



UNITED STATES  
 CONSUMER PRODUCT SAFETY COMMISSION  
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 BETHESDA, MD 20814

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**BALLOT VOTE SHEET**

Date: April 29, 2020

TO : The Commission  
 Alberta E. Mills, Secretary

THROUGH: John G. Mullan, General Counsel  
 Mary T. Boyle, Executive Director

FROM : Hyun S. Kim, Acting Assistant General Counsel  
 David M. DiMatteo, Attorney

SUBJECT : Draft Final Rule: *Children’s Toys and Child Care Articles: Determinations Regarding ASTM F963 Elements and Phthalates for Unfinished Manufactured Fibers*

BALLOT VOTE DATE: Tuesday, May 5, 2020

Staff is forwarding to the Commission a memorandum recommending that the Commission issue a final rule for determinations that certain unfinished manufactured fibers would not contain the ASTM F963 elements or specified phthalates at concentrations that exceed the required limits under the CPSC’s statutes and regulations for children’s toys and child care articles. Based on the determinations, the specified unfinished manufactured fibers would not require third party testing for compliance with these requirements. The Office of the General Counsel is providing for Commission consideration the attached draft final rule for publication in the *Federal Register*.

Please indicate your vote on the following options:

- I. Approve publication of the attached document in the *Federal Register*, as drafted.

\_\_\_\_\_  
 (Signature)

\_\_\_\_\_  
 (Date)

II. Approve publication of the attached document in the *Federal Register*, with the specified changes.

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\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

III. Do not approve publication of the attached document in the *Federal Register*.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

IV. Take other action specified below.

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(Signature)

\_\_\_\_\_  
(Date)

Attachment: Draft *Federal Register* notice, titled, “Children’s Toys and Child Care Articles: Determinations Regarding ASTM F963 Elements and Phthalates for Unfinished Manufactured Fibers”

**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]**.

**FOR FURTHER INFORMATION CONTACT:** Stephen W. Lee, Compliance Officer, Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814-4408; telephone 301-504-7814; email: [slee@cpsc.gov](mailto:slee@cpsc.gov).

**SUPPLEMENTARY INFORMATION:**

**A. Background**

*1. Third Party Testing and Burden Reduction*

Section 14(a) of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires that manufacturers of products subject to a consumer product safety rule or similar rule, ban, standard, or regulation enforced by the CPSC, must certify that the product complies with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). For children’s products, certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* Public Law 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.<sup>1</sup> 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.<sup>2</sup> 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 ingested<sup>3</sup> must comply with the solubility limits of eight elements given in Table 1 of the toy standard.

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<sup>1</sup> 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.

<sup>2</sup> The Commission is not incorporating ASTM F963 by reference into part 1253.

<sup>3</sup> 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) <sup>4</sup>
Antimony (Sb)	60
Arsenic (As)	25
Barium (Ba)	1000
Cadmium (Cd)	75
Chromium (Cr)	60
Lead (Pb)	90
Mercury (Hg)	60
Selenium (Se)	500

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

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<sup>4</sup> 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 unfinished<sup>5</sup> 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

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<sup>5</sup> 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 memorandum and the staff recommendations, the unfinished fiber is free of these chemical additives.



certification purposes.<sup>6</sup> 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 concentrations<sup>7</sup> 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).<sup>8</sup> TERA’s Task 17 report formed the basis for the unfinished manufactured fiber determinations.<sup>9</sup>

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<sup>6</sup> 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.

<sup>7</sup> 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).

<sup>8</sup> 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>.

<sup>9</sup> 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

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[%20Children%27s%20Toys%20and%20Child%20Care%20Articles-%20Determinations%20Regar....pdf?IB4eKjJ\\_meZH1vdT5uQeojG8FfYGeqD9.](#)

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. [INSERT LINK]. 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 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 to add 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.

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Alberta E. Mills, Secretary  
Consumer Product Safety Commission



## **Briefing Package**

### **Final Rule: Recommendation for Determinations Regarding Third Party Testing of Manufactured Fibers for the ASTM F963 Elements and Phthalates**

April 29, 2020

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

**Table of Contents**

Executive Summary ..... 1

Introduction..... 2

Discussion ..... 3

    TERA Report ..... 3

    High Degree of Assurance Required to Issue Children’s Product Certificate (CPC)..... 5

    Required Compliance with ASTM F963 and Phthalates Content Limits and Third Party  
    Testing Requirements ..... 5

Impact on Manufacturers and Importers of Children's Toys and Childcare Articles ..... 6

CPSC Staff Conclusions and Recommendations..... 7

    Recommendations ..... 7

    Recommended Effective Date ..... 9

Tab A: Final Regulatory Flexibility Analysis..... 10



UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
BETHESDA, MD 20814

**Memorandum**

Date: April 29, 2020

TO: The Commission  
Alberta E. Mills, Secretary

THROUGH: John G. Mullan, General Counsel  
  
Mary T. Boyle, Executive Director  
  
DeWane Ray, Deputy Executive Director for Safety Operations

FROM: Duane E. Boniface, Assistant Executive Director, Office of Hazard  
Identification and Reduction  
  
Jacqueline H. Campbell, Project Manager, Directorate for Engineering  
Sciences, Office of Hazard Identification and Reduction

SUBJECT : Draft Final Rule: Recommendation for Determinations Regarding Third  
Party Testing of Manufactured Fibers for the ASTM F963 Elements and  
Phthalates

## Executive Summary

The Consumer Product Safety Improvement Act directs the CPSC to take actions to eliminate unnecessary third party testing burdens while assuring compliance. Accordingly, CPSC contracted with Toxicology Excellence for Risk Assessment (TERA) to conduct literature reviews on the production of certain undyed manufactured fibers<sup>1</sup> and to evaluate whether the specified manufactured fibers potentially contain:

1. Any of the chemical elements that are specified in the safety standard for toys, ASTM F963, *Standard Consumer Safety Specification for Toy Safety*, incorporated in 16 CFR part 1307 in concentrations exceeding specified limits; or
2. Any of 10 specified phthalates in concentrations greater than 0.1 percent (1000 ppm).

TERA identified thousands of references for screening by their search method, which it believes is representative of the relevant references available. CPSC undertook this work to support its efforts to eliminate unnecessary third party testing burdens while assuring compliance.

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<sup>1</sup> The manufactured fibers within scope of the study include the following generic fiber types: polyester (polyethylene terephthalate, PET), nylon, natural latex rubber, polyurethane (spandex), rayon, acrylic, and modacrylic.

On October 9, 2019, the Commission published a notice of proposed rulemaking (NPR) in the *Federal Register*. The NPR proposed that certain unfinished<sup>2</sup> 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 certification purposes.<sup>3</sup> We received one public comment relevant to the NPR that supported the recommendation.

Staff recommends that the Commission issue a final rule determining that:

- All fibers (in an unfinished state) in-scope of the contractor report, except for polyester, do not contain the ASTM F963 elements; and
- All fibers (in an unfinished state) in-scope of the contractor report do not contain the specified phthalates.

Staff based its recommendations for unfinished fibers on TERA’s report, which documented positive findings for the use of the ASTM F963 elements and specified phthalates in finished fibers. Under the draft final rule, therefore, the scope of any determinations regarding the ASTM F963 elements and the specified phthalates would be limited to certain specified unfinished manufactured fibers. CPSC staff recognizes that most consumer products made from these fibers will have other components, such as colorants or other finishes that are added to, or applied onto, the fibers (or yarns or fabrics) after the fibers have been manufactured. Unless these other components also have a determination, they would be subject to third party testing.

## Introduction

Section 14(a)(2) of the Consumer Product Safety Act (CPSA),<sup>4</sup> as amended by the CPSIA,<sup>5</sup> requires that manufacturers of children’s products subject to a children’s product safety rule certify compliance based on testing by a CPSC accepted third party testing laboratory. A “children’s product” is defined as a consumer product designed or intended primarily for children 12 years of age or younger.

Section 14(d)(1)(3) of the CPSA states that the Commission:

. . . may 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.

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<sup>2</sup> 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 memorandum, and the staff recommendations, the unfinished fiber is free of these chemical additives.

<sup>3</sup> 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 CFR § 1500.91.

<sup>4</sup> <https://www.cpsc.gov/Regulations-Laws--Standards/Statutes/Summary-List/Consumer-Product-Safety-Act>.

<sup>5</sup> <https://www.cpsc.gov/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act>.

On November 8, 2011, the Commission issued a rule on component parts, *Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Testing and Certification Requirements*, 16 CFR part 1109 (the 1109 rule).<sup>6</sup> Under the 1109 rule, parties who test or certify consumer products pursuant to sections 14(a) and 14(i) of the CPSA may test products at the component level, rather than as a finished consumer product. Accordingly, if the Commission determines that certain component parts do not require third party testing, then those parts may be declared on a certificate at the component level.

On October 9, 2019, the Commission published an NPR in the *Federal Register*. The Commission proposed that certain unfinished<sup>7</sup> 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 CPSIA and 16 CFR part 1307 that are made with these manufactured fibers would not require third party testing for certification purposes.<sup>8</sup> We received one public comment relevant to the NPR. That 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.

## Discussion

### TERA 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 concentrations<sup>9</sup> exceeding specified limits, or (2) any of 10 specified phthalates in concentrations greater than 0.1 percent (1000 ppm). 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).<sup>10</sup> Staff's recommendations for determinations are based on technical information documented in the report. We did not receive any comments

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<sup>6</sup> 76 FR 69546.

<sup>7</sup> 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 memorandum, and the staff recommendations, the unfinished fiber is free of these chemical additives.

<sup>8</sup> 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 CFR § 1500.91.

<sup>9</sup> 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 100 percent solubility of the chemical from solubility testing).

<sup>10</sup> 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>.

providing additional information or suggested changes to the proposed rule in response to the publication of the proposed rule in the *Federal Register*.

A determination concerning manufactured fibers would apply to children's toys and child care articles. Examples of children's toys that could potentially be affected by a Commission determination about phthalate content are: coverings or fill of stuffed, plush, or other soft toys; doll clothes; puzzle mats or other play mats; and other similar toys. Under the child care article category, products potentially affected by a Commission determination about phthalate content may include sleepwear, bibs, and other products that facilitate sleep or feeding.

The chemical requirements in the ASTM F963 toy safety standard cover accessible substrates of toys that can be sucked, mouthed, or ingested. The specified manufactured fibers (or yarns or fabrics) could be used in coverings or fill of stuffed, plush, or other soft toys, doll clothes, puzzle mats or other play mats, and other similar toys.

### Unfinished Fibers

The manufactured fibers within scope of the TERA report include the following generic fiber types: polyester (polyethylene terephthalate, PET), nylon, natural latex rubber, polyurethane (spandex), rayon, acrylic, and modacrylic. The TERA report found that 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 its review of the source material, staff has not found 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. Staff concludes that any impurities will be at levels well below the relevant limits.

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

As noted in the NPR staff briefing package, the contractor reported the use of ASTM F963 elements, such as mercury, arsenic, barium, or chromium, in dyes or dye auxiliaries. 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. 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 rules, the mechanism by which colorants are applied to fibers could be extended 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<sup>11</sup>; *i.e.*, migration of the elements from the product or material. However, if the total content for a specific element does

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<sup>11</sup> Excluding lead, which has separate specific restrictions under the CPSIA.

not exceed the solubility limit, the solubility requirement is met. Due to a lack of information on chemical solubility or migration from products or materials available in the scientific literature or other data sources, staff relies on existing chemical content information to understand possible chemical uses and presence in products. If sufficient solubility testing data were available, such data may help inform decisions about testing requirements under the ASTM F963 standard.

Based on the information provided in the TERA Task 17 report and staff's review of TERA's source references in the Task report, staff's recommendations for the final rule are unchanged from the proposed rule.

### High Degree of Assurance Required to Issue Children's Product Certificate (CPC)

A *High Degree of Assurance* is defined in 16 CFR § 1107.2 as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture." Section 1107.20(d) of the regulation states:

A manufacturer cannot certify the children's product until the manufacturer establishes, with a high degree of assurance, that the finished product does comply with all applicable children's product safety rules.

Thus, certifiers of children's products require a high degree of assurance that their product complies with the applicable children's product safety rules before they issue a CPC.

### Required Compliance with ASTM F963 and Phthalates Content Limits and Third Party Testing Requirements

Determinations for the specified manufactured fibers would relieve children's product certifiers from third party testing burdens, while assuring compliance with sections 106 and 108 of the CPSIA and 16 CFR part 1307 for component parts made from the specified manufactured fibers. However, the determinations would only relieve the manufacturers' obligation to have the specified manufactured fibers tested by a CPSC-accepted third party laboratory. 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. Thus, a manufacturer or importer who certifies a children's toy or child care article, must ensure the product's compliance. The presence of the ASTM F963 elements or the specified phthalates does not have to be intentional to be determined noncompliant. 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 a manufactured fiber does not contain any specified phthalate in concentrations greater than 0.1 percent, the manufacturer must ensure that the product is one on which such a determination has been made.

Furthermore, under the draft final rule, any determinations that are made on manufactured fibers are limited to unfinished manufactured fibers. Children's products made from these manufactured fibers may have other materials added after the fibers were manufactured, such as treatments, finishes, or colorants. Such component parts fall outside of the scope of the proposed determinations and would be subject to third party testing requirements. Finally, even if a



product is subject to a determination and third party testing is not required, a certifier must still issue a certificate.

## Impact on Manufacturers and Importers of Children's Toys and Childcare Articles

As detailed in Tab A, the draft final rule would reduce the burden of third party testing on manufacturers and importers of children's toys and child care articles. The draft final rule would eliminate the requirement for third party testing on accessible component parts made of certain unfinished manufactured fibers that do not contain any of the specified ASTM F963 elements in excess of specified concentrations and any of the prohibited phthalates in concentrations greater than 0.1 percent.

The impact of the determinations on small businesses would be to reduce the burden of third party testing for the ASTM F963 elements and the specified phthalates, and this impact on small businesses would be expected to be entirely beneficial. Based on published invoices and price lists, the cost of a third party test using inductively coupled plasma atomic emission spectroscopy (ICP-AES) testing for the ASTM F963 elements, ranges from around \$60 in China, up to around \$190 in the United States. This cost can be greatly reduced with the use of high-definition X-ray fluorescence spectrometry (HDXRF), which is an acceptable method for certifying third party testing for the presence of the ASTM elements. The cost can be reduced to about \$40 per component using HDXRF.

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

Moreover, 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 sales volume than larger businesses, these determinations could have a disproportionately beneficial impact on small businesses. This beneficial impact derives from 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 unfinished manufactured fibers could significantly benefit a substantial number of firms.

On the other hand, making the determinations could be less beneficial for certain manufacturers than staff expects. For example, some firms might have been able to reduce their third party testing costs substantially, by using component part testing as allowed by 16 CFR part 1109. Thus, the marginal benefit that might be derived from making the determinations could be lower. 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. Although the manufactured fibers are widely used, the determinations are limited to unfinished fibers, which might be less widely used. Finally, some firms, particularly importers, might not know the specific fibers used in the products being imported, or whether

they are unfinished, and therefore, they might opt to conduct the testing anyway, to ensure that they are not in violation of the requirements.

Based on staff's research, the burden reduction from this determination rule could result in testing cost reductions that would have a significant positive impact on a substantial number of manufacturers, importers, or retailers of children's toys and child care articles. However, because staff does not have data on the extent to which unfinished manufactured fibers are used in these products, this determination cannot be made categorically.

## CPSC Staff Conclusions and Recommendations

Considering the available evidence related to the factors researched in the Task 17 Report, CPSC staff concludes, with a high degree of assurance, that certain manufactured fibers do not require third party testing by a CPSC-accepted laboratory in order to issue a CPC. The Task 17 Report focused on the possibility of the ASTM F963 elements and specified phthalates being present in seven manufactured fiber types.

Section 14(d)(3) of the CPSA (as amended by Pub. L. No. 112-28) authorizes the Commission to issue regulations that the Commission determines "will reduce third party testing costs consistent with assuring compliance" with applicable children's product safety rules. Thus, to issue a determination, the Commission must have sufficient evidence to conclude that the material would consistently comply with the CPSC requirements so that third party testing is unnecessary to provide a high degree of assurance of compliance. Staff concludes that the Task 17 Report provides a basis for the Commission to determine that certain unfinished manufactured fibers do not require third party testing by a CPSC-accepted laboratory for a certifier to issue a CPC.

For accessible component parts of children's toys or child care articles made of these unfinished manufactured fibers on which a determination has been made, no adulteration or contamination of the fibers with an ASTM F963 element or a specified phthalate greater than the specified limits is allowed during the product's manufacture, transport, storage, or application to a subject product.

## Recommendations

CPSC staff recommends, with the exceptions listed below, that the Commission determine that the following seven unfinished manufactured fibers do not contain the ASTM F963 elements and the specified phthalates in concentrations greater than their specified limits, and thus, would not be required to be third party tested to assure compliance with sections 106 and 108 of the CPSIA, and regulations the Commission has promulgated pursuant to sections 106 and 108 of the CPSIA. This recommendation is unchanged from that proposed in the NPR.

## Polyester

CPSC staff recommends that the Commission determine with a high degree of assurance that unfinished polyester does not contain any of the following:

- Any of the eight phthalates subject to 16 CFR part 1307 in concentrations greater than 0.1 percent.<sup>12</sup>

## Nylon

CPSC staff recommends that the Commission determine with a high degree of assurance that unfinished nylon fiber does not contain any of the following:

- Any of the ASTM F963 elements in concentrations greater than their specified solubility limits; or
- Any of the eight phthalates subject to 16 CFR part 1307 in concentrations greater than 0.1 percent.

## Polyurethane (Spandex)

CPSC staff recommends that the Commission determine with a high degree of assurance that unfinished polyurethane (spandex) fiber does not contain any of the following:

- Any of the ASTM F963 elements in concentrations greater than their specified solubility limits; or
- Any of the eight phthalates subject to 16 CFR part 1307 in concentrations greater than 0.1 percent.

## Viscose Rayon

CPSC staff recommends that the Commission determine with a high degree of assurance that unfinished viscose rayon fiber does not contain any of the following:

- Any of the ASTM F963 elements in concentrations greater than their specified solubility limits; or
- Any of the eight phthalates subject to 16 CFR part 1307 in concentrations greater than 0.1 percent.

## Acrylic and Modacrylic

CPSC staff recommends that the Commission determine with a high degree of assurance that unfinished acrylic and unfinished modacrylic fiber do not contain any of the following:

- Any of the ASTM F963 elements in concentrations greater than their specified solubility limits; or
- Any of the eight phthalates subject to 16 CFR part 1307 in concentrations greater than 0.1 percent.

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<sup>12</sup> Staff cannot recommend that the Commission determine that polyester fiber does not contain any of the ASTM F963 elements in concentrations greater than their specified solubility limits, due to findings in the contractor report regarding the use of antimony compounds in polyester manufacturing.

## Natural Rubber Latex

CPSC staff recommends that the Commission determine with a high degree of assurance that unfinished natural rubber latex fiber does not contain any of the following:

- Any of the ASTM F963 elements in concentrations greater than their specified solubility limits; or
- Any of the eight phthalates subject to 16 CFR part 1307 in concentrations greater than 0.1 percent.

## Recommended Effective Date

The proposed rule recommended a 30-day effective date for the final rule. We received no comments on the effective date. Because the determinations for the seven unfinished manufactured fibers would reduce the testing burden on certifiers of children's toys and child care articles, staff recommends that the Commission establish an effective date 30 days from the final rule's publication in the *Federal Register*.

## Tab A: Final Regulatory Flexibility Analysis

### **Draft Final Regulatory Flexibility Analysis**





UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
BETHESDA, MD 20814

**Memorandum**

**Date:** February 27, 2020

**TO:** Jacqueline Campbell, Project Manager, Directorate for Engineering Sciences, Office of Hazard Identification and Reduction

**THROUGH:** Gregory B. Rodgers, Ph.D., Associate Executive Director  
Robert L. Franklin, Senior Staff Coordinator  
Directorate for Economic Analysis

**FROM:** Charles L. Smith, Directorate for Economic Analysis

**SUBJECT:** Recommendation for Determinations Regarding Third Party Testing of Manufactured Fibers for ASTM F963 Elements and Phthalates;  
Final Regulatory Flexibility Analysis

**Background**

The Consumer Product Safety Commission (Commission) is considering a draft final rule that would establish determinations that certain unfinished<sup>13</sup> manufactured fibers do not contain: (1) any of the chemical elements that are specified in the safety standard for toys, ASTM F963, *Standard Consumer Safety Specification for Toy Safety*, incorporated in 16 CFR part 1250 in concentrations exceeding the specified limits,<sup>14</sup> or (2) any of eight specified phthalates in concentrations greater than 0.1 percent (1000 ppm) in section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) and 16 CFR part 1307.<sup>15</sup> The draft final rule would establish that unfinished polyester (polyethylene terephthalate, PET), nylon, natural latex rubber, spandex, rayon, acrylic, and modacrylic fibers do not contain the

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<sup>13</sup> 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 fire-retardancy. For unfinished fibers, as described in this memorandum and the staff recommendations, the unfinished fiber is free of these chemical additives.

<sup>14</sup> The eight ASTM F963 chemical elements are Antimony (Sb); Arsenic (As); Barium (Ba); Cadmium (Cd); Chromium (Cr); Lead (Pb); Mercury (Hg), and; Selenium (Se). The Commission has previously determined that certain products and materials do not contain lead at levels that exceed that limits for lead established under section 101 of the CPSIA. These determinations regarding lead included textiles consisting of natural and manufactured fibers (dyed or undyed). Thus, in the case of unfinished manufactured fibers, a determination regarding the need for third -party testing for lead has already been made.

<sup>15</sup> The specified phthalates are: DEHP (di-(2-ethylhexyl) phthalate); DBP (dibutyl phthalate); BBP (benzyl butyl phthalate); DINP (diisononyl phthalate); DIBP (diisobutyl phthalate); DPENP (di-n-pentyl phthalate); DHEXP (di-n-hexyl phthalate), and; DCHP (dicyclohexyl phthalate).

eight specified phthalates. The draft final rule also would establish a determination that unfinished nylon, natural rubber latex, spandex, rayon, acrylic, and modacrylic fibers do not contain the elements specified in ASTM F963.<sup>16</sup>

If the Commission makes these determinations and adopts the draft final rule, manufacturers of children's toys and child care articles<sup>17</sup> will not have to obtain third party testing for accessible component parts made of these unfinished manufactured fibers to certify that the component parts do not contain the ASTM F963 elements or the specified phthalates in excess of allowable levels. The draft final rule is part of an effort by CPSC to reduce the cost of third party testing requirements that are consistent with assuring compliance with the applicable children's product safety rules. Section 14 of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires that manufacturers and importers certify that their children's products comply with all applicable children's product safety rules, based on results of third party testing.

CPSC staff recommended that the Commission propose these determinations based on an extensive literature review<sup>18</sup> of information on the raw materials used in the manufacture of the specified manufactured fibers, the worldwide manufacturing practices for these fibers, the typical applications, and the potential for exposure to the ASTM F963 elements and the specified phthalates through the use of recycled materials or due to contamination.

The Regulatory Flexibility Act<sup>19</sup> (RFA) requires that agencies review rules for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires agencies to prepare a final regulatory flexibility analysis, describing the impact of the rule on small entities. The final regulatory flexibility analysis is to contain:

- 1) a statement of the need for, and objectives of, the rule;
- 2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- 3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
- 4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- 5) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for the preparation of the

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<sup>16</sup> CPSC Staff does not recommend that the Commission determine that polyester fiber does not contain any of the ASTM F963 elements in concentrations greater than their specified solubility limits, due to findings that antimony compounds can be used in manufacturing polyester.

<sup>17</sup> Under section 108(e)(1)(C) of the CPSIA, the term "child care article" means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.

<sup>18</sup> CPSC contracted with Toxicology Excellence for Risk Assessment (TERA) to conduct the literature reviews on the production of certain undyed manufactured fibers and to evaluate whether the specified manufactured fibers potentially contain the ASTM F963 elements or the phthalates of interest.

<sup>19</sup> 5 U.S.C. §§ 601 – 612.

report or record; and

6) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including 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.

According to the Small Business Administration's Office of Advocacy, "Congress considered the term 'significant' to be neutral with respect to whether the impact is beneficial or harmful to small businesses. Under this interpretation, agencies need to consider both beneficial and adverse impacts in an analysis."<sup>20</sup> The SBA guidance may seem counterintuitive in that burden reduction, although beneficial, could still be found to have a significant economic impact on a substantial number of small businesses. However, the SBA guidance states in a footnote, ". . . an agency cannot certify a proposed rule if the economic impact will be significant but positive."<sup>21</sup> Therefore, although the draft final rule would have a positive impact on small entities, staff has prepared a final regulatory flexibility analysis.

### **Why the Commission Is Considering this Action**

The Commission is considering this draft final rule to reduce the burden of third party testing on manufacturers of children's toys and child care articles, especially the burden on firms that are small businesses. Based on an extensive literature review, CPSC staff has concluded that there is a high degree of assurance that the specified unfinished manufactured fibers will not contain any of eight specified phthalates in concentrations greater than 0.1 percent when used in children's toys and child care articles, and, with the exception of polyester fibers, any of the chemical elements that are specified in the ASTM F963 standard for toys in concentrations exceeding the specified limits. Therefore, there is no safety benefit requiring manufacturers to incur the expense of third party testing to certify that components made from these unfinished manufactured fibers do not contain the prohibited phthalates or chemical elements.

### **Objectives and Legal Basis of the Rule**

The objective of the draft final rule is to reduce the burden of third party testing on manufacturers of children's toys and child care articles, consistent with assuring compliance with CPSC requirements. The legal basis is section 14(d)(3) of the CPSA, as amended by Public Law No. 112-28.

### **Issues Raised by Public Comments or by the Chief Counsel for Advocacy of the Small Business Administration**

No significant issues were raised by commenters or the Chief Counsel for Advocacy of the SBA. We received one public comment relevant to the NPR. This commenter, who reportedly works with small batch manufacturers, urged approval of the proposed rule. The commenter stated that the small businesses that create unique items from home to sell on various online commerce platforms could benefit from the reduced financial burden of testing. The commenter did not provide data or other specific comments or suggestions on the proposed rule,

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<sup>20</sup> SBA Office of Advocacy, "A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act," August 2017, p. 23. Accessed at: <https://www.sba.gov/sites/default/files/advocacy/How-to-Comply-with-the-RFA-WEB.pdf>.

<sup>21</sup> Ibid. p.20, footnote 70.



however.

### **Small Entities to Which the Rule Would Apply**

The draft final rule would apply to small entities that manufacture or import children's toys and child care articles that contain the specified manufactured fibers. The subjects of these determinations—the specified phthalates and the chemical elements in the ASTM F963 toy safety standard—relate to the particular children's products specified in the respective requirements. The phthalates prohibitions apply to children's toys and child care articles. Regarding the specified manufactured fibers (or yarns or fabrics) in the children's toy category, products potentially affected by a Commission determination about phthalate content may include coverings or fill of stuffed, plush, or other soft toys, doll clothes, puzzle mats or other play mats, and other similar toys. Under the child care article category, products potentially affected by a Commission determination about phthalate content may include sleepwear, bibs, and other products that facilitate sleeping or feeding. The chemical requirements in the ASTM F963 toy safety standard cover accessible substrates of toys that can be sucked, mouthed, or ingested. Among the uses of specified manufactured fibers (or yarns or fabrics) could be in coverings or fill of stuffed, plush, or other soft toys, doll clothes, puzzle mats or other play mats, and other similar toys.

The rule would apply to small entities that manufacture or import children's toys or child care articles that contain accessible polyester (polyethylene terephthalate, PET), nylon, natural latex rubber, spandex, rayon, acrylic, and modacrylic component parts. Toy manufacturers are classified in North American Industry Classification System (NAICS) category 339930 (Doll, Toy, and Game Manufacturing). According to the U.S. Bureau of the Census, in 2016, there were 548 toy manufacturers in the United States, of which 543 had fewer than 500 employees and would be considered small entities according to the SBA criteria.<sup>22</sup> Of the small manufacturers, 338 had fewer than five employees.

Toy importers may be either wholesale merchants or retailers. The draft final rule would not apply to toy wholesalers or retailers if they obtain their merchandise from domestic manufacturers or importers and do not import toys or child care articles themselves. Toy wholesalers are classified in NAICS category 423920 (Toy and Hobby Goods and Supplies Merchant Wholesalers). According to the U.S. Bureau of the Census, there were 1,979 firms in this category in 2016. Of these, 1,904 had fewer than 100 employees and would be considered small businesses, according to SBA criteria. Toy retailers are classified in NAICS category 451120 (Hobby, Toy, and Game Stores). There could be about 4,536 toy retailers that would meet the SBA criteria to be considered a small entity.<sup>23</sup> Although importers are responsible for certifying the children's products that they import, they may rely upon third party testing

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<sup>22</sup> U.S. Bureau of the Census, "Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2016," County Business Patterns. Available at: [https://www2.census.gov/programs-surveys/susb/tables/2016/us\\_6digitnaics\\_2016.xlsx](https://www2.census.gov/programs-surveys/susb/tables/2016/us_6digitnaics_2016.xlsx).

<sup>23</sup> The SBA considers a toy retailer (NAICS 451120) to be a small entity if its annual sales are less than \$27.5 million. According to the U.S. Bureau of the Census, in 2012, the average receipts for toy manufacturers with more than 500 employees was almost \$900 million. The average receipts for the next largest category for which summary data were published, toy retailers with at least 100, but fewer than 500 employees, was about \$10 million (U.S. Census Bureau, Number of Firms, Number of Establishments, Employment, Annual Payroll, and Estimated Receipts by Enterprise Employment Size for the United States, All Industries: 2012.) The U.S. Census Bureau reports that there were 4,536 toy retailers with fewer than 500 employees in 2016 (U.S. Census Bureau, *op. cit.*).

arranged by their foreign suppliers to certify. Staff does not know the number of small toy wholesalers or retailers that import toys, as opposed to obtaining their product from domestic sources. Staff also does not know the number of small importers that must obtain or pay for the third party testing of their products.

The phthalates regulation also applies to manufacturers and importers of child care articles. Child care articles include many types of products, for which the CPSC has recently promulgated or proposed new or amended mandatory safety standards. Under the child care article category, products potentially affected by a Commission determination about phthalate content of unfinished manufactured fibers may include bedside sleepers, sleepwear, bibs, and other products that facilitate sleep or feeding, or to help such children with sucking or teething. Several types of these child care products likely use the types of manufactured fibers that are addressed by the draft final rule. In its recent market research, CPSC staff identified 364 suppliers of these products that would be considered small according to criteria established by the SBA.<sup>24</sup> Additionally, there could be other child care articles, not listed above, for which CPSC has not yet developed a mandatory or proposed standard, but which, nevertheless, are covered by the phthalate requirements.

Although the number of small businesses that supply children's toys or child care articles to the U.S. market might be close to 10,000, staff does not know the number that actually supply products with the unfinished manufactured fibers in accessible component parts. Staff also does not know the number of children's toys and child care articles that contain these fibers. 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, staff believes that a substantial number of small entities could be positively impacted by the draft final rule.

### **Reporting, Recordkeeping and Other Compliance Requirements and Impact on Small Businesses**

The draft final rule would not impose any reporting, recordkeeping, or other compliance requirements on small entities. In fact, the draft proposed rule would eliminate a requirement that third party testing be done, resulting in 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 the specified unfinished manufactured fibers.

The impact of the determinations on small businesses would be to reduce the burden of third party testing for the ASTM F963 elements, and the specified phthalates and would be expected to be entirely beneficial. Based on published invoices and price lists, the cost of a third party test using inductively coupled plasma atomic emission spectroscopy (ICP-AES) testing for the ASTM F963 elements, ranges from around \$60 in China, up to around \$190 in the United States. 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.

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<sup>24</sup> Krishnan, Charu S., Memorandum: Determinations that Certain Plastics Will Not Contain Specified Phthalates: Regulatory Flexibility Analysis, Directorate for Economic Analysis, CPSC. June 26, 2017.

The cost of phthalate testing is 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.

Moreover, 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 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; 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 manufactured fibers could significantly benefit a substantial number of firms.

On the other hand, there are reasons to believe that the benefit of making the determinations could be less than staff expects. Although the manufactured fibers are widely used, the determinations are limited to unfinished fibers, which might be less widely used. Additionally, some firms might have been able to reduce their third party testing costs substantially by using component part testing as allowed by 16 CFR 1109. Accordingly, the marginal benefit to manufacturers from making the determinations might be low. 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 know whether fibers are unfinished; so they might opt to conduct the testing anyway, to ensure that the products do not violate the requirements.

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 we solicited public comments on the potential impact of the draft proposed rule on small entities were solicited, we received just one comment 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, the commenter did not provide specific estimates of the benefits to small businesses.

### **Federal Rules Which May Duplicate, Overlap or Conflict with the Draft Final Rule**

We have not identified any federal rules that duplicate or conflict with the draft final rule.

### **Steps the Agency Has Taken to Minimize the Significant Impact on Small Entities**

Under section 603(c) of the Regulatory Flexibility Act, 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." The draft final rule is itself the result of CPSC's efforts to reduce third party testing costs consistent with assuring compliance with all applicable

consumer product safety rules. Because the draft final 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 other alternatives to this specific draft final rule.