



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 4330 EAST WEST HIGHWAY
 BETHESDA, MD 20814

This document has been electronically approved and signed.

BALLOT VOTE SHEET

Date: September 18, 2019

TO : The Commission
 Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
 Mary T. Boyle, Executive Director

FROM : Patricia M. Pollitzer, Assistant General Counsel
 David M. DiMatteo, Attorney

SUBJECT : Draft Notice of Proposed Rulemaking: *Children's Toys and Child Care Articles: Determinations Regarding ASTM F963 Elements and Phthalates for Unfinished Manufactured Fibers*

BALLOT VOTE DATE: Tuesday, September 24, 2019

Staff is forwarding to the Commission a memorandum recommending that the Commission issue a notice of proposed rulemaking (NPR) 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 proposed 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 NPR 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.

(Signature)

(Date)

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

(Signature)

(Date)

IV. Take other action specified below.

(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-2019-00XX]

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: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (CPSC) is proposing a rule to determine that certain unfinished manufactured fibers would 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 proposed 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: Submit comments by **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2019-00XX by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: www.regulations.gov. Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (e-mail), except through

www.regulations.gov. The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: www.regulations.gov, and insert the docket number CPSC-2019-00XX, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Jacqueline Campbell, Senior Textile Technologist, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850: telephone 301-987-2024; email: jcampbell@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. Third Party Testing and Burden Reduction

Section 14(a) of the Consumer Product Safety Act, (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires that manufacturers of products subject to a consumer product safety rule or similar rule, ban, standard, or regulation enforced by the CPSC, must certify that the product complies with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). For children’s products, 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. If the Commission determines that such materials will comply with CPSC’s requirements with a high degree of assurance, manufacturers do not need to have those materials tested by a third party testing laboratory to issue a Children’s Product Certificate (CPC).

2. ASTM F963 Elements

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

Section 4.3.5 of ASTM F963 requires that surface coating materials and accessible substrates of children’s toys that can be sucked, mouthed, or ingested² must comply with the 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 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) ³
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

³ The method to assess the solubility of a listed element is detailed in section 8.3.2, *Method to Dissolve Soluble Matter for Surface Coatings*, of ASTM F963. Modeling clays included as part of a toy have different solubility limits for several of the elements.

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.

B. Contractor's Research

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 concentrations⁴ 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*

⁴ 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).

Manufactured Fibers and their Colorants (the report, Task 17).⁵ TERA’s Task 17 report formed the basis for the proposed unfinished manufactured fiber determinations. For more detailed information on the Task 17 report and staff analysis please see the staff briefing package. **[INSERT LINK]**.

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.

C. CPSC Staff Analysis of TERA Task 17 Report

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 TERA report found one significant use of an ASTM element in unfinished manufactured fibers: antimony in the production of polyester (PET) fibers at

⁵ 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>.

concentrations of about 150–300 ppm, amounts that would exceed the solubility limit specified in ASTM F963. Staff does not have information identifying the amount of the antimony that is soluble when tested according to ASTM F963. PET fiber is widely used in consumer textile products, including children’s toys. The contractor report did not identify any other instances of the use of ASTM elements or phthalates in the routine manufacturing processes for the specified unfinished fibers.

Compliance to the ASTM F963 standard can be demonstrated by measuring the chemical content of a material—if the total content for a specific element does not exceed the solubility limit, then it must be the case that the solubility requirement is met. Because information about solubility or migration of chemicals from products or materials is rarely available in the scientific literature or other data sources, staff relies on information about chemical content to understand possible uses and presence of chemicals in products. If sufficient solubility testing data were available, especially if data show low levels of migration, such data may help inform decisions about testing requirements under the ASTM F963 standard.

In addition to intentional use of the specified chemicals, staff considered whether contaminants or impurities may be present in unfinished fibers, yarns, or fabrics. In the review of the contractor report, the reports referenced by the contractor, and other reference materials, staff has not found any information or data that suggest contaminants would be present in fibers at significant levels. Reported contaminant levels, such as for arsenic, chromium, mercury, or cadmium, are no higher than a few parts per million. Staff believes that contaminants or impurities are unintentional (*i.e.*, not added by the manufacturer intentionally), and largely represent the ubiquity of some substances in the

environment at trace levels or general industrial practices and conditions. Given the available data and staff's understanding of the raw materials and manufacturing practices for the fibers currently under consideration, staff concludes that any impurities will be at levels well below the relevant limits for this proceeding.

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

Colorants, such as dyes, often contain metals in their structure. The contractor report cited 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 report cited the potential use of some of the specified phthalates as dye auxiliaries or carriers for pigments. Although some of the findings may have been with products not necessarily within the scope of the subject rules, the mechanism by which colorants are applied to fibers could be extended to those products.

Finishes may also be added at the fiber (yarn or fabric) stage to impart desirable characteristics. The contractor report highlighted the use of antimony compounds as flame retardants. Other chemicals of interest may be used in finished fiber (yarn or fabric); however, those finishes were not within the scope of the contractor report, and more information is necessary to consider whether determinations for finished fiber (yarn or fabric) are appropriate. Staff notes that in the case of the ASTM elements

(excluding lead, which has separate specific restrictions under the CPSIA), the restriction in the ASTM F963 standard is based on solubility; *i.e.*, migration of the elements from the product or material.

Recycled Content

TERA did not examine the potential use of recycled materials in the subject manufactured fibers. Staff is aware that recycled content is present in some textile fibers; however, staff does not know the extent to which recycled content can be expected in products within the scope of the ASTM F963 elements or phthalates requirements. Due to findings in the contractor report on colorants and finishes in manufactured fibers, staff does not recommend determinations for fibers with recycled content unless such content was from unfinished recycled materials.

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 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 part 1107 section 1107.2, “a high degree of assurance” is defined as “an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.”

For accessible component parts of children’s 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 intended to require compliance. The presence of these chemicals, whether for any functional purpose, as a trace material, or as a contaminant, must be in concentrations less than the specified content or solubility limits for the material to be compliant. Additionally, the manufacturer or importer must have a high degree of assurance that the product has not been adulterated or contaminated to an extent that would render it noncompliant. For example, if a manufacturer or importer is relying on a determination that 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 proposed 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 proposed determinations 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.

The six unfinished manufactured fibers for which determinations are proposed for the ASTM F963 elements are: 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 C. of the preamble, the Commission is proposing determinations that there is a high degree of assurance that these unfinished manufactured fibers will not contain the ASTM F963 elements in concentrations greater than their specified limits. We note that based on staff’s review of the Task 17 report we are not proposing a determination that polyester (PET) 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.

The Commission is also proposing 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.

Based on staff’s review of the TERA report as discussed in section C. of the preamble, the Commission is proposing determinations that there is a high degree of assurance that these unfinished manufactured fibers will not contain the prohibited phthalates in concentrations greater than their specified limits.

These determinations would 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 proposes to make these determinations to reduce the third party testing burden on children’s product certifiers while continuing to assure compliance.

2. Statutory Authority

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. Public Law 110-314, sec. 3, Aug. 14, 2008. Section 14 of the CPSA, which was amended by the CPSIA, requires third party testing for children’s products subject to a children’s product safety rule. 15 U.S.C. 2063(a)(2). Section 14(d)(3)(B) of the CPSA, as amended by Public Law 112-28, gives the Commission the authority to “prescribe new or revised third party testing regulations if it determines that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.” *Id.* 2063(d)(3)(B). These statutory provisions authorize the Commission to propose a rule determining that certain unfinished manufactured fibers do not contain the ASTM F963 elements and the specified prohibited phthalates in concentrations greater than their 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 proposed determinations would relieve manufacturers using the specified unfinished manufactured fibers from the third party testing requirements of section 14 of the CPSIA for purposes of supporting the required certification. However, the proposed determinations would not be applicable to any other manufactured fibers beyond those listed in the proposed rule. The proposed determinations would only relieve the manufacturers' 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 Proposed Rule

This proposed rule would create 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 proposed rule would determine 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 proposed rule explains the statutorily-created requirements for limiting the ASTM F963 elements in children's toys under the CPSIA and the third party testing requirements for children's toys.

Section 1253.1(b) of the proposed 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 proposed rule would provide a definition of the term unfinished manufactured fiber that would apply to part 1253.

Section 1253.2(b) of the proposed rule would establish 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 proposed rule would establish 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 proposed 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 proposed § 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 proposed rule states that accessible component parts of children’s toys and child care articles that are not specifically listed in the determinations in proposed § 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.

4. Requested Comments on the Proposed Rule

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

- Are there any data or examples that indicate that the manufactured fibers identified in the proposed rule can and do contain the ASTM F963 elements (besides the identified use of antimony in PET) or prohibited phthalates at levels that are not compliant in an unfinished state? Please provide data supporting your assertion.
- The TERA Task 17 Report identified the use of antimony, an ASTM F963 element, as a catalyst used to manufacture PET. Although TERA looked for the presence and total concentration of antimony, the ASTM F963-17 requirement is for the concentration that migrates out of the subject material. Please provide any information that supports or refutes the claim that antimony will not be present in concentrations greater than the specified limits in PET fiber in an unfinished state without colorants. Please provide any information that antimony will not migrate out of polyester in concentrations greater than the specified limits in PET fiber in an unfinished state with no colorants.
- Are there any data or examples that the colorants or other finishes used for the manufactured fibers identified in the proposed rule never contain the ASTM F963 elements or prohibited phthalates at levels that are not compliant? Please provide data supporting your assertion. These data may be by type of dye, a specific dye, by fiber type, or some other relevant grouping.

- Are there any data or examples that the use of recycled content in the manufactured fibers identified in the proposed rule never contain the ASTM F963 elements or prohibited phthalates at levels that are not compliant? Please provide data supporting your assertion. These data may be by fiber type, product type, or some other relevant grouping.
- In addition to the manufactured fibers within scope of this study, are there other manufactured fibers widely used in children’s toys and childcare articles that have not been identified in the proposed rule that do not, and will not contain the ASTM F963 elements or prohibited phthalates? Please provide supporting data to show that these manufactured fibers do not and will not contain the ASTM F963 elements or prohibited phthalates in concentrations above the mandatory limits?

E. Effective Date

The Administrative Procedure Act (APA) generally requires that a substantive rule must be published not less than 30 days before its effective date. 5 U.S.C. 553(d)(1). Because the proposed rule would provide relief from existing testing requirements under the CPSIA, the Commission proposes a 30 day effective date for the final rule.

F. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule’s potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency is required to publish a notice of proposed rulemaking, unless

the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives which accomplish the statutory objectives and may reduce the significant economic impact of the proposed rule on small entities. We provide a summary of the IRFA.

2. Small Entities to Which the Proposed Rule Would Apply

The proposed rule would apply to small entities that manufacture or import children's toys and child care articles that contain the specified manufactured fibers. The chemical elements in the ASTM F963 toy safety standard and the specified phthalates apply 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. 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.

The rule would apply to small entities that manufacture or import children's toys

or child care articles that contain accessible polyester (PET), nylon, natural latex rubber, polyurethane (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 2015 there were 566 toy manufacturers in the United States, of which 562 had fewer than 500 employees and would be considered small entities according to the SBA criteria.⁶ Of the small manufacturers, 347 had fewer than five employees.

Toy importers may be either wholesale merchants or retailers. The proposed 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 2,009 firms in this category in 2015. Of these, 1,937 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 4,632 toy retailers that would meet the SBA criteria to be considered a small entity.⁷ Although importers are responsible for certifying the

⁶ 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: 2015,” County Business Patterns. Available at: https://www2.census.gov/programs-surveys/susb/tables/2015/us_6digitnaics_2015.xlsx

⁷ 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. There were 4,647 firms in this NAICS category, of which 4,632 had fewer than 500 employees. (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.)

children’s products that they import, they may rely upon third party testing performed by their foreign suppliers for purposes of certification. We do not know the number of small toy wholesalers or retailers that import toys, as opposed to obtaining their product from domestic sources. We also do 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. Several types of these child care products likely use the types of manufactured fibers that are addressed by the proposed 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.⁸ 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, we do not know the number that actually supply products with the unfinished manufactured fibers in accessible component parts. We also do not know the number of children’s toys and child care articles that contain these fibers. Nevertheless, based on the number of domestic toy

⁸ Krishnan, Charu S., Memorandum: Determinations that Certain Plastics Will Not Contain Specified Phthalates: Regulatory Flexibility Analysis, Directorate for Economic Analysis, CPSC. June 26, 2017.

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, we believe a substantial number of small entities would be positively impacted by the proposed rule.

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

The proposed rule would not impose any reporting, recordkeeping, or other compliance requirements on small entities. In fact, the 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 for the ASTM F963 elements ranges from around \$60 in China, up to around \$190 in the United States using Inductively Coupled Plasma (ICP) testing. 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.

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.

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

However, it is possible 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 substantially reduce their third party testing costs by using component part testing as allowed by 16 CFR 1109, so the marginal benefit to manufacturers from making the determinations might be low. Also, some firms have reduced their testing costs by using XRF or HDXRF technology, which is less expensive than ICP, and would reduce the marginal benefit of these determinations. 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 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. Therefore, we cannot determine whether the reduced burden would be significant for a substantial number of the small entities. We welcome public comments on the potential impact of the proposed rule on small entities. Comments are especially welcome on the following topics:

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

4. Alternatives Considered to Reduce the Burden on Small Entities

Under section 603(c) of the RFA, an initial regulatory flexibility analysis should “contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any

significant impact of the proposed rule on small entities.” Because the proposed rule is intended to reduce the cost of third party testing on small businesses and will not impose any additional burden, the Commission did not consider alternatives to the proposed rule that would reduce the burden of this rule on small businesses.

G. Environmental Considerations

The Commission’s regulations provide a categorical exclusion for Commission rules from any requirement to prepare an environmental assessment or an environmental impact statement because they “have little or no potential for affecting the human environment.” 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required. The Commission’s regulations state that safety standards for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this rule alters that expectation.

List of Subjects in 16 CFR Part 1253

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

For the reasons stated in the preamble, the Commission proposes to amend title 16 of the CFR to add part 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 the provisions of ASTM F963, Consumer Product Safety Specifications for Toy Safety, a mandatory consumer product safety standard. Among the mandated provisions is section 4.3.5 of ASTM F963, which requires that surface coating materials and accessible substrates of children’s toys that can be sucked, mouthed, or ingested, must comply with solubility limits that the toy standard establishes for eight elements. Materials used in children’s toys subject to section 4.3.5 of the toy standard must comply with the third party testing requirements of section 14(a)(2) of the CPSA, unless listed in 16 CFR 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 16 CFR 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.

Dated: _____

Alberta E. Mills, Secretary
Consumer Product Safety Commission



Briefing Package

Recommendation for Determinations Regarding Third Party Testing of Manufactured Fibers for the ASTM F963 Elements and Phthalates

September 18, 2019

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.

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: September 18, 2019

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
Mary T. Boyle, Executive Director
DeWane Ray, Deputy Executive Director for Safety Operations

FROM: Duane E. Boniface, Acting 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 : Recommendation for Determinations Regarding Third Party Testing of Manufactured Fibers for the ASTM F963 Elements and Phthalates

Executive Summary

CPSC contracted with Toxicology Excellence for Risk Assessment (TERA) to conduct literature reviews on the production of certain undyed manufactured fibers¹ 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.

CPSC staff recommends that the Commission issue a proposed rule determining that certain unfinished² manufactured fibers do not contain any of the specified ASTM F963 elements in

¹ 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.

² 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

excess of specified concentrations and any of the specified phthalates in concentrations greater than 0.1 percent (1000 ppm). If the Commission makes this determination, then accessible component parts of children's toys and child care articles subject to sections 106 and 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) that are made with these manufactured fibers would not require third party testing for certification purposes.³ Examples of the specified manufactured fibers used in the children's toy products potentially affected by a Commission determination for ASTM F963 elements content may include coverings for or filler in stuffed, plush, or other soft toys, doll clothes, puzzle mats or other play mats, and other similar toys. Examples of child care articles potentially affected by a Commission determination for phthalate content may include sleepwear, bibs, and other products that facilitate sleeping or feeding.

Under the draft proposed rule, 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.

Staff recommends that the Commission propose to determine 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 was only able to make these recommendations for unfinished fibers because the TERA report documented positive findings for the use of the ASTM F963 elements and specified phthalates in finished fibers.

Introduction

Section 14(a)(2) of the Consumer Product Safety Act (CPSA),⁴ as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA),⁵ requires that manufacturers of children's products subject to an applicable rule, ban, standard or regulation must have their products tested by a third party testing body for compliance. 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:

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.

³ 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.

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

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

. . . 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.

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).⁶ 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, those parts may be declared on a certificate at the component level.

ASTM F963 Elements

Section 106 of the CPSIA states that the provisions of ASTM International (ASTM) *Standard Consumer Safety Specifications for Toy Safety* (ASTM F963, toy standard) “shall be considered to be consumer product safety standards issued by the Commission under section 9 of the CPSA (15 U.S.C. § 2058).”⁷ Thus, toys⁸ subject to ASTM F963⁹ must meet the toy standards’ requirements, and manufacturers (or importers) must certify the toys’ compliance with the toy standard based on testing conducted by a CPSC-accepted third party laboratory. Before the toys can enter commerce, the domestic manufacturer or importer must issue a Children’s Product Certificate (CPC).

Section 4.3.5 of ASTM F963-17 requires that surface coating materials and accessible substrates of toys that can be sucked, mouthed, or ingested,¹⁰ must comply with the solubility limits of eight elements given in Table 1 of the toy standard. The materials and their solubility limits are shown in Table 1 of this document.

⁶ 76 FR 69546.

⁷ ASTM F963-17 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.

⁸ A “children’s toy” is defined in section 1.3 of ASTM F963-17 as any object designed, manufactured, or marketed as a plaything for children under 14 years of age. However, the term “children’s toy” is defined in section 108(e)(1)(B) of the CPSIA as a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays. Only toys intended for a child 12 years of age or younger are subject to certification requirements.

⁹ While the TERA report focused on the -11 version of ASTM F963, the current version at the time, the currently accepted version is ASTM F963-17. There are no changes to the content requirements from the -11 to the -17 version, but there was a change to the testing method for the specified elements to allow High-Definition X-Ray Fluorescence Spectroscopy (HDXRF) for total element screening. See section 8.3.1.4 of ASTM F963-17.

¹⁰ ASTM F963-17 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 toys or parts likely to be sucked, mouthed or ingested: (1) All toy parts intended to be mouthed or contact food or drink, components of toys which are cosmetics, and components of writing instruments categorized as toys; (2) Toys intended for children less than 6 years of age, that is, all accessible parts and components where there is a probability that those parts and components may come into contact with the mouth.

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) ¹¹
Antimony (Sb)	60
Arsenic (As)	25
Barium (Ba)	1000
Cadmium (Cd)	75
Chromium (Cr)	60
Lead (Pb) ¹²	90
Mercury (Hg)	60
Selenium (Se)	500

To reduce third party testing burdens, all eight elements in Table 1 must have concentrations below their solubility limits. Because laboratories typically run one test for all of the ASTM F963 elements, if any one of the eight elements is present, companies must conduct compliance testing. CPSC staff recognizes that some consumer products made from manufactured fibers will likely contain colorants, and potentially, other finishes that are added to or applied onto the fibers at a later stage of processing. Those additional materials fall outside the scope of this proposed determination and would require third party testing for compliance with the ASTM F963 elements requirements.

Phthalates

Section 108 of the CPSIA originally prohibited children’s toys and child care articles¹³ with greater than 0.1 percent of six specified phthalates in “accessible¹⁴ plasticized component parts and other component parts made of materials that may contain phthalates.” On October 27, 2017, the Commission issued a rule under section 108 of the CPSIA that made certain changes to the phthalate restrictions.¹⁵ Effective April 25, 2018, children’s toys and child care articles

¹¹ The method to assess the solubility of a listed element is detailed in section 8.3.2, *Method to Dissolve Soluble Matter for Surface Coatings*, of ASTM F963-17. Modeling clays included as part of a toy have different solubility limits for several of the elements.

¹² Lead is not included in the scope of this proceeding. 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 lead determinations include textiles consisting of natural and manufactured fibers (dyed or undyed). 16 CFR § 1500.91.

¹³ 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.

¹⁴ Public Law No. 112–28 amended section 108(d) of the CPSIA to provide an exclusion for certain products containing inaccessible phthalates in component parts. The Commission adopted the same guidance for inaccessible phthalates that was adopted by the Commission for inaccessible lead. See [16 CFR part 1199](#).

¹⁵ 16 CFR part 1307; 82 FR 49938. Available at: <https://www.federalregister.gov/documents/2017/10/27/2017-23267/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates>.

containing any of the following eight phthalates at concentrations greater than 0.1 percent are prohibited (Table 3).

Table 3: Phthalates Prohibited in Children’s Toys and Child Care Articles in Concentrations Greater than 0.1 Percent	
Phthalate	CASRN
DEHP: di-(2-ethylhexyl) phthalate	117-81-7
DBP: dibutyl phthalate	84-74-2
BBP: benzyl butyl phthalate	85-68-7
DINP: diisononyl phthalate	28553-12-0, 68515-48-0
DIBP: diisobutyl phthalate	84-69-5
DPENP: di-n-pentyl phthalate	131-18-0
DHEXP: di-n-hexyl phthalate	84-75-3
DCHP: dicyclohexyl phthalate	84-61-7

Phthalates generally are not naturally occurring materials, but are intentionally created and used in specific applications (*e.g.*, plastics, surface coatings, solvents, inks, adhesives, and some rubberized materials). Phthalates are mainly used as plasticizers, especially in polyvinyl chloride plastic materials.¹⁶ As for manufactured fibers (or yarns or fabrics), phthalates may have utility as solvents or carriers for dyes, pigments, or other materials used in manufacturing, processing, or finishing.

Tests for phthalate concentration are among the most expensive certification tests to conduct on a children’s product. Each accessible component part subject to section 108 of the CPSIA must be tested.¹⁷ Third party testing burden reductions can occur only if the concentration of every specified phthalate is below 0.1 percent (1000 ppm). Because laboratories typically run one test for all of the specified phthalates, staff assumes that no testing burden reduction is achieved if a product requires compliance testing for any one of the phthalates. CPSC staff recognizes that some consumer products made from manufactured fibers will likely contain colorants and potentially, other finishes that are added to or applied onto the fiber (or yarn or fabric) at a later stage of processing. Those additional materials fall outside the scope of this proposed determination and would require third party testing for compliance with the phthalates requirements.

¹⁶ The Merriam-Webster online dictionary defines a “plasticizer” as “a chemical added especially to rubbers and resins to impart flexibility, workability, or stretchability.”

¹⁷ Test costs for the content of all the specified phthalates have been reported to range from \$125 to \$350 per component, depending upon where the tests are conducted and any discounts that might apply.

Overview of TERA Research

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 concentrations¹⁸ 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).¹⁹

Overview of TERA Research Strategy

TERA used a four-tiered strategy to identify sources for review from among the “universe” of available data. For the Task 17 Report, TERA first researched authoritative sources, such as reference books and textbooks, along with Internet resources, for general information about the specified fibers, raw materials, manufacturing processes, and common dyes and the potential for the 10 specified phthalates²⁰ and ASTM elements to be present. Tier 1 relied on secondary sources to identify the “universe” of available information. Tier 2 focused on authoritative secondary sources, mostly reports and databases from federal, national, and international entities. Tier 3 entailed searches of primary literature related to the fibers, their components, and the presence of any of the specified phthalates or ASTM elements. Tier 4 involved filling in missing information or “gap searching” where certain topics with little information were targeted.

This tiered approach resulted in a comprehensive review of the available literature concerning the potential that any of the specified chemicals would be found in the seven specified fibers.

Report Findings

All of the fibers covered in this report are manufactured and do not naturally occur in a fiber state. Although their raw starting materials may differ, these fibers are generally extruded into a fiber form. In many cases, additional chemicals may be added before the extrusion process so that they are embedded in the fiber structure. To 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. For more detailed information on the chemical characteristics and manufacture of these fibers, see section 3 *Undyed Fibers* in the TERA report.

¹⁸ 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).

¹⁹ 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>.

²⁰ The TERA report included 10 phthalates to cover the existing phthalates under regulation at the time of the report, plus any potential phthalates that could be included in the final phthalate rule. The final rule, which published on October 27, 2017, covered eight phthalates, and these eight were included in the TERA report.

Polyester

Polyester refers to a group of polymers with an ester functional group in the backbone. As summarized by TERA, polyester fibers used in the textile industry are mainly semi-aromatic polyesters, produced with aromatic dicarboxylic acids, such as terephthalic acid, phthalic acid or anhydride, and naphthalene dicarboxylic acid. “Polyester” is often used to refer specifically to polyethylene terephthalate (PET or PETE), the most widely used polyester fiber, but the term also includes polytrimethylene terephthalate (PTT), polyethylene naphthalate (PEN), and polybutylene terephthalate (PBT). TERA research focused on PET for this effort as it is the fiber most used in consumer products, as specified by the CPSC contract.

Polyester fibers generally exhibit hydrophobicity (*i.e.*, they are water repellent), high resistance to bending deformations and abrasion, and resistance to oxidizing and reducing agents and other damage from common chemicals.

TERA reports that the raw materials used to produce polyester fibers and undyed polyester textile fabrics include:

- *Monomers*: dimethyl terephthalate (DMT); terephthalic acid (TPA); ethylene glycol (EG); 1,3-propanediol (PDO); 2,6-naphthalene dicarboxylic acid dimethyl ester (2,6-NDC); 2,6-naphthalene dicarboxylic acid (2,6-NDCA); 1,4-butanediol (BDO)
- *Initiators/catalysts/reaction accelerators*: zinc acetate; zinc chloride; calcium acetate; manganese acetate; antimony trioxide; antimony acetate; antimony pentoxide; antimony triacetate; germanium dioxide; lead; stannous (tin) octanoate; tin oxalate; tetrabutyl titanate; dibutyltin oxide; sodium methoxide
- *Dispersing agents*: soap powder; Turkey Red Oil (sulphated castor oil); alkylsulfates; alkylarylsulfonates; fatty alcohol ethylene oxide condensates; naphthalene- β -sulfonate; formaldehyde; ligninsulfonates; alkyl naphthalene formaldehyde condensates; sodium oleyl-p-anisidide sulphonate; polycondensates of arylsulfonic acids with formaldehyde; condensation products of naphthalene-beta-sulfonate and formaldehyde; the product obtained by condensing cresol with formaldehyde in the presence of sodium sulfite and further condensing with beta-naphthol-6-sulfonic acid
- *Crystallization of PEN prepolymer*: a low molar mass poly(ethylene); a low molar mass poly(amide); poly(1,4-butylene sebacate)
- *Stabilizers*: phosphates; phosphonates; phosphonic acid
- *Antioxidants*: sterically hindered phenols
- *Lubricants*: vegetable and mineral oils (unspecified); finishing oils (unspecified); 4-ethyl-4-hexadecyl morpholinium ethyl sulfate
- *Ultraviolet (UV) stabilizers or absorbers*: sterically hindered phenols; benzotriazole; hydroxybenzophenones
- *Fillers*: titanium dioxide; carbon black.

Although the specific raw materials and some steps of the manufacturing processes differ for the four main polyester types (PET, PTT, PEN, PBT), the general process is similar for all four.

Notably, the manufacturing process for PET and the other polyester types commonly uses antimony compounds as catalysts. One reference²¹ summarized by TERA indicated that,

²¹ Thiele UK. 2004. Raw Materials – Quo vadis polyester catalyst? Chem Fibers Int, 54:162-163.

worldwide, more than 90 percent of polyester is manufactured using antimony-based catalysts at concentrations of 150–300 ppm antimony. In general, catalysts for chemical reactions do not become part of the resulting reaction product. In many cases, catalysts are recovered from the reaction vessels and reused or otherwise disposed. However, it is also possible that some amount of catalyst may remain in the finished material. In this case, it is possible that some of the antimony-based catalyst may remain in the polyester fiber.

Nylon

The term “nylon” is synonymous with polyamide (PA). Nylons are synthetic, long-chain polyamides with repeating aliphatic or semi-aromatic units connected by amide linkages. Nylon must contain “less than 85 percent of the amide groups directly connected to two aromatic groups,” according to the U.S. Federal Trade Commission.²² Aramids, polyamides with greater than or equal to 85 percent aromatic ring linkages, were not a focus of the Task 17 report.

The TERA report describes the three main processes for synthesizing nylon. The raw materials used in the production of undyed nylon fibers/textiles do not indicate the presence of phthalates or the specified elements. TERA reports that these raw materials include:

- *Monomers*: hexamethylenediamine; adipic acid; sebacic acid; decane-1, 10-dicarboxylic acid (dodecanedioic acid); azelaic acid; 1,4-diaminobutane; hexamethylenediammonium adipate; caprolactam; laurolactam; dodecanolactam; acetic caprolactam; 11-aminoundecanoic acid
- *Initiators/catalysts/reaction accelerators*: water; unspecified acid, base, or amino acid; nylon-6,6 salt; phosphoric acid; hypophosphoric acid
- *Solvents*: water; methanol
- *Molecular weight modifier or chain termination agents*: acetic acid; bislactams; bisoxazolines.

Additionally, there are three types of additives which are used to give nylon products their required characteristics:

1. Stabilizers (also referred to as endcappers), such as acetic acid, are used to limit the length of the polymer strand.
2. Branching agents (unspecified) are used to prevent the branching off of multiple polymer strands from a single location, as a linear configuration is best suited for nylon.
3. Chain extenders (also referred to as chain-couplers) connect two nylon molecules at the ends to create one longer nylon molecule. Bislactams and bisoxazolines are used for such purpose.

Polyurethane (Spandex)

The generic fiber name “spandex” is defined by the U.S. Federal Trade Commission (FTC) as: “[a] manufactured fiber in which the fiber-forming substance is a long chain synthetic polymer comprised of at least 85 percent of a segmented polyurethane.”²³ Spandex, known for its exceptional stretch and recovery, results from a reaction of a macroglycol with a diisocyanate.

²² Kirk-Othmer. 2014. Kirk-Othmer Encyclopedia of Chemical Technology. Volume 20.

²³ 16 CFR 303.7(k)

Spandex is typically used in small percentages with other fiber types to impart improved stretch performance to yarns and fabrics.

The contractor report lists the following raw materials in the manufacture of spandex:

- *Monomers*: poly(tetramethylene ether) glycol; bis(4-isocyanatophenyl) methane (or diphenylmethane-4, 4'-diisocyanate); hexamethylene diisocyanate (HDI); 3,3'-dimethyl-4,4'-biphenyl diisocyanate (TODI); adipates; polycaprolactones; polycarbonates; polyethers such as poly(oxypropylene diols) and poly(oxytetramethylene diols)
- *Solvents*: N,N-dimethylformamide; N,N-dimethylacetamide
- *Initiators/catalysts/reaction accelerators*: diazobicyclo[2.2.2]octane
- *Molecular weight controls*: low molecular weight amines (unspecified)
- *Chain extenders*: ethylene glycol; 1,4-butadiene diol; 1,6-hexanediol; hydroquinone
- *Cross-linkers*: glycerol; 2-ethyl-2-(hydroxymethyl)-1,3-propanediol
- *Stabilizers*: unspecified
- *Pigments*: unspecified.

Viscose Rayon

Rayon is a manufactured fiber made from naturally occurring starting materials, including wood pulp, cotton linters, and bamboo. The FTC defines “rayon” as “a manufactured fiber composed of regenerated cellulose, as well as manufactured fibers composed of regenerated cellulose in which substituents have replaced not more than 15 percent of the hydrogens of the hydroxyl groups.” While the contractor report focused on the most commonly used type of rayon, viscose rayon, there are several other types, such as acetate rayon, modal, cuprammonium rayon, and pyroxilin rayon.

The raw materials used for manufacturing viscose rayon are:

- *Cellulose*: a natural polymer of D-glucose from a variety of sources such as wood pulp, cotton linters, or bamboo
- *Solvents and reactants*: sodium hydroxide solution (caustic soda); carbon disulfide; sulfuric acid; zinc sulfate; sodium sulfate; water
- *Catalysts*: manganese; cobalt
- *Surface-active agent*: unspecified.

Acrylic and Modacrylic

Acrylic and Modacrylic fibers are typically made from the polymerization of acrylonitrile to create polyacrylonitrile (PAN). In the United States, “acrylic fibers” are defined as fibers containing at least 85 percent by weight of acrylonitrile monomer. Similarly, in the United States and by ISO, modacrylic fibers are defined as containing 35 to 85 percent by weight of acrylonitrile monomer; while in Europe, modacrylic fibers are defined as containing 50 to 85 percent by weight of acrylonitrile monomer. The remaining composition of acrylic fibers may consist of methyl methacrylate, methyl acrylate, vinyl acetate, vinyl chloride, or vinylidene chloride. These fibers are inert, hygroscopic, resistant to UV degradation, resistant to insect and microbiological attack, and can soften above their glass transition temperature. According to the TERA report, chemicals and materials used for creating acrylic and modacrylic fibers include:

- *Monomers*: acrylonitrile

- *Comonomers*: methyl methacrylate, methyl acrylate, vinyl acetate, vinyl chloride, vinylidene chloride
- *Solvents*: sodium thiocyanate, dimethyl sulfoxide, N,N-dimethylformamide, N,N-dimethylacetamide
- *Emulsifier*: sodium lauryl sulfate
- *Initiators/catalyst/reaction accelerators*: sodium bisulfate, ammonium persulfate, sodium persulfate, potassium persulfate, sulfur dioxide, sodium bisulfite, sodium metabisulfite, azobisisobutyronitrile, benzoyl peroxide, ammonium persulfate-sodium bisulfite-copper system, sodium chlorate, hydrogen, ferric or ferrous ion
- *Buffering agent*: sodium bicarbonate
- *Molecular weight modifier or chain termination agent*: dimethyl sulfoxide, dimethylformamide, methyl acrylate, vinyl acetate, sodium bisulfite, ethylene diamine, tetraacetic acid, tetrasodium salt (EDTA), sodium oxalate, sodium bicarbonate
- *Dispersing agent*: surfactant or soap
- *Stabilizers*: unspecified.

Natural Rubber Latex

TERA states that natural rubber latex is obtained from the Brazilian rubber tree. It is primarily the polymer of cis-1,4-polyisoprene. Natural rubber latex has high elasticity, the ability to stretch, mechanical strength, and resists aging, temperature changes, dilution, and electrolytes. TERA reports that the raw materials used to produce natural rubber latex fiber include:

- *Preservatives*: ammonia; tetramethyl thiuram and zinc oxide; formaldehyde; LATZ²⁴ latex; boric acid; sodium pentachlorophenate; sodium sulfite; sodium carbonate;
- Ammonium alginate; acetic acid; formic acid;
- Diammonium phosphate;
- *Accelerators*: dithiocarbamates (zinc diethyldithiocarbamate, zinc dibutyl dithiocarbamate); thiazole (zinc mercaptobenzothiazole); thiuram (tetramethyl thiuram disulfide);
- Sulfur;
- Clay fillers.

Colorants Used with Manufactured Fibers

As summarized by TERA, a number of chemistries and processes may be used to provide color to manufactured fibers and textiles.²⁵ The specific characteristics of the fiber determines

²⁴ LATZ=low ammonia latex concentrate.

²⁵ Unless otherwise noted in the text, the information summarized in this section is derived from the TERA report and these specific references included there:

Afirm Group. 2016. Chemical Guidance Document.

Alliance Organics. 2016. Rubber Industry.

Aspland JR. 1991. Direct dyes and their applications. Text Chem Color. 23(11): 41-45.

Aspland JR. 1992. Disperse dyes and their application to polyester. Text Chem Color. 24: 18-18.

Aspland JR. 1993. The structure and properties of disperse dyes and related topics. Text Chem Color. 25: 21-25.

Baptista J. 2009. The Chemistry and Manufacture of Vat Dyes.

Broadbent AD. 2001. Basic Principles of Textile Coloration. Society of Dyers and Colourists. ISBN 0 901956 76 7.

the appropriate dyes and methods used. Dyes are divided into classes based on their chemical structure and affinity for certain fiber types. Table 4 summarizes the most relevant dye classes and the fibers with affinity²⁶ for each class.²⁷

Table 4: Fiber Colorants and Dye Classes	
Colorant/Dye Class	Fiber Type
Pigments	Natural rubber latex
Acid	Nylon; spandex (limited); acrylic/modacrylic and polyester (only with modification)
Basic/Cationic	Acrylic/modacrylic; nylon and polyester (only with modification)
Direct	Rayon
Disperse	Polyester, acrylic/modacrylic, nylon; spandex (limited)
Mordant/Metal Complex	Nylon; spandex (limited)
Azoic/Naphthol	Rayon (limited); nylon and polyester (only with modification)
Reactive	Nylon, rayon
Sulfur and Vat	Rayon

The sections below discuss the dye classes relevant to the fibers within scope of the contractor report, emphasizing fiber affinity, chemical structure, and additional chemicals typically used in the dyeing process (dye auxiliaries).

Chakraborty A, Saha PS, Datta C. 2010. Synthesis and Application of Azo-Naphthol Dyes on Wool, Silk and Nylon Fabrics. Proceedings of the International Conference on Czech Republic.

EC (European Commission). 2003. Integrated Pollution Prevention and Control – Reference Document on Best Available Techniques for the Textile Industry.

Freeman HS, Mock GN. 2012. Dye Application, Manufacture of Dye Intermediates and Dyes. In: Handbook of Industrial Chemistry and Biotechnology, pp 475-548. Springer US.

Greenpeace. 2005. An Overview of Textiles Processing and Related Environmental Concerns. Greenpeace Research Laboratories, Department of Biological Sciences, University of Exeter, UK.

Holme I. 2002. Recent developments in colorants for textile applications. Surface Coatings International Part B: Coatings Transactions. 85 (B4): 243-332.

Kent A. 2012. Handbook of Industrial Chemistry and Biotechnology. Springer, US. ISBN 978-0-387-27842-1.

Kirk-Othmer. 2009. Kirk-Othmer Encyclopedia of Chemical Technology. John Wiley and Sons, Inc.

Koh J. 2011. Dyeing with Disperse Dyes. INTECH Open Access Publisher.

Kolorjet. 2016. Rubber Industry.

Lacasse K, Baumann W. 2004. Textile Chemicals: Environmental Data and Facts. Springer-Verlag Berlin Heidelberg, Dortmund, Germany.

McLaughlin T. 2013. Natural latex rubber as a puppet-making material. The Puppetry Journal, p. 22-25.

Noble RJ. 1953. Latex in Industry. 2nd Ed. Palmerton Publishing Company, Inc.

NPCS Board of Consultants and Engineers. 2000. Handbook on Textile Auxiliaries, Dyes and Dye Intermediates Technology. Asia Pacific Business Press, Inc.

²⁶ The dye classes in this section will be discussed only with regard to the fiber types within the scope of the contractor report.

²⁷ For more detailed information on colorants, see section 4. *Fiber Colorants* in the contractor report.

Pigments

Although not considered dyes, pigments are used as a colorant for natural rubber latex and can be added to manufactured fibers at the molten polymer stage before fiber formation. The Color Pigment Manufacturers Association, Inc., defines “pigments” as:

... colored, black, white or fluorescent particulate organic or inorganic solids which usually are insoluble in, and essentially physically and chemically unaffected by, the vehicle or substrate in which they are incorporated. They alter appearance by selective absorption and/or by scattering of light. Pigments are usually dispersed in vehicles or substrates for application, as for instance in the manufacture of inks, paints, plastics or other polymeric materials. Pigments retain a crystal or particulate structure throughout the coloration process.²⁸

If not applied at the molten polymer stage, pigments require binders to adhere the pigment to the fiber surface.²⁹ Examples of pigments used with natural rubber latex include organic pigment powders, titanium dioxide, carbon black, fluorescent pigments, molybdenum, cadmium, zinc oxide, and bifunctional organic silicon compounds. The contractor report also notes limited evidence of the use of pigment-containing water soluble paints and dispersions and bacterial prodigiosin.³⁰ The contractor report noted a very old reference stating that antimony sulfide and chrome green are likely not used, due to the availability of better colorants. A more recent reference stated that oil-based paints could be applied to the surface of natural rubber latex, but noted that the paint did not perform well, due to flaking or other adverse effects to the latex.

Acid

Acid dyes are applied mostly to nylon fibers. Although the contractor report identified that polyester, acrylic, and modacrylic fibers are incompatible with acid dyes, it also noted that, with modification, polyester, acrylic, and modacrylic fibers may accept dyes of these types. Additionally, the contractor found very limited evidence of their use with spandex. Acid dyes non-covalently bond³¹ with fibers and are applied in an acidic, aqueous solution. These dyes are chemically characterized as azo (majority), anthraquinone, (copper) phthalocyanine, or triphenylmethane/ triarylmethane compounds. Metal-complex or mordant dyes are a subset of acid dyes, but those are discussed in a separate section below. Common dye auxiliaries are retarding agents (which slow dye uptake to promote level dyeing), surfactants (additional retarding or leveling agents), salts (sodium sulfate, sodium acetate, and ammonium sulfate, ammonia salts, phosphoric acid salts), and acids (acetic acid, formic acid, sulfuric acid, higher (hydroxy)carboxylates).

Basic

Basic dyes are cationic (positively charged) compounds applied almost exclusively to acrylic and modacrylic fibers (although the contractor report identified limited evidence discussing their use on chemically-modified nylon and polyester). Basic dyes non-covalently bond to fibers,

²⁸ Color Pigment Manufacturers Association, Inc. Available at: <https://www.pigments.org/>.

²⁹ Aspland JR. 1993. A Series on Dyeing, Chapter 14: Pigments as Textile Colorants: Pigmenting or Pigmentation. Text Chem Color. 25(10): 31-37.

³⁰ A biologically-derived natural pigment.

³¹ Chemical bonding other than through shared electrons. Non-covalent bonds are less stable than covalent bonds. <https://www.britannica.com/science/covalent-bond>

using a slightly acidic, aqueous dyebath. According to the contractor report, these dyes are chemically characterized as primarily azo and anthraquinone compounds, but some use arylcarbonium ions, tri- or diphenylmethane, triarylmethane, ketone imines, acridine, oxazine, thiazine, azine, xanthenes, polymethines, and other groups. Common dye auxiliaries are sequestrants to remove metal ions that would interfere with the dyes, wetting agents, pH adjusters, salts, and retardants or levelers.

Direct

Direct dyes are applied mostly to rayon fibers, although the contractor report identifies some limited documentation of their use on polyamide fibers, such as nylon. Direct dyes non-covalently bond to cellulosic fibers. These dyes are chemically characterized as mostly azo compounds³² and applied in neutral pH aqueous solutions due to their good solubility in water. Although most direct dyes (82 percent) are azo compounds, the contractor report stated that stilbene, oxazine, and phthalocyanine, with some thiazole and copper complex compounds, may also be direct dyes, adding that direct dyes did not differ from acid dyes, chemically, beyond the molecular weight. Common dye auxiliaries are salts, wetting agents, fixatives, retardants, and buffers. Salt compounds are used to promote dye uptake by the fiber and dyebath exhaustion.

Disperse

Disperse dyes are used with acrylic/modacrylic, nylon, and polyester fibers, with some limited use on spandex. Disperse dyes are non-ionic and have low solubility in water, thereby allowing for high affinity with hydrophobic manufactured fibers. Chemically, these dyes are made up mostly of non-ionic azo (mono and bisazo) and anthraquinone compounds (which uses a mercuric ion catalyst), with a few comprised of diphenylamine, methine, nitro, benzodifuranone, or naphthoquinone. Common dye auxiliaries are carriers or dispersants (increases the rate of dyeing), reducing agents, and proprietary auxiliaries. The contractor report notes that dimethyl phthalate (DMP), DBP, and DEHP can be used as carriers in some PET fiber blends.

Metal Complex/Mordant

While not technically a separate dye class (the contractor report noted that these dyes can be regarded as a subclass under acid, direct, and reactive dyes), these dyes are used mostly on nylon fibers, with some limited references to use on spandex fibers. These dyes are water soluble and comprised of an azo or formazan compound with a metal ion in the structure of the dye bound to a hydroxyl, carboxyl, amino, or other functional groups. Chromium is the primary metal used, but cobalt, nickel, and copper could also be used. Common dye auxiliaries are pH regulators (such as sulfuric, formic, and acetic acids, or other organic acids such as tartaric), electrolytes (sodium sulfate, ammonium acetate, ammonium sulfate) and leveling agents (mixtures of anionic and non-ionic surfactants). The contractor report notes a reference stating that metal-complex/mordant dye use is declining due to water quality standards (particularly for chromium and cobalt), and the interest in sustainable and environmentally friendly dyeing practices.

Azoic/Naphthol

³² Compounds with the azo functional group (R-N=N-R'). <https://www.sciencedirect.com/topics/chemistry/azo-compound>

Azoic/Naphthol dyes are used somewhat on rayon fibers and potentially with modified polyester and nylon fibers and may be more useful for printing on these fibers than as a dye. While the majority of dyes may be chemically classified as azo compounds, azoic/naphthol dyes lack a sulphonic acid group and require a fixation step to stabilize the dye in the fiber pores. Azoic/naphthol dyes all contain a naphthol component (derivatives of the anilides of 2-hydroxy-3-naphthoic acid), and so are also known as naphthol dyes, which are formed using caustic soda, and in some cases alcohol or formaldehyde. These dyes are water insoluble and considered dye "combinations" because the colorant is actually formed inside the pores of the textile fiber in a coupling reaction, rather than when the dye is manufactured. These dyes are not often used due to the complexity of the dyeing process.

Reactive

Reactive dyes are used on rayon and nylon fibers. These dyes are water soluble and react to form a covalent bond with hydroxyl groups on the fiber. Most reactive dyes are azo compounds, with a small amount (5 percent) comprised of anthraquinone, dioxazine, and phthalocyanine compounds. Vinylsulfone, chlorinated triazines, fluoropyrimidine, or chlorofluoropyrimidine are the most commonly used molecules for the reactive component of the dyes. The dye chromophores can be azo (mono), anthraquinone, triphenodioxazine, formazan, or metal-complex molecules, (using copper or nickel complexes of phthalocyanines). Dye auxiliaries include alkalis (the dyes are applied under alkali conditions using compounds such as sodium carbonate, bicarbonate, caustic soda), salts (sodium chloride and sodium sulfate), urea (but its use is reportedly in decline since the 1990s), and specialty leveling agents.

Sulfur and Vat

Both sulfur and vat dyes are applied to cellulosic fibers, although the contractor paper reported limited evidence of their use on rayon. These dyes are insoluble in water until reduced in an alkali dye bath. Once oxidized, the dye is adsorbed onto the fiber surface. Sulphur dyes result from the reaction of sulfur compounds with amines, phenols, or nitro compounds such as amino derivatives, nitrobenzenes, nitro and aminobiphenyls, substituted phenols, substituted naphthalenes, condensed aromatic compounds, indophenols, azines, oxazine, thiazole, azine, or thiazine rings. Vat dyes, such as indigo, contain a quinonoid system with a pair of conjugated carbonyl groups and are mostly composed of either anthraquinone-based compounds or polycyclic quinones/indigoids. The contractor report states that heavy metal catalysts and reagents (mercury, arsenic, barium, copper, iron, manganese, lead, and chromium) are used in the manufacture of vat dyes. Sulfur dye auxiliaries include a reducing agent, wetting or penetration agents, sequesterants, salts, and complexing agent. The contractor report mentions use of chromium salts as an oxidizing and after dyeing treatment, but that its use is in decline due to environmental concerns. Vat dye auxiliaries are reducing agents, oxidizing agents, alkali agents, dispersing agents, anti-migration agents (polyacrylates and alginates), and leveling agents and surfactants.

Potential for the Use of the ASTM Elements or Specified Phthalates

Studies in Which the ASTM Elements or Phthalates Were Detected

Findings Related to Unfinished Manufactured Fibers

The contractor noted one significant use of an ASTM element in unfinished manufactured fibers: antimony in the production of polyester (PET) fibers. The contractor report does not identify any other instances of the use of ASTM elements or phthalates in the routine manufacturing processes for the specific undyed synthetic fibers (or uncolored natural latex).

In the production of polyester (PET) fibers, antimony compounds may be used as a catalyst, depending on the manufacturing process and starting materials. A catalyst accelerates the rate of reaction by lowering the energy of activation required for the reaction to occur. However, a catalyst is not consumed during the course of the reaction. Sometimes manufacturers recover catalysts after the reaction has completed, but TERA reported no indication of antimony recovery in polyester production. Examples of antimony compounds used in the manufacture of polyester are:

1. Antimony trioxide
2. Antimony acetate
3. Antimony pentoxide
4. Antimony triacetate

The contractor report states that worldwide, more than 90 percent of polyester is produced with antimony-based catalysts with concentrations in the range of a few hundred parts per million.^{33,34,35} We can compare the possible antimony concentration of a few hundred ppm in polyester to the allowable solubility limit of 60 ppm under the ASTM F963 toy safety standard. Because the antimony concentration may exceed the solubility limit, without additional data on the migration of antimony from polyester when it is present, we conclude that the standard's solubility limit could be exceeded.

In addition to researching the chemicals and materials used intentionally to produce the specific fibers, the contractor reported studies on impurities or contaminants in fibers and textile products. For unfinished fibers, studies noted inorganic contaminants, such as arsenic, chromium, mercury, or cadmium. Reported levels in the range of a few parts per million or less^{36,37,38} would be low, compared to the solubility limit in the ASTM F963 toy safety standard.

Findings Related to Finished Manufactured Fibers

TERA reported possible uses of the ASTM F963 elements and the specified phthalates in these manufactured fibers beyond just the creation of the fiber. Chemicals may sometimes be

³³ Thiele UK. 2004. Raw Materials – Quo vadis polyester catalyst? Chem Fibers Int, 54:162-163.

³⁴ AFIRM Group. 2016. Chemical Guidance Document.

³⁵ Kirk-Othmer. 2014. Kirk-Othmer Encyclopedia of Chemical Technology. Volume 20.

³⁶ Fakirov S. 2002. Handbook of Thermoplastic Polyesters, Homopolymers, Copolymers, Blends and Composites. 1st Edition. Wiley-VCH. ISBN-10: 3527301135.

³⁷ Banat Y. El-Rub AA. 2001. A Technical and Economic Feasibility Study of: Production of Polyethylene Terephthalate by Direct Esterification Using Pervaporation. PART I: The Report.

³⁸ Lacasse K, Baumann W. 2004. Textile Chemicals: Environmental Data and Facts. Springer-Verlag Berlin Heidelberg, Dortmund, Germany.

added to manufactured fibers or films to impart color or specific performance characteristics. For example, an ASTM element, antimony, may be used in flame retardant applications. Common antimony compounds used in flame retardants are antimony trioxide (auxiliary), antimony pentoxide (additive), or antimony trichloride (additive).

Of the types of manufactured fibers within the scope of the TERA report, certain fiber types are dyed with specific dye classes that have the potential to contain the ASTM F963 elements and specified phthalates. Along with the dye molecules themselves, the dyeing and finishing processes may use other auxiliaries that aid in the dyeing process or add other properties to the textile fibers. For example, most synthetic manufactured fibers use disperse dyes, which can contain mercury (catalyst), DBP (carrier/accelerant), and/or DEHP (carrier/accelerant). Metal complex dyes can be used on nylon fibers and may contain chromium as a mordant. Chromium salts can be used as fixative cationic agents for direct dyes (Table 14, TERA Report). Pigments are used as an additional way to color textile fibers and can be applied to most fiber types. Barium sulfate and dioctylphthalate are two compounds that were identified by the TERA report to be used as a coloring “pigment” auxiliary. Many of these auxiliaries are not fiber specific and can be used in various combinations to achieve the desired properties of the textile fibers.

- Antimony trioxide/oxide, antimony pentoxide, and antimony trichloride can be used as flame retardant auxiliary or additive.
- Cadmium selenide and mercury can be used as biocides.
- At least one reference cited in the contractor report indicated that cadmium can also be found as a metal impurity from fiber production.
- Diisodecyl phthalate can be used as a plasticizer.
- Arsenic can be used as catalyst/reagent.
- Barium chloride and Barium hydroxide can be used as a dyeing auxiliary, mordant, and/or catalyst.
- Butyl benzyl phthalate can be used as a fixative agent.
- Chromium compounds have a variety of uses as dyeing auxiliaries.
- Chromic acid can be used as an oxidizing agent.
- Chromium (III) oxide can be used as a catalyst and/or mordant.
- Chromium IV can be used as a fixative agent. (See Table 15, TERA Report)

As stated above, these chemicals may or may not be used in the dyeing of manufactured fibers. Additional information is needed to know the concentrations of the specified chemicals present in these fiber types, and if they are soluble or can be extracted from the fiber. The contractor report also noted that other finishing processes may exist that were outside the scope of the report, and that, therefore, there may be other sources of the specified elements and phthalates that were not covered in the TERA Report. Because finished fibers may contain ASTM elements and the specified phthalates, staff recommends limiting the determination to unfinished fibers.

Polyester

For the phthalates and the other chemical elements of current interest, staff notes two possible colorant-related processes relevant for polyester. First, certain disperse dye processes may use mercury-based compounds as catalysts, although use of mercury may be limited in current manufacturing. TERA did not give information about the levels of mercury that might remain in a fiber. Second, the TERA report references a report³⁹ that indicates that phthalates may be used in dye carrier formulations for polyester blends, such as wool/polyester, with concentrations in finished products up to 2.7 percent. The TERA report included another reference⁴⁰ indicating that carriers may be used at 1-12 percent, calculated as weight of the fiber, although that reference was for certain phthalates that are not among the specific phthalates of interest to CPSC.

Nylon

Although production of undyed nylon appears to be free of phthalates or specified elements, the fast black dyeing of nylon can be carried out using chromium-containing dyes such as C. I. Mordant Black 11. In one study⁴¹, black fabric samples were found to contain more than 800 ppm chromium. Thus, chromium content is above the soluble limit for chromium of 60 ppm. Solubility testing would have to be performed to determine whether the chromium migration from the sample could exceed the limits established in the ASTM F963 standard. In this study, the investigators evaluated solubility using a synthetic sweat solution, and reported that migration did not exceed 3 ppm chromium. However, the solubility test method in the ASTM F963 standard uses a different mild acid extraction solution, which may produce different chromium migration results.

Rayon

Some direct dyes, which can be used to dye rayon, can contain chromium as an after-treatment or for metal-complex formation. However, not all direct dyes require the use of chromium, meaning that not all dyed rayon fibers will contain chromium. Additional information is needed to determine if the chromium concentration would be above the prescribed limit and if the chromium is soluble or can be extracted at all. Vat and sulfur dyes can also be used to dye rayon fibers. Vat dyes can contain mercury, arsenic, barium or chromium as a catalyst or reagent. Sulfur dyes may contain chromium, which is used as an after-treatment or oxidizer.

Natural Rubber Latex

For the phthalates and the other chemical elements of current interest, staff notes possible colorant-related processes relevant for natural rubber latex. First, actual formulations used to deliver pigments to the material are not fully described in the TERA report. Of possible relevance, phthalates can be used as solvents or carriers for other substances. Without information that use of phthalates is incompatible with natural rubber latex products, we cannot rule out that phthalates could be used in colorants in natural rubber latex products. Second,

³⁹ Greenpeace. 2005. An Overview of Textiles Processing and Related Environmental Concerns. Greenpeace Research Laboratories, Department of Biological Sciences, University of Exeter, UK.

⁴⁰ Kirk-Othmer. 2013. Kirk-Othmer Encyclopedia of Chemical Technology. John Wiley and Sons, Inc.

⁴¹ Matoso E, Cadore S. 2012. Determination of inorganic contaminants in polyamide textiles used for manufacturing sport T-shirts. *Talanta* 88: 496-501.

although antimony- and chromium-based pigments may not be in common use, given better alternatives, we have no information that they cannot be used or are never used in current production practices.

Supporting the possibility that phthalates can be found in natural rubber latex products, Jayawardena et al. (2016)⁴² reported natural latex balloons containing the phthalates DBP, DIBP, BBP, and DEP. The study investigators found that the colorants used in the balloons were the source of the phthalates. The investigators did not report the concentrations of the phthalates but measured phthalate migration from the balloons using an artificial saliva solution. The migration results, in the range of one to three percent, exceed the 0.1 percent content limit for any one of the phthalates included in the CPSC restrictions, indicating that the total concentration for each phthalate would exceed the CPSC content limit for phthalates for products subject to the restrictions.

Recycled Content

TERA did not examine the potential use of recycled materials in the subject manufactured fibers. Staff is aware that recycled content is present in some textile fibers; however, staff does not know the extent to which recycled content can be expected in products within the scope of the ASTM F963 elements or phthalates requirements. Due to findings in the contractor report on colorants and finishes in manufactured fibers, staff cannot recommend determinations for fibers with recycled content unless such content was from unfinished recycled materials.

Staff Conclusions on TERA Report Findings

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 TERA report found that noncompliant concentrations of antimony are used in the manufacture of undyed and unfinished PET. Staff does not have information identifying the concentration of antimony that is soluble when tested according to ASTM F963. PET fiber is widely used in consumer textile products, including children's toys.

Staff considered whether contaminants or impurities, such as cadmium from fiber production, are likely to be present in unfinished fibers, yarns, or fabrics. In its review of the contractor report, the reports referenced by the contractor, or other reference materials, staff has not found any information or data that suggest contaminants could be present in fibers at significant levels. Reported contaminant levels are no higher than a few parts per million. Staff

⁴² Jayawardena I, Godakumbura PI, Prashantha MAB. 2016. Migration of BTEX and phthalates from natural rubber latex balloons obtained from the Sri Lankan market. SpringerPlus 5:20.

believes that contaminants or impurities are unintentional (*i.e.*, not added by the manufacture intentionally), and largely represent the ubiquity of some substances in the environment at trace levels or general industrial practices and conditions. Given the available data and staff's understanding of the raw materials and manufacturing practices for the fibers currently under consideration, staff concludes that any impurities will be at levels well below the relevant limits for this proceeding.

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

Colorants, such as dyes, often contain metals in their structure. The contractor report cited 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 report cited the potential use of some of the specified phthalates as dye auxiliaries or carriers for pigments. While some of the findings may have been with products not necessarily within the scope of the subject rules, the mechanism by which colorants are applied to fibers could be extended to those products.

Finishes may also be added at the fiber (yarn or fabric) stage to impart desirable characteristics. The contractor report highlighted the use of antimony compounds as flame retardants. Other chemicals of interest may be used in finished fiber (yarn or fabric), however those finishes were not within the scope of the contractor report, and more information is needed for staff to propose that determinations be made for finished fiber (yarn or fabric). Staff notes that in the case of the ASTM elements (excluding lead, which has separate specific restrictions under the CPSIA), the restriction in the ASTM F963 standard is based on solubility; *i.e.*, migration of the elements from the product or material. However, conformance to the standard can be demonstrated by measuring the chemical content of a material—if the total content for a specific element does not exceed the solubility limit, then it must be the case that the solubility requirement is met. Because information about solubility or migration of chemicals from products or materials is rarely available in the scientific literature or other data sources, staff relies on information about chemical content to understand possible uses and presence of chemicals in products. If sufficient solubility testing data were available, especially if data show low levels of migration, such data may help inform decisions about testing requirements under the ASTM F963 standard.

Discussion

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

A *High Degree of Assurance* is defined in 16 C.F.R. § 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 to the applicable children's product safety rules before they issue a CPC.

Required Compliance to the 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 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 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 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 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 proposed 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.

CPSC Staff Conclusions

Considering the available evidence discussed above relating 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 in order for a certifier to issue a CPC.

Recommendations

CPSC staff recommends, with the exceptions listed below, that the Commission propose determinations 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.

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 into a subject product.

Polyester

CPSC staff recommends that the Commission propose to determine, with a high degree of assurance, that unfinished polyester be determined not to contain any of the following:

- Any of the eight phthalates subject to 16 CFR part 1307 in concentrations greater than 0.1 percent.⁴³

Nylon

CPSC staff recommends that the Commission propose to determine, with a high degree of assurance, that unfinished nylon fiber be determined not to 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 propose to determine, with a high degree of assurance, that unfinished polyurethane (spandex) fiber be determined not to 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 propose to determine, with a high degree of assurance, that unfinished viscose rayon fiber be determined not to contain any of the following:

⁴³ Staff cannot recommend that the Commission propose a determination 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.

- 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 propose to determine, with a high degree of assurance, that unfinished acrylic and unfinished modacrylic fiber be determined not to 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.

Natural Rubber Latex

CPSC staff recommends that the Commission propose to determine, with a high degree of assurance, that unfinished natural rubber latex fiber be determined not to 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

Because the proposed determinations for the seven unfinished manufactured fibers would reduce the testing burden on certifiers of children's products, children's toys and child care articles, staff recommends that the Commission propose an effective date 30 days from the final rule's publication in the *Federal Register*.

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

As detailed in Tab A, the draft proposed rule would reduce the burden of third party testing on manufacturers and importers of children's toys, and child care articles by eliminating the requirement for third party testing to certify that 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 for the ASTM F963 elements ranges from around \$60 in China, up to around \$190 in the United States using Inductively Coupled Plasma (ICP) testing. 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 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 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 volumes than larger businesses, these determinations could 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, which 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, the benefit of making the determinations could be less than staff expects. For example, some firms might have been able to substantially reduce their third-party testing costs by using component part testing as allowed by 16 C.F.R. part 1109, so the marginal benefit that might be derived from making the determinations might be low. Also, some firms have reduced their testing costs by using XRF or HDXRF technology, which is less expensive than ICP, and would reduce the marginal benefit of these determinations. Finally, some firms, particularly importers might not know the specific fibers used in the products being imported or whether they are unfinished and 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 exceed 1 percent of the gross revenues for a substantial number of manufacturers, importers, or retailers of the relevant product categories.

Questions for Public Comment

Staff is interested in obtaining more information on the following topics:

1. Are there any data or examples that indicate that the manufactured fibers identified in the draft proposed rule can and do contain the ASTM F963 elements (besides the identified use of antimony in PET) or prohibited phthalates at levels that are not compliant in an unfinished state? Please provide data supporting your assertion.
2. The TERA Task 17 Report identified the use of antimony, an ASTM F963 element, as a catalyst used to manufacture PET. Although TERA looked for the presence and total concentration of antimony, the ASTM F963-17 requirement is for the concentration that migrates out of the subject material. Please provide any information that supports or refutes the claim that antimony will not be present in concentrations greater than the specified limits in PET fiber in an unfinished state without colorants. Please provide any information that antimony will not migrate out of polyester in concentrations greater than the specified limits in PET fiber in an unfinished state with no colorants.

3. Are there any data or examples that the colorants or other finishes used for the manufactured fibers identified in the draft proposed rule never contain the ASTM F963 elements or prohibited phthalates at levels that are not compliant? Please provide data supporting your assertion. These data may be by type of dye, a specific dye, by fiber type, or some other relevant grouping.
4. Are there any data or examples that the use of recycled content in the manufactured fibers identified in the draft proposed rule never contain the ASTM F963 elements or prohibited phthalates at levels that are not compliant? Please provide data supporting your assertion. These data may be by fiber type, product type, or some other relevant grouping.
5. In addition to the manufactured fibers within scope of this study, are there other manufactured fibers widely used in children's toys and childcare articles that have not been identified in the draft proposed rule that do not, and will not contain the ASTM F963 elements or prohibited phthalates? Please provide supporting data to show that these manufactured fibers do not and will not contain the ASTM F963 elements or prohibited phthalates in concentrations above the mandatory limits?

Options for Future Commission Action Regarding Determinations on Manufactured Fibers

CPSC staff recommends that the Commission publish a notice of proposed rulemaking (NPR) regarding third party testing requirements for the ASTM F963 elements and the specified phthalates for the specified manufactured fibers, as described above.

The Commission could take one or more of the following actions:

- Direct staff to publish the NPR as drafted;
- Direct staff to publish the NPR with changes, as directed by the Commission;
- Direct staff to develop other documentation, such as Manufacturer Guidance; or
- Take other actions the Commission decides.

Conclusions

CPSC contracted with TERA to conduct a literature review of the potential presence of the ASTM F963 elements or specified phthalates in seven unfinished fibers and their colorants. TERA screened thousands of references identified by their multipronged search method for relevance to this issue. TERA believes their method generated a sample that is representative of all the relevant references available. CPSC staff reviewed the information provided in the contractor report and formulated recommendations for Commission consideration. Staff recommends that the Commission proposed to determine that all fibers in scope of the contractor report, except for polyester, do not contain the ASTM F963 elements in an unfinished state. Staff recommends that the Commission propose to determine that all fibers in scope of the contractor report do not contain the specified phthalates in an unfinished state. The recommendations extend to unfinished fibers only because TERA found ASTM F963 elements and specified phthalates in finished fibers.

Tab A: Initial Regulatory Flexibility Analysis

Draft Initial Regulatory Flexibility Analysis





UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: August 14, 2019

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;
Initial Regulatory Flexibility Analysis

Background

The Consumer Product Safety Commission (Commission) is considering a draft proposed rule that would establish determinations that certain unfinished⁴⁴ 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 1307 in concentrations exceeding specified limits,⁴⁵ or (2) any of eight specified phthalates in concentrations greater than 0.1 percent (1000 ppm).⁴⁶ CPSC staff recommends that the Commission propose to make determinations that unfinished polyester (polyethylene terephthalate, PET), nylon, natural latex rubber, spandex, rayon, acrylic, and modacrylic fibers

⁴⁴ 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.

⁴⁵ 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.

⁴⁶ 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).

do not contain the eight specified phthalates. The staff also recommends that the Commission propose to make the determination that nylon, natural rubber latex, spandex, rayon, acrylic, and modacrylic fibers do not contain the elements specified in ASTM F963.⁴⁷

If the Commission makes these determinations, manufacturers of children's toys and child care articles⁴⁸ will not have to obtain passing third-party test results for accessible component parts made of these unfinished manufactured fibers in order to certify that the component parts do not contain the ASTM F963 elements or the specified phthalates in excess of allowable levels. The draft proposed 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 rule, based on the results of third-party testing.

CPSC staff recommends that the Commission propose to make these determinations based on an extensive literature review⁴⁹ 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. Under the draft proposed rule, accessible component parts made from such manufactured fibers in children's toys⁵⁰ and child care articles subject to sections 106 (mandating the ASTM F963 toy standard) and 108 (regarding the use of specific phthalates in children's toys and child care articles) of the CPSIA would not require third-party testing for certification purposes.

Whenever an agency is required to publish a proposed rule, the Regulatory Flexibility Act (5 U.S.C. §§ 601 – 612) requires that the agency prepare an initial regulatory flexibility analysis (IRFA) that describes the impact that the rule would have on small businesses and other small entities, unless the agency certifies that the rule will not have significant economic impact on a substantial number of small entities. The initial regulatory flexibility analysis must contain:

- (1) a description of why action by the agency is being considered;
- (2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
- (3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

⁴⁷ CPSC 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 that antimony compounds can be used in manufacturing polyester.

⁴⁸ 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.

⁴⁹ 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.

⁵⁰ A "children's toy" is defined in section 1.3 of ASTM F963-17 as any object designed, manufactured, or marketed as a plaything for children under 14 years of age. However, the term "children's toy" is defined in section 108(e)(1)(B) of the CPSIA as a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays. Only toys intended for a child 12 years of age or younger are subject to certification requirements.

- (4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed 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 preparation of the report or record; and
- (5) an identification to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

The IRFA also must describe any significant alternatives to the proposed rule which would accomplish the stated statutory objectives and minimize any significant economic impact of the draft proposed rule on small entities.

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."⁵¹ 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."⁵² Therefore, although the draft proposed rule would have a positive impact on small entities, staff has prepared an initial regulatory flexibility analysis.

Why the Commission Is Considering this Action

The Commission is considering this draft proposed 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 safety standard for toys in concentrations exceeding 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 manufactured fibers do not contain the prohibited phthalates or chemical elements.

Objectives and Legal Basis of the Draft Proposed Rule

The objective of the draft proposed rule is to reduce the burden of third-party testing on manufacturers of children's products, 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.

Small Entities to Which the Draft Proposed Rule Would Apply

The proposed 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 discussions—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.

⁵¹ 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>.

⁵² Ibid. p.20, footnote 70.

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 2015 there were 566 toy manufacturers in the United States, of which 562 had fewer than 500 employees and would be considered small entities according to the SBA criteria.⁵³ Of the small manufacturers, 347 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 2,009 firms in this category in 2015. Of these, 1,937 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 4,632 toy retailers that would meet the SBA criteria to be considered a small entity.⁵⁴ Although importers are responsible for certifying the children's products that they import, they may rely upon third-party testing performed by their foreign suppliers for purposes of certification. 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

⁵³ 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: 2015," County Business Patterns. Available at: https://www2.census.gov/programs-surveys/susb/tables/2015/us_6digitnaics_2015.xlsx

⁵⁴ 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. There were 4,647 firms in this NAICS category, of which 4,632 had fewer than 500 employees. (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.)

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. Several types of these child care products likely use the types of manufactured fibers that are addressed by the draft proposed 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.⁵⁵ 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 a substantial number of small entities would be positively impacted by the draft proposed rule.

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

The draft proposed 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 C.F.R. 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 for the ASTM F963 elements ranges from around \$60 in China, up to around \$190 in the United States using Inductively Coupled Plasma (ICP) testing. 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.

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.

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 volumes than larger businesses, these determinations would be

⁵⁵ Krishnan, Charu S., Memorandum: Determinations that Certain Plastics Will Not Contain Specified Phthalates: Regulatory Flexibility Analysis, Directorate for Economic Analysis, CPSC. June 26, 2017.

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 substantially reduce their third-party testing costs by using component part testing as allowed by 16 C.F.R. 1109, so the marginal benefit to manufacturers from making the determinations might be low. Also, some firms have reduced their testing costs by using XRF or HDXRF technology, which is less expensive than ICP, and would reduce the marginal benefit of these determinations. 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 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. Therefore, we cannot determine whether the reduced burden would be significant for a substantial number of the small entities. CPSC staff welcomes public comments on the potential impact of the draft proposed rule on small entities. Comments are especially welcome on the following topics:

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

Federal Rules Which May Duplicate, Overlap or Conflict with the Draft Proposed Rule

We have not identified any Federal rules that duplicate or conflict with the draft proposed 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 proposed 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 proposed 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 proposed rule.