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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1253

[Docket No. CPSC-2019-0023]

Children's Toys and Child Care Articles: Determinations Regarding ASTM F963

Elements and Phthalates for Unfinished Manufactured Fibers

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (CPSC) is issuing a final rule determining that certain unfinished manufactured fibers do not contain the ASTM F963 elements or specified phthalates that exceed the limits set forth under the CPSC's statutes and regulations for children's toys and child care articles. Based on these determinations, the specified unfinished manufactured fibers would not be required to have third party testing for compliance with the requirements of the ASTM F963 elements or phthalates for children's toys and child care articles.

DATES: The rule is effective on **[insert date 30 days after publication in the FEDERAL REGISTER]**.

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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 No. 112-28 (August 12, 2011) directed the CPSC to seek comment on "opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation." Public Law No. 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 toys and child care articles manufactured with seven manufactured fibers: polyester (polyethylene terephthalate (PET)), nylon, polyurethane (spandex), viscose rayon, natural rubber latex,

acrylic, and modacrylic, would comply with CPSC's requirements for ASTM F963 elements or phthalates. The Commission determines that such materials will comply with CPSC's requirements with a high degree of assurance. Therefore, manufacturers do not need to have those materials tested by a third party testing laboratory in order to issue a Children's Product Certificate (CPC).

2. *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 at 16 CFR part 1250.² 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 ingested³ must comply with the solubility limits of eight elements given in Table 1 of the toy standard.

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 The Commission is not incorporating ASTM F963 by reference into part 1253.

³ 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 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.

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) ⁴
Antimony (Sb)	60
Arsenic (As)	25
Barium (Ba)	1000
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 party 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

⁴ The method to assess the solubility of a listed element is detailed in section 8.3, *Test Methods for Determination of Heavy Element Content in Toys, Toy Components, and Materials*, of ASTM F963.

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. 16 CFR part 1251. The Commission also has determined that untreated and unfinished engineered wood products would not require third party testing for the ASTM elements or specified phthalates (discussed below) for children's products, children's toys, and child care products. 16 CFR part 1252.

3. *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 phthalate (BBP). 15 U.S.C. 2057c(a).

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. On October 27, 2017, the Commission published a final rule in the *Federal Register*, "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates," 82 FR 49938, prohibiting children's toys and child care articles containing concentrations greater than 0.1 percent of: di-(2-ethylhexyl) phthalate (DEHP); dibutyl phthalate (DBP); benzyl butyl phthalate (BBP); diisononyl phthalate (DINP); diisobutyl phthalate (DIBP); di-n-pentyl phthalate (DPENP); di-n-hexyl phthalate (DHEXP); or dicyclohexyl phthalate (DCHP). These restrictions apply to any plasticized component part of a children's toy or child care

article or any other component part of a children's toy or child care article that is made of other materials that may contain phthalates. The phthalates prohibitions are set forth in 16 CFR part 1307.

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. 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.

4. Notice of Proposed Rulemaking

On October 9, 2019, the Commission published a notice of proposed rulemaking (NPR) in the *Federal Register* for the unfinished manufactured fibers determinations. (84 FR 54055). The Commission proposed that certain unfinished⁵ manufactured fibers do not contain any of the specified ASTM F963 elements in excess of specified concentrations and any of the specified phthalates in concentrations greater than 0.1 percent (1000 ppm). Thus, accessible component parts made from such manufactured fibers in children's toys and child care articles subject to sections 106 and 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) and 16 CFR part 1307 that are made with these manufactured fibers would not require third party testing for

⁵ An unfinished fiber is one that has no chemical additives beyond those required to manufacture the fiber. Manufactured fibers, unlike naturally occurring fibers, could have chemicals added before fiber formation to impart color or some desirable performance property, such as flame retardancy. For unfinished fibers as described in this rule, the unfinished fiber is free of these chemical additives.

certification purposes.⁶ The comments to the NPR are addressed in section C of this preamble.

B. Contractor's Research

1. TERA Task 17 Contractor's Report

The CPSC contracted with the Toxicology Excellence for Risk Assessment (TERA, or the contractor) to conduct literature reviews on the production of certain undyed manufactured fibers and to evaluate whether the specified manufactured fibers potentially contain: (1) any of the specified chemical elements that are included in the toy standard in concentrations⁷ exceeding specified limits; or (2) any of 10 specified phthalates in concentrations greater than 0.1 percent (1000 ppm). TERA researched the following manufactured fibers: polyester (polyethylene terephthalate (PET)), nylon, polyurethane (spandex), viscose rayon, natural rubber latex, acrylic, and modacrylic. Staff reviewed the information provided in the TERA report, *Exposure Assessment: Potential for the Presence of Phthalates and Other Specified Elements in Undyed Manufactured Fibers and their Colorants* (the report, Task 17).⁸ TERA's Task 17 report formed the basis for the unfinished manufactured fiber determinations.⁹

⁶ The Commission has previously determined that certain products and materials do not contain lead at levels that exceed the limits for lead established under section 101 of the CPSIA. These lead determinations include textiles consisting of natural and manufactured fibers (dyed or undyed). 16 C.F.R § 1500.91.

⁷ Although the ASTM F963-17 standard for chemical elements is a solubility requirement, TERA researched total content, in part because of the expected availability of content data versus solubility data and because content is a conservative stand-in for chemical solubility (*i.e.*, the content of a chemical is the same value as one hundred percent solubility of the chemical from solubility testing).

⁸ Task Order 17, Contract Number CPSC-D-12-0001. Available at: <https://www.cpsc.gov/s3fs-public/TERA%20Task17%20Report%20Phthalates%20and%20ASTM%20Elements%20in%20Manufactured%20Fibers.pdf>.

⁹ The staff briefing package for the NPR contains detailed information on the Task 17 report and staff analysis of the report. <https://www.cpsc.gov/s3fs-public/Draft%20NPR->

All of the fibers covered in the Task 17 report are manufactured and do not naturally occur in a fiber state. Although their raw starting materials may be different, these fibers are generally extruded into a fiber form. In many cases, additional chemicals may be added before the extrusion process so that the chemicals are embedded in the fiber structure. To better understand where the specified phthalates or ASTM elements may be present, TERA documented the fiber chemical characteristics, manufacturing processes, typical colorants, and any other relevant information found through their search strategy.

2. CPSC Staff Analysis of TERA Task 17 Report

As described in the preamble of the NPR, CPSC staff reviewed the TERA Task 17 Report. CPSC staff also examined TERA's source references to better understand the report's findings. The Task 17 Report focused on the possibility of the ASTM F963 elements and specified phthalates being present in seven manufactured fiber types.

Unfinished fibers

The manufactured fibers within scope of the TERA report included the following generic fiber types: polyester (polyethylene terephthalate (PET)), nylon, natural latex rubber, polyurethane (spandex), rayon, acrylic, and modacrylic. The TERA report found concentrations of antimony exceeding specified limits are used in the manufacture of undyed and unfinished PET. However, staff does not know the soluble concentration

when tested according to ASTM F963. PET fiber is widely used in consumer textile products, including children's toys.

In staff's review of the source material, staff did not find any information or data suggesting intentional use of any of the other chemicals of interest or presence of contaminants in fibers at significant levels, with reported contaminant levels no higher than a few parts per million. Staff believes that contaminants or impurities are unintentional (*i.e.*, not added by the manufacturer intentionally), existing in the environment at trace levels, or present in general industrial practices and conditions. We conclude that any impurities will be at levels below the relevant limits.

Dyed or Finished Fibers (or Fibers with Chemical Additives Pre-Fiber Formation)

Colorants, such as dyes, often contain metals in their structure. The contractor reported the use of mercury, arsenic, barium, or chromium in dyes or dye auxiliaries. For example, chrome dyes are a type of acid dye that can be used on nylon fibers and contains chromium to form a complex between the dye and the fiber. Because the use of these metals is not necessarily limited to a specific dye class or fiber type, staff cannot rule out the use of these metals at concentrations greater than those specified in ASTM F963 without more information. Furthermore, the contractor reported that some of the specified phthalates could be used as dye auxiliaries or carriers for pigments. Although some of the findings may have been with products potentially out of the scope of the subject rule, the mechanism by which colorants are applied to fibers could extend to relevant products.

Finishes may also be added at the fiber (yarn or fabric) stage to impart desirable characteristics. The contractor report cited the potential use of antimony-containing flame retardants and noted that other chemicals of interest could be used in finished fiber (yarn or fabric). However, those finishes were not within the scope of the contractor report. Staff notes that the restriction in the ASTM F963 standard is based on solubility (excluding lead, which has separate specific restrictions under the CPSIA); *i.e.*, migration of the elements from the product or material.

C. Discussion of Comments to the NPR

The CPSC received one comment in response to the NPR. The commenter, who works with small batch manufacturers, urged approval of the proposed rule. The commenter did not provide data or specific comments or suggestions on the proposed rule.

D. Determinations for Unfinished Manufactured Fibers

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 toys must comply with the limits on the ASTM F963 elements incorporated in 16 CFR part 1250. Children's toys and child care articles must also comply with the phthalates prohibitions in section 108 of the CPSIA and 16 CFR part 1307. 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 toys and child care articles would not require third party testing.

To issue a determination that a manufactured fiber 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 manufactured fiber is subject so that third party testing is unnecessary to provide a high degree of assurance of compliance. Under 16 CFR 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 toys and child care articles subject to sections 106 and 108 of the CPSIA and 16 CFR part 1307, compliance to the specified content limits is always required, irrespective of any testing exemptions. Thus, a manufacturer or importer who certifies a children's toy or child care article, must assure the product's compliance. The presence of the ASTM F963 elements or the specified phthalates does not have to be intentional 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 below 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 a manufactured fiber does not contain the ASTM F963 elements or specified phthalates in concentrations greater than the specified limits in a children's toy

or child care article, the manufacturer must ensure that the manufactured fiber is one on which a determination has been made.

Furthermore, under the rule, any determinations that are made on manufactured fibers are limited to unfinished manufactured fibers. Children's toys and child care articles made from these manufactured fibers may have other materials that are applied to or added on to the manufactured fiber after it is manufactured, such as colorants and flame retardants. Such component parts fall outside of the scope of the determinations in the rule and would be subject to third party testing requirements, unless the component part has a separate determination that 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 of compliance.

For ASTM F963 elements, determinations are made for six unfinished manufactured fibers: nylon, polyurethane (spandex), viscose rayon, acrylic, and modacrylic, and natural rubber latex. Based on staff's review of the TERA report as discussed in section B of the preamble, the Commission finds that there is a high degree of assurance that these unfinished manufactured fibers will not contain the ASTM F963 elements in concentrations greater than the specified limits. We note that based on staff's review of the Task 17 report, a determination that polyester (PET) fiber does not contain any of the ASTM F963 elements in concentrations greater than their specified solubility limits is not warranted due to findings in the contractor report regarding the use of antimony compounds in polyester manufacturing.

The Commission also finds that determinations for seven unfinished manufactured fibers for the specified phthalates prohibitions: polyester (PET), nylon, polyurethane

(spandex), viscose rayon, acrylic, and modacrylic, and natural rubber latex are warranted. Based on staff's review of the TERA report as discussed in section B. of the preamble, the Commission finds that there is a high degree of assurance that these unfinished manufactured fibers will not contain the prohibited phthalates in concentrations greater than the specified limits.

These determinations mean that for the specified unfinished manufactured fibers, third party testing is not required to assure compliance with sections 106 and 108 of the CPSIA and 16 CFR part 1307. The Commission is making 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(a)(2) of the CPSA, as 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 issue a rule determining that certain unfinished manufactured fibers do not contain the ASTM F963 elements and the specified prohibited phthalates in concentrations greater than the specified limits, and thus, are not required to be third

party tested to assure compliance with sections 106 and 108 of the CPSIA and 16 CFR part 1307.

The determinations in the rule relieve manufacturers who use the specified unfinished manufactured fibers from the third party testing requirements of section 14 of the CPSA for purposes of supporting the required certification. However, the determinations are not applicable to any other manufactured fibers beyond those listed in the rule. The determinations only relieve the manufacturers of the obligation to have the specified unfinished manufactured fibers tested by a CPSC-accepted third party conformity assessment body. Children's toys and child care articles must still comply with the substantive content limits in sections 106 and 108 of the CPSIA and 16 CFR part 1307 regardless of any relief on third party testing requirements.

3. Description of the Rule

This rule creates a new Part 1253 for "Children's Toys and Child Care Articles: Determinations Regarding the ASTM F963 Elements and Phthalates for Unfinished Manufactured Fibers." The text of the rule is being finalized unchanged from the proposed text in the NPR. The rule determines that the specified unfinished manufactured fibers do not contain any of the ASTM F963 elements in excess of specified concentrations, and any of the phthalates (DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP, and DCHP) prohibited by statute or regulation in concentrations greater than 0.1 percent.

- Section 1253.1(a) of the 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 1253.1(b) of the rule explains the statutory and regulatory 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 1253.2(a) of the rule provides a definition of the term “unfinished manufactured fiber” that applies to part 1253.
- Section 1253.2(b) of the rule establishes the Commission’s determinations that specified unfinished manufactured fibers 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 1253.2(c) of the rule establishes the Commission’s determinations that specified unfinished manufactured fibers do not exceed the phthalates content limits with a high degree of assurance as that term is defined in 16 CFR part 1107.
- Section 1253.2(d) of the rule states that accessible component parts of children’s toys and child care articles made with the specified unfinished manufactured fibers specifically listed in the determinations in § 1253.3(b) and (c) are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.
- Section 1253.2(e) of the rule states that accessible component parts of children’s toys and child care articles that are not specifically listed in the determinations in § 1253.3(b) and (c) are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

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 final rule provides relief from existing testing requirements under the CPSIA, the Commission concludes a 30 day effective date is sufficient. This is the same effective date proposed in the NPR. Thus, the effective date is **[insert date 30 days after publication in the FEDERAL REGISTER]**.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed and final rules on small entities, including small businesses. Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis (FRFA) when promulgating final rules, unless the head of the agency certifies that the rule will not have a significant impact on a substantial number of small entities. The FRFA must describe the impact of the rule on small entities. CPSC staff prepared a FRFA that may be found in Tab A of the staff briefing package.¹⁰ The staff FRFA is summarized below.

CPSC staff's review shows that comprehensive estimates of the number of children's toys and child care articles that contain component parts made from the specified unfinished manufactured fibers are not available. However, based on the number of domestic producers and sellers of these products, staff believes that a

¹⁰ <https://www.cpsc.gov/s3fs-public/Draft%20Final%20Rule-%20Children%27s%20Toys%20and%20Child%20Care%20Articles%20-%20Determinations%20Regarding%20ASTM%20F963%20Elements%20and%20Phthalates%20for%20Unfinished%20Manufactured%20Fibers.pdf?LFcbYLvpcSdVanRkTUp.jI4.mEcY05GA>.

substantial number of small entities could be impacted by this regulation. Staff's review indicates that there be might be close to 10,000 small firms that supply children's toy or child care articles with unfinished manufactured fibers in accessible component parts. However, staff does not know the number of small firms that actually supply products with the unfinished manufactured fibers in accessible component parts, or the number of children's toys and child care article. Nevertheless, based on the number of domestic toy manufacturers that are classified as small businesses (according to SBA size standards and data provided by the U.S. Bureau of the Census) and evidence that the specified fibers could be used extensively in toys and child care articles, even if only a small proportion of these firms manufacture or sell products using the unfinished manufactured fibers of interest, we find that a substantial number would benefit from the reduced testing burden. The impact of the determinations on small businesses would be to reduce the burden of third party testing for firms and are expected to be entirely beneficial. The current cost of testing, on a per-test basis, is reflective of the expected cost reductions that would result from the determinations, and are as follows:

- ASTM F963 Elements - 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 inductively coupled plasma atomic emission spectroscopy (ICP-AES). 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 elements. The cost can be reduced to about \$40 per component part.

- Phthalates - The cost of phthalate testing is relatively high: between about \$125 and \$350 per component, depending upon where the testing is conducted and any discounts that are applicable. Because one product might have multiple components that require testing, the cost of testing a single product for phthalates could exceed \$1,000 in some cases.

More than one sample might have to be tested to provide a high degree of assurance of compliance with the requirements for testing. To the extent that small businesses have lower production or lower sales volume 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. However, small entities that need fewer third party tests may not qualify for discounts that some laboratories may offer their larger customers. In addition, the possible benefits associated with the determinations might be somewhat lower to the extent that firms were already taking advantage of component part testing as allowed by 16 CFR part 1109. Additionally, some firms have reduced their testing costs by using XRF or HDXRF technology, which is less expensive than ICP-AES, and would reduce the marginal benefit of these determinations. Finally, some firms, particularly importers, might not know the specific fibers used in the products they import or whether fibers are unfinished and might opt to conduct the testing anyway to ensure that the products do not violate requirements.

The determinations would not impose any new reporting, recordkeeping, or other compliance requirements on small entities. In fact, because the 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 unfinished manufactured fibers the ASTM F963 elements or the specified phthalates.

In summary, although there are a substantial number of small entities that manufacture or import children's toys and childcare articles in which manufactured fibers could be used, we do not have data on the number or the extent to which unfinished manufactured fibers are used in these products. Consequently, although the rule could potentially have a significant positive impact on a substantial number of small entities, we cannot make this determination categorically. Although public comments on the potential impact of the proposed rule on small entities were solicited, just one comment was received in response to the proposal. While that comment supported the adoption of the rule as a means to reduce the burden of third-party testing on small batch toy producers, specific estimates of the benefits to small businesses were not provided. Based on staff's review, the Commission finds that that the burden reduction from this rule could potentially result in significant benefits for a substantial number of manufacturers, importers, or retailers of the relevant product categories.

Under section 604 of the Regulatory Flexibility Act, a FRFA should include a "statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected." The final rule is being issued to reduce third party testing costs consistent with assuring compliance with all applicable consumer product safety rules. Therefore, because the rule is intended to reduce the cost of third-party testing on small businesses and will not impose any

additional burden on small businesses, the staff did not consider alternatives to the rule. We note, the Commission did not receive any comments or other information on any additional manufactured fibers for further burden-reduction activities.

G. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement where 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.

H. The Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801-808) states that, before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The submission must indicate whether the rule is a "major rule." The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a "major rule." Pursuant to the CRA, this rule does not qualify as a "major rule," as defined in 5 U.S.C. 804(2). To comply with the CRA, the Office of the General Counsel will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1253

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

For the reasons stated in the preamble, the Commission amends title 16 of the CFR by adding part 1253 to read as follows:

**PART 1253—CHILDREN’S TOYS AND CHILD CARE ARTICLES:
DETERMINATIONS REGARDING THE ASTM F963 ELEMENTS AND
PHTHALATES FOR UNFINISHED MANUFACTURED FIBERS**

Sec.

1253.1 Children’s toys and child care articles containing the ASTM F963 elements and phthalates in manufactured fibers and testing requirements.

1253.2 Determinations for unfinished manufactured fibers.

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

§ 1253.1 Children’s toys and child care articles containing the ASTM F963 elements and phthalates in manufactured fibers and testing requirements.

(a) Section 106 of the CPSIA made most provisions of ASTM F963, Consumer Product Safety Specifications for Toy Safety, a mandatory consumer product safety standard. 16 CFR part 1250 codified these provisions by incorporating by reference ASTM F963, *see* 16 CFR1250.1. 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 § 1253.2.

(b) Section 108(a) of the Consumer Product Safety Improvement Act of 2008 (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). In accordance with section 108(b)(3) of the CPSIA, 16 CFR part 1307 prohibits any children's toy or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisobutyl phthalate (DIBP), di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), or dicyclohexyl phthalate (DCHP). Materials used in children's toys and child care articles subject to section 108(a) of the CPSIA and 16 CFR part 1307 must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act (CPSA), unless listed in § 1253.2.

§ 1253.2 Determinations for unfinished manufactured fibers.

(a) The following definition for an unfinished manufactured fiber applies for this part 1253. An unfinished manufactured fiber is one that has no chemical additives beyond those required to manufacture the fiber. For unfinished manufactured fibers as defined in this rule, the unfinished manufactured fiber is free of any chemical additives added to impart color or some desirable performance property, such as flame retardancy.

(b) The following unfinished manufactured fibers 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:

- (1) Nylon;
- (2) Polyurethane (Spandex);
- (3) Viscose Rayon;

(4) Acrylic and Modacrylic; and

(5) Natural Rubber Latex.

(c) The following unfinished manufactured fibers do not exceed the phthalates content limits set forth in 16 CFR part 1307 with a high degree of assurance as that term is defined in 16 CFR part 1107:

(1) Polyester (polyethylene terephthalate, PET);

(2) Nylon;

(3) Polyurethane (Spandex);

(4) Viscose Rayon;

(5) Acrylic and Modacrylic; and

(6) Natural Rubber Latex.

(d) Accessible component parts of children's toys and child care articles made with the unfinished manufactured fibers, listed in paragraphs (b) and (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 toys and child care articles made with manufactured fibers not listed in paragraphs (b) and (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, Secretary
Consumer Product Safety Commission

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