but potentially used for moisture resistance), urea-formaldehyde (most commonly identified), methylene-diphenyl-diisocyanate (pMDI), melamine-formaldehyde, or melamine-urea-formaldehyde;
- Waxes (less than 1 percent); or
- Other additives (10–30 percent).

TERA researched the possibility of lead, the ASTM F963 elements, or the specified phthalates in concentrations greater than those specified in MDF. TERA did not identify any references that reported the presence of lead, the ASTM F963 elements, or the specified phthalates in MDF made with virgin wood.

Aside from the studies on recycled wood waste that may contain post-consumer wood waste or post-manufacturing treatments, TERA reported that no studies found lead, the ASTM F963 elements, or the specified phthalates in concentrations greater than the specified limits in untreated and unfinished MDF.

d. TERA's Findings on EWP Constituent Parts

Because few references were found directly addressing lead, the ASTM F963 elements, and the specified phthalates in EWPs, TERA also researched the constituent parts that could be used to manufacture EWPs, including wood and adhesives.

Wood

According to the manufacturing process information provided by TERA, virgin wood and wood residues are the main source of wood fiber used in North America to manufacture EWPs. Typically, these sources include low value logs, industrial wood residues, or scraps and trim from furniture and EWP production. For example, hardwood plywood requires the trunks of trees to obtain the thin layers of veneer used to construct a sheet. TERA relied on the Task 9 Report and Commission findings on unfinished and untreated wood (80 FR 78651 (Dec. 17, 2015)) to determine that untreated and unfinished wood from the trunks of trees do not contain lead or the ASTM F963 elements in concentrations greater than the specified solubility limits. TERA also noted that, although phthalates can be taken up by trees and plants, the concentrations are negligible and less than the specified limit (0.1 percent).

Although TERA reported that the majority of EWPs are manufactured with virgin wood or pre-consumer wood waste fiber or chips, the wood component also can originate from recycled material. For EWPs made from recycled wood waste that may contain post-consumer wood waste, the TERA report highlighted the potential for lead, the ASTM F963 elements, or the specified phthalates to be present in concentrations greater than those specified through the use of contaminated recycled material. The TERA report cited multiple examples of the use of reclaimed or post-consumer wood material used to produce EWPs, both domestically and internationally. Specifically, TERA found studies showing that reclaimed lumber and wood waste could contain a myriad of contaminants, such as surface treatments (e.g., paints, stains), metals, glues and adhesives, glass, paper,

plastic, rubber and chemical treatments. Metals and organic materials may be present in paints, stains, varnishes, and polishes that are used on wood products (e.g., furniture, window frames) and nails, screws, and other metal hardware might be attached to the recycled and recovered wood. These contaminants are intimately attached to the wood, and therefore, some contaminants may pass through cleaning systems, contaminating the entire recovered wood stream.

TERA also reviewed another study, based in Italy that evaluated the "recyclability" of used wood by conducting elemental analysis of wood residues from wood recycling plants using a handheld fast energy dispersive X-ray fluorescence spectroscopy (ED-XRF) device. TERA found that the study provided some indication of types and levels of contamination in various kinds of post-consumer wood waste. Elemental analysis results were compared to EU Community Ecolabel limits.¹⁵ For all wood products tested, 16 percent exceeded one or more of the Ecolabel limits, with the highest concentrations from lead, chromium, chlorine, copper, cadmium, and mercury. No samples had levels of arsenic over the 25 ppm limit (except a CCA-treated utility pole). Barium and lead were found in 10 percent to 20 percent of the samples, chromium and cadmium in 3 percent to 4 percent, and antimony, mercury, and arsenic ranged from 0.3 percent to 1.2 percent of samples. The sources most contaminated with non-wood content were from furniture and building materials, while pallets and shipping containers were least likely to be contaminated.¹⁶

TERA concluded that, with an increased interest and use of post-consumer recycled materials in EWP production, potential contamination by the specified elements and phthalates must be considered. To ensure that EWPs made from used wood fibers do not contain ASTM F963 elements or phthalates that exceed the specified

¹⁵ Ecolabel element concentrations are less than 25 mg/kg of arsenic, 25 mg/kg of mercury, 25 mg/kg of chromium, 50 mg/kg cadmium, 90 mg/kg lead, and 40 mg/kg copper (EU, 2004). Ecolabel limits are similar to ASTM solubility limits for the ASTM F963 elements.

¹⁶ Twenty-four percent of furniture and 18 percent of building materials had one or more ASTM F963 elements exceeding the limits which may be due to manufacturing processes such as painting, preservation, and overlaying, which are common with furniture and building materials. The most polluted types of wood waste were particleboard (37% exceeded Ecolabel limits), recycled particleboard (25% exceeded), and plywood (18% exceeded); while fiberboard (MDF and HDF) exceeded limits in 9 percent of samples.

limits, TERA indicated that the materials would need to be sorted carefully and tested to be assured that they are not contaminated.

Adhesive Formulations

Adhesive formulations hold the wood chips, layers, or fibers together to make EWP mats and sheets. Some of the formulations use a metal catalyst during the curing process. TERA identified a number of references describing the presence of the ASTM F963 elements in adhesive formulations. However, TERA found very few references that would implicate EWPs. Although the use of barium was noted in multiple references, only one study appeared to be relevant to EWPs. This study suggested that barium, when used as a catalyst in an adhesive, could result in an EWP that exceeded the ASTM solubility level for barium.¹⁷ However, this method does not appear to be used currently in EWP production. TERA also noted studies that indicate the possible use of chromium as a catalyst in phenol formaldehyde resin as well as the possible use of antimony or arsenic in a drier formulation for certain polymeric coatings. However, no references included information on concentrations or appeared relevant to EWPs.

Although many different adhesive formulations may be used in hardwood plywood, TERA noted that PVAc can be used as an adhesive system for hardwood plywood. The report cited sources (The Handbook of Adhesive Technology, USDA) that mentioned the use of some of the specified phthalates in PVAc adhesive formulations.¹⁸ TERA also identified research papers which included the use of DBP and DEHP in PVAc at concentrations greater than 0.1 percent.

¹⁷ Wang and Zhang (2011) studied the use of calcium hydroxide, Ba(OH)₂, and magnesium hydroxide and their effect on cure times for phenol formaldehyde adhesive formulations, finding that the use of Ba(OH)₂ could be a viable means to speed up cure times. Both calcium hydroxide and Ba(OH)₂ had similar cure times and are about the same price in bulk. Because the compounds would be used in an adhesive system, the catalyst is not expected to be recovered and so would remain in situ once curing is complete. If the catalyst remained in the adhesive, it could result in concentrations of barium exceeding the ASTM solubility limits.

¹⁸ The USDA publication Wood Handbook: Wood as an Engineering Material (2010) explains that "Plasticizers, for example dibutyl phthalate, are used to soften the brittle vinyl acetate homopolymer in poly(vinyl acetate) emulsion adhesives. This is necessary to facilitate adhesive spreading and formation of a flexible adhesive film from the emulsion at and below room temperature."

C. CPSC Staff Analysis of TERA Reports

1. EWPs Made From Virgin Wood or Pre-Consumer Wood Waste

CPSC staff reviewed the TERA Task 9, 11 and 14 Reports. CPSC staff also examined TERA's source references to better understand the reports' findings. CPSC's review of TERA's Task 14 Report showed that there were few studies characterizing the content of EWPs, as manufactured, in relation to lead and the ASTM F963 elements, and no studies were found on the phthalates of interest. Where there were studies, staff's review of the TERA report showed there was no evidence that untreated and unfinished EWPs made from virgin wood or pre-consumer wood waste, using generally used manufacturing practices and materials, had content levels greater than the specified limits.

Staff finds that, based on the TERA reports, untreated and unfinished EPWs (particleboard, hardwood plywood, and medium-density fiberboard) made from virgin wood or pre-consumer wood waste, do not contain lead, or any of the specified elements in ASTM F963 that exceed the specified limits. In addition, with the exception of hardwood plywood that contains PVAc adhesive formulations, discussed further in this section, the specified EWPs do not contain any of the specified phthalates in concentrations greater than 0.1 percent.

2. EWPs Made From Reclaimed or Post-Consumer Wood Waste

The TERA Task 14 Report highlighted the risk of introducing materials contaminated with lead, the ASTM F963 elements, and the specified phthalates when using reclaimed or post-consumer wood waste to manufacture EWPs. Staff is aware that there is increasing interest in using recycled materials, rather than landfilling. Environmentally oriented initiatives encourage recycled wood content, especially in the European Union (E.U.). The E.U. Waste Framework Directive requires recycling or reuse of at least 70 percent of construction and demolition waste in member states by 2020.¹⁹

Staff's review of TERA's reclaimed or post-consumer waste assessment in EWPs indicates that, although most manufacturing in the Americas currently does not use post-consumer wood waste as a constituent part, EWPs with post-consumer wood content are not only technologically feasible, but

also are currently available. Although the majority of the post-consumer wood waste used to manufacture EWPs is "clean," consisting of wood pallets, spools, or shipping crates, reclaimed materials could be contaminated with paint, coatings, or chemical treatments. There are some standards (e.g., European Panel Federation, E.U. Community Ecolabel) for EWPs with content requirements that roughly align with the ASTM F963 requirements; however, many are voluntary and have no third party testing requirements.

Staff notes that manufacturers do have an incentive to avoid contamination of EWPs because the addition of recycled materials could be detrimental to manufacturing equipment or the finished product's performance. Surface coatings, such as paint or stains, metals from nails or fasteners, adhesive formulations, such as resins or glues, and other non-wood content can potentially damage equipment, stop a production line, or adversely impact the uniformity of the product. However, staff is not aware of any current manufacturer processing protocols that would keep unwanted contaminants out of EWP manufacturing. Because of the contamination issues identified, the staff does not have a high degree of assurance that EWPs made from post-consumer wood waste are compliant with sections 101, 106, or 108 of the CPSIA at this time.

3. EWPs With Post-Manufacturing Treatments or Finishes

Staff's review of the Task 14 Report shows that most consumer products made from EWPs will have some additional treatments or finishes that are applied to the EWPs after their manufacture. TERA's report identified that certain surface treatments (e.g., paints, stains), metals, glues and adhesives, glass, paper, plastic, rubber and chemical treatments may be added to EWPs. Metals and organic materials may be present in paints, stains, varnishes, and polishes that are used on wood products (e.g., furniture, window frames) and nails, screws, and other metal hardware might be attached to the recycled and recovered wood.

Staff's review shows that post-manufacturing treatments or finishes made be applied to EWPs manufactured from virgin or pre-consumer wood waste, as well as EWPs manufactured from post-consumer wood waste. Such treatments or finishes may include paint or similar surface coating materials, flame retardants, rot resistant finishes, wood glue, or metal fasteners. The TERA report indicated that coatings, finishes, and chemical treatments, such

flame-retardant coatings or rot resistant finishes, are a potential source of phthalates or the ASTM F963 elements. Staff's review of EWPs that have post-manufacturing treatments or finishes shows that there is potential for lead, the ASTM F963 elements, or the specified phthalates to be present in concentrations greater than at the specified levels. Unless a post-manufacture treatment or finish has been determined by the CPSC to be compliant with sections 101, 106, or 108 of the CPSIA,²⁰ staff does not have a high degree of assurance that EWPs that have post-manufacturing treatments or finishes are compliant with sections 101, 106, or 108 of the CPSIA at this time.

4. Adhesive Formulations in EWPs

The Task 14 Report generally found that there was little evidence to suggest that the ASTM F963 elements are likely to be present in any of the commonly used adhesives in concentrations greater than the ASTM solubility limits. Staff notes, that although one study suggested that barium, when used as a catalyst in an adhesive, could result in an EWP that exceeded the ASTM solubility level for barium, this method does not appear to be used currently in EWP production.

Staff's review of the Task 11 Report indicates that phthalates could be used in some adhesive formulations, including in PVAc adhesives, such as wood or craft glues. In addition, the Task 14 Report identified the adhesive formulations used in the manufacture of EWPs and found that one, PVAc, could contain at least one of the specified phthalates. TERA also reported that PVAc could be used in hardwood plywood manufacturing. However, TERA was unable to identify whether the specific PVAc adhesive formulations used currently in the manufacture of hardwood plywood contained any of the specified phthalates in concentrations greater than the specified limits.

CPSC staff research indicates that PVAc may be associated with the manufacture of hardwood plywood, consistent with TERA's finding. One manufacturer of EWP adhesive formulations provided information through a contact at the USDA Forest Products Laboratory. The manufacturer confirmed that, while current formulations no longer use phthalates, PVAc adhesive formulations they manufacture contained phthalates in the past. The manufacturer also stated that there is greater use of PVAc adhesive formulations in hardwood plywood

¹⁹ http://ec.europa.eu/environment/waste/construction_demolition.htm.

²⁰ See 16 CFR 1500.91; 16 CFR 1250.2; 16 CFR part 1308.

than indicated in the TERA report, perhaps due to an increasing interest in lowering formaldehyde emissions from EWPs. Because of the lack of information regarding the use of PVAc adhesives containing the specified phthalates in concentrations greater than those allowed, staff does not have a high degree of assurance that EWPs that include PVAc adhesive formulations in hardwood plywood are compliant with sections 101, 106, or 108 of the CPSIA at this time.

D. Determinations for EWPs

1. Legal Requirements for a Determination

As discussed in section A.1. of the preamble, 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). Children's products must comply with the lead limits in section 101 of the CPSIA. 15 U.S.C. 1278a. Children's toys must comply with the solubility limits for elements under the ASTM toy standard in section 106 of the CPSIA. 15 U.S.C. 2056b. Children's toys and child care articles must comply with the phthalates prohibitions in section 108 of the CPSIA. 15 U.S.C. 2057c. 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 children's products, children's toys, and child care articles would not require third party testing.

To issue a determination that an EWP does not require third party testing, the Commission must have sufficient evidence to conclude that the product consistently complies with the CPSC requirements to which the EWP is subject so that third party testing is unnecessary to provide a high degree of assurance of compliance. Under 16 CFR part 1107 section 1107.2, "a high degree of assurance" is defined as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture."

For accessible component parts of children's products, children's toys, and child care articles subject to sections 101, 106, and 108 of the CPSIA, compliance to the specified content limits is always required, irrespective of any testing exemptions. Thus, a manufacturer or importer who certifies a children's product, toy or child care

article, must assure the product's compliance. The presence of lead, the ASTM F963 elements, or the specified phthalates does not have to be intended to require compliance. The presence of these chemicals, whether for any functional purpose, as a trace material, or as a contaminant, must be in concentrations less than the specified content or solubility limits for the material to be compliant. Additionally, the manufacturer or importer must have a high degree of assurance that the product has not been adulterated or contaminated to an extent that would render it noncompliant. For example, if a manufacturer or importer is relying on a determination that an EWP does not contain lead, ASTM F963 elements, or specified phthalates in concentrations greater than the specified limits in a children's product, children's toy, or child care article, the manufacturer must ensure that the EWP is one on which a determination has been made.

Furthermore, under the proposed rule, any determinations that are made on EWPs are limited to unfinished and untreated EWPs made from virgin wood or pre-consumer wood waste. Children's products, children's toys, and child care articles made from these EWPs may have other materials that are applied to or added on to the EWP after it is manufactured, such as treatments and finishes. Such component parts fall outside of the scope of the proposed determinations and would be subject to third party testing requirements, unless the component part has a separate determination which does not require third-party testing for certification purposes. Finally, even if a determination is in effect and third party testing is not required, a certifier must still issue a certificate.

The three engineered woods for which the determinations are proposed are: Particleboard, hardwood plywood, and medium-density fiberboard. Based on staff's review of the TERA reports as discussed in section C. of the preamble, the Commission is proposing determinations that there is a high degree of assurance that these three EWPs in an untreated and unfinished state made from virgin or pre-consumer wood waste will not contain lead, the ASTM F963 elements, or the specified phthalates in excess of allowable levels. Specifically, the Commission is proposing determinations that would find that particleboard and MDF that is untreated and unfinished and made with virgin wood or pre-consumer wood waste, would not contain lead, the ASTM F963 elements, or the specified phthalates (DEHP, DBP, BBP, DINP,

DIDP, or DnOP) in concentrations greater than their specified limits.

In addition, with the exception of hardwood plywood that contains PVAc adhesive formulations, untreated and unfinished hardwood plywood made with virgin wood or pre-consumer wood waste would be determined not to contain lead, the ASTM F963 elements, and the specified phthalates in concentrations greater than their specified limits.

These determinations would mean that, for the specified EWPs, third party testing is not required to assure compliance with sections 101, 106, and 108 of the CPSIA. The Commission proposes to make these determinations to reduce the third party testing burden on children's product certifiers while continuing to assure compliance.

2. 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. Section 14 of the CPSA, which was amended by the CPSIA, requires third party testing for children's products 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 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 propose a rule determining that certain EWPs would not be determined to contain lead, the ASTM F963 elements, and the specified phthalates (DEHP, DBP, BBP, DINP, DIDP, or DnOP)²¹ in concentrations greater than their specified limits, and thus, are not required to be third party tested to assure compliance with sections 101, 106, and 108 of the CPSIA.

The proposed determinations would relieve the three specified EWPs from the third party testing requirement of section 14 of the CPSA for purposes of supporting the required certification. However, the proposed determinations would not be applicable to any other EWPs beyond those listed in the proposed rule. Moreover, the proposed determinations are not applicable to EWPs that are not made of virgin wood or pre-consumer wood waste, or to

²¹ See *supra* note 13.

EWPs that have post-manufacture treatments or finishes. The proposed determinations also are not applicable to hardwood plywood that contain PVAc adhesive formulations. The proposed determinations would only relieve the manufacturers' obligation to have the specified EWPs tested by a CPSC accepted third party conformity assessment body. Children's products, children's toys, and child care articles must still comply with the substantive content limits in section 101, 106, and 108 of the CPSIA regardless of any relief on third party testing requirements.

3. Description of the Proposed Rule

This proposed rule would create a new Part 1252 for "Children's Products, Children's toys, and Child Care Articles: Determinations Regarding Lead, ASTM F963 Elements, and Phthalates for Engineered Wood Products." The proposed rule would determine that the specified three EWPs do not contain lead in concentrations exceeding 100 ppm, any of the ASTM F963 elements in excess of specified concentrations, and any of the statutorily prohibited phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP) in concentrations greater than 0.1 percent. As discussed in section A.4. of the preamble, the agency is currently involved in rulemaking to determine whether to continue the interim prohibitions in section 108 and whether to prohibit any other phthalates in children's toys or child care articles. TERA's examination covered all phthalates that are subject to the current permanent and interim prohibitions, as well as the additional phthalates the Commission proposed restricting in the Phthalates NPR. If the Commission issues a final rule in the phthalates rulemaking before finalizing this determinations rulemaking, the final determinations rule for EPWs would cover the same phthalates restricted by the final phthalates rule.

Section 1252.1(a) of the proposed rule explains the statutorily-created requirements that limit lead in children's products under the CPSIA and the third party testing requirements for children's products.

Section 1252.1(b) of the proposed rule explains the statutorily-created requirements for limiting the ASTM F963 elements in children's toys under the CPSIA and the third party testing requirements for children's toys.

Section 1252.1(c) of the proposed rule explains the statutorily-created requirements limiting phthalates for children's toys and child care articles under the CPSIA and the third party testing requirements for children's toys and child care articles.

Section 1252.2 of the proposed rule would provide definitions that apply to part 1252.

Section 1252.3(a) of the proposed rule would establish the Commission's determinations that specified EWPs do not exceed the lead content limits with a high degree of assurance as that term is defined in 16 CFR part 1107.

Section 1252.3(b) of the proposed rule would establish the Commission's determinations that specified EWPs do not exceed the solubility limits for ASTM F963 elements with a high degree of assurance as that term is defined in 16 CFR part 1107.

Section 1252.3(c) of the proposed rule would establish the Commission's determinations that specified EWPs do not exceed the phthalates content limits, with the exception of hardwood plywood containing PVAc, with a high degree of assurance as that term is defined in 16 CFR part 1107.

Section 1252.3(d) of the proposed rule states that accessible component parts of children's products, children's toys, and child care articles made with the specified EWPs, are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Section 1252.3(e) of the proposed rule states that accessible component parts of children's products, children's toys, and child care articles that are not specifically listed in the determinations in proposed § 1252.3(a) through (c) are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

4. Comments on the Proposed Rule

The Commission seeks comments on all aspects of the proposed rule. In particular, comments of the following topics are welcome.

- Are there any data or examples that indicate that the EWPs identified in the proposed rule can and do contain lead, the ASTM F963 elements, or prohibited phthalates at levels that are not compliant? Please provide data supporting your assertion.

- The TERA Task 14 Report identified the use of some of the ASTM F963 elements as catalysts in adhesive formulations used to manufacture EWPs. Please provide any information that supports or refutes the claim that these elements will not be present in concentrations greater than their specified limits in EWPs.

- CPSC staff has heard from a manufacturer of PVAc adhesive formulations used in the manufacture of hardwood plywood that, although phthalates are no longer used in domestic production, they were once

used. What phthalates were used in PVAc in the past? Could any of the specified phthalates be used? Why or why not? Are any of the specified phthalates used in domestic or international manufacturing of EWPs? Why or why not?

- How can one determine if a hardwood plywood sheet contains a PVAc adhesive system? How can one determine whether a PVAc adhesive system used in the manufacture of hardwood plywood contains a specified phthalate in concentrations greater than the specified limits? Can this type of information be found on labels, SDSs, company Web sites, or in some other way?

- Other than PVAc, are there additional adhesive formulations used in the manufacture of EWPs that could contain the specified phthalates in concentrations greater than those specified? If yes, what phthalates are used and at what concentration?

- Are there any post-consumer recycled EWPs that consistently comply with the limits for lead, ASTM F963 elements, or prohibited phthalates?

- Please describe the methods used to determine whether post-consumer recycled material is used in the manufacture of EWPs. How can this type of information be found (on labels, SDSs, company Web sites, or in some other way)?

- In addition to particleboard, hardwood plywood, and medium-density fiberboard, are there other EWPs widely used in children's products, children's toys, and child care articles that have not been identified in the proposed rule that do not, and will not, contain lead, the ASTM F963 elements, or prohibited phthalates in concentrations greater than the mandatory limits? Please provide supporting data.

E. Effective Date

The Administrative Procedure Act (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 proposed rule would provide relief from existing testing requirements under the CPSIA, the Commission proposes a 30 day effective date for the final rule.

F. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies

prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency is required to publish a notice of proposed rulemaking, unless the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives which accomplish the statutory objectives and may reduce the significant economic impact of the proposed rule on small entities. We provide a summary of the IRFA.

2. Small Entities to Which the Proposed Rule Would Apply

The proposed rule would apply to small entities that manufacture or import children's products, children's toys, and child care articles that contain particleboard, hardwood plywood, or medium-density fiberboard. The number of domestic manufacturers classified in the North American Industrial Classification System (NAICS) categories that could manufacture children's products, children's toys, or child care articles that may contain accessible particleboard, hardwood plywood, or medium-density fiberboard component parts and would be responsible for the certification of these products may include 7,059 firms that can be categorized as small.²² Of these, 3,705 have fewer than 5 employees. However, it is doubtful that all of the firms in some of these categories produce children's products. Moreover, of those firms that do produce children's products, we do not know how many of the firms manufacture products with accessible particleboard, hardwood plywood, or medium-density fiberboard component parts.

The number of domestic wholesalers by NAICS code that could distribute children's products, children's toys, or child care articles that may contain accessible particleboard, hardwood plywood, or medium-density fiberboard component parts may include 26,113 firms that can be categorized as small. Of these, 15,947 have less than 5 employees. Wholesalers who obtain their products strictly from domestic manufacturers or from other wholesalers would not be impacted by the rule because the manufacturer or importer would be responsible for certifying the products. Although importers are

responsible for the certification of the children's products that they import, they may rely upon third party testing performed by their foreign suppliers for purposes of certification. The number of small wholesalers that import children's products, children's toys, or child care articles as opposed to obtaining their product from domestic sources is not known. Also unknown is the number of small importers that must obtain or pay for the third party testing of their products.

The number of domestic retailers by NAICS code that could sell children's products, children's toys, or child care articles that may contain accessible particleboard, hardwood plywood, or medium-density fiberboard component parts may include 49,358 firms that can be categorized as small. Of these, 27,506 have less than 5 employees. Although there are almost 50,000 retailers in the NAICS categories, the only retailers that would be directly impacted by the proposed rule are those that import children's products themselves. Retailers that obtain all of their products from domestic manufacturers or wholesalers will not be directly impacted by the rule because the manufacturers or wholesalers would be responsible for certifying the products.

Although comprehensive estimates of the number of children's products, children's toys, and child care articles that contain component parts made from the specified engineered woods are not available, there is evidence that these engineered woods are used in children's furniture, sporting equipment, children's toys, and some musical instruments. Based on the number of domestic toy manufacturers that are classified as small businesses by the U.S. Bureau of the Census and evidence that the specified engineered woods are used in children's products, children's toys, and child care articles, the Commission believes a substantial number of small entities would be impacted by this regulation.

3. Reporting, Recordkeeping, and Other Compliance Requirements and Impact on Small Businesses

The proposed rule would determine that there is a high degree of assurance that the certain EWP's be determined not to contain lead, the ASTM F963 elements, and the specified phthalates (DEHP, DBP, BBP, DINP, DIDP, or DnOP) in concentrations greater than their specified limits. Under this proposed determination, manufacturers, importers, and private labelers of children's products, children's toys, and child care articles that have accessible component parts that consist of these

engineered woods would not require third party testing for certification that these components comply with the lead, ASTM F963 elements, or phthalate requirements.

The proposed rule would not impose any reporting, recordkeeping, or other compliance requirements on small entities. In fact, because the proposed rule would eliminate a testing requirement, there would be a small reduction in some of the recordkeeping burden under 16 CFR parts 1107 and 1109 because manufacturers would no longer have to maintain records of third party tests for the component parts manufactured from these engineered woods for lead, the ASTM F963 elements, or the specified phthalates.

The impact of the determinations on small businesses would be to reduce the burden of third party testing for the content of lead, the ASTM F963 elements, and the specified phthalates and would be expected to be entirely beneficial. The cost of lead testing ranges from \$50 to more than \$100 per component through Inductively Coupled Plasma testing (ICP). If one uses X-ray fluorescence spectrometry (XRF), which is an acceptable method for certification of third-party testing for lead content, the costs can be greatly reduced to approximately \$5 per component part. If a component part made with one of the specified engineered woods is painted, the component part would be exempt from the third party testing requirement, but the paint would still require lead testing.

Based on published invoices and price lists, the cost of a third party test for the ASTM F963 elements ranges from around \$60 in China, up to around \$190 in the United States using ICP. This cost can be greatly reduced with the use of high definition X-ray fluorescence spectrometry (HDXRF), which is an acceptable method for certification of third-party testing for the presence of the ASTM F963 elements. The cost can be reduced to about \$40 per component. It should be noted that lead is one of the ASTM F963 elements, so this testing would also cover the cost of lead testing for component parts.

The cost of phthalate testing is relatively high: Between about \$125 and \$350 per component part, depending upon where the testing is conducted and any discounts that are applicable. Because one product might have multiple component parts that require testing, the cost of testing a single product for phthalates could exceed \$1,000 in some cases. Moreover, more than one sample might have to be tested to provide a high degree of assurance of

²² The numbers of small firms for each NAICS code are from the Census Bureau and generally based on the SBA criteria for small firms.

compliance with the requirements for testing. To the extent that small businesses have lower production or sales volumes than larger businesses, these determinations would be expected to have a disproportionately beneficial impact on small businesses. This beneficial impact is due to spreading the costs of the testing over fewer units; and the benefit of the Commission making the determinations would be greater on a per unit basis for small businesses. Additionally, some testing laboratories may offer their larger customers discounts that might not be available to small businesses that need fewer third party tests. Making the determinations for these engineered woods could potentially significantly benefit a substantial number of firms.

On the other hand, the benefit of making the determinations could be less than might be expected. For example, some firms might have been able to substantially reduce their third party testing costs by using component part testing as allowed under 16 CFR 1109, so the marginal benefit that might be derived from making the determinations might be low. Also, some firms have reduced their testing costs by using XRF or HDXRF technology, which is less expensive than ICP, and would reduce the marginal benefit of these determinations. The Commission seeks public comments on the potential impact of the proposed rule on small entities. Comments are especially welcome on the following topics:

- The extent to which particleboard, hardwood plywood, and medium-density fiberboard are used in children's products, children's toys, and child care articles, especially those manufactured or imported by small firms;
- The potential reduction in third party testing costs that might be provided by the Commission making the determinations, including the extent to which component part testing is already being used and the current cost of testing components made from these engineered woods for compliance with the lead, ASTM F963 elements, and phthalate requirements;
- Any situations or conditions in the proposed rule that would make it difficult to make use of the determinations to reduce third party testing costs; and
- Although the Commission expects that the impact of the proposed rule will be entirely beneficial, any potential negative impacts of the proposed rule.

4. Alternatives Considered To Reduce the Burden on Small Entities

Under section 603(c) of the RFA, an initial regulatory flexibility analysis

should "contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant impact of the proposed rule on small entities." Because the proposed rule is intended to reduce the cost of third party testing on small businesses and will not impose any additional burden, the Commission did not consider alternatives to the proposed rule that would reduce the burden of this rule on small businesses.

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 1252

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

For the reasons stated in the preamble, the Commission proposes to amend title 16 of the CFR to add part 1252 to read as follows:

PART 1252—CHILDREN'S PRODUCTS, CHILDREN'S TOYS, AND CHILD CARE ARTICLES: DETERMINATIONS REGARDING LEAD, ASTM F963 ELEMENTS, AND PHTHALATES FOR ENGINEERED WOOD PRODUCTS

Sec.

1252.1 Children's products, children's toys, and child care articles containing lead, ASTM F963 elements, and phthalates in engineered wood products and testing requirements.

1252.2 Definitions.

1252.3 Determinations for engineered wood products.

Authority: Sec. 3, Pub. L. 110–314, 122 Stat. 3016; 15 U.S.C. 2063(d)(3)(B).

§ 1252.1 Children's products, children's toys, and child care articles containing lead, ASTM F963 elements, and phthalates in engineered wood products and testing requirements.

(a) Section 101(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) provides that any

children's product, material, or component part or a children's product must comply with a lead content limit that does not exceed 100 parts per million. Materials used in children's products subject to section 101 of the CPSIA must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act (CPSA), unless listed in 16 CFR 1500.91.

(b) Section 106 of the CPSIA made provisions of ASTM F963, Consumer Product Safety Specifications for Toy Safety, 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 children's toys that can be sucked, mouthed, or ingested, must comply with solubility limits that the toy standard establishes for eight elements. Materials used in children's 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 CPSA, unless listed in 16 CFR 1251.2.

(c) Section 108(a) of the CPSIA permanently prohibits any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). Section 108(b)(1) of the CPSIA prohibits on an interim basis any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP). Materials used in children's toys and child care articles subject to section 108(a) and (b)(1) of the CPSIA must comply with the third party testing requirements of section 14(a)(2) of the CPSA, unless listed in 16 CFR part 1308.

§ 1252.2 Definitions.

In addition to the definitions given in sections 101, 106, and 108 of the CPSIA, the following definitions apply for this part 1252.

(a) *Post-consumer wood waste* describes wood waste that is comprised of materials that are recovered from their original use and subsequently used in a new product. Examples of this type of waste include recycled demolition wood, packaging materials such as pallets and crates, used wood from landscape care (*i.e.*, from urban and highway trees, hedges, and gardens), discarded furniture, and waste wood from industrial, construction, and commercial activities.

(b) *Pre-consumer wood waste* describes wood materials that have been recycled from an industrial process

before being made available for consumer use. Examples of this type of waste include trimmings from engineered wood product (EWP) panel manufacturing, sawdust from cutting logs, or remaining wood pieces from sawing a log into framing lumber.

(c) *Unfinished* means an EWP that does not have any surface treatments applied at manufacture, such as factory-applied coatings. Examples of such treatments may include paint or similar surface coating materials, wood glue, or metal fasteners, such as nails or screws.

(d) *Untreated* means an EWP that does not have any additional finishes applied at manufacture. Examples of such finishes may include flame retardants or rot resistant finishes.

(e) *Virgin wood* describes wood logs, fibers, chips, or layers that have not been recycled from a previous use.

§ 1252.3 Determinations for engineered wood products.

(a) The following engineered wood products do not exceed the lead content limits with a high degree of assurance as that term is defined in 16 CFR part 1107:

(i) Particleboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste;

(ii) Hardwood plywood that is untreated and unfinished made from virgin wood or pre-consumer wood waste; and

(iii) Medium-density fiberboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste.

(b) The following engineered wood products do not exceed the ASTM F963 elements solubility limits set forth in 16 CFR part 1250 with a high degree of assurance as that term is defined in 16 CFR part 1107:

(i) Particleboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste;

(ii) Hardwood plywood that is untreated and unfinished made from virgin wood or pre-consumer wood waste; and

(iii) Medium-density fiberboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste.

(c) The following engineered wood products do not exceed the phthalates content limits with a high degree of assurance as that term is defined in 16 CFR part 1107:

(i) Particleboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste;

(ii) Hardwood plywood that is untreated and unfinished made from virgin wood or pre-consumer wood

waste and does not contain PVAc adhesive formulations; and

(iii) Medium-density fiberboard that is untreated and unfinished made from virgin wood or pre-consumer wood waste.

(d) Accessible component parts of children's products, children's toys, and child care articles made with EWPs, listed in paragraphs (a) through (c) of this section are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

(e) Accessible component parts of children's products, children's toys, and child care articles made with engineered wood products not listed in paragraphs (a)–(c) of this section are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–21980 Filed 10–12–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA–2011–N–0921]

RIN 0910–ZA50

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is correcting a proposed rule that published in the **Federal Register** of September 13, 2017. That proposed rule proposes to extend, for covered produce other than sprouts, the dates for compliance with the agricultural water provisions in the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” regulation. We are placing a corrected copy of the proposed rule in the docket.

DATES: October 13, 2017.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 13, 2017 (82 FR 42963), FDA published the proposed rule “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E” with an omission.

In FR Doc. 2017–19434, appearing on page 42963 in the **Federal Register** of September 13, 2017, the following correction is made:

On page 42967, in the third column, the paragraph above the table is corrected to include the fourth sentence as follows: “There would be a reduction in benefits associated with extending the compliance dates as described previously. Consumers eating non-sprout covered produce would not enjoy the potential health benefits (*i.e.*, reduced risk of illness) provided by the provisions of subpart E until 2 to 4 years (depending on the specific provision) later than originally established in the produce safety regulation. Thus, the annualized total benefits to consumers, discounted at 3 percent over 10 years, would decrease by \$108 million from \$1.033 billion to \$925 million. Taking into consideration both the reduction in costs and the reduction in benefits, using a 3 (7) percent discount rate, the proposed rule would have negative annualized net benefits of \$96 (\$97) million. Estimated changes in benefits and costs as a result of this proposed extension are summarized in the following table.”

Dated: October 10, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22182 Filed 10–12–17; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–129631–17]

RIN 1545–BN91

Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act; Proposed Rulemaking

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.