

STAFF BRIEFING PACKAGE

Section 610 Rule Review of 16 CFR Part 1107 “Testing and Labeling Pertaining to Product Certification” and 16 CFR Part 1109 “Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party’s Finished Product Certification, to Meet Testing and Certification Requirements”

Executive Summary

Section 610 of the Regulatory Flexibility Act (RFA) requires federal agencies to review regulations that have a significant economic impact on a substantial number of small entities within 10 years of their publication as a final rule. The purpose of a rule review under section 610 is to determine whether, consistent with the agency's statutory obligations, a regulation should be maintained without change, rescinded, or amended, to minimize any significant impact of the rule on a substantial number of small entities.

The regulation at 16 CFR part 1107, "Testing and Labeling Pertaining to Product Certification" (the testing rule) and 16 CFR part 1109, "Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Certification, to Meet Testing and Certification Requirements" (the component part testing rule), were published on November 8, 2011. Accordingly, both regulations are due for section 610 review in 2021. The purpose of both rules is to provide requirements for manufacturers regarding the testing and certification obligations under section 14 of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA) and Public Law No. 112-28.

On August 24, 2020, the U.S. Consumer Product Safety Commission (CPSC or Commission) published a notice in the *Federal Register*, announcing a Regulatory Flexibility Act (RFA) section 610 review for the testing and component part testing regulations (85 Fed. Reg. 52078). The *Federal Register* notice also sought information about the past and current economic impact of the rules on small entities, information on how the market for children's products has changed since 2011, and suggestions about ways CPSC could reduce the burden of the rules on small entities without reducing compliance with underlying safety standards. The public comment period was 60 days. The CPSC received five written comments representing the views of a small business that sells handmade items, a small business that sells wooden toys and gifts, a small importer of European toys, the American Apparel & Footwear Association (AAFA), and the Juvenile Products Manufacturers Association (JPMA).

After reviewing public comments and analyzing the five factors specified in the RFA, staff does not recommend any changes to the testing and component part testing rules at this time. The public comments did not offer any specific suggestions for changing either rule that were within CPSC's statutory authority. Commenters suggested additional outreach and guidance for small businesses on how to comply with the rules. Some commenters provided information about the cost of the required testing that was consistent with previous CPSC staff analysis. Commenters also sought exemptions to certain requirements specified in other CPSC regulations or determinations that certain materials do not require particular tests. Commenters expressed support for several actions taken by CPSC since the enactment of the CPSIA. They noted that these actions had been effective in reducing the third party testing burden for small businesses, including the CPSC Small Business Ombudsman's "Regulatory Robot," the Small Batch manufacturer exemptions specified in Public Law No. 112-28, and the exemptions to lead, phthalate, and small parts testing specified in other CPSC regulations.

The comments indicate that the cost of certifying compliance through third party testing remains significant for some small businesses, even with exemptions for certain materials and Small Batch manufacturers. While commenters provided specific examples of how the relief provided to Small Batch manufacturers by Public Law No. 112-28 reduces testing burdens, many manufacturers of children's products that are small by U.S. Small Business Administration (SBA) size standards have annual revenues that exceed the limits established by the statute to qualify as a Small Batch manufacturer.

The public comments expressed some concerns with the component part testing rule and requested additional guidance. While some commenters reported that component part testing certification has reduced their third party testing costs, other manufacturers said they continue to struggle with using the component part testing rule effectively to reduce burden. Staff notes that additional guidance on using the component part testing rule could help some small manufacturers use the rule to reduce their third party testing costs.



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814**

This document has been electronically
approved and signed.

Memorandum

Date: May 19, 2021

TO : The Commission
Alberta A. Mills, Secretary

THROUGH: Jennifer Sultan, Acting General Counsel
Mary Boyle, Executive Director
DeWane Ray, Deputy Executive Director for Operations

FROM : Gregory Rodgers, PhD, Associate Executive Director
Directorate for Economic Analysis

Susan Proper
Economist, Directorate for Economic Analysis

SUBJECT : Section 610 Rule Review of 16 CFR part 1107 "Testing and Labeling
Pertaining to Product Certification" and 16 CFR part 1109 "Conditions and
Requirements for Relying on Component Part Testing or Certification, or
Another Party's Finished Product Certification, to Meet Testing and
Certification Requirements"

I. Introduction

The Regulatory Flexibility Act (RFA) requires federal agencies to review periodically certain regulations for their impact on small business and to consider less burdensome alternatives. Section 610 of the RFA requires federal agencies to review regulations that have a significant economic impact on a substantial number of small entities within 10 years of their publication as final rules.

On August 24, 2020, the U.S. Consumer Product Safety Commission (CPSC) published a notice in the *Federal Register*, announcing review under section 610 of the RFA of the "Testing and Labeling Regulations Pertaining to Product Certification of Children's Products, Including Reliance on Component Part Testing." (85 Fed. Reg. 52078). The notice solicited public

comments on the review, particularly comments on the burden of these regulations on small businesses, and ways to reduce that burden.

During the 60-day comment period, the CPSC received five comments addressing the rule review. The comments came from a small business that sells handmade items, a small business that sells wooden toys and gifts, a small importer of European toys, the American Apparel & Footwear Association (AAFA), and the Juvenile Products Manufacturers Association (JPMA). The small business selling handmade items, and the small importer, also provide compliance advisory services to similar small businesses, and they discussed the burden of the rules on other small businesses that are their clients. AAFA and JPMA represent large and small businesses; the vast majority of businesses in their represented sectors are small businesses by SBA size standards. In preparing this analysis, we also considered public input on the testing and component part testing regulations received during the 610 review of the safety standards for full-size and non-full-size baby crib regulations conducted in FY 2020, and also comments on the 2017 RFI “Request for Information on Potentially Reducing Regulatory Burdens Without Harming Consumers” (82 Fed. Reg. 27636) that specifically addressed testing burdens for small businesses.

This package presents staff’s review of the testing and component part testing regulations’ impact on small businesses, using the criteria specified in section 610 of the RFA, including our analysis of the public comments received.

II. Background

A. 2011 Testing and Component Part Testing Regulations

Section 14 of the CPSA, as amended by the Consumer Product Safety Improvement Act (CPSIA), establishes requirements for the testing and certification of products subject to consumer product safety rules under the CPSA, or similar rules, bans, standards, or regulations, under any other Act enforced by the Commission. Manufacturers must issue a certificate that the product complies with applicable safety standards. Under section 14(a)(2) of the CPSA, the certification of children’s products must be based on testing conducted by an accredited third party conformity assessment body (a testing laboratory). Section 14(i)(2) further requires the CPSC to “initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements” and to establish protocols and standards for:

- ensuring that a children’s product is subject to testing periodically and when there has been a material change in the product’s design or manufacturing process;
- the testing of random samples to ensure continued compliance;
- verifying that a children’s product tested by a conformity assessment body complies with applicable children’s product safety rules; and
- safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

To implement the requirements of Section 14(i)(2) of the CPSA, and to codify the statutory requirements for certifying the compliance of children’s products with all applicable children’s

product safety rules based on third party testing, CPSC published in the *Federal Register* 16 CFR part 1107 “Testing and Labeling Pertaining to Product Certification” (the testing rule) on November 8, 2011. The testing rule specifies the requirements for the certification of compliance of children’s products and provides the protocols and standards for manufacturers to follow in obtaining third party testing for children’s products periodically and when there has been a material change in a product’s design or manufacturing process. It also specifies how products may be labeled to indicate that they have met the requirements of Section 14 of the CPSA.

On November 8, 2011, CPSC also published 16 CFR part 1109 “Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party’s Finished Product Certification, to Meet Testing and Certification Requirements” (the component part testing rule) in the *Federal Register*. The component part testing rule specifies how manufacturers can use third party tests of component parts of products to certify the compliance of the finished product. The intent of the component part testing rule was to reduce the costs and other burdens of testing finished products. There are specific requirements that apply to component part testing for lead, paint, and phthalates. The rule also sets requirements for importers and other suppliers for relying upon third party testing and certificates for finished products provided by their suppliers. Part 1109 also specifies record-keeping requirements for the testing of the component parts, and traceability requirements to ensure that a certifier of a finished product can identify all of the testing conducted on a component part or finished product supplied by a third party.

The component part testing rule had an effective date of December 8, 2011, while the testing rule had an effective date of February 8, 2013. The testing rule was subsequently amended in 2012, to implement changes required by Public No. Law 112-28 regarding using representative samples for testing. The component part testing rule was amended in 2015 to clarify when component part testing can be used and when exemptions of certain materials from lead and phthalate testing apply.

In the Final Regulatory Flexibility Analysis (FRFA) for the 2011 testing rule, CPSC staff concluded that the third party testing requirements would impose a significant burden¹ on a substantial number of small entities supplying children’s products. The burdens on suppliers included initial third party testing to demonstrate compliance, periodic re-testing, and recordkeeping of such testing. Tens of thousands of small businesses in multiple North American Industry Classification System (NAICS)² categories would be impacted. In the FRFA for the component part testing rule, CPSC staff concluded that the component part testing rule would not have a significant burden on small businesses. This conclusion was based on the fact that companies were not required to use component part testing and because the rule was intended to reduce the burden on businesses of all sizes by allowing them to rely on certifications of compliance by component part suppliers, or by suppliers of finished products.

¹ The FRFA assumed that a cost of more than 1 percent of annual revenue could be a significant cost, which is consistent with what other federal agencies consider to be a “significant” impact in cost/benefit analyses and regulatory flexibility analyses.

² NAICS is the system used by federal statistical agencies to classify business establishments for the purpose of collecting, analyzing, and publishing statistical data. For more information, see: <https://www.census.gov/naics/>.

B. CPSIA Amendments in 2011 and Other CPSC Efforts to Reduce Testing Burden on Small Businesses

The Commission recognized that the requirement for children's products to be certified as compliant with all applicable children's product safety rules, based on third party testing, would impose significant costs on manufacturers and importers, and also recognized that these costs would disproportionately impact the smallest firms. Beginning soon after enactment of the CPSIA, the Commission acted to reduce the burden. These efforts began even before the testing and component part testing rules were finalized in 2011. In 2009, CPSC determined that certain materials, such as most natural and manufactured fibers, wood, some printing inks, and some metals and gemstones, do not exceed the lead content limits specified in the CPSIA, and therefore, do not require third party testing. Under this determination, most fabrics used in apparel will not contain lead in excess of the regulated limits. In addition, CPSC issued rules providing determinations for additional materials regarding lead content, and for certain materials regarding the other chemicals restricted by the toy safety standard (ASTM F963) and the phthalates restricted in certain children's products. CPSC also determined that manufacturers of children's products would not have to re-test their products when the underlying standards were updated, if they were already compliant with the previous version, and the relevant tests in the revised standard were unchanged or functionally equivalent to the previous version. These determinations have been updated through rulemaking since 2009 to include additional provisions. CPSC also developed a list of materials for which third party testing laboratories could use X-ray fluorescence (XRF) testing for total lead content, a less expensive and quicker method than traditional laboratory chemistry testing methods.

Both large and small businesses benefitted from the burden reduction in the regulations' determinations concerning certain chemicals and materials, but it is likely that small businesses benefited more from the burden reductions because testing costs tend to disproportionately burden small volume producers.

The Commission determinations are reflected in the following regulations:

- 16 CFR part 1251 "Toys: Determinations Regarding Heavy Elements Limits for Certain Materials," which specifies that components of unfinished wood do not exceed the regulated levels of the heavy elements in the CPSC toy standard;
- 16 CFR part 1252 "Children's Products, Children's Toys, and Child Care Articles: Determinations Regarding Lead, ASTM F963 Elements, and Phthalates for Engineered Wood Products," which specifies that certain engineered wood products do not contain lead, heavy metals, or phthalates in excess of the regulated levels and are not required to be third party tested;
- 16 CFR part 1253 "Children's Toys and Child Care Articles: Determinations Regarding ASTM F963 Elements and Phthalates for Unfinished Manufactured Fibers," (added to the CFR in 2020) which specifies that certain manufactured fibers do not contain heavy metals or phthalates in excess of the regulated levels and are not required to be third party tested;

- 16 CFR part 1308 “Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics,” which specifies that certain specified plastics do not contain phthalates in excess of the regulated levels and are not required to be third party tested; and
- 16 CFR part 1500 “Hazardous Substances and Articles: Administration and Enforcement Regulations,” which includes exemptions to third party testing requirements for some types of natural and synthetic textiles, inks, and wood.

In August 2011, after the proposed testing and component part testing regulations had been published, but before the final rules were effective, Congress passed Public Law No. 112-28, “An Act to Provide the Consumer Product Safety Commission with Greater Authority and Discretion in Enforcing the Consumer Product Safety Laws, and for Other Purposes,” which amended various sections of the CPSIA. Among other things, Public Law No. 112-28 directed the CPSC to seek comment on “opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation.” Public Law 112-28 also authorized the Commission to issue new or amended 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.*, 15 U.S.C. § 2063(d)(3)(B). Finally, Public Law 112-28 limited the third party testing requirements for companies that qualified and registered as “Small Batch manufacturers,” and limited the required testing for lead content for “ordinary books” and other paper products in which conventional methods were used for printing, binding, and finishing.

In accordance with Public Law No. 112-28, the Small Batch Registry was set up in December 2011. To register as a Small Batch manufacturer, a business must attest that the company's annual revenue, and the number of units of the covered product manufactured for which relief is sought, both fall within the statutory limits to receive relief from the third party testing requirements. Importers can qualify as Small Batch manufacturers if they are importing from small foreign businesses, including foreign home-based businesses. Approximately 2,300 businesses registered as Small Batch manufacturers in 2019.

In 2015, CPSC published a direct final rule (see 80 Fed. Reg. 61729) amending 16 CFR parts 1109 and 1500, entitled, “Amendment to Clarify When Component Part Testing Can Be Used and Which Textile Products Have Been Determined Not to Exceed the Allowable Lead Content Limits.” The amendment to the component part testing rule clarified that component part testing could be used for materials and components not specifically listed in the rule. It also clarified when parts may be considered inaccessible and not subject to testing for phthalate content. The amendment to part 1500 clarified that dyed textiles are not subject to testing for lead content.

In 2017, the Commission published a Request for Information (RFI) titled, “Request for Information on Potentially Reducing Regulatory Burdens Without Harming Consumers” (82 Fed. Reg. 27636). In response to the comments on this RFI and previous public input on burden reduction, CPSC provided sample conformity certificates, an enhanced mobile-friendly “Regulatory Robot³” available in seven languages to help small businesses determine regulatory

³ An earlier version of the Regulatory Robot was made available in 2016.

requirements that apply to them, and additional outreach documents and plain language instructions for small manufacturers on how to achieve compliance with the regulations. The Office of the Small Business Ombudsman developed multiple short instructional videos for small batch manufacturers and small importers to provide a plain language overview of testing requirements. Additional burden reduction options are under consideration, within the limits of the Commission's statutory authority. Specifically, there are some recommendations from the Burden Reduction Recommendations briefing memo from May 2020⁴ which may be suitable for future guidance documents, including a stuffed toy testing manual for Small Batch producers, and suggestions for additional periodic testing exemptions for very small businesses.

III. Impact on Small Entities of 2011 Testing and Component Part Testing Rules

The purpose of a rule review under section 610 of the RFA is to determine whether, consistent with the CPSC's statutory obligations, the rules should be maintained without change, rescinded, or modified to minimize any significant impact of the rule on a substantial number of small entities. To perform the section 610 rule review, staff examined the public comments received in response to the *Federal Register* notice announcing this review. Staff also considered public input on the testing and component part testing regulations received during the section 610 review of the safety standards for full-size and non-full-size baby crib regulations conducted in FY 2020⁵ and the RFI on general regulatory burden conducted in 2017. The public input received on the section 610 review of the cribs regulation and the 2017 RFI on testing burden, reflected many of the same issues and concerns as the public comments on the current section 610 review; although the comments came from additional types of suppliers, including suppliers of durable nursery goods and additional trade associations.

The section 610 review comments on the testing and component part testing rule *Federal Register* notice discussed the burden of the regulations on manufacturers and importers of children's products, including very small hand-crafter businesses. We did not receive any information regarding the burden of the regulations on other types of small entities, such as small retailers, component part suppliers, or testing laboratories. The comments mentioning specific products concerned toys, apparel, footwear, and pacifiers/teethers.

Staff also reviewed the original analyses of small business impact (the FRFA) conducted for the 2011 testing and component part testing rules, and the extent to which market conditions and other factors may have changed since 2011, to determine whether the changes have affected the impact of the rules on small businesses. Staff analysis found that small businesses remain the vast majority of businesses in relevant market sectors such as toys, dolls, games, and children's apparel, and that sources and dollar values of imports of children's products have remained stable. The growth of online marketing platforms has expanded the opportunities for some small

⁴ See <https://www.cpsc.gov/s3fs-public/Burden-Reduction-Recommendations-for-Commission-Consideration.pdf?oO59Sa.HdS4c8tRH9bMuTzMSyNrfaJs> for the Briefing Package to the Commission on the results of the RFI, which summarizes comments received, as well as staff's recommendations and analysis.

⁵ See https://www.cpsc.gov/s3fs-public/Cribs-RFA-610-review.pdf?ewchE7O7ckIOExPYwTPkIR5gu_IAC6QN for the Briefing Package to the Commission.

firms, providing the potential for higher sales to a larger customer base, but has not impacted the testing burden for those businesses.

Overall, staff's review of the public comments and retrospective analysis of the small business analysis from the original FRFA for the rule found that the burden of the testing rule remains significant for many small entities. However, the component part testing rule has substantially reduced third party testing costs for businesses that are able to use it. Other actions that CPSC has taken related to lead, phthalates, and heavy metals testing for certain materials and categories of products have also reduced testing costs for suppliers subject to those provisions. Several commenters noted that the Regulatory Robot tool and Small Batch manufacturer exemptions have been particularly helpful for small businesses, although one commenter found the Regulatory Robot tool of limited use and the exemptions inadequate at reducing burden.

Section 610 requires agencies to consider five factors in reviewing rules to minimize any significant economic impact of the rule on a substantial number of small entities. The five factors are:

- (1) The continued need for the rule;
- (2) The nature of complaints or comments received concerning the rule from the public;
- (3) The complexity of the rule;
- (4) The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and
- (5) The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Staff analysis of the testing and component part rules using these five factors follows.

RFA Factor #1 – Continued Need for the Rule

Third party testing and certification of children's products are required by statute. Section 14(a)(2) of the CPSA (15 U.S.C. 2063(a)(2)) requires that every manufacturer of a children's product that is subject to a children's product safety rule certify that the product complies with the applicable children's product safety rule based on testing conducted by a third party conformity assessment body (testing laboratory) accredited to conduct such tests. Additionally, section 14(i)(2) requires CPSC to establish protocols and standards for ensuring that a children's product tested for compliance with an applicable children's product safety rule is subject to testing periodically and when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts. Therefore, the need for the rule, and specifically for third party testing, is established by statute. However, the statute does not specify how often periodic testing must take place, or the specific recordkeeping requirements. Accordingly, the Commission has discretion to modify some aspects of the testing rule to reduce burden.

The component part testing rule is not expressly required by statute. It was promulgated specifically to reduce the burden of the third party testing requirements. The component part

testing rule provides manufacturers with the ability to test components used in multiple products and to rely upon certifications provided by suppliers of both components and finished products. This rule can significantly reduce the costs of testing and certification for firms that are able to take advantage of it. We received multiple comments providing examples of how the component part testing rule has reduced the burden on small entities. An additional comment provided examples of how it was ineffective at reducing the cost of certifying compliance to the underlying safety standards in its specific case. However, that commenter did not suggest that the component part rule increased the burden; rather, it only suggested that the rule was not effective at reducing the burden substantially in some cases. We did not receive any public comments asking us to rescind or amend the component part testing rule. For these reasons, the component part testing rule should be maintained so long as the requirements for the third party testing of children's products exist.

RFA Factor #2 - Nature of complaints or comments received concerning the rule from the public

We received a total of five comments from the public in response to the *Federal Register* notice. We also considered public input on testing burden received during the section 610 review of the crib regulations and the 2017 Burden Reduction RFI. The specific comments about the burden of the testing and component part testing rules, or the burden on small entities of testing, in general, are discussed below. The comments that requested changes to other CPSC rules are discussed in an appendix. As noted earlier, the comments on the section 610 review *Federal Register* notice represented two trade associations, a small importer, a small domestic manufacturer, and a small hand-crafter business. The small importer and the small hand-crafter business also provide compliance guidance consulting services to other small businesses. No commenter provided suggestions for specific changes to the testing rule. Three of the five commenters support maintaining the component part testing rule; one found it ineffective at reducing burden; and one did not comment on it. Three of the five commenters suggested changes to other rules. The comments from the crib regulation section 610 review and the 2017 Burden Reduction RFI raised many of the same issues, from some of the same commenters, and also raised the issue of periodic testing.

Comment in General Support of the Rules

Comment: One commenter, representing a trade association, stated: "seeking to modify the regulations to provide relief to small entities is not warranted." They stated that the CPSC has already made efforts to "reduce the cost and minimize the burden of third-party testing requirements, and we believe the agency has done so in this regard to the degree possible by implementing 16 CFR parts 1500.91, 1251, 1252, 1253, and 1308, as well as developing and upgrading the Regulatory Robot to assist manufacturers with identifying the required testing for specific products, and by releasing the June 2017 RFI seeking feedback from stakeholders on the impact of such rules. 16 CFR 1107 and 1109 are integral to ensuring compliance with mandatory rules."

Comments on the Component Part Testing Rule

Comment: One commenter representing a small manufacturer of wooden toys and gifts expressed strong support for the component part testing rule. The commenter has a product line of about 1,000 products, and their initial estimate in 2008 of the cost of third party testing was \$1 million per testing cycle. By using component part testing, the commenter has been able to reduce third party testing costs to about \$50,000 per testing cycle. The commenter provided a specific example of how component part testing reduced the cost of testing low-volume (under 100 units per year) products from \$2000 to \$200 or less, per product per testing cycle. However, this commenter also noted that the requirements for the third party testing of children's products have caused it to change its product line. It noted discontinuing "many products that were low volume and design outliers, not for safety reasons but for testing costs, even using component part testing." The commenter added that most of its "new product development now looks toward add-ons to existing product platforms to take advantage of shared testing costs." However, the commenter did not provide any specific examples of products that were discontinued.

Another commenter reported: "small (micro) batch manufacturers heavily utilize both existing exemptions and allowances for reliance on their trusted suppliers' testing statements" and that "if each maker were required to test non-exempt items on their own, they would not have a business because the cost would be in excess of \$100-\$300 for many of their products (clothing, bibs, toys, etc.) frequently constituting 30%+ of their annual revenue."

An importer that was unable to take advantage of Small Batch exemptions reported testing costs of \$2,350 for a low-volume, hand-crafted doll from Germany, even after considering component part testing options, which made the product not "economically viable" to import to the United States.

Response: The experiences of these suppliers are consistent with staff's analysis in the Final Regulatory Flexibility Analysis (FRFA) for the 2011 component part testing rule. Although CPSC predicted that the component part testing rule could reduce testing costs, staff's analysis suggested that the costs could remain significant for many manufacturers and could cause changes in product design aimed at reducing testing costs.

The cost of \$200 per testing cycle noted in one commenter's example while provided to demonstrate how component part testing had reduced testing costs, would still likely represent a significant cost for the small business. For example, if a children's toy retails for \$25, the small business would need to sell more than 800 units a year for a testing cost of \$200, to be less than 1 percent of annual revenue generated by that product, assuming annual testing. The testing costs of \$100 to \$300, which were reported as potentially more than 30 percent of annual revenue by another commenter, reflect that even modest testing costs can be significant for very small home-based businesses. The testing costs of \$2,350 reported by the importer are almost certainly significant, unless the foreign manufacturer was able to spread the costs of testing over multiple U.S. importers.

Comment: One commenter, representing a small, home-based business, stated that even with discounts and composite testing, the compliance testing costs are still quite high when testing for lead in paint and other similar coatings. The commenter stated that most manufacturers accepted

these requirements as necessary, but added: “when they are using brand name companies who have recent testing reports from well-known CPSC-accepted labs, it’s hard to swallow that cost.” The commenter requested: “an allowance to be able to use these existing reports for our records, as long as we can assure that they are full lab reports showing actual results from within a year of the request.”

Response: The commenter seems to be making a request that is already allowed under the component part testing rule. The use of component test results up to 1 year old for paint is already allowed, so long as the testing was documented, as required in the testing and component part testing rules, and likewise, applied specifically to that specific batch of paint. A children’s product supplier must base its Children’s Product Certificate (CPC) on third party testing performed by a CPSC-accepted laboratory. Periodic testing must be conducted at a minimum of 1-, 2-, or 3-year intervals, depending upon whether the manufacturer has a periodic testing plan, a production testing plan, or plans to conduct continued testing using an accredited ISO/IEC 17025 laboratory, as specified in the testing rule.

Comment: One commenter noted that although they had successfully used component part testing to significantly reduce its testing costs, they have also experienced difficulties getting an online retailer to accept the results of such testing. They requested that CPSC provide additional guidance targeted at retailers explaining the component part testing rule. A comment from a trade association on the 2017 Burden Reduction RFI expressed similar concerns, requesting that CPSC provide guidance to retailers explaining that retailers do not need to require extra tests, more frequent tests, or tests by particular laboratories.

Response: CPSC does not have the statutory authority to require retailers to accept component part testing results. Section 14 of the CPSA, as amended by the CPSIA, and CPSC’s implementing rules specify the *minimum* required actions that suppliers must take to demonstrate a reasonable assurance of compliance with relevant safety standards; retailers are free to require additional tests, additional recordkeeping, or tests by particular laboratories.

Comment: One commenter noted that Small Batch manufacturers are “frequently making one of a kind items for their shop in a ready to ship format or through personal customizations based on the needs and desires of their customers.” This commenter indicated that “for most, the items they make are easy in terms of compliance,” given the existing options related to burden reduction, but for other manufacturers, the burden is “still quite high.” Another commenter noted that the component part testing rule had allowed them to make custom versions of their product, specifically referring to “taking a standard product base and adding a completely custom decoration.” During the section 610 review of crib regulations, several suppliers noted that the testing rules had caused small suppliers of custom cribs to exit the market. The customized crib products included customized structural elements in some cases, and customized decorations in others.

Response: These comments reflect the opportunities and limitations of the component part testing rule to reduce burden for customized products. The component part testing rule can reduce burden where component parts are the distinct custom elements, such as a personalized decoration. However, in cases where the product itself is a custom design with unique structural

elements, and the item is subject to structural performance requirements in applicable standards, component part testing is not useful in reducing testing burden, because the new design would constitute a material change that would require new testing.

Comment Concerning Amount of Discretion Allowable in Determining “A High Degree of Assurance”

Comment: A commenter noted that small manufacturers of pacifiers might “create over 50 variations of pacifier leashes and teethingers with regards to size, number, and shape of beads that are finished identically and will test identically.” The commenter stated that the cost of testing these variations, even at a discount, “will still exceed thousands of dollars.” The commenter requested that the CPSC allow small batch manufacturers to “utilize some amount of educated assumptions based on the actual testing they’ve done and scope what the testing shows utilizing the current general guidelines of ‘a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children’s product to meet all applicable children’s product safety rules.’”

Response: Manufacturers do have discretion in selecting the number of representative samples needed to provide “a high degree of assurance.” The regulation at 16 CFR §1107.20 specifies that “Manufacturers must submit a sufficient number of samples of a children's product, or samples that are identical in all material respects to the children's product, to a third party conformity assessment body for testing to support certification. The number of samples selected must be sufficient to provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children's product to meet all applicable children's product safety rules.” However, if the products described have different sizes and shapes of beads, they might not be “identical in all material respects” if the differences could affect compliance with a children’s product safety rule.

In addition, there is not a general Small Batch manufacturer third-party testing exemption for certain children’s products, like durable infant or toddler products, or pacifiers, or for certain testing categories, such as small parts testing. Small Batch manufacturers must always use third party testing from a CPSC-accepted laboratory to demonstrate compliance with certain children's product safety rules (Group A). The Group A regulations include “Pacifiers,” at 16 CFR part 1511, and “Small parts for children under 3 years of age,” at 16 CFR part 1501. Leashes and teethingers must meet the requirements in 16 CFR part 1501 for testing of items for children under 3 years of age for small parts.⁶

Comment on Recordkeeping, Including the Children’s Product Certificate

Comment: One commenter stated: “Recordkeeping isn’t much of a burden, however we request that instead of creating a Children’s Product Certificate monthly for products that we personally make every single month, we could either create a new document quarterly, yearly, or upon new testing. When we create them monthly, we are effectively making a copy and editing the date listed. This updating does nothing for actual safety and only satisfies paperwork. Since most

⁶ See: <https://www.cpsc.gov/Business--Manufacturing/Small-Business-Resources/Small-Batch-Manufacturers-and-Third-Party-> for more details.

makers are alone in their business and sell on their own in their business (no outside distributors, etc.), the time to do this adds up and takes away from the time makers use to run other parts of their businesses.”

Response: The current requirement for the date range on the Certificate of Compliance is specified in the regulations. For the date(s) when the product was manufactured, according to the content of the certificate requirements specified under 16 CFR §1110.11(e), the certifier must provide at least the month and year. It is not evident the extent to which amending this requirement would reduce burden, given that the commenter characterized the recordkeeping as “not much of a burden.” The current requirement is needed for an assurance of recent and documented compliance with the underlying standards; staff disagrees that it “does nothing for actual safety.”

Comments Concerning the Impact of Existing Determinations on Small Businesses⁷

Comment: One commenter stated that the determinations related to lead content, heavy elements, and phthalates, as well as the ability to rely on testing by their suppliers, have saved Small Batch manufacturers hundreds of thousands of dollars over the period from 2019 through 2020. The commenter requested that these provisions be kept in place.

Another commenter described the determinations as “narrow” and “fragmented” and stated that the determinations “can be valuable and helpful for small businesses seeking to reduce compliance costs but there is sometimes a gap between determinations for lead and determinations for other heavy metals required by ASTM-F963. In addition, there is no single source that lists all exempt materials and which tests they are exempt from creating a confusing pot of burden reduction possibilities.”

Response: It is common for multiple safety standards to apply to a single product. The Regulatory Robot, as well as other guidance documents provided by the CPSC’s Office of the Small Business Ombudsman, was developed to help manufacturers of all sizes understand which safety standards apply to their product, including highlighting relevant testing determinations, exceptions, or exemptions that may provide testing burden relief.

Although CPSC cannot change the statutory requirements that set limits for certain chemicals in children’s products, the Commission has determined that some materials do not require third party testing for some chemicals, because we can be confident that the materials do not contain the specified chemicals at levels that would exceed the regulated limits, due to the specific inherent characteristics of the materials. Many of these determinations were described earlier in this report. Most recently, CPSC published a final rule in 2020 (See 85 Fed. Reg. 33015), adding a new part to the CFR entitled, “Children's Toys and Child Care Articles: Determinations Regarding ASTM F963 Elements and Phthalates for Unfinished Manufactured Fibers” (16 CFR Part 1253).

⁷ Multiple commenters requested additional exemptions or determinations for certain products or materials. Those comments are discussed in an appendix, because they address rules other than the testing or component part testing rules under review here.

Comments Related to Impact of Testing Requirements on Small Batch Manufacturers

Comment: One commenter stated that a result of the testing required by the CPSIA is “the gradual removal of small batch European Toys from the US market and the demise of businesses that depended on that supply. The cost for a small company and small importer to conform to two regulatory standards was simply too high. There are small batch toy manufacturers all over the world, but predominately, those large enough to consider international markets are concentrated in the European Union. These second tier companies often produce toys by hand and not in completely automated factories, and have single SKU volumes of less than 1000 units per year.” The commenter noted that the Small Batch exemptions do not reduce burden for businesses that are not small enough to meet the criteria to qualify as a small batch manufacturer, but also “not large enough to amortize regulatory costs effectively.” It cited a recent example of considering importing dolls from Germany. The volume would be 100 units or less per doll but the testing costs would be at least \$2,350 or \$23.50 per unit, which it said would make the item “economically unviable” to import. This commenter asked CPSC to consider only the revenue of the U.S. importer, not the foreign manufacturer, when considering which firms qualify as a Small Batch manufacturer.

Another commenter noted that Small Batch manufacturers “frequently find they have no testing to do thanks to the existing exemptions, or, if they need flammability testing, they are able to rely on their trusted suppliers having already done the testing needed.”

Response: It is true that businesses that are “small” by Small Business Administration (SBA) size standards may be too large to qualify as a Small Batch manufacturer under Public Law No.112-28. The SBA size standards for what constitutes a small business are generally 500 employees for manufacturing firms, and 100 employees for wholesalers. (Importers may be considered manufacturers, wholesalers, or distributors, depending on their primary business.) Thus, a manufacturing company employing 300 people might be “small” by the SBA standards, but not qualify for Small Batch exemptions. Similarly, an importer distributing toys made in a foreign factory employing 75 people might be “small” by SBA size standards, but have revenue or production volume too great to qualify for Small Batch exemptions.

As for the definition of what constitutes a “small business” for the purpose of Small Batch manufacturer exemptions, the CPSA (15 U.S.C. 2063(d)(4)) specifically requires the Commission to include the total gross revenue of *all* sales of *all* consumer products by a manufacturer and any entities it controls or is controlled by, not just U.S. sales, as suggested by the commenter. Specifically, it states: “For purposes of determining the total gross revenue for all sales of all consumer products of a manufacturer under this subparagraph, such total gross revenue shall be considered to include all gross revenue from all sales of all consumer products of each entity that controls, is controlled by, or is under common control with such manufacturer. The Commission shall take steps to ensure that all relevant business affiliations are considered in determining whether or not a manufacturer meets this definition.” Additionally, CPSC does not have the statutory authority to change what constitutes Small Batch (other than annual adjustments for inflation); the criteria for number of units sold annually and annual revenue are also specified in the CPSA (15 U.S.C. 2063(d)(4)). However, a U.S. importer of toys or other children’s items

made by foreign small businesses or hand-crafters in foreign countries could qualify as a Small Batch manufacturer.

For suppliers that meet the Small Batch production and revenue criteria, the Small Batch exemptions, combined with other actions that CPSC has taken since 2011 to reduce the burden on small businesses, have exempted a few categories of children's products from third party testing requirements entirely, or reduced the number of applicable standards for which third party testing is required. For example, a non-apparel textile product with no screen printing made entirely of natural fibers or polyester by a Small Batch manufacturer might not require third party testing, but would still need to have a certificate of compliance listing the applicable exemptions and assurance of compliance. A wooden unpainted toy without wheels intended for children over 3 years of age might only be subject to labeling requirements for its intended age, as well as the certificate of compliance.

Comments Regarding Frequency of Periodic Testing

Comment: During the section 610 review of the crib regulations in FY 2020, a crib manufacturer requested a periodic testing frequency of once every 5 years or longer, rather than once every 1 to 3 years, as specified in 16 CFR §1107.21, because according to the commenter, if the design of the crib model has not changed, then more frequent testing does not improve either compliance or safety. Some of the comments received in response to the 2017 RFI also suggested increasing the maximum time between required third-party periodic testing, especially in the case of low-volume "micro" manufacturers. Commenters suggested changing the testing requirement to once per a certain number of units manufactured, rather than once per 1 to 3 years, or when the product has a material change, as currently specified in the testing rule.

Response: The Commission is mandated by statute to require periodic testing to assure continued compliance with the underlying children's product safety standard. The statute doesn't specify the time interval for that testing, so CPSC has the statutory authority to consider changing the requirements for periodic testing to specify a shorter or longer period between tests. Increasing the maximum period between periodic third-party testing could reduce the testing burden on small manufacturers that do not frequently change their models or designs. However, we note that increasing the maximum time between periodic testing would not affect manufacturers' obligation to conduct third party testing when there is a material change in the product, including in the design or the sourcing of component parts. In addition, extending the interval between periodic testing could have negative impacts on the assurance of compliance with the underlying safety standards.

Manufacturers already may reduce their periodic third party re-testing frequency to once every 2 years, instead of every year, with a production testing plan, as specified in the testing rule. As described in 16 CFR § 1107.21(c)(2), a production testing plan is a written plan describing actions taken by a manufacturer, other than third party testing, to help ensure continued compliance of a children's product. This written plan would include a description of the actions (e.g., inspection of raw materials, first party testing, quality assurance/quality control systems) that a manufacturer uses to control for potential variability in its production process that could affect the product's compliance. Although periodic third-party re-testing every 2 years is still

required in a production testing plan, the test methods employed by the manufacturer during the interim 2 years are not required to be CPSC-accepted test methods, nor must the tests be completed by a CPSC-accepted accredited laboratory.

Other comments

Commenters asked for exemptions to requirements specified in other CPSC regulations (not the testing or component part testing regulations), or determinations that certain materials do not require certain tests, including:

- small parts testing for toys made entirely from fabric;
- allowing fabric as a barrier for inaccessible parts to test for lead in apparel and footwear;
- lead testing for pad printed labels; and
- use of XRF testing to demonstrate lead content at levels well below the 100 ppm content limit.

These comments that would not involve changes to the testing or component part testing rules are discussed in the appendix.

RFA Factor #3 - Complexity of the rule

The comments as a whole reflect that some small businesses struggle to understand which testing requirements apply to their products. The third party testing requirements faced by manufacturers can indeed be complicated, because more than one product safety rule often may apply to a single product. Much of this complexity is the result of statutory requirements over which the Commission has little to no discretion. CPSC has acted to help manufacturers navigate this complexity, including the Regulatory Robot and numerous guidance documents. The Office of the Small Business Ombudsman provides guidance documents for specific product categories, such as the simple one-page guide to the requirements of ASTM F963-17,⁸ as well as frequent webinars and training sessions targeted to specific topics and specific stakeholder groups. However, one commenter noted that although the Regulatory Robot is helpful, there is no single document that “lists all the exempt materials and which tests they are exempt from, creating a confusing pot of burden reduction possibilities.”

Multiple comments indicated that small businesses continue to struggle to use the component part testing rule to reduce burden effectively. One commenter asked for an exemption for a component part (ink for apparel) that is commonly available from suppliers who provide certification of third party testing to the relevant standards, or in other cases, may already be exempt. Another asked for a change in the rules to accept component part testing results up to a year old, which would already be allowed. During the section 610 review of the cribs standards in FY 2020, several small manufacturers and importers reported difficulties understanding how to apply the component part testing rule to paints and varnishes. CPSC amended the component part testing rule in 2015, in part to clarify misunderstandings about the applicability of the

⁸ <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Toy-Safety/ASTM-F-963-Chart>

component part testing rule to testing other than for lead and phthalates. However, commenters on this section 610 review provided input demonstrating some misunderstandings still exist.

One commenter stated that they were having problems getting retailers to accept Children's Product Certificates that were based on component part testing. The statutory requirements for third party testing and the specific requirements of the 16 CFR part 1107 are minimum requirements only. Retailers may establish their own testing requirements they expect their supplier to meet, including requirements for additional testing, or testing by specific laboratories.

In summary, although the third party testing requirements are complex, the complexity stems from the statutory requirement that all children's products be tested for compliance with all applicable children's product safety rules using third party testing and the myriad of product safety rules that might apply to any given product, and largely not as a result of any complexity added by the testing rule or the component part testing rule. No commenter provided information on how these particular rules could be modified to lessen the complexity.

Subpart D of the testing rule specifies how consumer products may be labeled to indicate that the certification requirements of section 14 of the CPSA have been met. As specified in the testing rule, such labels are not required, but if labels are used, they must meet the requirements of the section. We received one comment on labeling, which was that the requirements in the testing rule and the guidance on the CPSC website for labeling of children's products are "easily followed."

RFA Factor #4 - The extent to which the rule overlaps, duplicates, or conflicts with other federal rules, and, to the extent feasible, with state and local governmental rules

We received no information from the public comments indicating that either of these rules currently duplicate or conflict with other federal rules, or with state and local governmental rules.

RFA Factor #5 - Length of time since the rule has been evaluated, or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule

Commenters provided differing opinions on how the market has changed since 2011, how the changes impact small businesses, and how those changes interact with the rules. None of the comments, summarized below, provided information about market changes that would merit an amendment or withdrawal of the rules.

- AAFA noted: "over the past decade, the CPSIA has demonstrated the ongoing need for children's product safety regulations by removing unsafe products from the market and maintaining a competitive market for those companies who center safety in their products without fear of being undermined by unscrupulous actors making cheap, unsafe products."
- EuroSource, LLC, stated: "one consequence of these new regulations was the gradual removal of small batch European toys from the U.S. market and the demise of businesses that depended on that supply"; and the commenter provided specific examples of burdensome costs for testing German toys. The commenter did not provide specific

examples of small European companies that had stopped exporting to the United States. U.S. Department of Commerce International Trade Administration data⁹ show that total U.S. imports of dolls, toys, and games from Germany increased steadily from 2011 to 2019, from \$55 million to \$69 million, but did not report on the size of the companies involved.

- The owner of a small domestic wood toy and gift company noted that the testing rule has forced changes to the product line to reduce third party testing costs. This was predicted as a likely impact of the testing rule in the original FRFA in 2011. It is also consistent with input received on the 610 review of the cribs regulations, where several suppliers noted that manufacturers of custom products had exited the market due to testing requirements.
- Product Safety and Consulting Services LLC noted that they were “exceptionally pleased with the changes we’ve seen in the market on both the maker side and the consumer side,” noting that both groups have improved their knowledge of product safety and that recalls have decreased as a result. (Toy recalls declined from 172 recalls in 2008, to 12 in FY 2019. See <https://www.cpsc.gov/Safety-Education/Safety-Education-Centers/Toy-Recall-Statistics>).

The input from suppliers regarding changes to the market since 2010, and input gathered during the section 610 review of the crib regulations, revealed that some suppliers felt they had benefited from the new online marketing channels that have emerged in the last decade. However, other suppliers provided input that brick and mortar marketing channels have shrunk as many small, independent baby product stores, and one large chain retailer that was a major buyer, have gone out of business. The rise of Internet shopping over the past decade has made it easier for small businesses to enter and exit the market quickly, based on demand for specific products. However, as noted by the crib suppliers, the rise of Internet shopping has also further fragmented the retail market for children’s products and created new costs, such as consumer expectations of free shipping. One commenter on this section 610 review of testing rules suggested providing additional guidance documents targeted to online retailers. Overall, the rise of Internet shopping does not appear to have changed the burden of compliance with the rules on small entities.

Several of the crib suppliers provided information that the crib standards and testing regulations, in combination, had driven suppliers of custom cribs from the marketplace, resulting in a more homogenous product selection for consumers. In contrast, several commenters on this section 610 review noted that they had been able to use the component part testing rule to make compliant products with customized components, particularly decorative elements on a standardized base product.

The FRFA for the 2011 testing rule estimated that tens of thousands of small businesses would be impacted by the testing rule, including virtually all manufacturers and importers of children’s products, because nearly all children’s products are subject to at least one safety regulation that would require third-party compliance testing. The FRFA found that the final rule would have a significant impact on a substantial number of small businesses. The impact was expected to be

⁹ U.S. Department of Commerce, International Trade Administration, Global Patterns of U.S. Merchandise Trade, NAICS code 33993.

disproportionately large for small and low-volume manufacturers. This is because testing costs per product are relatively fixed, and do not depend on the volume sold. Therefore, the impact of testing costs per unit was projected to be greater on low-volume producers than on high-volume producers. The costs would vary by product type, because some products require more tests than others, and some types of tests cost more than other types. In a hypothetical example of toy manufacturers with different production volumes, the 2011 FRFA found that the impact could be significant even for a relatively large firm, given the low profit margins for some toys. However, it also found that small businesses could reduce the costs of testing by redesigning products to reduce the number of applicable tests required, and relying on component part testing.

The 2011 FRFA considered the impact on specific NAICS manufacturing categories that could include children's product manufacturers, using 2008 U.S. Census data¹⁰ on numbers of small businesses. Staff analysis of more recent 2017 Census data¹¹ shows that there are slightly fewer total U.S. firms in the manufacturing industry categories within scope of this rule since 2008, but the proportion of small firms remains very high. Small businesses in 2017, the most recent Census data, remain more than 98 percent of firms in manufacturing of dolls, toys, games, and 99 percent of the firms in apparel manufacturing, the same percentages as in 2008. Firms that import products might be classified as manufacturers, wholesalers, or retailers in the NAICS categories. The number of small business wholesalers in relevant categories has increased slightly in some categories and decreased in others, but the percentage of small businesses remains above 95 percent. There has been an increase in non-employer businesses in children's product manufacturing categories since 2008. Non-employer businesses are businesses with no employees, and are typically very small businesses, such as home-based crafters and small importers. These increases are consistent with the rise of online marketplaces and direct to consumer marketing in the last decade, both of which have made it easier and cheaper for very small businesses to market their products to a larger group of potential customers.

Staff finds no evidence that imports of children's products have been substantially reduced or increased by the regulations or other market factors since the regulations were published. The amount of imports of toys, dolls, and games by dollar value has remained stable over the past 10 years. For example, U.S. Department of Commerce International Trade Administration data show that total U.S. imports of toys, dolls and games in 2019, was \$20.13 billion, approximately the same as the \$20.06 billion of imports in 2009 (in nominal dollars), before the regulations were promulgated.¹² Intervening years show no trend. The top three sources of imports in that NAICS category were China, Japan, and Mexico in 2009, versus China, Vietnam, and Mexico in 2019. This is consistent with input received during the 610 review of crib regulations, in which suppliers noted that imports and offshore production of domestically designed products were a large portion of the market before and after publication of the crib rules.

¹⁰ The FRFA used U.S. Department of Commerce, Bureau of the Census data from 2008, the most recent data available at the time.

¹¹ Source: U.S. Department of Commerce, Bureau of the Census, "Number of Firms, Number of Establishments, Employment, Annual Payroll, and Preliminary Receipts by Enterprise Employment Size for the United States, All Industries: 2017" (https://www2.census.gov/programs-surveys/susb/tables/2017/us_6digitnaics_2017.xlsx)

¹² Trade data, Ibid.

As for technology changes since 2011, we received one comment about XRF technology improvements that could support reductions in testing burden, which is discussed in the appendix.

Public comments and staff analysis find relatively few changes in the market for children's products, other than the rise of Internet shopping, since the regulations were published in 2011. There is no evidence that the testing burden has increased market concentration. Small businesses are still more than 95 percent of businesses in applicable NAICS sectors, for both manufacturers and importers. The number of non-employer (very small) businesses has increased. There is no evidence that testing burden has disproportionally driven small companies out of the marketplace. If that had happened, the percentage of large businesses in relevant NAICS categories would have increased. There is also no evidence that the rules have reduced the competitiveness of domestic manufacturers and wholesalers; the dollar value of imports and sources of imports has remained largely unchanged. The section 610 review of the cribs regulations found that the number of crib suppliers in the United States had *increased* slightly during the decade since the crib safety standard rules were published.

It is difficult to determine whether any of the market changes since 2011, that impacted children's product suppliers, such as the rise of Internet marketplaces, or the increase in very small non-employer businesses in certain sectors, were caused or exacerbated by the rules, given that these changes might well have happened without the rules. The only change to the market that was almost certainly due to the rules, was the removal from the marketplace products that could not demonstrate compliance through the third party testing requirement. Several commenters noted favorably that they benefited not only from the removal of competing cheap and noncompliant products from the marketplace, but also from the surrounding public outreach campaigns by CPSC and consumer interest groups making consumers aware of the dangers of noncompliant products.

IV. Conclusion

The burden of third party testing requirements is still significant for many small businesses. The continued significant impact of the regulations on small businesses is largely consistent with the findings in the 2011 FRFA, although the actions the Commission has taken to reduce burden since 2011 have reduced the burden for some categories of businesses and products. The burden of testing is almost entirely due to the requirements of the underlying statute, which generally requires third party testing for children's products, rather than the specific language in the testing or component part testing rules. Despite testing burdens, small businesses remain the vast majority of children's product suppliers.

CPSC's actions have reduced the third party testing costs over what they could have been, absent such actions. Commenters specifically noted that the component part testing rule, Small Batch exemptions, and various determinations that testing may not be required in certain circumstances have reduced testing costs. The actions taken by CPSC since 2011 to reduce the burden on small businesses have exempted a few categories of children's products from third party testing requirements entirely, or reduced the number of applicable standards for which third party testing

is required, particularly for Small Batch manufacturers. Three of the five commenters on this rule review suggested additional exemptions to the underlying safety regulations, rather than amendments to the testing and component part testing rules, to reduce testing burden.

Commenters on this section 610 review, on the cribs section 610 review conducted in FY 2020, and the Burden Reduction RFI conducted in 2017, all indicated some stakeholders were unable to understand and fully use the component part testing rule to reduce burden. Other commenters indicated they were able to use it successfully to reduce burden. Commenters did not suggest amendments to the component part testing rule to make it less complex. Additional guidance documents could be considered, perhaps as part of the redesign of the public website in FY 2021.

The suggestion to provide additional guidance to retailers about accepting component part testing, or accepting tests from any CPSC-accepted accredited laboratory, is unlikely to reduce burden. Although CPSC could provide guidance targeted to retailers explaining component part testing, CPSC's implementing rules specify the *minimum* required actions that suppliers must take to demonstrate a reasonable assurance of compliance with relevant safety standards. However, retailers are free to require additional tests, additional recordkeeping, or tests from particular laboratories.

The comment requesting a change in compliance certificate date formats could be considered, along with other public comments on the Proposed Rule from 2013 to amend 16 CFR part 1110 (see 78 Fed. Reg. 28079), if and when the Commission decides to publish a final rule amending that part. That regulatory action is currently inactive, but the Regulatory Identification Number (RIN) remains reserved for possible future use.¹³ However, it is unclear how this could be done without reducing the assurance of compliance with the underlying safety standards.

The Commission has the statutory authority to consider reducing the required frequency of periodic retesting; and it would reduce the burden on some small entities, although we cannot determine how many small businesses, or the magnitude of the cost reduction in relation to annual revenue. Reducing the frequency of periodic testing (as distinct from the initial certification testing of a product and testing conducted because there has been a material change) could reduce the cost burden of the third party testing requirements. However, to amend the requirements, the Commission would first have to determine the scope of any new periodic testing requirements and any resulting effects on product compliance with underlying safety standards. For example, the Commission could determine that the reduced periodic testing requirements apply to all children's products or specific products only, or to all producers versus only certain very small producers. An option already allowed under the current rule for reducing the frequency of periodic testing to once every 2 years, is the use of a formal production test plan. Production testing consists of the management techniques and tests used by a firm to assure continued compliance on an ongoing basis with applicable product safety rules and may or may not include third party testing. However, input provided to the Small Business Ombudsman on the 2017 burden reduction RFI, and in previous public input on burden reduction, suggests that some small firms might not be familiar with this option, or do not understand how to use it effectively.

¹³ <https://www.reginfo.gov/public/do/eAgendaInactive>.

Although suppliers offered a few suggestions for additional guidance documents, most of the commenters expressed the belief that the regulations are necessary to ensure a fair and competitive market for compliant products.

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Appendix One – Discussion of Other General Testing Comments

Five members of the public submitted comments in response to the *Federal Register* notice soliciting comments on the review of the testing rule and component testing rule under section 610 of the Regulatory Flexibility Act. Each comment raised several issues, many of which were suggestions for amendments to other CPSC rules, particularly those involving determinations or exemptions from testing for lead, small parts, and phthalates. This appendix discusses the comments that suggest changing specific safety standards, testing methods, testing policy, and exemptions to testing, rather than the testing and component part rules.

Requested Exemption for Pad Printed Labels

Comment: One commenter noted: “We appreciate the Commission’s work, as mentioned in the request for comment, to exempt testing requirements for fabric apparel products that have been proven as low risk for lead content. Pad printing on garments, which prints product information directly on an apparel product to avoid an uncomfortable sewn-in label, is a very similar case to the Commission’s findings on fabric because it also low risk for lead content. We believe that the Commission should also consider exempting pad printed labels from required third-party testing in children’s apparel.”

Response: This comment is about a specific material that the commenter asserts is low risk for lead content, and therefore, should be exempt from required third-party testing. Such considerations are not included in the scope of 16 CFR parts 1107 or 1109. Staff agrees that the Commission could consider additional determinations for materials that do not, and will not, contain lead at levels in excess of the specified limits for lead content in component parts of children’s products.

Commission determinations, to date, have focused on specific consumer products or materials for which the chemicals under consideration generally have no application in the manufacturing process. The Commission has already determined that most textiles do not contain levels of lead in excess of the established limits and do not need to be third party tested (16 CFR § 1500.91). This determination excluded any textiles that contain treatments or applications that do not consist entirely of dyes. For pad printed labels, one consideration is whether the material is a paint or coating, because paints and coatings, including coatings for use on clothing, have been found to contain lead compounds. If the material performs like a dye and is not a paint or coating, the textile product may already fall within the determination for textiles at 16 CFR §1500.91.

Requested Exemption for Fabric as an Impenetrable Barrier to Lead

Comment: One commenter noted that the CPSC should update the determinations on inaccessible component parts for children’s products containing lead, specifically for footwear and clothing. In a 2009 guidance to industry titled, “Inaccessible Component Parts for Children’s Products Containing Lead,” the CPSC stated: “unlike other children’s products that have lead-containing components that are accessible, children will not touch the lead containing

component with the hands or fingers if the component is enclosed or encased in fabric.” The commenter noted: “Determining that fabric is a proper inaccessibility barrier – as practical experience suggests – would lower testing costs in the apparel and footwear industry by eliminating testing requirements for certain components that will be covered by fabric once the article is made.”

Response: This comment is about specific provisions of the CPSIA and the interpretive rule on inaccessible component parts, 16 CFR §1500.88. Considerations of these provisions are not included in the scope of 16 CFR parts 1107 or 1109.

Staff understands that apparel and footwear are not considered toys. However, staff disagrees that the interpretive rule on inaccessible component parts was promulgated specifically for toys, or that it is most appropriate for application to toys compared to other children’s products. The lead restriction specified in section 101 of the CPSIA applies to children’s products, including children’s clothing and footwear.

Section 101(b)(2) of the CPSIA provides that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children’s activities, and the aging of the product, as determined by the Commission.

The Commission’s interpretive rule provides guidance and methods for evaluating children’s products subject to the lead content requirement for accessibility of component parts, regardless of the type of product. References to toys in the interpretive rule are only in the context of the tools and test methods that have already been established for evaluating toy safety, including accessibility probes and use and abuse procedures. Although specific types of products or component parts of products may be more or less likely to be mouthed by children, it is unlikely that such interactions can be ruled out for a product class. For example, for apparel and footwear, children may mouth buttons, zipper pulls, sleeves, collars or lapels, and even shoes, when the items are being worn or not.

In the accessible component parts interpretive rule, fabric coverings represent a special case. While fabric can be considered to be a physical barrier in many cases, fabric cannot be considered an effective barrier to the migration of lead from a lead-containing material, if the part can be placed in the mouth or swallowed. This is because saliva or beverages from a child’s mouth may pass through the fabric and then serve as the mechanism to transfer lead residue or particles from the lead-containing part, through the fabric to the mouth, where the lead can be swallowed. This type of exposure scenario is the basis for the provision in the interpretive rule that a children’s product that is, or contains, a lead-containing part which is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is inaccessible to a child *unless the product or part of the product in one dimension is smaller than 5 centimeters*. [Emphasis added]. Although the 5-centimeter dimension is part of the definition of “children’s toy” that can be placed in a children’s mouth under section 108(s)(2)(B) of the

CPSIA, the Commission concluded that the definition is helpful in assessing whether any part of any children's product can be placed in a child's mouth.

Suggested exemption to 16 CFR Part 1501 "Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts"

Comment: One commenter asked for an exemption to small parts testing for 100 percent fabric toys.

Response: Specific exemptions from small parts testing are listed in 16 CFR §1501.3, and 100 percent fabric toys are not included there. However, the CPSC mandatory toy standard, ASTM F963-17 (incorporated as a mandatory standard under 16 CFR part 1250) does state that fragments of toys made completely of fabric that separate during small parts testing are excluded from the Small Objects requirements of the Toy Standard. This means that although small parts testing is required, a fabric toy would not fail the test if a fabric part came off during use and abuse testing.

Adding an exemption to the small parts regulation for 100 percent fabric toys would likely not reduce testing cost, because the toy would still have to be tested to all the other applicable Toy Standard requirements, like chemical testing and labeling; and the supplier would still need to have the CPSC-accepted laboratory testing report showing compliance to the Toy Standard for their Children's Product Certificate.

Allow XRF Testing to Screen Products Before Requiring Chemical Testing

Comment: One commenter noted: "We believe that the CPSC has received enough scientific evidence to allow for XRF testing to be used as a screening process for further testing. The advantages and disadvantages of XRF testing are well known by the CPSC, which has hosted many hearings and discussions on the possible uses of XRF to benefit small batch manufacturers. The hindering factor of XRF testing continues to be that it has not always been reliable enough to give accurate readings under 100ppm lead level. While XRF technology is quickly improving and becoming more accurate, we understand that it is still not capable of being 100 percent reliable for an accurate result. It has, however, shown to be very capable for determining if a product requires further testing. By allowing a third-party lab to accept XRF results for lead under 40ppm the CPSC could drastically reduce the cost of third-party testing by reducing the need for further wet chemistry testing while still maintaining the high degree of assurance of compliance."

Response: This comment recommends that CPSC should accept testing for lead content using XRF (instrumentation and method not specified) in the case that the result is no more than 40 ppm. While the commenter admits that the technology may not provide accurate lead content readings in the lower range of the instruments' capabilities, the commenter suggests that the technology is good enough to support that readings of low lead content can be understood as evidence that the product conforms to the 100 ppm limit for lead content for children's products, and that additional, more accurate (and more costly) analytical methods are not needed. CPSC

staff acknowledges the advantages of XRF methods related to testing costs, and has already addressed use of XRF instrumentation in CPSC test methods. Specifically, test method CPSC-CH-E1002-08.3 (Standard Operating Procedure for Determining Total Lead (Pb) in Nonmetal Children's Products) includes use of XRF under certain conditions and with consideration of certain limitations. Thus, for children's product materials that are non-metallic and homogenous, the test method indicates that XRF methods could be used and relied on for results less than 70 ppm, and the more-involved chemical testing may not be required to certify compliance. On the other hand, XRF methods are not suitable for inhomogeneous materials because of the potential for inaccurate results, including false negative results. Furthermore, in specific cases, other product characteristics and limitations of the technology could preclude use of XRF. Staff continues to monitor for advances in analytical technologies for opportunities to reduce testing burdens while assuring compliance with applicable requirements.

CPSC Should Consider Recognizing EN-71 and ISO-8124 Toy Safety Standards as Substantially Equivalent to ASTM F963

Comment: Multiple commenters asked CPSC to recognize the international toy safety standards, EN-71 and ISO-8124, as substantially equivalent to ASTM F963, and determine areas where the CPSC can accept test results of conformance to those standards as indicative of conformity to the corresponding requirements of CPSC safety standards for children's products. The purpose would be to reduce the burden of duplicative testing. One commenter stated that for small importers wishing to import European toys, and European companies wishing to export to the United States: "The cost for a small company and small importer to conform to two regulatory standards was simply too high."

Response: The issue of ISO or EN standards equivalence has been addressed by Commission staff in the past, notably the 2012 staff briefing package to the Commission, on "Considerations of Opportunities to Reduce Third Party Testing Costs Consistent with Assuring the Compliance of Children's Products."¹⁴ In the 2012 analysis, staff found that some tests in the EN and ISO standards could be equivalent to, or more stringent than, the tests in the then-current ASTM F963 standard, which is the basis for the CPSC mandatory toy standard; and if these tests were conducted by a CPSC-accepted accredited testing laboratory, these tests could be substituted for some of the tests required by ASTM F963. Staff recommended in 2012 that an effort be undertaken to identify the specific European and International tests that could be substituted for specific tests in ASTM F963. This issue was later researched by both Commission staff and career staff, and found to be not feasible for reducing burden, because staff research found that in general, some of the required test methods specified different parameters, which makes comparing results between the different standards difficult and uncertain.

In addition, even if CPSC were to accept test results to international standards as equivalent to conformance with ASTM F963, certification pursuant to the CPSIA still requires testing conducted by a CPSC-accepted testing laboratory. In this case, the savings to small firms might be limited, because a test result to an equivalent international standard by a non-CPSC-accepted

¹⁴ https://www.cpsc.gov/s3fs-public/pdfs/foia_reduce3pt.pdf.

accredited laboratory would not be acceptable. Additionally, the EU toy safety directive does not require third party testing; self-verification to European standards is allowed.¹⁵

Finally, suppliers of children's toys may be able to negotiate for simultaneous testing to multiple standards conformance with their third party testing laboratories, provided that those laboratories are accredited to test to both international and CPSC safety standards, and are also CPSC-accepted laboratories.

Use authority in Public Law No. 112-28 to report to Congress on opportunities to reduce testing burden that require legislative changes

Comment: One commenter noted that Pub. L. No. 112-28 includes the authority for the Commission to ask Congress for legislative changes needed to reduce testing burden. Specifically, the commenters asked that for the of recognizing EN-71 and ISO-8124 as substantially equivalent for the purpose of testing, that "If at any point the CPSC feels it has not been given the authority by congress to make this ruling, utilize subsection (C) to acquire the authority." Elsewhere, the commenter makes it clear that this refers to 15 U.S.C. 2063 (d)(3)(C), which reads "*REPORT.—If the Commission determines that it lacks authority to implement an opportunity for reducing the costs of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations, it shall transmit a report to Congress reviewing those opportunities, along with any recommendations for any legislation to permit such implementation.*"

Response: The Commission has not determined that new legislative authority is needed to address the issue of European or ISO toy standard equivalence. As discussed above, CPSC's recognition of international standards or part of the standards as equivalent would not remove the requirement to conduct compliance tests at a CPSC-accepted and accredited third party testing laboratory. Therefore, it is unclear the extent to which this would actually reduce burden. CPSC staff participate in the U.S. technical advisory group to ISO TC 181 on Toy Safety, supporting efforts to harmonize the ASTM, EN, and ISO toy safety standards.

¹⁵ The EU Toy Safety Directive, 2009/48/EC, is described in detail at: https://ec.europa.eu/growth/sectors/toys/safety_en, which specifically states that self-verification using European harmonized standards is acceptable to demonstrate compliance.