



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISION MEETING ON THIS MATTER IS SCHEDULED ON: October 12, 2011

DATE: September 21, 2011

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM: Philip L. Chao, Assistant General Counsel
David M. DiMatteo, Attorney, OGC

SUBJECT: Final Rule: Testing and Labeling Pertaining to Product Certification

Section 14(i) of the Consumer Product Safety Improvement Act ("CPSA"), as amended by the Consumer Product Safety Improvement Act of 2008 ("CPSIA," Pub. L. 110-314), requires the Commission, by regulation, to establish protocols and standards for the continued testing of children's products and to establish a program for voluntary labeling of consumer products as compliant with the certification requirements of section 14(a) of the CPSA. Attached is a briefing memorandum from staff, recommending that the Commission issue a final rule that establishes the protocols and standards for the continued testing of children's products and requirements for labeling of consumer products. A draft final rule is attached for your consideration.

Please indicate your vote on the following options:

I. Approve publication of the draft final rule in the *Federal Register*.

(Signature)

(Date)

II. Approve publication of the draft final rule in the *Federal Register*, with changes. (Please specify.)

(Signature)

(Date)

III. Do not approve publication of the draft final rule in the *Federal Register*.

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)



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

Memorandum

This document has been electronically
approved and signed.

Date: September 20, 2011

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM: J. DeWane Ray
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SUBJECT: Draft Final Rule for Testing and Labeling Pertaining to Product Certification

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1 Purpose

The mission of the U.S. Consumer Product Safety Commission (CPSC) is to protect the public against unreasonable risks of injury from consumer products through education, safety standards activities, regulation, and enforcement. This draft final rule is intended to ensure that manufacturers and importers produce or import safe and compliant children's products. Provisions are included to ensure that children's products are subject to certification testing before distribution in commerce, and are subject to testing to ensure continued compliance as they are manufactured or imported. Testing is not an end in itself, but rather one part of a process to ensure the safety of children's products.

The purpose of this draft final rule is to reduce the incidents of deaths and injuries associated with children's products. This will be accomplished by increasing the safety of children's products. The likelihood of noncompliant product being detected before it is introduced to the public will be increased. Consequently, consumer confidence in children's products certified to comply with the applicable product safety rules may be increased. Potentially, the number of recalls for children's products could be reduced and, with continued assessment of compliance, the scope of necessary recalls could be reduced. Further, third party testing during continuing production or importation can serve as an objective assessment of the effectiveness of a manufacturer's or importer's internal processes to ensure compliance, which would also serve to enhance the safety of children's products in the market.

2 Background

On August 14, 2008, the Consumer Product Safety Improvement Act (hereafter referred to as the "Act" or the "CPSIA") was signed into law [Public Law 110-314]. Section 102 of the CPSIA amended section 14 of the Consumer Product Safety Act (CPSA) [15 U.S.C. § 2063] by establishing requirements for third party testing of children's products that are subject to a children's product safety rule.

Section 14(a)(1) of the CPSA, as amended by the CPSIA, establishes requirements for the testing and certification of products subject to a consumer product safety rule under the CPSA or similar rule, ban, standard, or regulation under any other Act enforced by the Commission (hereafter referred to as applicable product safety rules) and which are imported for consumption or warehousing or distributed in commerce. Under this subsection, manufacturers and private labelers must issue a certificate which "shall certify, based on a test of each product or upon a reasonable testing program, that such product complies with all rules, bans, standards, or regulations applicable to the product under the CPSA or any other Act enforced by the Commission." This certificate is referred to as a General Conformity Certificate. The Commission published a final rule, 16 CFR part 1110, limiting the persons who must comply with the certification requirements of section 14(a) of the CPSA to the importer and to the domestic manufacturer. In this memorandum, an importer or domestic manufacturer required to certify products is referred to as a manufacturer.

Requirements for the certification of children's products are found in section 14(a)(2) of the CPSA. Section 3(a)(2) of the CPSA defines a "children's product" as a consumer product designed or intended primarily for children 12 years of age or younger. Before a manufacturer or private labeler can import or distribute in commerce any children's product subject to a children's product safety rule (as defined in section 14(f)(1) of the CPSA), it must submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to a CPSC-accepted third party conformity assessment body whose scope includes the required tests to be tested for compliance with the applicable children's product safety rules. Based on such testing, the manufacturer or private labeler must issue a Children's Product Certificate that affirms that such children's product complies with the applicable children's product safety rules.

Section 14(i)(2)(A) of the CPSA,¹ as amended by the CPSIA, also requires the Commission to initiate, by regulation, a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements for consumer and children's products. Such a program for labeling a consumer product, including children's products, as compliant with all applicable product safety requirements, is based on the requirements for issuing a certificate, as specified in section 14(a) of the CPSA.

Section 14(i)(2)(B) of the CPSA requires the Commission to establish protocols and standards for:

1. ensuring that a children's product subject to a children's product safety rule undergoes periodic testing;
2. testing when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts;
3. testing random samples to ensure continued compliance;²
4. verifying that a children's product tested by a CPSC-recognized third party conformity assessment body complies with applicable children's product safety rules; and
5. safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

These requirements are intended to ensure the continued compliance of children's products subject to the applicable children's product safety rules.

The Commission issued a Notice of Proposed Rulemaking (NPR) on May 20, 2010, to implement these legal requirements, with the exception of number 4 in the list above, which is section 14(i)(2)(B)(iii) of the CPSA. The comment period for this NPR extended through August 3, 2010. This briefing package presents the CPSC staff's draft final rule for establishing

¹ On August 12, 2011, the President signed H.R. 2715 into law. Among other things, H.R. 2715 corrected an editorial error in section 14 of the CPSA, by renumbering a second section 14(d) of the CPSA on Additional Regulations for Third Party Testing to section 14(i) of the CPSA. Accordingly, throughout the regulation text and this memorandum, including comment summaries and responses, references to section 14(d) of the CPSA have been revised to section 14(i) of the CPSA to be consistent with this renumbering.

² H.R. 2715 replaces "random samples" with "representative samples." A notice of proposed rulemaking (NPR) to implement this change will be issued.

the labeling requirements in section 14(i)(2)(A) of the CPSA, and requirements for sections 14(i)(2)(B)(i) and (iv) of the CPSA in the draft final rule. In addition, the CPSC staff's responses to the comments on the NPR and a final regulatory flexibility analysis to evaluate the possible economic impact of the draft final rule on small businesses are included in the briefing package.

The original NPR reflected the consensus view of the staff as to the best way to approach the announcement of protocols and standards to address continued testing of children's products as well as answer stakeholder concerns regarding the meaning of a reasonable testing program. In response to stakeholder comments regarding the cost of the rule as well as concerns expressed by the Commissioners' staff representatives, the staff altered many of their original suggestions. The range of options available between the original NPR and the final are too numerous to describe in detail, but significant changes have been made after months of work. Among the changes made to the final rule to reduce the burden are: (1) reserving subpart B requirements regarding a reasonable testing program; (2) eliminating certain required features of the testing program required for children's products such as the remedial action plan; (3) reducing the recordkeeping requirements in several respects; and (4) allowing the use of in-house ISO/IEC 17025:2005 laboratories to reduce the frequency of third party periodic testing. While the staff was working on the final rule, the President signed H.R. 2715, which changed the applicable statutory language from the issuance of protocols and standards with regard to testing "random samples" to ensure continued compliance to children's product safety rules to the testing of "representative samples." H.R. 2715 also requires the Commission to seek additional comment regarding the cost of the rule and "prescribe new or revised third party testing regulations" if the CPSC 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." Considering the likelihood that additional changes would need to be made to the original NPR as a result in the change in the statutory language as well as in response to further input on cost, the staff considered proposing the rule again. However, the final rule being presented for vote reserves and deletes sections impacted by H.R. 2715 and finalizes those sections of the rule unaffected by H.R. 2715 with changes in response to comments, including many burden reduction measures.

The mission of the CPSC is to protect the public against unreasonable risks of injury from consumer products through education, safety standards activities, regulation, and enforcement. This regulation intends to ensure that manufactures produce safe and compliant products.

3 Public Comments (Tab A)

Sixty comments were received during the comment period. The commenters included individuals, small crafters, small and large manufacturers, consumer advocacy groups, certification bodies, and trade associations.

Among the topics referenced in the comments were:

- the reasonable testing program for non-children's products;
- the necessity of third party conformity assessment testing for children's product certification;
- the remedial action plan (children's and non-children's products);
- periodic testing of children's products;
- the selection of random samples for periodic testing;
- material change (children's and non-children's products);
- undue influence;
- recordkeeping requirements; and
- the labeling program for children's and non-children's products.

CPSC staff reviewed the comments and summarized them by topic. The comment summaries and CPSC staff's responses are found in Tab A.

4 Draft Final Rule

The draft final rule establishes requirements for the initial certification of children's products, periodic testing, testing after a material change, and safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

The draft final rule also establishes a voluntary labeling program for children's and non-children's products.

Nonsubstantive Changes in the Codified Text

Several of the proposed requirements in the NPR were not substantively changed in the draft final rule. For instance, there were no substantive changes to the requirements for certification of children's and non-children's products; and likewise, there no imposition of any verification obligations on manufacturers.

In addition, the definition of "samples," found in § 1107.10(b)(2)(i) of the proposed rule, was eliminated because it was not considered necessary to define a commonly used term; in addition, the requirement that the samples be identical to the product in all material respects was redundant with the same wording in § 1107.10(b)(2) of the proposed rule.

Numerous nonsubstantive changes were made to the draft final rule to eliminate redundant text or clarify the text without any change in meaning.

Subpart B, the Reasonable Testing Program for Non-children's Products

For non-children's products, we received many comments on proposed subpart B. The commenters raised many practical issues, which illustrated the difficulty of drafting a regulation that can apply to many different types of products and manufacturing processes, yet still provide sufficient guidance to enable manufacturers to implement the requirements of a reasonable testing program effectively. Consequently, we are deferring action with respect to finalizing subpart B. We will, instead, reserve subpart B in the final rule and continue evaluating the issues raised in the comments.

Subpart C - Certification of Children's Products

As required by section 14(a)(2) of the CPSA, children's products must be submitted for certification testing to a CPSC-accepted third party conformity assessment body whose scope includes the required tests. In the draft final rule, the requirements for periodic testing have been modified, and the testing of random samples to ensure continued compliance has been reserved for a future rulemaking. The requirement for annual undue influence training in § 1107.24 of the proposed rule has been revised to require training only upon substantive changes to the requirements regarding undue influence under that section. The recordkeeping requirements for children's products in the draft final rule have been revised to make recordkeeping more uniform and less burdensome.

Periodic Testing

The periodic test requirements in the draft final rule were changed from those in the proposed rule in two areas: (1) the selection of samples for periodic tests, and (2) the options available to a manufacturer of a children's product to extend the maximum periodic testing interval beyond one year.

Similar to tests for certification, component part testing may be used for periodic testing purposes.

Periodic Testing Plan (Manufacturers with No Production Testing Plan or Laboratory Testing)

As described in the proposed rule, and unchanged in the draft final rule, if a manufacturer does not implement testing as described below, the maximum periodic test interval is one year. Also unchanged from the proposed rule, a manufacturer without additional testing must develop a periodic testing plan and select a testing interval short enough to ensure that if the samples pass the tests, there is a high degree of assurance that

the other untested children's products manufactured or imported during the testing interval comply with the applicable children's product safety rules.

Production Testing Plan

In the proposed rule, if a manufacturer implemented a reasonable testing program for a children's product, the maximum testing interval was extended from one to two years. The draft final rule has removed the requirement that a children's product manufacturer have a reasonable testing program but retained a key component of the original reasonable testing program, the production testing plan. In the draft final rule, a manufacturer of a children's product that implements a production testing plan must conduct periodic testing at least once every two years. The production testing program is essentially the same as the one proposed in the reasonable testing program in the NPR. The manufacturer that has implemented a production testing plan has more knowledge about the compliance of the children's product than a manufacturer with no production testing plan in place. The draft final rule still requires a manufacturer of a children's product that chooses this option to have a production testing plan. CPSC staff decided to maintain the requirement for a production testing plan because children are a vulnerable population and the CPSC traditionally has had a greater interest in ensuring the safety of children's products. Additionally, Congress indicated with the passage of the CPSIA that it intended for children's products be subject to more stringent requirements than non-children's products, as demonstrated by the requirements for third party testing and the protocols and standards for continuing testing for children's products promulgated in this rulemaking.

Similar to the production testing plan in the proposed rule's reasonable testing program, the tests do not have to be the tests described in the applicable children's product safety rule, and the tests do not have to be conducted by a CPSC-accepted third party conformity assessment body. However, the implementation of the production testing plan still requires some testing. Purely mathematical techniques, such as a Failure Modes and Effects Analysis only, or a computer simulation of the product, are not allowed. Purely mathematical techniques without verifying measurements may not characterize the product with sufficient fidelity to predict accurately its compliance to the applicable rules.

Production Testing Using an ISO/IEC 17025:2005 Laboratory

Several commenters stated that they had in-house testing laboratories accredited to ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*. The commenters noted that laboratories accredited to this international standard provide an added measure of assurance to production testing. The laboratories are accredited by an independent body as competent to perform specified tests and as having instituted a management system that establishes procedures and properly maintains records. Laboratory accreditation also establishes controls concerning data integrity, equipment calibration, and procedures to resist undue influence over testing results.

Based upon these comments, CPSC staff added an additional option in the draft final rule allowing for a maximum periodic testing interval of up to three years for a manufacturer using an ISO/IEC 17025:2005-accredited laboratory for production testing purposes. The laboratory must be accredited by an accreditation body that is itself accredited to ISO/IEC 17011:2004 (*Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*), and must employ the same test method(s) used for certification testing when conducting testing to ensure continued compliance. CPSC staff chose the 3-year time period for three reasons. First, having a laboratory accredited by an independent body as competent to perform specified tests provides an additional measure of assurance in the accuracy and the integrity of the testing results. Second, a laboratory accredited to ISO/IEC 17025:2005 must have implemented a management system that established and follows procedures, properly maintains records, and establishes controls concerning data integrity equipment calibration, and procedures to resist undue influence. Third, using the same tests as the tests used for product certification provides a more direct assessment of compliance to the applicable children's product safety rules than process control techniques.

Random Samples

H.R. 2715 revised section 14(i)(2)(B)(ii) of the CPSA by replacing testing of "random samples" to ensure continued compliance with testing of "representative samples." Given this change in the statute, the draft final rule omits § 1107.22 (which would have pertained to "Random Samples"). An NPR to implement section 14(i)(2)(B)(ii) of the CPSA, as revised by H.R. 2715 will be issued.

Following a Material Change, a New Certificate Must Be Issued

The draft final rule was revised to clarify that when a material change is made to a children's product, a new Children's Product Certificate must be issued. This certificate is based on passing certification test results for the applicable children's product safety rules affected by the change and the existing passing test results for those rules unaffected by the material change. Component part testing may be used for recertification purposes after a material change has been made on a children's product.

Elimination of Remedial Action Plan for Children's Products

In the proposed rule, a manufacturer was required to have a remedial action plan and to take remedial action upon the receipt of a testing failure. Depending on the product and the nature of the test failure, remedial actions may take many different forms. However, while it may be efficient and useful to have a formal process to follow upon receiving failing test reports, such preformulated plans are not essential, either for certification or for ensuring continued compliance of children's products. Further, as noted above, some manufacturers, such as importers, may have difficulty implementing the requirements of the remedial action plan as described in the proposed rule.

Ultimately, the manufacturer or importer is responsible for ensuring that the children's product that they make or import complies with the applicable product safety rules. For some

products and types of failing test reports, ad hoc methods may be as effective as pre-established plans in addressing test failures and ensuring that products are compliant. For these reasons, CPSC staff removed the requirements for remedial action plans for non-children's products in § 1107.25 of the proposed rule. The CPSC staff encourages manufacturers who believe that remedial action plans would be advantageous for their product to develop such plans as part of their overall quality assurance system.

Undue Influence

Some comments remarked on the perceived burden of requiring training to avoid undue influence on a third party conformity assessment body. One commenter urged the Commission to drop its proposed requirement for appropriate staff to receive "annual training" on avoiding such undue influence. The commenter felt that an annual training mandate would be unnecessary and would impose excessive costs and burdens on manufacturers of children's products.

While section 14(i)(2)(B)(iv) requires that the CPSC establish protocols and standards to safeguard third party conformity assessment bodies against undue influence exercised by a manufacturer or private labeler, CPSC staff agrees with the commenter that an annual training requirement to reiterate previously presented procedures can impose costs and burdens the benefits of which are unclear.

In response to this comment, the requirement in the proposed rule for annual training was changed in the draft final rule to a requirement for retraining when a substantive change to the draft final rule regarding undue influence is made. Manufacturers of children's products are free to modify their procedures and conduct retraining as often as they feel it is necessary to institute effectively their policies regarding safeguarding against the exercise of undue influence.

Recordkeeping for Children's Products

The recordkeeping requirements for children's products were revised to reflect the testing changes in periodic testing (the replacement of the implementation of a reasonable testing program with a production testing plan and the use of an ISO/IEC 17025:2005 accredited laboratory for production testing) and the elimination of the remedial action plan,

The recordkeeping requirements for children's products were also changed to address commenters' concerns regarding the burden of recordkeeping. To address this concern, three changes were made to the recordkeeping requirements.

First, the draft final rule no longer requires that records other than the certificate be maintained in English. Some commenters noted that because few records are likely to be requested as a part of an investigation, it would be inefficient to translate all records. If a manufacturer can provide copies of the records (in their original language) immediately to the CPSC and provide an accurate translation of the records within 48 hours, or as otherwise arranged, records may be maintained in languages other than English.

Second, the requirement that records be maintained in the United States was eliminated in the draft final rule. Some manufacturers use the records generated during production as part of their overall quality assurance program. Requiring the records to be kept in the United States would necessitate duplicating the records for certification tests, material changes, and periodic testing (including possibly production testing as well) conducted overseas. However, § 1107.26(b) of the draft final rule requires that the records must be provided to the CPSC upon request, either in hardcopy or in electronic form, such as through an Internet site.

Third, the recordkeeping requirement for records other than test records was changed in the draft final rule from the life of the product plus five years to five years. With this change, the draft final rule does not distinguish between test records and other records regarding the retention time period as was the case in the proposed rule. All records for a children's product are to be maintained for five years unless the specific product's regulation specifies a different required period. The burden of maintaining records for the life of a product plus five years could be unduly burdensome and difficult to implement where products undergo changes over time. Moreover, having a different time period for the retention of test reports versus other records may be confusing. If a children's product does not comply with an applicable product safety rule in a significant way, it is likely that the noncompliant aspect of the product would become apparent within the 5-year period. This change should result in less confusion for the regulated community regarding how long records for a particular product must be maintained.

Subpart D - Consumer Product Labeling Program

The labeling to indicate compliance with the certification requirements of section 14 of the CPSA has been revised to eliminate the requirement for a specified minimum font size and font style for the consumer product label. The requirement was replaced by a statement indicating that the label must be visible and legible. The text of the label did not change.

A few comments were submitted regarding the proposed consumer product labeling program. Some commenters stated that the CPSC should not specify the features that must be used for the label. They mentioned that different types of products would be better served by different choices of fonts and character size. Another commenter noted the possibility that the specified font and label size may not be compatible with the internal systems developed by retailers and manufacturers to meet the needs of the affected product. It might be difficult applying a label with a minimum font size of 12 points to small containers.

In response to these comments, the labeling requirements in § 1107.30(b) of the draft final rule, renumbered from § 1107.40(b) of the proposed rule, specify that the label must be visible and legible, rather than set forth a particular font and a minimum size. Manufacturers have the flexibility to implement a labeling system tailored to their product. We note that the text of the message on the label remains: "Meets CPSC Safety Requirements."

In reviewing the comments submitted regarding labels and the provisions of subpart D of the proposed rule, CPSC staff noticed that § 1107.40(d) of the proposed rule, renumbered as § 1107.30(d) in the draft final rule, could be misunderstood to imply that an alternative label may be used in place of the label specified in § 1107.40(b). Section 1107.30(d) in the draft final rule

has been clarified to state that other labels in addition to the label specified in § 1107.30(b) may be placed on the product as long as the additional labels do not change the meaning of the label specified in § 1107.30(b).

5 Final Regulatory Flexibility Analysis (Tab B)

As required by the Regulatory Flexibility Act, the staff prepared a final regulatory flexibility analysis, which describes the impact that the draft final rule will have on small businesses. Because testing costs are relatively fixed (*i.e.*, it costs a small business about the same as it costs a large business to test a product), the draft final rule will have a disproportionate impact on small businesses.

The Final Regulatory Flexibility Analysis concludes that the draft final rule will have a significant adverse impact on a substantial number of small businesses. However, the draft final rule contains some provisions that are intended to mitigate the impact on small businesses. As described in the Final Regulatory Flexibility Analysis, these include: providing for longer maximum periodic testing intervals under some circumstances; permitting component part testing that may reduce the cost of testing for manufacturers who use common components in multiple products; and allowing manufacturers to rely on certifications made by other parties.

The Final Regulatory Flexibility Analysis also describes additional alternatives that could further reduce the impact of the rule on small businesses and explains why the staff did not include these alternatives in the draft final rule. Among the alternatives not included in the draft final rule were: offering additional testing relief for low-volume manufacturers of children's products; reducing the number of repeated third party tests required for certification; and allowing the increased use of XRF analysis in third party testing,

6 Effective Date of Final Rule

The preamble to the proposed rule indicated that a final rule would become effective 180 days after its date of publication in the *Federal Register* (75 FR at 28361). However, on August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 revised the CPSIA in several different ways and also affected section 14(i)(2)(B)(ii) of the CPSA. H.R. 2715 also created a new section 14(i)(3)(B) of the CPSA, which requires the CPSC, no later than 1 year after H.R. 2715's date of enactment, to review the public comments (on opportunities to reduce the costs of third party testing requirements) and directs the CPSC to: "prescribe new or revised third party testing regulations" if we determine that "such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." Consequently, the draft final rule has an effective date 15 months after the date of publication in the *Federal Register* so that parties can begin taking steps to develop internal processes, such as recordkeeping, and so that the CPSC and other interested parties can consider how H.R. 2715 interacts with the final rule.

7 Commission Options

CPSC staff provides three options for the Commission to consider:

1. Publish the final rule as drafted by the Office of the General Counsel.
2. Publish the final rule with changes as directed by the Commission.
3. Consider other options as directed by the Commission.

**Tab A: Response to Comments Received from the Notice of Proposed
Rulemaking on Testing and Labeling Pertaining to Product Certification**



United States
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Memorandum

Date: September 8, 2011

TO : Randy Butturini
Office of Hazard Identification and Reduction

FROM: Jacqueline Campbell
Directorate for Engineering Sciences

SUBJECT: Responses to Comments Received from the Notice of Proposed
Rulemaking on Testing and Labeling Pertaining to Product Certification

1 Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act of 2008 (CPSIA) was signed into law. Section 102 of the CPSIA amended section 14(a)(1) of the Consumer Product Safety Act (CPSA), and requires that manufacturers of non-children's products subject to a rule enforced by the U.S. Consumer Product Safety Commission (CPSC), certify that such product complies with all the rules, bans, standards, or regulations applicable to the product. The CPSIA also requires manufacturers of children's products subject to an applicable children's product safety rule to submit sufficient samples to a CPSC-accepted third party conformity assessment body (laboratory) for testing and, based on those tests, issue a certificate that such product complies with the applicable children's product safety rules. Section 102(d)(2)(B) of the CPSIA (section 14(i)(2)(B) of the CPSA)³ requires the Commission, by regulation, 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. Section 102(d)(2)(A) of the CPSIA (section 14(i)(2)(A) of the CPSA) requires the Commission to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements of section 14(a) of the CPSA.

³ On August 12, 2011, the President signed H.R. 2715 into law. Among other things, H.R. 2715 corrected an editorial error in section 14 of the CPSA, by renumbering a second section 14(d) of the CPSA on Additional Regulations for Third Party Testing to section 14(i) of the CPSA. Accordingly, throughout the regulation text and this memorandum, including comment summaries and responses, references to section 14(d) of the CPSA have been revised to section 14(i) of the CPSA to be consistent with this renumbering.

On May 20, 2010, the Commission published a notice of proposed rulemaking (NPR) in the *Federal Register* (75 FR 28336) that would establish the conditions and requirements for meeting the requirements of section 102(a) and section 102(d)(2) of the Act. The period for submission of comments closed on August 3, 2010. The CPSC received 60 comments. This memorandum summarizes the comments and presents CPSC staff's responses.

2 Background

The proposed rule defined a reasonable testing program for manufacturers of non-children's products. Additionally, the proposed rule outlines the certification and periodic testing requirements for children's products. Sections on random samples, material change, undue influence, and recordkeeping for children's products also are included. Labeling requirements for all consumer products are included in the draft final rule.

In the draft final rule, the reasonable testing program for non-children's products has been reserved. The draft final rule contains sections on children's product certification, periodic testing, and testing after a material change. The remedial action plan for children's products and the testing of random samples of children's products have been deleted.

3 Comments Received and Staff Responses

A summary of each of the commenter's topics is presented, and each topic is followed by staff's response. For ease of reading, each topic will be prefaced with a numbered "Comment"; and each response will be prefaced by a corresponding numbered "Response." Each "Comment" is numbered to help distinguish between different topics. The number assigned to each comment is for organization purposes only and does not signify the comment's value or importance or the order in which it was received. Comments on similar topics are grouped together.

Several commenters made general comments supporting the overall purpose of the rule. For example, one commenter stated that third party testing is a good and necessary proactive measure to ensure the safety of children's products. The commenter added that if a product has to be recalled, the damage already has been done.

General Comments About the Proposed Rule

Comment 1:

One commenter warned that because the overwhelming majority of consumer products sold in the United States are produced overseas, nearly all of the work necessary to ensure compliance with the regulations will be performed overseas. The commenter stated that because the cost of compliance for foreign manufacturers can be relatively high—while the risks associated with noncompliance can be relatively low—it is important that the Commission's regulations balance the need for a high degree of assurance of compliance with the need to develop a practical regulatory structure that foreign manufacturers can and will implement.

Response 1:

The draft final rule is not meant to be overly prescriptive; accordingly, it provides manufacturers with a degree of flexibility to design their testing and certification programs to be consistent with the statutory requirements. For example, the draft final rule allows the manufacturer of a children's product to determine the number of samples that must be tested as long as the manufacturer has a high degree of assurance that the products represented by the samples are in compliance with all applicable children's product safety rules. Furthermore, while the draft final rule requires that manufacturers document their compliance, it allows manufacturers the flexibility to determine how to maintain this information. In addition, the draft final rule does not require any documentation, except certificates, to be maintained in English or kept in the United States.

On August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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. H.R. 2715 directs us to seek public comment on seven specific issues, including the extent to which modification of the certification requirements may have the effect of reducing redundant third party testing by or on behalf of two or more importers of a product that is substantially similar or identical in all material respects and other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. We intend to issue a notice seeking public comment on these issues in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 2:

Two commenters stated that the CPSC should conduct a full cost-benefit analysis of the rule. One commenter added that costs of complying with the testing and certification rule, in combination with other requirements under other provisions of the CPSIA and other rules administered by the CPSC, will result in a major rule with major implications to consumer product manufacturers, particularly children's product manufacturers, as well as the entire supply chain. The commenter urged the Commission to examine in greater detail and quantify the full cost and burden of these rules. A third commenter implored the CPSC to consider the reduction in risk, if any, associated with each regulatory requirement and impose only those that enhance meaningfully consumer safety in a way that makes increased cost and use of resources worthwhile.

Response 2:

This rule is being promulgated under the Administrative Procedure Act, which does not require a cost-benefit analysis. Nevertheless, CPSC staff agrees with the comment that the proposed testing and certification rule constitutes a major rule, as defined by the Congressional Review

Act of 1996. CPSC staff has changed the draft final rule to address some of the economic burden. For example, records do not have to be kept in the United States or translated into English unless requested.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 3:

One commenter stated that many manufacturers are being required to submit their products to as many as four different laboratories because some retailers want to see test results from specific laboratories. The commenter stated that the CPSC should clarify to retailers that this redundant testing is not necessary.

Response 3:

The Commission emphasizes, as it did in the preamble to the proposed rule, that retailers and sellers of children's products can rely on certificates provided by finished product certifiers, without conducting additional testing, if those certificates are based on testing conducted by a CPSC-accepted third party conformity assessment body.

CPSC staff recommends no change to the draft final rule based on this comment.

Definitions

Due Care

Comment 4:

One commenter noted that the due care requirement only applies to a few specific provisions of the proposed rule, such as §1107.23(a) of the proposed rule, regarding "material change" in the product's design, manufacturing process, or sourcing of component parts. In some instances, this defined duty of "due care" is coupled with a CPSC-created standard of a "high degree of assurance." The commenter said they appreciate the CPSC's recognition that both the "due care" standard of conduct and the "high degree of assurance" standard for compliance are anchored in the judgment and knowledge of the manufacturer. For that reason, the commenter felt that the due care requirement should have general applicability to all elements of compliance for implementation of the CPSIA's testing and certification requirements. The commenter stated that manufacturers should not have to wonder whether more than their exercise of reasonable judgment and practice, based on their manufacturing experience and sound knowledge of the product, is required for those aspects of the rules that do not explicitly reference these standards.

Response 4:

With respect to the commenter's suggestion that the due care standard should be applied to all elements of the draft final rule, the definition of "due care" in § 1107.2 of the proposed rule refers to the actions of a prudent and competent person. The CPSC expects that prudence and competence will be exercised by all parties involved in the testing and certification of products. Due care, as noted by the commenter, is emphasized in particular sections of the draft final rule; this is because these are areas that require additional care in order to prevent noncompliant products from being produced and certified.

CPSC staff recognizes that manufacturers' knowledge of their products and their production can serve as a basis for determining what steps are necessary for them to achieve a high degree of assurance that their products comply with the applicable product safety rules. Based on that knowledge, manufacturers are uniquely situated to know what actions are necessary to exercise due care and demonstrate a high degree of assurance regarding their specific circumstances.

CPSC staff recommends no change to the draft final rule based on this comment.

High Degree of Assurance

Comment 5:

Multiple commenters questioned the definition of a "high degree of assurance." One commenter would like the rule to define the term "high degree of assurance" in a more understandable or quantitative way. The commenter considers this term to be confusing and misleading and believes this could lead to unnecessary conflicts between manufacturers and conformity assessment bodies when a judgment has to be made in certain cases. The commenter wonders if this requirement is targeting the design area, manufacturing process control, quality control, or testing procedures.

Another commenter said that manufacturers would benefit from additional guidance on how to achieve a "high degree of assurance" through their testing programs. The preamble to the proposed regulation refers to a 95 percent statistical significance level as constituting a "high degree" of assurance. However, the proposed rule does not mandate a 95 percent confidence threshold. The commenter asked what factors would permit a manufacturer to satisfy the "high degree of assurance" requirement with a statistical significance level below 95 percent and asked could the CPSC provide an example of a situation where a manufacturer could still achieve a high degree of assurance with less than 95 percent confidence.

Another commenter also argued that the term "high degree of assurance" is subjective and subject to varied interpretations. The commenter suggests that a statistical confidence limit would help remove the subjectivity and set a specific threshold by which the CPSC can better enforce its rules. The commenter was also concerned that this wording may lead some manufacturers to believe that they are not required to test to the standard in all cases, as long as they foresee little risk of noncompliance or assume that the risk of being discovered having noncompliant products in the marketplace is low. The commenter concluded that the rule should clarify that testing to applicable standards is required.

Response 5:

The determination of a "high degree of assurance" for a given product will vary by industry, by product, by component part, and by manufacturer. Therefore, selecting an example using a hypothetical certifier would be of little value to manufacturers. We have intentionally defined the term in a manner that allows the manufacturer the flexibility to develop a testing program to ensure their product complies with all applicable children's product safety rules. This rule provides broad protocols and standards for regulated firms to follow and adapt to their particularized needs, given their products and processes. The use of quantitative values for the

definition of “high degree of assurance” could lead to difficulties for some manufacturers. The preamble to the proposed rule stated: “we decided against defining ‘high degree of assurance’ with respect to a 95 percent probability or confidence level because there may be difficulty in applying the statistical methods to all manufacturing processes” (75 FR at 28344). The intent of the definition is to enable a manufacturer to have a degree of confidence, based on evidence (rather than only on a belief) that all of the product manufactured is compliant with the applicable product safety rules. Some elements that can be used to demonstrate a “high degree of assurance” include: (1) knowledge of a product’s design and how it is manufactured; (2) control over component parts; and (3) measurements showing consistent performance.

Section 1107.20 (a) of the draft final rule states that manufacturers must submit samples of a children’s product to a third party conformity assessment body for testing. CPSC staff believes that these statements convey that certification testing involves tests.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 6:

Two commenters agreed that a numerical target for defining what constitutes a high degree of assurance is misplaced in the context of good manufacturing practices- (GMP) based programs. The commenter noted that the explanation of the definition of “high degree of assurance” provided in the preamble implies that the Commission prefers the 95 percent statistical level of confidence for a high-degree-of-assurance approach and considers it the default. The commenter is concerned that the 95 percent language in the preamble may prompt third party laboratories and retailers to adopt standardized testing protocols that demand large sample sizes, which will be a particular burden for the initial certification and may not be warranted in many cases. The commenter believes that the goal, across a broad range of different products subject to different manufacturing requirements and material sourcing, must be a standard that correlates “a high degree of assurance” with an “evidence-based demonstration of consistent performance,” which relies more appropriately upon process controls to assure conformance. While generally accepted process controls may include statistical sampling as part of process control programs, in and of themselves, they are not preferable to GMP. The commenter said that the final rule must be clear in this regard.

Response 6:

Standards for good manufacturing practices are generally industry-specific in areas such as: cosmetics, pharmaceutical operations, food handling, and medical devices. It is unlikely that any GMP-based program would be deemed workable or acceptable for all children’s product manufacturing methods.

A certifier’s determination that a product complies with the applicable children’s product safety rules with a high degree of assurance may derive from statistically based testing, the application of good manufacturing practices, or other knowledge of the product and its manufacture. Because GMP-based programs are industry-specific, CPSC staff disagrees with the commenter’s assertion that the programs are preferable to other accepted process controls in all manufacturing situations.

A “high degree of assurance” is defined in general terms in the draft final rule because it is intended to be applied to a wide variety of products that use many different manufacturing processes. Customizing the definition of “high degree of assurance” to fit one type of product or GMP-based program will necessarily increase the difficulty of manufacturers applying the definition to dissimilar products or manufacturing processes. Further, because GMP-based programs vary across industries—and the comments were not specific as to which aspect(s) of a GMP program we should adopt or which GMPs we should adopt—CPSC staff will not revise the draft final rule as requested.

CPSC staff does not consider a numerically based definition of a “high degree of assurance” to be the default position, as the commenter asserted. Defining a “high degree of assurance” with respect to a 95 percent probability or confidence level would be difficult to apply to all manufacturing processes for children’s products. Defining a “high degree of assurance” as a 95 percent or greater probability could result in more testing demands on small manufacturers. As discussed in the preamble to the proposed rule (75 FR at 28344), a statistical definition is not needed in order to provide an evidence-based high degree of assurance.

Regarding the concern that conformity assessment bodies and retailers may require large numbers of samples for certification testing, under the proposed rule, the children’s product certifier (not the conformity assessment body or retailer) specifies the number of samples to be tested. The draft final rule requires the number of samples to be sufficient to give the certifier a high degree of assurance that the tests conducted accurately demonstrate the ability of the product to comply with the applicable children’s product safety rules. As the Commission previously stated in the preamble to the proposed rule:

The Commission wants to emphasize to retailers and sellers of children’s products that they can rely on certificates provided by product suppliers if those certificates are based on testing conducted by a third party conformity assessment body.

(75 FR at 28337).

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 7:

Two commenters contended that the definition of a “high degree of assurance” in the proposed rule lacks clarity. Both commenters noted that the rule should have additional illustrative examples of what constitutes a high degree of assurance. One commenter acknowledged that the discussion in the preamble to the proposed rule makes clear that the definition mandates no specific formula (75 FR at 28344). However, the commenter noted that no specific examples are given in the proposed rule other than the use of statistical methods. The commenter argued that other means to achieve this confidence level should be recognized in the final rule, including means that do not rely solely on product testing or statistical methods. These methods, the commenter suggested, include appropriate quality assurance processes and risk management. Quality assurance processes can include factory/supplier evaluations, design reviews, manufacturing process controls, process auditing, or similar controls or reviews, the commenter asserted. Risk management includes analysis of a given possible failure, the likelihood of the

failure, and the potential consequences associated with the failure. The commenter argued that importers can use all of these activities to boost desired outcomes and reduce unexpected outcomes and can be performed in a feedback loop that facilitates true root cause analysis and correction, if there is a failure.

The commenters suggested substitute definitions that are practically identical. One suggested definition reads: “A high degree of assurance means an evidence-based determination of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture. Acceptable evidence-based determinations may be based on evidence derived through any appropriate process or control or combination of processes and/or controls, such as (but not limited to):

- Design validation;
- Manufacturing process control audits;
- In-process manufacturing controls, measurements, and tests;
- Component and material testing as defined in 16 CFR part 1109;
- Finished product testing;
- Raw materials certification; and
- Other controls or processes that provide information about the safety or compliance of a product.”

The other commenter’s suggested definition reads: “*High degree of assurance* means an evidence-based determination of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture. Acceptable determinations may be based on evidence derived through any appropriate tool or control methodology (or combination of tools and/or control methodologies), such as but not limited to:

- Design Validation
- Process Validation
- Manufacturing Process Control Audits
- Raw material validation and controls
- In-process manufacturing controls, measurements, and tests
- Component and material testing as defined at 16 CFR Part 1109
- Finished Product Testing”

Response 7:

The commenters are correct that certifiers can use process controls, mathematical techniques, simulations, and other aspects of a product and its manufacture as part of the basis for determining whether a particular product complies with the applicable product safety rules with a high degree of assurance. The commenter is also correct that the preamble to the proposed rule (75 FR at 28344) provides statistically based examples in the definition of a “high degree of assurance.” However, a method on the commenters’ list may be adequate for one rule but inadequate for another. As an example, design validation may be a good technique to ensure that a toy does not have a hole large enough to allow access to a sharp edge or point. However,

design validation may be inadequate for controlling lead content because its techniques are ill-suited for controlling continuing production of component parts. As another example, component part testing is a useful technique for determining the chemical content of lead and the prohibited phthalates, but it is inadequate for determining compliance to the pacifier pull tests because the entire product is required to conduct the test. A “high degree of assurance” is defined in general terms because it is intended to be applied to a wide variety of products that use many different manufacturing processes. Providing a list of the intended applications as part of the definition would introduce the risk of a manufacturer applying techniques that are inappropriate for evaluating the applicable children’s product safety rule.

Therefore, CPSC staff did not amend the definition of a “high degree of assurance” in the draft final rule as suggested by the commenters. Specific examples are not universally applicable and, therefore, they should not be included in the definition of a “high degree of assurance.” Any such list would be necessarily under-inclusive or possibly confusing or misleading. Additionally, certification and periodic testing of children’s products must be based on tests of the finished product or its component parts, sufficient to show compliance (or continuing compliance, in the case of periodic testing), with all applicable children’s product safety rules. A definition of a “high degree of assurance” that includes methods other than testing might lead some certifiers to conclude mistakenly that certification or periodic test requirements might be met by means other than testing.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 8:

A commenter proposed that the rule allow a company’s prior safety record to replace product safety testing as evidence that a company has met the requirement for a high degree of assurance (“HDA”). The commenter wrote:

The “high degree of assurance” should be based on an overall assessment of the safety record of the company. It should NOT be based on the results of an individual product, even if recalled or deemed dangerous.

The commenter pointed out that its company had a very good safety record. The commenter added:

With this record over so many years, our company should be deemed to have satisfied this HDA requirement and be endorsed as having a reasonable testing program without further inquiry.

Response 8:

Section 14(a)(2) of the CPSA makes clear that children’s product certification is based upon third party testing of the product and not the safety record of a company. For this reason, the draft final rule does not provide relief from the testing requirements in the statute. In addition, the commenter’s suggestion that a manufacturer should be allowed to rely upon its prior safety record to demonstrate a high degree of assurance would be a difficult concept to apply in practice because of the likely changes in any given manufacturer’s safety record over time.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 9:

One commenter stated that a “high degree of assurance” could be provided best by using an accredited product certification program that meets the requirements of the International Standards Organization/International Electrotechnical Commission (ISO/IEC) Guide 65, *General requirements for bodies operating product certification systems*, and the fundamentals of System 5 product certification requirements of ISO/IEC Guide 67, *Conformity assessment -- Fundamentals of product certification*.

Response 9:

The various activities a certification body undertakes, such as testing, conformity assessment, and surveillance can be used to demonstrate a high degree of assurance that a product complies with the applicable product safety rules. However, the techniques used by certification bodies are not the only means a manufacturer could use. Process control techniques, failure modes and effects analyses, and other quality assurance methods, depending on the product under consideration, could be as effective as methods employed by a certification body. Because the CPSC wants to allow finished product certifiers flexibility in deciding which methods apply best to their particular products, CPSC staff declines the commenter’s recommendation to define a “high degree of assurance” using ISO/IEC Guide 65 and Guide 67 requirements. A manufacturer who wishes to employ those requirements to ensure a high degree of assurance of compliance may do so. However, CPSC staff reiterates that testing in support of certification of a children’s product must be performed by a CPSC-accepted third party conformity assessment body whose scope of accreditation includes the tests required for certification; certification of a product cannot be delegated to another party, such as a certification body.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 10:

A commenter suggested that the language related to periodic testing intervals and sample sizes is inconsistent in the preamble. The commenter conceded that it is difficult to specify the exact number of products that must be tested in order to reach a high degree of assurance that a product is compliant. The commenter noted that the response to comments section of the preamble to the proposed rule titled, *Additional Third Party Testing Requirements for Children’s Products*, stated that “the sample size for periodic testing will depend upon the number of samples that need to be tested to provide that statistical assurance.” The commenter agreed with this statement but noted the inconsistency between the language used in that section and the language found in the response to comments section titled, *The Reasonable Testing Program*, which specifies that the testing intervals must provide “reasonable assurance” that the product meets the requirements of the applicable product safety rules. The commenter noted that there is a difference between a “high degree of assurance” and “reasonable assurance.” The commenter believes that the testing program should be statistically based, such that a confidence level of 95 percent must be achieved to indicate compliance. This requirement would eliminate the possibility of testing only a single sample to indicate compliance.

Response 10:

In the proposed rule, under the response to comments section of the preamble titled, *Additional Third Party Testing Requirements for Children's Products* (75 FR at 28342), the Commission stated the following:

If a high degree of assurance is interpreted to be a statistical likelihood of not producing noncompliant products, the sample size for periodic testing will depend upon the number of samples that need to be tested to provide *that* statistical assurance (*italics added*)...

The word *that* refers to “a high degree of assurance,” which appears at the beginning of the sentence. With respect to the other alleged inconsistencies mentioned in the comment, it is worth noting that the proposed rule uses the phrase “high degree of assurance” 20 times; whereas, the codified text of the proposed rule did not use the term “reasonable assurance” at all. The term “reasonable assurance” appears only once in the preamble to the proposed rule, in the introduction to the response to comments section, titled, *The Reasonable Testing Program*, where it is listed as one of the previous questions that the agency asked in the *Federal Register* notice announcing the December 2009 public workshop.

CPSC staff does not agree with the commenter that there should be a specific probability level (*i.e.*, 95 percent) in the definition of a “high degree of assurance.” As previously noted in the preamble to the proposed rule: “we decided against defining ‘high degree of assurance’ with respect to a 95 percent probability or confidence level because there may be difficulty in applying the statistical methods to all manufacturing processes.” Many manufacturing processes, such as low-volume and continuous manufacturing, are ill-suited to use a sampling technique for quality control purposes. In addition, for small-volume manufacturers, the number of samples required to achieve 95 percent confidence could be excessive, even to the point of requiring all of the product manufactured to be tested. Because the testing requirements of the draft final rule apply to a wide variety of products, to manufacturers of various sizes, and to many different manufacturing processes, the rule must allow flexibility to enable the manufacturer to determine the best way to comply with the requirements of the draft final rule.

The intent of the definition is for a manufacturer to have a high degree of assurance based upon evidence (rather than only on a belief) that all of the product manufactured is compliant with the applicable safety rules. Knowledge of the product’s design and how the product is manufactured, control over component parts, measurements showing consistent or inconsistent performance, the associated hazard, and many other elements such as these can be used to determine the number of samples required for certification and for the periodic testing intervals, as noted in the draft final rule.

CPSC staff recommends no change to the draft final rule based on this comment.

Identical in All Material Respects

Comment 11:

Several commenters suggested that the definition of “identical in all material respects” in § 1107.2 of the proposed rule should be clarified. One commenter noted that the existing

definition appears absolute in that it does not allow *any* “difference with respect to compliance.” This definition makes testing requirements unnecessarily rigid and costly, the commenter suggested.

Another commenter contended that the definition of “identical in all material respects” cannot be absolute. One commenter said they would revise the definition to read: “‘*Identical in all material respects*’ means there is no difference between the sample and the finished product that could affect compliance to the applicable rules.” Another commenter suggested revising the definition of “identical in all material respects” to mean “to a high degree of assurance, there is no difference between the samples and the finished product that is material to compliance of the applicable rule.” One commenter suggested that the definition of “identical in all material respects” should mean “a manufacturer possess [sic] a reasonable belief that, there is no difference between the samples and the finished product is not materially compliant.”

Response 11:

CPSC staff does not regard the definitions proposed by the commenters as improving the existing definition of “identical in all material respects.” One commenter suggested that the definition (“*Identical in all material respects* means there is no difference between the sample and the finished product that could affect compliance to the applicable rules.”) appears to be so similar to the proposed rule’s definition that adopting it would not alter the rule. Samples used for certification testing and the finished product may be different, just not different in any way that would affect the sample’s ability to demonstrate compliance of the finished product. The definition of “identical in all material respects” in the proposed rule is intended to emphasize that if anything other than the finished product is subjected to testing, then the characteristics of that sample, insofar as complying with the applicable product safety rule at issue, must be identical to the testing of the finished product. Otherwise, the test may not indicate that the finished product, in fact, complies with the applicable product safety rule.

The second suggested definition of “identical in all material respects” (“To a high degree of assurance, there is no difference between the samples and the finished product that is material to compliance of the applicable rule.”) also fails to emphasize adequately that it is the finished product that must comply with the applicable rules. In addition, using the phrase “to a high degree of assurance” in describing the similarity (with respect to conformance to the applicable rules), results in at least some doubt that the samples, in fact, are “identical in all material respects.” Further, § 1107.20(a) of the draft final rule states:

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 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.

Using a “high degree of assurance” in the definition of samples would involve double use of the term with no increase in clarity.

In a similar manner, the third proposed definition of “identical in all material respects” introduces doubt that the samples are identical to the finished product with respect to compliance by using the term “a reasonable belief.” Additionally, “a reasonable belief” standard in the definition would result in an inquiry into the state of mind of a particular manufacturer and could lead to disagreements between the CPSC and manufacturers of whether a manufacturer’s belief was reasonable in a specific instance. Further, the commenter did not explain or clarify interpretation of the phrase “materially compliant”; the absence of such an explanation or interpretation would result in additional uncertainty in the definition.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 12:

One commenter urged the CPSC to state that the phrase “identical in all material respects” in the proposed rule is intended to be consistent with the “objectively reasonable basis” standard from 16 CFR part 1633 and that the CPSC would consider individual subordinate mattresses that meet the requirements of 16 CFR part 1633 to be “identical in all material respects” to the qualified prototype to which a specific mattress is subordinate.

Response 12:

CPSC staff agrees with the commenter that “identical in all material respects” is consistent with a demonstration on an “objectively reasonable basis,” as stated in 16 CFR § 1633.4(b)(3). CPSC staff considers individual subordinate mattresses that meet the requirements of 16 CFR part 1633 to be “identical in all material respects” to the qualified prototype to which a specific mattress is subordinate.

CPSC staff recommends no change to the draft final rule based on this comment.

Manufacturing Process

Comment 13:

Two commenters noted that the term “manufacturing process” under proposed § 1107.2 includes “personnel used to create the component parts and assemble a finished product.” The commenters argued that this should not be construed to mean that any change in the employees who are involved in the production of a part or product is equivalent to a change in the manufacturing process.

Response 13:

Regarding the commenters’ suggestion on the definition of “manufacturing process,” the commenters may be confusing a change in the manufacturing process with a material change that could affect compliance to an applicable product safety rule. The commenters are partly correct that any change in personnel involved with a manufacturing process does not necessarily constitute a material change with respect to the product’s compliance. However, for manufacturing processes that rely on high levels of craftsmanship or technical expertise, such a personnel change could affect compliance and, therefore, might be considered a material change to the manufacturing process.

CPSC staff recommends no change to the draft final rule based on this comment.

Reasonable Testing Program

We received many comments on proposed subpart B. The commenters raised many practical issues that illustrate the difficulty of drafting a regulation that can apply to many different types of products and manufacturing processes, yet still provide sufficient guidance to enable manufacturers to implement the requirements of a reasonable testing program effectively.

Consequently, we are deferring action with respect to finalizing subpart B. We will, instead, reserve subpart B in the final rule and continue evaluating the issues raised in the comments. Therefore, we will not provide responses to comments received on subpart B.

Children's Products

General Comments

Comment 14:

One commenter argued that the terms “reasonable assurance” and “sufficient number of samples” are likely to result in widely disparate interpretations. The commenter urged that “reasonable assurance” should be defined as a statistically significant number with a confidence level of 95 percent, based on testing enough samples to provide statistical validity. Setting a specific confidence limit enables the Commission to enforce this section of the rule better by avoiding subjectivity and by creating uniformity and consistency among manufacturers and conformity assessment bodies.

The commenter noted that “upstream” controls (*i.e.*, by “upstream” the commenter means the processes, inspections, and tests conducted prior to or during product assembly intended to assure product quality), product risk assessments, and design analyses are reasonable tools for manufacturers to use, but currently, they are not rigorous enough or sufficiently specific to ensure “downstream” compliance. Until they are, compliance must be determined by final product testing, the commenter asserted.

Response 14:

CPSC staff declines to adopt the suggestion to set a 95 percent confidence level based on testing enough samples to provide statistical validity. Many manufacturing processes, such as those using continuous flow processes, are ill-suited to use a sampling technique for quality control purposes. In addition, for small-volume manufacturers, the number of samples required to achieve 95 percent confidence could be excessive, even to the point of requiring all of the product manufactured to be tested.

Because the testing requirements of the rule must apply to a wide variety of children's products, to manufacturers of various sizes, and to many different manufacturing processes, the rule must allow flexibility for the manufacturer to determine the best way to comply with the rule's requirements. CPSC staff is aware of numerous “upstream” quality assurance tools and

processes that are widely used to ensure high levels of product performance. For example, techniques, such as component part testing, are particularly well-suited for determining compliance with the lead content limits for accessible parts on children's products. Numerous international standards address quality control and assurance processes applied "upstream" in the product production process and can be used to extend the maximum periodic testing interval. Thus, CPSC staff disagrees with the commenter that none of these quality assurance tools and processes is rigorous or specific enough to ensure compliance.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 15:

One commenter recommended a system of product risk assessment that would tailor the third party certification schedule for low-volume firms, as follows:

Children's products: High-risk children's products would require third party certification annually. Low-risk children's products would require third party certification every three years.

Any test failure would automatically move the product into the next most stringent category. This system would focus the inspection of products on the products most dangerous to public safety. The commenter stated that an unintended consequence of this strategy would be to reward the firms that make the safest products.

Response 15:

The commenter appears to be applying the proposed low-volume exception to periodic testing (stated in § 1107.21(d) of the proposed rule) to certification testing. The low-volume exception did not apply to certification testing. There is no schedule for when a product is subject to certification testing for any manufacturer, regardless of production volume. Instead, periodic testing is required for children's products to ensure continued compliance with a high degree of assurance.

Section 14(a) of the CPSA requires certification testing for children's products before they may be imported for consumption or warehousing or distributed into commerce. This initial testing of children's products does not depend on product risk. Continuing compliance is demonstrated through periodic testing for children's products, which specifies a maximum testing interval, based on the implementation of a production testing plan by the manufacturer. The final rule allows a manufacturer to consider risk to the extent it permits consideration of "the potential for serious injury or death resulting from a noncompliant product" in determining the product testing interval for continued testing of the product to ensure compliance.

Regarding the commenter's suggestion to devise a system of categorizing all children's and non-children's products subject to an applicable rule into risk categories, such a system would require a separate rulemaking effort and is beyond the scope of this rule.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 16:

One commenter noted that recognized industry terminology is not used consistently throughout the proposed rule. The commenter noted that the proposed rule relies on the terms “test” or “testing” as if all consumer product safety requirements could be evaluated by performing tests to ensure ongoing compliance. The commenter noted that, while full product testing is appropriate in some cases, current consumer product safety regulations imply or specify evaluation activities not considered to be actual testing (*e.g.*, inspections, reviews, audits) may be appropriate.

The commenter noted that it recommended previously to the CPSC that it should refer to Annex A of ISO/IEC 17000, *Conformity assessment–Vocabulary and general principles*, which provides a general description of the functional approach to activities that constitute conformity assessment, to address the question of the interpretation of the use of the terms “test” or “testing.”

Response 16:

The word “test” was chosen for the draft final rule because of its usage in section 14(a) of the CPSA. Certification tests are tests on samples of the product that are identical in all material respects to the finished product. Section 14(i)(2)(B)(i) of the CPSA states that children’s products are subject to testing periodically and after a material change.

The words “test” and “testing” are used throughout the draft final rule to mean a process used to determine whether a product is compliant with the applicable product safety rules. The process is geared to the particular product and safety rule. As such, testing may include inspection of labels and manuals, audits, and measurements to determine compliance with the applicable product safety rules. CPSC staff believes that the definition of “test” and “testing” are clear.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 17:

One commenter noted that the Commission is not allowing the use of existing federally registered certification marks of third party conformity assessment bodies as an acceptable substitute for a certificate of conformity. The commenter added that introducing the new certificate of conformity will immediately cause confusion in the marketplace. The commenter suggested that the Commission should have to justify, through a comprehensive and independent study, why it is departing from the existing system and why its proposed system would be better and more reliable.

Another commenter stated that the CPSC should recognize certification marks issued by established third party certification programs as a substitute for the certificates of conformity described in the proposed rule when the product has been certified as compliant with associated product standards through a program that reflects CPSA requirements by an ISO/IEC Guide 65-accredited certification body.

Response 17:

Certification marks are symbols that a manufacturer is authorized to affix to their product to indicate that the product has been certified by a certification body. Third party certification involves testing, declarations of conformance, factory inspections, and continuing surveillance activities. The certification body certifies that the product complies with the specified product safety rules that were evaluated.

A certification mark does not contain the information required on a certificate by section 14(g) of the CPSA and cannot be used as a substitute for a Children's Product Certificate. Section 14(a) of the CPSA requires manufacturers of a consumer product that is subject to an applicable product safety rule to issue a certificate certifying conformance of the children's product to the applicable safety standards. Section 14(a) of the CPSA does not allow a party other than the manufacturer, importer, or private labeler to issue a Children's Product Certificate.

Since the CPSA was enacted in 2008, CPSC staff has not observed immediate confusion in the marketplace regarding certificates. As noted above, certification marks cannot be used as a substitute for certificates in the event of confusion in the marketplace. Thus, because section 14(a) of the CPSA requires the manufacturer to issue a certificate of conformity, an independent study is not warranted.

On August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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.

We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 also requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with ensuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 18:

One commenter noted that a publisher of ordinary books may have varying titles and content, but all of the books are made with the same materials in the same manner. The commenter asserted that the differences between ordinary books are not material to compliance with the applicable rules. Accordingly, the commenter said that having accredited third party conformity assessment body testing for a finished book would constitute finished product testing for all other books (International Standard Book Numbers, or ISBNs) that do not materially differ from the tested book with respect to compliance with CPSC safety standards. The commenter said a publisher with a reasonable testing program and without material changes could rely on the component part certifications for all materials published within a 2-year period.

Response 18:

Section 14(i)(5)(A)(i) of the CPSA, as amended by H.R. 2715, excludes ordinary books and ordinary paper-based printed materials from the third party testing requirements in section 14(a)

of the CPSA. Additionally, the final rule reserves subpart B, which would pertain to a reasonable testing program for non-children's products. Therefore, it is unnecessary for us to consider how third party testing results for a book might be extended to all other books.

Comment 19:

One commenter asserted that only good design and comprehensive design review by qualified individuals will improve the safety of products. Therefore, the commenter suggested that the CPSC should require "design hazard analysis" in the certification of children's products sections of the final rule. Design hazard analysis, according to the commenter, identifies potential safety hazards in a consumer product resulting from the design of the product and involves determinations made by skilled professionals from disciplines such as engineering, chemistry, and biology as to the features of a product that would result in safety hazards. The commenter asserted that the Commission has the legal authority to require design hazard analysis of consumer products.

The commenter suggested the following changes:

In Subpart C, *Certification of Children's Products*

Insert a new subsection 1107.20(a), *Children's Product Certification*: (Note: The commenter may have meant to create a new subsection (a) and renumber the remaining subsections accordingly.)

Prior to submitting samples of a children's product for testing by a third party conformity assessment body, manufacturers must conduct a design hazard analysis and produce a design appraisal of the product that identifies and characterizes the potential hazards associated with that consumer product that are related to the design of a product. The design appraisal should include, at a minimum, an engineering, chemical, and biological analysis of the product, as appropriate to the type of product and the materials contained in the product.

Insert in § 1107.26(c), *Remedial Action*, after ". . . children's product safety rules":

If the manufacturer knows or reasonably should know that the failure of the product is related to the product's design, the manufacturer shall conduct a revised design hazard review and produce a new design appraisal.

Response 19:

CPSC staff agrees that designing safety into a children's product is an important part of a comprehensive quality control program. We decline, however, to adopt the commenter's suggestion to include requirements mandating design hazard analyses for children's products in its draft final rule. This rulemaking is intended to implement the testing and certification requirements of section 14(a) and section 14(i)(2)(B) of the CPSA. Requiring a design hazard analysis goes beyond the statutory requirements because such an analysis would consider factors other than what is required to demonstrate compliance with the applicable product safety rules.

This action would extend the draft final rule to address activities that would occur before a product is manufactured.

Currently, given the range of products that are subject to section 14 of the CPSA, CPSC staff has no practical means of identifying or evaluating those individuals whose credentials and experience, under the commenter's suggested changes to the rule, would render them qualified to conduct design hazard analyses on products. Although the draft final rule will not impose a requirement on manufacturers to conduct a design hazard analysis on their products, manufacturers are free to engage in such analyses when developing or manufacturing a product.

Further, as explained the section on remedial action, the requirement for a remedial action plan for children's products has been removed from the draft final rule.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 20:

One commenter suggested that final testing and certification should defer to the Occupational Safety and Health Administration (OSHA) -designated Nationally Recognized Testing Laboratory (NRTL) certification program by determining that such products, as they are manufactured and distributed for consumer use, are *per se* compliant with the proposed testing and certification rules. The CPSC would still maintain its authority to recall products, seek civil penalties, and other remedies available to the Commission, if violations are found.

Response 20:

Pursuant to section 14(a)(3)(C) of the CPSA, we have chosen to designate accrediting bodies that are full-member signatories to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA) to conduct third party testing. Given that children's products intended for the U.S. market are manufactured in nations throughout the world, we decided to avoid designating accreditation programs or entities that are recognized only in a specific region, nation, or locality. The reasons for this are: (1) to keep the program as simple as possible for use by manufacturers, private labelers, importers, testing laboratories, and other interested parties; (2) to establish uniform requirements regardless of location; (3) to establish a program that is manageable within agency resources; and (4) to maintain a degree of consistency in the procedures used by the designated accrediting bodies.

Moreover, the commenter appears to misstate testing requirements. Consumer products are not tested for whether they are compliant with the testing and certification rule (*i.e.*, parts 1107 and 1109), rather, consumer products are tested for compliance with applicable rules, bans, standards, and regulations which the CPSC enforces. Moreover, section 14(i)(2)(B)(i) of the CPSA requires such testing periodically and when there has been a material change. Therefore, continued testing is required by the statute and "*per se* conformance" with the applicable product safety rules is not allowed. Additionally, section 14(a) of the CPSA requires manufacturers (including importers) to certify that their products comply with the applicable product safety rules. This responsibility cannot be delegated to another party, such as a certification body.

The qualifications of testing laboratories performing certification tests are outside the scope of this final rule. Such qualifications are addressed in the various notices of requirements that we have published pursuant to section 14(a)(3) of the CPSA.

Finally, we acknowledge that the recently-enacted H.R. 2715 requires us to seek public comment on “opportunities to reduce the cost of third part testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation.” One topic which H.R. 2715 requires us to address pertains to “the extent to which evidence of conformity with other national or international governmental standards may provide assurance of conformity to consumer product safety rules, bans, standards, or regulations applicable under [the Consumer Product Safety Act].” Elsewhere in this issue of the *Federal Register*, we have published a notice inviting public comment on the issues identified in H.R. 2715, so the commenter’s argument would be more appropriately raised and addressed in that proceeding. We note, however, that very few products covered under the OSHA–designated Nationally Recognized Testing Laboratory certification program would be children’s products for which third party testing would be required. Moreover, those products that are subject to the OSHA certification program would likely be covered by CPSC regulations, if at all, for which the only requirement is a general conformity certificate based on a reasonable testing program. OSHA certification testing may be a sufficient basis for such certifications depending on the product and the type of testing involved. Given that CPSC does not have jurisdiction of products when the risks of injury associated with the consumer product could be eliminated or reduced to a sufficient extent by the actions of OSHA, there may be very little overlap between a particular product’s results under OSHA’s testing program and any CPSC required testing.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 21:

One commenter suggested an evidenced-based approach to certification, based on historical performance and risk for the product type and manufacturing process. The commenter suggested that an importer/retailer may implement a program requiring:

- sample testing using materially identical components to be completed before production begins;
- certification from samples selected during the start of production; and
- periodic testing as the item remains in production.

At each of these stages, a representative set of samples would be pulled to cover all tests related to the applicable rules, bans, standards, and regulations.

The commenter suggested the following example:

For a child’s solid-rubber ball, more than 10,000 finished products that are materially identical could be made in less than one manufacturing shift. In this scenario, it would be appropriate to select samples when material changes occur and or meet historically defined frequency intervals in order to maintain and validate that products meet all rules, bans, standards, and regulations.

The commenter would like the CPSC to acknowledge that for children's products, samples selected from a lot of finished product consisting of more than 10,000 pieces, but produced in a short time period, may be used to satisfy both certification testing and periodic testing requirements.

Response 21:

Section 14(a)(2) of the CPSA requires a manufacturer or importer of a children's product subject to a children's product safety rule to submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to a third party conformity assessment body whose accreditation has been accepted by the CPSC to be tested for compliance with the applicable children's product safety rules. This requirement is also set forth in § 1107.20(a) of the draft final rule. Thus, both of the commenter's first two suggestions, to choose samples for testing using materially identical components and to select samples during the start of production, would likely fulfill the statutory requirement to submit samples that are identical in all material respects to the product for purposes of certification testing.

Section 14(i)(2)(B)(i) of the CPSA requires, in part, that the Commission establish protocols and standards to ensure that a certified children's product is tested for compliance periodically. Section 1107.21 of the draft final rule details periodic testing requirements for children's products. Accordingly, the commenter's suggestion regarding periodic testing is required by the statute and our expectation with regard to periodic testing is articulated in the draft final rule.

Regarding the commenter's suggestion regarding short period production runs of children's products, the same samples may be used for certification and periodic tests. If a testing plan is designed and implemented to meet the requirements of §§ 1107.20 and 1107.21, then the requirements to demonstrate the product's ability to meet all applicable children's product safety rules and ensure that continuing production is compliant may be met in this manner. If the manufacturer has a high degree of assurance of the children's product's compliance and the production run does not extend beyond the maximum periodic testing interval, then no third party periodic tests may be required. However, no children's product that is subject to a children's product safety rule may enter into commerce without a Children's Product Certificate based on passing test results from CPSC-accepted third party conformity assessment body certification tests.

CPSC staff recommends no change to the draft final rule based on this comment.

Certification Tests: General

Comment 22:

Some commenters stated that the safety performance of a finished product may not be able to be based solely on the compliance of its component parts. The commenters asserted that some requirements can be evaluated only with finished product samples. The commenters requested that the CPSC clarify which products and which regulations would be amenable to component part testing. One commenter suggested that electrical safety standards and regulations (*i.e.*, fire and shock hazard testing) should not be allowed to rely solely on component part testing.

Response 22:

The commenters are correct that some requirements can be evaluated only with finished product samples, and not with tests on component parts. However, both this draft final rule and the draft final rule on *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) contain restrictions on the use of component part testing. For example, § 1107.20(c) of the draft final rule states:

Except where otherwise specified by a children's product safety rule, component part testing pursuant to 16 CFR part 1109 may be used to support the certification testing requirements of this section.

The draft final rule for 16 CFR part 1109 states that if a certifier has doubts about whether component part testing is sufficient to demonstrate compliance with all the applicable rules, bans, standards, or regulations, those doubts should be resolved in favor of testing the finished product.

Therefore, CPSC staff believes that the concern of the commenters is addressed by the requirements of the two rules and recommends no change to the draft final rule based on this comment.

Comment 23:

One commenter expressed concern about the effect this rule would have on laboratory testing capacity and suggested removing references to statistical sampling and the use of ANSI/ASQ Z1.4, *Sampling Procedures and Tables for Inspection by Attributes* and Z1.9, *Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming*, for determining the number of samples required for certification testing, production testing, and periodic testing. The commenter said the frequency of testing and the number of samples tested should be set or determined by retailers and manufacturers to ensure compliance with all applicable rules, bans, standards and regulations. The commenter stated that referencing the use of statistical sampling, confidence levels, and ANSI/ASQ Z1.4 & Z1.9 implies a very significant increase in the number of samples required for product testing.

Response 23:

For manufacturers or importers using tests on samples of a product to ensure continued compliance to the applicable product safety rules, the rule permits manufacturers or importers to determine the frequency of testing and the number of samples tested to ensure compliance. Retailers only have testing or certification obligations if they are importers. The commenter did not explain how removing references to quality management and control standards and sampling procedures, which are not required but may be used voluntarily by certifiers, would address the issue of laboratory testing capacity. However, the proposed rule's reference to ANSI/ASQ Z1.4 and Z1.9 may be misleading to manufacturers because they include uses of the phrase "Acceptable Quality Level (AQL)." An AQL can be interpreted as an acceptable percentage of nonconforming products, which is not appropriate when applied to the case of compliance of products to health and safety standards. Therefore, CPSC staff has deleted references to these standards in the draft final rule.

Comment 24:

One commenter noted that proposed § 1107.20 stated that, for manufacturing processes that have greater inherent variability, more samples may be needed for testing to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules. The commenter added that phrases, such as "sufficient number of samples" and "variability in composition or quality," can be confusing. The commenter concluded by stating that regular internal monitoring and periodic testing should be able to provide sufficient data and information to support any assessment of product quality.

Response 24:

The commenter is correct that internal monitoring and testing can provide data to support the assessment of product quality. Because § 1107.20 of the draft final rule applies to both tightly- and loosely controlled manufacturing processes, the Commission emphasizes in § 1107.20(b) of the draft final rule that the number of samples needed to give the certifier a high degree of assurance of the product's compliance is affected by how well the product's manufacturing process controls those variables associated with compliance. A sufficient number of samples would be the quantity of samples selected for certification testing that gives the certifier a high degree of assurance that the product complies with all the applicable children's product safety rules. "Variability in the composition or quality" means unit-to-unit differences of a product that can affect its compliance with the applicable children's product safety rules.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 25:

One commenter noted that the Labeling of Hazardous Art Materials Act (LHAMA), established the requirements for the labeling of art materials in ASTM D-4236, which is referenced in 16 CFR § 1500.14(b)(8). The commenter asked that the Commission: (1) clarify the meaning of this provision with respect to the certification of art materials under section 14 of the CPSA; and (2) state whether LHAMA is a labeling rule under the Federal Hazardous Substances Act (FHSA) that would not require testing and certification to LHAMA under the CPSA. The commenter further proposed the use of existing facilities and procedures used for LHAMA to certify compliance with the CPSIA.

Response 25:

LHAMA requires that the manufacturer, importer, or repackager of art materials have a product's formulation reviewed by a toxicologist for its potential to cause chronic adverse health effects. A conformance statement on the product is used to certify that the product has been so reviewed. However, section 101 of the CPSIA introduces additional testing requirements for lead in children's products beyond what is required under LHAMA, so certification of art materials under LHAMA is not necessarily equivalent to testing for lead pursuant to section 101 of the CPSIA and section 14 of the CPSA.

Regarding whether LHAMA is a labeling requirement under the FHSA that would not require testing and certification, we note that LHAMA does not contain a performance standard similar to those in consumer product safety rules, but rather, requires labeling in the form of a

conformance statement that the product formulation has been reviewed by a toxicologist. The requirements of LHAMA are similar to the labeling requirements of the FHSA of which it is a part. Therefore, third party testing for conformance to LHAMA is not required. An art material designed or intended primarily for children 12 years of age or younger would have to be tested by a CPSC-accepted third party laboratory to demonstrate compliance with the lead content limits, but it would not require third party testing and certification to the LHAMA requirements.

Regarding using facilities for LHAMA to certify to CPSIA requirements, section 14(f)(2)(C) of the CPSA states that a certifying organization, as defined in appendix A to 16 CFR § 1500.14(b)(8), “meets the requirements” for consideration as a third party conformity assessment body “with respect to the certification of art materials and art products required under this section or by regulations prescribed under the Federal Hazardous Substances Act.” Thus, an organization that is a certifying organization with respect to LHAMA is a third party conformity assessment body and may test children’s art materials and art products for their compliance with LHAMA. Thus, insofar as certifying organizations and LHAMA are concerned, no changes to the proposed rule are necessary. Accreditation requirements for testing for compliance with the CPSIA other than LHAMA are beyond the scope of this rulemaking and may be addressed in a separate rulemaking.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 26:

One commenter requested that the CPSC make an explicit statement about component testing where certain components are exempt from testing and certification. The commenter is concerned that, without specific language, the final customer will not accept component testing, if exempt parts are not tested. The commenter recommended revising proposed § 1107.20(c) as follows:

(c) Except where otherwise specified by a children’s product safety rule, a manufacturer may substitute component part testing for complete product testing pursuant to 16 CFR [part] 1109 if the component part, without the remainder of the finished product, is sufficient to determine compliance for the entire product. *Component part testing can be used to substantiate compliance for those children’s products where part of the product has been exempted from testing pursuant to Section 1500.91.* (Italics indicate proposed language.)

Response 26:

CPSC staff agrees that language similar to that suggested by the commenter would be helpful, but we believe that the commenter’s change belongs in the rulemaking pertaining to component part testing, specifically with component part testing for the lead content of children’s products under proposed 16 CFR § 1109.12. Therefore, CPSC staff has considered this comment under the proposed rule for component part testing.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 27:

Multiple commenters noted that manufacturers have established first party testing laboratories that are accredited to ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*. The commenters suggested that, for manufacturers with such laboratories, the CPSC should allow test results from those facilities to be used for children's product certification purposes. Many commenters suggested that one half of the testing for certification should be allowed at in-house testing facilities; others recommended that the number of samples sent to third party laboratories for certification purposes should be reduced "to a minimum." Some commenters stated that the CPSC should recognize internal laboratories as a way to reduce dependence on third party laboratories. The reasons for the suggestions include: a desire to reduce testing costs, encourage other manufacturers to develop their own internal testing facilities, and encourage continuous product improvements.

Response 27:

Section 14(a)(2) of the CPSA explicitly requires that testing of children's products be conducted by a third party conformity assessment body as a condition of certification. Further, those third party conformity assessment bodies must have a CPSC-accepted accreditation for the scope of the testing undertaken in support of product certification. Unless the manufacturer's laboratory is a CPSC-accepted firewalled laboratory, first party testing facilities, regardless of ISO/IEC 17025:2005 accreditation status, cannot be used for children's product certification purposes.

CPSC staff notes that, in response to these comments and concerns raised about cost, § 1107.21(d) of the draft final rule allows manufacturers using in-house testing laboratories accredited to ISO/IEC 17025:2005—to ensure continued compliance—to conduct periodic testing at a maximum testing interval of three years.

On August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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.

We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 28:

One commenter noted that carpets and rugs currently require flammability testing in accordance with 16 CFR parts 1630 and 1631 and suggested that there is no need for an additional flammability testing procedure for youth carpets and rugs.

Response 28:

Section 14(a)(2) of the CPSA requires third party conformity assessment body testing of children's products (or samples that are identical in all material respects) subject to a children's product safety rule for initial certification purposes. Further, section 14(f)(1) of the CPSA defines a children's product safety rule as a consumer product safety rule enforced by the Commission. Section 3(a)(2) of the CPSA defines a children's product as a consumer product designed or intended primarily for children 12 years of age or younger. Thus, because youth carpets and rugs are children's products and are subject to the consumer product safety rules 16 CFR 1630 and 1631, third party testing is required.

For these reasons, initial certification testing for youth carpets and rugs must be performed by a CPSC-accepted third party conformity assessment body whose accreditation includes the scope of the tests. Second, children's products are subject to requirements for periodic testing, material changes, undue influence, and recordkeeping in subpart C of the draft final rule. The test methods in 16 CFR parts 1630 and 1631 are still applicable.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 29:

One commenter stated that the statutory requirements for certificates in section 14(a) of the CPSA imposes strict and detailed requirements for the contents and availability of certificates of conformity that document compliance of a children's product as demonstrated through test results. A certificate based on accredited third party conformity assessment body testing must be issued by the manufacturer and private labeler of any children's product that is subject to a CPSC rule, and it must comply not only with the requirements of section 14(g) of CPSA, but also with the requirements of a finished product certifier's reliance on component materials testing certification. Thus, a finished product certifier could rely on a test report showing passing test results for one or more component materials used in the product, based on accredited third party conformity assessment body testing conducted by another person.

The commenter stated that inclusion of this information in the certificate accompanying the finished children's product would create logistical nightmares for the manufacturers and private labelers of children's products. The commenter did not object to the "recordkeeping" requirements in § 1107.26 of the proposed rule but urged the CPSC to note that compliance with these requirements should make it unnecessary for the manufacturer or private labeler of the finished children's product to ensure that every certificate required under section 14 of the CPSA accompanies the product or shipment of products is furnished to each distributor or retailer of the product.

The commenter also urged the CPSC to adopt certificate requirements that reflect the key concept in the tracking label provisions, which require that the manufacturer (as well as the "ultimate purchaser") of the finished children's product be able to "ascertain" certain information similar to that required to be included in certificates of conformity. The commenter suggested that the certificate, like the "tracking labels," could be mandated for children's products under section 103 of CPSIA to use codes or other means to point all interested parties to a source where such information readily can be found. This code could be contact information where the

manufacturer or private labeler could include an Internet URL for the manufacturer's website where the information could be accessed.

Response 29:

Section 14(g)(1) of the CPSA and 16 CFR § 1110.11 require specific information on each certificate. In addition, section 14(g)(3) of the CPSA states that the required certificate shall accompany the applicable product or shipment of products covered by the same certificate and a copy of the certificate shall be furnished to each distributor or retailer of the product. However, 16 CFR § 1110.9 allows a manufacturer to file certificates electronically, which may be accomplished by providing an Internet URL for the manufacturer's Website where the information could be accessed as the commenter suggested. CPSC staff notes that the listing of component parts or component part test results does not have to be included on the finished product certificate.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 30:

Multiple commenters mentioned the high costs associated with third party testing and noted that the proposed rule under-recognizes the in-house quality assurance and testing capabilities of manufacturers.

Response 30:

CPSC staff is aware of many effective quality assurance techniques that are widely used to control quality in product manufacturing. However, section 14(a)(2) of the CPSA requires third party conformity assessment body testing of children's products for initial certification. Unless the manufacturer's in-house testing facility is a CPSC-accepted firewalled laboratory, data from those facilities cannot be used for children's product certification purposes. No exclusion is included in the statute for first party certification or periodic testing of children's products based on the costs of testing.

CPSC staff notes that, in response to these comments and in response to concerns about the cost of third party testing, § 1107.21(d) of the draft final rule allows manufacturers implementing a production testing plan to ensure the compliance of continuing production to conduct periodic testing at a maximum testing interval of two years. In addition, the draft final rule allows manufacturers using in-house testing laboratories accredited to ISO/IEC 17025:2005 to ensure continued compliance, to conduct periodic testing at a maximum testing interval of three years.

On August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires the CPSC to seek public 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.

We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 also requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing

costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

CPSC staff recommends no change to the draft final rule based on this comment.

Certification Tests

Comment 31:

Two commenters wanted more detail on what is meant by “a sufficient number of samples,” expressing concern that, if left to conformity assessment bodies, there will be too much variability among conformity assessment bodies about what is a sufficient number.

Response 31:

A “sufficient number of samples” are the number of samples necessary to give the manufacturer or importer a high degree of assurance of the product’s compliance with the applicable rules when tested. Because a high degree of assurance is based upon the manufacturer’s or importer’s knowledge of the product and its manufacture, a sufficient number of samples will vary based on those factors. For example, for products with highly consistent part-to-part manufacturing processes (*e.g.*, die casting), fewer samples may be necessary to give the manufacturer/importer a high degree of assurance of compliance. For processes with more variability (such as hand assembly), it is likely that more samples will be necessary to achieve the same high degree of assurance.

The commenters also may have misunderstood the role of conformity assessment bodies in the testing and certification requirements of the rule. The conformity assessment body does not specify the number of samples to be tested. The manufacturer or importer specifies to the conformity assessment body the number of samples to be tested.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 32:

One commenter stated that the language covering samples needs to be clarified. The commenter stated that the rule proposes requiring testing with a “sufficient number of samples” to provide a “high degree of assurance” (for minimum certification testing), while maintaining that the sampling does not have to meet minimum standards of statistical confidence. However, the commenter noted that the comments accompanying the Notice of Proposed Rulemaking recognize that “there may be difficulty in applying statistical methods to all manufacturing processes.”

The commenter further stated that if testing a “sufficient number of samples to provide a high degree of assurance” is required when applying a reasonable testing program to children’s products, then the CPSC should provide guidance on alternatives that certifiers may use to fulfill the duty to justify their plan, were they to choose anything less than a random statistical sample. The commenter noted that the CPSC has historically relied on a sample of 12 or fewer units, without regard to the size of the production run and that certain statistical models used by

auditors impose a maximum sample of 25 units, no matter the size of the cohort from which the samples are selected.

Based on these points, the commenter recommended that the CPSC delete the requirement to test a “sufficient number of samples to provide a high degree of assurance” under a reasonable testing program. The commenter said that the premise of a “reasonable testing program”---in order to differentiate it from the mandatory periodic testing required for children’s products that do not rely on a reasonable testing program---must be that for some specific products, testing will not be the basis for certifying to the applicable rule. The commenter stated that the Commission appropriately acknowledges the implications of differences between product categories and industries attempting to develop programs under the proposed rule in the following observation: “*A manufacturer may develop the scope and details of each element of a reasonable testing program based on knowledge and expertise regarding the product and its manufacturing processes*” (75 FR at 28345). The commenter stated that this discretion also must extend to the sample selection method of test programs, provided that all population elements have a chance of selection and due care is exercised to avoid selection bias through documented procedures.

The commenter also stated that the Commission should propose separate regulations for specific products that may warrant prescribed methods as has been done with bicycle helmets. The commenter believes this is the kind of evidence-based decision making that the CPSC envisioned when it rejected a single definition of “high degree of assurance” within a reasonable testing program for non-children’s products.

Response 32:

Although subpart B, describing a reasonable testing program, has been reserved in the draft final rule, the concept of certification testing and testing a sufficient number of samples to provide a high degree of assurance of compliance with applicable rules, bans, standards, and regulations with regard to children’s products remains in the draft final rule in § 1107.20(a). CPSC staff disagrees with the commenter’s assertion that “testing with a sufficient number of samples to provide a high degree of assurance” requires the testing method to meet minimum standards of statistical confidence. In the preamble to the proposed rule (75 FR at 28344), the discussion of a high degree of assurance intentionally avoided choosing a statistically based definition for the term. Therefore, the certifier is allowed to choose other means, using its knowledge of the product and how it is manufactured, to determine what would be a sufficient number of samples. A certifier may use statistical methods, but the determination of a sufficient number of samples to achieve a high degree of assurance is not required to be statistically based.

CPSC staff declines to provide guidance on alternatives that certifiers may use to fulfill the duty to justify their plan if they were to choose anything other than a random statistical sample. With the wide variety of children’s products and manufacturing processes that will be subject to the draft final rule, it would be impractical to attempt to provide guidance applicable to all or to attempt to provide individualized guidance for some or all products, as requested by the commenter. Because the certifier typically possesses greater knowledge of the product and how it is made than other parties, the certifier is in the best position to determine how to achieve a

high degree of assurance that its products are compliant with all the applicable children's product safety rules.

Regarding the commenter's observation of the CPSC's use of 12 or fewer samples, those samples were not used for children's product certification purposes. Thus, tests run by CPSC staff are not germane to the discussion of product certification. Depending on the manufacturer's knowledge of a children's product and its manufacture, a sufficient number of samples to provide a high degree of assurance of compliance with the applicable children's product safety rules may be greater or less than 12.

The commenter may be misunderstanding the rule as it relates to random samples. In the proposed rule, § 1107.22 on the testing of random samples, was required only during periodic tests of children's products subject to an applicable children's product safety rule. Pursuant to H.R. 2715, the testing of "random samples" to ensure continued compliance has been replaced with testing of "representative samples" to ensure continued compliance. Section 1107.22 is reserved in the draft final rule. Regardless, certification testing in the proposed rule never required the selection of random samples for children's products.

For children's products, section 14(a)(2)(A) of the CPSA requires that every manufacturer or private labeler of a children's product

submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to a third party conformity assessment body accredited . . . to be tested for compliance with such children's product safety rule.

Therefore, children's products are required by law to be tested before they can be certified, and the statutory requirements for third party testing and periodic testing apply.

CPSC staff agrees that there are instances in which it may be preferable to specify a testing program in a particular regulation, and several of the CPSC's existing regulations require such programs. The Commission may do so in the future when a particular standard necessitates such an approach.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 33:

Regarding proposed § 1107.20(b) (considerations on how the manufacturing process for a children's product can affect the number of samples chosen for certification testing), one commenter stated that regular internal monitoring and periodic testing should be able to provide sufficient data and information to support any assessment of product quality. The commenter noted that currently, this procedure is commonly practiced by many manufacturers.

Response 33:

Section 1107.20(b) of the draft final rule states, in part:

If the manufacturing process for a children's product consistently creates finished products that are uniform in composition and quality, a manufacturer may submit fewer samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules.

CPSC staff interprets the comment as asserting that internal manufacturing controls and regular testing should obviate the need for numerous samples for product certification. The commenter is correct in that the manufacturer's internal controls and testing can provide information to use in determining how many certification test samples would be required to give the certifier a high degree of assurance of the product's compliance with the applicable rule.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 34:

One commenter expressed concern about the requirement to perform certification tests. The commenter does not believe that a requirement to test preproduction samples should be part of a reasonable testing program, stating that it may be impractical for seasonal items or short production runs. The commenter stated that preproduction samples cannot be tested because the CPSC will not accept the test results on samples as test results on the finished product. The commenter asked if the preproduction samples fail and the retailer/importer has the product re-worked by the manufacturer to correct any defects, and the production units pass tests to meet all applicable standards, then why should it matter if the samples failed as long as the final product meets the requirements. The commenter expressed the belief that sample testing should be optional but not required.

Response 34:

Although subpart B describing a reasonable testing program has been reserved in the draft final rule, the concept of certification testing and testing a sufficient number of samples to provide a high degree of assurance of compliance with applicable rules, bans, standards, and regulations remains in the draft final rule with regard to children's products in § 1107.20(a). Section 1107.20(a) of the draft final rule states that certification tests must be performed on samples that are identical in all material respects to the children's product distributed in commerce. Thus, finished children's product samples or preproduction samples are acceptable for certification test purposes if their performance for the test under consideration is the same as the finished product.

The commenter did not explain why it believes that certification tests may be impractical for seasonal or short production run items. Thus, we cannot respond to the commenter's concern. The draft final rule requires passing certification test results before a Children's Product Certificate can be issued.

With regard to the commenter's concern regarding a test failure of preproduction samples, the commenter may have misunderstood the requirements of certification testing. The commenter described a circumstance where a manufacturer tested samples for compliance to a regulation. Upon receiving a failing test result, the manufacturer addressed the causes of the failing test

results and conducted new certification tests on samples of the “corrected” product and received passing test results. This describes an acceptable process for initial product certification.

CPSC staff disagrees with the commenter’s suggestion that certification tests should be optional. Section 14(a)(2) of the CPSA expressly refers to testing as being the basis of a certification and it does not make such testing optional.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 35:

A commenter suggested that the CPSC should not require finished product/component part testing and should allow samples that are identical in all material respects to the finished product to be tested. The commenter added that testing on samples since the 1950s has not resulted in a recall for failing to comply with the applicable rule. Thus, requiring finished product/component testing would be extremely costly and burdensome and would not increase safety.

The commenter suggested that the wording of the proposed rule should be changed to make it clear that component parts that are materially similar to the finished part can be used for certification testing.

Response 35:

CPSC staff agrees with the commenter regarding the testing of samples. Section 1107.20(a) of the draft final rule states that samples must be identical in all material respects to the children’s product.

CPSC staff agrees with the suggestion and clarified the text in § 1107.20(c) of the draft final rule to state that component part testing may be used for certification of a finished product for those applicable children’s product safety rules for which the finished product is not required to assess compliance.

Comment 36:

One commenter expressed the belief that the manufacturer should determine the number of units to be tested but did not believe that statistical sampling is appropriate.

Response 36:

A manufacturer may use statistical or qualitative means to determine how many units of a product are needed for certification testing to give the manufacturer a high degree of assurance that the product complies with the applicable rules. The manufacturer is not required to use statistical methods but should be prepared to describe how their technique shows the product’s compliance.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 37:

One commenter expressed concern that proposed § 1107.10(b)(2)(i)(A) indicated that only finished products or *component parts listed on a product specification* can be submitted for

certification testing. The commenter said this limits the extent to which a party may test subcomponents or raw materials. The commenter stated that raw (or base) material testing is critical to their ability to develop programs to comply with the law. The commenter noted that, although they are a component manufacturer, they have more than 384,000 stock keeping units (SKUs). These hundreds of thousands of products could be seen as different combinations of a smaller population of subcomponents and raw materials. The commenter stated that it was through working with this smaller population of subcomponents and raw materials that they could effectively manage quality in areas such as lead levels.

Response 37:

Component part testing of raw materials is beyond the scope of this rule and is considered in the draft final rule on *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). However, in that draft final rule, in many cases, raw materials or subcomponents may be considered component parts, as long as due care has been taken to ensure that no action subsequent to component part testing has adversely affected the raw materials' or subcomponents' compliance with the applicable product safety rules.

With regard to the component parts listed on a product specification, the requirement for a product specification is in subpart B, which has been reserved in the draft final rule, and the comment no longer applies.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 38:

One commenter noted that products using "food grade" materials have supplier certificates stating that these materials meet the requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) and/or the packaging requirements for the Coalition of Northeastern Governors (CONEG). The commenter suggested supplementing these certificates with other analyses as part of the certification (*e.g.*, gas chromatography – mass spectrometry, GC-MS) and a reasonable testing program. The commenter said that such assurances also can be used, consistent with the Commission's authority under section 3 of the CPSIA, to reduce the burden of testing on manufacturers of consumer products. Because the Commission acknowledges that children's product manufacturers who implement a reasonable testing program have a reduced third party test burden from the standpoint of third party periodic testing, such compliance assurances can be incorporated into a program for children's products as well.

Response 38:

Section 14(a)(2) of the CPSA requires third party conformity assessment body testing of children's products as a condition of certification. Additionally, those third party conformity assessment bodies must have a CPSC-accepted accreditation for the scope of the testing undertaken in support of product certification. "Food grade" materials and CONEG requirements are not conducted by these laboratories and do not necessarily demonstrate compliance with the requirements of applicable children's product safety rules or compliance with the third party testing requirement in section 14(a)(2) of the CPSA. Accordingly, the

Commission cannot adopt those certifications in lieu of the certification required under section 14(a)(2) of the CPSA.

While manufacturer-supplied certificates stating that these materials meet FFDCA or CONEG requirements may not be used as the basis for a third party-supported product certification, they can be used as part of a production testing plan implemented to extend the maximum periodic testing interval from one year to two years if they are sufficient to demonstrate compliance with a children's product safety rule such as the lead content limits. CPSC staff notes that some food additives are GRAS, or "generally recognized as safe." However, these designations might not be based on scientific analyses. Instead, the GRAS status for a material might be based on longstanding acceptance or belief.

On August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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. H.R. 2715 directs us to seek public comment on seven specific issues, including the extent to which the use of materials subject to regulations of another government agency that requires third party testing of those materials may provide sufficient assurance of conformity with an applicable consumer product safety rule, ban, standard, or regulation without further third party testing.

H.R. 2715 also requires us to review the public comments, and it states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. Should new information become available, the Commission may revisit this issue in the future.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 39:

Two commenters raised questions about what action must be taken when a product fails a test. One commenter interpreted the proposed rule to mean that all similar toys are also not compliant, resulting in a factory shutdown. The other commenter noted that different products vary in design and manufacture; and if one product fails, it does not mean that other products would have the same problem.

Response 39:

Section 1107.20(d) of the draft final rule states:

If a product sample fails certification testing to the applicable children's product safety rule(s), even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure.

Generally, certification testing of a children's product requires all samples tested to pass the applicable children's product safety standard. Otherwise, the certifier cannot ensure with 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, some regulations allow for some individual samples of a test set to exceed the limit but still comply with the regulation. For example, in the *Standard for the Surface Flammability of Small Carpets and Rugs* (FF 2-70) in 16 CFR part 1631, there is an allowance within the standard for a single failure during a test or a prescribed action (labeling). Because the regulation specifies the procedure for dealing with a sample test failure, or through labeling, CPSC staff would view such a product as meeting the applicable product safety standard.

A test failure for one children's product only applies to that product and is not necessarily representative of all products in the factory. An exception to this might be a test on a component part used in many products. In that circumstance, the nature of the test failure and the component part's use in the other products would affect to which products the failing test result applies. For example, if a component over the lead content limit is inaccessible, the use of that component would not make the children's product noncompliant.

CPSC staff recommends no change to the draft final rule based on this comment.

Periodic Testing

Comment 40:

One commenter asserted that the language of proposed § 1107.21, which addresses periodic testing of children's products, is not explicitly limited to children's products. The commenter recommended that the language in the final rule be revised so that the term "manufacturer" is changed to "manufacturer of a children's product" to clarify that § 1107.21 only applies to children's products. The commenter also stated that the same revision should be made throughout subpart C wherever the term "manufacturer" appears without the qualifier "of a children's product."

Response 40:

CPSC staff believes it is clear that Subpart C applies only to children's products. While we believe the commenter's suggested change is unnecessary, we have made other revisions to the text and have added a reference to children's products in § 1107.21(a) of the draft final rule to reiterate that the requirement applies only to children's products.

Comment 41:

A commenter strongly recommended that the CPSC should recognize or endorse certain in-house testing facilities that conform to the ISO 17025:2000 standard. The commenter felt that this recognition would greatly expedite testing procedures and time for certain required testing and reduce costs and lessen dependence upon the third party conformity assessment bodies. Another commenter stated that the CPSC should recognize internal laboratories as a way to reduce dependence on third party laboratories. The reasons for the suggestions include: better monitoring of product safety, a desire to reduce testing costs, encouraging other manufacturers to develop their own internal testing facilities, and encourage continuous product improvements.

Response 41:

CPSC staff recognizes that using ISO/IEC 17025:2005-accredited laboratories for testing purposes provides an added measure of assurance to production testing. The laboratories are accredited by an independent body as competent to perform specified tests and as having instituted a management system that establishes procedures and properly maintains records. Laboratory accreditation also establishes controls concerning data integrity, equipment calibration, and procedures to resist undue influence over testing results.

For these reasons, the maximum periodic testing interval for a manufacturer using an ISO/IEC 17025:2005-accredited laboratory for production testing purposes was increased from two years to three years in the draft final rule. The laboratory must be accredited by an ISO/IEC 17011:2004 (*Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies*) accreditation body, and must use the same test method(s) employed for certification testing when conducting testing to ensure continued compliance.

Comment 42:

Two commenters stated that periodic testing or auditing should be considered a regular internal function. One commenter stated that any manufacturer with qualified internal testing facilities should perform such duties easily and regularly to ensure product quality. Having a third party laboratory conduct periodic testing would result in a significant cost impact and would create production delays and difficulties. The commenter suggested that the CPSC should not specify the frequencies of testing under different manufacturing conditions. The commenter stated that product safety rules should apply to finished products.

Another commenter noted that a consistent good product testing record should reflect the competency of qualified internal testing facilities and expertise. Accredited and qualified in-house testing facilities should be able to handle this effectively and economically. The commenter noted that smaller manufacturers may have to use the services of third party laboratories per the agreed schedule, which needs to be defined and specified.

Response 42:

The draft final rule will require periodic testing to be conducted by a CPSC-accepted third party conformity assessment body. If the “qualified internal testing facility” is a CPSC-accepted firewalled laboratory, then tests from that facility can be used for periodic testing purposes. Otherwise, an internal testing facility is considered a first party laboratory and its test results would not be allowed for periodic testing purposes.

Regarding the commenter’s assertion of significant costs, the commenter did not describe how third party testing would result in significant costs and production difficulties relative to internal testing. However, a manufacturer with internal testing facilities may use product test data from those facilities to increase its knowledge of the product and its manufacture and, thus, may reduce the number of samples required for periodic testing purposes as a means of controlling costs. Section 1107.21(c)(1) of the draft final rule states that if a manufacturer has implemented a production testing plan, the maximum testing interval for periodic testing is extended to two years. Additionally, under §1107.21(d)(1) of the draft final rule if the manufacturer uses an ISO/IEC 17025:2005-accredited testing laboratory for the production testing (and other

requirements are met), the maximum testing interval is extended to three years. These methods may be used by a manufacturer to reduce the costs of third party conformity assessment body testing.

CPSC staff agrees with the commenter on the undesirability of specifying testing frequencies for different manufacturing conditions. Thus, the draft final rule specifies only the maximum testing interval for periodic testing and lists some factors to be considered by manufacturers in developing their periodic testing plans. CPSC staff agrees with the commenter that product safety rules should apply to finished products.

As noted above, pursuant to H.R. 2715, the CPSC intends to seek comment on other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Comment 43:

One commenter supported the proposal to have third party testing for the initial certification for any new products. Any major changes in design, critical component changes, or meeting changing regulations should require recertification by third party testing bodies. The commenter also supported the idea of periodic testing by third party laboratories of any products, provided that a much more refined and more specific requirement can be presented and confirmed by a proper authority. The commenter noted that it would be difficult and extremely risky to leave such a decision and ruling to the related parties. However, the commenter supported the earlier proposal of component part testing that certifies recognized components for toy production because it would enhance the elimination of certain repetitive and redundant testing on the finished product.

Response 43:

The commenter was unclear what is meant by a “proper authority” or which parties are the “related parties” dealing with the difficulty and risk of periodic testing. In the draft final rule, the certifier (domestic manufacturer or importer) of a children’s product must determine the frequency of periodic testing and the number of samples to be tested. The frequency of testing (within specified maximum periodic testing intervals) and the number of samples required must be sufficient to give the certifier a high degree of assurance that continuing production or importation of the children’s product continues to meet the requirements of all applicable children’s product safety rules.

The commenter did not indicate what factors should be added to the periodic testing requirements to make them more refined or specific. Thus, it is unclear in what way the commenter wants the requirements to be modified. Further, identifying or creating a “proper authority” to confirm periodic testing programs would present practical difficulties due to the number of products requiring periodic testing plans and the variety of manufacturing techniques used in their production. Because periodic testing requirements apply to many different types of children’s products, and manufacturing techniques for those products vary widely, one set of refined or specific requirements for periodic testing is unlikely to be applicable to all children’s products that require periodic testing.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 44:

One commenter noted that some children's products are not produced on a regular basis, and more than 1 year may pass between production runs. Because there are no production units on which to perform periodic testing, the commenter suggested that an "Inactive" product status should be created for a children's product that has passed certification testing but is not currently being produced. Once production resumes, periodic testing can be performed on the new units.

Response 44:

A new "Inactive" status is unnecessary because periodic testing of children's products is only required for continuing production after certification. If, in the commenter's example, more than 1 year passes between production runs, under the draft final rule, when production recommences, periodic tests on new production are required to assure continued compliance. The certifier must use due care to ensure that no material change has occurred in the product's design or manufacturing process, including the sourcing of component parts. Otherwise, new certification tests must be conducted on the newly manufactured product.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 45:

One commenter said that the Commission should clarify what level of detail or generality it is allowing in mandating that a production testing plan describe the tests to be conducted or the measurements to be tested. The commenter assumed that a manufacturer would have the flexibility to create a test plan that could be applied to multiple products. For example, the commenter suggested that a production testing plan could address testing by generic specifications of products, such as die cast cars or fashion dolls. However, if the Commission expects a production testing plan to specify the testing details for each product, then it would be so burdensome as to be economically not feasible, the commenter asserted.

Response 45:

The use of production testing, as a means to increase the maximum periodic test interval to 2 years, is intended to be general in nature and flexible enough to be adaptable to many different products and manufacturing processes. It is the responsibility of the manufacturer to tailor its production testing to its specific products. As stated in § 1107.20(c)(2) of the draft final rule, production testing is intended to ensure continued compliance of the product to the applicable product safety rules with a high degree of assurance. It is not a requirement that a manufacturer's production testing plan specify all of the testing details for each product. However, § 1107.20(c)(2)(i) of the draft final rule specifies that a production testing plan must include:

a description of the process management techniques used, the tests to be conducted, or the measurements to be taken; the intervals at which the tests or measurements will be made; the number of samples tested; and the basis for determining that the combination of process management techniques and tests provide a high degree of assurance of

compliance if they are not the tests prescribed for the applicable children's product safety rule.

This is necessary because techniques and test methods other than those prescribed in the applicable children's product safety rule may be used in production testing and are needed to show the effectiveness of the production testing plan.

Comment 46:

Two commenters stated that, although the CPSC acknowledges that a production testing plan could include procedures such as process management techniques, statistical process control programs, or failure mode analysis, the CPSC goes on to describe a rather rigid product testing plan. One commenter characterized the following two requirements as "a rigid product testing plan": (1) the requirement for each site to have a separate production testing plan, and (2) the production testing interval should be short enough to ensure that, if the samples selected for production testing comply with an applicable rule, ban, standard, or regulation, there is a high degree of assurance that the untested product will comply with the applicable rule, ban, standard, or regulation. The commenter urged the Commission to acknowledge more clearly that the elements of a production testing plan enumerated in the rule are not the only elements that the Commission will recognize and that other processes, such as statistical process control mechanisms, also may be used to show compliance.

One commenter suggested that the terms "production testing plan" and "remedial action plan" be replaced with "production testing plan or procedures" and "remedial action plan or procedures" because the use of the word "plan" may be interpreted too narrowly to allow for the range of methods that manufacturers may use to meet the requirements.

Response 46:

Manufacturers may use production testing plans with any procedure that is as effective in detecting noncompliant products (with the requirement that purely mathematical methods with no testing are not allowed). Statistical process control mechanisms, properly applied, are acceptable methods for production testing. The production testing plan implemented at each manufacturing site may be identical, if appropriate; but each site must have identifiable production testing for the products produced at that site. This is a matter of documentation, and the commenter has not provided a reason why this creates a problem. The draft final rule does not mandate a specific testing interval for all products. Rather, the requirement in the draft final rule is for production testing to be effective in detecting noncompliant products with whatever fixed or variable testing interval achieves a high degree of assurance of compliance to the applicable product safety rules.

CPSC staff declines the suggestion to change "production testing plan" to "production testing plan or procedures." Dictionary definitions of "plan" and "procedure" are so similar that to use both terms would be redundant. CPSC staff believes that the description of a production testing plan in § 1107.20(c) of the draft final rule provides an adequate description of its scope.

Because a remedial action plan for children's products is no longer required in the draft final rule, the suggestion to replace the term "remedial action plan" with "remedial action plan or procedures" is no longer applicable.

Comment 47:

One commenter supported the acknowledgement that the same production testing plan that is available to both the manufacturing site and the importer of records (retailers) is sufficient. The commenter gave the example of a manufacturer who developed a production testing plan and demonstrated to their customers (the importers of record or retailers) that their production testing plan provides a high degree of assurance of compliance. The importers could validate critical aspects of the plan through factory audits and evaluations, production inspections that ensure that the testing plan records are present and match the specifications, and periodic testing using a CPSC-accepted laboratory.

Response 47:

An importer can arrange for another party (*e.g.*, a foreign manufacturer) to develop and conduct production testing for a product. The same production testing plan from another party may be used by multiple importers as a means of increasing the importers' maximum periodic test interval to 2 years. The importer, as the product certifier, must use due care to ensure that the implementation of a production testing plan ensures with a high degree of assurance that continuing production complies with the applicable product safety rules.

Comment 48:

One commenter noted that § 1107.21(b) of the proposed rule specifies that if a manufacturer's reasonable testing program fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, the Commission may require the manufacturer to meet the requirements of paragraph (c) of that section or modify its reasonable testing program to ensure a high degree of assurance of compliance. The commenter asked who would determine whether a reasonable testing program provides a high degree of assurance of compliance, and how.

Response 48:

With regard to the language in proposed § 1107.21(b) referenced by the commenter, in light of the removal of the reasonable testing program option for periodic testing in the draft final rule, that language has been moved to §§ 1107.21(c)(3) and (d)(2) (renumbered in the draft final rule) and modified to refer to the production testing plan option with a maximum periodic testing interval of two years and or the testing by an ISO/IEC 17025: 2005-accredited testing laboratory option with a maximum periodic test interval of three years. With that change in mind, the CPSC will decide, based on the available evidence, whether a children's product's production testing plan provides a high degree of assurance of continuing compliance to the applicable children's product safety rules.

Comment 49:

One commenter noted that while the proposed rule accepts the use of component part testing for certification purposes, it does not address its use for periodic testing. The commenter recommended that proposed § 1107.21(c)(1) be amended to include language allowing for the

use of a component part testing program to meet the periodic testing requirements. The commenter stated that specific regulatory language needs to be inserted into the text. The commenter stated that it could foresee customers requiring the development of a periodic testing program as a contractual requirement.

Another commenter remarked that the language proposed by the CPSC for periodic testing does not recognize those items that are exempt from testing pursuant to 16 CFR § 1500.91, *Determinations regarding lead content for certain materials or products under section 101 of the Consumer Product Safety Improvement Act*.

Response 49:

Section 1107.21(a) of the draft final rule states that manufacturers must conduct periodic testing. This testing is to ensure that children's products manufactured after the issuance of a Children's Product Certificate, or since the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules. Periodic testing can use component part testing to ensure compliance with some or all of the applicable children's product safety rules. CPSC staff has clarified the language of § 1107.21(a) of the draft final rule to state that component part testing may be used to meet the periodic testing requirements, subject to the conditions of § 1107.21.

Regarding items that are exempt from testing for lead content, those items are also exempt from any periodic testing requirements. In 16 CFR §1500.91, the Commission has determined that these materials fall under the lead content limit and no testing is required.

Comment 50:

One commenter noted that the voluntary establishment of a reasonable testing program for a children's product increases the period between periodic tests to at least once every two years from the requirement of annual periodic testing for children's products without a reasonable testing program. The commenter suggested that the CPSC should consider the costs involved in establishing and maintaining a reasonable testing program and that it reasonably warrants more of a relaxation of the periodic testing frequency standard, particularly when the manufacturing process inherently results in uniform production, with very little variability in the composition or quality.

The commenter also noted that the preamble to the proposed rule stated that not all periodic testing was required to be conducted by a third party conformity assessment body. The preamble also states that the appropriate periodic testing interval "may vary for a manufacturer depending on the manufacturer's knowledge of the product and its manufacturing processes."

The commenter urged the CPSC to permit a manufacturer of a children's product with a reasonable testing program in place to determine when to obtain third party conformity assessment body testing of ordinary children's books or other children's paper-based ordinary printed products under a testing frequency standard of at least once every four years. The commenter noted that third party conformity assessment body testing still would occur in response to a material change to the children's product.

Response 50:

The draft final rule extends the maximum testing interval for periodic testing from one to two years for manufacturers that have implemented a production testing plan as a means of ensuring continued compliance of the product to the applicable children's product safety rules. The production testing plan in § 1107.21(c) of the draft final rule is the same production testing plan in the reasonable testing program described in § 1107.10(b)(3) of the proposed rule. This increase in the maximum testing interval was not based on the costs of third party testing or on the costs of implementing a production testing plan. When a manufacturer implements a production testing plan and conducts production testing, this provides more information about a product's manufacture and compliance with the applicable children's product safety rules, which justifies allowing a longer period of time between periodic tests. If a manufacturer uses an ISO/IEC 17025:2005-accredited testing laboratory for testing to assure continued compliance, the maximum periodic testing interval is extended to three years.

The commenter is correct that the preamble to the proposed rule states that not every periodic test has to be done by a third party conformity assessment body if the manufacturer has implemented four elements of a reasonable testing program. However, the text in § 1107.21(c) of the draft final rule states that a manufacturer who has implemented a production testing plan for a children's product must submit samples of the product to a third party conformity assessment body for periodic testing at least once every two years. CPSC staff recognizes that these two statements may be confusing and has clarified the text in the draft final rule. In the draft final rule, all periodic testing is required to be conducted by a CPSC-accepted third party conformity assessment body accredited to the scope of the tests required.

On August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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.

We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 also requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Regarding the commenter's suggestion on testing ordinary children's books or other children's ordinary paper-based printed products, section 14(i)(4) of the CPSA, as amended by H.R. 2715, excludes ordinary books from the third party testing requirements in section 14(a) of the CPSA. Additionally, we have decided to reserve, rather than finalize, subpart B, which would have pertained to a reasonable testing program for non-children's products. Therefore, it is unnecessary for us to address the commenter's suggestion.

Comment 51:

One commenter recommended that in § 1107.21 of the proposed rule, *Periodic Testing*, the Commission require that children's products be tested by a third party conformity assessment body at least every year, not every two years, as proposed. The commenter felt that many

changes can occur over time in the manufacturing process, materials, test standards, and test protocols that could cause products tested infrequently to drift away from compliance with applicable children's product safety rules. The commenter felt that more frequent independent testing would better be able to keep this in check.

Response 51:

CPSC staff disagrees with the commenter's inference that a production testing plan will not be capable of detecting "drift" in a product's compliance with the applicable safety rules. CPSC staff is aware of numerous forms of production testing techniques that have been successfully implemented to control product quality and ensure continuing compliance.

CPSC staff recommends no changes to the draft final rule based on this comment.

Comment 52:

One commenter stated that the testing frequency should be left to the manufacturer and to the market and that a rule requiring manufacturers to test according to these standards every year is an unaffordable economic burden. The commenter predicted that it is unrealistic to imagine that testing cost savings from maintaining a reasonable testing program (as described in the proposed rule) will be useful since that program is "wasteful and gargantuan." The commenter felt that a firewalled laboratory would be unrealistic for small businesses. The commenter also felt that component part and composite testing will likewise provide no relief. The commenter asked that if a firm has a good long-term record of safety, then why are they required to test according to the proposed rule.

Response 52:

Section 14(i)(2)(B)(i) of the CPSA requires the CPSC to establish protocols and standards for ensuring that children's products are subject to testing periodically. Section 1107.21 of the draft final rule has been revised to allow periodic testing: at least once per year; at least once every two years for children's products with a production testing plan; or at least once every three years for a production testing plan utilizing an ISO/IEC 17025:2005-accredited testing laboratory (and other requirements are met). It is expected that manufacturers will select the option that is the most advantageous to them. Allowing firms with a good long-term record of safety to bypass testing their children's products would not comply with the law, which requires periodic testing of children's products, regardless of past performance.

As noted above, pursuant to H.R. 2715, the CPSC intends to seek comment on other techniques to lower the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

The draft final rule does not require that small businesses have a firewalled laboratory.

The comment regarding component part testing and composite part testing is addressed in the response to comments for the draft final rule, *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).

Comment 53:

One commenter stated that periodic testing is unnecessary because, when a product is manufactured in China, the initial product sample is inspected by the China Entry-Exit Inspection and Quarantine Bureau to ensure that it complies with all European Union, United States, and China product safety standards. Additionally, the commenter observed, the China Entry-Exit Inspection and Quarantine Bureau will conduct the random sample in-line inspection to inspect a number of samples in the production twice a year. Products that fail the inspection will not be allowed to be exported. The commenter said that the strict product safety inspections by China Entry-Exit Inspection and Quarantine Bureau are enough to have the high degree of product safety assurance and that a periodic testing requirement would be duplicative.

The commenter also said that periodic testing is unnecessary because, as the manufacturer, they have a high degree of self-discipline and strictly supervise their products' safety. Furthermore, the commenter stated that 90 percent of manufacturers have their own testing laboratories that conform to international laboratory standards and have a series of internal product safety testing already in order to maintain a high degree of product safety and quality assurance. In addition, the commenter stated that most customers require testing by the third party conformity assessment body for each order—before the manufacturer exports the goods—to ensure a high degree of product safety.

Response 53:

The draft final rule will require periodic testing to be conducted by a CPSC-accepted third party conformity assessment body. China Entry-Exit Inspection and Quarantine Bureaus do not currently meet the conditions specified in the Consumer Product Safety Improvement Act for governmental conformity assessment bodies to participate in the CPSC's program. Further, the third party testing requirements apply irrespective of the level of a manufacturer's self-supervision of product safety.

With regard to internal testing facilities, these are considered first party laboratories and their tests are not allowed for periodic test purposes unless the laboratory is a CPSC-accepted firewalled laboratory. However, if the third party laboratories testing the manufacturer's products for the customer are CPSC-accepted for the scope of the testing, test results from those laboratories may be used for fulfilling the periodic testing requirements. CPSC staff notes that internal testing facilities can be used to extend the maximum testing interval for periodic testing from one year to two years. Further, if the internal testing facility is ISO/IEC 17025:2005-accredited and other conditions are met the maximum testing interval for periodic testing is extended to three years.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 54:

One commenter stated that the importer who purchases a product from a manufacturer and takes possession of the product prior to importation does not have full visibility and knowledge of the manufacturing process and must treat each shipment produced by the manufacturer as a discrete lot.

Response 54:

An importer is responsible for issuing a Children's Product Certificate for the children's products they import. If a foreign manufacturer certifies a children's product and provides the importer with the certificate and other required documentation, then the importer, exercising due care, may, using the manufacturer's test data as a basis, issue its own Children's Product Certificate.

In this circumstance, due care by the importer involves ensuring that the foreign manufacturer conducts periodic tests. If the foreign manufacturer does not certify the children's product, but the importer has documentation of the manufacture and testing of the children's product, then the importer is responsible for certifying the children's product and is subject to the requirement for periodic testing. However, if the importer has no knowledge of the manufacture of the product, then each shipment should be treated as a discrete lot and is subject to certification testing because the importer does not know whether material changes have been made to the product since its last shipment. In this circumstance, the shipment that has undergone certification testing is not considered continuing production of the product and is not subject to the periodic testing requirements.

CPSC staff recommends no change to the draft final rule based on this comment.

Low-Volume Products

Several commenter remarked on proposed § 1107.21(e), the exclusion from the periodic testing requirements of children's products with fewer than 10,000 manufactured units. One commenter said that because the production or importation volumes for different children's products may vary substantially, such as large electrical motorcycles and small stuffed toys, it is not reasonable to apply the same number of 10,000 to all children's products. The commenter asked if periodic testing is necessary when a large number of products are produced in a short time; for example, 100,000 toys produced in 3 months. Another commenter expressed the belief that exempting production of less than 10,000 units per 1 year from the periodic testing requirement is too small.

One commenter noted that the proposed rule does not specify over what time period this quantity of production may occur. The commenter urged the CPSC to state in its final rule that for industries, such as the mattress industry, the periodic testing requirement can be met by testing no more than one product for every 10,000 units of production of a given product, provided that a material change to that product has not occurred since the last periodic test.

A commenter asked if a facility that produces both children's and non-children's products, does the 10,000 production volume only apply to the children's products produced. The commenter also asked if the low-volume figure of 10,000 units apply to each unique product or to the production of all possible children's products at the facility

Another commenter interpreted the section on relief for "low-volume manufacturers" as an acknowledgement by the CPSC that the periodic testing frequency standard is not essential to the safety scheme because the CPSC dispensed with periodic testing altogether in the case of manufacturers that produce or import no more than 10,000 units of a product.

One commenter did not agree with the Commission's limit for random sampling of low-volume production, currently set at 10,000 units or less. Their analysis of CPSC-announced recalls in calendar year 2009 shows that 47 percent of the recalls were for unsafe products of 10,000 units or less.

A commenter contended that the CPSC has failed to persuade that the 10,000 unit limit is an appropriate break point for periodic testing. The commenter said the limit is cumulative and bears no relationship to risk of injury.

On August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 requires, among other things, that we seek public 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. It also contains special rules for small batch manufacturers and directs us to consider alternative testing requirements or to exempt small batch manufacturers from certain third party testing requirements. Given these new statutory obligations resulting from H.R. 2715, we are reserving § 1107.21(e) so that we may consider how to address cost, low-volume products, and small batch issues more fully.

Random Samples

H.R. 2715 revised section 14(i)(2)(B)(ii) of the CPSA (formerly section 14(d)(2)(B)(ii)) by replacing the word "random" with "representative." The new section now reads that the Commission shall by regulation establish protocols and standards "for the testing of representative samples to ensure continued compliance." Given this change in the statute, we are not finalizing § 1107.22 and will delete the section pending an NPR to implement section 14(i)(2)(B)(ii) of the CPSA, as revised by H.R. 2715.

Undue Influence

Comment 55:

Several commenters disagreed with the requirement in § 1107.24(a) of the proposed rule that manufacturers must establish procedures to safeguard against the exercise of undue influence on a third party conformity assessment body. One commenter noted that the Commission already requires third party conformity assessment bodies to train their staff to detect, avoid, and report undue influence. Another commenter stated that third party testing facilities already have these training programs in place. Two commenters asserted that third party conformity assessment bodies are not likely to be influenced unduly because their accreditation would be withdrawn.

Response 55:

Section 14(i)(2)(B)(iv) of the CPSA requires the Commission to establish by rule protocols and standards for safeguarding against the exercise of undue influence by a manufacturer or private labeler on a third party conformity assessment body. Section 1107.24 of the draft final rule requires manufacturers of children's products to establish procedures to avoid actions that could undermine the integrity of laboratory test data. The CPSC has an interest in ensuring the integrity of laboratory test results used in the certification of children's products.

The Commission, in a separate rulemaking, will address the issue of requiring third party conformity assessment bodies to report undue influence.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 56:

Several commenters made remarks about training programs. Two commenters stated that the training program and recordkeeping requirements (§ 1107.26(a)(5) of the proposed rule) are burdensome and redundant because companies already have requirements to prohibit unethical behavior, such as exerting undue influence over third party conformity assessment body staff. Other commenters described this requirement as excessive and unreasonable. One commenter stated that the requirements for training are vague and urged the Commission to describe what needs to be included. Another commenter raised questions about the content and form of the training, especially whether a written manual would be enough. Another commenter recommended deletion of these requirements.

One commenter urged the Commission to drop its proposed requirement for appropriate staff to receive "annual training" on avoiding such undue influence. The commenter felt that an annual training mandate would be unnecessary and would impose excessive costs and burdens on manufacturers of children's products.

Response 56:

Section 14(i)(2)(B)(iv) of the CPSA requires the Commission to establish protocols and standards by rule for safeguarding against the exercise of undue influence on third party conformity assessment bodies by a manufacturer or private labeler. Therefore, CPSC staff declines the suggestion to delete these requirements from the draft final rule.

Section 1107.24 of the draft final rule implements the statutory mandate by requiring manufacturers to establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. The rule does not prescribe the form or content of these programs in order to provide manufacturers flexibility in implementing the requirements. For example, manufacturers may wish to create written manuals and may include this training along with other forms of employee training. Manufacturers must keep records of employee participation in the training to be able to assure that all relevant staff members receive this training pursuant to § 1107.26(a)(6) of the draft final rule.

After consideration of the comments, however, CPSC staff agrees with the commenter that an annual training requirement to reiterate previously-presented procedures can impose costs and

burdens, the benefits of which are unclear. In response to this comment, the requirement in the proposed rule for annual training was changed in the draft final rule to a requirement for retraining when a substantive change to the final rule is made regarding undue influence. Manufacturers of children's products are free to modify their procedures and conduct retraining as often as they feel it is necessary to effectively institute their policies regarding safeguarding against the exercise of undue influence.

Comment 57:

Some commenters expressed concern regarding foreign manufacturers and the undue influence requirements. One commenter suggested that the Commission will be unable to enforce this requirement on foreign manufacturers and importers. Another commenter said that the importer of record should not be responsible for undue influence initiated by people not directly employed by the importer of record. The commenter requested confirmation that importers will only be responsible for training their own employees, and will not have the responsibility of training the employees of other companies, such as manufacturers, vendors, freight handlers, or laboratories.

Response 57:

The requirement in § 1107.24 of the draft final rule that "each manufacturer" establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body does not apply to foreign manufacturers. Section 1107.2 of the draft final rule defines a "manufacturer" as "the parties responsible for certification of a consumer product pursuant to 16 CFR part 1110." Under 16 CFR part 1110, a foreign manufacturer is not required to certify a finished product; only a domestic manufacturer or the importer of a product made outside the United States is required to issue a finished product certificate. Thus, under § 1107.24 of the draft final rule, it is a domestic manufacturer or the importer that must establish procedures to safeguard against undue influence.

CPSC staff agrees that an importer is not directly responsible for training employees of other companies. This fact, however, does not absolve the importer issuing a finished product certificate of its duty to exercise due care when relying on test results provided by another company or laboratory. A manufacturer or importer that issues a finished product certificate that is based on test reports from a laboratory on which undue influence has been exercised provides a basis for the CPSC to deem the certificate invalid. The CPSC will hold the finished product certifier responsible for exercising due care that component part or finished product manufacturers or suppliers have not exercised undue influence over third party conformity assessment bodies.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 58:

Two commenters stated that because the term "undue" is undefined, nothing should be construed to prohibit a manufacturer from exercising its rights to challenge third party conformity assessment body test results based upon the manufacturer's belief that they are inaccurate.

Response 58:

The intent of § 1107.24 of the proposed rule was not to preclude a manufacturer from challenging failing test results in appropriate circumstances. If a manufacturer has reason to think a test result received from a third party conformity assessment body is in error, it is appropriate to inquire from the third party conformity assessment body about the test result. Such inquiry does not constitute undue influence. Additionally, section 1107.20(d) of the draft final rule requires a manufacturer to investigate the reasons for a negative certification test result and to take action to address failing test results before a Children's Product Certificate can be issued. This investigation may involve discussions about the test results with the third party conformity assessment body.

CPSC staff recommends no change to the draft final rule based on this comment.

Material Change (Children's Products)

Comment 59:

A commenter suggested that the definition of the phrase "material change" should be moved from § 1107.10(b)(2)(ii) of the proposed rule to the definitions in § 1107.2.

Response 59:

Section 1107.10 has been reserved in the final rule. CPSC staff agrees with the commenter and has moved the definition of "material change" to § 1107.2 in the draft final rule, as this definition still applies to § 1107.23 regarding material changes in children's products.

Comment 60:

Some commenters suggested that the definition of "material change" in the proposed rule should be changed to refer only to changes that "reasonably could affect" compliance.

Response 60:

The commenters are concerned about a remote possibility that some set of circumstances could combine such that a seemingly innocuous change could, in fact, affect the product's compliance to an applicable product safety rule. CPSC staff realizes that it would be difficult for a manufacturer to identify every conceivable theoretical effect a change could have on a children's product's compliance. Therefore, prudence and competence should be exercised by the manufacturer in determining the effects of a change to the product, and whether that change is material. This prudence and competence is contained in the manufacturer's use of due care in evaluating the change.

CPSC staff declines the commenters' suggestion to modify the definition of "material change" because the definition, now in § 1107.2 of the draft final rule, includes the phrase "a manufacturer exercising due care." Because the definition of due care includes the exercise of prudence and competence by the manufacturer, the addition of "reasonably could" is duplicative.

CPSC staff recommends no change in the draft final rule based on this comment.

Comment 61:

One commenter stated that different versions of the same product (e.g., color, packaging) should not require different tests.

Response 61:

The commenter is correct that different versions of the same product that are not materially different do not require separate certification tests. A “material change” is defined in § 1107.2 of the draft final rule as:

... any change in the product’s design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product’s ability to comply with the applicable rules, bans, standards, or regulations.

Therefore, if the differences between different versions of the same product are not material changes, no additional testing is required. It is the manufacturer’s responsibility to determine if a difference between versions of a product constitutes a material change.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 62:

One commenter suggested that after certification testing of a product, if another product differs by a few minor components from the certified product, and proper proof of equivalent specifications are documented, a reduced sample size for certification should be allowed.

Response 62:

In the circumstance described by the commenter, if a new product differs from an existing certified product by a few component parts, the manufacturer’s knowledge of the new product and its manufacture might be extensive enough to result in requiring fewer samples for certification testing than the number required for the existing certified product. CPSC staff reiterates that if a new product is based on changes to an existing certified product, only the applicable product safety rules affected by the changes require certification testing. The number of samples still must be sufficient to give the manufacturer a high degree of assurance of the new product’s compliance with the applicable product safety rules. The certifier also may use component part testing as a means of reducing the number of finished samples needed for certification. If the changes from the existing certified product to the newer product are not material, then the certification tests on the existing certified product can be used for certification purposes on the newer product.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 63:

Two commenters raised issues related to products subject to 16 CFR part 1201, *Safety Standard for Architectural Glazing Materials*, although the issues they raised have wider implications that involve other products, including children’s products. The products subject to that safety standard are glazing materials (glass) used or intended for use in doors and enclosures.

The commenters noted that these types of glass normally are manufactured in a continuous process that is subject to numerous minor and ongoing adjustments to respond to atmospheric and other factors and to make sure that the tempering process continues properly. In addition, there can be numerous minor variations in format, size, and thickness of the glass, as well as other product characteristics that are a normal part of shifting from one product to another to meet customers' orders. This industry's current process of certification and quality control involves periodic third party "certification" testing to the requirements of 16 CFR part 1201 and using alternate means for checking breakage performance of samples from subsequent production, such as a center punch test for tempered glass and the drop-ball and/or pummel test for laminated glass, to monitor ongoing compliance with the standard. If a potential failure of the standard is detected by these alternate tests, corrective action is taken, and product distribution is not resumed until a subsequent production test shows that the breakage performance has been restored.

The commenters requested clarification that the ongoing adjustments described above would not be "material changes" that would require recertification of the product. The proposed rule defines "material change" as one that "could affect the product's ability to comply with the applicable rules" One commenter requested that the Commission state that:

An adjustment to equipment or machinery made in order to maintain, achieve, or assure compliance with the applicable rules . . . is *not* a material change within the meaning of section 1107.10.

The other commenter suggested the following addition to the proposed rule:

Adjustments in the equipment or machinery to affect the product's ability to comply with any applicable rules or standards should not be considered a "material change" in the manufacturing process . . . but will require the manufacturer, following those adjustments to subject the product to its production testing plan and to achieve passing production test results before the manufacturer may resume production of that product.

Response 63:

Although regulated non-children's products must still meet the certification requirements in section 14(a)(1) of the CPSA, the reasonable testing program described in proposed § 1107.10 has not been finalized and is reserved in the draft final rule. However, the broader issue presented by this commenter, which is related to adjustments in equipment or machinery, is applicable to children's products as well, so we will address this issue with regard to children's products.

In order for a change to be a material change, it should be one that could *adversely* affect the product's ability to comply with the rule, ban, standard, or regulation. Minor and ongoing adjustments during manufacturing, especially in continuous flow processes, to maintain compliance with the applicable product safety rules are not considered material changes. However, CPSC staff does not agree entirely with the commenters' suggested language because that language would include adjustments made to "achieve" compliance (*i.e.*, to change a product

from noncompliance to compliance). Such a change would constitute a “material” change, thus, additional certification testing would be required.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 64:

One commenter suggested that in proposed § 1107.10(b)(2), *Certification Tests*, it also should be noted that testing of units within a common family of products should allow a test of one unit to represent all others within the family of products if the other models are materially the same. Regarding proposed § 1107.10(b)(2)(ii)(B), the commenter added that a manufacturer should not be required to conduct additional “certification” testing upon a change to the parts or materials, if the change does not affect the overall safety of the system. The commenter suggested that the section should be rewritten to allow manufacturers the ability to make changes to parts and materials without having to undergo costly and time-consuming certification testing. Manufacturers can conduct in-house testing that would show that the results of any change do not materially alter the performance of that part or system with regard to the safety elements in the applicable rule.

Response 64:

Although regulated non-children’s products must still meet the certification requirements in section 14(a)(1) of the CPSA, the reasonable testing program described in proposed § 1107.10 has not been finalized and is reserved in the draft final rule. However, the broader issue presented by this commenter, which relates to certification testing of units within a common family and when there has been a material change, is applicable to children’s products as well, so we will address this issue with regard to children’s products.

The commenter’s suggestion that testing of units within a common family of products be allowed to represent all of the other units within the family currently is allowed by the draft final rule. Section 1107.20(a) of the draft final rule states that samples used for certification must be identical in all material respects to the finished children’s product. If, as the commenter has stated, the tested units are identical in all material respects as others within the product family, then the test results can be applied to the other units within the product family.

Section 1107.23(a) describes testing requirements when there has been a material change in a children’s product. If a change could adversely affect compliance with the applicable children’s product safety rules, then it is considered a material change and retesting is required. If, by “does not affect the overall safety of the system,” the manufacturer means the change does not affect compliance with the applicable rules, then that is not considered a material change, and no recertification testing is required.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 65:

Some commenters stated that the requirement to submit a sufficient number of samples of a materially changed product for third party testing prior to certifying the changes would be costly

and would inhibit manufacturers from making continuous product improvements. Ultimately, according to the commenters, this will reduce the safety of children's products.

Response 65:

Section 14(i)(2)(B)(i) of the CPSA requires children's products to be subject to third party conformity assessment body testing when there has been a material change in the product's design or manufacturing process. These types of changes may introduce new hazards or may result in the product no longer being in compliance with the applicable children's product safety rules. After a material change to the product, only those applicable product safety rules that could adversely be affected require recertification. The samples selected must be of a sufficient number to provide a high degree of assurance that the test conducted demonstrates accurately the ability of the children's product to meet all applicable children's product safety rules.

Regarding continuous product improvements, those changes that do not adversely affect compliance to the applicable children's product safety rules are not material changes and do not require recertification testing. However, manufacturers will need to factor possible material change testing into their product improvement processes.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 66:

Three commenters characterized the testing requirements resulting from the proposed rule's definition of "material change" as "overly burdensome" and "very unreasonable." The commenters differed in their reasons for arriving at this conclusion. One commenter characterized the proposed rule's material change testing requirements as too "open ended" because of imprecise language. The consequence of this lack of specificity, according to the commenter, is that "either you will always test or you take a big risk. This is completely unfair and unreasonable," The commenter asserted.

Another commenter expressed concern with the examples in § 1107.23(c) of the proposed rule. Specifically, the commenter stated that manufacturing process changes "such as new solvents to clean equipment or a new mold for an accessible metal component part of a children's product pose undue burdens on manufacturers without advancing safety goals." The commenter contended that "to require companies to develop new product specifications for every new solvent used in a facility or installation of a new mold made to the exact specifications as a prior mold" would require new third party testing, adding that this could not have been Congress's intent. The commenter suggested that "it should be left to the consumer product manufacturer to assess whether changes are likely to affect the ability of the particular product to meet a specific standard, ban, rule, or regulation."

The third commenter stated that the definition of "material change" is not clear and asked whether "using the same quality level of component part but just the different brand is a material change." The commenter stated that if third party testing of each such change is necessary, then "it is very unreasonable."

Response 66:

The intent of § 1107.23 for children's products is not to be overly burdensome, but rather, to demonstrate the product's continued compliance with applicable children's product safety rules when a change in the product's design, manufacturing process, or component part sourcing has been made that could adversely affect a previously certified product's compliance. Because the draft final rule applies to a variety of products and manufacturing methods, it is impractical to anticipate every type of product change that could occur to all affected products and that might adversely affect compliance to an applicable product safety rule and to provide specific language to address those myriad changes. Therefore, the draft final rule is written using general language to allow manufacturers the flexibility to determine, in each particular circumstance, whether a product change could adversely affect the product's compliance with an applicable children's product safety rule. Manufacturers should use their specialized knowledge of a product's design, components, and manufacturing processes to differentiate what changes may constitute a material change and require certification testing versus what constitutes a nonmaterial change.

After initial certification of a product, a "material change" is a change that "could affect the product's ability to comply with applicable rules, standards or regulations." The ability to adversely affect compliance is what distinguishes a "material change" from a nonmaterial change. The draft final rule acknowledges that a manufacturer has specialized knowledge of its product design, components and, production processes and states that a "manufacturer exercising due care knows or should know" when a change is material. For example, a new solvent that does not contain any of the prohibited chemicals (lead and the prohibited phthalates), or a replacement mold shown to be made to the same specifications as a compliant mold, would not be examples of material changes.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 67:

One commenter noted that § 1107.10(b)(2)(ii)(A) of the proposed rule states that for material changes that only affect product compliance to certain rules, certification may be based on the materially changed component, unless the change affects the finished product; in that instance, the certification must be based on the finished product. (The commenter is referring to the proposed rule in § 1107.10(b)(2)(ii)(A) and (C).) The commenter asked, when a disagreement arises, who makes the final determination of whether the material change affects the finished product's compliance?

Response 67:

The reasonable testing program described in proposed § 1107.10 has not been finalized and is reserved in the draft final rule. However, the broader issue presented by this commenter, which relates to certification testing of units when there has been a material change, is applicable to children's products as well, so we will address this issue with regard to children's products.

The commenter is correct that when a material change to a product occurs, only product safety rules affected by the material change would require recertification. If the material change affects

a component part of a children's product only and does not affect the ability of other component parts or the finished product to comply with applicable children's product safety rules, § 1107.23(a) allows a manufacturer to base certification on earlier third party certification tests and on third party testing of the changed component part.

With regard to disagreements regarding whether the finished children's product is needed for certification after a material change, a manufacturer must use due care in determining if testing the finished product or a component part is required. This due care is applied on a per-rule basis. Some rules, such as prohibited phthalate content, can be evaluated on component parts. Other rules, such as 16 CFR part 1219, for full-size and non-full-size cribs, always require the finished product for certification testing. Assuming the disagreement is between the manufacturer and the CPSC regarding whether a finished product is required for certification after a product change, the CPSC will decide, based on the available evidence, whether a material change requires samples of the finished product for certification.

CPSC staff recommends no change to the draft final rule based on this comment.

Remedial Action (Children's Products)

Comment 68:

One commenter stated that requiring each manufacturer to have an actual remedial action plan to address failing test results is unnecessary because the remedial action will likely be different, depending upon the situation. Another commenter stated that because they are familiar with how to resolve compliance and quality issues, the preparation of a detailed written remedial action plan is a waste of time, money, resources, and intellect.

Response 68:

The commenter is correct that, depending on the product and the nature of the test failure, remedial actions may take many different forms. The development of a remedial action plan before production commences could help in the determination of factors such as lot size or what tracking information to maintain. These factors could help limit the number of production units subject to recall in the event that noncompliant products are introduced into commerce.

However, although it may be efficient and useful to have a formal process to follow (such as the remedial action plan in proposed § 1107.25) after receiving failing test reports, such preformulated plans are not essential either for certification or for ensuring continued compliance of consumer products. Ultimately, the manufacturer is responsible for ensuring that its product complies with the applicable product safety rules. For some products and types of test report failures, ad hoc methods may be as effective as pre-established plans in addressing the test failures and in ensuring that products are compliant. For these reasons, CPSC staff removed the requirements for remedial action plans for children's products in § 1107.25 of the draft final rule. The Commission encourages manufacturers who believe that remedial action plans would be advantageous for their product to develop such plans as part of their overall quality assurance system.

Comment 69:

One commenter appreciated the acknowledgement that a remedial action plan could be a formal standard operating procedure (SOP) along with recordkeeping of each event.

The commenter asked whether, when a particular component causes a product to become noncompliant with a rule, and the remedial action eliminates this specific component from the product, would certification have to be repeated. The commenter noted that documentation would be provided that the noncompliant component had been removed and that the product specification was revised. The commenter stated that there would be an SOP that requires a corrective action, along with documentation of the instance of noncompliance, to provide evidence that the product has been corrected and is compliant.

Response 69:

As noted previously the requirement for a remedial action plan for children's products was eliminated from the draft final rule. If a finished product has a noncompliant component part (such as an accessory item), and that item is removed from the finished product, the finished product certifier does not have to repeat certification testing on the newly-constituted finished product because the certifier has certification test data demonstrating compliance with all applicable product safety rules for that product. The certifier must make sure that eliminating the noncompliant component part does not affect compliance with another applicable children's product safety rule for the finished product.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 70:

Several comments were received on the issue of retesting samples. Some commenters noted that often, a testing failure might result from a faulty laboratory test and not from a noncompliant product. The commenters said that the rule should allow retesting in appropriate situations when there is suspicion about the manner in which a sample was handled or processed, or the certifier is challenging the results of a third party test.

One commenter asserted that if the manufacturer documents and supports any assertions related to the faulty test and the product's compliance, there should be no need for remedial action. Another commenter suggested that the implication in the rule is that any test failure, no matter how trivial, would trigger the need for remedial action, which would be costly. The commenter suggested that establishing tolerances for test results is necessary to reduce testing costs, as well as the burden of remedial actions, while still assuring product safety. The commenter added that children's products are not so consistent that every test produces the same test result. The commenter asserted that retesting is a valid means of responding to a failing test result. Banning retesting due to the fear that some unscrupulous parties will attempt to test the product into compliance will create severe problems.

Response 70:

As noted previously the requirement for a remedial action plan for children's products was eliminated from the draft final rule. However, CPSC staff recognizes that an error or failure in the testing of a sample may lead to a failing test result, and therefore, investigating the test method and test execution is a legitimate avenue of investigation in those instances. Such an

investigation can include: examining the test procedures, sample preparation steps, equipment calibration, and other factors, including tests on samples of the product as part of the investigation, which may affect test results, but are not indicative of a noncompliant product.

Regarding children's products § 1107.20(d) of the draft final rule states:

If a product sample fails certification testing to the applicable children's product safety rule(s), even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure. 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.

While the codified text has been revised in the draft final rule to remove the reference to the no-longer-required remedial action plan, a manufacture still "must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure." Retesting a product without investigating why the test yielded failing results, and taking whatever action addresses the situation (for example, calibrating the testing machine before retesting, or correcting a manufacturing problem) to achieve passing results is not acceptable for certification purposes because the certifier would not have a high degree of assurance that the products produced will be compliant with the applicable product safety rules.

Retesting should not be conducted to "shop" for passing test results or to keep testing the product until a sample finally passes (and disregarding all other tests that suggest the product is not in compliance). One commenter did not explain what was meant by a "trivial test failure" and why investigating the reasons for the failure necessarily must be costly.

With regard to establishing tolerances for test results, the acceptable values for test results are established in each rule, ban, regulation, or standard and are beyond the scope of this rule.

Comment 71:

One commenter stated that some standards, such as the standard for the surface flammability of carpets and rugs (16 CFR part 1630), have alternative requirements for products that fail tests. The commenter suggested modifying the language to refer to a product that does not pass the applicable product safety standard rather than refer to it as a product that fails a test.

Response 71:

In 16 CFR part 1630, the standard allows for a single failure in eight tests. Because there is an allowance in the standard for a failing test result, CPSC staff would view such a product as compliant with the standard.

Recordkeeping (Children's Products)

Comment 72:

One commenter expressed concerned about the recordkeeping requirements in § 1107.10(b)(5) of the proposed rule and asked for clarification of the phrase "for as long as the product is in

production or imported.” The commenter noted that the requirements would lead to a massive undertaking for any manufacturer or importer, especially if all of the records must be maintained within the United States.

Another commenter stated that the Commission should clarify the relationship between the requirement to maintain records and the proposed rule’s treatment of material changes requiring recertification, and thus, effectively creating a new product (§ 1107.23 of the proposed and the draft final rule for children’s products). To simplify the recordkeeping requirements, the commenter asked that the recordkeeping requirements apply “for as long as the product, *without a material change*, is in production or imported by the manufacturer plus five years.” Otherwise, the commenter stated, manufacturers of long-running products would have to maintain records into perpetuity, which would increase costs without assisting safety or compliance.

Response 72:

Section 1107.10(b)(5) of the proposed rule on recordkeeping requirements for a reasonable testing program has not been finalized but has been reserved in this draft final rule. However, the length of the recordkeeping requirement is applicable to the length of the recordkeeping requirement for children’s products in § 1107.26 of the draft final rule, so we address this issue here for children’s products.

After considering the comments on the recordkeeping burden, CPSC staff agrees that the burden of maintaining records for the life of a product plus five years could be unduly burdensome and difficult to implement where products undergo changes over time. Moreover, having a different time period for the retention of test reports versus other records may be confusing. Accordingly, the recordkeeping provision has been changed and simplified in the draft final rule such that all records must be maintained for at least five years from the date of their creation (§ 1107.26(b) of the draft final rule). If a product does not comply with an applicable children’s product safety rule in a significant way, it is likely that the noncompliant aspect of the product would become apparent within the 5-year period. This change should result in less confusion for the regulated community regarding how long records for a particular product must be maintained.

Comment 73:

Several commenters expressed concern about the requirement in the rule that records be maintained in English. Some commenters stated that records should be allowed to be kept in the local language and only require translation into English by the manufacturer or importer when the CPSC requests documentation. One commenter noted that the proposed rule will require millions of test reports and records to be created and maintained in English, even though only a small fraction of a percent of these test reports will ever be reviewed by the CPSC or other third parties. The commenter maintained that this would be very expensive for the manufacturer because they must find and hire English-speaking technicians to perform the testing.

The commenter also contended that this requirement could be potentially hazardous. The commenter posed this example:

For example, a quality assurance technician in Vietnam may be excellent at maintaining the quality of a product, and she may even have a passable grasp of English, but her

English skills may not be sufficient to communicate precise technical findings in English. If she is nonetheless required to record her findings in English, then there is a risk the test results will be transcribed, described and maintained inaccurately. Thus, we ask that the Commission reconsider this English-only requirement in the proposed rule.

Another commenter asserted that a method for making documents available in English in the United States would need to be created to comply with the rule. The commenter contended that the requirement to have English language documents available within the United States does not offer additional confidence in product safety for U.S. consumers. Alternatively, the commenter suggested that a 3-year stay of the requirement that documents be maintained in English would allow a transition period to establish and implement appropriate infrastructure and processes for expanded recordkeeping.

Response 73:

CPSC staff agrees that it would be burdensome in many cases for all records to be maintained in English. Therefore, CPSC staff has modified § 1107.26(c) of the proposed rule, renumbered to § 1107.26(b) in the draft final rule, to allow records to be maintained in languages other than English, if the records in the original language can be provided immediately by the manufacturer to the CPSC, and if an accurate English translation can be provided within 48 hours, or within such longer period as may be negotiated with CPSC staff. Because the requirement that records be maintained in English is being revised, CPSC staff declines the suggestion that a 3-year stay of enforcement be implemented for this part of the rule.

Comment 74:

Many commenters expressed concern about the requirement in § 1107.26(b) of the proposed rule that all records be maintained in the United States. Several commenters suggested that instead of requiring manufacturers to maintain records at a location within the United States, the Commission should allow the records to be maintained outside the United States, so long as the records can be accessed from a location in the United States that is specified on the certificate. Some commenters noted that this requirement would be a burdensome and massive undertaking. One commenter did not believe that storing foreign manufacturing documents in the United States for every regulated product increases product safety. The commenter noted that these documents could be stored in their existing location and submitted to the CPSC upon request. Alternatively, the commenter suggested that a 3-year stay of the requirement that documents be maintained in the United States would allow a transition period to establish and implement appropriate infrastructure and processes for expanded recordkeeping.

Another commenter noted that ISO 9001, *Quality management systems – Requirements*, requires manufacturers to maintain these types of records at the factory where a product subject to certification is manufactured. Rather than requiring foreign manufacturers to maintain duplicate records in the United States, the commenter suggested that the final rule should harmonize CPSC requirements with the ISO's and require that the records be made available to the Commission for inspection, either in hard copy or electronically, through the U.S. subsidiary or other U.S. corporate entity, within a reasonable time after the agency makes a request for them, pursuant to section 16(b) of the Consumer Product Safety Act.

Response 74:

CPSC staff agrees that it may be burdensome and duplicative in many cases to maintain all records in the United States. To reduce this burden and still maintain prompt access to records when needed, CPSC staff has deleted § 1107.26(b) of the proposed rule. Revised § 1107.26(b) of the draft final rule allows required records to be maintained outside the United States. However, all records must be made available, either in hard copy or electronically, such as through an Internet website, for inspection by the CPSC, upon request. Because the change eliminates the requirement that records be kept in the United States, CPSC staff declines to adopt the suggestion of a 3-year stay of enforcement of this part of the rule.

Regarding harmonization with the requirements of ISO 9001, the commenter did not specify which requirements in ISO 9001 should be harmonized. However, eliminating the requirement that records be maintained at a location within the United States would be consistent with sections 4.2.3.d (to ensure that relevant versions of applicable documents are available at points of use), and 4.2.3.g (to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose) of ISO 9001.

Comment 75:

One commenter stated that some of the required recordkeeping is “redundant and unnecessarily duplicative,” such as production testing plans for multiple factories. Fees for outsourcing these services could be significant and burdensome to many small businesses, the commenter asserted.

Response 75:

In the draft final rule, the option to implement a production testing plan to increase the maximum periodic test interval is set forth in § 1107.21(c)(2). The concept of having production testing at each manufacturing site has been maintained from the proposed rule in § 1107.21(c)(2)(ii). Section 1107.21(c)(2)(ii) of the draft final rule requires that each manufacturing site conduct separate production testing because the location at which a product is manufactured could have a material effect on the product’s ability to comply with the applicable rules. Factors such as power quality, climate, personnel, and factory equipment could materially affect the manufacture of a product. Because it cannot be assumed that units of the same product manufactured in more than one location are identical in all material respects, the finished product certifier must conduct separate production testing for the product for each manufacturing site. CPSC staff has taken other steps to reduce the recordkeeping burden, such as not requiring that records be kept in the United States, and eliminating the requirement that all records must be in English.

Comment 76:

One commenter noted that companies have established processes and formats and, in many cases, invested in information technology solutions to prepare and transmit these certificates in accordance with the law. The commenter added: “Retailers are relying upon such certificates as they can with the benefit of reduced liability under section 19 of the CPSA” as evidence that the products comply with all the applicable product safety rules. The commenter stated that the Commission needs to clarify that the form of delivery of title, in and of itself, should not require additional testing, documentation, and certification. The commenter also asked that the Commission clarify that retailers can rely upon domestically located supplier certifications without duplication of testing and certification requirements.

Response 76:

A certificate must accompany the product, as specified in 16 CFR part 1110. Certificates can be in paper or electronic form, as described by the commenter. The commenter is correct that the issuance of a Children's Product Certificate means that the children's product has passed its certification tests. If the commenter is referring to additional third party tests requested by retailers after the issuance of a certificate, the Commission emphasizes, as it did in the preamble to the proposed rule, that retailers and sellers of children's products can rely on certificates provided by product certifiers without having to conduct additional testing, if those certificates are based on testing conducted by a CPSC-accepted third party conformity assessment body.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 77:

One commenter stated that the proposed provisions of the rule having the largest immediate impact to the retail industry would be the recordkeeping requirements in §§ 1107.10(b)(5) and 1107.26 of the proposed rule. The commenter stated that in order to meet these provisions, a process to centrally maintain records for an estimated 300,000 items per year would need to be created. The number of pages of documentation covering a portion of products for one large general merchandise retailer acting as importer of record, would range from a low of 375,000,000 pages to more than 1,000,000,000 pages per year. This estimate was based upon the following:

- Full product specification (150–200 pages);
- Certification testing (30–100 pages);
- Production testing plan (inspection records, testing documents, and production plans quality control documents) (1000–3000 pages); and
- Periodic testing (50–200 pages).

This estimate did not include records of remedial action, if necessary.

Another commenter stated that the standards of recordkeeping outlined in the proposed rule are clear and should not present an unreasonable burden on manufacturers or importers. The commenter asserted that any responsible firm would maintain these records even without the rule, and they further asserted that establishing a reasonable baseline for product safety recordkeeping is crucial to enforcement.

Response 77:

Section 1107.10(b)(5) of the proposed rule on recordkeeping requirements for a reasonable testing program has not been finalized but has been reserved in this draft final rule. However, the length of the recordkeeping requirement is applicable to the length of the recordkeeping requirement for children's products in § 1107.26 of the draft final rule, so we address this issue here for children's products.

CPSC staff has modified the draft final rule to reduce costs associated with recordkeeping requirements, such as reducing and simplifying the record retention period to 5 years from the date of creation for all records; eliminating the requirement that records must be maintained in

English; and eliminating the requirement that records must be maintained in the United States. Moreover, removal of the remedial action plan requirement for children's products should further reduce the recordkeeping burden for manufacturers.

Even with these changes, the burden associated with the rule's recordkeeping requirements will vary among manufacturers or importers. As the commenters indicate, some manufacturers will consider the burden to be significant, whereas others will feel that the recordkeeping requirements are comparable to those at "any responsible firm." The recordkeeping burden could be fairly heavy for some products and relatively light for others, depending upon the complexity of the product, the number of product safety rules that are applicable to the product, and the amount of testing required. However, as stated in the preamble to the proposed rule (75 FR at 28360), documentation and recordkeeping are required to establish the identity of the product and to demonstrate that the product complies with the applicable safety rules, not only when it is certified, but also on a continuing basis after certification.

The rule provides manufacturers and importers with flexibility in how to maintain the records. The rule does not require that the records be maintained in a specific CPSC format. While the rule specifies what records or information must be maintained, a manufacturer may maintain—as the commenter suggested—the records within their own recordkeeping systems, if those systems meet the traceability requirements and ensure that products are certified properly before they enter into commerce.

Comment 78:

One commenter stated that manufacturers of children's furniture cannot provide any data on the cost of the recordkeeping requirements because they do not know yet the storage capacity that will be required to comply with the rule. Furniture manufacturers of non-children's products have reported that the cost of creating the system to collect their data on 16 CFR part 1303 compliance was approximately \$100,000, and the cost of records maintenance was in the range of \$30,000 - \$50,000 per year. Based on this estimate, furniture manufacturers of children's products are certain that it will cost them in excess of \$100,000 to build and program such a system. These furniture companies will require additional staff to maintain and update the system, and that will require the expenditure of at least \$30-50,000 a year, per person.

Response 78:

The CPSC acknowledges that there will be costs for tracking the data and maintaining the records, which could involve the development of software for tracking and managing the data and hiring additional staff. However, the draft final rule's recordkeeping requirements give manufacturers flexibility in determining how to meet them. Further, CPSC staff has modified the draft final rule to reduce costs associated with recordkeeping requirements, such as reducing and simplifying the record retention period to five years from the date of creation for all records, eliminating the requirement that records must be maintained in English, and eliminating the requirement that records must be maintained in the United States.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 79:

One commenter stated that as long as the manufacturer can use existing documentation, then there should not be an undue burden on the regulated community to comply with third party testing requirements for children's products. However, the commenter noted that if the CPSC intends to require that the manufacturer maintain documentation in a different format, then there will be a cost associated with maintaining this information.

Response 79:

Section 1107.26 does require manufacturers of children's products to maintain records of certification and supporting documentation of certification test records, periodic testing records, descriptions of any material changes, and records of undue influence procedures. Section 1107.26 of the draft final rule does not require manufacturers to develop codes, numbering systems, or special data formats. A manufacturer is free to use any format, provided that the required information is available to the CPSC, when requested.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 80:

One commenter objected to the requirement that records must be maintained for five years. (Note that the proposed rule required test records be maintained for five years; other records had to be maintained for as long as the product was in production or imported [without a material change], plus five years.). The commenter pointed out that the larger suppliers to the U.S. market, including chain stores, divide an order and ship separately to different states. Without giving details, the commenter implied that this would make the requirement to keep all required records for five years a heavy burden on manufacturers.

Response 80:

This comment is from a trade association for a foreign manufacturer of children's products. A foreign manufacturer has no obligation to keep the records specified under § 1107.26 of the draft final rule, unless it agrees contractually to maintain the records on behalf of the importer. Even under these circumstances, only the importer has the obligation to keep records. The importer, as the certifier, is responsible for maintaining the records or having another party maintain the records for it. As for the retailer in the distribution chain, they are not required to keep the required records unless they are also the importer. An importer's obligation to maintain the records for the product is independent of how many different retailers distribute the product. Regarding the burden of keeping records for five years, the 5-year record retention requirement was selected to be consistent with the 5-year statute of limitations in 28 U.S.C. § 2462. However, this requirement is not intended to supersede record retention times that are specified in existing regulations because this rulemaking cannot amend those other existing regulations.

CPSC staff recommends no change to the draft final rule based on this comment.

Labeling Consumer Products

Comment 81:

One commenter stated that the CPSC should not specify the features that must be used for the optional label indicating that a product meets the CPSC's safety requirements. The commenter did not think the CPSC should specify features such as size, color, font, or location because these will depend on the product. The commenter noted that there is the possibility that the specified text type and size will not be compatible with the different internal systems developed by retailers and manufacturers to meet the needs of the affected product. The commenter said that to specify any requirements other than what works with a firm's own internal systems would have absolutely no benefit at all.

Another commenter expressed concern with the font size being "no less than 12 points" because that could be a problem on some small containers. The commenter encouraged the CPSC to use the font size requirements in the Federal Hazardous Substances Act instead of those in the proposed rule.

One commenter agreed with the Commission's approach to labeling products to indicate compliance with the rules. The commenter recommended that the CPSC's labeling program should include guidelines for the type, style, color, and font of such labels and should consider use of symbols or a mark, rather than words or initials, as proposed. Symbols also would help overcome language barriers for communicating compliance. The commenter said that the guidelines should allow variations in the label's size to accommodate products of different physical dimensions, but the general appearance of the label must remain consistent. They recommended that the labels appear as a permanent mark on the product packaging, as well as on the product itself.

Response 81:

After reviewing the comments CPSC staff agrees with the commenters that specifying particular fonts and minimum sizes could make adding a label difficult for some products. Depending on the product's characteristics, such as size, surface finish, and the presence of a smooth flat area for the label, a label with a minimum font size may be difficult to apply. Therefore, the labeling requirements in § 1107.30(b) of the draft final rule, renumbered from § 1107.40(b) of the proposed rule, specify that the label must be visible and legible, instead of specifying a font and a minimum size. Manufacturers have the flexibility to implement a labeling system tailored to their product.

We note that the text of the message on the label remains, "Meets CPSC Safety Requirements." The label may be affixed to the product or provided with the product to allow flexibility to the manufacturer or private labeler in their implementation of the labeling requirements. Because the labeling requirements will apply to all consumer products covered by an applicable product safety rule, it would be impossible to design a label that would work with every firm's internal system.

Regarding the labeling requirements in the Federal Hazardous Substances Act, the commenter did not specify which labeling requirements should be used. The general labeling requirements

for labeling certain toys and games in section 24(d) of the FHSA state that the label shall be displayed in the English language, in conspicuous and legible type, in contrast by typography, layout, or color with other printed matter. The changes to the draft final rule are consistent with the FHSA in this regard.

The draft final rule does not allow for the use of a symbol or mark because such a symbol or mark might be misinterpreted as a CPSC certification mark or CPSC endorsement of the product. Additionally, the recommendation that a label be affixed to the product and its packaging may reduce the flexibility of manufacturers that choose to use the labeling program.

In reviewing the comments submitted regarding labels and the provisions of subpart D of the proposed rule, CPSC staff noticed that § 1107.40(d) of the proposed rule, renumbered as § 1107.30(d) in the draft final rule, could be misunderstood to imply that an alternative label may be used in place of the label specified in § 1107.40(b). Section 1107.30(d) in the draft final rule has been clarified to state that other labels, in addition to the label specified in § 1107.30(b), may be placed on the product, as long as the additional labels do not change the meaning of the label specified in § 1107.30(b).

Comment 82:

One commenter argued that the requirement to provide only the statement, “Meets CPSC Safety Requirements” is not adequate for indicating compliance. The commenter asserted that a registered certification mark is the only way to indicate adequately full compliance and noted that the use of a registered certification mark is also used as a tool to address counterfeiting activities.

Response 82:

The consumer product labeling program described in § 1107.40 of the proposed rule, renumbered as § 1107.30 of the draft final rule, is voluntary on the part of a manufacturer, importer, or private labeler. Section 14(a) of the CPSA requires the manufacturer, importer, and private labeler to issue a General Conformity Certificate or a Children’s Product Certificate for any product covered by an applicable product safety rule, regardless of whether a manufacturer elects to label their product under § 1107.30 of the draft final rule. A registered certification mark authorized by a certification body for a manufacturer to include with the product does not contain the information required by a certificate as specified in 16 CFR part 1110, and cannot be used in place of the certificate. CPSC staff disagrees with the commenter that certification marks are the only way to indicate full compliance. Other products, such as mattress sets, indicate compliance (in this case to 16 CFR part 1633) without the use of certification marks. Furthermore, CPSC staff is aware of multiple instances of counterfeit certification marks on consumer products.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 83:

One commenter contended that allowing manufacturers to place an optional label on their products that states: “Meets CPSC Safety Requirements,” could give manufacturers who use such a label an unfair market advantage over manufacturers who choose not to include the label.

The commenter stated that some manufacturers will not use the label because it will increase their product's cost. The commenter suggested that some consumers may choose the labeled product based upon a false assumption that the product without the label is somehow less safe. The commenter stated that some manufacturers will use the label as a misleading marketing tool or even alter the font type or size of the label for marketing purposes.

Response 83:

Section 14(i)(2)(A) of the CPSA 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 of section 14(a) of the CPSA. Section 1107.30 of the draft final rule implements this requirement. Use of the labeling program is at the discretion of the manufacturer or private labeler, and the manufacturer or private labeler must determine costs versus benefits for their particular products. The label specifications are designed to avoid giving consumers the false impression that the product is CPSC-tested, -approved, or -endorsed. Section 1107.30(d) of the draft final rule prohibits manufacturers or private labelers from implying, through manipulation of the font type, font size, or other means, that the CPSC has tested, approved, or endorsed the product.

CPSC staff recommends no change to the draft final rule based on this comment.

Safe Harbors

Comment 84:

Two commenters suggested that the rule should clearly allow for recognition of "safe harbors" based upon adherence to national standards for good manufacturing practices, international ISO standards governing GMP, and industry-based GMP category-specific guidelines that manufacturers may use as evidence of their good faith commitment to attaining a high degree of assurance that their products meet or exceed applicable federal safety standards. These commenters noted that the CPSC has recognized that such programs may be considered evidence in meeting the requirements under the proposed rule, but the CPSC has not yet recognized its authority to provide for such safe harbors, claiming that the CPSIA did not make such specific provision (75 FR at 28339). According to the commenters, specific statutory authority is not a precondition to the agency acting under its rulemaking and enforcement authority to recognize such safe harbors. The commenters contended that the CPSC should provide such recognition.

Response 84:

As we noted previously in the preamble to the proposed rule, section 14 of the CPSA does not contain a safe harbor exception, nor does it establish any criteria by which the Commission could recognize testing programs for purposes of a safe harbor.

The draft final rule does not contain a safe harbor provision based upon a manufacturer's participation in a voluntary or industry-sponsored program; nor has the Commission recognized any such program to indicate compliance with the draft final rule. CPSC staff notes that ISO standards for good manufacturing practices are generally industry-specific in areas such as cosmetics, pharmaceutical operations, food handling, and medical devices, products largely

beyond the CPSC's jurisdiction. It is unlikely that any one GMP standard would be deemed workable or acceptable for all manufacturing methods for children's products.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 85:

One commenter noted that the preamble to the proposed rule refers to a 95 percent statistical significance level as constituting a "high degree" of assurance. The commenter asked whether the CPSC would consider 95 percent confidence to be a safe harbor level.

Response 85:

In the preamble to the proposed rule, the 95 percent probability level was discussed as an alternative definition of a "high degree of assurance" that the Commission considered and subsequently rejected. The Commission "decided against defining 'high degree of assurance' with respect to a 95 percent probability or confidence level (or any other level of statistical confidence) because there may be difficulty in applying the statistical methods to all manufacturing processes." (See 75 FR at 28344). Therefore, the Commission does not consider a 95 percent confidence level to constitute automatically a "high degree of assurance"; nor does the Commission consider it to constitute a safe harbor level for purposes of compliance with the draft final rule. Determining what constitutes a "high degree of assurance" varies, depending upon the product manufactured and the manufacturing processes used. The determination must be made by individual manufacturers, based upon their knowledge of their products and manufacturing processes.

CPSC staff recommends no change to the draft final rule based on this comment.

Effective Date

Comment 86:

One commenter noted that for most major retailers the creation of a product begins with a design specification that originates 12 months or more prior to manufacture or import into the United States. Therefore, the commenter said, retroactively applying all the requirements of the final rule would be unduly burdensome. Manufacturers of compliant products that are currently on retailers' shelves may not have any or all of the components of a reasonable testing program. The commenter added that generating this documentation "after the fact" is simply not possible. The commenter requested that the Commission apply the rule only to products whose development begins 180 days on or after adoption. Accordingly, products would begin to be certified based upon a reasonable testing program with all accompanying documentation approximately 18 months after adoption of the final rule.

One commenter suggested that the effective date be set at one year from the publication of the final rule because that is how long it would take their industry to change its manufacturing processes in order to be able to comply with the requirements of a reasonable testing program.

Another commenter said that they simply do not have the staff or the resources to get the third party testing done on all of the products that could fall within the definition of "children's

product” and record it in a data collection and storage system (yet to be designed and implemented) within the 180-day timeframe specified in the proposed rule. The commenter suggested that they needed at least 365 days and therefore, requested that the Commission extend the stay of enforcement until February 2012.

Response 86:

The preamble to the proposed rule indicated that a final rule would become effective 180 days after its date of publication in the *Federal Register* (75 FR at 28361). However, on August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 revised the CPSIA in several different ways and also affected section 14(i)(2)(B)(ii) of the CPSA. H.R. 2715 also created a new section 14(i)(3)(B) of the CPSA, which requires us, no later than one year after H.R. 2715’s date of enactment, to review the public comments (on opportunities to reduce the costs of third party testing requirements) and directs us to “prescribe new or revised third party testing regulations” if we determine that “such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.” Consequently, we have finalized the provisions that H.R. 2715 did not affect directly. We also have decided to make the final rule effective 15 months after the date of publication in the *Federal Register* so that parties can begin taking steps to develop internal processes, such as recordkeeping, and so that we and interested parties can consider how H.R. 2715 interacts with the final rule.

We note the effective date for the draft final rule is not calculated based on when development of a product begins, but rather, it is calculated based on the date the product is manufactured. The requirements of the draft final rule apply only to products manufactured on or after the effective date of the draft final rule and do not apply retroactively to products already manufactured and certified.

Comment 87:

One commenter expressed concern that the rule has the potential to multiply the current volume of product testing by severalfold and that third party testing laboratories will be unable to accurately and efficiently provide the increased testing capacity needed by retailers/importers to comply with this rule. The commenter asserted that currently, without the rule being in effect, retailers already are experiencing delayed turnarounds in product testing, and it is not uncommon to have special requests denied due to the current backlog in testing.

The commenter also expressed concern that the increased testing demand may affect lab execution, potentially resulting in incorrect lab results, which may cause compliant product to be lost or may allow noncompliant product to enter commerce. The commenter said that if the capacity of the third party test laboratories is exceeded, retailers’ and manufacturers’ ability to meet the rule’s effective date could be jeopardized. The commenter asked that the laboratory capacity issue be taken into consideration when establishing the effective date of the final rule.

Response 87:

CPSC staff is aware that implementation of section 14(a)(2) of the CPSA potentially could result in insufficient testing capacity at CPSC-accepted testing laboratories. The Commission notes that in the majority of notices of requirements that have issued since 2008, there have been very

few claims of insufficient laboratory capacity, and when such issues have arisen, the Commission has taken steps to address the matter (See 75 FR 34360, June 17, 2010). The Commission will address any lab capacity issues that arise after implementation of the draft final rule.

CPSC staff recommends no change to the draft final rule based on this comment.

Regulatory Flexibility Analysis

Comment 88:

One commenter noted that in estimating the number of firms that could be impacted by the proposed rule, the book publishing industry (NAICS code 511130) and printing industry (NAICS code 323117) were not included. The commenter recommended their inclusion for the final regulatory flexibility analysis.

Response 88:

CPSC staff acknowledges that these industries were inadvertently omitted in the initial regulatory flexibility. However, the recently passed H.R. 2715 exempts ordinary books and ordinary paper-based printed materials from the third party testing requirements, which renders this omission moot.

Comment 89:

One commenter indicated that the cost of complying with the reasonable testing program requirements for furniture will vary according to: (1) whether the furniture is children's or non-children's furniture; (2) whether the furniture is produced domestically or imported; and (3) whether the manufacturer produces a high or low volume of products. High-volume producers can rely on a component part certificate from their paint suppliers, and the cost of testing would be relatively low. Higher quality, lower volume producers would have greater difficulty because these items often are made to order and "as needed." These producers will use small batches of finishes issued in a number of different finishing materials, each of which would need to be tested.

Response 89:

CPSC staff concurs that the costs of complying with the requirements will vary among products and manufacturers. Generally, the costs will be more significant for manufacturers of lower volume products. It should also be noted that subpart B of the proposed rule, which contained the requirements applicable to non-children's products is not being finalized at this time. Therefore, the draft final rule will not impose any requirements on non-children's furniture.

Comment 90:

Two commenters expressed concern about costs. One commenter noted that reliance on third party conformity assessment body testing raises costs and imposes production delays. Another commenter, a charitable organization that makes wooden toys for donation to needy children, commented that it lacked the resources to pay for certification testing and would need to discontinue activities unless granted an exemption or some other type of relief.

Response 90:

Section 14(a)(2) of the CPSA requires third party conformity assessment bodies to test children's products for compliance with applicable children's product safety rules. CPSC staff recognizes that testing costs may be substantial and will have a significant adverse affect on some manufacturers, especially small businesses that may have limited financial resources. CPSC staff also recognizes that the testing will take time and could result in some delays in the production process.

The recently passed legislation, H.R. 2715, obligates the CPSC to seek public 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. H.R. 2715 directs the Commission to seek public comment on seven specific issues, including techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

The Commission intends to issue a notice seeking public comment on this issue in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

H.R. 2715 also obligates the Commission to consider alternative requirements for the covered products of small batch manufacturers and, if no alternative requirements are available or economically practical, exempts small batch manufacturers from the third party testing requirements, with some exceptions. Covered products are those for which fewer than 7,500 units were produced in the previous year, and a small batch manufacturer is one whose gross sales revenue from all consumer products in the previous calendar year was less than \$1,000,000. In the case of toys, however, no alternative requirements or exemptions would be permitted for third party testing for the lead content of paint, small parts, and pacifiers. Where possible, the Commission tried to reduce testing costs by allowing the use of component part testing

Comment 91:

One commenter provided several comments on the initial regulatory flexibility analysis. The commenter noted that the analysis acknowledged that the examples used in the analysis only considered the out-of-pocket testing costs. Costs not considered in the examples include: samples destroyed or damaged in testing; transportation of the samples; administrative costs for managing testing; administrative costs for managing the testing data and recordkeeping; an allocation of general management time; legal expenses, among other costs. The commenter estimated that, depending on the scale of the business, these costs will add 15 to 50 percent to the out-of-pocket testing costs.

The commenter also noted that the initial regulatory flexibility analysis considered the probability that some manufacturers or private labelers will have to test multiple samples to obtain the high degree of assurance required by the proposed rule. The commenter asserted that over the last 20 years of product testing at his company, multiple safety tests of the same product have not revealed anything useful. The commenter asserted that the testing rule is complex; that

many small businesses will not have the skills necessary to understand what is expected of them in terms of compliance; and that many small businesses will exit the market for children's products.

Response 91:

The initial regulatory flexibility analysis focused on the cost of third party testing because it will likely be the most significant cost for small manufacturers of children's products. Considering only the third party testing costs, the initial regulatory flexibility analysis found that the rule could have a significant impact on a substantial number of small entities. The initial regulatory flexibility analysis explicitly stated that the only costs considered in the analysis were the costs that the laboratories would charge to conduct the testing. The commenter is correct that the rule would impose other costs, including the cost of the samples destroyed in testing and freight, as well as the costs involved in administering and managing the testing and paperwork. The commenter's estimate that these costs would add 15 to 50 percent to the out-of-pocket testing costs, depending upon factors such as the product involved and the scale of the business, seems reasonable.

The commenter is also correct that the initial regulatory flexibility analysis considered the impact on firms that had to test more than one sample of a product in order for the manufacturer to obtain a high degree of assurance that the product complies with the applicable product safety rules. However, the draft final rule does not specify the number of samples that must be tested. It is possible that if the commenter, as asserted, has never found multiple tests on its products to reveal anything useful, then the products manufactured could be of such uniform composition and quality that the number of samples the commenter will be required to submit for testing will be small. However, because the rule would require that every children's product be tested by a third party conformity assessment periodically, the commenter might be required to conduct more testing than the commenter believes is necessary.

The CPSC acknowledges that the rule is complex, and some small businesses might have to consult with legal, statistical, or quality control experts to help them comply with the regulations. As a result, some small firms may change the number and types of children's products they manufacture, including exiting the market.

Comment 92:

One commenter stated that the testing rule would accelerate the decline of domestic manufacturing firms, as more manufacturers go offshore to minimize the cost of testing. The commenter asserted that the furniture industry will have no choice but to close down more and more factories in the United States and take those jobs offshore to benefit from the lower testing costs. The commenter stated that some small manufacturers have abandoned plans to offer products intended for the youth market.

Response 92:

The initial regulatory flexibility analysis noted that the costs of some third party tests are less expensive abroad than they are in the United States. For example, while typical prices for lead content tests range from \$50 to more than \$100 in the United States, the same lead content test, in some cases, can be obtained for as little as \$20 in China (75 FR at 28355). Higher third party

testing costs in the United States would be an incentive for manufacturers to produce children's products abroad to take advantage of the lower testing costs.

Given all the factors that go into a decision by a manufacturer to produce consumer products abroad rather than in the United States, the impact of third party testing costs on such a decision might be small. It seems unlikely that the independent effect of higher third party testing costs, by itself, would result in a large number of factories in the United States closing down. With regard to small domestic manufacturers, it is possible that the third party testing costs associated with children's furniture could lead some to manufacturers to reduce their children's furniture product lines or even cease their production of children's furniture. Any small manufacturer of children's furniture that qualifies as a small batch manufacturer might be offered relief by the alternative requirements or exemptions that are provided by H.R. 2715.

As noted above, the CPSC intends to issue a notice seeking public comment on other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Comment 93:

One commenter stated that the cost to test a finish used in the furniture industry is about \$50 (which is consistent with the discussion of testing costs in the initial regulatory flexibility analysis). A youth bed, which is also subject to the lead content requirements of section 101 of the CPSIA, might require 29 tests at a third party testing facility, which would bring the total cost of lead testing to \$1,450. In addition, testing to the bunk bed standard would add \$600 to \$800 to the cost. A crib or toddler bed would cost an additional \$750 to \$765 (\$450 to \$520 in China) to test to the relevant children's product safety rules. The cost of testing other items of youth furniture, such as desks, entertainment centers, and bookcases averages approximately \$235. These costs do not include the cost of the samples, freight, random sampling, or the cost for employees to track and administer the recordkeeping requirements.

Response 93:

As described in the initial regulatory flexibility analysis (See 75 FR at 28352-62), the testing of some children's products by third party conformity assessment bodies can be costly. The testing costs described by the commenter do not appear to be unreasonable estimates, based on cost estimates obtained by CPSC staff. In cases where the same component is used in more than one product, manufacturers may be able to reduce their testing costs by using component part testing. However, component part testing will not offer any relief from the costs of tests that must be performed on the finished product, such as tests for conformity to the crib and bunk bed standards.

Comment 94:

One commenter stated that furniture manufacturers that deal in high quality, but lower volume furniture manufacturing, may offer products with between 30 to more than 2,000 possible combinations of finishes. Many of these finishes are custom-made or made-to-order so that a batch can range from a 5-gallon bucket to a 55-gallon drum. Each custom finish consists of at least 10 different materials. The manufacturer must create a panel for each possible combination of finishing materials and then have it analyzed by a third party testing facility. An x-ray

fluorescence (XRF) gun is then used to verify that the finished piece, in fact, complies with the lead-in-paint standard. It is estimated that 6 to 10 employees will be required to track the testing and compile the certificates of conformity. It is estimated that the cost to comply with the rule for non-children's products could range from \$200,000 to \$410,000 annually.

Response 94:

We received many comments on subpart B of the proposed rule, the section of the proposed rule that was concerned with reasonable testing programs for non-children's products. The comments raised many practical issues, which illustrates the difficulty of drafting a regulation that can apply to many different types of products and manufacturing processes and still provide sufficient guidance to enable manufacturers to implement the requirements effectively. Consequently, the Commission is deferring action with respect to finalizing subpart B. Instead the Commission will reserve subpart B in the final rule and continue evaluating the issues raised in the comments.

It should be noted, however, that although the Commission is not finalizing subpart B at this time, manufacturers of non-children's products that are subject to a product safety rule, ban, standard, or regulation are still obligated by the CPSA, as amended by the CPSIA to certify that their products comply with all applicable safety rule, based on a test of each product or a reasonable testing program.

In the case of testing the lead content of paint, which is mentioned by one commenter, the use of component part or composite testing—as would be allowed by the draft final rule and the proposed rule on component part testing—might allow some manufacturers to reduce their testing costs. For example, if the same 10 raw materials (and only those materials) are combined in different portions to produce 30 different finishes, a manufacturer could test the lead content of each of the materials, and if each of the materials met the lead content requirement, then the manufacturer would not need to test each of the 30 finishes separately.

Comment 95:

One commenter stated that because the cost of testing and recordkeeping will be passed on to the consumer, this could create an “upside down” market in furniture, in which youth furniture is more expensive than adult furniture. This could lead some consumers to purchase “adult” furniture for children instead of youth furniture that has been third party tested.

Response 95:

Section 14(a)(2) of the CPSA requires third party testing of children's products, including children's and youth furniture. Depending upon the structure of the market and market conditions, some or all of the testing costs may be passed on to consumers. We cannot determine whether passing on these costs will make children's furniture more expensive than adult furniture in an absolute sense, but it likely would increase the relative price of children's furniture and could provide a price incentive for parents to substitute adult furniture for children's furniture.

Comment 96:

One commenter stated that the proposed rule will impose significant new costs on the mattress industry because mattresses are already subject to an expensive mandatory testing program pursuant to 16 CFR part 1633. The commenter asserted that because most manufacturers of mattresses are small businesses, the proposed rule would have a substantially greater impact on the mattress industry, given the nature of the products, the types of standards that the products must meet, the destructive nature of the testing involved, and the cost of the samples tested.

The commenter also noted that mattress testing entails costs such as: the cost of the samples tested, the laboratory test fees, freight costs to ship samples to the laboratory, and the manufacturers' staff sent to witness the test. The total cost of conducting a full test for 16 CFR part 1633 can range from \$850 to \$1,650 per sample tested, plus added travel costs and salary expenses for company personnel to witness the test. The commenter urged the CPSC to take into account the significant new costs that the proposed rules will impose on the mattress industry, which is comprised, overwhelmingly, of small businesses.

Response 96:

The CPSC acknowledges that the rule will probably impose additional costs on some mattress manufacturers. However, section 14(a)(2) if the CPSA requires third party testing of children's products that are subject to an applicable children's product safety rule.

On August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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. H.R. 2715 directs us to seek public comment on seven specific issues. These issues are:

- The extent to which manufacturers with a sizeable number of substantially similar products subject to third party testing may reasonably make use of sampling procedures that reduce the overall test burden without compromising the benefits of third party testing.
- Other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

We intend to issue a notice seeking public comment on these issues in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Another provision of H.R. 2715 created a new section 14(i)(4) of the CPSA to provide for special rules for small batch manufacturers. The provision contemplates the possible development of alternative testing requirements for "covered products" made by "small batch manufacturers." The provision also provides for possible exemptions of small batch manufacturers from the third party testing requirements and imposes certain limits on third party

testing requirements. A covered product is one where no more than 7,500 units of the product in the previous calendar year and a small batch manufacturer is a manufacturer that had no more than \$1,000,000 in gross revenue from sales of all consumer products in the previous calendar year. Any small mattress manufacturer that meets the definition of a small batch manufacturer might benefit from this provision.

Comment 97:

One commenter stated that the discussion of sample size is unrealistic. An example was used in the initial regulatory flexibility analysis that provided the sample sizes that would be required to meet a specified statistical confidence level, assuming that both the historical variability (standard deviation) and the historical mean of the variable (lead content) were known. The commenter stated that continuously variable data on commonly available testing reports is generally not provided by the laboratories, and data for samples with a result below the method detection limit is generally provided in the form “ $\leq X$ ppm,” where X is the method detection limit. The commenter noted that these data cannot be included for calculations of the mean or standard deviation. The commenter stated that the example used is invalid, unless the data can be captured and tracked in full resolution, which is not the current state.

Response 97:

To the extent that continuously variable data from testing results are unavailable, the discussion of sample size in the initial regulatory flexibility analysis may be unrealistic. Because the example is not widely applicable, and because the Commission is not requiring that the periodic third party testing be used to provide a high degree of statistical assurance (*e.g.*, 95 percent confidence) that no children’s products violate consumer product safety standards, the example has been omitted in the final regulatory flexibility analysis.

Paperwork Reduction Act

Comment 98:

Some commenters noted that the preamble to the proposed rule states that the CPSC will likely request access to these records only when it is investigating potentially defective or noncompliant products. The commenters concluded that having to integrate multiple systems to compile data should not be needed, as long as companies can provide the data upon request. The commenter noted that § 1107.10 (b)(5)(i)(C) of the proposed rule requires not only records of each certification test, but also “a description of how the product was certified as meeting the requirements, including how each applicable rule was evaluated, the test results and the actual values of the tests.”

One commenter stated that it receives more than a thousand finished good test reports annually from CPSC-accepted third party labs. These reports often run 50 to 125 pages in length and contain hundreds of data points and assessments. The commenter asserted that adding additional descriptive text to explain “how” the product was certified, simply adds no value. The commenter concluded that if the test report references an ASTM standard and the results are acceptable, that should be sufficient without additional explanations.

Response 98:

With respect to non-children's products (proposed § 1107.10), the Commission is deferring action with respect to finalizing subpart B of the proposed rule, which contained requirements for a reasonable test program for non-children's products, including the recordkeeping requirements. Therefore, the final rule does not impose any recordkeeping requirements related to non-children's products.

With respect to children's products, the recordkeeping requirements at § 1107.26 of the draft final rule do not require descriptive text to explain "how" the children's product was certified. The certification test methods are prescribed for children's products. It should only be necessary for the manufacturer or importer to additionally identify and store the new requirements that are not already part of their current recordkeeping systems and to be certain that the remaining documentation can be produced, upon request, in a manner that identifies clearly the requisite parts.

CPSC staff recommends no change to the draft final rule based on this comment.

Comment 99:

Several commenters remarked about the CPSC's estimated resource requirements to manage the general recordkeeping requirements for testing and certification. One commenter stated that the toy industries' experience in meeting the recordkeeping requirements of the interim enforcement policy is that the requirements are extremely burdensome, and the recordkeeping requirements contained in the proposed rule are much more extensive and will be even more costly. The commenter stated that the CPSC's estimate of 200,000 to 300,000 hours to manage recordkeeping, equating to no more than 200 people across all industries impacted by the CPSIA, is much too low. Within the toy industry alone, the commenter estimated 10 times that many persons have been engaged along the global supply chain to manage the data and recordkeeping associated with the CPSIA's existing requirements. Although the CPSC references a calculation of 100,000 to 150,000 products to which the recordkeeping requirements would apply, the commenter stated that companies typically certify each SKU, and there is recordkeeping for every version, even if it is identical in all material respects.

One commenter estimated that the true number of toys and games was closer to 2.5 million. The commenter's estimate was based on a listing of 808,465 toys and games on a popular commercial website (on August 3, 2010); plus its estimate that the website only lists about one-third of the toys available. Given some specialty and other submarkets, the commenter thought that the final number of items in the toys, games, and educational items category could be in excess of 4 to 5 million individual products or stock-keeping units. The commenter also provided an estimate of 8 million apparel items for children being available. However, the commenter did not provide the method or data sources it used for the latter estimates. Another commenter noted that its company had about 1,700 individual products annually, requiring testing, certification, and recordkeeping, or more than 1 percent of the CPSC's entire estimated number of products across all affected industries.

Response 99:

The CPSC acknowledges that its original estimate of the number of products that would be impacted was low and has increased significantly its estimate of the recordkeeping burden associated with the testing and certification requirements of the draft final rule. Based on the comments, and other staff research, the CPSC staff has revised its estimate of the number of children's products. In the categories of toys, art and creative materials, furniture, and jewelry, the staff estimates that there are perhaps 241,000 different products. There are additional products in other categories, such as nursery or juvenile products, non-traditional toys (e.g., video games), CDs, bicycles, ATVs, party favors, and greeting cards intended for children, and some educational materials that could be affected by the draft final rule for which specific estimates have not been made. The estimates do not consider that some products might be produced at more than one location or certified by more than one importer. Therefore, the staff concluded that there could be 300,000 non-apparel products that are covered by the rule.

The original estimate did not account for the very large number of apparel products that would be covered by the draft final rule. The number of apparel products intended for children, including footwear, is estimated to be about 1.3 million. This would bring the total number of children's products to about 1.6 million.

The draft final rule has been changed to address some of the burdens mentioned by the commenters, such as not requiring that the records be kept in the United States or translated into English unless requested.

As noted above, the CPSC intends to issue a notice seeking public comment on other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Comment 100:

One commenter asserted that its company's testing program has been highly effective for more than 26 years, but it does not maintain the records that would be required by the proposed rules, and it would be very costly to do so. One commenter questioned whether the extensive recordkeeping on every item is necessary for the proper performance of CPSC's functions.

Another commenter echoed the concern that the cost of the recordkeeping requirements would be high without providing any clear benefit to the agency's mission or product safety. The commenter estimated that a major retailer would need to maintain records on 300,000 unique products, which would cost the retailer \$22 million annually, using the estimated per-product recordkeeping burden employed in the notice of proposed rulemaking. Another commenter stated that the CPSC should reduce the reporting burden by allowing manufacturers or importers to maintain their own recordkeeping systems if they meet the traceability requirements and ensure that products are certified properly before they enter into commerce.

Response 100:

With respect to recordkeeping requirements for reasonable testing programs for non-children's products, the Commission is deferring action on finalizing subpart B of the proposed rule, which proposed requirements for reasonable testing programs for non-children's products. Therefore, the draft final rule does not impose any recordkeeping requirements on manufacturers of non-children's products.

With respect to children's products, the CPSC acknowledges that the recordkeeping requirements could require considerable resources to track the data and manage recordkeeping. As a result, the costs associated with the recordkeeping requirements could be a significant expense for some firms. However, as stated in the preamble to the proposed rule, the purpose of the documentation and recordkeeping requirements in the rule are to establish the identity of the product and to demonstrate that each product complies with the applicable rules when it is certified and on a continuing basis thereafter. Additionally, we note that retailers are not required to comply with the recordkeeping requirements of the rule unless they are also the importer of the product.

CPSC staff has implemented changes in the draft final rule that are intended to reduce the costs associated with the recordkeeping requirements. For example, manufacturers will not be required to maintain the records at a location in the United States, as long as they can provide the records to the CPSC after receiving a request to do so. Also, with the exception of the certificates of conformity, the records will not have to be maintained in the English language.

Finally, the rule does not require that the records be in a specific format. The rule specifies the records or information that is required. However, manufacturers may maintain the records within their own recordkeeping systems if they, as suggested by the commenter, meet the traceability requirements and ensure that products are certified properly before they enter into commerce.

Comment 101:

Several comments provided estimates on the amount of time required for recordkeeping or information from which estimates could be derived. One commenter (a large toy manufacturer) stated that they had added six full time employees to manage the data and recordkeeping associated with the CPSIA's existing testing and certification requirements and that they had 1,700 products tested annually for which recordkeeping would be required. The test reports are from 50 to 125 pages in length and require maintaining for all products tested. The commenter estimated that their one company accounted for greater than one percent of all the hours the CPSC had estimated for all children's products. The commenter concluded that, based on this estimate, the actual number of hours required for recordkeeping by all companies would be higher than CPSC's estimate.

Another commenter estimated that the recordkeeping time will require about 2.25 hours per test submitted, but due to varying lot sizes and requirements, they estimate that multiple tests per year could be required on a product. They estimate that the burden will be 3 hours for one category of products it manufactures and 5 hours for another, with an average across their product line of 3.5 hours.

One commenter said that the time required for recordkeeping would be higher for manufacturers that specialize in high quality, but low volume products. The commenter estimated that it would take six to ten employees to track the testing data and compile it into certificates of conformity, or about six to ten times the per-product labor required by the high volume, mass production manufacturers. The commenter estimated about 3 to 7.5 hours of recordkeeping would be required for high quality, low volume products.

Response 101:

Based on these comments, the staff has determined that, for many children's products, substantially more than two hours will be required for the associated recordkeeping. For products, such as toys, jewelry, children's furniture and other children's products, which are subject to third party testing to several different standards, the staff determined that five hours is a reasonable estimate.

More hours will be required for some products to which many rules apply. Simpler products with few, or only one, applicable rule should require fewer hours for recordkeeping. For apparel and footwear products, the staff determined it was reasonable to use a lower estimate of the number of hours required for recordkeeping, such as three hours. This estimate recognizes that there could be substantial recordkeeping required for some items, such as those that require testing for flammability and that contain various components (e.g., zippers, snaps, buttons, accessories) that require testing, while other items, might require little testing.

Outside the Scope of the Rule

Comment 102:

One commenter objected to the application of the regulation to some juvenile furniture. The commenter stated that it is difficult to estimate the cost of testing for children's products when the Commission has not yet decided on the definition of a children's product. Another commenter generally supported the idea of third party testing of children's products but was unclear about what products are included in the category of children's products.

Response 102:

This rulemaking does not address what products fall within the definition of "children's products," and therefore, the comment is outside the scope of the rule. However, after the comment was submitted, the Commission issued an interpretative rule regarding the definition of children's product providing the guidance the commenter is seeking. See 75 FR 63067 (Oct. 14, 2010).

Comment 103:

One commenter wondered whether a manufacturer or importer of a children's product subject to a children's product safety rule for which no third party testing laboratories have been accredited by CPSC, is required to certify the product based on such testing. The commenter also wondered whether an importer is prohibited from importing the children's product until the CPSC accredits third party testing laboratories for the children's product safety rule.

Response 103:

This rulemaking does not address the issuance of notices of requirements for accreditation of third party conformity assessment bodies, and therefore, the comment is outside the scope of the rule. However, if there are no CPSC-accepted third party laboratories whose scope includes a rule applicable to a children's product, those products are not prohibited from being imported. The children's products are still required to comply with the requirements of the applicable children's product safety rules.

Comment 104:

One commenter recommended that conformity assessment bodies should: (a) comply with the standards in ISO/IEC Guide 65, or (b) in fulfillment of the requirements in ISO/IEC 17025:2005, during each audit review and resubmission of CPSC Form 223, demonstrate independence from "... financial and other pressures and influences that may adversely affect the quality of their work..."; the commenter also suggested requirements for audits of conformity assessment bodies.

Another commenter expressed ongoing concern over the distinct possibility that accredited testing organizations, especially "firewalled" and "government laboratories," could be subject to influence and threats to impartiality by outside or related interests. The commenter expressed concern that the new audit procedures stated that all types of third party conformity assessment bodies—independent, firewalled suppliers, and government-owned or -controlled—would be treated the same and are all called third party conformity assessment bodies. The commenter stated that these different types of conformity assessment bodies have different modes of operation, and they need to be treated differently by the CPSC, in both the auditing and accreditation requirements. The commenter suggested that the CPSC should require applicants to submit the evidence used to validate the fulfillment of ISO/IEC 17025:2005 requirements for the laboratory to "have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work," not only as part of their application to the CPSC, but also on an ongoing basis, as part of each audit review and resubmission of CPSC Form 223.

Two commenters stated that the proposed rule fails to differentiate between firewalled and independent laboratories. According to one commenter, a manufacturer can submit samples to its firewalled laboratory even if its reasonable testing program fails to provide a high degree of assurance of compliance with the applicable children's product safety rules. This commenter sought clarification of the provision that a manufacturer of children's products with a reasonable testing program may submit samples to its firewalled laboratory every two years.

Response 104:

This rulemaking does not address the requirements for conformity assessment bodies and therefore, the comments are outside the scope of the rule. Conformity assessment body requirements are being addressed in a separate rulemaking. Further, section 14(f) of the CPSA defines "third party," "firewalled," and "governmental" conformity assessment bodies.

However, regarding firewalled laboratories, a manufacturer who has implemented a production testing plan for a children's product is required to submit samples for periodic testing to a CPSC-approved laboratory at least once every two years. Because a firewalled laboratory is CPSC-approved, a manufacturer may use its firewalled laboratory for periodic testing purposes.

Comment 105:

Two commenters recommended that the Commission consider a number of steps to ensure that laboratories are protected against undue influence. These include the following: (1) adopting the requirements in Clause 4.2 of the ISO/IEC Guide 65; (2) using the OSHA NRTL program as a model for laboratory accreditation; and (3) requiring all laboratories applying to the Commission to submit evidence that they fulfilled ISO/IEC 17025:2005 section 4.1.5 b. One commenter made the recommendation for "firewalled" laboratories. Another commenter added a requirement of annual reassessments of laboratories.

Response 105:

This rulemaking does not address undue influence requirements for third party conformity assessment bodies, and therefore, the comments are outside the scope of this rule. This rule establishes the requirements for manufacturers to safeguard against the exercise of undue influence on third party conformity assessment bodies.

Comment 106:

Several commenters submitted comments on the concurrent rulemaking for component part testing in proposed 16 CFR part 1109.

Response 106:

This rule does not establish the requirements for component part testing, and therefore, these comments are outside the scope of this rule. Comments on component part testing are addressed in that rulemaking. (See *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)).

Comment 107:

One commenter opined that an existing third party certification system under the OSHA NRTL program, in conjunction with testing being carried out in testing facilities accredited to ISO/IEC 17025, is the preferred method for product certification for the CPSC. The commenter recommended that a similar program or an accredited certification program that meets the requirements of ISO/IEC Guide 65 and ISO/IEC Guide 67 be considered by the CPSC.

Response 107:

This rulemaking does not address certification systems or accreditation, such as ISO/IEC Guides 65 and 67, and therefore, the comment is outside the scope of this rule.

Comment 108:

Several commenters requested that silk be exempted from 16 CFR part 1610. They argued that the regulation exempts plain surface fabrics weighing at least 2.6 ounces per square yard and fabrics made from acrylic, modacrylic, nylon, olefin, polyester, and wool, but not silk. The

commenters stated that silk's reaction to fire is comparable to wool, and better than the synthetics that are exempted.

Response 108:

This rulemaking does not address amendments to 16 CFR part 1610, and therefore, the comments are outside the scope of this rule.

Comment 109:

One commenter noted that heavy element and phthalates testing use some chemicals. With increased testing, there will be more chemical waste, which may not be desirable.

Response 109:

This rulemaking does not address testing methods for specific substances, and therefore, the comment is outside the scope of the rule.

Comment 110:

One commenter suggested developing an exemption list for vinyl fabrics produced in accordance with 16 CFR part 1611, *Standard for the Flammability of Vinyl Plastic Film*, using a process similar to that used to develop the exemption list in 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*. In the latter case, testing over a number of years showed that certain types of fabrics always produce passing results when tested according to 16 CFR part 1610, and those types of fabrics eventually were exempted from the standard.

Response 110:

This rulemaking does not address amendments to 16 CFR part 1611, and therefore, the comment is outside the scope of the rule.

Comment 111:

One commenter disagreed that a standard of general application to all consumer products in a category should be considered a "children's product safety rule" for purposes of the CPSIA.

Response 111:

This rule establishes the requirements for the testing and certification of children's products and for the labeling of compliant consumer products. Determinations of whether a particular safety standard is a children's product safety rule are outside the scope of this rule.

Comment 112:

One commenter suggested that the CPSC should consider developing training guidelines for the regulated community and testing laboratories that explain key elements of a reasonable testing program for non-children's and children's products. The guidelines could include helpful training aids and presentations to increase the knowledge and understanding. The guidelines could include helpful examples and scenarios for most common issues (*e.g.*, developing a random sampling program) and even infrequent but complex issues (*e.g.*, traceability for raw materials and product components).

Response 112:

This rule is limited to establishing the requirements for testing and certification requirements for children's products and for labeling of consumer products as compliant; therefore, the comment is outside the scope of the rule. Further, subpart B of the NPR (the reasonable testing program for non-children's products) has been reserved for future consideration. Establishing training programs may be addressed by the Commission in the implementation of the final rule.

Comment 113:

One commenter noted that the proposed rule had to be worded very generally to be applicable to a wide range of products. This has had the effect of making it more difficult to understand how the rules will be applied in any specific industry. The commenter suggested that the CPSC conduct regional industry-specific workshops to explain to the regulated manufacturers how these general rules will apply to their existing procedures and where new regulatory obligations exist.

Response 113:

This rule is limited to establishing the testing and certification requirements for children's products and for labeling of consumer products as compliant; therefore, the comment is outside the scope of the rule. Establishing regional industry-specific workshops may be addressed by the Commission in the implementation of the final rule.

Comment 114:

One commenter recommended that the labels for toys be used to communicate not only compliance with the standards, but also the appropriate age range for the toy. The European Union uses a universal mark that indicates the inappropriate age ranges of a toy if it presents a choking hazard. The commenter said that the CPSC's program could expand on that concept, by recommending labeling that caregivers can use to separate toys intended for siblings of differing ages, while also preventing parents and other caregivers from buying toys that may be inappropriate for the age of the child. The commenter believes that this could help enhance toy safety by reducing children's exposure to inappropriate toys.

Response 114:

This rulemaking does not address labeling for the appropriate age ranges for a toy; therefore, the comment is outside the scope of the rulemaking. Section 14(i)(2)(A) of the CPSA requires the Commission to implement a program by which a manufacturer may label a product to comply with the certification requirements of section 14(a) of the CPSA. However, CPSC staff has issued *Age Determination Guidelines: Relating Children's Ages to Toy Characteristics and Play Behavior*, T. P. Smith (Ed.) (2002) (which can be found on the CPSC website at <http://www.cpsc.gov/BUSINFO/adg.pdf>), which addresses the issue raised by the commenter.

Comment 115:

One commenter asserted that the best approach would be to allow businesses to manage their compliance risks as best they can because "... the prophylactic approach to testing adopted by the CPSC will inevitably put many small or micro businesses into bankruptcy If the law does not permit the agency to adopt sensible rules that allow businesses to manage their compliance risks as best they can (where the standards remain in place, but the government stops trying to

tell businesses HOW to comply), then the Commission must finally tell Mr. Waxman what he doesn't want to hear—that his law is broken and can't be fixed” The commenter then wrote: “... I don't believe the agency can devise sensible regulations to fix this problem short of a legislative change.”

Response 115:

Comments about the merits of the statutory requirements of section 14 of the CPSA are beyond the scope of this rulemaking. The Commission is required to issue implementing regulations for section 14(i)(2) of the CPSA and has done so in this rulemaking.

However, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 provides relief for small batch manufacturers. Another provision requires the CPSC to seek public 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. H.R. 2715 directs the CPSC to seek public comment on seven specific issues, including other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. We intend to issue a notice seeking public comment on this issue in the near future. HR. 2715 further requires the CPSC to review the public comments and states that the CPSC may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Comment 116:

One commenter, who manufactures die-cast metal toys, commented that the 90 ppm lead content limit is too low to allow use of the usual aluminum for casting their products, even though the same metal is used to make cooking utensils.

Furthermore, the commenter stated that it costs \$3,700 to test one unit and asserted that the market will not absorb the costs of testing multiple units per batch. The commenter implied that these costs would cause it either to go out of business or make its products in China. The commenter believes that it should not have to test using third party laboratories because:

1. they are ISO 9001:2008 compliant;
2. they document all their supplier receipts of metal, plastic, and powder paint materials; and
3. they conduct a metal analysis for each production run with their spectrometer.

Response 116:

The 90 ppm lead limit pertains to paints and surface coatings. For lead content, the limit is 100 ppm. These limits were established by statute. This rulemaking does not address lead content and surface coating limits. Therefore, comments on the allowable concentration levels are outside the scope of this rule.

Further, section 14(a) of the CPSA requires third party certification testing of children's products. The methods listed by the commenter refer to first-party inspection and testing, and are not allowed by the CPSA to be used for children's product certification.

However, as noted above, H.R. 2715 directs the CPSC to seek public comment on seven specific issues, including the extent to which evidence of conformity with other national or international governmental standards may provide assurance of conformity to consumer product safety rules, bans, standards, or regulations applicable under this Act, and the extent to which technology, other than the technology already approved by the Commission, exists for third party conformity assessment bodies to test or to screen for testing consumer products subject to a third party testing requirement.

Tab B: Final Regulatory Flexibility Analysis for a Rule Requiring Testing and Labeling Pertaining to Product Certification



United States
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Memorandum

Date: 25 August 2011

TO : Randy Butturini
Office of Hazard Identification and Reduction

THROUGH : Gregory B. Rodgers, Ph.D.,
Associate Executive Director
Directorate for Economic Analysis

Deborah V. Aiken, Ph.D.
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT : Final Regulatory Flexibility Analysis for the Final Rule On Testing and Labeling
Pertaining to Certification

Attached is a draft final regulatory flexibility analysis for the rule for testing and labeling
pertaining to product certification.

Final Regulatory Flexibility Analysis for the Final Rule on Testing and Labeling Pertaining to Product Certification



Robert Franklin
Directorate for Economic Analysis
25 August 2011

1 Introduction

This report provides a final regulatory flexibility analysis of a final rule that would implement portions of sections 14(a) and 14(i)¹ of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA). The proposed rule was published on May 20, 2010. The proposed rule contained provisions that: would establish the minimum requirements for a reasonable testing program under section 14(a)(1) of the CPSA; would establish requirements for the certification of children's products; and set forth requirements that would implement the mandates of sections 14(i)(2)(i), (ii), and (iv) of the CPSA. The preamble to the proposed rule included an initial regulatory flexibility analysis of the proposed rule.

Several sections that were included in the proposed rule are not included in the draft final rule but are being reserved for future rulemaking by the Commission. The section of the proposed rule that pertained to a reasonable testing program for non-children's products (§ 1107.10) is not included in the draft final rule, but the issue may be addressed by the Commission in a future rulemaking. The section of the proposed rule pertaining to the selection of random samples for children's products (§ 1107.22) is not included in the draft final rule in order to provide Commission staff more time to consider the implications of the recently passed legislation H.R. 2715, which amended section 14(i)(2)(B)(ii) of the CPSA to require the CPSC to establish protocols and standards for the testing of *representative* samples, instead of *random* samples. Finally, § 1107.21(d) of the proposed rule, which provided a partial exemption from periodic testing for low-volume products is not included in the draft final rule. This section is not included because H.R. 2715 asked the CPSC to examine more holistic means to reduce the burden on certifiers. Therefore, the CPSC will consider the low-volume exemption in the proposed rule in light of the broader effort before deciding whether to add this or a similar exemption for low-volume products at a later date. Any exemption from periodic testing for low-volume products that is included at a later date would be in addition to the exemption for small batch manufacturers that was included in H.R. 2715.

Before promulgating a final rule, the Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis of the rule that analyzes the impact that the rule will have on small entities. The final regulatory flexibility analysis must contain:

- (1) a succinct statement of the need for, and objectives of, the rule;
- (2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

¹ This section was renumbered from 14(d) to 14(i) of the CPSA by H.R. 2715, which the President signed into law on August, 12, 2011. References to section 14(d) of the CPSA in the proposed rule correspond to section 14(i) of the CPSA, as amended.

- (3) a description of, and an estimate of, the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- (4) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
- (5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency that affect the impact on small entities was rejected.

2 Need for and Objectives of the Rule

Section 14(a)(2) of the CPSA 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. The rule establishes requirements and procedures for manufacturers to certify children's products under this section of the CPSA.

Section 14(i)(2)(A) of the CPSA, as amended by the CPSIA, requires the Commission to initiate a program by which a manufacturer or private labeler may label a product as complying with the applicable safety rules. The Commission is further required by section 14(i)(2)(B) to establish protocols and standards: (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product, (ii) for the testing of representative samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. With the exception of items (ii) (standards and protocols for the testing representative samples) and (iii) (establish protocols and standards for verifying that a product tested by a conformity assessment body complies with applicable safety rules), this rule implements these requirements.

The objective of the draft final rule is to reduce the number of children's products that are distributed each year that fail to comply with one or more children's product safety rules. The applicable children's product safety rules were established to reduce the unreasonable risk of injury or death due to foreseeable hazards associated with particular children's products.

3 Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis

Several comments provided information about the cost of testing and the impact of the testing requirements on their firms or industry. Generally, this information did not contradict information in the initial regulatory flexibility analysis, but it provided CPSC staff with additional information, which has been considered in conducting the final regulatory flexibility analysis.

Several commenters discussed some adverse consequences the rule could have on small businesses. One commenter noted that the requirement to obtain third party testing for children's products could result in production delays. Another stated that the testing rule is complex and that many small businesses will not have the skills necessary to understand what is expected of them in terms of compliance; the commenter predicted that many small businesses will exit the market for children's products. One commenter asserted that some manufacturers had abandoned plans to offer products intended for the children's market. Another commenter, a charitable organization that makes wooden toys for donation to needy children, stated that it lacked the resources to pay for certification testing and would need to discontinue activities unless granted an exemption or some type of relief.

These impacts are consistent with the conclusions of the initial regulatory flexibility analysis. The initial regulatory flexibility analysis noted that compliance with the proposed rule would require a variety of professional skills. It also noted that some firms could exit the market for children's products.

One commenter stated that the testing rule would accelerate the decline of domestic manufacturing as more manufacturers go offshore to minimize the cost of the testing. The commenter stated that the furniture industry will have no choice but to close down more and more factories in the United States and take those jobs offshore to avail themselves of the lower testing costs.

The initial regulatory flexibility analysis noted that the costs of some third party tests are less expensive abroad than they are in the United States; therefore, higher third party testing costs in the United States would result in an incentive for manufacturers to produce children's products abroad to take advantage of the lower testing costs. However, given all of the factors that go into a decision by a manufacturer to produce consumer products abroad rather than in the United States, the impact of third party testing costs is only one consideration. It seems unlikely that the independent effect of higher third party testing costs, by itself, would result in a large number of factories in the United States closing down. However, to the extent that the higher testing costs encourage firms to manufacture consumer products abroad, they would result in fewer jobs in U.S. factories.

One commenter noted that the initial regulatory flexibility analysis only explicitly considered the costs that manufacturers were likely to be charged by the third party conformity

assessment bodies. The commenter stated that there were other significant costs that should be included, such as the cost of samples destroyed or damaged in testing, transportation of the samples, administrative costs for managing testing, administrative costs for managing the testing data and recordkeeping, an allocation of general management time, legal expenses, and so on. The commenter estimated that, depending upon the scale of the business, these costs will add 15 to 50 percent to the out-of-pocket testing costs.

The initial regulatory flexibility analysis reported that there would be costs other than the costs charged by the third party conformity assessment bodies. However, the analysis focused on the cost of the third party testing because it will likely be the most significant cost for small manufacturers of children's products. Even considering only the third party testing costs, the initial regulatory flexibility analysis found that the rule would have a significant impact on a substantial number of small entities. The commenter is correct that the rule would impose other costs, including the cost of the samples destroyed in testing, freight, and costs involved in administering and managing the testing and paperwork. The commenter's estimate that these costs would add 15 percent to 50 percent to the out-of-pocket testing costs—depending upon factors such as the product involved and the scale of the business—seems to be reasonable.

One commenter stated that an example used in the regulatory flexibility analysis for determining the sample sizes required to meet a specified statistical confidence level was unrealistic. The example assumed that both the historical variability (standard deviation) and the historical mean of the variable (*e.g.*, lead content) were known, which the commenter stated is not always the case.

CPSC staff acknowledges that the example would not be applicable to every situation. Moreover, the draft final rule does not require manufacturers to submit sufficient samples to provide a statistical confidence level (*e.g.*, a 95 percent confidence level that all products comply with the applicable safety rules). Rather, the rule requires that 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. Consequently, the examples in this analysis have been simplified.

One commenter noted that in estimating the number of firms that could be impacted by the proposed rule, the book publishing industry (NAICS code 511130) and printing industry (NAICS code 323117) were not included in the estimates in the initial regulatory flexibility analysis.

CPSC acknowledges that these NAICS codes were omitted from the applicable tables in the initial regulatory flexibility analysis. However, this omission has been rendered moot by H.R. 2715, which excludes ordinary books from the third party testing requirements.

4 Small Entities to Which the Rule Will Apply

By regulation (16 CFR part 1110), the Commission has determined that the domestic manufacturer or importer is responsible for ensuring that a consumer product is properly tested, and, based on the testing results, certifying that it conforms to all applicable consumer product

safety rules. Manufacturers of children's products that are subject to a children's product safety rule must certify that the children's products comply with all applicable children's product safety rules based on testing conducted by third party conformity assessment bodies that are accredited to conduct such tests. The definition of a children's product is broad and includes bicycles, books, furniture, apparel, jewelry, televisions, electronic games, toys, and so on, if designed or intended primarily for a child 12 years of age or younger. Virtually all children's products are subject to one or more children's product safety rules. For example, the lead content of paint and all nonexcluded accessible component parts of children's products are subject to limits. Therefore, virtually all manufacturers of children's products will have to certify, based on tests by accredited third party conformity assessment bodies, that their products comply with the lead content limits. The Commission has excluded a few materials that do not inherently contain lead from the requirement to test for lead content. The excluded materials are limited to materials including most fabrics, precious metals, paper, gemstones, and a limited number of other items. These can be found at 16 CFR § 1500.91. The Commission has also issued a rule excluding from the lead content requirements inaccessible component parts in children's products (16 CFR § 1500.87). Section 1(b)(3) of H.R. 2715 excludes from testing for lead content certain used children's products. All other materials used in products intended for children must be tested for lead content.

In addition to the requirements to test for lead content, manufacturers will be required to test for conformity with a wide variety of other children's product safety rules. For example, there are product safety rules that establish standards for children's products, such as toys, cribs, bicycles, bicycle helmets, youth all-terrain vehicles, bunk beds, baby walkers, and the flammability of clothing textiles. The CPSIA also limits the amount of six phthalates that can be present in toys and child care articles; thus, many plastic component parts will need to be tested for phthalate content. A full list of the children's product safety rules for which third party testing and certification will be required is given in Table 1.

Table 1. Product Safety Rules Applicable to Children's Products

16 CFR Part # (or Test Method or Standard)	Description
1420	All-Terrain Vehicles
1203	Bicycle Helmets
1512	Bicycles
1513	Bunk Beds
1500.86(a)(5)	Clacker Balls
1500.86(a)(7) and (8)	Dive Sticks and Other Similar Articles
1505	Electrically Operated Toys or Articles
1615	Flammability of Children's Sleepwear, Sizes 0 through 6X
1616	Flammability of Children's Sleepwear, Sizes 7 through 14
1610	Flammability of Clothing Textiles
1632	Flammability of Mattresses and Mattress Pads
1633	Flammability (Open Flame) of Mattress Sets
1611	Flammability of Vinyl Plastic Film
1219	Full-Size Cribs
1215	Infant Bath Seats
1216	Infant Walkers
Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08, CPSC-CH-E1001-08.1 or 2005 CPSC Laboratory SOP)	Lead Content in Children's Metal Jewelry
Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08 or CPSC-CH-E1001-08.1)	Lead Content in Children's Metal Products
Sec. 101 of CPSIA (Test Method CPSC-CH-E1002-08 and/or CPSC-CH-E1002-08.1)	Lead Content in Children's Non-Metal Products
1303	Lead Paint
1220	Non-Full-Size Cribs
1511	Pacifiers
Sec. 108 of CPSIA (Test Method CPSC-CH-C1001-09.3)	Phthalate Content of Children's Toys and Child Care Articles
1510	Rattles
1501	Small Parts Rule
1630	Surface Flammability of Carpets and Rugs
1631	Surface Flammability of Small Carpets and Rugs
1217	Toddler Beds
(ASTM F963)	Toys

Number of Small Firms Affected

The number of firms that potentially could be impacted was estimated by reviewing every industry in the North American Industrial Classification System (NAICS) and selecting firms that could manufacture or sell any children's product that could be covered by a consumer product safety rule. Firms are classified in the NAICS category that describes their primary activity. Therefore, firms that might manufacture or import consumer products covered by a safety rule as a secondary or tertiary activity may not have been counted. There is no separate NAICS category for importers. Firms that import products might be classified as manufacturers, wholesalers, or retailers.

Manufacturers

According to the criteria established by the U.S. Small Business Administration, manufacturers are generally considered to be small entities if they have fewer than 500 employees. Table 2 shows the number of manufacturing firms by the North American Industrial Classification System (NAICS) categories that cover most children's products that are subject to a product safety rule. Although there are more than 26,000 manufacturers that would be considered small in these categories, not all of these firms are engaged in manufacturing children's products that are subject to a product safety rule. It would be expected that most of the firms in the category, *Doll, Toy, and Game* manufacturing, produce some products that are intended for children age 12 and younger. On the other hand, the *Surgical Appliance and Supplies Manufacturing* category includes crash helmets, but most of the other products in this category are not under CPSC jurisdiction.

Table 2. Manufacturers

NAICS Code	Description	Small Firms	Total Firms
31411	Carpet and Rug Mills	244	262
315	Apparel Manufacturing	7,126	7,195
316211	Rubber and Plastic Footwear Manufacturing	43	45
316212	House Slipper Manufacturing	1	1
316219	Other Footwear Manufacturing	53	54
326299	All Other Rubber Product Manufacturing	622	666
336991	Motorcycle, Bicycle, and Parts Manufacturing	447	452
33712	Household and Institutional Furniture Manufacturing	6,058	6,154
33791	Mattress Manufacturing	427	441
339113	Surgical Appliance and Supplies Manufacturing	1,817	1,916
33991	Jewelry and Silverware Manufacturing	2,470	2,484
33992	Sporting and Athletic Goods Manufacturing	1,707	1,748
33993	Doll, Toy and Game Manufacturing	694	705
339942	Lead Pencil and Art Good Manufacturing	124	129
339999	All Other Miscellaneous Manufacturing	4,646	4,695

	Total Manufacturers	26,479	26,947
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Source: U.S. Department of Commerce, Bureau of the Census, 2008 County Business Patterns, Number of Firms, Number of Establishments, Employment, and Annual Payroll by Small Enterprise Employment Sizes for the United States, NAICS Sectors: 2008. (available at: http://www2.census.gov/econ/susb/data/2008/us_naicssector_small_emplsize_2008.xls , last accessed on 16 August 2011.

In addition to the manufacturers in Table 3, there were 25,184 nonemployer businesses classified in NAICS 315 (Apparel Manufacturing) and 61,180 classified in NAICS 3399 (Other Miscellaneous Manufacturers) in 2008. Nonemployer businesses are generally very small businesses with no employees. They are generally sole proprietorships, and they may or may not be the owner's principal source of income. The average receipts for the nonemployer businesses classified in apparel manufacturing were about \$31,000, and the average receipts for the nonemployer businesses classified other miscellaneous manufacturers were about \$41,000.²

Wholesalers

Wholesalers would be impacted by the rule if they import any children's product that is subject to a product safety rule. Wholesalers that obtain their products strictly from domestic manufacturers or from other wholesalers would not be impacted by the rule because the manufacturer or importer would be responsible for certifying the products. Table 3 shows the number of wholesalers by NAICS code that would cover most children's products that are subject to a product safety rule. According to the U.S. Small Business Administration (SBA) criteria, wholesalers are generally considered to be small entities if they have fewer than 100 employees. Although there are more than 78,000 wholesalers who would be considered small in these categories, not all of these firms are engaged in importing children's products that are subject to a consumer product safety rule. A significant proportion of the firms classified as *Toy and Hobby Goods and Supplies Merchant Wholesalers* probably import at least some children's products. However, the only firms classified as *Motor Vehicle and Motor Vehicle Parts and Suppliers* that would be impacted by the draft final rule are those that import all-terrain vehicles that are intended for children 12 year old or younger.

² U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics Table." available at <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

Table 3. Wholesalers

NAICS Code	Description	Small Firms	Total Firms
4231	Motor Vehicle and Motor Vehicle Parts and Suppliers	17,734	18,769
4232	Furniture and Home Furnishing Merchant Wholesalers	11,353	11,844
42362	Electrical and Electronic Appliance, Television, and Radio Set Merchant Wholesalers	2,444	2,591
42391	Sporting and Recreational Goods and Supplies Merchant Wholesalers	5,019	5,196
42392	Toy and Hobby Goods and Supplies Merchant Wholesalers	2,227	2,302
42394	Jewelry, Watch, Precious Stone, and Precious Metal Merchant Wholesalers	7,363	7,447
42399	Other Miscellaneous Durable Goods Merchant Wholesalers	9,040	9,302
42432	Men's and Boy's Clothing and Furnishings Merchant Wholesalers	3,557	3,722
42433	Women's, Children's, and Infant's Clothing, and Accessories Merchant Wholesalers	6,797	7,029
42434	Footwear Merchant Wholesalers	1,521	1,593
42499	Other Miscellaneous Nondurable Goods Merchant Wholesalers	11,203	11,490
	Total	78,258	81,285

Source: U.S. Department of Commerce, Bureau of the Census, 2008 County Business Patterns, Number of Firms, Number of Establishments, Employment, and Annual Payroll by Small Enterprise Employment Sizes for the United States, NAICS Sectors: 2008. (available at: http://www2.census.gov/econ/susb/data/2008/us_naicssector_small_emplsize_2008.xls, last accessed on 16 August 2011).

In addition to the wholesalers tabulated in Table 3, the U.S. Census Bureau estimated that there were 206,072 nonemployer businesses classified in NAICS categories that could include wholesalers of children's products. As noted above, nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business wholesalers were about \$86,000.³ An unknown number of nonemployer wholesalers could import children's products.

³ U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics Table." available at <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

Retailers

Retailers that obtain all of their products from domestic manufacturers or wholesalers will not be directly impacted by the rule because the manufacturers or wholesalers would be responsible for the testing and certification of the products. However, there are some retailers who manufacture or directly import some products and, therefore, will be responsible for ensuring that these products are properly tested and certified. The number of such retailers is not known. Table 4 shows the number of retailers by NAICS code that would cover most children's products. According to the SBA size standards, retailers are generally considered to be small entities if their annual sales are less than \$7 million to \$30 million, depending on the specific NAICS category. Because of the way in which the data were reported by the Bureau of the Census, the estimates of the number of small firms in each category in Table 4 are based on similar, but different criteria. Although there are more than 100,000 firms that would be considered to be small businesses in these categories, it is not known how many of these firms are engaged in importing or manufacturing children's products. Many of these firms probably obtain all of their products from domestic wholesalers or manufacturers and would not be directly impacted by the rule.

Table 4. Retailers

NAICS Code	Description	SBA Size Standard (millions of dollars of annual sales)	Criteria Used for Estimate of Small Firms (millions of dollars of annual sales)	Small Firms	Total Firms
441221	Motorcycle, ATV, and Personal Watercraft Dealers	<30	<25	4,794	4,879
4421	Furniture Stores	<19	<10	16,033	16,611
44813	Children's and Infant's Clothing Stores	<30	<25	2,057	2,074
44814	Family Clothing Stores	<25.5	<25	6,588	6,684
44815	Clothing Accessories Stores	<14	<10	2,757	2,774
44819	Other Clothing Stores	<19	<10	6,331	6,393
4482103	Children's & Juveniles' Shoe Stores	<25.5	<25	227	230
4482104	Family Shoe Stores	<25.5	<25	2,905	2,941
45111	Sporting goods stores	<14	<10	14,388	14,545
45112	Hobby, Toy, & Game stores	<25.5	<25	4,612	4,629

452	General Merchandise Stores	<30	<25	6,873	6,971
45322	Gift, Novelty, and Souvenir Store	<30	<25	19,297	19,339
454111	Electronic Shopping	<30	<25	11,374	11,646
454113	Mail Order Houses	<35.5	<25	5,281	5,645
4542	Vending Machine Operators	<10	<10	3,796	3,887
	Total			107,313	124,700

Source: U.S. Census Bureau, 2007 Economic Census, Release date 11/02/2010.

In addition to the retailers tabulated in Table 4, the U.S. Census Bureau estimated that there were 324,918 nonemployer businesses classified in NAICS categories that could include retailers of children's products. As noted above, nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business wholesalers were about \$40,000.⁴ An unknown number of nonemployer wholesalers could import children's products.

5 Compliance, Reporting, and Recordkeeping Requirements of the Rule

The draft final rule establishes some requirements for the certification of children's products. It also establishes protocols and standards for ensuring that children's products are subject to testing periodically, when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts, as well as to safeguard against the exercise of undue influence on a third party conformity assessment body by a children's product manufacturer or private labeler. The requirements are discussed in more detail below, and the impact that these could have on manufacturers is discussed in a later section of this report.

The draft final rule will impact virtually all manufacturers and importers of children's products because virtually all children's products are subject to some children's product safety rules. For example, the restrictions on lead content cover almost all children's products. Even products that contain some of the materials that have been excluded from the restrictions (see 16 CFR § 1500.88) or that have been determined not to inherently contain lead in excess of the legal requirement (see 16 CFR § 1500.91) might have to be tested for compliance with other rules. For example, although the fabric in wearing apparel might be excluded from the requirement to test for lead content, it may have to be tested for compliance with flammability requirements. Any

⁴ U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics Table." available at: <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

other objects on the apparel that are not excluded, such as buttons, snaps, zippers, or appliques will also need to be tested for lead content.

In meeting the requirements of the draft final rule, manufacturers and importers may be able to use component part testing, as provided for by 16 CFR part 1109. This means that manufacturers, for example, could submit samples of paint that they are using on their products to a third party testing laboratory to be tested for lead and heavy metal content. This could reduce the amount of testing required because the results from the component part tests could be relied upon for demonstrating the compliance of all products on which that paint was used rather than retesting the paint multiple times because it was used on multiple products.

The draft final rule also allows manufacturers and importers to rely upon testing of component parts that were procured by their suppliers, provided that the testing meets all of the requirements in 16 CFR part 1109. The requirements include the mandate that the testing be performed by a third party conformity assessment body whose accreditation has been accepted by the CPSC. In order to rely upon component part testing, whether conducted by the children's product manufacturer or by a supplier of the component part, there must be sufficient documentation so that the component part can be traced back to the party that procured the third party test results demonstrating that the component part complied with the applicable safety rules.

Provisions in 16 CFR part 1109 also allow an importer to rely upon testing procured by or a certificate issued by a supplier of a finished good in issuing their own certificate for a product. Therefore, if a foreign manufacturer has tested and certified a children's product in accordance with the requirements of 16 CFR part 1109, an importer may rely upon that testing or certification in issuing their own certificate for the product.

Partial Exemption for Small Batch Manufacturers

H.R. 2715, which was enacted in August, 2011, may provide some relief from the third party testing requirements contained in the draft final rule for certain small batch manufacturers. H.R. 2715 requires the Commission to consider alternative testing requirements for small batch manufacturers; if the Commission determines that no alternative testing requirement is available or economically practicable, it must exempt small batch manufacturers from third party testing requirements. Until the Commission determines what alternative requirements are suitable for small batch manufacturers or has provided an exemption, small batch manufacturers are not required to obtain third party testing results to confirm that their covered children's products conform to several children's product safety rules. However, small batch manufacturers are still subject to the third party testing requirements of the draft final rule with respect to the lead content of paint; full-size and non-full-size cribs; pacifiers; small parts; children's metal jewelry; baby bouncers, walkers, and jumpers; and durable infant or toddler products, as defined in section 104(f) of the CPSIA.

A “small batch manufacturer” is defined in H.R. 2715 as a manufacturer who had no more than \$1,000,000 in total gross revenue from sales of all consumer products in the previous calendar year (which will be adjusted annually by the percentage increase in the Consumer Price Index for all urban consumers). The children’s products that are covered by the exemption applies to products manufactured by small batch manufacturers for which no more than 7,500 units were manufactured in the previous year. To take advantage of this partial exemption, small batch manufacturers must register with the CPSC. The CPSC will issue the procedures for registration at a later date. For the purposes of this analysis, we assume that a registration system has been established and small batch manufacturers have registered with the CPSC.

Certification Tests

In order to certify that a children’s product complies with all applicable children’s product safety rules, the draft final rule requires that manufacturers submit samples of the product to a third party conformity assessment body whose accreditation has been accepted by the CPSC. The rule requires that the number of samples submitted 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. Fewer samples are needed if the manufacturing process consistently results in products that are uniform in composition and quality. More samples will be needed if there is more variability in the finished products. If any product fails certification testing, the manufacturer must investigate and address the cause of the failure, even if other samples passed the certification tests.

The cost of the third party testing is discussed in more detail later. Manufacturers may also incur costs for any consultants required to provide advice for determining the number of samples that should be submitted for testing and to ensure that it was in compliance with the requirements. There will also be some administrative and recordkeeping costs associated with this requirement.

Periodic Third Party Testing

The draft final rule requires manufacturers and importers of children’s products to periodically submit samples of their products to third party conformity assessment bodies whose accreditation has been accepted by the CPSC for testing to ensure their products continue to comply with all applicable children’s product safety rules. Manufacturers need to conduct periodic third party testing frequently enough to ensure, with a high degree of assurance, that the product continues to comply with all applicable children’s product safety rules, but in no case can the interval between periodic tests exceed the maximum periodic testing interval applicable to the manufacturer.

Depending upon other testing procedures that a manufacturer may opt to use, one of three possible maximum periodic testing intervals will apply to a children’s product manufacturer. The first option applies to manufacturers who do not conduct other production testing of a children’s

product. Manufacturers who do not undertake other production testing must conduct periodic third party testing of the product at least once a year. The rule requires manufacturers to develop a periodic testing plan that will ensure that the children's products manufactured after the certification or since the previous periodic testing was conducted continue to comply with all applicable children's product safety rules. The periodic testing plan must include the tests to be conducted, the intervals at which the tests will be conducted, and the number of samples that will be tested. Although the manufacturer has some discretion in determining the interval between periodic tests, it must be short enough to ensure that, if the samples selected for periodic third party testing pass the tests, then there is a high degree of assurance that the untested products manufactured during the interval comply with all applicable children's product safety rules and must be no longer than one year.

The second option applies to manufacturers who implement a production testing plan (which can use first or third party testing). If a manufacturer has implemented a production testing plan that meets the requirement of § 1107.21(c) of the draft final rule, the manufacturer must conduct third party periodic testing at least once every two years. The production testing plan must describe the production management techniques and tests that must be performed to provide a high degree of assurance that products manufactured after certification continue to meet all applicable children's product safety rules. The production testing plan must also include information such as the intervals at which tests must be conducted or measurements will be made. The test methods used in the production testing plan need not be the same test methods used for certification, but they must be effective in determining compliance with the applicable children's product safety rules.

Manufacturers or importers who choose this second option will need to ensure that its quality assurance or testing program meets the requirements of the draft final rule for production testing and that it provides a high degree of assurance that all products manufactured or imported continue to comply with all applicable children's product safety rules. In addition, at least once every two years, this option requires the manufacturer or importer to submit samples to a CPSC-accepted third party conformity assessment body to be tested for conformity with all applicable children's product safety rules. The rule does not specify how many samples must be submitted to the third party conformity assessment body or the appropriate periodic testing interval (other than stating it must not be greater than two years). However, the expectation is that this option will require less testing by third party conformity assessment bodies because under this option, the (first party or third party) production testing provides the manufacturer or importer with a high degree of assurance that the products continue to comply with the applicable children's product safety rules and can provide manufacturers with information that can be used to determine the interval and number of samples required for the periodic third party testing.

The third option applies to manufacturers that conduct testing to ensure continuing compliance with the applicable children's product safety rules using a testing laboratory accredited to ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*, but whose accreditation has not been accepted by the CPSC. In most cases these will be in-house testing laboratories. If a manufacturer conducts testing using such a testing laboratory, the manufacturer must conduct periodic third party testing at least once every three years. Any testing laboratory used under this option must be accredited by an accreditation

body that is accredited to ISO/IEC 17011:2004, *Conformity assessment – General requirements for accrediting conformity assessment bodies*. The tests used under this option must be the same tests used for certification to the applicable children's product safety rules. The testing must be conducted frequently enough to provide a high degree of assurance that the product continues to comply with all applicable children's product safety rules.

The draft final rule does not specify how many samples a manufacturer using the third option must submit to the third party conformity assessment body or the appropriate periodic testing interval (other than stating it must not be greater than three years). However, as with the second option, the intent for including this option in the draft final rule is to reduce the cost that the rule imposes on children's product manufacturers by reducing the amount of testing that they must obtain from third party conformity assessment bodies. The testing that the manufacturer performs in an ISO/IEC 17025-accredited testing laboratory provides a high degree of assurance that the products comply with the applicable children's product safety rules and can provide the manufacturer with information that can be used to determine interval and number of samples required for the periodic third party testing.

Like the second option, the intent of the third option is to reduce the cost of the draft final rule to manufacturers by reducing the amount of testing they must conduct using third party conformity assessment bodies. However, the manufacturers that are most likely to benefit from this third option are manufacturers who have their own in-house ISO/IEC 17025:2005-accredited testing laboratories. These are likely to be larger manufacturers, so this option is not expected to provide much relief to smaller manufacturers. To the extent that the smaller manufacturers compete with the larger manufacturers, this option may adversely affect the competitiveness of the smaller manufacturers relative to larger manufacturers because any cost reduction will disproportionately benefit larger manufacturers.

Under all periodic testing options, a manufacturer may need statistical or other knowledge in order to develop their testing plans, including determining the appropriate testing intervals and number of samples required to provide the manufacturer with a high degree of assurance that its children's products are in compliance with all applicable children's product safety rules. If these services are not available in-house, the firm may have to hire outside consultants. Additionally, firms will incur administrative and recordkeeping costs associated with the periodic testing requirement, in addition to the cost of the third party testing, which is described in more detail later in this analysis.

Third Party Testing Due to Material Changes

If a children's product undergoes a material change in product design or manufacturing processes, including the sourcing of component parts, which could affect the product's ability to comply with the applicable children's product safety rules, the draft final rule requires the manufacturer to submit samples of the materially changed product to a third party conformity assessment body for testing. The number of samples must be sufficient to provide a high degree of assurance that the materially changed product complies with all applicable children's product safety rules. The testing can be limited to the portion or component part of the finished product

that was changed and for compliance with those children's product safety rules for which compliance might have been affected.

The primary cost of this requirement will be the cost of the third party testing. There will also be some administrative and recordkeeping costs associated with this requirement. The professional skills required by the manufacturer are the same skills required for the initial certification and periodic tests.

Protection Against Undue Influence

The draft final rule requires that each manufacturer of children's products establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. At a minimum, these procedures must include: written policy statements from company officials that the exercise of undue influence is not acceptable; directing that appropriate staff receive training on avoiding undue influence; and requiring staff to sign a statement attesting to their participation in the training. The procedures must also include a requirement to retrain the appropriate staff if there are substantive changes in the requirements for safeguarding against the exercise of undue influence. The training procedures must include a requirement to notify the Commission immediately of any attempt by the manufacturer to hide or exert undue influence over test results, as well as a requirement to inform employees that allegations of undue influence may be reported confidentially to the Commission, and a description of the manner in which such a report can be made.

Firms will incur some costs in establishing the safeguards against undue influence. Although several commenters stated that establishing these safeguards would be burdensome, none provided estimates of what the cost would be. The draft final rule provides firms with a high degree of flexibility in meeting these requirements. For example, the draft final rule does not prescribe the form of the training, and firms may include this training along with other types of employee training.

Recordkeeping

The rule requires manufacturers of children's products to keep the following records:

- 1) A copy of the Children's Product Certificate for each product. The children's product covered by the certificate must be clearly identifiable and distinguishable from other products;
- 2) Records of each certification test. The manufacturer must have separate certification test records for each manufacturing site;
- 3) Records of one of the following for periodic tests of a children's product:
 - i) periodic testing plan and periodic test results;
 - ii) production testing plan, production test results, and periodic test results; or
 - iii) testing results of tests conducted by a testing laboratory accredited to ISO/IEC 17025:2005 and periodic test results.

- 4) Records of descriptions of all material changes in product design, manufacturing processes, and sourcing of component parts, the certification tests run, and the test values; and
- 5) Records of the undue influence procedures, including training materials and training records of all employees trained on these procedures.

These records must be maintained for five years from the date of their creation. The records must be made available for inspection by the CPSC upon request. The records may be maintained in languages other than English if they can be provided immediately to the CPSC and accurately translated into English within 48 hours of a request by the CPSC, or a longer period, as negotiated with CPSC staff.

CPSC staff has estimated that, on average, about three to five hours per product will be required for recordkeeping. However, the time required for recordkeeping for any particular product could be substantially higher or lower. For example, recordkeeping for products that are subject to multiple standards or that require a substantial amount of testing could require substantially more hours. For other products, such as those subject to only one standard and for which little testing is required, the number of hours required for recordkeeping might be less.

Consumer Product Labeling Program

The draft final rule establishes a program by which any manufacturer or private labeler of a consumer product may label product as complying with the applicable certification requirements for the product. If the manufacturer has certified that a consumer product complies with all applicable consumer product safety rules, the manufacturer or private labeler may affix a label to the product that states that the product “*Meets CPSC Safety Requirements.*” The label must be visible and legible. This program is voluntary in that manufacturers and private labelers are not required to affix this label to their products. However, opting not to affix the label to the product would not relieve the firm of their responsibility to ensure that the products comply with the applicable safety rules and with all other provisions of the rule. This provision is not expected to have a significant impact on firms because the program is voluntary, and the costs of adding or modifying a label on a product are expected to be low.

6 Cost of Third Party Testing and Potential Impact of the Rule

The costs of the third party testing requirements of the draft final rule are expected to be significant for some manufacturers and are expected to have a disproportionate impact on small- and low-volume manufacturers. This section discusses the cost of third party testing and the potential impact of the third party testing and other requirements of the draft final rule on manufacturers.

Cost of Third Party Testing

The cost of third party testing is influenced by many factors, including the amount and skill of the labor required to conduct the tests, the cost of the equipment involved, the cost of transporting the product samples to the test facility, and the geographic area where the tests are conducted. Some tests require a substantial amount of time to conduct the tests, including the preparation of the samples. It might take a couple of days, for example, to test a bicycle for compliance with the bicycle standard (16 CFR part 1512). Similarly, a chemist testing the lead content of a product might be able to test only a few metal component parts per day, due to the amount of time required to prepare the samples and clean and calibrate the equipment between tests.

It should be noted that the price that a given manufacturer pays for testing is often the result of negotiations between the testing laboratory and the manufacturer. Manufacturers who do a large volume of business with a testing laboratory frequently can obtain discounts on the testing laboratory's normal charges, but manufacturers who only do a small volume of business may not be able to negotiate a discount.

Some information on the cost of the third party testing for determining compliance with some children's product safety rules is provided below. The information was collected from a number of sources, including published price lists from some testing laboratories, conversations with representatives of testing laboratories, actual invoices provided by consumer product manufacturers, and public comments received by the Commission. The data are not based upon a statistically valid survey of testing laboratories. Additionally, the costs discussed below include only those costs that would be charged by the testing laboratory. Not included are the costs of the samples consumed in destructive tests, the cost of shipping the samples to the testing laboratories, and any related administrative or recordkeeping activity costs. According to one commenter, these costs could add 15 to 50 percent to the third party testing costs.

Lead Content and Lead-in-Paint

The cost per component part for testing for lead content and lead-in-paint using inductive coupled plasma (ICP) analysis will range from a low of about \$20 per test, to more than \$100 per test. The lowest per-unit cost represents a substantially discounted price charged to a particular customer by a testing laboratory in China and might not be typical. Within the United States, typical prices range from around \$50 to more than \$100 per test.

The cost of testing for lead content using X-Ray fluorescence (XRF) technology is significantly less expensive. Some firms have offered to screen products for lead content for as little as \$2 per test. These offers are generally directed to stores or businesses who wish to check their inventory for conformity with the retroactive lead content requirements contained in the CPSIA. Some testing laboratories will charge for XRF testing at an hourly rate, which can be around \$100. Ten to 30 tests can be conducted in an hour.

The CPSC has approved XRF test methods for determining the lead content of homogenous polymer products. On the assumption that 10 to 30 tests can be conducted in an hour at a rate of \$100 per hour, the cost of XRF testing for homogenous polymer products would be between \$3 and \$10 per test.

For testing the lead content of paint, the Commission has approved the use of a specific XRF test method described in ASTM F2853, which uses energy dispersive XRF employing multiple monochromatic beams. Generally, fewer tests can be conducted in an hour using this test method. If 6 to 12 tests can be conducted in an hour, at a rate of \$100 an hour, then the cost of testing a paint for lead content using the approved XRF technique would be about \$8 to \$17.

Other than for homogenous polymer components and the lead content of paint, the Commission has not approved the use of XRF techniques for testing any other materials. For these other materials, such as metal components, manufacturers will be required to use ICP analyses techniques to test for lead content.

Phthalates

The cost of testing for phthalate content will range from around \$100 (a discounted price by a testing laboratory in China) to about \$350. These are the costs per component part and include testing for all six of the individual phthalates, whose content is restricted.

Bicycle Standard (16 CFR part 1503)

According to one testing laboratory, it takes one to two days to test a bicycle. The estimated price for testing one bicycle may range from around \$700, if the testing is performed in China, to around \$1,100 if the testing is performed in the United States. A manufacturer who needs several models of bicycles tested at the same time might be able to obtain discounts. This does not include the testing of the nonmetal component parts for lead or phthalates. H.R. 2715 exempted the metal components of bicycles from the third party testing requirements for lead content.

Bicycle Helmets

One testing laboratory quoted a price of \$600 for testing one model of a bicycle helmet to the CPSC bicycle helmet standard. A price list from another testing laboratory stated that conducting the certification testing to the Snell Foundation's bicycle helmet standard, which is similar to the CPSC's standard, was \$830.

Full-Size Cribs

As with bicycles, testing cribs requires a substantial amount of labor to assemble the crib, take the appropriate measurements, and perform the required tests. The cost of testing a full-size crib to the pre-2010 standard was about \$750 to \$1,200 in the United States. The cost of testing a full-size crib to the current standard may be somewhat higher. The cost can vary, depending on the features of the individual cribs that require testing and can along vary among testing laboratories. Some manufacturers might receive discounted prices. This does not include testing the crib for lead and phthalates, which, to the extent necessary, would add to the cost of testing a crib to all applicable safety rules.

Toys

The product safety rules applicable to toys, including the ASTM F963 standard made mandatory by the CPSIA, encompass a wide variety tests, including tests for soluble heavy metals in surface coatings and for various physical and mechanical criteria. Based on the itemized prices on several invoices provided to CPSC staff or otherwise made public by testing laboratories, the cost of the physical and mechanical tests range from about \$50 to \$245. The cost of the chemical test for the presence of heavy metals ranges from about \$60 to \$190 per surface coating. Again, these costs do not include testing for lead and phthalates, which add to the total cost.

The flammability requirements of ASTM F963 were not made mandatory by the CPSIA, but the Commission was directed to examine the flammability requirements and consider promulgating rules addressing the issue. If some flammability tests are eventually required, the cost per test could be in the range of \$20 to \$50, based on some observed costs for the ASTM F963 flammability tests.

Cost of Third Party Testing by Product

The cost to obtain the required third party testing for a product depends on the types and number of tests that must be performed; the number of samples that are required to provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the product to meet the applicable children's product safety rules; or to ensure continuing compliance with the applicable children's product safety rules. The cost of the testing will also be affected by the extent to which the manufacturer can use component part testing. Because of the wide variety of manufacturers and products that would be affected by the rule, we cannot provide comprehensive estimates of the impact of the rule on all manufacturers or products. The discussion below is intended only to provide some perspective on the potential impact.

Number of Samples Required

The draft final rule does not specify the exact number of samples that must be submitted to third party conformity assessment bodies, nor does it specify the testing interval, other than providing maximum intervals. Rather, as described below, the draft final rule requires manufacturers to determine the number of samples and the testing interval necessary based on factors such as the variability of the product, manufacturing processes, and information obtained from other testing. However, it is likely that between certification testing, testing after a material change, and periodic testing, many manufacturers will be required to submit more than one sample of a given product to third party conformity assessment bodies during a given year. Because some children's product safety rules require more than one unit of the product to complete all of the required tests, one sample may consist of multiple units of the product.

For purposes of certifying a children's product (including testing after a material change), the draft final rule requires manufacturers to submit enough samples to a third party conformity assessment body to provide a high degree of assurance that tests conducted for certification purposes accurately demonstrate the ability of the product to comply with all applicable children's product safety rules. In determining how many samples to submit, a manufacturer is to consider the variability in the product and manufacturing processes. If the manufacturing process for a children's product consistently creates finished products that are uniform in composition and quality, such as with die casting, a manufacturer may be able to submit a relatively small number of samples to the third party conformity assessment body. If the manufacturing process for a children's product results in variations in the composition or quality of children's products, such as might be expected with hand assembly, a manufacturer may need to submit a greater number of samples.

For periodic testing, the draft final rule requires that the number of samples selected must be sufficient to assess the continuing compliance of the children's product with all applicable safety rules with a high degree of assurance. Additionally, the testing interval for periodic testing must be short enough to ensure that, if the samples selected for periodic testing pass the test, there is a high degree of assurance that the other untested children's products manufactured during the interval comply with the applicable children's product safety rules. Manufacturers who have implemented a production testing plan or test in an ISO/IEC 17025:2005-accredited testing laboratory may consider the information obtained from the testing in determining the testing interval and the number of samples required.

Hypothetical Toy Testing Example

In order to provide some information on what the magnitude of the third party testing costs may be for some manufacturers of children's products, this section discusses the potential cost of obtaining third party testing for a hypothetical toy. This example is hypothetical and is intended to illustrate some potential cost implications of the rule. The example is not intended to be representative of every product or manufacturer. The costs per test that are assumed in the examples are based on the cost of tests discussed above, but the actual costs can vary significantly between conformity assessment bodies. The testing costs for any particular

manufacturer also depend upon factors such as the complexity of the products, the variation in the materials used, manufacturing processes used, opportunities to use component part testing, and so forth. A similar example was used in the initial regulatory flexibility analysis. The discussion has been changed to reflect the fact that energy dispersive XRF analysis is allowed to test for lead in paint, in addition to XRF testing in homogenous polymer products. The discussion has also been modified to deemphasize references to statistical measurements because, although statistical measurements might be useful, the number of samples that must be tested need not be one that provides a particular confidence level, such as a 95 percent confidence level that all products in a lot were compliant.

Toys must meet requirements concerning lead and phthalate content, and several physical and mechanical requirements, including the requirements of ASTM F963, which was made a mandatory standard by the CPSIA. In this example, it is assumed that the testing costs are at the low to middle part of the ranges discussed above and that the hypothesized toy contains one metal component part that must be tested for lead content using ICP analysis (at \$50) and two plastic component parts for which XRF analysis can be used for determining the lead content (two tests at \$6 each). The plastic component parts also must be tested for phthalate content (two tests at \$225 each). Additionally, it is assumed that the toy contains four different paints that must be tested for both lead content (\$13/test, assuming energy dispersive XRF analysis) and soluble heavy metals (\$125/test). Finally, it is assumed that the toy is subject to some mechanical requirements that include use and abuse testing (\$50 per test). Thus, the cost of testing this toy for compliance to each applicable rule one time would be \$1,114; \$1,064 is associated with the chemical (lead, heavy metal, and phthalate) testing; and \$50 is associated with the mechanical testing (including use and abuse testing).

As noted, having one sample tested by a third party conformity assessment body will probably not be sufficient to meet the requirements of the draft final rule. Therefore, the cost of the third party testing to the manufacturer of this hypothetical toy would be greater than \$1,114. For example, if four samples were required, the cost would be \$4,456. The cost would be higher if some tests had to be conducted more than four times to provide the required high degree of assurance.

The manufacturer might be able to reduce the third party testing costs if they were able to use component part testing for the chemical content tests. For example, if the plastic resins, metal component part, and paints were used on other products, the manufacturer could test the component parts independently of the individual finished products and spread the cost of the chemical content tests over more than one finished product. If the average cost of the chemical content tests could be reduced by a factor of four through component part testing, then the cost of testing the toy in this example for conformity with all applicable safety rules one time would be \$316 (cost of chemical testing of \$1,064/4 and cost of the mechanical and use and abuse testing of \$50). However, the cost of third party testing to the manufacturer would likely be higher because testing one sample will seldom be sufficient to provide the required high degree of assurance. For example, if each component part required four tests, and the mechanical testing were required to be repeated four times to provide the required high degree of assurance, then the cost of the third party testing for the hypothetical toy would be \$1,264.

7 Impact of Draft Final Rule on Firms

Whether the third party testing costs would have a substantial adverse impact on a firm depends upon the individual circumstances of the firm. One factor is the magnitude of the impact in relation to the revenue of the firm. A typical profit rate is about 5 percent of revenue. In other words, for every one dollar of revenue, only five cents might remain after paying all expenses. Therefore, a new cost that amounted to 1 percent of revenue, all other things equal, could reduce the profit by 20 percent and would be considered to be a significant impact by most firms. This would be consistent with what some other agencies consider to be significant. The Occupational Safety and Health Administration (OSHA), for example, considers an impact to be significant if the costs exceed 1 percent of revenue or 5 percent of profit.⁵

Some insight on the disparate impact that the draft final rule could have on small businesses can be provided by examining how the rule might impact three hypothetical toy manufacturers of different sizes. The costs associated with third party testing that the hypothetical manufacturers will face will be described and the potential impact on the hypothetical manufacturers will be discussed. This discussion is summarized in Table 5.

Three Hypothetical Manufacturers

The first hypothetical manufacturer, Firm A, is a large toy manufacturer who offers 1,000 different toys with an annual production or sales volume of 100,000 units each. Its total annual production volume is then 100 million units (1,000 products x 100,000 units each), which is shown in Row 3 of Table 5. The second hypothetical manufacturer, Firm B, is a smaller toy manufacturer who offers 100 different products with an annual production or sales volume of 10,000 units each. Finally, the third hypothetical toy manufacturer is a “small batch manufacturer,” as defined by H.R. 2715, who offers only 10 products with an annual production or sales volume of about 1,000 units each.

⁵ OSHA, Assigned Protection Factors, Final Rule, Federal Register (71:50121-50192), 24 August 2006.

Table 5. Impact of Rule on Three Hypothetical Firms

		Hypothetical Firm A - Large Manufacturer	Hypothetical Firm B - Small Manufacturer	Hypothetical Firm C - Small Batch Manufacturer
1	Number of Different Products	1,000	100	10
2	Annual Production Volume per Product	100,000	10,000	1,000
3	Total Annual Production Volume (Row 1 x Row 2)	100,000,000	1,000,000	10,000
4	Revenue per unit sold	\$4	\$4	\$4
5	Total Annual Revenue (Row 4 x Row 3)	\$400,000,000	\$4,000,000	\$40,000
6	Cost of testing each product for compliance with all rules once	\$1,114	\$1,114	\$102
7	Cost of Testing Each Product 4 Times (Row 6 x 4)	\$4,456	\$4,456	\$408
8	Total Third Party Testing Cost (Row 7 x Row 1)	\$4,456,000	\$445,600	\$4,080
9	Cost of Samples (4 samples of 2 units of each product)	\$32,000	\$3,200	\$320
10	Recordkeeping (5 hours/product at \$36.43/hour)	\$182,150	\$18,215	\$1,822
11	Total Testing Cost for One Year (Sum of Rows 8 through 10)	\$4,670,150	\$467,015	\$6,222
12	Testing Cost as Percent of Revenue (Row 11/Row5)	1.2%	11.7%	15.6%

Revenue

The average price of a toy is \$7 to \$8.⁶ However, because the retailer and any wholesalers or distributors would also get a share of the revenue, the manufacturer would be expected to get a fraction of the retail price. Therefore, the revenue received by a manufacturer of a toy that retails for \$7 to \$8 might be about \$4 per unit. For some toys, the revenue per unit received by the manufacturer might be lower, and for others it might be higher. To begin the example, we assume that the average revenue is \$4 per unit. The Total Annual Revenue of the Firm (Row 5) is found by multiplying the Revenue per unit (Row 4) by the Total Annual Production Volume (Row 3).

Third Party Testing Costs

The draft final rule requires manufacturers to have children's products tested by a third party conformity assessment body before the products are distributed, periodically after that, and when there has been a material change in the product. In these hypothetical examples, it is assumed that the manufacturers must submit samples of their products to conformity assessment bodies annually, whether for initial certification of products, periodic testing, or recertification after a material change.

As discussed earlier, the cost of the third party testing for a toy is a function of the characteristics of the toy, such as the number and type of component parts, the materials used in its construction, and the specific toy standards and tests that apply to it. The cost of third party tests would not be expected to be affected by the size of the manufacturer (although some conformity assessment bodies might offer discounts to firms for whom they conduct a lot of testing). In the hypothetical example, it is assumed that the conformity assessment bodies will charge the manufacturer \$1,114 to test the toy for conformance with each applicable children's product safety rule (Row 6), which is the same cost used in the earlier discussion of the cost to test a hypothetical toy.

In the case of Firm C, a small batch manufacturer, the third party testing costs are lower. Unless the Commission establishes alternate requirements for small batch manufacturers, H.R. 2715 effectively has exempted the qualifying products of small batch manufacturers from many third party testing requirements, including for phthalates limits in accessible parts, certain heavy metal content limits applicable to paints, and the lead content limits applicable to substrates (but not as to lead in paint or children's metal jewelry). In the case of the toy example, Firm C will be required to have the paints used tested for lead content and the toys themselves tested for small parts. Using the costs assumed in the hypothetical toy example, the cost to Firm C for testing

⁶ Retail sales of toys in the United States are about \$22 billion per year (Toy Industry Association press release dated 27 June 2011). A representative of the Toy Industry Association estimated that there are about 3 billion individual toys sold annually in the United States. This suggests an average retail price of \$7 to \$8 (\$22 billion/3 billion).

each product once to the two applicable requirements would be \$102 (4 paints, at \$13 each, and for small parts at \$50).

This hypothetical example assumes that it is necessary to conduct each applicable test four times to provide the manufacturer with the necessary high degree of assurance, whether for the initial certification of the product, or to meet the periodic testing requirement. Therefore, the total cost the manufacturer will be charged by a third party conformity assessment body is \$4,456 per product for Firms A and B, and \$408 per product for Firm C (Row 7). Because each manufacturer produces more than one product, total third party testing cost (Row 8) is equal to the cost per product multiplied by the number of products produced (Row 7 x Row 1).

In this hypothetical example, it is further assumed that to conduct each test at least once, the manufacturer must submit two units of the toy to the conformity assessment body. In other words, a sample consists of two units of the product. The cost of the samples consumed by testing is the revenue that the manufacturer forgoes because the units were used for testing and not sold. Therefore, the cost of the samples consumed in the testing (given in Row 9) is calculated as the product of the 8 units required to conduct the tests, the revenue per product, and the number of different products (*i.e.*, 8 x Row 4 x Row 1).

Although component part testing has the potential for reducing third party testing costs, component part testing is not considered initially in these examples. One reason it is not considered is that it has not been determined how extensively it will be used in practice. Component part testing might not generally be an option for component parts that are not used in multiple products or for which only a small portion of the production is used in children's products. It also might not be applicable to some importers or manufacturers who obtain products from suppliers that do not have the capability for component part testing or for which the manufacturer or importer, exercising due care, has not yet developed the degree of confidence in the supplier to rely upon test reports and records provided by the supplier.

Recordkeeping

Firms will incur costs for preparing and maintaining the records and documentation required by the draft final rule. In this example, it is assumed that the recordkeeping will require approximately five hours per toy. Assuming that the total compensation per hour for the employees involved in the recordkeeping is \$36.43,⁷ the recordkeeping cost would be about \$182 per product. The total recordkeeping burden (given in Row 10) is the cost per product (\$182), multiplied by the number of products (Row 1). This estimate of the recordkeeping burden assumes that the manufacturer will not be required to acquire any additional equipment or software to comply with the recordkeeping requirements of the draft final rule.

⁷ This is based on the assumption that about half the labor is management or professional and the other half is sales or office labor. For the all workers in private industry, the total hourly compensation for management, professional, and related occupations is \$50.08 and \$22.78 office and administrative occupations (Bureau of Labor Statistics, Employer Cost for Employee Compensations, March, 2011).

Total Testing Cost

The total cost of testing for one year is the sum of the cost of the third party testing, the cost of the samples consumed in the testing, the cost of the recordkeeping, and the cost of developing the sampling plans. This is given in Row 11 of Table 5.

Manufacturers may incur other costs that were not considered above. For example the proposed rule contained provisions requiring manufacturers to select the samples for periodic testing using techniques that would result in a statistical simple random sample. There will likely be costs associated with such requirements. These potential costs include the cost of hiring consultants to design a sampling plan for selecting a sample that meets established requirements and the cost of the added time and effort that might be required in selecting such a sample. However, H.R. 2715 revised section 14(i)(2)(B)(ii) of the CPSA by replacing “the testing of *random samples* to ensure continued compliance” with “the testing of *representative samples* to ensure continued compliance.” Because of this change in the statute, the Commission is not finalizing this section of the proposed rule. These costs will be addressed in more detail when the Commission considers how to implement section 14(i)(2)(B)(ii) of the CPSA, as amended by the CPSIA and H.R. 2715.

Another cost that was not considered in the above example is the cost to small batch manufacturers of registering with the CPSC, which is required by H.R. 2715 for any small batch manufacturer that seeks to take advantage of an alternate testing requirement or an exemption. This cost shall be considered in more detail when the Commission develops the registration process for small batch manufacturers.

Impact on Hypothetical Firms

The impact of the testing costs on each of the hypothetical firms is summarized in Row 12 of Table 5. For the large manufacturer, Firm A, the testing costs could amount to 1.2 percent of the firm’s revenue (total testing cost divided by the total revenue) if the firm received about \$4 per product. This could be considered a significant impact. (As mentioned earlier, a typical profit is about 5 percent of total revenue. Thus a 1.2 percent increase in costs could decrease profit for a typical firm by 24 percent.) If the average revenue this firm received was somewhat higher, however, the impact probably would not be considered significant.

For Hypothetical Firm B, a smaller manufacturer, the testing costs would amount to about 11.8 percent of the firm’s revenue, if the firm received an average of \$4 for each unit produced. For the small batch manufacturer, Firm C, the testing costs would amount to about 15.6 percent of its revenue. In both of these cases (*i.e.*, Firms B and C), costs amounting to 11.8 percent and 15.6 percent of revenue would be considered a significant impact. These hypothetical examples illustrate the disproportionate impact that the draft final rule may have on small businesses. As illustrated, the draft final rule could also have a significant impact on even a

large manufacturer. The significance of the impact increases as the production or sales volume of the manufacturer decrease.

The example of Firm C can be used to demonstrate the potential relief that H.R. 2715 may provide to small batch manufacturers. If not for the testing exemptions provided by H.R. 2715, Firm C would have faced the same per unit testing costs as the other firms in this example: \$1,114 instead of \$102. Under that scenario, the total testing cost for Firm C would have been over \$46,000, which would have exceeded its revenue of \$40,000.

Some small manufacturers probably have average revenues per product that exceed \$4. This might especially be the case if it is a specialty or niche market in which only a few manufacturers participate or if the product requires a substantial amount of skilled labor to create. Table 6 shows what the impact would be on Firm C, the hypothetical small batch manufacturer, if it received an average of \$50 per unit for each unit it sold. Its total revenue would increase to \$500,000 per year. The cost of the samples consumed in testing would increase to \$4,000 (Row 9), which would increase the cost of testing to \$9,902 (Row 11). The testing costs would amount to about 1.9 percent of the firm's revenue, which might be considered significant, but is much lower than it would have been if its revenue per unit were lower. It should be noted that if the manufacturer receives \$50 per unit sold of a product, the retail price is likely substantially higher (unless the manufacturer sells a substantial portion of the product directly to the final consumer).

Table 6. Impact on Hypothetical Firm C If Revenue per Unit is \$50

		Hypothetical Firm C - Very Small Manufacturer
1	Number of Different Products	10
2	Annual Production Volume per Product	1,000
3	Total Annual Production Volume (Row 1 x Row 2)	10,000
4	Revenue per unit sold	\$50
5	Total Annual Revenue (Row 4 x Row 3)	\$500,000
6	Cost of testing each product for compliance with all rule once	\$102
7	Cost of Testing Each Product 4 Times (Row 6 x 4)	\$408
8	Total Third Party Testing Cost (Row 7 x Row 1)	\$4,080
9	Cost of Samples (4 samples of 2 units of each product)	\$4,000
10	Recordkeeping (5 hours/product at \$36.43/hour)	\$1,822
11	Total Testing Cost for One Year (Sum of Rows 8 through 11)	\$9,902
12	Testing Cost as Percent of Revenue (Row 12/Row5)	1.9%

There will also be other costs that could be associated with the rule for which no quantification was attempted in the above hypothetical examples. One cost that was not considered is the additional administrative costs that are likely associated with the requirements of the draft final rule. These include the cost of tracking when each product or component part needs to be tested. It also includes the cost of monitoring the suppliers and component parts that are used, the production techniques used, and any changes in product design to determine when products need to be tested due to material changes. There may also be administrative costs in matching up test reports to finished goods and giving the approval to ship products that the manufacturer has certified.

Another cost that could impact manufacturers for which quantification was not attempted is the cost of receiving test reports that inaccurately indicate that the product did not comply with a children's product safety rule. When a manufacturer receives a test report that inaccurately indicates that a product does not meet a standard, the manufacturer may take one of two courses, both of which could involve significant costs. On the one hand, the manufacturer could assume that the test was accurate and needlessly dispose of or attempt to rework the products covered by the test result. On the other hand, the manufacturer might suspect the test report was inaccurate and undertake an investigation to determine the reason for the test failure. This could involve retesting samples of the product at other conformity assessment bodies and having the conformity assessment body that produced the inaccurate result attempt to determine if any error was made in testing the product. In any case, this could result in delays in shipping product and lost sales.

Component part testing may offer some manufacturers relief from some of the testing costs. Component part testing may allow the cost of the third party testing to be spread over more units of the component part, which ultimately lowers the cost of third party testing per unit of the finished product. For example, if the hypothetical firms in the above examples were able to reduce the cost of third party testing by a factor of four using component part testing, in several (but not all) of the scenarios examined the impact could be reduced to the point where it would no longer be considered significant. However, as noted above, component part testing is not likely to be an option for all manufacturers, for all component parts, or be possible for all tests. Moreover, although it can reduce the cost of the third party testing, it may not reduce other costs associated with the draft final rule, such as the cost of samples, the cost of the recordkeeping, and other administrative costs.

It should be noted that the examples discussed above were for illustration purposes only. The number of times a product may have to be tested for certification purposes or for periodic testing purposes may be more or less than four times. The cost of testing some toys and other children's products could be higher or lower than the cost used in the above examples. The cost would be higher, for example, for products that had more component parts or the variability in the test results was greater, which could require more samples to be tested. The cost of testing could be lower for products that were subject to fewer safety rules or that contained fewer component parts. For some apparel articles, for example, the only tests required might be for flammability and for lead content on some component parts for which component part testing might be possible. Although the examples suggest that some small businesses will be significantly adversely impacted by the draft final rule, some small businesses may have

sufficient volume, sufficiently low testing costs, or sufficiently high revenue that the impact will not be significant.

Possible Market Reactions and Caveats

Manufacturers can be expected to react to a significant increase in their costs due to the draft final rule in several ways. Some manufacturers might attempt to redesign their products to reduce the number of tests required by reducing the features or the number of component parts requiring testing used in the products. Manufacturers and importers could also be expected to reduce the number of children's products that they offer or, in some cases, exit the market for children's products entirely. Some may go out of business altogether.

The requirements of the draft final rule could be a barrier that inhibits new firms from entering the children's product market unless they expect to have relatively high-volume products. This could be an important factor for firms that expected to serve a niche market, such as products intended for children with special needs. Although H.R. 2715 may provide significant relief to certain small batch manufacturers, the requirements could still be a barrier for some small batch manufacturers, home-based manufacturers, and craftspeople. The requirement for third party testing when there is a material change in a product's design or manufacturing process could cause some small or low-volume manufacturers to forgo or delay implementing some improvements to a product's design or manufacturing process in order to avoid the costs of the third party testing.

Although component part testing has the potential to reduce the costs of testing, component part testing might not be an option for all products or manufacturers. Component part testing is most likely to be an option for component parts that are common to multiple products (*e.g.*, paints, bolts of a standard size). The potential for component part testing to reduce the cost of testing would be less for products that have component parts that are unique to that product. Component part testing is also not likely to offer significant cost savings for low-volume component parts or for component parts from which the component part manufacturer derives only a small percentage of revenue from regulated or children's products. Moreover, in order to use component part testing, the manufacturer must be able to trace each component part for which component part testing was used to the party who procured the test. Maintaining this traceability will involve some administrative and recordkeeping costs, which will reduce the potential benefit of component part testing.

Manufacturers may be able to mitigate the adverse impacts if they are able to raise their prices to cover their costs. However, since few companies have perfectly inelastic demand curves, most firms will likely have to absorb some of the cost increases that result from the draft final rule.

8 Conclusion

The draft final rule will have a significant adverse impact on a substantial number of small businesses. The parts of the rule that are expected to have the most significant impact are provisions related to requirements for the third party testing of children's products and the associated administrative and recordkeeping requirements. The impact is expected to be disproportionate on small and low-volume manufacturers. This is because testing costs are relatively fixed. Therefore, the impact of testing costs per unit will be greater on low-volume producers than on high-volume producers.

H.R. 2715 may provide significant relief from the third party testing costs to manufacturers that meet the definition of a small batch manufacturer. However, although the impact will be substantially reduced, some small batch manufacturers may still be significantly impacted by the requirements in the draft final rule.

The other provisions of the rule, related to protections against undue influence over a conformity assessment body and the voluntary consumer product labeling program are likely to have less significant impacts on small businesses.

9 Federal Rules which may Duplicate, Overlap, or Conflict with the Draft Final Rule

The draft final rule implements provisions of the CPSA pertaining to the certification and continued testing of children's products for compliance with children's product safety rules. Some children's product safety rules contain some requirements for certification tests and reasonable test programs. However, any duplication, overlap, or conflict should be minimal. For example, the requirements for third party certification tests required by the draft final rule would satisfy the requirements for certification tests in any existing children's product safety rule. Any production testing required by an existing children's product safety rule can be used to increase the maximum period between periodic tests according to the provisions of the draft final rule.

10 Alternatives for Reducing the Adverse Impact on Small Businesses

The Commission recognizes that the draft final rule will have a disproportionate impact on small and low-volume manufacturers. To a large degree, the impact is not avoidable because the CPSA, as amended by the CPSIA requires that the certification of children's products be based on test results from accredited third party conformity assessment bodies. However, some provisions that are intended to lessen the impact on small businesses have been incorporated into the draft final rule. These include provisions allowing for longer maximum intervals between periodic testing if the manufacturer conducts other testing allowing manufacturers to use

component part testing and allowing manufacturers and importers to rely upon the certifications issued by other parties as a basis for issuing their own finished product certificates, as provided by 16 CFR part 1109. The recordkeeping requirements have been changed in three ways to help reduce the burden on finished product certifiers, including small businesses. The records are not required to be kept in the United States; they are not required to be in English unless the CPSC requests a translation; and they are not required to be maintained beyond five years.

CPSC staff also identified and considered several alternatives that could have reduced the impact on small businesses, but which for reasons discussed below were not adopted in the draft final rule. These include, providing additional testing relief for low-volume products, reducing the number of samples that must be tested by third party conformity assessment bodies, basing the frequency of third party testing on the risk of injury from the product, and allowing the use of XRF testing for lead content for more materials.

Provisions Incorporated in the Draft Final Rule

Longer Maximum Periodic Testing Interval If Manufacturer Conducts Other Testing

The draft final rule provides for a longer maximum periodic testing interval if the manufacturer implements a production testing plan, as provided for in § 1107.21(c) of the draft final rule. The manufacturer may consider the information obtained from the production testing in determining the appropriate interval and number of samples required for third party periodic testing, provided that third party periodic testing occurs at least once every two years.

If the manufacturer conducts testing in an ISO/IEC 17025:2005-accredited testing laboratory in accordance with § 1107.21(d) of the draft final rule, the maximum periodic testing interval is three years. However, this provision is expected to be of benefit primarily to larger manufacturers.

Component Part Testing

The draft final rule allows firms to conduct component part testing pursuant to the requirements in 16 CFR part 1109. This can reduce the cost to manufacturers where one component part might be common to more than one product. Such component parts might include paints, polymers used in molding different parts, and fasteners. In these cases the component parts might be received in larger lots than the production lots of the products in which they are used. Therefore, the testing costs for those component parts will be spread over more units than if they were required to be tested on the final products only.

Reliance on Certifications by Other Parties

The draft final rule allows manufacturers and importers to rely upon testing obtained by or certifications made by another party as the basis for their own certificates, as allowed by 16 CFR part 1109. These certifications can be for component parts or for finished products. This provision would be of value to importers, who may base their own certificate of conformity on the certificate for a finished product issued by a foreign manufacturer, provided that the requirements of 16 CFR 1109 are met.

11 Alternatives That May Further Reduce the Impact on Small Businesses

Additional Testing Relief for Low-volume Manufacturers of Children's Products

The proposed rule included a provision that would provide some relief to low-volume manufacturers of children's products by exempting products from the periodic testing requirement until 10,000 units of the product have been manufactured or imported. Once 10,000 units have been manufactured or imported, the periodic testing requirements would apply to the product. This provision did not relieve the manufacturer or importer from the obligation to have the product tested by a third party conformity assessment body (1) for certification purposes and (2) when there had been a material change in the product's design or manufacturing processes or sourcing of component parts. Thus, the manufacturer would have still been obligated to submit samples to a third party conformity assessment body to demonstrate that the product conforms with the applicable children's product safety rules prior to introducing the product and when there has been a material change. The provision only relieved the manufacturer from the periodic testing requirements until 10,000 units of the children's product had been manufactured or imported.

Since the proposed rule was issued, H.R. 2715 was passed by Congress and signed by the President. H.R. 2715 potentially provides substantial relief to small batch manufacturers, which are defined as manufacturers that had no more than \$1,000,000 in total gross revenue from sales of all consumer products in the previous calendar year and had covered products, which are products where no more than 7,500 units of the same product were manufactured in the previous calendar year. Because the provisions covering small batch manufacturers in H.R. 2715 may provide relief to many of the same manufacturers at which the low-volume exemption in the proposed rule was aimed, the low-volume exemption in the proposed rule was not included in the draft final rule.

For most small batch manufacturers, the relief provided by H.R. 2715 is greater than the relief that would have been provided by the low volume-exemption from in the proposed rule because H.R. 2715 provides small batch manufacturers with relief from both certification and periodic testing, with some exceptions, while the low volume exemption in the proposed rule only provided some relief from periodic testing. However, the partial exemption from periodic testing that the proposed rule provided for products where fewer than 10,000 units had been

imported or manufactured could provide some relief for some manufacturers of low-volume products that are not categorized as small batch manufacturers by H.R. 2715. There are likely some manufacturers that have low volume products, but that also have gross sales that exceed \$1,000,000. These manufacturers will receive no relief from the small batch manufacturer exceptions in H.R. 2715, but would have been provided some relief by the low volume exemption in the draft proposed rule. Consequently, including the partial exemption from periodic testing for low-volume products from the proposed rule could provide some relief to manufacturers of low-volume products that do not meet the definition of a small batch manufacturer.

The Commission is not finalizing the provision of the proposed rule that provided partial relief from periodic testing for low volume products at this time. The reason is that H.R. 2715 also contained special rules for small batch manufacturers and directed the CPSC to consider alternative testing requirements or to exempt small batch manufacturers from certain third party testing requirements. Given these new statutory obligations resulting from H.R. 2715, we are reserving § 1107.21(e) so that we may consider how to address cost, low-volume products, and small batch issues more fully. As the Commission receives public comments and considers other opportunities for reducing third party testing costs, it may reconsider this option.

Reduce the Number of Repeated Third Party Tests Required for Certification

The draft final rule requires that manufacturers submit samples of children's products to third party conformity assessment bodies in order to (1) certify that they comply with all applicable children's product safety rules before they are distributed; (2) after material changes, and (3) periodically to ensure continued compliance with all applicable children's product safety rules. The number of samples required is not specified but would be based upon factors, such as the degree to which the manufacturing processes create products that are uniform in composition and quality, the testing interval, and number of samples required to ensure with a high degree of assurance that a certified product continues to comply with all applicable safety rules. As noted, it is likely that most manufacturers will be required to have a product third party tested multiple times for both certification and periodic testing purposes.

An alternative that could provide some relief to small businesses is to simply require for purposes of certifying a product manufacturers to submit sufficient units of the product to conformity assessment bodies to ensure that the product can be tested for compliance with each applicable children's safety rule at least once or as many times as required by the specific regulation, if different. The same requirement could apply to periodic testing: at least once during the periodic testing interval established by the rule (e.g., once a year) manufacturers would be required to submit sufficient units of the product to ensure that each applicable children's product safety rule is evaluated at least once. In some cases all of the required tests could be performed on one unit of the product. In other cases, more than one unit of the product might be required to test the product to all applicable safety rules. For example, more than one unit of a toy might be required to subject the toy to each use and abuse test that is applicable to the toy; the tests specified in the bicycle helmet standard requires eight helmets. Nevertheless,

each required test would only be required to be conducted one time. This could reduce the financial burden of the third party testing requirements on small businesses.

Under this alternative, manufacturers could still be required to have a high degree of assurance that their children's products complied with all applicable safety rules. However, the testing or inspections needed to provide the manufacturer with a high degree of assurance of compliance could be first or third party testing, or by other process control means, at the option of the manufacturer. The purpose of the required third party tests would be to provide objective evidence of compliance.

CPSC staff did not accept this alternative because although it would arguably provide a greater level of evidence of compliance than existed before the enactment of the CPSIA, it would not require enough third party testing to provide a high degree of assurance that children's products complied with all applicable children's product safety rules. An analysis of CPSC compliance data for children's shoes found several examples where test results for one sample of an article indicated compliance with the lead content requirements but tests results for a different sample of the same article showed lead levels that exceeded the standard.⁸ This suggests that testing one sample may not always be sufficient to detect noncomplying products.

Allow Increased Use of XRF Analysis

XRF analysis is a testing technique that can be used to measure the heavy metal content of materials. As discussed earlier, the cost of using XRF analysis testing is generally less expensive than using ICP analysis. Currently, the Commission has approved XRF analysis for determining the lead content of homogenous polymer products and one type of XRF analysis (energy dispersive XRF using multiple monochromatic beams using the test method in ASTM F2853-10) for paints. The Commission has not approved the use of XRF analysis for determining the lead content of metal component parts. However, allowing the use of XRF analysis for determining the lead content of metal component parts could substantially reduce the cost of the third party testing. The reduction could be especially significant for manufacturers of children's products that have a lot of metal component parts.

The CPSC opted not to recommend the expanded allowed use of XRF analysis to determining the lead content at this time. However, CPSC staff is continuing to evaluate the potential use of XRF analysis, and should the staff determine that XRF analysis can be sufficiently accurate in determining lead content, the Commission could, in a separate rulemaking, consider expanding the allowable use of XRF analysis for third party testing. Moreover, H.R. 2715 directed the Commission to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable children's product safety rule. Further, H.R. 2715 directs the Commission to seek public comment on the extent to which technology, other than the technology already approved by the Commission, exists for third party conformity assessment bodies to test or to screen for

⁸ CPSC Memorandum to the Commission, from John W. Boja, Howard N. Tarnoff, Mary F. Toro, and Marc J. Schoem, "The Technological Feasibility of Reducing the Lead Content to 100 ppm: Compliance Data" (29 June 2011).

testing consumer products subject to a third party testing requirement. Therefore, the CPSC may consider alternatives to reduce the cost of third party testing requirements more fully at a later date.

Basing the Frequency of Periodic Testing on Risk of Injury or Illness

The rule requires that periodic testing be performed at least once every one to three years depending on the other testing that a manufacturer opts to perform. An alternative that would reduce the burden of the rule on some small businesses is to lengthen the time period between required periodic tests for products, component parts, or rules for which the risk of serious injury or illness from a violation of a children's product safety rule is low. This would reduce the burden on some manufacturers since it could reduce the amount of required third party testing.

This alternative was not accepted because, given the number of children's product safety rules and the large number and wide variety of children's products to which they apply, its administration would be complex and would require a large investment of resources to analyze and rank the risk of serious injury or illness that could result from each product or product category failing to comply with each applicable children's product safety rule, and then determining the appropriate periodic testing requirements for the product or product category. Therefore, due to the impracticality of establishing periodic testing requirements based on risk, CPSC staff recommended the general requirements in the draft final rule.

12 Alternatives Not Considered Because They Would Conflict with the Statute

The Commission is aware of some alternatives that could reduce the burden of the rule but that were not considered in this rulemaking because adopting the alternative would conflict with the statute. For example, although the Commission has been able to exempt some materials from the testing requirements that inherently do not contain lead in excess of the limits established by the CPSIA, it is not able to exempt materials from testing that can exceed those limits even if the health hazard associated with the materials or component parts is believed to be minimal. Likewise, the Commission would not be able to exempt from the testing requirements products for which compliance with the applicable safety rule is thought to be very high even without a mandatory third party testing requirement. The Commission also may not be able to extend many of the alternate requirements or exemptions provided to small batch manufacturers by H.R. 2715 to manufacturers or products that did not meet the definitions of small batch manufacturer or covered product in H.R. 2715.

DRAFT

[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1107

[CPSC Docket No. CPSC-2010-0038]

Testing and Labeling Pertaining to Product Certification

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (“CPSC,” “Commission,” or “we”) is issuing a final rule that establishes protocols and standards with respect to certification and continued testing for children’s products. The final rule also establishes requirements for labeling of consumer products to show that the product complies with the certification requirements under a section 14(a) of the Consumer Product Safety Act (“CPSA”). The final rule implements section 14(a)(2) and (i) of the CPSA, as amended by section 102(b) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”).

DATES: The rule will become effective on [insert date 15 months after date of publication in the FEDERAL REGISTER] and applies to products manufactured after that date.

FOR FURTHER INFORMATION CONTACT: Randy Butturini, Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; 301-504-7562; e-mail: RButturini@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Statutory Authority

A. The Consumer Product Safety Act, as amended by the Consumer Product Safety Improvement Act of 2008

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Section 14(a)(1) of the CPSA, (15 U.S.C. 2063(a)(1)), as amended by section 102 of the CPSIA, establishes requirements for the testing and certification of products subject to a consumer product safety rule under the CPSA or similar rule, ban, standard, or regulation under any other act enforced by the Commission and which are imported for consumption or warehousing or distributed in commerce. Under section 14(a)(1)(A) of the CPSA, manufacturers and private labelers must issue a certificate, which “shall certify, based on a test of each product or upon a reasonable testing program, that such product complies with all rules, bans, standards, or regulations applicable to the product under the CPSA or any other Act enforced by the Commission.” CPSC regulations, at 16 CFR part 1110, limit the certificate requirement to importers and domestic manufacturers. Section 14(a)(1)(B) of the CPSA further requires that the certificate provided by the importer or domestic manufacturer “specify each such rule, ban, standard, or regulation applicable to the product.” The certificate described in section 14(a)(1) of the CPSA is known as a General Conformity Certification (GCC).

Section 14(a)(2) of the CPSA (15 U.S.C. 2063(a)(2)) establishes testing requirements for children’s products that are subject to a children’s product safety rule. (Section 3(a)(2) of the CPSA (15 U.S.C. 2052(a)(2)) defines a children’s product, in part, as a consumer product designed or intended primarily for children 12 years of age or younger.) Section 14(a)(2)(A) of the CPSA also states that, before a children’s product subject to a children’s product safety rule is imported for consumption or warehousing or distributed in commerce, the manufacturer or private labeler of such children’s product must submit sufficient samples of the children’s product “or samples that are identical in all material respects to the product” to an accredited “third party conformity assessment body” to be tested for compliance with the children’s product safety rule. Based on such testing, the manufacturer or private labeler, under section 14(a)(2)(B)

of the CPSA, must issue a certificate that certifies that such children's product complies with the children's product safety rule based on the assessment of a third party conformity assessment body accredited to perform such tests.

Section 14(i)(2)(A) of the CPSA requires the Commission to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements. This provision applies to all consumer products that are subject to a product safety rule administered by the Commission. (On August 12, 2011, the President signed into law H.R. 2715, which amended both the CPSA and the CPSIA. Section 10(a) of H.R. 2715 redesignates what was identified as section 14(d) of the CPSA in the preamble of the proposed rule as section 14(i) of the CPSA; consequently, except where we are citing language from the proposed rule, the remainder of this document will refer to section 14(i) of the CPSA.)

Section 14(i)(2)(B) of the CPSA requires the Commission to establish protocols and standards for:

- Ensuring that a children's product tested for compliance with a 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;
- Testing of representative samples;
- 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.

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Section 14(i)(2)(B)(iii) of the CPSA provides for verification that a children's product tested by a conformity assessment body complies with applicable children's product safety rules. At this time, we are not imposing any verification obligations on manufacturers because we intend to conduct the verification ourselves under our inherent authorities while we gain more experience with the testing and certification requirements. When we find that a children's product accompanied by a certificate of conformity does not pass the tests upon which the certification was based, we may initiate an investigation of the manufacturer, third party conformity assessment body, and any other relevant party in the supply chain, to determine the cause of the discrepancy.

To implement sections 14(a) and (d) (now renumbered by H.R. 2715 as section 14(i)) of the CPSA, as amended by section 102 of the CPSIA, we published a proposed rule in the *Federal Register* on May 20, 2010 (75 FR 28336). The proposed rule would:

- Define the elements of a "reasonable testing program" for purposes of section 14(a)(1)(A) of the CPSA;
- Establish the protocols and standards for continuing testing of children's products under section 14(d)(2)(B)(i), (ii), and (iv) (renumbered as sections 14(i)(2)(B)(i), (ii), and (iv)) of the CPSA; and
- Describe the label that manufacturers may place on a consumer product to show that the product complies with the certification requirements for purposes of what was numbered previously as section 14(d)(2)(A) of the CPSA (now renumbered by H.R. 2715 as section 14(i)(2)(A) of the CPSA).

B. H.R. 2715 and its Impact on this Rulemaking

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On August 12, 2011, the President signed into law H.R. 2715. H.R. 2715 amended the CPSA and the CPSIA in several ways. For example, section 2, “Application of Third Party Testing Requirements,” of H.R. 2715, revised section 14(d) of the CPSA, in part, by:

- Renumbering the second paragraph of section 14(d) of the CPSA as section 14(i) of the CPSA. (When the CPSIA was enacted, it created mistakenly, two paragraph (d)s in section 14 of the CPSA. The paragraph at issue in the proposed rule was the second of the two paragraphs numbered (d); H.R. 2715 contained a technical amendment to renumber the second paragraph (d) as a new paragraph (i) of section 14 of the CPSA);
- Revising section 14(i)(2)(B)(ii) of the CPSA to require the testing of “representative samples,” rather than the testing of “random samples”;
- Creating a new section 14(i)(3)(A) of the CPSA requiring, no later than 60 days after the date of enactment, that we “seek public 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.” H.R. 2715 lists seven topics for public comment:
 - o The extent to which the use of materials subject to regulations of another government agency that requires third party testing of those materials may provide sufficient assurance of conformity with an applicable consumer product safety rule, ban, standard, or regulation without further third party testing;
 - o The extent to which modification of the certification requirements may have the effect of reducing redundant third party testing by or on behalf of 2 or more

importers of a product that is substantially similar or identical in all material respects;

- o The extent to which products with a substantial number of different components subject to third party testing may be evaluated to show compliance with an applicable rule, ban, standard, or regulation by third party testing of a subset of such components selected by a third party conformity assessment body;
 - o The extent to which manufacturers with a substantial number of substantially similar products subject to third party testing may reasonably make use of sampling procedures that reduce the overall test burden without compromising the benefits of third party testing;
 - o The extent to which evidence of conformity with other national or international governmental standards may provide assurance of conformity to consumer product safety rules, bans, standards, or regulations applicable under the CPSA;
 - o The extent to which technology, other than the technology already approved by the Commission, exists for third party conformity assessment bodies to test or to screen for testing consumer products subject to a third party testing requirement; and
 - o Other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.
- Creating a new section 14(i)(3)(B) of the CPSA, requiring us to review the public comments and stating that we “may prescribe new or revised third party testing regulations if [we determine] that such regulations will reduce third party testing costs

consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations; and

- Creating a new section 14(i)(4) of the CPSA, titled, “Special rules for small batch manufacturers,” to provide “alternative testing requirements” for “covered products” manufactured by small batch manufacturers or to exempt small batch manufacturers from third party testing requirements. H.R. 2715 defines a “covered product” as “a consumer product manufactured by a small batch manufacturer where no more than 7,500 units of the same product were manufactured in the previous calendar year.” It defines a “small batch manufacturer,” in part, as “a manufacturer that had no more than \$1,000,000 in total gross revenue from sales of all consumer products in the previous calendar year.”

H.R. 2715 also contains (among other things) provisions on registration of small batch manufacturers and exclusions of certain materials from third party testing. For example, H.R. 2715 created a new section 14(i)(5)(A)(i) of the CPSA, which states that the third party testing requirements do not apply to “ordinary books or ordinary paper-based printed materials.”

The Commission has chosen to finalize those parts of the proposed rule that were not affected directly or significantly by H.R. 2715, and we will reserve other subparts or provisions in the final rule, pending our consideration and implementation of H.R. 2715. For example, because section 14(i)(2)(B)(ii) of the CPSA, as amended by H.R. 2715, now refers to the testing of “representative samples,” we have decided to removed § 1107.22 from subpart C of the final, which would have pertained to “Random Samples.”

II. Comments on the Proposed Rule and Our Responses

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Below, we describe and explain each subpart and section of the final rule, as well as describe and respond to the comments on the proposed rule. A summary of each of the commenters' topics is presented, and each topic is followed by our response. For ease of reading, each comment will be prefaced by a numbered "Comment"; and each response will be prefaced by a corresponding numbered "Response." Each "Comment" is numbered to help distinguish between different topics. The number assigned to each comment is for organizational purposes only and does not signify the comment's value or importance or the order in which it was received. Comments on similar topics are grouped together.

A. General Comments

Several commenters addressed issues regarding testing and costs, generally.

(Comment 1) - One commenter warned that because the overwhelming majority of consumer products sold in the United States are produced overseas, nearly all of the work necessary to ensure compliance with the regulations will be performed overseas. The commenter stated that because the cost of compliance for foreign manufacturers can be relatively high—while the risks associated with noncompliance can be relatively low—it is important that our regulation balance the need for a high degree of assurance of compliance against the need to develop a practical regulatory structure that foreign manufacturers can and will implement.

(Response 1) - The final rule is designed not to be overly prescriptive, thereby giving manufacturers some flexibility in designing their testing and certification programs to be consistent with the statutory requirements. For example, the final rule allows the manufacturer to determine the number of samples that are tested, as long as the manufacturer has a high degree of assurance that the products represented by the samples are in compliance with all applicable children's product safety rules. Further, while the final rule requires that manufacturers

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document their compliance, it gives manufacturers the flexibility to determine how to maintain this information. In addition, the final rule does not require any documentation to be maintained in English or kept in the United States, except the certificate.

We also note that, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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. H.R. 2715 directs us to seek public comment on seven specific issues, including the extent to which modification of the certification requirements may have the effect of reducing redundant third party testing by or on behalf of two or more importers of a product that is substantially similar or identical in all material respects, and other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. We intend to issue a notice seeking public comment on these issues in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 2) - Two commenters stated that we should conduct a full cost-benefit analysis of the rule. One commenter added that costs of complying with the testing and certification rule, in combination with other requirements under the CPSIA and other rules administered by the CPSC, will result in a major rule with major implications to consumer product manufacturers, particularly children's product manufacturers, as well as to the entire supply chain. The commenter urged us to examine in greater detail, and to quantify, the full cost

and burden of these rules. A third commenter implored us to consider the reduction in risk, if any, associated with each regulatory requirement and impose only those requirements that meaningfully enhance consumer safety in a way that makes increased costs and use of resources worthwhile.

(Response 2) - This rule is being promulgated under the Administrative Procedure Act and also section 3 of the CPSIA; neither authority requires us to conduct a cost-benefit analysis. Nevertheless, we agree that the final rule constitutes a major rule, as defined by the Congressional Review Act of 1996. Although we decline to conduct a cost-benefit analysis for the final rule, we have changed the final rule to address some of the economic burden on manufacturers. Among the changes made to the final rule to reduce the burden are: (1) reserving the subpart B requirements regarding a reasonable testing program; (2) eliminating certain requirements of the proposed rule for children's products such as the remedial action plan; (3) reducing the recordkeeping requirements in several respects; and (4) allowing the use of in-house ISO/IEC 17025:2005 laboratories to reduce the frequency of third party periodic testing. By way of further example, with regard to the reduction in the recordkeeping requirements, the final rule does not require records to be kept in the United States, nor does it require records to be translated into English, unless requested.

Additionally, we note that a cost-benefit analysis would not necessarily be confined to manufacturers or those in a supply chain (as implied by one commenter). Consumers, for example, might benefit from the testing and certification of consumer products, particularly if such testing revealed potential problems associated with a product or its components, or if such testing prompted a manufacturer to redesign or remanufacture the product to make it safer.

(Comment 3) - One commenter stated that some retailers are requiring many manufacturers to submit their products to as many as four different laboratories because the retailers want to see test results from specific laboratories. The commenter stated that we should clarify to retailers that this redundant testing is not necessary.

(Response 3) – The preamble to the proposed rule stated that retailers and sellers of children’s products can rely on certificates provided by finished product certifiers—without conducting additional testing themselves—if those certificates are based on testing conducted by a CPSC-accepted third party conformity assessment body (75 FR at 28337).

B. Proposed Subpart A - General Provisions

1. Proposed § 1107.1 - Purpose

Proposed § 1107.1 would state that part 1107 establishes the requirements for a reasonable testing program for non-children’s products; third party conformity assessment body testing to support certification and continuing testing of children’s products; and labeling of consumer products to indicate that the certification requirements have been met pursuant to sections 14(a)(1), and (a)(2), (d)(2)(B) of the CPSA (15 U.S.C. 2063(a)(1), (a)(2), (d)(2)(B)).

We did not receive any comments on this section. However, because we have decided to reserve subpart B, which would pertain to the reasonable testing program for non-children’s products, we have removed the reference to the “reasonable testing program for non-children’s products.” (We explain our decision to reserve subpart B of the proposed rule in part B.2 of this preamble below.)

Additionally, because H.R. 2715 revised section 14(i)(2)(B)(ii) of the CPSA to refer to testing of “representative” rather than “random” samples, we have, on our own initiative, elected to simplify § 1107.1 to reflect the final rule’s narrower purpose and have made minor, non-

substantive changes to follow the language of the statute. This helps clarify which requirements in the statute this final rule is intended to address and which have been reserved for a later date. Additionally, proposed § 1107.1 was silent regarding procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body, even though proposed § 1107.24, “Undue influence,” would contain such safeguards. Consequently, the final rule now mentions the establishment of procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. Thus, § 1107.1 now states that:

This part establishes the protocols and standards for ensuring continued testing of children’s products periodically and when there has been a material change in the product’s design or manufacturing process and safeguarding against the exercise of undue influence by a manufacturer on a third party conformity assessment body. It also establishes a program for labeling of consumer products to indicate that the certification requirements have been met pursuant to sections 14(a)(2) and (i)(2)(B) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(a)(2) and (i)(2)(B)).

2. Proposed § 1107.2 - Definitions

Proposed § 1107.2 would define various terms used in the rule.

a. CPSA

Proposed § 1107.2 would define “CPSA” to mean the Consumer Product Safety Act.

We received no comments on this definition and have finalized it without change.

b. CPSC

Proposed § 1107.2 would define “CPSC” to mean the Consumer Product Safety Commission.

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We received no comments on this definition and have finalized it without change.

c. CPSIA

Proposed § 1107.2 would define “CPSIA” to mean the Consumer Product Safety Improvement Act of 2008.

We received no comments on this definition and have finalized it without change.

d. Detailed Bill of Materials

Proposed § 1107.2 would define “detailed bill of materials” to mean a list of the raw materials, subassemblies, intermediate assemblies, subcomponent parts, component parts, and the quantities of each needed to manufacture a finished product.

We received no comments on this definition. However, because the term “detailed bill of materials” appeared only in proposed § 1107.10(b)(1) (which would require a product specification as part of the reasonable testing program), and because the final rule now reserves subpart B, we have removed the definition of “detailed bill of materials” from the final rule.

e. Due Care

Proposed § 1107.2 would define “due care” to mean the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances.

(Comment 4) - One commenter noted that the due care requirement only applies to a few specific provisions of the proposed rule, such as proposed § 1107.23(a) regarding “material change” in the product’s design, manufacturing process, or sourcing of component parts. In some instances, this defined duty of “due care” would be coupled with a CPSC-created standard of “high degree of assurance.” The commenter appreciated our recognition that both the “due care” standard of conduct and the “high degree of assurance” standard for compliance are

anchored in the judgment and knowledge of the manufacturer. For that reason, the commenter felt that the due care requirement should have general applicability to all elements of compliance for implementation of the CPSIA's testing and certification requirements. The commenter stated that manufacturers should not have to wonder whether more than their exercise of reasonable judgment and practice, based on their manufacturing experience and sound knowledge of the product, is required for aspects of the rules that do not explicitly reference these standards.

(Response 4) - The definition of "due care" in § 1107.2 refers to the actions of a prudent and competent person. We expect that all parties will exercise prudence and competence in the testing and certification of products. The final rule emphasizes due care in particular sections, as noted by the commenter, because these are areas that require additional care in order to prevent noncompliant products from being produced and certified.

We recognize that manufacturers' knowledge of their products and their manufacture can serve as a basis for determining what steps are necessary to achieve a high degree of assurance that their products comply with the applicable product safety rules. Based on that knowledge, manufacturers are uniquely situated to know what actions are necessary to exercise due care and demonstrate a high degree of assurance regarding their specific circumstances.

On our own initiative, we have revised the definition of "due care" in the final rule. The final rule's definition of "due care" includes a sentence stating that "Due care does not permit willful ignorance." This is not intended to be a substantive change because any party who is willfully ignorant of material facts, by definition, would not be exercising due care. However, the Commission wants to emphasize in the final rule that a party cannot purposely avoid knowing their business partner's testing and certification practices to avoid violating section 19 of the CPSA. A party will not be shielded from violating section 19 of the CPSA when that

party knows or should know about testing and/or certification problems which may affect the ability of a consumer product to be compliant with all rules, bans, standards, or regulations. Certifiers and testing parties have an obligation to resolve known or knowable problems with testing and/or certification before relying upon or passing on test reports or certifications.

f. High Degree of Assurance

Proposed § 1107.2 would define “high degree of assurance” as “an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.”

(Comment 5) - Multiple commenters questioned the definition of a “high degree of assurance.” One commenter would like the rule to define the term “high degree of assurance” in a more understandable or quantitative way. The commenter considered the term to be confusing and misleading and believed this could lead to unnecessary conflicts between manufacturers and conformity assessment bodies when a judgment has to be made in certain cases. The commenter wondered if this requirement is targeting the design area, manufacturing process control, quality control, or testing procedures.

Another commenter said that manufacturers would benefit from additional guidance on how to achieve a “high degree of assurance” through their testing programs. The preamble to the proposed rule referred to a 95 percent statistical significance level as constituting a “high degree” of assurance, but the proposed rule would not mandate a 95 percent confidence threshold. The commenter asked what factors would permit a manufacturer to satisfy the “high degree of assurance” requirement with a statistical significance level below 95 percent and asked us to provide an example of a situation where a manufacturer could still achieve a high degree of assurance with less than 95 percent assurance.

Another commenter argued that the term “high degree of assurance” is subjective and subject to varied interpretations. The commenter suggested that a statistical confidence limit would help remove the subjectivity and set a specific threshold by which we can enforce our rules better. The commenter also was concerned that the wording may lead some manufacturers to believe that they do not have to test to the standard in all cases, as long as they foresee little risk of noncompliance, or assume that the risk is low of being discovered having noncompliant products in the marketplace. The commenter said the final rule should clarify that testing to applicable standards is required.

(Response 5) - The determination of a “high degree of assurance” for a given product will vary by industry, product, component part, and by manufacturer. Therefore, selecting an example using a hypothetical certifier would be of little value to manufacturers. We have intentionally defined the term in a manner that allows the manufacturer the flexibility to develop a testing program to ensure their product complies with all applicable children’s product safety rules. This rule provides broad protocols and standards for regulated firms to follow and adapt to their particularized needs given their products and processes. The use of quantitative values for the definition of “high degree of assurance” could lead to difficulties for some manufacturers. The preamble to the proposed rule stated: “we decided against defining ‘high degree of assurance’ with respect to a 95 percent probability or confidence level because there may be difficulty in applying the statistical methods to all manufacturing processes” (75 FR 28344). The intent of the definition is to enable a manufacturer to have a degree of confidence, based on evidence (rather than only on a belief) that all of the products manufactured are compliant with the applicable product safety rules. Knowledge of a product’s design and how it is

manufactured, control over component parts, and measurements showing consistent performance, are some elements that can be used to demonstrate a “high degree of assurance.”

As for the commenter asking us to clarify that testing to applicable standards is required, § 1107.20 (a) of the final rule states that manufacturers must submit samples of a children’s product to a third party conformity assessment body for testing. We believe these statements are clear enough to convey that certification testing involves tests.

(Comment 6) - Two commenters agreed that a numerical target for defining what constitutes a high degree of assurance—in the context of programs based on good manufacturing practices (GMP)—is misplaced. One commenter noted that the explanation of the definition of “high degree of assurance” provided in the preamble to the proposed rule (75 FR at 28344) implies that we prefer the 95 percent statistical level of confidence for a high-degree-of-assurance approach and consider it the default. The commenter is concerned that the 95-percent-confidence-level language may prompt third party conformity assessment bodies and retailers to adopt standardized testing protocols that demand large sample sizes, which will be a particular burden for the initial certification and may not be warranted in many cases. The commenter expressed the belief that the goal, across a broad range of different products that are subject to different manufacturing requirements and material sourcing, must be a standard that correlates “a high degree of assurance” with an “evidence-based demonstration of consistent performance” that relies more appropriately upon process controls to assure conformance. The commenter indicated that, while generally accepted process controls may include statistical sampling as part of process control programs, in and of themselves, they are not preferable to good manufacturing practices. The commenter said that the final rule must be clear in this regard.

(Response 6) - Standards for GMPs are generally industry-specific in areas such as: cosmetics, pharmaceutical operations, food handling, and medical devices. It is unlikely that any GMP-based program would be deemed workable or acceptable for all children's product manufacturing methods.

A certifier's determination that a product complies—with a high degree of assurance—with the applicable children's product safety rules, may derive from statistically based testing, the application of good manufacturing practices, or other knowledge of the product and its manufacture. Because GMP-based programs are industry-specific, we disagree with the commenter's assertion that the programs are preferable to other accepted process controls in all manufacturing situations.

The final rule defines a "high degree of assurance" in general terms because the definition is intended to be applied to a wide variety of products that use many different manufacturing processes. Customizing the definition of "high degree of assurance" to fit one type of product or GMP-based program will necessarily increase the difficulty of manufacturers applying the definition to dissimilar products or manufacturing processes. Further, because GMP-based programs vary across industries—and the comments were not specific about which aspect(s) of a GMP program we should adopt, or which GMPs we should adopt—we cannot revise the definition, as requested by the commenter.

As for the commenter who interpreted the preamble to the proposed rule as expressing a preference for a 95 percent confidence level, we do not consider a numerically based definition of a "high degree of assurance" to be the default position. Defining a "high degree of assurance" with respect to a 95 percent probability or confidence level would be difficult to apply to all manufacturing processes for children's products. Defining a "high degree of assurance" as a 95

percent, or higher, probability or confidence level could result in greater testing demands on small manufacturers. As discussed in the preamble of the proposed rule (75 FR at 28344), a statistical definition is not needed in order to provide an evidence-based high degree of assurance.

Regarding the concern that conformity assessment bodies and retailers may require large numbers of samples for certification testing, the children's product certifier (not the conformity assessment body or retailer) specifies the number of samples to be tested. The final rule requires the number of samples to be sufficient to give the certifier a high degree of assurance that the tests conducted demonstrate accurately the ability of the product to comply with the applicable children's product safety rules. As we previously stated in the preamble to the proposed rule:

The Commission wants to emphasize to retailers and sellers of children's products that they can rely on certificates provided by product suppliers if those certificates are based on testing conducted by a third party conformity assessment body.

75 FR at 28337.

(Comment 7) - Two commenters contended that the proposed definition of a "high degree of assurance" lacks clarity. Both commenters said that the rule should have additional examples of what constitutes "a high degree of assurance." One commenter acknowledged that the discussion in the preamble to the proposed rule makes clear that the definition mandates no specific formula (75 FR at 28344). However, the commenter noted that the preamble to the proposed rule gave no specific examples, other than the use of statistical methods. The commenter argued that the final rule should recognize other means of achieving this confidence level, including ways that do not rely solely on product testing or statistical methods. These methods include appropriate quality assurance processes and risk management. Quality assurance processes can include: factory/supplier evaluations, design reviews, manufacturing

process controls, process auditing, or similar controls or reviews. Risk management includes: analysis of a given possible failure, the likelihood of the failure, and the potential consequences associated with the failure. The commenter argued that importers can use these activities to boost desired outcomes and reduce unexpected outcomes; and the commenter further maintained that the activities can be performed in a feedback loop that facilitates true root-cause analysis and correction, if there is a failure.

The commenters suggested substitute definitions for “a high degree of assurance” that are practically identical. One suggested definition reads: “A high degree of assurance means an evidence-based determination of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.” Acceptable evidence-based determinations may be based on evidence derived through any appropriate process or control or combination of processes and/or controls, such as (but not limited to):

- Design validation;
- Manufacturing process control audits;
- In-process manufacturing controls, measurements, and tests;
- Component and material testing, as defined in 16 CFR part 1109;
- Finished product testing;
- Raw materials certification; and
- Other controls or processes that provide information about the safety or compliance of a product.

The other commenter’s suggested definition reads: “*High degree of assurance* means an evidence-based determination of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture. Acceptable determinations may be based

on evidence derived through any appropriate tool or control methodology (or combination of tools and/or control methodologies), such as but not limited to:

- Design Validation
- Process Validation
- Manufacturing Process Control Audits
- Raw material validation and controls
- In-process manufacturing controls, measurements, and tests
- Component and material testing as defined at 16 CFR Part 1109
- Finished Product Testing”

(Response 7) - The commenters are correct that certifiers can use process controls, mathematical techniques, simulations, and other aspects of a product and its manufacture, as part of the basis for determining whether a particular product complies with the applicable product safety rules with a high degree of assurance. The commenters also are correct that the preamble to the proposed rule (75 FR at 28344) provided statistically based examples in the definition of a “high degree of assurance.” However, a method on the commenters’ list may be adequate for one rule, but inadequate for another. As an example, *Design Validation* may be a good technique to ensure that a toy does not have a hole large enough to allow access to a sharp edge or point. However, *Design Validation* may be inadequate for controlling lead content because its techniques are ill-suited for controlling continuing production of component parts. As another example, component part testing is a useful technique for determining the chemical content of lead and the prohibited phthalates, but it is inadequate for determining compliance to the pacifier pull tests because the entire product is required to conduct the test. “A high degree of assurance” is defined in general terms because it is intended to be applied to a wide variety of products that

use many different manufacturing processes. Providing a list of the intended applications as part of the definition would introduce the risk of a manufacturer applying techniques that are inappropriate for evaluating the applicable children's product safety rule.

Therefore, we decline to amend the definition of "a high degree of assurance," as suggested by the commenters. Specific examples are not universally applicable; and therefore, they should not be included in the definition of "a high degree of assurance." Any such list necessarily would be underinclusive or possibly confusing or misleading. Additionally, certification and periodic testing of children's products must be based on tests of the finished product, or its component parts, sufficient to show compliance (or continuing compliance, in the case of periodic testing) with all applicable children's product safety rules. A definition of a "high degree of assurance," that includes methods other than testing, might lead some certifiers to conclude mistakenly that certification or periodic test requirements might be met by means other than testing.

(Comment 8) - One commenter suggested that the final rule allow a company's prior safety record to replace product safety testing as evidence that a company has met the requirement for a high degree of assurance ("HDA"). The commenter wrote:

The "high degree of assurance" should be based on an overall assessment of the safety record of the company. It should NOT be based on the results of an individual product, even if recalled or deemed dangerous.

The commenter pointed out that its company had a very good safety record. The commenter added:

With this record over so many years, our company should be deemed to have satisfied this HDA requirement and be endorsed as having a reasonable testing program without further inquiry.

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(Response 8) - Section 14(a)(2) of the CPSA makes clear that children's product certification is based upon third party testing of the product and not a company's safety record. For this reason, the final rule does not provide relief from the testing requirements in the statute. In addition, the commenter's suggestion that a manufacturer should be allowed to rely upon its prior safety record to demonstrate a high degree of assurance would be a difficult concept to apply in practice because of the likely changes in any given manufacturer's safety record over time and potential disagreements as to whether a product caused a safety problem, whether the safety problem resulted from product misuse, and whether safety issues had to occur at a particular rate of frequency before testing was warranted.

(Comment 9) - One commenter stated that a "high degree of assurance" could be provided best by using an accredited product certification program that meets the requirements of the International Standards Organization/International Electrotechnical Commission (ISO/IEC) Guide 65, *General requirements for bodies operating product certification systems*, and the fundamentals of System 5 product certification requirements of ISO/IEC Guide 67, *Conformity assessment -- Fundamentals of product certification*.

(Response 9) - The various activities a certification body undertakes, such as testing, conformity assessment, and surveillance can be used to demonstrate a high degree of assurance that a product complies with the applicable product safety rules. However, the techniques used by certification bodies are not the only means a manufacturer could use. Process control techniques, failure modes and effects analyses, and other quality assurance methods, depending upon the product under consideration, could be as effective as certification body methods. Because we want to give certifiers the flexibility to decide which methods apply best to their particular products, we decline to define a "high degree of assurance" using ISO/IEC Guide 65

and Guide 67 requirements. A manufacturer who wishes to use those requirements to ensure a high degree of assurance of compliance may do so. However, we reiterate that testing in support of certification of a children's product must be performed by a CPSC-accepted third party conformity assessment body whose scope of accreditation includes the tests required for certification, and certification of a product cannot be delegated to another party, such as a certification body.

(Comment 10) - A commenter suggested that the language related to periodic testing intervals and sample sizes is inconsistent in the preamble to the proposed rule. The commenter conceded that it is difficult to specify the exact number of products that must be tested in order to reach a high degree of assurance that a product is compliant. The commenter noted that the response to comments section of the preamble to the proposed rule titled, *Additional Third Party Testing Requirements for Children's Products*, stated that "the sample size for periodic testing will depend upon the number of samples that need to be tested to provide that statistical assurance" (75 FR at 28342). The commenter agreed with this statement but noted the inconsistency between the language used in that section and the language found in the response to comments section titled, *The Reasonable Testing Program*, which specifies that the testing intervals must provide "reasonable assurance" that the product meets the requirements of the applicable product safety rules (75 FR at 28338). The commenter noted that there is a difference between a "high degree of assurance" and "reasonable assurance." The commenter expressed the belief that the testing program should be statistically based, such that a confidence level of 95 percent must be achieved to indicate compliance. This requirement would eliminate the possibility of testing only a single sample to indicate compliance, the commenter asserted.

(Response 10) - In the preamble to the proposed rule, under the response to comments section, *Additional Third Party Testing Requirements for Children's Products* (75 FR at 28342), we stated the following:

If a high degree of assurance is interpreted to be a statistical likelihood of not producing noncompliant products, the sample size for periodic testing will depend upon the number of samples that need to be tested to provide *that* statistical assurance (italics added)

The word “that” refers to “a high degree of assurance,” which appears at the beginning of the sentence. With respect to the other alleged inconsistencies mentioned in the comment, it is worth noting that the preamble to the proposed rule uses the phrase “high degree of assurance” 20 times; whereas, the codified text of the proposed rule does not use the term “reasonable assurance” at all. The term “reasonable assurance” appears only once in the preamble to the proposed rule, in the introduction to the response to comments section titled, *The Reasonable Testing Program*, where it is listed as one of the previous questions that we asked in the *Federal Register* notice announcing the December 2009 public workshop.

We also do not agree with the commenter that there should be a specific probability level (*i.e.*, 95 percent) in the definition of “a high degree of assurance.” As previously noted in the preamble to the proposed rule (75 FR at 28344), “we decided against defining ‘high degree of assurance’ with respect to a 95 percent probability or confidence level because there may be difficulty in applying the statistical methods to all manufacturing processes.” Many manufacturing processes, such as low-volume and continuous manufacturing, are ill-suited to use a sampling technique for quality control purposes. In addition, for small-volume manufacturers, the number of samples required to achieve 95 percent confidence could be excessive, even to the point of requiring all of the products manufactured to be tested. Because the final rule’s testing requirements apply to a wide variety of products, manufacturers, and manufacturing processes,

the rule must give manufacturers the flexibility to determine the best way to comply with the testing requirements.

The intent of the definition is for a manufacturer to have a high degree of assurance based upon evidence (rather than only a belief) that all of the products manufactured are compliant with the applicable safety rules. Knowledge of the product's design and how the product is manufactured, control over component parts, measurements showing consistent or inconsistent performance, the associated hazard, and many other elements such as these, can be used to determine the number of samples required for certification and for the periodic testing intervals, as noted in the final rule.

g. Identical in All Material Respects

Proposed § 1107.2 would define “identical in all material respects” to mean that there is no difference with respect to compliance to the applicable rules between the samples and the finished product.

(Comment 11) - Several commenters asked us to clarify the definition of “identical in all material respects.” One commenter said that the definition appears absolute in that it does not allow *any* “difference with respect to compliance.” The commenter indicated that such a definition would make testing requirements unnecessarily rigid and costly.

Another commenter contended that the definition of “identical in all material respects” cannot be absolute. One commenter would revise the definition to read: “*Identical in all material respects*’ means there is no difference between the sample and the finished product that could affect compliance to the applicable rules.” Another commenter suggested revising the definition of “identical in all material respects” to mean “to a high degree of assurance, there is no difference between the samples and the finished product that is material to compliance of the

applicable rule.” One commenter suggested that the definition of “identical in all material respects” should mean “a manufacturer possess [sic] a reasonable belief that, there is no difference between the samples and the finished product is not materially compliant.”

(Response 11) - We do not regard the definitions suggested by the commenters to be improvements of the existing definition of “identical in all material respects.” For example, defining “identical in all material respects” to mean “there is no difference between the sample and the finished product that could affect compliance to the applicable rules” appears to be so similar to the proposed definition that adopting the commenter’s suggested definition would not alter the rule. Samples used for certification testing and the finished product may be different—just not different in any way that would affect the sample’s ability to demonstrate compliance of the finished product. The definition of “identical in all material respects” is intended to emphasize that if anything other than the finished product is subjected to testing, then the characteristics of that sample must be identical to the testing of the finished product, insofar as complying with the applicable product safety rule. Otherwise, the test may not indicate that the finished product, in fact, complies with the applicable product safety rule.

The second definition suggested for “identical in all material respects” (“To a high degree of assurance, there is no difference between the samples and the finished product that is material to compliance of the applicable rule.”) also does not emphasize adequately that the finished product is what must comply with the applicable rules. In addition, using the phrase “to a high degree of assurance” in describing the similarity (with respect to conformance to the applicable rules), results in some doubt that the samples, in fact, are “identical in all material respects.”

Further, § 1107.20(a) of the final rule states:

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 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.

Using a "high degree of assurance" in the definition of "samples" would involve a double use of the term with no corresponding increase in clarity.

In a similar manner, the third definition suggested for "identical in all material respects," which uses the phrase "a reasonable belief," introduces doubt that the samples are identical to the finished product with respect to compliance. Additionally, "a reasonable belief" standard in the definition would result in an inquiry into the state of mind of a particular manufacturer and could lead to disagreements between the CPSC and manufacturers over whether a manufacturer's belief was "reasonable" in a specific instance. Further, the commenter did not explain or clarify their interpretation of the phrase "materially compliant;" the absence of such an explanation or interpretation would result in additional uncertainty in the definition.

Nevertheless, on our own initiative, we have revised the definition of "identical in all material respects" to make minor clarifications to improve the definition's accuracy and consistency with the statute. For example, the proposed definition would refer to "compliance to the applicable rules;" the final definition now adds: "bans, standards, or regulations" after "rules," to be more consistent with section 14(f)(1) of the CPSA. We also have revised the phrase "between the samples and the finished product" to read: "between the samples to be tested for compliance and the finished product distributed in commerce," to reflect that, under the final rule, the items that must be "identical in all material respects" are the samples that are to be tested for compliance (as opposed to samples that are tested for any other purpose) and the product that is actually distributed in commerce.

(Comment 12) - One commenter urged us to state that the phrase “identical in all material respects” is intended to be consistent with the “objectively reasonable basis” standard from 16 CFR part 1633, and that we would consider individual subordinate mattresses that meet the requirements of 16 CFR 1633 to be “identical in all material respects” to the qualified prototype to which a specific mattress is subordinate.

(Response 12) - We agree with the commenter that “identical in all material respects” is consistent with a demonstration on an “objectively reasonable basis,” as stated in 16 CFR § 1633.4(b)(3). We consider individual subordinate mattresses that meet the requirements of 16 CFR part 1633 to be “identical in all material respects” to the qualified prototype to which a specific mattress is subordinate.

h. Manufacturer

Proposed § 1107.2 would define “manufacturer” as “the parties responsible for certification of a consumer product pursuant to 16 CFR part 1110.”

We received no comments on this definition and have finalized it without change.

i. Manufacturing Process

Proposed § 1107.2 would define “manufacturing process” as “the techniques, fixtures, tools, materials, and personnel used to create the component parts and assemble a finished product.”

(Comment 13) - Two commenters noted that the proposed definition includes “personnel used to create the component parts and assemble a finished product.” The commenters argued that this should not be construed to mean that any change in the employees who are involved in the production of a part or product is equivalent to a change in the manufacturing process.

(Response 13) - Regarding the commenters' suggestion on the definition of "manufacturing process," the commenters may be confusing a change in the manufacturing process with a material change that could affect compliance to an applicable product safety rule. The commenters are partly correct that any change in personnel involved with a manufacturing process does not necessarily constitute a material change with respect to the product's compliance. However, for manufacturing processes that rely on high levels of craftsmanship or technical expertise, such a personnel change could affect compliance and, therefore, might be considered a material change to the manufacturing process.

Therefore, we have finalized the definition of "manufacturing process" without change.

j. Production Testing Plan

Proposed § 1107.2 would define "production testing plan" as "a document that shows what tests must be performed and the frequency at which those tests must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all the applicable safety rules."

We received no comments on this definition, but, on our own initiative, we have chosen to remove it from the final rule. We have removed the definition because it is duplicative of the description and requirements of "a production testing plan" in § 1107.21(c)(2) of the final rule.

k. Third Party Conformity Assessment Body

Proposed § 1107.2 would define "third party conformity assessment body" to mean a third party conformity assessment body recognized by the CPSC to conduct certification testing on children's products.

We received no comments on this definition. However, on our own initiative, we have revised the definition by making editorial changes to describe more accurately our accreditation

process and to indicate that the third party conformity assessment body's scope of accreditation must include the applicable CPSC-required tests. Thus, the final rule now defines "third party conformity assessment body" as "a testing laboratory whose accreditation has been accepted by the CPSC to conduct certification testing on children's products. Only third party conformity assessment bodies whose scope of accreditation includes the applicable required tests can be used for children's product certification or periodic testing purposes."

C. Proposed Subpart B – Reasonable Testing Program for Non-Children's Products

Proposed subpart B would consist of one provision and would describe the "reasonable testing program" for non-children's products. For example, proposed § 1107.10(a) would explain that, except as otherwise provided by a specific CPSC regulation or a specific standard prescribed by law, a manufacturer certifying a product pursuant to a reasonable testing program must ensure that the program "provides a high degree of assurance that the consumer products covered by the program will comply with all applicable rules, bans, standards, or regulations." Proposed § 1107.10(b) would state that a reasonable testing program must consist of five elements: (1) product specification; (2) certification tests; (3) a production testing plan; (4) a remedial action plan; and (5) recordkeeping. The proposal would describe, in greater detail, the requirements for each element of the reasonable testing program.

We received many comments on proposed subpart B. The comments addressed issues regarding the proposed provisions of a reasonable testing program on topics such as: product specifications, certification tests, samples for certification testing, production testing, remedial action, and recordkeeping. The commenters raised many concerns about the cost and burden of the proposal as well as practical issues, which illustrates the difficulty of drafting a regulation that can apply to many different types of products and manufacturing processes, yet still provide

sufficient guidance to enable manufacturers to implement the requirements of a reasonable testing program effectively. Consequently, we are deferring action with respect to finalizing subpart B. We will reserve subpart B in the final rule and, except as stated otherwise in this preamble, continue evaluating the issues raised in the comments regarding a reasonable testing program.

D. Proposed Subpart C - Certification of Children's Products

Proposed subpart C would contain the requirements for the certification of children's products. The proposed subpart C would consist of seven sections and would implement most requirements in section 14(i)(2)(B) of the CPSA.

1. General Comments

Several commenters raised issues with respect to proposed subpart C generally, or on general concepts, such as testing.

(Comment 14) - One commenter argued that the terms "reasonable assurance" and "sufficient number of samples" are likely to result in widely disparate interpretations. The commenter urged that "reasonable assurance" should be defined as a statistically significant number with a confidence level of 95 percent, based on testing enough samples to provide statistical validity. The commenter said that setting a specific confidence limit would enable us to enforce this section by avoiding subjectivity and by creating uniformity and consistency among manufacturers and conformity assessment bodies.

The commenter noted that "upstream" controls (*i.e.*, processes, inspections, and tests conducted prior to or during product assembly intended to assure product quality), product risk assessments, and design analyses are reasonable tools for manufacturers to use but currently are

not rigorous or specific enough to ensure “downstream” compliance. Until they are, compliance must be determined by final product testing, the commenter asserted.

(Response 14) - We decline to adopt the suggestion to set a 95 percent confidence level based on testing enough samples to provide statistical validity. Many manufacturing processes, such as those using continuous flow processes, are ill-suited to use a sampling technique for quality control purposes. In addition, for small-volume manufacturers, the number of samples required to achieve 95 percent confidence could be excessive, even to the point of requiring all of the products manufactured to be tested.

Because the final rule’s testing requirements apply to a wide variety of children’s products, as well as to manufacturers of various sizes and different manufacturing processes, the rule must be flexible enough to allow the manufacturer to determine the best way to comply with the rule’s requirements. We are aware of numerous “upstream” quality assurance tools and processes that are widely used to ensure high levels of product performance. For example, techniques such as component part testing are particularly well-suited for determining compliance with the lead content limits for accessible parts on children’s products. Numerous international standards address quality control and assurance processes applied “upstream” in the product production process and can be used to extend the maximum periodic testing interval. Thus, we disagree with the commenter that none of these quality assurance tools and processes is rigorous or specific enough to ensure compliance.

(Comment 15) - One commenter recommended a system of product risk assessment that would tailor the third party certification schedule for low-volume firms, as follows:

Children’s products: High-risk children’s products would require third party certification annually. Low-risk children’s products would require third party certification every three years.

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The commenter said that any test failure automatically would move the product into the next most stringent category. This system would focus the inspection of products on products that are the most dangerous to public safety. The commenter stated that an unintended consequence of this strategy would be to reward firms that make the safest products.

(Response 15) - The commenter appears to be applying the proposed low-volume exception to periodic testing (stated in proposed § 1107.21(d)) to certification testing. The low-volume exception did not apply to certification testing. There is no schedule for any manufacturer for when a product is subject to certification testing, regardless of production volume. Instead, periodic testing is required for children's products to ensure continued compliance with a high degree of assurance.

Section 14(a)(2) of the CPSA requires certification testing for children's products before they may be imported for consumption or warehousing or distributed in commerce. This initial testing of children's products does not depend on product risk. Continuing compliance is demonstrated through periodic testing for children's products, which specifies a maximum testing interval, based on the implementation of a production testing plan by the manufacturer. The final rule allows a manufacturer to consider risk to the extent it permits consideration of "the potential for serious injury or death resulting from a noncompliant product" as a factor in determining the appropriate periodic testing interval under a periodic test plan.

Regarding the commenter's suggestion of devising a system of categorizing all children's and non-children's products subject to an applicable rule into risk categories, such a system would require a separate rulemaking effort and is beyond the scope of this rule.

(Comment 16) - One commenter noted that the proposed rule did not use recognized industry terminology consistently. The commenter noted that the proposed rule relies on the

terms “test” or “testing,” as if all consumer product safety requirements could be evaluated by performing tests to ensure ongoing compliance. The commenter noted that, while full product testing is appropriate in some cases, current consumer product safety regulations imply or specify evaluation activities, not considered to be actual testing (*e.g.*, inspections, reviews, audits), may be appropriate.

The commenter noted that it recommended previously that we refer to Annex A of ISO/IEC 17000, *Conformity assessment—Vocabulary and general principles*, which provides a general description of the functional approach to activities that constitute conformity assessment, to address the question of the interpretation of the use of the terms “test” or “testing.”

(Response 16) - The word “test” was chosen because of its use in section 14(a) of the CPSA. “Certification tests” are tests on samples of the product that are identical in all material respects to the finished product. Section 14(i) (2)(B)(i) of the CPSA states that children’s products are subject to testing periodically and after a material change.

The words “test” and “testing” are used throughout the final rule to mean a process used to determine whether a product is compliant with the applicable product safety rules. The process is geared to the particular product and specific safety rule. As such, testing may include inspection of labels and manuals, audits, and measurements to determine compliance with the applicable product safety rules. We believe that the definition of “test” and “testing” are clear.

(Comment 17) - One commenter noted that we are not allowing the use of existing federally registered certification marks of third party conformity assessment bodies as an acceptable substitute for a certificate of conformity. The commenter added that introducing the new certificate of conformity will cause immediate confusion in the marketplace. The commenter suggested that we should have to justify, through a comprehensive and independent

study, why we are departing from the existing system and why our proposed system would be better and more reliable.

Another commenter stated that we should recognize certification marks issued by established third party certification programs as a substitute for the certificates of conformity described in the proposed rule when the product has been certified as compliant with associated product standards through a program that reflects CPSA requirements by an ISO/IEC Guide 65-accredited certification body.

(Response 17) - Certification marks are symbols that a manufacturer is authorized to affix to their product to indicate that the product has been certified by a certification body. Third party certification involves testing, declarations of conformance, factory inspections, and continuing surveillance activities. The certification body attests that the product complies with the specified product safety rules that were evaluated.

A certification mark does not contain the information required on a certificate by section 14(g) of the CPSA and cannot be used as a substitute for a Children's Product Certificate. Section 14(a)(2) of the CPSA requires manufacturers of a consumer product that is subject to an applicable children's product safety rule to issue a certificate certifying conformance of the children's product to the applicable children's product safety rules. Section 14(a)(2) of the CPSA does not allow a party other than the manufacturer, importer, or private labeler to issue a Children's Product Certificate.

Since the CPSIA was enacted in 2008, we have not observed immediate confusion in the marketplace regarding certificates. As noted above, certification marks cannot be used as a substitute for certificates if there is confusion in the marketplace. Thus, because section 14(a) of

the CPSA requires the manufacturer to issue a certificate of conformity, an independent study is not warranted.

Furthermore, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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. We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 18) - One commenter noted that a publisher of ordinary books may have varying titles and content, but all of the books are made of the same materials in the same manner. The commenter asserted that the differences between ordinary books are not material to compliance with the applicable rules. Accordingly, the commenter said that having accredited third party conformity assessment body testing for a finished book would constitute finished product testing for all other books (International Standard Book Numbers, or ISBNs) that do not materially differ from the tested book with respect to compliance with CPSC safety standards. The commenter said a publisher with a reasonable testing program and a product without material changes could rely on the component part certifications for all materials published within a 2-year period.

(Response 18) - Section 14(i)(5)(A)(i) of the CPSA, as amended by H.R. 2715, excludes ordinary books and ordinary paper-based printed materials from the third party testing

requirements in 14(a)(2) of the CPSA. Additionally, the final rule reserves subpart B, which would pertain to a reasonable testing program for non-children's products. Therefore, it is unnecessary for us to consider how third party testing results for a book might be extended to all other books.

(Comment 19) - One commenter asserted that only good design and comprehensive design review by qualified individuals will improve the safety of products. Therefore, the commenter suggested that we require "design hazard analysis" in the certification of children's products section of the final rule. "Design hazard analysis," according to the commenter, identifies potential safety hazards in a consumer product that result from the design of the product. It involves determinations made by skilled professionals including engineers, chemists, and biologist about the features of a product that might result in safety hazards. The commenter asserted that the CPSC has the legal authority to require design hazard analysis of consumer products.

The commenter suggested the following changes:

- In Subpart C, *Certification of Children's Products*, insert a new subsection 1107.20(a), *Children's Product Certification*. (Note: The commenter may have meant to create a new subsection (a) and renumber the remaining subsections accordingly.) The new subsection would state:

Prior to submitting samples of a children's product for testing by a third party conformity assessment body, manufacturers must conduct a design hazard analysis and produce a design appraisal of the product that identifies and characterizes the potential hazards associated with that consumer product that are related to the design of a product. The design appraisal should include, at a minimum, an engineering, chemical, and biological analysis of the product, as appropriate to the type of product and the materials contained in the product.

- Insert in § 1107.26(c), *Remedial Action*, after "... children's product safety rules":

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If the manufacturer knows or reasonably should know that the failure of the product is related to the product's design, the manufacturer shall conduct a revised design hazard review and produce a new design appraisal.

(Response 19) – We agree that designing safety into a children's product is an important part of a comprehensive quality control program. We decline, however, the commenter's suggestion to include in the final rule requirements mandating design hazard analyses for children's products. The current rulemaking is intended to implement the testing and certification requirements of section 14(a) and section 14(i)(2)(B) of the CPSA. Requiring a design hazard analysis goes beyond the statutory requirements because such an analysis would consider factors other than the factors required to demonstrate compliance with the applicable product safety rules. This action would extend the final rule to address activities that would occur before a product is manufactured.

Currently, given the range of products that are subject to section 14 of the CPSA, we have no practical means of identifying or evaluating individuals whose credentials and experience, under the commenter's suggested changes, would render them qualified to conduct design hazard analyses on products. Although the final rule does not require manufacturers to conduct a design hazard analysis on their products, manufacturers are free to engage in such analyses when developing or manufacturing a product.

Further, as explained the section on remedial action in part II.D.7. below, we have removed from the final rule, the requirement for a remedial action plan for children's products.

(Comment 20) - One commenter suggested that final testing and certification should defer to the Occupational Safety and Health Administration (OSHA)-designated Nationally Recognized Testing Laboratory (NRTL) certification program by determining that such products, as they are manufactured and distributed for consumer use, are *per se* compliant with

the proposed testing and certification rules. The commenter said we would still maintain our authority to recall products, seek civil penalties, and other remedies available to the Commission, if violations are found.

(Response 20) - Pursuant to section 14(a)(3)(C) of the CPSA, we have chosen to designate accrediting bodies that are full-member signatories to the International Laboratory Accreditation Cooperation–Mutual Recognition Arrangement (ILAC-MRA) to conduct third party testing. Given that children’s products intended for the U.S. market are manufactured in nations throughout the world, we decided to avoid designating accreditation programs or entities that are recognized only in a specific region, nation, or locality. The reasons for this are: (1) to keep the program as simple as possible for use by manufacturers, private labelers, importers, testing laboratories, and other interested parties; (2) to establish uniform requirements regardless of location; (3) to establish a program that is manageable within agency resources; and (4) to maintain a degree of consistency in the procedures used by the designated accrediting bodies.

Moreover, the commenter appears to misstate testing requirements. Consumer products are not tested for whether they are compliant with the testing and certification rules (*i.e.*, parts 1107 and 1109), rather, consumer products are tested for compliance with the applicable rules, bans, standards, and regulations which the CPSC enforces. Moreover, section 14(i)(2)(B)(i) of the CPSA requires such testing periodically and when there has been a material change. Therefore, continued testing is required by the statute and “*per se* conformance” with the applicable product safety rules is not allowed. Additionally, section 14(a) of the CPSA requires manufacturers (including importers) to certify that their products comply with the applicable product safety rules. This responsibility cannot be delegated to another party, such as a certification body.

The qualifications of testing laboratories performing certification tests are outside the scope of this final rule. Such qualifications are addressed in the various notices of requirements that we have published pursuant to section 14(a)(3) of the CPSA.

Finally, we acknowledge that the recently-enacted H.R. 2715 requires us to seek public comment on “opportunities to reduce the cost of third part testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation.” One topic which H.R. 2715 requires us to address pertains to “the extent to which evidence of conformity with other national or international governmental standards may provide assurance of conformity to consumer product safety rules, bans, standards, or regulations applicable under [the Consumer Product Safety Act].” Elsewhere in this issue of the *Federal Register*, we have published a notice inviting public comment on the issues identified in H.R. 2715, so the commenter’s argument would be more appropriately raised and addressed in that proceeding. We note, however, that very few products covered under the OSHA-designated Nationally Recognized Testing Laboratory certification program would be children’s products for which third party testing would be required. Moreover, those products that are subject to the OSHA certification program would likely be covered by CPSC regulations, if at all, for which the only requirement is a General Conformity Certificate based on a reasonable testing program. OSHA certification testing may be a sufficient basis for such certifications depending on the product and the type of testing involved. Given that CPSC does not have jurisdiction of products when the risks of injury associated with the consumer product could be eliminated or reduced to a sufficient extent by the actions of OSHA, there may be very little overlap between a particular product’s results under OSHA’s testing program and any CPSC required testing.

(Comment 21) - One commenter suggested an evidenced-based approach to certification, based on historical performance and risk for the product type and manufacturing process. The commenter suggested that an importer/retailer may implement a program requiring:

- Sample testing using materially identical components to be completed before production begins;
- Certification from samples selected during the start of production; and
- Periodic testing as the item remains in production.

At each of these stages, a representative set of samples would be pulled to cover all tests related to the applicable rules, bans, standards, and regulations.

The commenter suggested the following example:

For a child's solid rubber ball, more than 10,000 finished products that are materially identical could be made in less than one manufacturing shift. In this scenario, it would be appropriate to select samples when material changes occur and or meet historically defined frequency intervals in order to maintain and validate that products meet all rules, bans, standards, and regulations.

The commenter would like the CPSC to acknowledge that for children's products, samples selected from a lot of finished product over 10,000 pieces, but produced in a short time period, may be used to satisfy certification testing and periodic testing requirements.

(Response 21) - Section 14(a)(2) of the CPSA requires a manufacturer or importer of a children's product subject to a children's product safety rule to submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to a third party conformity assessment body whose accreditation has been accepted by us to be tested for compliance with the applicable children's product safety rules. This requirement is also set forth in § 1107.20(a) of the final rule. Thus, the commenter's first two suggestions—to choose samples for testing using materially identical components, and to select samples during the start of production, would likely fulfill the statutory requirement to submit samples that are identical in all material respects to the product, for purposes of certification testing.

Section 14(i)(2)(B)(i) of the CPSA requires, in part, that we establish protocols and standards to ensure that a certified children's product is tested for compliance periodically. Section 1107.21 of the final rule details periodic testing requirements for children's products. Accordingly, the commenter's suggestion regarding periodic testing is required by the statute, and our expectation with regard to periodic testing is articulated in the final rule.

Regarding the commenter's suggestion regarding short-period production runs of children's products, the same samples may be used for certification and periodic tests. If a testing plan is designed and implemented to meet the requirements of §§ 1107.20 and 1107.21, then the requirements to demonstrate the product's ability to meet all applicable children's product safety rules and ensure that continuing production is compliant may be met in this manner. If the manufacturer has a high degree of assurance of the children's product compliance, and the production run does not extend beyond the maximum periodic testing interval, then no third party periodic tests may be required. However, no children's product may enter into commerce without a Children's Product Certificate based on passing test results from a CPSC-accepted third party conformity assessment body certification.

(Comment 22) - Some commenters stated that the safety performance of a finished product may not be able to be based solely on the compliance of its component parts. The commenters asserted that some requirements can be evaluated only with finished product samples. The commenters asked us to clarify which products and which regulations would be amenable to component part testing. One commenter suggested that electrical safety standards and regulations (*i.e.*, fire and shock hazard testing) should not be allowed to rely solely on component part testing.

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(Response 22) - The commenters are correct that some requirements can be evaluated only with finished product samples, and not with tests on component parts. However, both this final rule and the final rule on *Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Requirements in Sections 14(a) and 14(i) of the Consumer Product Safety Act* (16 CFR part 1109) contain restrictions on the use of component part testing. For example, § 1107.20(c) of the final rule states:

Except where otherwise specified by a children's product safety rule, component part testing pursuant to 16 CFR part 1109 may be used to support the certification testing requirements of this section.

The final rule for 16 CFR part 1109 states that if a certifier has doubts about whether component part testing is sufficient to demonstrate compliance with all the applicable rules, bans, standards, or regulations, those doubts should be resolved in favor of testing the finished product.

Therefore, the commenters' concerns are addressed by the requirements of the two rules.

(Comment 23) - One commenter expressed concern about the final rule's effect on laboratory testing capacity and suggested removing references to statistical sampling and the use of ANSI/ASQ Z1.4, *Sampling Procedures and Tables for Inspection by Attributes* and Z1.9, *Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming*, for determining the number of samples required for certification testing, production testing, and periodic testing. The commenter said the frequency of testing and the number of samples tested should be set or determined by retailers and manufacturers to assure compliance with all applicable rules, bans, standards and regulations. The commenter stated that referencing the use of statistical sampling, confidence levels, and ANSI/ASQ Z1.4 & Z1.9 implies a very significant increase in the number of samples required for product testing.

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(Response 23) - For manufacturers or importers using tests on samples of a product to ensure continued compliance to the applicable product safety rules, the rule permits manufacturers or importers to determine the frequency of testing and the number of samples tested to ensure compliance. Retailers only have testing or certification obligations if they are importers. The commenter did not explain how removing references to quality management and control standards and sampling procedures, which are not required, but may be used voluntarily by certifiers, would address the issue of third party conformity assessment body testing capacity. However, the proposed rule's reference to ASNI/ASQ Z1.4 and Z1.9 had the potential to mislead manufacturers because it would use the term "Acceptable Quality Level (AQL)." An AQL can be interpreted as an acceptable percentage of nonconforming products, which is not appropriate when applied to the case of compliance of products to health and safety standards. Therefore, we have deleted references to these standards in the final rule.

(Comment 24) - One commenter noted that the Labeling of Hazardous Art Materials Act (LHAMA) established the requirements for the labeling of art materials in ASTM D-4236, which is referenced in 16 CFR § 1500.14(b)(8). The commenter asked that we: (1) clarify the meaning of this provision with respect to the certification of art materials under section 14 of the CPSA; and (2) state whether LHAMA is a labeling rule under the Federal Hazardous Substances Act (FHSA) that would not require testing and certification to LHAMA under the CPSA. The commenter further proposed the use of existing facilities and procedures allowed for LHAMA to certify compliance with the CPSIA.

(Response 24) - LHAMA requires that the manufacturer, importer, or repackager of art materials have a product's formulation reviewed by a toxicologist for its potential to cause chronic adverse health effects. A conformance statement on the product is used to certify that

the product has been so reviewed. However, section 101 of the CPSIA introduces additional testing requirements for lead in children's products beyond what is required under LHAMA, so certification of art materials under LHAMA is not necessarily equivalent to testing for lead pursuant to section 101 of the CPSIA and section 14 of the CPSA.

Regarding whether LHAMA is a labeling requirement under the FHSA that would not require testing and certification, we note that LHAMA does not contain a performance standard similar to those in consumer product safety rules but rather, requires labeling in the form of a conformance statement that the product formulation has been reviewed by a toxicologist. The requirements of LHAMA are similar to the labeling requirements of the FHSA, of which LHAMA is a part. Therefore, third party testing for conformance to LHAMA is not required. Art materials designed or intended primarily for children 12 years of age or younger would have to be tested by a CPSC-accepted third party conformity assessment body to demonstrate compliance with the lead content limits, but they would not require third party testing and certification to the LHAMA requirements.

Regarding using facilities for LHAMA to certify to CPSIA requirements, section 14(f)(2)(C) of the CPSA states that a certifying organization, as defined in appendix A to 16 CFR § 1500.14(b)(8), "meets the requirements" for consideration as a third party conformity assessment body "with respect to the certification of art materials and art products required under this section or by regulations prescribed under the Federal Hazardous Substances Act." Thus, an organization that is a certifying organization with respect to LHAMA is a third party conformity assessment body and may test children's art materials and art products for compliance with LHAMA. Thus, insofar as certifying organizations and LHAMA are concerned, no changes to the proposed rule are necessary. Accreditation requirements for testing for compliance with the

CPSIA, other than LHAMA, are beyond the scope of this rulemaking and may be addressed in a separate rulemaking.

(Comment 25) - Multiple commenters noted that manufacturers have established first party testing laboratories that are accredited to ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*. The commenters suggested that for manufacturers with such laboratories, we should allow test results from those facilities to be used for children's product certification purposes. Many commenters suggested that one half of the testing for certification should be allowed at in-house testing facilities; others recommended that the number of samples sent to third party conformity assessment bodies for certification purposes be reduced "to a minimum." Some commenters stated that we should recognize internal laboratories as a way to reduce dependence on third party conformity assessment bodies. The reasons for the suggestions include: a desire to reduce testing costs, to encourage other manufacturers to develop their own internal testing facilities, and to promote continuous product improvements.

(Response 25) - Section 14(a)(2) of the CPSA explicitly requires that testing of children's products be conducted by a third party conformity assessment body as a condition of certification. Further, third party conformity assessment bodies must have a CPSC-accepted accreditation for the scope of the testing undertaken in support of product certification. Unless the manufacturer's laboratory is a CPSC-accepted firewalled conformity assessment body, first party testing facilities, regardless of ISO/IEC 17025:2005 accreditation status, cannot be used for children's product certification purposes.

We note that, in response to these comments and concerns raised about cost, § 1107.21(d) of the final rule allows manufacturers using in-house testing laboratories accredited to ISO/IEC

17025:2005 to ensure continued compliance, to conduct periodic testing at a maximum testing interval of three years.

We further note that on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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.

We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs, consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 26) - One commenter noted that carpets and rugs currently require flammability testing in accordance with 16 CFR parts 1630 and 1631 and suggested that there is no need for an additional flammability testing procedure for youth carpets and rugs.

(Response 26) - Section 14(a)(2) of the CPSA requires third party conformity assessment body testing of children's products (or samples that are identical in all material respects) subject to a children's product safety rule for initial certification purposes. Further, section 14(f)(1) of the CPSA defines a "children's product safety rule" as a consumer product safety rule enforced by the Commission. Section 3(a)(2) of the CPSA defines a "children's product" as a consumer product designed or intended primarily for children 12 years of age or younger. Thus, because youth carpets and rugs are children's products and are subject to the consumer product safety rules 16 CFR 1630 and 1631, third party testing is required.

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For these reasons, initial certification testing for youth carpets and rugs must be performed by a CPSC-accepted third party conformity assessment body whose accreditation includes the scope of the tests. Second, children's products are subject to requirements for periodic testing, material changes, undue influence, and recordkeeping in subpart C of the final rule. The test methods in 16 CFR parts 1630 and 1631 are still applicable.

(Comment 27) - One commenter stated that the statutory requirements for certificates in section 14(a) of the CPSA impose strict and detailed requirements for the contents and availability of certificates of conformity that document compliance of a children's product as demonstrated through test results. A certificate based on accredited third party conformity assessment body testing must be issued by the manufacturer and private labeler of any children's product that is subject to a CPSC rule, and it must comply not only with the requirements of section 14(g) of CPSA, but also with the requirements of a finished product certifier's reliance on component materials testing certification. Thus, a finished product certifier could rely on a test report showing passing test results for one or more component materials used in the product, based upon accredited third party conformity assessment body testing conducted by another person.

The commenter stated that including this information in the certificate accompanying the finished children's product would create logistical nightmares for the manufacturers and private labelers of children's products. The commenter did not object to the "recordkeeping" requirements in proposed § 1107.26; however, the commenter urged us to note that compliance with these requirements should make it unnecessary for the manufacturer or private labeler of the finished children's product, to ensure that every certificate required under section 14 of the

CPSA accompanies the product or shipment of products, is furnished to each distributor or retailer of the product.

The commenter also urged us to adopt certificate requirements that reflect the key concept in the tracking label provisions, which require that the manufacturer (as well as the “ultimate purchaser”) of the finished children’s product be able to “ascertain” certain information similar to what is required for certificates of conformity. The commenter suggested that certificates, like “tracking labels,” for children’s products under section 103 of CPSIA, could be mandated to use codes or other means to point all interested parties to a source where such information readily can be found. This code could be contact information, where the manufacturer or private labeler could include an Internet URL for the manufacturer’s Website, where the information could be accessed.

(Response 27) - Section 14(g)(1) of the CPSA and 16 CFR § 1110.11 require specific information on each certificate. In addition, section 14(g)(3) of the CPSA states that the required certificate shall accompany the applicable product or shipment of products covered by the same certificate and a copy of the certificate shall be furnished to each distributor or retailer of the product. However, 16 CFR § 1110.9 allows a manufacturer to file certificates electronically by providing an Internet URL for the manufacturer’s website, where the information could be accessed, as the commenter suggested. We note that the listing of component parts or component part test results does not have to be included on the finished product certificate.

(Comment 28) - Multiple commenters mentioned the high costs associated with third party testing and noted that the proposed rule under-recognizes the in-house quality assurance and testing capabilities of manufacturers.

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(Response 28) – We are aware of many effective quality assurance techniques that are widely used to control quality in product manufacturing. However, section 14(a)(2) of the CPSA requires third party conformity assessment body testing of children’s products for initial certification. Unless the manufacturer’s in-house testing facility is a CPSC-accepted firewalled conformity assessment body, data from those facilities cannot be used for children’s product certification purposes. No exclusion is included in the statute for first party certification or periodic testing of children’s products based on the costs of testing.

In response to these comments, and in response to concerns about the cost of third party testing, § 1107.21(d) of the final rule allows manufacturers who are implementing a production testing plan to ensure the compliance of continuing production, are allowed to conduct periodic testing at a maximum testing interval of two years. Further, the final rule allows manufacturers using in-house testing laboratories accredited to ISO/IEC 17025:2005 to ensure continued compliance by conducting periodic testing at a maximum testing interval of three years. We believe this balances the desire for unbiased and objective test results with the cost concerns expressed in the comments.

Additionally, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires the CPSC to seek public 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. We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce

third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

2. Proposed § 1107.20 - General Requirements

a. The Number of Samples

Proposed § 1107.20(a) would require manufacturers to 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 proposal would require that the number of samples selected 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.

(Comment 29) - Two commenters wanted more detail on what is meant by "a sufficient number of samples." The commenters expressed concern that, if the number is left to conformity assessment bodies, there will be too much variability among conformity assessment bodies about what is a sufficient number.

(Response 29) - A "sufficient number of samples" are the number of samples necessary to give the manufacturer or importer a high degree of assurance of the product's compliance with the applicable rules when tested. Because a high degree of assurance is based upon the manufacturer's or importer's knowledge of the product and its manufacture, a sufficient number of samples will vary based on those factors. For example, for products with highly consistent part-to-part manufacturing processes (*e.g.*, die casting), fewer samples may be necessary to give the manufacturer/importer a high degree of assurance of compliance. For processes with more variability (such as hand assembly), it is likely that more samples will be necessary to achieve the same high degree of assurance.

The commenters also may have misunderstood the role of conformity assessment bodies in the testing and certification requirements of the rule. The conformity assessment body does not specify the number of samples to be tested. The manufacturer or importer specifies to the conformity assessment body the number of samples to be tested.

Finally, on our own initiative, we revised the second sentence to say that the number of samples selected must “be sufficient to” provide a high degree of assurance. We added this language to be consistent with the requirement to “submit a sufficient number of samples” language in the first sentence of the section. This change is also consistent with section 14(a)(2)(A) of the CPSA, which requires a manufacturer to “submit sufficient samples of the children’s product” for testing.

(Comment 30) - One commenter stated that the language covering samples needs to be clarified. The commenter stated that the proposal would require testing with a “sufficient number of samples” to provide a “high degree of assurance” (for minimum certification testing), while maintaining that the sampling does not have to meet minimum standards of statistical confidence. However, the commenter noted that the comments accompanying the proposed rule recognize that “there may be difficulty in applying statistical methods to all manufacturing processes.”

The commenter further stated that if testing a “sufficient number of samples to provide a high degree of assurance” is required when applying a reasonable testing program to children’s products, then we should provide guidance on alternatives that certifiers may use to fulfill the duty to justify their plan, were they to choose anything less than a random statistical sample. The commenter noted that historically, we have relied on a sample of 12 or fewer units, without regard to the size of the production run and that certain statistical models used by auditors

impose a maximum sample of 25 units, no matter the size of the cohort from which the samples are selected.

Based on these points, the commenter recommended that we delete the requirement to test a “sufficient number of samples to provide a high degree of assurance” under a reasonable testing program. The commenter said that the premise of a “reasonable testing program”—in order to differentiate it from the mandatory periodic testing required for children’s products not relying upon a reasonable testing program—must be that, for some specific products, testing will not be the basis for certifying to the applicable rule. The commenter stated that we appropriately acknowledged the implications of differences between product categories and industries attempting to develop programs when, in the preamble to the proposed rule, we observed: “*A manufacturer may develop the scope and details of each element of a reasonable testing program based on knowledge and expertise regarding the product and its manufacturing processes*” (75 FR at 28345). The commenter stated that this discretion also must extend to the sample selection method of test programs, provided that all population elements have a chance of selection and due care is exercised to avoid selection bias through documented procedures.

The commenter also stated that we should suggest separate regulations for specific products that may warrant prescribed methods, as has been done with bicycle helmets. The commenter expressed the belief that this is the kind of evidence-based decision making we envisioned in rejecting a single definition of “high degree of assurance” within a reasonable testing program for non-children’s products.

(Response 30) - Although subpart B, describing a reasonable testing program, has been reserved in the final rule, the concept of certification testing and testing a sufficient number of samples to provide a high degree of assurance of compliance with applicable rules, bans,

standards, and regulations remains in the final rule with regard to children's products in § 1107.20(a). We disagree with the commenter's assertion that "testing with a sufficient number of samples to provide a high degree of assurance" requires the testing method to meet minimum standards of statistical confidence. In the preamble to the proposed rule (75 FR at 28344), the discussion of a high degree of assurance intentionally avoided choosing a statistically based definition for the term. Therefore, the certifier is allowed to choose other means, using its knowledge of the product and how it is manufactured, to determine what would be a sufficient number of samples. A certifier may use statistical methods, but the determination of a sufficient number of samples to achieve a high degree of assurance is not required to be statistically based.

We decline to provide guidance on alternatives that certifiers may use to fulfill the duty to justify their plan if they were to choose anything other than a random statistical sample. With the wide variety of children's products, manufacturers, and manufacturing processes that will be subject to the final rule, it would be impractical to attempt to provide guidance applicable to all or to attempt to provide individualized guidance for some or all products, as requested by the commenter. Because the certifier typically possesses greater knowledge of the product and how it is made than other parties possess, the certifier is in the best position to determine how to achieve a high degree of assurance that its products are compliant with all the applicable children's product safety rules.

Regarding the commenter's observation of the CPSC's use of 12 or fewer samples, those samples were not used for children's product certification purposes. Thus, tests run by CPSC staff are not germane to the discussion of product certification. Depending upon the manufacturer's knowledge of a children's product and its manufacture, a sufficient number of

samples to provide a high degree of assurance of compliance with the applicable children's product safety rules may be greater, or fewer, than 12.

The commenter may be misunderstanding the rule as it relates to random samples. In proposed § 1107.22, the testing of random samples was required only during periodic tests of children's products subject to an applicable children's product safety rule. Pursuant to H.R. 2715, the testing of "random samples" to ensure continued compliance has been replaced with testing of "representative samples" to ensure continued compliance. Given the change in the statute, we have decided to remove § 1107.22 in the final rule. Regardless, certification testing in the proposed rule never required the selection of random samples for children's products.

For children's products, section 14(a)(2)(A) of the CPSA requires that every manufacturer or private labeler of a children's product:

submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to a third party conformity assessment body accredited . . . to be tested for compliance with such children's product safety rule.

Therefore, the statute requires children's products to be tested before they can be certified, and the statutory requirements for third party testing and periodic testing apply.

We agree that there are instances in which it may be preferable to specify a testing program in a particular regulation, and several of our existing regulations require such programs. We may do so in the future, when a particular standard necessitates such an approach.

(Comment 31) - One commenter expressed concern about the requirement to perform certification tests. The commenter said they did not believe that a requirement to test pre-production samples should be part of a reasonable testing program, adding that it may be impractical for seasonal items or short production runs. The commenter stated that preproduction samples cannot be tested because we will not accept the test results on samples as

test results on the finished product. The commenter asked: if the preproduction samples fail and the retailer/importer has the product reworked by the manufacturer to correct any defects, and the production units pass tests to meet all applicable standards, then why should it matter if the samples failed, as long as the final product meets the requirements? The commenter expressed the belief that sample testing should be optional, not required.

(Response 31) - Although subpart B, describing a reasonable testing program, has been reserved in the final rule, the concept of certification testing and testing a sufficient number of samples to provide a high degree of assurance of compliance with applicable rules, bans, standards, and regulations remains in the final rule with regard to children's products in § 1107.20(a). Section 1107.20(a) states that certification tests must be performed on samples that are identical in all material respects to the children's product distributed in commerce. Thus, finished children's product samples or preproduction samples are acceptable for certification test purposes if their performance for the test under consideration is the same as the finished product.

The commenter did not explain why they believe that certification tests may be impractical for seasonal or short production run items. Thus, we cannot respond to the commenter's concern. The final rule requires passing certification test results before a Children's Product Certificate can be issued.

With regard to the commenter's concern regarding a test failure of preproduction samples, the commenter may have misunderstood the requirements of certification testing. The commenter described a circumstance in which a manufacturer tested samples for compliance to a regulation. Upon receiving a failing test result, the manufacturer addressed the causes of the failing test results and conducted new certification tests on samples of the "corrected" product

and received passing test results. This describes an acceptable process for initial product certification.

We disagree with the commenter's suggestion that certification tests should be optional. Section 14 (a)(2) of the CPSA expressly refer to testing as being the basis of a certification and does not make such testing optional.

(Comment 32) - A commenter suggested that the final rule not require finished product/component part testing and should allow samples that are identical in all material respects to the finished product to be tested. The commenter added that testing on samples since the 1950s has not resulted in a recall for failing to comply with the applicable rule. Thus, requiring finished product/component testing would be extremely costly and burdensome and would not increase safety. The commenter would revise the rule to make it clear that component parts that are materially similar to the finished part can be used for certification testing.

(Response 32) - We agree with the commenter regarding the testing of samples. Section 1107.20(a) states that samples must be identical in all material respects to the children's product.

We also agree with the commenter's suggestion that we clarify the rule; therefore, we have revised § 1107.20(c) to state that component part testing may be used for certification of a finished product.

(Comment 33) - One commenter expressed the belief that the manufacturer should determine the number of units to be tested, but added that they do not believe that statistical sampling is appropriate.

(Response 33) - A manufacturer may use statistical or qualitative means to determine how many units of a product are needed for certification testing to give the manufacturer a high degree of assurance that the product complies with the applicable rules. The manufacturer is not

required to use statistical methods, but they should be prepared to describe how their technique shows the product's compliance.

(Comment 34) - One commenter noted that products using "food grade" materials have supplier certificates stating that these materials meet the requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) and/or the packaging requirements for the Coalition of Northeastern Governors (CONEG). The commenter suggested supplementing these certificates with other analyses, as part of the certification (*e.g.*, gas chromatography – mass spectrometry, GC-MS) and a reasonable testing program. The commenter said that such assurances also can be used, consistent with the Commission's authority under section 3 of the CPSIA, to reduce the burden of testing on manufacturers of consumer products. Because the proposed rule would acknowledge that children's product manufacturers who implement a reasonable testing program have a reduced third party test burden from the standpoint of third party periodic testing, the commenter said that such compliance assurances can be incorporated into a program for children's products as well.

(Response 34) - Section 14(a)(2) of the CPSA requires third party conformity assessment body testing of children's products as a condition of certification. Additionally, those third party conformity assessment bodies must have a CPSC-accepted accreditation for the scope of the testing undertaken in support of product certification. "Food grade" materials and CONEG requirements are not conducted by these laboratories and do not necessarily demonstrate compliance with the requirements of applicable children's product safety rules or compliance with the third party testing requirement in section 14(a)(2) of the CPSA. Accordingly, we cannot adopt those certifications in lieu of the certification required under section 14(a)(2) of the CPSA.

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While manufacturer-supplied certificates stating that these materials meet FFDCA or CONEG requirements may not be used as the basis for a third party-supported product certification, they can be used as part of a production testing plan implemented to extend the maximum periodic testing interval from one year to two years if they are sufficient to demonstrate compliance with a children's product safety rule such as the lead content limits. We note that some food additives are GRAS, or "generally recognized as safe." However, these designations might not be based on scientific analyses or testing. Instead, the GRAS status for a material might be based on longstanding acceptance or belief.

Furthermore, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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. H.R. 2715 directs us to seek public comment on seven specific issues, including the extent to which the use of materials subject to regulations of another government agency that requires third party testing of those materials may provide sufficient assurance of conformity with an applicable consumer product safety rule, ban, standard, or regulation without further third party testing.

H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. Should new information become available, the Commission may revisit this issue in the future.

b. The Interaction Between the Manufacturing Process and Samples

Proposed § 1107.20(b) would state that, if the manufacturing process for a children's product consistently creates parts that are uniform in composition and quality, a manufacturer may submit fewer samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules. If the manufacturing process for a children's product results in variability in the composition or quality of children's products, a manufacturer may need to submit more samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules.

(Comment 35) - One commenter stated that phrases, such as "sufficient number of samples" and "variability in composition or quality," can be confusing. The commenter said that regular internal monitoring and periodic testing should be able to provide sufficient data and information to support any assessment of product quality.

(Response 35) - The commenter is correct that internal monitoring and testing can provide data to support the assessment of product quality. Because § 1107.20 applies to both tightly and loosely controlled manufacturing processes, we emphasize in § 1107.20(b) of the final rule that the number of samples needed to give the certifier a high degree of assurance of the product's compliance is affected by how well the product's manufacturing process controls those variables associated with compliance. A sufficient number of samples would be the quantity of samples selected for certification testing that gives the certifier a high degree of assurance that the product complies with all the applicable children's product safety rules.

"Variability in the composition or quality," for purposes of § 1107.20, means unit-to-unit differences of a product that can affect its compliance with the applicable children's product safety rules.

We have finalized this paragraph without change.

(Comment 36) - One commenter stated that regular internal monitoring and periodic testing should be able to provide sufficient data and information to support any assessment of product quality. The commenter noted that this procedure is commonly practiced by many manufacturers at present.

(Response 36) - Section 1107.20(b) of the final rule states, in part:

If the manufacturing process for a children's product consistently creates finished products that are uniform in composition and quality, a manufacturer may submit fewer samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules.

We interpret the comment to assert that internal manufacturing controls and regular testing should obviate the need for numerous samples for product certification. The commenter is correct in that the manufacturer's internal controls and testing can provide information to use in determining how many certification test samples would be required to give the certifier a high degree of assurance of the product's compliance with the applicable rule.

c. Component Part Testing

Proposed § 1107.20(c) would state that, except where otherwise specified by a children's product safety rule, a manufacturer may substitute component part testing for finished product testing pursuant to 16 CFR part 1109, if the component part, without the remainder of the finished product, is sufficient to determine compliance for the finished product.

(Comment 37) - One commenter requested that we make an explicit statement about component testing indicating that certain components are exempt from testing and certification. The commenter was concerned that, without specific language, the final customer will not accept component testing if exempt parts are not tested. The commenter recommended revising proposed § 1107.20(c) as follows:

(c) Except where otherwise specified by a children's product safety rule, a manufacturer may substitute component part testing for complete product testing pursuant to 16 CFR [part] 1109 if the component part, without the remainder of the finished product, is sufficient to determine compliance for the entire product. *Component part testing can be used to substantiate compliance for those children's products where part of the product has been exempted from testing pursuant to Section 1500.91.* (Italics indicate proposed language.)

(Response 37) – We agree that language similar to what the commenter suggested would be helpful, but we believe that the commenter's change is more appropriate in the rulemaking pertaining to component part testing, specifically with component part testing for the lead content of children's products under proposed 16 CFR § 1109.12. Therefore, we have considered this comment under the proposed rule for component part testing.

On our own initiative, we have revised § 1107.20(c) to state: "Except where otherwise specified by a children's product safety rule, component part testing pursuant to 16 CFR part 1109 may be used to support the certification testing requirements of this section." We made these changes to simplify the language in § 1107.20(c) and to remove descriptions of 16 CFR part 1109 to avoid potential confusion over what the final rule requires and what 16 CFR part 1109 mandates.

(Comment 38) - One commenter stated that raw (or base) material testing is critical to its ability to develop programs to comply with the law. The commenter noted that, although it is a component manufacturer, it has more than 384,000 stock-keeping units (SKUs). These hundreds of thousands of products could be seen as different combinations of a smaller population of subcomponents and raw materials. The commenter stated that it is through working with this smaller population of subcomponents and raw materials that they can effectively manage quality in areas such as lead levels.

(Response 38) - Component part testing of raw materials is beyond the scope of this rule and is considered in the final rule on *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). However, in that final rule, in many cases, raw materials or subcomponents may be considered component parts, as long as due care has been taken to ensure that no action subsequent to component part testing has adversely affected the raw materials' or subcomponents' compliance with the applicable product safety rules.

d. Remedial Action

Proposed § 1107.20(d) would state that, if a product sample fails certification testing, even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take remedial action. A manufacturer would not be allowed to certify the children's product until the manufacturer establishes with a high degree of assurance that the finished product complies with all applicable children's product safety rules.

(Comment 39) - Two commenters raised questions about what action must be taken when a product fails a test. One commenter interpreted the proposed rule to mean that all similar toys are also not compliant, resulting in a factory shutdown. The other commenter noted that different products vary in design and manufacture, and if one product fails, it does not mean that other products would have the same problem.

(Response 39) - Section 1107.20(d) of the final rule states:

If a product sample fails certification testing to the applicable children's product safety rule(s), even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure.

Generally, certification testing of a children's product requires all samples tested to pass the applicable children's product safety standard. Otherwise, the certifier cannot ensure with 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, some regulations allow for some individual samples of a test set to exceed the limit but still comply with the regulation. For example, in the *Standard for the Surface Flammability of Small Carpets and Rugs* (FF 2-70) in 16 CFR part 1631, there is an allowance within the standard for a failure during a test and a prescribed action. Because the regulation specifies the procedure for dealing with a sample test failure, or through labeling, we would view such a properly labeled product as meeting the applicable product safety standard.

A test failure for one children's product applies only to that product and is not necessarily representative of all products in the factory. An exception to this might be a test on a component part used in many products. In that circumstance, the nature of the test failure and the component part's use in the other products would affect which products the failing test result applies. For example, if a component part over the lead content limit is inaccessible, the use of that component part would not make the children's product noncompliant.

Additionally, on our own initiative, we have revised § 1107.20(d) by adding the phrase: "to the applicable children's product safety rule(s)" after the phrase "if a product sample fails certification testing." This change is for clarification purposes and is not intended to have a substantive effect on the final rule. We also replaced the phrase "take remedial action" with the phrase "take the necessary steps to address the reasons for the failure" because we have removed the remedial action plan requirement in § 1107.25 from the final rule. We discuss the removal of the remedial action plan requirement in part II.D.7. of this document, below.

3. Proposed § 1107.21 Periodic Testing

a. General Periodic Testing Requirements

Proposed § 1107.21(a) would implement the periodic testing requirement in section 14(i)(2)(B)(i) (renumbered by H.R. 2715 from section 14(b)(2)(B) of the CPSA by requiring each manufacturer to conduct periodic testing at least annually, except as otherwise provided in proposed § 1107.21(b) and (d), or as provided in regulations under this title. The proposal also would explain that manufacturers may need to conduct periodic tests more frequently than on an annual basis to ensure a high degree of assurance that the product being tested complies with all applicable children's product safety rules and that more frequent periodic testing may help a manufacturer identify noncompliant products quicker and, as a result, may limit the scope of any potential product recall. In addition, more frequent testing may reduce the manufacturer's liability for civil penalties resulting from a noncompliant product, reduce potential damage to a manufacturer's reputation, and increase the manufacturer's confidence in the effectiveness of the periodic testing.

(Comment 40) - One commenter asserted that the language of proposed § 1107.21 is not explicitly limited to children's products. The commenter recommended that the language in the final rule be revised so that the term "manufacturer" is changed to the phrase "manufacturer of a children's product" to clarify that § 1107.21 applies only to children's products. The commenter also stated that the same revision should be made throughout subpart C, wherever the term "manufacturer" appears without the qualifier "of a children's product."

(Response 40) - We believe it is clear that Subpart C applies only to children's products. While we believe the commenter's suggested change is unnecessary, we have made other

revisions to the text and have added a reference to manufacturers of children's product in § 1107.21(a) of the final rule to reiterate that the requirement applies only to children's products.

On our own initiative, we have revised § 1107.21 to reflect changes to the periodic testing frequency in § 1107.21(b), (c), and (d) of the final rule, to mention component part testing, and to make nonsubstantive clarifications. For example, § 1107.21(a) of the final rule states: "All periodic testing must be conducted by a third party conformity assessment body." The proposed rule had mentioned third party testing in proposed § 1107.21(b), but not in proposed § 1107.21(a), so adding this sentence to a revised § 1107.21(a) of the final rule reinforces the notion that (with limited exceptions) periodic testing of children's products must be done by a third party conformity assessment body. Thus, § 1107.21(a), as revised, reads as follows:

(a) General requirements for all manufacturers. All manufacturers of children's products must conduct periodic testing. All periodic testing must be conducted by a third party conformity assessment body. Periodic testing must be conducted pursuant to either paragraph (b), (c), or (d) of this section or as provided in regulations under this title. The testing interval selected for periodic testing may be based on a fixed production interval, a set number of units produced, or another method chosen by the manufacturer based on the product produced and its manufacturing process, so long as the applicable maximum testing interval specified in paragraph (b), (c), or (d) of this section is not exceeded. Component part testing pursuant to 16 CFR part 1109 may be used to support the periodic testing requirements of this section.

As the revised text also indicates, we have reorganized § 1107.21 to state the general requirements at § 1107.21(a) and then identify different options for periodic testing frequencies at § 1107.21(b), (c), and (d). Thus, for example, we have modified and moved the annual periodic testing mentioned in proposed § 1107.21(a) to § 1107.21(b) in the final rule, and we have combined it with the periodic test elements that were at proposed § 1107.21(c). Consequently, § 1107.21(b) of the final rule states that a manufacturer must conduct periodic testing to ensure compliance with the applicable children's product safety rules at least once a

year, except as otherwise provided in § 1107.21(c) and (d), or as provided in our regulations. (The final rule states that the periodic testing under § 1107.21(b) must be done “once a year,” as opposed to “annually,” to eliminate potential confusion in determining how to calculate the proper interval for periodic testing.) Under § 1107.21(b), the manufacturer must conduct periodic testing at least once a year when using a periodic test plan. Section 1107.21(b)(1) of the final rule (regarding the periodic test plan) is substantially the same as proposed § 1107.21(c)(1), except that the final rule states that manufacturers must develop a periodic test plan to “ensure with a high degree of assurance” that children’s products continue to comply with all applicable children’s product safety rules. (The proposal would state that the manufacturer must develop a periodic test plan to “assure that children’s products” continue to comply.) Section 1107.21(b)(2), “Testing Interval,” is substantially the same as proposed § 1107.21(c)(2), except that, for consistency, the final rule refers simply to a “testing interval,” rather than a “periodic testing interval.” (The proposed rule had used different terms, such as “periodic testing interval,” “testing interval,” “interval,” and “interval for periodic testing,” for the same concept.)

(Comment 41) - One commenter supported third party testing for the initial certification for any new products and said that any major changes in design, critical component changes, or meeting changing regulations should require recertification by third party testing bodies. The commenter also supported periodic testing by third party conformity assessment bodies of any products, providing that a much more refined and more specific requirement can be presented and confirmed by a proper authority. The commenter noted that it would be difficult and extremely risky to leave such a decision and ruling to the related parties. However, the commenter supported the earlier proposal of component part testing that certifies recognized

components for toy production because it would enhance the elimination of certain repetitive and redundant testing on the finished product.

(Response 41) - The commenter was unclear what it meant by a “proper authority” or which parties are the “related parties” dealing with the difficulty and risk of periodic testing. In the final rule, the certifier (domestic manufacturer or importer) of a children’s product must determine the frequency of periodic testing and the number of samples to be tested. The frequency of testing (within specified maximum periodic testing intervals) and the number of samples required must be sufficient to give the certifier a high degree of assurance that continuing production or importation of the children’s product continues to meet the requirements of all applicable children’s product safety rules.

The commenter did not indicate what factors should be added to the periodic testing requirements to make them more refined or specific. Thus, we have no basis to modify the rule to account for such factors. Further, identifying or creating a “proper authority” to confirm periodic testing programs would present practical difficulties due to the number of products requiring periodic testing plans and the variety of manufacturing techniques used in their production. Because periodic testing requirements apply to many different types of children’s products and manufacturers, and because manufacturing techniques for those products vary widely, one set of refined or specific requirements for periodic testing is unlikely to be applicable to all children’s products that require periodic testing.

(Comment 42) - One commenter noted that some children’s products are not produced on a regular basis, and more than one year may pass between production runs. Because there are no production units on which to perform periodic testing, the commenter suggested that an “Inactive” product status be created for a children’s product that has passed certification

testing—but currently is not being produced. Once production resumes, periodic testing can be performed on the new units.

(Response 42) - A new “Inactive” status is unnecessary because periodic testing of children’s products is only required for continuing production after certification. If, in the commenter’s example, more than a year passes between production runs, when production recommences, the final rule requires periodic tests on new production runs to assure continued compliance. The certifier must use due care to ensure that no material change has occurred in the product’s design or manufacturing process, including the sourcing of component parts. Otherwise, new certification tests must be conducted on the newly manufactured product.

(Comment 43) - One commenter noted that while the proposed rule would accept the use of component part testing for certification purposes, it does not address its use for periodic testing. The commenter would revise proposed § 1107.21(c)(1) to include language allowing for the use of a component part testing program to meet the periodic testing requirements. The commenter stated that it could foresee customers requiring the development of a periodic testing program as a contractual requirement.

Another commenter remarked that the proposed rule does not recognize items that are exempt from testing pursuant to 16 CFR § 1500.91, *Determinations regarding lead content for certain materials or products under section 101 of the Consumer Product Safety Improvement Act*.

(Response 43) - Section 1107.21(a) of the final rule states that manufacturers must conduct periodic testing. This testing is to ensure that children’s products manufactured after the issuance of a Children’s Product Certificate, or since the previous periodic testing was conducted, continue to comply with all applicable children’s product safety rules. Periodic

testing can use component part testing to ensure compliance with some or all of the applicable children's product safety rules. We have clarified the language of § 1107.21(a) of the final rule to state that component part testing may be used to meet the periodic testing requirements, subject to the conditions of § 1107.21.

Regarding items that are exempt from testing for lead content, those items are also exempt from any periodic testing requirements. In 16 CFR §1500.91, we have determined that these materials fall under the lead content limit, and no testing is required.

(Comment 44) - One commenter stated that the testing frequency should be left to the manufacturer and to the market; and the commenter further asserted that a rule requiring manufacturers to test according to these standards every year is an unaffordable economic burden. The commenter indicated that it is unrealistic to imagine that testing cost savings from maintaining a reasonable testing program (as described in the proposed rule) will be useful because that program is "wasteful and gargantuan." The commenter asserted that a firewalled conformity assessment body would be unrealistic for small businesses. The commenter also maintained that component part and composite testing likewise, will provide no relief. The commenter asked: if a firm has a good long-term record of safety, then why are they required to test according to the proposed rule?

(Response 44) - Section 14(i)(2)(B)(i) of the CPSA requires us to establish protocols and standards for ensuring that children's products are subject to testing periodically. We have revised § 1107.21 to allow periodic testing: at least once per year for children's product with a periodic testing plan; at least once every two years for children's products with a production testing plan; or at least once every three years for a production testing plan using an ISO/IEC 17025:2005-accredited testing laboratory (and provided other requirements are met). Allowing

firms with a good long-term record of safety to forego testing their children's products would not comply with the law, which requires periodic testing of children's products, regardless of past performance.

Regarding the commenter's assertion that children's product manufacturers will not attempt to save on testing costs because implementing a reasonable testing program is "wasteful and gargantuan," the final rule does not require manufacturers of children's products to have a reasonable testing program in order to save on third party conformity assessment body testing costs. By increasing the manufacturer's options to qualify for an extension of the maximum periodic testing interval, we hope that more manufacturers wishing to implement such a program will find it advantageous to do so.

Additionally, pursuant to H.R. 2715, we intend to seek comment on other techniques for lowering the cost of third party testing, consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

As for the commenter's remark about firewalled conformity assessment bodies, the final rule does not require that small businesses have a firewalled conformity assessment body.

Finally, regarding the commenter's statements on component part and composite part testing, we address those comments in the preamble to the final rule, *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).

(Comment 45) - One commenter stated that periodic testing is unnecessary because when a product is manufactured in China, the initial product sample is inspected by the China Entry-Exit Inspection and Quarantine Bureau to ensure that it complies with all European Union,

United States, and China product safety standards. Additionally, the commenter observed, the China Entry-Exit Inspection and Quarantine Bureau will conduct the random sample in-line inspection to inspect a number of samples in the production twice a year. The commenter said that products that fail the inspection will not be allowed to be exported. The commenter said that the strict product safety inspections by China Entry-Exit Inspection and Quarantine Bureau are enough to have the high degree of product safety assurance and that a periodic testing requirement would be duplicative.

The commenter also said that periodic testing was unnecessary because, as the manufacturer, they have a high degree of self-discipline and strictly supervise their products' safety. Furthermore, the commenter stated that 90 percent of manufacturers have their own testing laboratories that conform to international laboratory standards and already have a series of internal product safety testing in place to maintain a high degree of product safety and quality assurance. In addition, the commenter stated that most customers require testing by the third party conformity assessment body per order before the manufacturer exports the goods to ensure a high degree of product safety.

(Response 45) - The final rule requires periodic testing to be conducted by a CPSC-accepted third party conformity assessment body. China Entry-Exit Inspection and Quarantine Bureaus do not currently meet the conditions specified in the Consumer Product Safety Improvement Act for governmental conformity assessment bodies to participate in the CPSC's program. Further, the third party testing requirements apply irrespective of the level of a manufacturer's self-supervision of product safety.

With regard to internal testing facilities, these are considered first party laboratories, and their tests are not allowed for periodic test purposes, unless the laboratory is a CPSC-accepted

firewalled conformity assessment body. However, if the third party laboratories testing the manufacturer's products for the customer are CPSC-accepted for the scope of the testing, test results from those laboratories may be used for fulfilling the periodic testing requirements. We note that internal testing facilities can be used to extend the maximum testing interval for periodic testing from one year to two years. Further, if the internal testing facility is ISO/IEC 17025:2005-accredited and other conditions are met, the maximum testing interval for periodic testing is extended to three years.

(Comment 46) - One commenter stated that the importer who purchases a product from a manufacturer and takes possession of the product prior to importation does not have full visibility and knowledge of the manufacturing process and must treat each shipment produced by the manufacturer as a discrete lot.

(Response 46) - An importer is responsible for issuing a Children's Product Certificate for the children's products they import. If a foreign manufacturer tests or certifies a children's product and provides the importer with the test results or certificate and other required documentation, then the importer, exercising due care, using the manufacturer's test data or certificate as a basis, may issue its own Children's Product Certificate.

In this circumstance, due care by the importer involves ensuring that the foreign manufacturer conducts periodic tests. If the foreign manufacturer does not certify the children's product, but the importer has documentation of the manufacture and testing of the children's product, then the importer is responsible for certifying the children's product and is subject to the requirement for periodic testing. However, if the importer has no knowledge of the manufacture of the product, then it should treat each shipment as a discrete lot and subject it to certification testing because the importer does not know whether material changes have been made to the

product since its last shipment. In this circumstance, the shipment that has undergone certification testing is not considered continuing production of the product, and is not subject to the periodic testing requirements.

b. Periodic Testing and Reasonable Testing Programs

Proposed § 1107.21(b) would state that if a manufacturer has implemented a reasonable testing program, as described in subpart B of this part (with the exception of the certification element which, for children's products, would have to comply with the requirements in proposed § 1107.20), it would have to submit samples of its product to a third party conformity assessment body for periodic testing to all applicable children's product safety rules at least once every two years. If a manufacturer's reasonable testing program fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, proposed § 1107.21(b) would state that we may require the manufacturer to meet the periodic testing requirements in proposed § 1107.21(c) or modify their reasonable testing program to ensure a high degree of assurance. One element of the reasonable testing program in proposed subpart B would be the "production testing plan" in proposed § 1107.10(b)(3); a production testing plan would describe what tests must be performed and the frequency with which those tests must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all applicable safety rules, bans, standards, or regulations.

(Comment 47) - One commenter recommended that we require children's products to be tested by a third party conformity assessment body at least every year, not every two years, as proposed. The commenter felt that many changes can occur over time in the manufacturing process, materials, test standards, and test protocols that could cause products tested infrequently

to drift away from compliance with applicable children's product safety rules. The commenter felt that more frequent independent testing would be able to keep this in check better.

(Response 47) - We disagree with the commenter's inference that a production testing plan will not be capable of detecting "drift" in a product's compliance with the applicable safety rules. We are aware of numerous forms of production testing techniques that have been implemented successfully to control product quality and ensure continuing compliance.

Manufacturers are free, however, to test their products more frequently than the rule would require.

Additionally, on our own initiative, we have reorganized § 1107.21 to move the requirements that were at proposed § 1107.21(b) to § 1107.21(c) of the final rule. Furthermore, because we have reserved subpart B (which would pertain to a reasonable testing program), we have removed references to a "reasonable testing program" in subpart C and replaced them with the key element of the "reasonable testing program," which is the "production testing plan." We decided to maintain the requirement for a production testing plan because children are a vulnerable population, and traditionally, we have had a greater interest in ensuring the safety of children's products. Additionally, with the passage of the CPSIA, Congress indicated that it intended for children's products to be subject to more stringent requirements than non-children's products, as demonstrated by the requirements for third party testing and the protocols and standards for continuing testing for children's products promulgated in this rulemaking.

Section 1107.21(c)(1) of the final rule states that if a manufacturer implements a production testing plan, as described in § 1107.21(c)(2), to ensure continued compliance of the children's product with a high degree of assurance to the applicable children's product safety rules, the manufacturer must submit samples of its children's product to a third party conformity

assessment body for periodic testing to the applicable children’s product safety rules at least once every two years. The 2-year period is derived from proposed § 1107.21(b) for manufacturers who have a reasonable testing program. Section 1107.21(c)(1) further states that a manufacturer may consider the information obtained from production testing when determining the appropriate testing interval and the number of samples needed for periodic testing to ensure that there is a high degree of assurance that the other untested children’s products manufactured during the testing interval comply with the applicable children’s product safety rules. The preamble to the proposed rule noted: “[t]he appropriate periodic testing interval may vary for a manufacturer depending on the manufacturer’s knowledge of the product and its manufacturing processes” for the factors to consider when determining the periodic testing interval under proposed § 1107.21(c)(2) (renumbered to § 1107.21(b)(2) in the final rule) (75 FR at 28349). This concept applies equally to the information obtained from production testing. Information gained from production testing can be used to determine the appropriate testing interval, and so we added this concept to § 1107.21(c)(1).

Section § 1107.21(c)(2) of the final rule describes the production testing plan, and it is substantially the same as the production testing plan in proposed § 1107.10(b)(3) (which is reserved in the final rule, along with the rest of subpart B). Section 1107.21(c)(2) explains that the production testing plan describes “the production management techniques and tests that must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all the applicable children’s product safety rules.” It further explains that a production testing plan may include: recurring testing or the use of process management techniques, such as control charts, statistical process control programs, or failure modes and effects analyses (FMEAs), designed to control potential variations in product

manufacturing that could affect the product's ability to comply with the applicable children's product safety rules.

Section 1107.21(c)(2) also states that a manufacturer may use measurement techniques that are nondestructive and that are tailored to the needs of an individual product to ensure that a product complies with all applicable children's product safety rules. Thus, the tests in a production testing plan under § 1107.21(c)(2) do not have to be the tests described in the applicable children's product safety rule, and they do not have to be conducted by a CPSC-accepted third party conformity assessment body. However, the implementation of the production testing plan still requires some testing. Purely mathematical techniques, such as a Failure Modes and Effects Analysis only, or a computer simulation of the product alone, are not allowed. Purely mathematical techniques, without verifying measurements, may not characterize the product with sufficient fidelity to predict accurately its compliance to the applicable rules.

Section 1107.21(c)(2) of the final rule has revised the requirement in proposed § 1107.10(b)(3)(iii)(B), which stated: "Any production test method used to conduct production testing must be as effective in detecting noncompliant products as the test used for certification" to "Any production test method used to conduct production testing must be effective in determining compliance" in the final rule. The language of the proposed rule could practically be interpreted to require the use of the test method mandated for certification because a manufacturer would be unclear about what "as effective" means and therefore, use the test method for certification. We changed the language in the final rule to clarify the point that production testing does not require the use of the test method for certification. Additionally, § 1107.10(b)(3)(iii)(C) of the proposed rule would state: "If a manufacturer is uncertain whether a production test is as effective as the certification test, the manufacturer must use the certification

test.” This provision has been eliminated from the final rule because it is no longer necessary after the above clarification that production testing does not require use of the test method for certification.

Finally, § 1107.21(c)(3) of the final rule states that if a production testing plan fails to provide a high degree of assurance of compliance with the applicable children’s product safety rules, we may require the manufacturer to meet the requirements of § 1107.21(b) for a periodic testing plan to ensure a high degree of assurance of compliance. This is not a new requirement. Proposed § 1107.21(b) had the same requirement for manufacturers with a reasonable testing program. Because we have removed the reasonable testing program and reserved subpart B in the final rule, the periodic testing requirement is no longer linked to the reasonable testing program. However, we have moved this requirement to the production testing plan option in § 1107.21(c)(3) and the ISO/IEC 17025:2005-accredited laboratories option in § 1107.21(d) of the final rule.

(Comment 48) - A commenter strongly recommended that we recognize or endorse certain internal in-house testing facilities that conform to ISO 17025:2000 standard. The commenter felt that this recognition would greatly expedite testing procedures and the time for certain required testing and reduce costs and lessen dependence on the third party conformity assessment bodies. Another commenter stated that we should recognize internal laboratories as a way to reduce dependence on third party conformity assessment bodies. The reasons for the suggestions include: better monitoring of product safety, a desire to reduce testing costs, encourage other manufacturers to develop their own internal testing facilities, and promote continuous product improvements.

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(Response 48) - We recognize that using ISO/IEC 17025:2005-accredited laboratories for testing purposes provides an added measure of assurance to production testing. The laboratories are accredited by an independent body as competent to perform specified tests. They are also recognized as having instituted a management system that establishes procedures and properly maintains records. Laboratory accreditation also establishes controls concerning data integrity, equipment calibration, and procedures to resist undue influence over testing results.

For these reasons, we have amended the final rule to include a new § 1107.21(d), which provides a maximum periodic testing interval of three years for a manufacturer using an ISO/IEC 17025:2005-accredited laboratory for production testing purposes. The laboratory must be accredited by an ISO/IEC 17011:2004 (*Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*) accreditation body, and must use the same test method(s) used for certification testing when conducting testing to ensure continued compliance. We chose the 3-year time period because: (1) having a laboratory accredited by an independent body as competent to perform specified tests provides an additional measure of assurance in the accuracy and the integrity of the testing results; (2) a laboratory accredited to ISO/IEC 17025: 2005 must have implemented a management system that establishes and follows procedures, properly maintains records, and establishes controls concerning data integrity equipment calibration, and procedures to resist undue influence; and (3) using the same tests as the tests used for product certification provides a more direct assessment of compliance to the applicable children's product safety rules than process control techniques. Section 1107.21(d)(1) of the final rule also states that manufacturers must conduct testing using the ISO/IEC 17025: 2005-accredited testing laboratory frequently enough to provide a high degree of assurance that the children's product continues to comply with the

applicable children's product safety rules. In addition, section 1107.21(d)(1) of the final rule states that a manufacturer may consider the information obtained from testing conducted by an ISO/IEC 17025: 2005-accredited testing laboratory when determining the appropriate testing interval and the number of samples for periodic testing that are needed to ensure that there is a high degree of assurance that the other untested children's products manufactured during the testing interval comply with the applicable children's product safety rules.

Section 1107.21(d)(2) of the final rule states that if the continued testing described in § 1107.21(d)(1) fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, then we may require the manufacturer to comply with § 1107.21(b) or modify the testing frequency or number of samples required to ensure a high degree of assurance of continued compliance. Section 1107.21(d)(2) is substantially the same, in this respect, as proposed § 1107.21(b), in requiring the use of other periodic testing options if a manufacturer's testing program fails to provide a high degree of assurance of compliance, except that § 1107.21(d)(2) refers to "continuing testing," rather than a "reasonable testing program."

Section 1107.21(d)(3) of the final rule describes the incorporation by reference of ISO/IEC 17025:2005 and ISO/IEC 17011:2004, as required by the Director of the Federal Register. This incorporation by reference is necessary because § 1107.21(d)(1) references ISO/IEC 17025:2005 and ISO/IEC 17011:2004.

(Comment 49) - Two commenters stated that periodic testing or auditing should be considered a regular internal function. One commenter stated that any manufacturer with qualified internal testing facilities should perform such duties easily and regularly to ensure product quality. Having a third party conformity assessment body conduct periodic testing would result in a significant cost impact and would create production delays and difficulties.

The commenter suggested that we not specify the frequencies of testing under different manufacturing conditions. The commenter stated that product safety rules should apply to finished products.

Another commenter noted that a consistently good product testing record should reflect the competency of qualified internal testing facilities and expertise. Accredited and qualified in-house testing facilities should be able to handle this effectively and economically. The commenter noted that smaller manufacturers may have to use the services of third party conformity assessment bodies per the agreed schedule, which needs to be defined and specified.

(Response 49) - The final rule requires periodic testing to be conducted by a CPSC-accepted third party conformity assessment body. If the “qualified internal testing facility” is a CPSC-accepted firewalled conformity assessment body, then tests from that conformity assessment body can be used for periodic testing purposes. Otherwise, an internal testing facility is considered a first party laboratory, and its test results would not be allowed for periodic testing purposes.

Regarding the commenter’s assertion of significant costs, the commenter did not describe how third party testing would result in significant costs and production difficulties relative to internal testing. However, a manufacturer with internal testing facilities may use product test data from those facilities to increase its knowledge of the product and its manufacture, and thus, may reduce the number of samples required for periodic testing purposes as a means of controlling costs. Section 1107.21(c)(1) of the final rule states that if a manufacturer has implemented a production testing plan, the maximum testing interval for periodic testing is extended to two years. Additionally, under §1107.21(d)(1) of the final rule, if the manufacturer uses an ISO/IEC 17025:2005-accredited testing laboratory for the production testing (and other

requirements are met), the maximum testing interval is extended to three years. These methods may be used by a manufacturer to reduce the costs of third party conformity assessment body testing. (We explain the reasons for adding § 1107.21(d) to the final rule at part II.D.3.b. of the preamble.)

We agree with the commenter on the undesirability of specifying testing frequencies for different manufacturing conditions. Thus, the final rule specifies only the maximum testing interval for periodic testing and lists some factors to be considered by manufacturers in developing their periodic test plans. We also agree with the commenter that product safety rules should apply to finished products.

As noted above, pursuant to H.R. 2715, we intend to seek comment on other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 50) - One commenter said we should clarify what level of detail or generality we would allow in mandating that a production test plan describe the tests to be conducted or the measurements to be tested. The commenter assumed that a manufacturer would have the flexibility to create a test plan that could be applied to multiple products. For example, the commenter suggested that a production testing plan could address testing by generic specifications of products, such as die-cast cars or fashion dolls. However, the commenter said that if we expect a production testing plan to specify the testing details for each product, then it would be so burdensome as to be economically not feasible.

(Response 50) - The use of production testing as a means to increase the maximum periodic test interval to two years is intended to be general in nature and flexible enough to be adaptable to many different products and manufacturing processes. It is the manufacturer's

responsibility to tailor its production testing to its specific products. As stated in § 1107.20(c)(2) of the final rule, production testing is intended to ensure continued compliance of the product to the applicable children's product safety rules with a high degree of assurance. It is not required that a manufacturer's production testing plan specify all testing details for each product.

However, § 1107.20(c)(2)(i) of the final rule specifies that a production testing plan must include:

a description of the process management techniques used, the tests to be conducted, or the measurements to be taken; the intervals at which the tests or measurements will be made; the number of samples tested; and the basis for determining that the combination of process management techniques and tests provide a high degree of assurance of compliance if they are not the tests prescribed for the applicable children's product safety rule.

This is necessary because techniques and test methods other than those prescribed in the applicable children's product safety rules may be used in production testing and are needed to show the effectiveness of the production testing plan.

(Comment 51) - Two commenters stated that, although we acknowledged that a production testing plan could include procedures such as process management techniques, statistical process control programs, or failure mode analysis, the proposed rule would describe a rather rigid product testing plan. One commenter characterized the following two requirements as "a rigid product testing plan": (1) the requirement for each site to have a separate production testing plan, and (2) the production testing interval should be short enough to ensure that, if the samples selected for production testing comply with an applicable rule, ban, standard, or regulation, there is a high degree of assurance that the untested product will comply with the applicable rule, ban, standard, or regulation. The commenter urged us to acknowledge more clearly that the elements of a production test plan enumerated in the rule are not the only

elements that we will recognize and that other processes, such as statistical process control mechanisms, also may be used to show compliance.

One commenter suggested that the terms “production testing plan” and “remedial action plan” be replaced with “production testing plan or procedures” and “remedial action plan or procedures” because the use of the word “plan” may be interpreted too narrowly to allow for the range of methods that manufacturers may use to meet the requirements.

(Response 51) - Manufacturers may use production testing plans with any procedure that is as effective in detecting noncompliant products (with the requirement that purely mathematical methods with no testing are not allowed). Statistical process control mechanisms, properly applied, are acceptable methods for production testing. The production testing plan implemented at each manufacturing site may be identical, if appropriate; but each site must have identifiable production testing for the products produced at that site. This is a matter of documentation, and the commenter has not provided a reason why this creates a problem. The final rule does not mandate a specific testing interval for all products. Rather, the requirement in the final rule is for production testing to be effective in detecting noncompliant products with whatever fixed or variable testing interval achieves a high degree of assurance of compliance to the applicable product safety rules.

We decline to adopt the suggestion to change “production testing plan” to “production testing plan or procedures.” Dictionary definitions of “plan” and “procedure” are so similar that to use both terms would be redundant. We believe that the description of a production testing plan in § 1107.20(c) of the final rule provides an adequate description of its scope.

Additionally, because the final rule does not require a remedial action plan for children's products, the suggestion to replace the term "remedial action plan" with "remedial action plan or procedures" is no longer applicable.

(Comment 52) - One commenter supported the acknowledgement that the same production testing plan that is available to the manufacturing site and the importer of record (retailers) is sufficient. The commenter gave the example of a manufacturer who developed a production testing plan and demonstrated to their customers (the importers of record or retailers) that their production testing plan provides a high degree of assurance of compliance. The commenter said that importers could validate critical aspects of the plan through factory audits and evaluations, production inspections that ensure that the testing plan records are present and match the specifications, and periodic testing using a CPSC-accepted third party conformity assessment body.

(Response 52) - An importer can arrange for another party (*e.g.*, a foreign manufacturer) to develop and conduct production testing for a product. The same production testing plan from another party may be used by multiple importers as a means of increasing the importers' maximum periodic test interval to two years. The importer, as the product certifier, must use due care to ensure that the implementation of a production testing plan ensures with a high degree of assurance that continuing production complies with the applicable product safety rules.

(Comment 53) - One commenter noted that proposed § 1107.21(b) would specify that if a manufacturer's reasonable testing program fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, we may require the manufacturer to meet the requirements of proposed § 1107.21(c) or modify its reasonable testing program to ensure a high degree of assurance of compliance. The commenter asked who would determine

whether a reasonable testing program provides a high degree of assurance of compliance, and how.

(Response 53) - With regard to the language in proposed § 1107.21(b) referenced by the commenter, because we have reserved the reasonable testing program option for periodic testing in the final rule, we have moved that language to §§ 1107.21(c)(3) and (d)(2) (renumbered in the final rule) and modified it to refer to the production testing plan option with a maximum periodic testing interval of two years and/or the testing by an ISO/IEC 17025:2005-accredited testing laboratory option with a maximum periodic test interval of three years. With these changes in mind, we will decide, based on the available evidence, whether a children's product's production testing plan provides a high degree of assurance of continuing compliance to the applicable children's product safety rules.

(Comment 54) - One commenter noted that the voluntary establishment of a reasonable testing program for a children's product increases the period between periodic tests to—at least once every two years—from the requirement of annual periodic testing for children's products without a reasonable testing program. The commenter suggested that we consider the costs involved in establishing and maintaining a reasonable testing program, and noted that a reasonable testing program reasonably warrants a more relaxed periodic testing frequency standard, particularly when the manufacturing process inherently results in uniform production, with very little variability in the composition or quality.

The commenter also noted that the preamble to the proposed rule stated that not all periodic testing was required to be conducted by a third party conformity assessment body (75 FR at 28348). In addition, the commenter pointed out that the preamble to the proposed rule also

stated that the appropriate periodic testing interval “may vary for a manufacturer depending on the manufacturer’s knowledge of the product and its manufacturing processes” (75 FR at 28349).

The commenter urged us to permit a manufacturer of a children’s product with a reasonable testing program in place to determine when to obtain third party conformity assessment body testing of ordinary children’s books or other children’s paper-based printed products under a testing frequency standard of at least once every four years. The commenter noted that third party conformity assessment body testing still would occur in response to a material change to the children’s product.

(Response 54) - The final rule extends the maximum testing interval for periodic testing from one to two years for manufacturers who have implemented a production testing plan as a means of ensuring continued compliance of the product to the applicable children’s product safety rules. The production testing plan in § 1107.21(c) of the final rule is the same production testing plan in the reasonable testing program described in proposed § 1107.10(b)(3). This increase in the maximum testing interval was not based on the costs of third party testing or on the costs of implementing a production testing plan. When a manufacturer implements a production testing plan and conducts production testing, such testing provides more information about a product’s manufacture and compliance with the applicable children’s product safety rules, which justifies allowing a longer period of time between periodic tests. If a manufacturer uses an ISO/IEC 17025:2005-accredited testing laboratory for testing to assure continued compliance, the maximum periodic testing interval is extended to three years.

The commenter is correct that the preamble to the proposed rule stated that not every periodic test has to be done by a third party conformity assessment body if the manufacturer has implemented four elements of a reasonable testing program. However, § 1107.21(c) of the final

rule states that a manufacturer who has implemented a production testing plan for a children's product must submit samples of the product to a third party conformity assessment body for periodic testing at least once every two years. We recognize that these two statements may be confusing, and we have clarified the text in § 1107.21(a) of the final rule to state that all periodic testing must be conducted by a CPSC-accepted third party conformity assessment body accredited to the scope of the tests required.

Additionally, on August 12, 2011, the President signed into law H.R. 2715 which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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. We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Regarding the commenter's suggestion on testing ordinary children's books or other children's ordinary paper-based printed materials, section 14(i)(4) of the CPSA, as amended by H.R. 2715, excludes ordinary books from the third party testing requirements in section 14(a) of the CPSA. Additionally, we have decided to reserve, rather than finalize, subpart B, which would have pertained to a reasonable testing program for nonchildren's products. Therefore, it is unnecessary for us to address the commenter's suggestion.

c. Periodic Testing in the Absence of a Reasonable Testing Program

Proposed § 1107.21(c) would state that if a manufacturer has not implemented a reasonable testing program, as described in subpart B of this part, then all periodic testing would be required to be conducted by a third party conformity assessment body, and the manufacturer would be required to conduct periodic testing, described in proposed § 1107.21(c)(1) and (c)(2).

Proposed § 1107.21(c)(1) would require the manufacturer to develop a periodic testing plan to ensure that children's products manufactured after issuance of a children's product certification, or when the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules.

Proposed § 1107.21(c)(2) would require the periodic testing interval selected to be short enough to ensure that, if the samples selected for periodic testing pass the test, then there is a high degree of assurance that the other untested children's products manufactured during the interval comply with the applicable children's product safety rules. The interval for periodic testing may vary, depending upon the specific children's product safety rules that apply to the children's product. Proposed § 1107.21(c)(2)(i) through (c)(2)(ix) listed factors to be considered when determining the periodic testing interval.

On our own initiative, we made several editorial and complementary changes to proposed § 1107.21(c). In brief:

- We have renumbered proposed § 1107.21(c) as § 1107.21(b) in the final rule.
- In § 1107.21(b), we have revised the text to state the periodic testing options more clearly. Section 1107.21(b) now states that a manufacturer “must conduct periodic testing to ensure compliance with the applicable children's product safety rules at least once a year,” except as otherwise provided in § 1107.21(c) and (d) (the other periodic testing options in the final rule), or as provided in regulations under this title.

Section 1107.21(b) of the final rule further states that if a manufacturer does not conduct production testing under § 1107.21(c), or testing by a testing laboratory under § 1107.21(d), the manufacturer must conduct periodic testing pursuant to the periodic test plan requirements at § 1107.21(b)(1) and the testing interval requirements in § 1107.21(b)(2).

- In § 1107.21(b)(1) (formerly proposed § 1107.21(c)(1)), we have replaced “assure” with “ensure with a high degree of assurance.” We made this change to be consistent with other language used throughout the final rule. We also replaced “children’s product certification” with “Children’s Product Certificate,” for consistency throughout the final rule, and we eliminated the requirement of providing a basis for determining that the periodic testing plan provides a high degree of assurance that the product being tested continues to comply with all applicable children’s product safety rules. We eliminated the requirement that a manufacturer provide the basis for determining that a periodic test plan provides a high degree of assurance because manufacturers would need to demonstrate how their production testing plan provides a high degree of assurance if we requested that information. However, it is unnecessarily burdensome to require a manufacturer to provide the basis for this in every instance, when we may never inquire about the basis for a particular periodic test plan. Therefore, we have eliminated this requirement from the final rule.
- In § 1107.21(b)(2) (pertaining to testing intervals), we have revised the text to refer to “testing interval” or “testing,” instead of “periodic testing interval” or “periodic testing.” “Testing Interval,” is substantially the same as proposed § 1107.21(c)(2), except that, for consistency, the final rule refers simply to a “testing interval,” rather

than a “periodic testing interval.” (The proposed rule had used different terms, such as “periodic testing interval,” “testing interval,” “interval,” and “interval for periodic testing,” for the same concept.) We removed the word “periodic” because it is redundant in the context of the section, which addresses “periodic testing.”

Additionally, § 1107.21(b)(2) states that the testing interval may vary, depending upon the specific children’s product safety rules that apply to the children’s product, “but may not exceed one year.” We added “but may not exceed one year” to clarify that, consistent with § 1107.21(b), the periodic testing must occur at least once a year.

- Section 1107.21(b)(2)(i) through (x) lists the factors to be considered in determining the testing interval. This list is almost identical to proposed § 1107.21(b)(2)(i) through (ix), except that the final rule separates the examples of nonmaterial changes that were at proposed § 1107.21(b)(2)(v). Proposed § 1107.21(b)(2)(v) would mention “Nonmaterial changes, such as introduction of a new set of component parts into the assembly process, or the manufacture of a fixed number of products.” Upon further consideration, we felt that the two examples were dissimilar, so § 1107.21(c)(2)(v) of the final rule now states: “Introduction of a new set of component parts into the assembly process”; and § 1107.21(c)(2)(vi) of the final rule states: “The manufacture of a fixed number of the products.” We have renumbered the remaining subparagraphs in § 1107.21(c)(2), accordingly.

d. Periodic Testing Frequency for Low-Volume Manufacturers

Proposed § 1107.21(d) would pertain to the periodic testing frequency for low-volume manufacturers. In brief, the proposal would not require a manufacturer to conduct periodic testing unless it has produced or imported more than 10,000 units of a particular product; instead,

once that threshold has been reached, the manufacturer would be subject to the periodic testing requirements of proposed § 1107.21(a), and (b), or (c).

Several commenters addressed proposed § 1107.21(d). The comments spanned a range of issues. For example, one commenter said that the production or importation volumes for different children's products may vary substantially, such as large electrical motorcycles and small stuffed toys, so the commenter said it is not reasonable to apply the same volume of 10,000 to all children's products. The commenter asked whether periodic testing is necessary when a large number of products are produced in a short timeframe, for example, 100,000 toys produced in three months. Other commenters also focused on the 10,000 figure, asking whether the figure applies only to the number of children's products produced, whether the number applies to each distinct product or to all children's products made at a facility, or whether the figure of 10,000 units is too high or too low. (One commenter stated that its analysis of CPSC-announced recalls in 2009, showed that 47 percent of the recalls involved products of 10,000 units or less.) Yet another commenter interpreted the provision as an acknowledgement by the CPSC that the periodic testing frequency standard is not essential to safety because it dispenses with periodic testing altogether in the case of manufacturers who produce or import no more than 10,000 units of a product.

On August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 requires, among other things, that we seek public 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. It also contains special rules for small batch manufacturers and directs us to consider alternative testing requirements or exempt small batch manufacturers from certain third party testing requirements. Given these new statutory

obligations resulting from H.R. 2715, we are reserving § 1107.21(e) so that we may consider how to address cost, low-volume products, and small batch issues more fully.

4. Proposed § 1107.22 - Random Samples

Proposed § 1107.22 would implement the testing of random samples requirement in former section 14(d)(2)(B)(ii) of the CPSA (renumbered by H.R. 2715 as section 14(i)(2)(B)(ii) of the CPSA), by requiring each manufacturer of a children's product to select samples for periodic testing by using a process that assigns each sample in the production population an equal probability of being selected.

We received many comments on proposed § 1107.22. The commenters made numerous assertions, such as: product samples should be reasonably representative of the product population; samples should not be golden samples; samples should be selected blindly; samples should not be selected with overt bias; and the rule should not use a statistical definition for random sample. Commenters also expressed concern over practical problems with the proposed section for random sampling. However, on August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 revised section 14(i)(2)(B)(ii) of the CPSA, by replacing testing of "random samples" to ensure continued compliance with testing of "representative samples" to ensure continued compliance. Given this change in the statute, we have removed § 1107.22 from the final rule. Elsewhere in this issue of the *Federal Register*, we have published a proposed rule that would implement the "representative samples" provision in H.R. 2715.

5. Proposed § 1107.23 - Material Change

a. General Requirements

Proposed § 1107.23(a) would state that if a children's product undergoes a material change in product design or manufacturing process, including the sourcing of component parts,

that a manufacturer exercising due care knows or should know that such material change could affect the product's ability to comply with the applicable children's product safety rules, the manufacturer must submit a sufficient number of samples of the materially changed product for testing by a third party conformity assessment body. Such testing would be required before a manufacturer could certify the children's product. The extent of such testing would depend on the nature of the material change. Proposed § 1107.23(a) also would state that, when a material change is limited to a component part of the finished children's product and does not affect the ability of the children's product to meet other applicable children's product safety rules, a manufacturer may issue a Children's Product Certificate based on the earlier third party certification tests and on test results of the changed component part conducted by a third party conformity assessment body. For example, if the paint is changed on a children's product, issuance of a Children's Product Certificate may be based on previous product testing and on tests of the new paint for compliance to lead, heavy metal, and phthalate concentrations. Proposed § 1107.23(a) also would state that changes that cause a children's product safety rule to no longer apply to a children's product are not considered to be material changes. For example, assume that a children's product consists of a cotton sweater with metal buttons and that the children's product would be subject to the lead limits in section 101 of the CPSIA. If the manufacturer decided to use wooden buttons instead of metal buttons, the use of wooden buttons would eliminate the need to test the product for lead, and the change to wooden buttons, while arguably a change in the product's component parts, would not be a "material change" under proposed § 1107.23(a) for the purposes of complying with the lead content limits. However, for other children's product safety rules, such as small parts, the change may be a material change.

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Additionally, proposed § 1107.23(a) would require a manufacturer to exercise due care to ensure that reliance on anything other than retesting of the finished product after a material change would not allow a noncompliant children's product to be distributed in commerce. A manufacturer should resolve any doubts in favor of retesting the finished product for certification. A manufacturer also would be required to exercise due care to ensure that any component part undergoing component-part-level testing is the same as the component part on the finished children's product in all material respects.

We received several comments regarding "material change" and proposed § 1107.23, as well as the corresponding provision at proposed § 1107.10(b)(2)(ii). Although we have decided to reserve subpart B in the final rule, to the extent that comments on proposed § 1107.10(b)(2)(ii) were equally applicable to proposed § 1107.23, we have considered those comments here.

(Comment 55) - A commenter suggested that the definition of "material change" should be moved from proposed § 1107.10(b)(2)(ii) to the definitions in § 1107.2.

(Response 55) - Section 1107.10 has been reserved in the final rule. We agree with the commenter, and we have moved the definition of "material change" to § 1107.2 in the final rule, as this definition still applies to § 1107.23 regarding material changes in children's products. Thus, § 1107.2 defines "material change" as "any change in the product's design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product's ability to comply with the applicable rules, bans, standards, or regulations."

(Comment 56) - Some commenters suggested revising the proposed definition of "material change" to refer only to changes that "reasonably could affect" compliance.

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(Response 56) - The commenters are concerned about a remote possibility that some set of circumstances could combine, such that a seemingly innocuous change could affect the product's compliance to an applicable product safety rule. We realize that it would be difficult for a manufacturer to identify every conceivable theoretical effect a change could have on a children's product's compliance. Therefore, manufacturers should exercise prudence and competence in determining the effects of a change to the product and in considering whether that change is material. This prudence and competence is encompassed in the manufacturer's use of due care in evaluating the change.

We decline the commenters' suggestion to modify the definition of "material change" because the definition now in § 1107.2 of the final rule includes the phrase "a manufacturer exercising due care." Because the definition of "due care" includes the exercise of prudence and competence by the manufacturer, the addition of "reasonably could" is duplicative.

(Comment 57) - One commenter stated that different versions of the same product (*e.g.*, color, packaging) should not require different tests.

(Response 57) - The commenter is correct that different versions of the same product that are not materially different do not require separate certification tests. The final rule defines a "material change" as:

. . . any change in the product's design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product's ability to comply with the applicable rules, bans, standards, or regulations.

Therefore, if the differences between various versions of the same product are not material changes, no additional testing is required. It is the manufacturer's responsibility to determine if a difference between versions of a product constitutes a "material change."

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(Comment 58) - One commenter suggested that after certification testing of a product, if another product differs by a few minor components from the certified product, and proper proof of equivalent specifications are documented, a reduced sample size for certification should be allowed.

(Response 58) - In the circumstance described by the commenter, if a new product differs from an existing certified product by a few component parts, the manufacturer's knowledge of the new product and its manufacture might be extensive enough to result in requiring fewer samples for certification testing than the number required for the existing certified product. We reiterate that if a new product is based on changes to an existing certified product, only the applicable product safety rules affected by the changes require certification testing. The number of samples still must be sufficient to give the manufacturer a high degree of assurance of the new product's compliance with the applicable children's product safety rules. The certifier also may use component part testing as a means of reducing the number of finished samples needed for certification. If the changes from the existing certified product to the newer product are not material, then the certification tests on the existing certified product can be used for certification purposes on the newer product.

Thus, on our own initiative, we have revised § 1107.23(a) to make several clarifying changes to the paragraph. First, we have added language to the final rule to require the number of samples submitted to be sufficient to provide a high degree of assurance that the materially changed component part or finished product complies with the applicable children's product safety rules. This language was added because third party testing that occurs after a material change serves as recertification of the product for the applicable children's product safety rules affected by the material change. This language is essentially the same requirement contained in

§ 1107.20(a) of the final rule for initial certification of children's products. Additionally, § 1107.23(a) was revised to add the following: "A manufacturer of a children's product that undergoes a material change cannot issue a new Children's Product Certificate for the product until the product meets the requirements of the applicable children's product safety rules for the component part or finished product for the material change based on testing by a third party conformity assessment body." This is not intended to be a substantive change, but rather, is meant to make clear what is already the case—that material changes require recertification based on passing test results. Finally, we have removed the language in proposed § 1107.23(a) that would require a manufacturer to exercise due care to ensure that reliance on anything other than retesting of the finished product after a material change would not allow a noncompliant children's product to be distributed in commerce. This provision was removed because this issue is addressed in § 1109.5(a)(1) of the accompanying component part testing rule. We also removed the requirement that a manufacturer should resolve any doubts in favor of retesting the finished product for certification. This provision was removed because the issue is addressed in § 1109.5(c) of the accompanying component part testing rule.

(Comment 59) - Two commenters raised issues related to products subject to 16 CFR part 1201, *Safety Standard for Architectural Glazing Materials*, although the issues they raised have wider implications that involve other products, including children's products. The products subject to that safety standard are glazing materials (glass) used or intended for use in doors and enclosures. The commenters noted that these types of glass normally are manufactured in a continuous process that is subject to numerous minor and ongoing adjustments to respond to atmospheric and other factors and to make sure that the tempering process continues properly. In addition, there can be numerous minor variations in format, size, and thickness of the glass, as

well as other product characteristics that are a normal part of shifting from one product to another to meet customers' orders. This industry's current process of certification and quality control involves periodic third party "certification" testing to the requirements of 16 CFR part 1201 and uses alternate means for checking breakage performance of samples from subsequent production, such as a center punch test for tempered glass and the drop-ball and/or pummel test for laminated glass, in order to monitor ongoing compliance with the standard. If a potential failure of the standard is detected by these alternate tests, corrective action is taken, and product distribution is not resumed until a subsequent production test shows that the breakage performance has been restored.

The commenters requested clarification that the ongoing adjustments described above would not be "material changes" that would require recertification of the product. The proposed rule defines "material change" as one that "could affect the product's ability to comply with the applicable rules" One commenter requested that we state:

An adjustment to equipment or machinery made in order to maintain, achieve, or assure compliance with the applicable rules . . . is *not* a material change within the meaning of section 1107.10.

The other commenter suggested the following addition to the rule:

Adjustments in the equipment or machinery to affect the product's ability to comply with any applicable rules or standards should not be considered a "material change" in the manufacturing process . . . but will require the manufacturer, following those adjustments to subject the product to its production testing plan and to achieve passing production test results before the manufacturer may resume production of that product.

(Response 59) - Although regulated non-children's products still must meet the certification requirements in section 14(a)(1) of the CPSA, we have reserved subpart B, including the reasonable testing program described in proposed § 1107.10. However, the broader issue presented by this commenter, which relates to adjustments in equipment or

machinery, is applicable to children's products as well, so we will address this issue with regard to children's products.

In order for a change to be a "material change," it should be one that could *adversely* affect the product's ability to comply with the rule, ban, standard, or regulation. Minor and ongoing adjustments during manufacturing, especially in continuous flow processes, to maintain compliance with the applicable product safety rules are not considered material changes. However, we do not agree entirely with the commenters' suggested language because that language would include adjustments made to "achieve" compliance (*i.e.*, to change a product from noncompliance to compliance). Such a change would constitute a "material change"; thus, additional certification testing would be required.

(Comment 60) - One commenter suggested that, in proposed § 1107.10(b)(2), it also should be noted that testing of units within a common family of products should allow a test of one unit to represent all others within the family of products if the other models are materially the same. The commenter added that, regarding proposed § 1107.10(b)(2)(ii)(B), a manufacturer should not be required to conduct additional "certification" testing upon a change to the parts or materials, if the change does not affect the overall safety of the system. The commenter suggested that we revise the section to give manufacturers the ability to make changes to parts and materials without having to undergo costly and time-consuming certification testing. The commenter would allow manufacturers to conduct in-house testing that would show that the results of any change do not materially alter the performance of that part or system with regard to the safety elements in the applicable rule.

(Response 60) - Although regulated non-children's product must still meet the certification requirements in section 14(a)(1) of the CPSA, we have reserved subpart B,

including the reasonable testing program described in proposed § 1107.10. However, the broader issue presented by this commenter related to certification testing of units within a common family and when there has been a material change to a product is applicable to children's products as well, so we will address this issue with regard to children's products.

The final rule does allow what the commenter is suggesting—that testing of units within a common family of products be allowed to represent all of the other units within the family. Section 1107.20(a) of the final rule states that samples used for certification must be identical in all material respects to the finished children's product. If, as the commenter has stated, the tested units are identical in all material respects as others within the product family, then the test results can be applied to the other units within the product family.

Section 1107.23(a) describes testing requirements when there has been a material change in a children's product. If a change could adversely affect compliance with the applicable children's product safety rules, then it is considered a "material change," and retesting is required. If the commenter's phrase "does not affect the overall safety of the system" means that the change does not affect compliance with the applicable rules, then the change is not considered a "material change," and no recertification testing is required.

(Comment 61) - Some commenters stated that the requirement to submit a sufficient number of samples of a materially changed product for third party testing before certifying the changes would be costly and would inhibit manufacturers from making continuous product improvements. Ultimately, according to the commenters, this will reduce the safety of children's products.

(Response 61) - Section 14(i)(2)(B)(i) of the CPSA requires children's products to be subject to third party conformity assessment body testing when there has been a material change

in the product's design or manufacturing process. These types of changes may introduce new hazards or may result in the product no longer being in compliance with the applicable children's product safety rules. After a material change to the product, only those applicable product safety rules that could adversely be affected require recertification. The samples selected must be of a sufficient number to provide a high degree of assurance that the test, conducted accurately, demonstrates the ability of the children's product to meet all applicable children's product safety rules.

Regarding continuous product improvements, changes that do not adversely affect compliance to the applicable children's product safety rules are not "material changes" under the final rule and do not require recertification testing. However, manufacturers may wish to consider possible material change testing as part of their product improvement processes.

(Comment 62) - Three commenters characterized the testing requirements resulting from the proposed definition of "material change" as "overly burdensome" and "very unreasonable." The commenters differed in their reasons for arriving at this conclusion. One commenter characterized the proposed rule's material change testing requirements as too "open ended" because of imprecise language. The consequence of this lack of specificity, according to the commenter, is that "either you will always test or you take a big risk. This is completely unfair and unreasonable."

Another commenter expressed concern with the examples in proposed § 1107.23(c). Specifically, the commenter stated that manufacturing process changes, "such as new solvents to clean equipment or a new mold for an accessible metal component part of a children's product pose undue burdens on manufacturers without advancing safety goals." The commenter contended that "to require companies to develop new product specifications for every new

solvent used in a facility or installation of a new mold made to the exact specifications as a prior mold” would require new third party testing, and this could not have been Congress’ intent. The commenter suggested: “it should be left to the consumer product manufacturer to assess whether changes are likely to affect the ability of the particular product to meet a specific standard, ban, rule, or regulation.”

The third commenter stated that the proposed definition is not clear and asked whether “using the same quality level of component part but just the different brand is a material change.” The commenter stated that if third party testing of each such change is necessary, then “it is very unreasonable.”

(Response 62) - The intent of § 1107.23 for children’s products is not to be overly burdensome, but rather, to demonstrate the product’s continued compliance with applicable children’s product safety rules when a change in the product’s design, manufacturing process, or component part sourcing has been made that could adversely affect a previously certified product’s compliance. Because the final rule applies to a variety of products and manufacturing methods, it is impractical to anticipate every type of product change that could occur to all affected products that might adversely affect compliance to an applicable product safety rule and provide specific language. Therefore, the final rule is written using general language to allow manufacturers the flexibility to determine, in each particular circumstance, whether a product change could adversely affect the product’s compliance with an applicable children’s product safety rule. Manufacturers should use their special knowledge of a product’s design, components, and manufacturing processes to differentiate what changes may constitute a “material change,” and require certification testing, as opposed to nonmaterial changes.

After initial certification of a product, a “material change” is a change that “could affect the product’s ability to comply with applicable rules, standards or regulations.” The ability to adversely affect compliance is what distinguishes a “material change” from nonmaterial changes. The final rule acknowledges that a manufacturer has special knowledge of its product design, components and, production processes, and the rule states that a “manufacturer exercising due care knows or should know” when a change is material. For example, a new solvent that does not contain any of the prohibited chemicals (lead and the prohibited phthalates), or a replacement mold shown to be made to the same specifications as a compliant mold, would not be examples of “material changes.”

(Comment 63) - One commenter noted that proposed § 1107.10(b)(2)(ii)(A) would state that, for material changes that only affect product compliance to certain rules, certification may be based on the materially changed component, unless the change affects the finished product. If the change affects the finished product, then the certification must be based on the finished product. (The commenter is referring to proposed § 1107.10(b)(2)(ii)(A) and (C).) The commenter asked, when a disagreement arises, who makes the final determination of whether the material change affects the finished product’s compliance?

(Response 63) - We have reserved subpart B, including the reasonable testing program described in proposed § 1107.10. However, the broader issue presented by this commenter relates to certification testing of units when there has been a material change is applicable to children’s products as well, so we will address this issue with regard to children’s products.

The commenter is correct that when a material change to a product occurs, only product safety rules affected by the material change would require recertification. If the material change solely affects a component part of a children’s product and does not affect the ability of other

component parts or the finished product to comply with applicable children's product safety rules, then § 1107.23(a) allows a manufacturer to base certification on earlier third party certification tests and on third party testing of the changed component part.

With regard to disagreements regarding whether the finished children's product is needed for certification after a material change, a manufacturer must use due care in determining whether testing the finished product or a component part is required. This due care is applied on a per-rule basis. Some rules, such as prohibited phthalate content, can be evaluated on component parts. Other rules, such as the safety standard for cribs, always require the use of the finished product for certification testing. Assuming the disagreement is between the manufacturer and the CPSC regarding whether a finished product is required for certification after a product change, we will decide, based on the available evidence, whether a material change requires samples of the finished product for certification.

b. Product Design

Proposed § 1107.23(b) would state that, for purposes of subpart C, the term "product design" includes all component parts, their composition, and their interaction and functionality when assembled. To determine which children's product safety rules apply to a children's product, a manufacturer should examine the product design for the children's product as received by the consumer. For example, if a children's product has a component part that contains lead or has a sharp edge, but is inaccessible when the product is assembled, then the lead and sharp edge requirements would not be applicable to the finished product. Changes to a product's design may result in a product being subject to additional children's product safety rules. For example, if a wooden button on a children's product is replaced with a plastic button, the wooden button previously excluded from testing for lead content has been replaced with a component part (the

plastic button) that would be subject to testing for compliance with the lead content requirements.

We received no comments on this paragraph. However, on our own initiative, we have revised the second sentence in § 1107.23(b) to state that a manufacturer should examine the product design for the children's product "as received or assembled by the consumer." We inserted the words "or assembled" because some children's product safety rules require the product to be tested in the finished product state in order to assess compliance with the applicable children's product safety rule. For example, assessing compliance with the inaccessibility requirements for the lead requirements mandates testing of the finished product in order to determine whether a component part of the product is accessible. The new language, "or assembled," was added to make it clear to the manufacturer that products must be tested as received or assembled by the consumer in those instances where the product is not received in assembled form.

c. Manufacturing Process

Proposed § 1107.23(c) would state that a material change in the manufacturing process is a change in how the children's product is made that could affect the finished children's product's ability to comply with the applicable children's product safety rules. For each change in the manufacturing process, a manufacturer should exercise due care to determine if compliance to an existing applicable children's product safety rule could be affected or if the change results in a newly applicable children's product safety rule. The following are some examples of a material change to the manufacturing process of a children's product:

- A new technique is used to fasten buttons to a doll's dress that could affect the children's product's ability to comply with the small parts rule;

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- New solvents are used to clean equipment employed in the manufacture of children's products; the new solvents could affect the children's product's ability to comply with the lead content and phthalates requirements; and
- A new mold for an accessible metal component part of a children's product is introduced into the assembly line that could affect the children's product's ability to comply with requirements for sharp edges.

We received no comments on this paragraph and have finalized it without change.

d. Sourcing of Component Parts

Proposed § 1107.23(d) would state that a material change in the sourcing of component parts results when the replacement of one component part of a children's product with another component part could affect compliance with the applicable children's product safety rules. This would include, but would not be limited to, changes in component part composition, component part supplier, or use of a different component part from the same supplier who provided the initial component part.

We received no comments on this paragraph. However, on our own initiative, we have revised the first sentence to replace the phrase "applicable children's product safety rules" with "applicable children's product safety rule." We made this change to avoid creating any misunderstanding of whether a material change results only if multiple children's product safety rules are affected; in other words, a material change can result, even if compliance with only one children's product safety rule is affected.

6. Proposed § 1107.24 - Undue Influence

Proposed § 1107.24(a) would implement the requirement to safeguard against undue influence, pursuant to section 14(i)(2)(B)(iv) of the CPSA, by requiring each manufacturer to

establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body.

a. Procedures to Safeguard Against the Exercise of Undue Influence

Proposed § 1107.24(a) would require the manufacturer to establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity body.

(Comment 64) - Several commenters disagreed with the requirement in proposed § 1107.24(a) that manufacturers must establish procedures to safeguard against the exercise of undue influence on a third party conformity assessment body. One commenter noted that we already require third party conformity assessment bodies to train their staff to detect, avoid, and report undue influence. Another commenter stated that third party testing facilities already have these training programs in place. Two commenters asserted that third party conformity assessment bodies are not likely to be influenced unduly because their accreditation would be withdrawn.

(Response 64) - Section 14(i)(2)(B)(iv) of the CPSA requires us to establish, by rule, protocols and standards for safeguarding against the exercise of undue influence by a manufacturer or private labeler on a third party conformity assessment body. This provision applies to manufacturers and private labelers as opposed to third party conformity assessment bodies. Consequently § 1107.24 of the final rule requires manufacturers of children's products to establish procedures to avoid actions that could undermine the integrity of laboratory test data. We have an interest in ensuring the integrity of laboratory test results used in the certification of children's products.

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In a separate rulemaking, we will address the issue of requiring third party conformity assessment bodies to report undue influence.

(Comment 65) - Some commenters expressed concern regarding foreign manufacturers and the undue influence requirement. One commenter suggested that we will be unable to enforce the undue influence requirement on foreign manufacturers and importers. Another commenter said that the importer of record should not be responsible for undue influence initiated by people not directly employed by the importer of record. The commenter requested confirmation that importers will be responsible for training their employees only, and will not have the responsibility of training the employees of other companies, such as manufacturers, vendors, freight handlers, or laboratories.

(Response 65) - Section 1107.24 of the final rule requires “each manufacturer” to establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. Section 1107.2 of the final rule defines a “manufacturer” as “the parties responsible for certification of a consumer product pursuant to 16 CFR part 1110.” Under 16 CFR part 1110, a foreign manufacturer is not required to certify a finished product; only a domestic manufacturer or the importer of a product made outside the United States is required to issue a finished product certificate. Thus, under § 1107.24, it is a domestic manufacturer or the importer who must establish procedures to safeguard against undue influence.

We agree that an importer is not directly responsible for training employees of other companies. This fact, however, does not absolve the importer issuing a finished product certificate of its duty to exercise due care when relying on test results provided by another company or third party conformity assessment body. A manufacturer or importer who issues a

finished product certificate that is based on test reports from a third party conformity assessment body over whom undue influence has been exercised provides a basis for the CPSC to deem the certificate invalid. We will hold the finished product certifier responsible for exercising due care that component part or finished product manufacturers or suppliers have not exercised undue influence over third party conformity assessment bodies.

(Comment 66) - Two commenters stated that because the term “undue” is undefined, nothing should be construed to prohibit a manufacturer from exercising its rights to challenge third party conformity assessment body test results based upon the manufacturer’s belief that they are inaccurate.

(Response 66) - Section 1107.24 is not intended to preclude a manufacturer from challenging failing test results in appropriate circumstances. If a manufacturer has reason to think a test result received from a third party conformity assessment body is in error, it is appropriate to ask the third party conformity assessment body about the test result. Such inquiry does not constitute undue influence. Additionally, § 1107.20(d) requires a manufacturer to investigate the reasons for a negative certification test result and to take action to address failing test results before a Children’s Product Certificate can be issued. This investigation may involve discussions about the test results with the third party conformity assessment body.

b. Minimum Requirements

Proposed § 1107.24(b) would require the procedures described in § 1107.24(a) to include minimal requirements. Proposed § 1107.24(b)(1) would require safeguards to prevent attempts by the manufacturer to exercise undue influence on a third party conformity assessment body, including a written policy statement from company officials that the exercise of undue influence is not acceptable, and directing that appropriate staff receive annual training on avoiding undue

influence and sign a statement attesting to participation in such training. Proposed § 1107.24(b)(2) would impose a requirement to notify the Commission immediately of any attempt by the manufacturer to hide or exert undue influence over test results. Proposed § 1107.24(b)(3) would impose a requirement to inform employees that allegations of undue influence may be reported confidentially to the Commission and describe to employees the manner in which such a report can be made.

(Comment 67) - Several commenters made remarks about training programs. Two commenters stated that the training program and recordkeeping requirements (proposed § 1107.26(a)(5)) are burdensome and redundant because companies already have requirements to prohibit unethical behavior, such as exerting undue influence over third party conformity assessment body staff. Other commenters described this requirement as excessive and unreasonable. One commenter stated that the requirements for training are vague and urged us to describe what needs to be included. Another commenter raised questions about the content and form of the training, especially whether a written manual would be enough. Another commenter recommended deleting these requirements.

One commenter urged us to delete the requirement for appropriate staff to receive “annual training” on how to avoid undue influence. The commenter felt that an annual training mandate would be unnecessary and impose excessive costs and burdens on manufacturers of children’s products.

(Response 67) - Section 14(i)(2)(B)(iv) of the CPSA requires us to establish protocols and standards, by rule, for safeguarding against the exercise of undue influence on third party conformity assessment bodies by a manufacturer or private labeler. Therefore, we decline the suggestion to delete these requirements from the final rule.

Section 1107.24 of the final rule implements the statutory mandate by requiring manufacturers to establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. The rule does not prescribe the form or content of these programs in order to provide manufacturers flexibility in implementing the requirements. For example, manufacturers may wish to create written manuals and may include this training along with other forms of employee training. Manufacturers must keep records of employee participation in the training to be able to ensure that all relevant staff members receive this training pursuant to § 1107.26(a)(6).

We do agree, however, with the commenter who suggested that an annual training requirement reiterating previously presented procedures can impose costs and burdens the benefits of which are unclear. Thus, we have replaced the proposed requirement for annual training with a requirement for retraining when a substantive change to the rule is made regarding undue influence; this requirement appears as a new § 1107.24(b)(2), and we have renumbered proposed §§ 1107.24(b)(2) and 1107.24(b)(3) as §§ 1107.24(b)(3) and 1107.24(b)(4), respectively, in the final rule. Manufacturers of children's products are free to modify their procedures and conduct retraining as often as they feel it is necessary to institute effectively their policies for safeguarding against the exercise of undue influence.

Additionally, on our own initiative, we have revised § 1107.24(b) of the final rule to make minor editorial or grammatical changes. We have revised § 1107.24(b)(1) to direct that "every appropriate staff member" receive training on how to avoid undue influence. The proposal would state that "appropriate staff receive annual training." By referring to "every appropriate staff member," the final rule clarifies that the emphasis is on training individuals rather than collections of individuals. Additionally, in § 1107.24(b)(4), we have replaced

“Commission” with “CPSC” and replaced “to describe the manner” with “a description of the manner.”

7. Proposed § 1107.25 Remedial Action

Proposed § 1107.25 would require each manufacturer of a children’s product to have a remedial action plan that contains procedures that the manufacturer must follow to investigate and address failing test results.

(Comment 68) - One commenter stated that requiring each manufacturer to have an actual remedial action plan to address failing test results is unnecessary because the remedial action will likely be different, depending upon the situation. Another commenter stated that because they are familiar with how to resolve compliance and quality issues, the preparation of a detailed written remedial action plan is a waste of time, money, resources, and intellect.

(Response 68) - The commenter is correct that, depending on the product and the nature of the test failure, remedial actions may take many different forms. The development of a remedial action plan before production commences could help in the determination of factors, such as lot size or what tracking information to maintain. These factors could help limit the number of production units subject to recall in the event that noncompliant products are introduced into commerce.

However, although it may be efficient and useful to have a formal process (such as the remedial action plan in proposed § 1107.25) to follow after receiving failing test reports, such preformulated plans are not essential, either for certification or for ensuring continued compliance of consumer products. Ultimately, the manufacturer is responsible for ensuring that the product that they make complies with the applicable product safety rules. For some products and types of failing test reports, *ad hoc* methods may be as effective as preestablished plans in

addressing the test failures and ensuring that products are compliant. For these reasons, we have removed the requirements for remedial action plans for children's products from the final rule. We encourage manufacturers who believe that remedial action plans would be advantageous for their product to develop such plans as part of their overall quality assurance system.

(Comment 69) - One commenter appreciated the acknowledgement that a remedial action plan could be a formal standard operating procedure (SOP), along with recordkeeping of each event. The commenter asked whether, when a particular component causes a product to become noncompliant with a rule, and the remedial action eliminates this specific component from the product, would certification have to be repeated. The commenter noted that documentation would be provided that the noncompliant component had been removed and that the product specification was revised. The commenter stated that there would be an SOP that requires a corrective action, along with documentation of the instance of noncompliance, to provide evidence that the product has been corrected and is compliant.

(Response 69) - As noted in our response to Comment 68, we have removed the requirement for a remedial action plan for children's products from the final rule. If a finished product has a noncompliant component part (such as an accessory item), and that item is removed from the finished product, the finished product certifier does not have to repeat certification testing on the newly constituted finished product because the certifier has certification test data demonstrating compliance with all applicable product safety rules for that product. The certifier should make sure that eliminating the noncompliant component part does not affect compliance with another applicable children's product safety rule for the finished product.

(Comment 70) - Several comments addressed the issue of retesting samples. Some commenters noted that often, a testing failure might result from a faulty laboratory test and not from a noncompliant product. The commenters said that the rule should allow retesting in appropriate situations when there is suspicion about the manner in which a sample was handled or processed, or the certifier is challenging the results of a third party test.

One commenter asserted that if the manufacturer documents and supports any assertions related to the faulty test and the product's compliance, there should be no need for remedial action. Another commenter suggested that the implication in the rule is that any test failure, no matter how trivial, would trigger the need for remedial action, which would be costly. The commenter suggested that establishing tolerances for test results is necessary to reduce testing costs, as well as the burden of remedial actions, and at the same time ensure product safety. The commenter added that children's products are not so consistent that every test produces the same test result. The commenter asserted that retesting is a valid means of responding to a failing test result. Banning retesting out of fear that some unscrupulous parties will attempt to test the product into compliance will create severe problems.

(Response 70) – We have removed the requirement for a remedial action plan for children's products from the final rule. However, we recognize that an error or failure in the testing of a sample may lead to a failing test result, and therefore, investigating the test method and test execution is a legitimate avenue of investigation in those instances. Such an investigation can include examining the test procedures, sample preparation steps, equipment calibration, and other factors, in addition to tests on samples of the product as part of the investigation, which may affect test results, but are not indicative of a noncompliant product.

Additionally, § 1107.20(d) of the final rule states:

If a product sample fails certification testing to the applicable children's product safety rule(s), even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure. 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.

While the final rule no longer refers to remedial action plans, a manufacture still "must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure." Retesting a product without investigating why the test yielded failing results, and taking whatever action addresses the situation (for example, calibrating the testing machine before retesting, or correcting a manufacturing problem) to achieve passing results, is not acceptable for certification purposes because the certifier would not have a high degree of assurance that the products produced will be compliant with the applicable product safety rules.

Retesting should not be conducted to "shop" for passing test results or to keep testing the product until a sample finally passes (and disregarding all other tests that suggest the product is not in compliance).

With regard to establishing tolerances for test results, the acceptable values for test results are established in each rule, ban, regulation, or standard and are beyond the scope of this rule.

(Comment 71) - One commenter stated that some standards, such as the standard for the surface flammability of carpets and rugs (16 CFR part 1630), have alternative requirements for products that fail tests. The commenter suggested modifying the language to refer to a product that does not pass the applicable product safety standard, rather than a product that "fails" a test.

(Response 71) - In 16 CFR part 1630, the standard allows for a single failure in eight tests. Because there is an allowance in the standard for a failing test result, we would view such a product as compliant with the standard.

8. Proposed § 1107.26 Recordkeeping

a. The Records to Be Kept

Proposed § 1107.26(a) would require a children's product manufacturer to maintain records pertaining to:

- The Children's Product Certificate for each product (proposed § 1107.26(a)(1));
- Each third party certification test (proposed § 1107.26(a)(2));
- The periodic test plan and periodic test results (proposed § 1107.26(a)(3));
- Descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, and the certification tests run and the test values (proposed § 1107.26(a)(4));
- Undue influence procedures (proposed § 1107.26(a)(5)); and
- All remedial actions taken following a failing test result (proposed § 1107.26(a)(6)).

We did not receive any comments directly addressing proposed § 1107.26(a). However, on our own initiative, or to complement other changes in the final rule, we have revised § 1107.26(a) as follows:

- In § 1107.26(a)(1), we have changed "Records of the children's product certificate" to "A copy of the Children's Product Certificate." This change is intended to simplify the language in the codified text and use a consistent style throughout part 1107 when referring to the Children's Product Certificate.
- We have finalized § 1107.26(a)(2) without change.
- In § 1107.26(a)(3), we have revised the recordkeeping elements to reflect changes to the periodic testing provision at § 1107.21. Thus, the final rule requires records of:

(1) the periodic test plan and periodic test results; (2) a production testing plan, production test results, and periodic test results; or (3) testing results of tests

conducted by a testing laboratory accredited to ISO/IEC 17025:2005 and periodic test results.

- We have reserved § 1107.26(a)(4). We intend to place any recordkeeping requirement associated with the testing of “representative samples” at § 1107.26(a)(4). As we stated earlier in part II.D.4 of this document, the final rule removes § 1107.22 because H.R. 2715 amended the CPSA to change “random samples” to “representative samples.”
- We have renumbered proposed § 1107.26(a)(4) as § 1107.26(a)(5), and we have finalized it without change.
- We have renumbered proposed § 1107.26(a)(5) as § 1107.26(a)(6), and we have finalized it without change.
- We have deleted proposed § 1107.26(a)(6), which would pertain to records of all remedial actions. We have deleted this provision from the recordkeeping requirements because the final rule does not establish remedial action requirements for children’s products.

b. The Location Where Records Are to Be Kept, the Recordkeeping Period, and the Records’ Availability in the English Language

Proposed § 1107.26(b) would require a manufacturer to maintain the records specified in subpart C at the location within the United States set forth in 16 CFR 1110.11(d) or, if the records are not maintained at the custodian’s address, at a location within the United States specified by the custodian. The manufacturer would be required to make these records available, either in hard copy or electronically, for inspection by the CPSC, upon request.

Proposed § 1107.26(c) also would require a manufacturer to maintain records (except for test records) for as long as the product is in production or imported by the manufacturer, plus five years. Test records would be required to be maintained for five years. All records would be required to be available in the English language.

(Comment 72) - One commenter expressed concern about the recordkeeping requirements in proposed § 1107.10(b)(5) and asked for clarification of the phrase “for as long as the product is in production or imported.” The commenter noted that the requirements would lead to a massive undertaking for any manufacturer or importer, especially if all of the records must be maintained within the United States.

Another commenter stated that we should clarify the relationship between the requirement to maintain records and the proposed rule’s treatment of material changes requiring recertification, and thus, effectively creating a new product. To simplify the recordkeeping requirements, the commenter asked that the recordkeeping requirements apply “for as long as the product, *without a material change*, is in production or imported by the manufacturer plus five years” (emphasis in original). Otherwise, the commenter stated, manufacturers of long-running products would have to maintain records in perpetuity, which would increase costs without assisting safety or compliance.

(Response 72) – Although the final rule reserves subpart B (which includes proposed § 1107.10(b)(5)), the issues raised by the commenters are applicable to the recordkeeping requirement for children’s products, so we address this issue here for children’s products.

We agree that the burden of maintaining records for the life of a product, plus five years, could be unduly burdensome and difficult to implement, in cases where products undergo changes over time. Moreover, having a different time period for the retention of test reports

versus other records may be confusing. Accordingly, we have revised the recordkeeping provision, such that all records must be maintained for at least five years from the date of their creation. If a product does not comply with an applicable children's product safety rule in a significant way, it is likely that the noncompliant aspect of the product would become apparent within the 5-year period. This change should result in less confusion for the regulated community regarding how long records for a particular product must be maintained.

Additionally, on our own initiative, we have reorganized proposed § 1107.26(b) and (c), by combining them into § 1107.26(b) of the final rule. We describe other changes in § 1107.26 immediately below.

(Comment 73) - Several commenters expressed concern about the requirement that records be maintained in English. Some commenters stated that we should allow records to be kept in the local language and only require translation into English by the manufacturer or importer when we request documentation. One commenter noted that the proposed rule will require millions of test reports and records to be created and maintained in English, even though only a small fraction of a percent of these test reports will ever be reviewed by the CPSC or other third parties. The commenter maintained that this would be very expensive for the manufacturer because they must find and hire English-speaking technicians to perform the testing.

The commenter also contended that this requirement could be potentially hazardous. The commenter posed this example:

For example, a quality assurance technician in Vietnam may be excellent at maintaining the quality of a product, and she may even have a passable grasp of English, but her English skills may not be sufficient to communicate precise technical findings in English. If she is nonetheless required to record her findings in English, then there is a risk the test results will be transcribed, described and maintained inaccurately. Thus, we ask that the Commission reconsider this English-only requirement in the proposed rule.

Another commenter asserted that a method for making documents available in English in the United States would need to be created to comply with the rule. The commenter contended that the requirement to have English language documents available within the United States does not offer additional confidence in product safety for U.S. consumers. Alternatively, the commenter suggested that a 3-year stay of the requirement that documents be maintained in English would allow a transition period to establish and implement appropriate infrastructure and processes for expanded recordkeeping.

(Response 73) - We agree that it would be burdensome in many cases for all records to be maintained in English. Therefore, § 1107.26(b) in the final rule allows records to be maintained in languages other than English, if the records in the original language can be provided immediately by the manufacturer to the CPSC, and if an accurate English translation can be provided within 48 hours, or within such longer period of time, as may be negotiated with CPSC staff. Given this change to the final rule, we decline to adopt the suggestion that a 3-year stay of enforcement be implemented for this part of the rule.

(Comment 74) - Many commenters expressed concern about the requirement in proposed § 1107.26(b) that all records be maintained in the United States. Several commenters suggested that instead of requiring manufacturers to maintain records at a location within the United States, we should allow the records to be maintained outside the United States, so long as the records can be accessed from a location within the United States that is specified on the certificate. Some commenters noted that this requirement would be a burdensome and massive undertaking. One commenter did not believe that storing foreign manufacturing documents in the United States for every regulated product increases product safety. The commenter noted that these documents could be stored in their existing location and be submitted to the CPSC, upon request.

Alternatively, the commenter suggested that a 3-year stay of the requirement that documents be maintained in the United States would allow a transition period to establish and implement appropriate infrastructure and processes for expanded recordkeeping.

Another commenter noted that ISO 9001, *Quality management systems – Requirements*, requires manufacturers to maintain these types of records at the factory where a product subject to certification is manufactured. Rather than requiring foreign manufacturers to maintain duplicate records in the United States, the commenter suggested that the final rule should harmonize CPSC requirements with ISO's, and require records to be made available to us for inspection, either in hard copy or electronically, through the U.S. subsidiary or other U.S. corporate entity, within a reasonable time after the CPSC requests them, pursuant to section 16(b) of the Consumer Product Safety Act.

(Response 74) - We agree that it may be burdensome and duplicative in many cases to maintain all records in the United States. To reduce this burden and still maintain prompt access to records when needed, § 1107.26(b) of the final rule no longer requires records to be maintained in the United States. However, all records must be made available, either in hard copy or electronically, such as through an Internet website, for inspection by the CPSC, upon request. Because the change eliminates the requirement that records be kept in the United States, we decline to adopt the suggestion of a 3-year stay of enforcement of this part of the rule.

Regarding harmonization with the requirements of ISO 9001, the commenter did not specify which requirements in ISO 9001 should be harmonized. However, eliminating the requirement that records be maintained at a location within the United States would be consistent with sections 4.2.3.d of ISO 9001 (to ensure that relevant versions of applicable documents are available at points of use), and section 4.2.3.g of ISO 9001 (to prevent the unintended use of

obsolete documents, and to apply suitable identification to them if they are retained for any purpose) of ISO 9001.

(Comment 75) - One commenter stated that some of the required recordkeeping is “redundant and unnecessarily duplicative,” such as production testing plans for multiple factories. Fees for outsourcing these services could be significant and burdensome to many small businesses, the commenter asserted.

(Response 75) – Section 1107.21(c)(2) of the final rule sets forth the option to implement a production testing plan to increase the maximum periodic test interval, and § 1107.21(c)(2)(ii) of the final rule requires that each manufacturing site conduct separate production testing because the location at which a product is manufactured could have a material effect on the product’s ability to comply with the applicable rules. Factors such as power quality, climate, personnel, and factory equipment could materially affect the manufacture of a product. Because it cannot be assumed that units of the same product manufactured in more than one location are identical in all material respects, the finished product certifier must conduct separate production testing for the product for each manufacturing site. We have taken other steps to reduce the recordkeeping burden, such as not requiring that records be kept in the United States, and we are eliminating the requirement that all records must be maintained in English.

(Comment 76) - One commenter noted that companies have established processes and formats and, in many cases, invested in information technology solutions to prepare and transmit these certificates in accordance with the law. The commenter added: “Retailers are relying upon such certificates as they can with the benefit of reduced liability under section 19 of the CPSA” as evidence that the products comply with all the applicable product safety rules. The commenter stated that we need to clarify that the form of delivery of title, in and of itself, should

not require additional testing, documentation, and certification. The commenter also asked us to clarify that retailers can rely upon domestically located supplier certifications without duplication of testing and certification requirements.

(Response 76) - A certificate must accompany the product, as specified in 16 CFR part 1110. Certificates can be in paper or electronic form, as described by the commenter. The commenter is correct that the issuance of a Children's Product Certificate means that the children's product has passed its certification tests. If the commenter is referring to additional third party tests requested by retailers after the issuance of a certificate, we emphasize, as we did in the preamble to the proposed rule, that retailers and sellers of children's products can rely on certificates provided by product certifiers without having to conduct additional testing, if those certificates are based on testing conducted by a CPSC-accepted third party conformity assessment body.

(Comment 77) - One commenter stated that the proposed recordkeeping requirements will have the largest immediate impact to the retail industry. The commenter stated that to meet these provisions, a process to centrally maintain records for an estimated 300,000 items per year would need to be created. The number of pages of documentation covering a portion of products for one large general merchandise retailer acting as importer of record, would range from a low of 375,000,000 pages to more than 1,000,000,000 pages per year. The commenter's estimate was based upon the following:

- Full product specification (150–200 pages);
- Certification testing (30–100 pages);
- Production testing plan (inspection records, testing documents, and production plans quality control documents) (1,000–3,000 pages); and
- Periodic testing (50–200 pages).

This estimate did not include records of remedial action, if necessary.

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Another commenter stated that the standards of recordkeeping outlined in the proposed rule are clear and should not present an unreasonable burden on manufacturers or importers. The commenter asserted that any responsible firm would maintain these records even without the rule, and they further asserted that establishing a reasonable baseline for product safety recordkeeping is crucial to enforcement.

(Response 77) – We have revised the final rule to reduce costs associated with recordkeeping requirements, such as reducing and simplifying the record retention period to five years from the date of creation for all records, eliminating the requirement that records must be maintained in English, and eliminating the requirement that records must be maintained in the United States. Moreover, removal of the remedial action plan requirement for children’s products should further reduce the recordkeeping burden for manufacturers.

Even with these changes, the burden associated with the rule’s recordkeeping requirements will vary among manufacturers or importers. As the commenters indicate, some manufacturers will consider the burden to be significant, whereas others will feel that the recordkeeping requirements are comparable to those at “any responsible firm.” The recordkeeping burden could be fairly heavy for some products and relatively light for others, depending upon the complexity of the product, the number of product safety rules that are applicable to the product, and the amount of testing required. However, as stated in the preamble to the proposed rule (75 FR at 28360), documentation and recordkeeping are required to establish the identity of the product and to demonstrate that the product complies with the applicable safety rules, not only when it is certified, but also on a continuing basis after certification.

The final rule gives manufacturers and importers the flexibility to maintain records. The final rule does not require that the records be maintained in a specific CPSC format. While the final rule specifies what records or information must be maintained, a manufacturer may maintain the records—as the commenter suggested—within their own recordkeeping systems, if those systems meet the traceability requirements and ensure that products are certified properly before they enter into commerce.

(Comment 78) - One commenter stated that manufacturers of children's furniture cannot provide any data on the cost of the recordkeeping requirements because they do not know yet the storage capacity that will be required to comply with the rule. Furniture manufacturers of non-children's products have reported that the cost of creating the system to collect their data on 16 CFR part 1303 compliance was approximately \$100,000, and the cost of records maintenance was in the range of \$30,000 to \$50,000 per year. Based on this, furniture manufacturers of children's products are certain that it will cost them in excess of \$100,000 to build and program such a system. These furniture companies will require additional staff to maintain and update the system, and that will require the expenditure of at least \$30,00 to \$50,000 a year, per person.

(Response 78) - We acknowledge that there will be costs for tracking the data and maintaining the records, which could involve the development of software for tracking and managing the data and hiring additional staff. However, the final rule's recordkeeping requirements give manufacturers flexibility in determining how to meet them. Further, we have revised the final rule to reduce costs associated with recordkeeping requirements, such as reducing and simplifying the record retention period to five years from the date of creation for all records, eliminating the requirement that records must be maintained in English, and eliminating the requirement that records must be maintained in the United States.

(Comment 79) - One commenter stated that as long as the manufacturer can use existing documentation, then there should not be an undue burden on the regulated community to comply with third party testing requirements for children's products. However, the commenter noted that if we intend to require that the manufacturer maintain documentation in a different format, then there will be a cost associated with maintaining this information.

(Response 79) – The final rule does not require manufacturers to develop codes, numbering systems, or special data formats. A manufacturer is free to use any format, provided that the required information is available to the CPSC, when requested.

(Comment 80) - One commenter objected to the requirement that records must be maintained for five years. The commenter pointed out that the larger suppliers to the U.S. market, including chain stores, divide an order and ship separately to different states. Without giving details, the commenter implied that this would make the requirement to keep all required records for five years a heavy burden on manufacturers.

(Response 80) - This comment is from a trade association for a foreign manufacturer of children's products that may have misinterpreted the proposed rule. The proposed rule would require test records to be maintained for five years; other records would be maintained for as long as the product was in production or imported (without a material change), plus five years. In any event, a foreign manufacturer has no obligation to keep the records specified under § 1107.26, unless it agrees contractually to maintain the records on behalf of the importer. Even under these circumstances, only the importer has the obligation to keep the records. The importer, as the certifier, is responsible for maintaining the records or having another party maintain the records on its behalf. As for the retailer in the distribution chain, they are not required to keep the records unless they are also the importer. An importer's obligation to

maintain the records for the product is independent of how many different retailers distribute the product. Regarding the burden of keeping records for five years, the 5-year record retention requirement was selected to be consistent with the 5-year statute of limitations in 28 U.S.C. § 2462. However, this requirement is not intended to supersede record retention times that are specified in existing regulations.

E. Proposed Subpart D - Consumer Product Labeling Program

1. Introduction

Proposed subpart D, consisting of one section, would implement the label provision at section 14(i)(2)(A) of the CPSA. Section 14(i)(2)(A) of the CPSA requires the Commission to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements in section 14(a) of the CPSA.

2. General Requirements

Proposed § 1107.40(a) would allow manufacturers and private labelers of a consumer product to indicate, by a uniform label on or provided with the product, that the product complies with any consumer product safety rule under the CPSA, or with any similar rule, ban, standard or regulation under any other act enforced by the CPSC.

(Comment 81) - One commenter contended that allowing manufacturers to place an optional label on their products that states: “Meets CPSC Safety Requirements,” could give manufacturers who use such a label an unfair market advantage over manufacturers who choose not to include the label. The commenter stated that some manufacturers will not use the label because it will increase their product’s cost. The commenter suggested that some consumers may choose the labeled product based upon a false assumption that a product without the label is

somehow less safe. The commenter stated that some manufacturers will use the label as a misleading marketing tool or even alter the font type or size of the label for marketing purposes.

(Response 81) - Section 14(i)(2)(A) of the CPSA requires us to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements of section 14(a) of the CPSA. Section 1107.30 of the final rule (formerly proposed § 1107.40) implements this requirement. Use of the labeling program is at the discretion of the manufacturer or private labeler, and the manufacturer or private labeler must determine costs versus benefits for their particular products. The label specifications are designed to avoid giving consumers the false impression that the product is CPSC-tested, -approved, or -endorsed. Section 1107.30(d) of the final rule prohibits manufacturers or private labelers from implying, through manipulation of the font type, font size, or other means that the CPSC has tested, approved, or endorsed the product.

Other than renumbering this section, we have finalized paragraph (a) without change.

3. Label Specifications

Proposed § 1107.40(b) would require the label to be printed in bold typeface, using an Arial font of not less than 12 points, be visible and legible, and state: “**Meets CPSC Safety Requirements.**”

(Comment 82) - One commenter stated that the final rule should not specify the features that must be used for the optional label indicating that a product meets the CPSC’s safety requirements. The commenter did not think we should specify features such as size, color, font, or location because these will depend on the product. The commenter noted that there is the possibility that the specified text type and size will not be compatible with the different internal systems developed by retailers and manufacturers to meet the needs of the affected product. The

commenter said that to specify any requirements other than what works with a firm's internal systems would have absolutely no benefit at all.

Another commenter expressed concern with the font size being "no less than 12 points" because that could be a problem on some small containers. The commenter said that we should use instead, the font size requirements in the Federal Hazardous Substances Act.

One commenter agreed with our approach of labeling products to indicate compliance with the rules. The commenter recommended that the CPSC's labeling program include guidelines for the type, style, color, and font of such labels and should consider use of symbols or a mark, rather than words or initials, as proposed. Symbols also would help overcome language barriers for communicating compliance. The commenter said that the guidelines should allow variations in the label's size to accommodate products of different physical dimensions, but the general appearance of the label must remain consistent. They recommended that the labels appear as a permanent mark on the product packaging, as well as on the product itself.

(Response 82) - We agree with the commenters that specifying particular fonts and minimum sizes for the label could make adding a label difficult for some products. Depending on the product's characteristics, such as size, surface finish, and the presence of a smooth, flat area for the label, a label with a minimum font size may be difficult to apply. Therefore, § 1107.30(b) of the final rule (renumbered from proposed § 1107.40(b)) specifies that the label must be visible and legible and does not specify a font and a minimum size. This change will give manufacturers the flexibility to implement a labeling system tailored to their product.

The text of the message on the label remains: "Meets CPSC Safety Requirements." The label may be affixed to the product or provided with the product to provide flexibility for the

manufacturer or private labeler in their implementation of the labeling requirements. Because the labeling requirements will apply to all consumer products covered by an applicable product safety rule, it would be impossible to design a label that would work with every firm's internal system.

Regarding the labeling requirements in the Federal Hazardous Substances Act (FHSA), the commenter did not specify which labeling requirements should be used. The general labeling requirements for labeling certain toys and games in section 24(d) of the FHSA states that the label shall be displayed in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter. The changes to the final rule are consistent with the FHSA in this regard.

The final rule does not allow for the use of a symbol or mark because a symbol or mark might be misinterpreted as a CPSC certification mark or CPSC endorsement of the product. Additionally, the recommendation that a label be affixed to the product and its packaging may reduce the flexibility of manufacturers who choose to use the labeling program.

In reviewing the comments submitted regarding labels and the provisions of subpart D of the proposed rule, we noticed that proposed § 1107.40(d) (renumbered as § 1107.30(d) in the final rule) could be misunderstood to imply that an alternative label may be used in place of the label specified in proposed § 1107.40(b). We have revised § 1107.30(d) in the final rule to state that other labels, in addition to the label specified in § 1107.30(b), may be placed on the product, as long as the additional labels do not change the meaning of the label specified in § 1107.30(b).

(Comment 83) - One commenter argued that the requirement to provide only the statement: "Meets CPSC Safety Requirements," is not adequate for indicating compliance. The commenter asserted that a registered certification mark is the only way to indicate adequately full

compliance, and they noted further that the use of a registered certification mark is also used as a tool to address counterfeiting activities.

(Response 83) - The consumer product labeling program described in proposed § 1107.40 (renumbered as § 1107.30 in the final rule) is voluntary on the part of a manufacturer, importer, or private labeler. Section 14(a) of the CPSA requires the manufacturer, importer, and private labeler to issue a General Conformity Certificate or a Children's Product Certificate for any product covered by an applicable product safety rule, regardless of whether a manufacturer elects to label their product under § 1107.30. A registered certification mark authorized by a certification body for a manufacturer to include with the product does not contain the information required by a certificate, as specified in 16 CFR part 1110, and it cannot be used in place of the certificate. Thus, we disagree with the commenter that certification marks are the only way to indicate full compliance. Other products, such as mattress sets, indicate compliance (in this case to 16 CFR part 1633) without the use of certification marks. Furthermore, we are aware of multiple instances of counterfeit certification marks on consumer products. As a result, we decline to revise the rule as suggested by the commenter.

4. Conditions Under Which a Consumer Product May Bear the Label

Proposed § 1107.40(c) would allow a consumer product to bear the label if the manufacturer or private labeler has certified, pursuant to section 14 of the CPSA, that the consumer product complies with all applicable consumer product safety rules under the CPSA and with all rules, bans, standards, or regulations applicable to the product under any other act enforced by the Consumer Product Safety Commission.

We received no comments on this paragraph and, other than renumbering § 1107.40 as § 1107.30, we have finalized it without change.

5. Use of Other Labels

Proposed § 1107.40(d) would allow a manufacturer or private labeler to use another label on the consumer product, as long as such label does not alter or mislead consumers as to the meaning of the label described in proposed § 1107.40(b). A manufacturer or private labeler would not be allowed to imply that the CPSC has tested, approved, or endorsed the product.

In reviewing the comments submitted regarding labels and proposed subpart D, we noticed that proposed § 1107.40(d) (renumbered as § 1107.30(d) in the final rule) could be misunderstood to imply that an alternative label may be used in place of the label specified in § 1107.40(b). Therefore, on our own initiative, we have revised § 1107.30(d) to state that other labels, in addition to the label specified in § 1107.30(b), may be placed on the product, as long as the additional labels do not change the meaning of the label specified in § 1107.30(b).

F. Other Comments Received

Several commenters raised questions on whether the final rule should contain “safe harbors” (where certain actions are considered to be complying with a particular requirement), and questioned the rule’s effective date. Other commenters raised issues that were outside the scope of the rulemaking, such as whether a particular product was a “children’s” product” or raised concerns on matters pertaining to the accreditation of third party conformity assessment bodies.

(Comment 84) - Two commenters suggested that the rule clearly should allow for recognition of “safe harbors” based upon adherence to national standards for good manufacturing practices, international ISO standards governing GMP, and industry-based GMP category-specific guidelines that manufacturers may use as evidence of their good faith commitment to attaining a high degree of assurance that their products meet or exceed applicable federal safety

standards. The commenters noted that we have recognized that such programs may be considered evidence of meeting the requirements under the proposed rule but noted as well that we have not yet recognized our authority to provide for such safe harbors, claiming the CPSIA did not make such specific provision (75 FR at 28339). According to the commenters, specific statutory authority is not a precondition to an agency acting under its rulemaking and enforcement authority to recognize such safe harbors. The commenters contended that we should provide such recognition.

(Response 84) - As we noted previously in the preamble to the proposed rule (75 FR at 28339), section 14 of the CPSA does not contain a safe harbor exception, nor does it establish any criteria by which the Commission could recognize testing programs for purposes of a safe harbor.

The final rule does not contain a safe harbor provision based upon a manufacturer's participation in a voluntary or industry-sponsored program; nor have we recognized any such program to indicate compliance with the final rule. We note that ISO standards for good manufacturing practices are generally industry-specific in areas such as cosmetics, pharmaceutical operations, food handling, and medical devices, products largely beyond the CPSC's jurisdiction. It is unlikely that any one GMP standard would be deemed workable or acceptable for all manufacturing methods for children's products.

(Comment 85) - One commenter noted that the preamble to the proposed rule refers to a 95 percent statistical significance level as constituting a "high degree" of assurance. The commenter asked whether the CPSC would consider 95 percent probability or confidence level to be a safe harbor level.

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(Response 85) - In the preamble to the proposed rule, the 95 percent probability level was discussed as an alternative definition of a “high degree of assurance” that we considered and subsequently rejected. We “decided against defining ‘high degree of assurance’ with respect to a 95 percent probability or confidence level (or any other level of statistical confidence) because there may be difficulty in applying the statistical methods to all manufacturing processes” (75 FR at 28344). Therefore, we do not consider a 95 percent confidence level to constitute automatically a “high degree of assurance”; nor do we consider it to constitute a safe harbor level for purposes of compliance with the final rule. Determining what constitutes a “high degree of assurance” varies, depending upon the product manufactured and the manufacturing processes used. The determination must be made by individual manufacturers, based upon their knowledge of their products and manufacturing processes.

(Comment 86) - One commenter noted that, for most major retailers, the creation of a product begins with a design specification that originates 12 months or more prior to manufacture or import into the United States. The commenter said that retroactively applying all the requirements of the final rule would be unduly burdensome. The commenter added that manufacturers of compliant products that are currently on retailers’ shelves may not have any or all of the components of a reasonable testing program. Generating this documentation “after the fact” is simply not possible. The commenter asked that the rule apply only to products whose development begins 180 days on or after adoption. Accordingly, products would begin to be certified based upon a reasonable testing program with all accompanying documentation approximately 18 months after adoption of the final rule.

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One commenter suggested that we set the effective date at one year from the publication of the final rule because that is how long it would take their industry to change its manufacturing processes to be able to comply with the requirements of a reasonable testing program.

Another commenter said that they simply do not have the staff or the resources to get the third party testing done on all of the products that could fall within the definition of “children’s product” and record it in a data collection and storage system (yet to be designed and implemented) within the 180-day timeframe mentioned in the preamble to the proposed rule. That commenter suggested that they needed at least 365 days, and therefore, they requested that we extend the stay of enforcement until February 2012.

(Response 86) - The preamble to the proposed rule indicated that a final rule would become effective 180 days after its date of publication in the *Federal Register* (75 FR at 28361). However, on August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 revised the CPSIA in several different ways, and it also affected section 14(i)(2)(B)(ii) of the CPSA. H.R. 2715 also created a new section 14(i)(3)(B) of the CPSA, which requires us, no later than one year after H.R. 2715’s date of enactment, to review the public comments (on opportunities to reduce the costs of third party testing requirements), and it directs us to “prescribe new or revised third party testing regulations,” if we determine that “such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.” Consequently, we have finalized those provisions that H.R. 2715 did not affect directly. We also have decided to make the final rule effective 15 months after date of publication in the *Federal Register* so that parties can begin taking steps to develop internal processes, such as recordkeeping, and so that we, and interested parties, can consider how H.R. 2715 interacts with the final rule.

We note that the effective date for the final rule is not calculated based on when development of a product begins, but rather, is calculated based on the date the product is manufactured. The requirements of the final rule apply only to products manufactured on or after the effective date of the final rule, and they do not apply retroactively to products already manufactured and certified.

(Comment 87) - One commenter expressed concern that the rule has the potential to multiply the current volume of product testing by several fold and that third party conformity assessment bodies will be unable to provide accurately and efficiently the increased testing capacity needed by retailers/importers to comply with this rule. The commenter asserted that currently, without the rule being in effect, retailers already are experiencing delayed turnarounds in product testing, and it is not uncommon to have special requests denied due to the current backlog in testing.

The commenter also expressed concern that the increased testing demand may affect laboratory execution, potentially resulting in incorrect laboratory results, which may cause compliant product to be lost, or may allow noncompliant product to enter commerce. The commenter said that if the capacity of the third party test conformity assessment bodies is exceeded, retailers' and manufacturers' ability to meet the rule's effective date could be jeopardized. The commenter asked that the third party conformity assessment body capacity issue be taken into consideration when establishing the effective date of the final rule.

(Response 87) – We are aware that implementation of section 14(a)(2) of the CPSA potentially could result in insufficient testing capacity at CPSC-accepted third party conformity assessment bodies. We note that in the majority of the notices of requirements that have issued since 2008, there have been very few claims of insufficient capacity, and when such issues have

arisen, we have taken steps to address the matter (see 75 FR 34360, June 17, 2010). We intend to address any capacity issues that arise after the final rule becomes effective.

(Comment 88) - One commenter objected to the application of the regulation to some juvenile furniture. The commenter stated that it is difficult to estimate the cost of testing for children's products when we have not yet decided on the definition of a children's product. Another commenter generally supported the idea of third party testing of children's products but was unclear about what products are included in the category of children's products.

(Response 88) – The final rule does not address what products fall within the definition of “children's products”; and therefore, the comment is outside the scope of the rule. However, after the comment was submitted, we issued an interpretative rule (now codified at 16 CFR part 1200) regarding the definition of children's product, providing the guidance the commenter is seeking.

(Comment 89) - One commenter wondered whether a manufacturer or importer of a children's product subject to a children's product safety rule for which no third party testing conformity assessment bodies have been accredited by CPSC, is required to certify the product based on such testing. The commenter also wondered whether an importer is prohibited from importing the children's product until we accredit third party testing conformity assessment bodies for the children's product safety rule.

(Response 89) – The final rule does not address the issuance of notices of requirements for accreditation of third party conformity assessment bodies; and therefore, the comment is outside the scope of the rule. However, if there are no CPSC-accepted third party conformity assessment bodies whose scope includes a rule applicable to a children's product, those products are not prohibited from being imported. The children's products must still comply with the

requirements of the applicable children's product safety rules. For example, if a rule established a limit of X for a particular chemical in children's products, but there were no CPSC-accepted third party conformity assessment bodies to test for X, the children's product would still be subject to the limit of X for that particular chemical; the absence of a CPSC-accepted third party conformity assessment body would not mean that the limit no longer applies.

(Comment 90) - One commenter recommended that conformity assessment bodies should: (a) comply with the standards in ISO/IEC Guide 65, or (b) in fulfillment of the requirements in ISO/IEC 17025:2005, during each audit review and resubmission of CPSC Form 223, demonstrate independence from “. . . financial and other pressures and influences that may adversely affect the quality of their work . . .”; the commenter also suggested requirements for audits of conformity assessment bodies.

Another commenter expressed ongoing concern over the distinct possibility that accredited testing organizations, especially “firewalled” and “government laboratories,” could be subject to influence and threats to impartiality by outside or related interests. The commenter expressed concern that the new audit procedures stated that all types of third party conformity assessment bodies: independent, firewalled suppliers, and government-owned or -controlled would be treated the same and were all called third party conformity assessment bodies. The commenter stated that these different types of conformity assessment bodies have different modes of operation, and they need to be treated differently by us in both the auditing and accreditation requirements. The commenter suggested that we require applicants to submit the evidence used to validate the fulfillment of ISO/IEC 17025:2005 requirements for the laboratory to “have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may

adversely affect the quality of their work,” not only as part of their application to the CPSC, but also on an ongoing basis, as part of each audit review and resubmission of CPSC Form 223.

Two commenters stated that the proposed rule fails to differentiate between firewalled and independent conformity assessment bodies. According to one commenter, a manufacturer can submit samples to its firewalled conformity assessment body even if its reasonable testing program fails to provide a high degree of assurance of compliance with the applicable children’s product safety rules. The commenter sought clarification of the provision that a manufacturer of children’s products with a reasonable testing program may submit samples to its firewalled conformity assessment body every two years.

(Response 90) – The final rule does not address the requirements for conformity assessment bodies; and therefore, the comments are outside the scope of the rule. Conformity assessment body requirements will be addressed in a separate rulemaking. Further, section 14(f) of the CPSA defines third party, firewalled, and governmental conformity assessment bodies.

(Comment 91) - Two commenters recommended that we consider a number of steps to ensure that third party conformity assessment bodies are protected against undue influence. These included the following: (1) adopting the requirements in Clause 4.2 of the ISO/IEC Guide 65; (2) using the OSHA NRTL program as a model for laboratory accreditation; and (3) requiring all laboratories applying to the Commission to submit evidence that they fulfilled ISO/IEC 17025:2005 section 4.1.5 b. One commenter made the recommendation for “firewalled” conformity assessment bodies. Another commenter would require annual reassessments of third party conformity assessment bodies.

(Response 91) – The final rule does not address undue influence requirements for third party conformity assessment bodies; and therefore, the comments are outside the scope of this

rule. This rule establishes the requirements for manufacturers to safeguard against the exercise of undue influence on third party conformity assessment bodies.

(Comment 92) - Several commenters submitted comments on the concurrent rulemaking for component part testing in proposed 16 CFR part 1109.

(Response 92) – The final rule does not establish the requirements for component part testing; and therefore, these comments are outside the scope of this rule. We have, instead, considered those comments in that rulemaking. (See *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)).

(Comment 93) - One commenter opined that an existing third party certification system under the OSHA NRTL program, in conjunction with testing being carried out in testing facilities accredited to ISO/IEC 17025, is the preferred method for product certification for the CPSC. The commenter recommended that we consider a similar program or an accredited certification program that meets the requirements of ISO/IEC Guide 65 and ISO/IEC Guide 67.

(Response 93) – The final rule does not address certification systems or accreditation, such as ISO/IEC Guides 65 and 67; and therefore, the comment is outside the scope of this rule.

(Comment 94) - Several commenters asked us to exempt silk from 16 CFR part 1610. They argued that the regulation exempts plain surface fabrics weighing at least 2.6 ounces per square yard and fabrics made from acrylic, modacrylic, nylon, olefin, polyester, and wool, but not silk. The commenters stated that silk’s reaction to fire is comparable to wool and better than the synthetics that are exempted.

(Response 94) – The final rule does not address 16 CFR part 1610; and therefore, the comments are outside the scope of this rule.

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(Comment 95) - One commenter noted that heavy element and phthalates testing use some chemicals. The commenter stated that, with increased testing, there will be more chemical waste, which may not be desirable.

(Response 95) – The final rule does not address testing methods for specific substances; and therefore, the comment is outside the scope of the rule.

(Comment 96) - One commenter suggested developing an exemption list for vinyl fabrics produced in accordance with 16 CFR part 1611, *Standard for the Flammability of Vinyl Plastic Film*, using a process similar to that used to develop the exemption list in 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*. In the latter case, testing over a number of years showed that certain types of fabrics always produce passing results when tested according to 16 CFR part 1610, and those types of fabrics eventually were exempted from the standard.

(Response 96) – The final rule does not address 16 CFR part 1611; and therefore, the comment is outside the scope of the rule.

(Comment 97) - One commenter disagreed that a standard of general application to all consumer products in a category should be considered a “children’s product safety rule” for purposes of the CPSIA.

(Response 97) – The final rule establishes the requirements for the testing and certification of children’s products and for the labeling of compliant consumer products. Determinations of whether a particular safety standard is a children’s product safety rule are outside the scope of this rule.

(Comment 98) - One commenter suggested that we consider developing training guidelines for the regulated community and testing laboratories that explain key elements of a reasonable testing program for non-children’s and children’s products. The guidelines could

include helpful training aids and presentations to increase knowledge and understanding. The guidelines could include helpful examples and scenarios for most common issues (*e.g.*, developing a random sampling program) and even infrequent but complex issues (*e.g.*, traceability for raw materials and product components).

(Response 98) – The final rule is limited to establishing the requirements for testing and certification for children’s products and for labeling of consumer products as compliant; therefore, the comment is outside the scope of the rule. Further, we have reserved proposed subpart B (the reasonable testing program for non-children’s products) for future consideration. We may consider establishing training programs in the implementation of the final rule.

(Comment 99) - One commenter noted that the proposed rule had to be worded very generally to be applicable to a wide range of products. This has had the effect of making it more difficult to understand how the rules will be applied in any specific industry. The commenter suggested that we conduct regional, industry-specific workshops to explain to the regulated manufacturers how these general rules will apply to their existing procedures and where new regulatory obligations exist.

(Response 99) – The final rule is limited to establishing the requirements for testing and certification for children’s products and for labeling of consumer products as compliant; therefore, the comment is outside the scope of the rule. We may consider establishing regional industry-specific workshops in the implementation of the final rule.

(Comment 100) - One commenter recommended that the labels for toys be used to communicate not only compliance with the standards, but also the appropriate age range for the toy. The commenter said that the European Union uses a universal mark that indicates the inappropriate age ranges of a toy if it presents a choking hazard. The commenter said that the

CPSC's program could expand on that concept, by recommending labeling that caregivers can use to separate toys intended for siblings of differing ages, while also preventing parents and other caregivers from buying toys that may be inappropriate for the age of the child. The commenter believes that this could help enhance toy safety by reducing children's exposure to inappropriate toys.

(Response 100) – The final rule does not address labeling for the appropriate ages ranges for a toy; therefore, the comment is outside the scope of the rulemaking. Section 14(i)(2)(A) of the CPSA requires us to implement a program by which a manufacturer may label a product to comply with the certification requirements of section 14(a) of the CPSA. However, the CPSC staff has issued *Age Determination Guidelines: Relating Children's Ages to Toy Characteristics and Play Behavior*, T. P. Smith (Ed.) (2002) (which can be found on the CPSC website at <http://www.cpsc.gov/BUSINFO/adg.pdf>) which addresses the issue raised by the commenter.

(Comment 101) - One commenter asserted that the best approach would be to allow businesses to manage their compliance risks as best they can because “. . . the prophylactic approach to testing adopted by the CPSC will inevitably put many small or micro businesses into bankruptcy If the law does not permit the agency to adopt sensible rules that allow businesses to manage their compliance risk as best they can (where the standards remain in place, but the government stops trying to tell businesses HOW to comply), then the Commission must finally tell Mr. Waxman what he doesn't want to hear—that his law is broken and can't be fixed” The commenter then wrote: “. . . I don't believe the agency can devise sensible regulations to fix this problem short of a legislative change.”

(Response 101) - Comments about the merits of section 14 of the CPSA or the CPSIA are beyond the scope of this rulemaking. However, on August 12, 2011, the President signed into

law H.R. 2715, which amended the CPSIA in several respects. One provision provides relief for small batch manufacturers. Another provision in H.R. 2715 requires the CPSC to seek public 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. H.R. 2715 directs the CPSC to seek public comment on seven specific issues, including other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 further requires the CPSC to review the public comments and states that the CPSC may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 102) - One commenter, who manufactures die-cast metal toys, commented that the 90 ppm lead content limit is too low to allow use of the usual aluminum for casting their products, even though the same metal is used to make cooking utensils.

Furthermore, the commenter stated that it costs \$3,700 to test one unit and that the market will not absorb the costs of testing multiple units per batch. The commenter implied that these costs would cause it to go out of business or make its products in China. The commenter expressed the belief that it should not have to test using third party conformity assessment bodies because:

1. They are ISO 9001:2008 compliant.
2. They document all of their supplier receipts of metal, plastic, and powder paint materials.
3. They conduct a metal analysis for each production run with their spectrometer.

(Response 102) – The final rule does not address lead content and surface coating limits and; therefore, comments on the allowable concentration levels are outside the scope of this rule.

However, H.R. 2715 directs the CPSC to seek public comment on seven specific issues, including the extent to which evidence of conformity with other national or international governmental standards may provide assurance of conformity to consumer product safety rules, bans, standards, or regulations, and the extent to which technology, other than the technology already approved by the Commission, exists for third party conformity assessment bodies to test or to screen for testing consumer products subject to a third party testing requirement. We intend to issue a notice seeking public comment on this issue in the near future.

III. Regulatory Flexibility Act

A. Introduction

We have examined the impacts of the final rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would reduce any significant impact of a rule on small entities.

Several sections that were included in the proposed rule are not included in the final rule, but they are being reserved for future rulemaking. Proposed subpart B, pertaining to a reasonable testing program for non-children’s products, is not included in the final rule, but we may address the issue in a future rulemaking. The proposed section pertaining to the selection of random samples for children’s products (§ 1107.22) is not included in the final rule, and it is addressed in a separate rulemaking published elsewhere in this issue of the *Federal Register*. Proposed § 1107.21(d), which would provide a partial exemption from periodic testing for low-volume products is not included in the final rule. The reason for omitting proposed § 1107.21(d)

from the final rule is that H.R. 2715 asked us to examine means to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. It also contained special rules for small batch manufacturers and directed us to consider alternative testing requirements or to exempt small batch manufacturers from certain third party testing requirements. Given these new statutory obligations resulting from H.R. 2715, we are reserving § 1107.21(e) (formerly proposed § 1107.21(d)) so that we may consider how to address cost, low-volume products, and small batch issues more fully. Finally, proposed § 1107.25, which would establish requirements for remedial action for children's products, has not been included in the final rule.

Before promulgating a final rule, the Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis of the rule that analyzes the impact that the rule will have on small entities. The final regulatory flexibility analysis must contain:

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

(5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

B. Need for, and Objectives of, the Rule

Section 14(a)(2) of the CPSA 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 accredited to conduct such tests. The final rule establishes requirements and procedures for manufacturers to certify children's products under this section of the CPSA.

Section 14(i)(2)(A) of the CPSA requires that we initiate a program by which a manufacturer or private labeler may label a product as complying with the applicable safety rules. The statute also requires us to establish protocols and standards: (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product, (ii) for the testing of representative samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. With the exception of items (ii) (standards and protocols for the testing representative samples), and (iii) (establish protocols and standards for verifying that a product tested by a conformity assessment body complies with applicable safety rules), the final rule implements these requirements.

The objective of the final rule is to reduce the number of children's products that are distributed each year that fail to comply with one or more children's product safety rules. The applicable children's product safety rules were established to reduce the unreasonable risk of injury or death due to foreseeable hazards associated with particular children's products.

C. Comments on the Initial Regulatory Flexibility Analysis, and Our Responses

The preamble to the proposed rule contained our initial regulatory flexibility analysis (76 FR at 28352 through 28360). Several commenters addressed issues pertaining to that analysis.

(Comment 103) - One commenter noted that in estimating the number of firms that could be impacted by the proposed rule, the book publishing industry (NAICS code 511130) and printing industry (NAICS code 323117) were not included. The commenter recommended their inclusion for the final regulatory flexibility analysis.

(Response 103) - We acknowledge that the initial regulatory flexibility analysis inadvertently omitted these industries. However, the recently enacted H.R. 2715 exempts ordinary books and ordinary paper-based printed materials from the third party testing requirements, so the commenter's concern no longer applies.

(Comment 104) - One commenter indicated that the cost of complying with the reasonable testing program requirements for furniture will vary according to: (1) whether the furniture is children's or non-children's furniture; (2) whether the furniture is produced domestically or imported; and (3) whether the manufacturer produces a high or low-volume of products. High-volume producers can rely on a component part certificate from their paint suppliers, and the cost of testing would be relatively low. Higher quality, lower volume producers would have greater difficulty because these items often are "made to order" and "as

needed.” These producers will use small batches of finishes issued in a number of different finishing materials, each of which would need to be tested.

(Response 104) – We agree that the costs of complying with the requirements will vary among products and manufacturers. Generally, the costs will be more significant for manufacturers of lower volume products. It should also be noted that proposed subpart B, which would contain the requirements applicable to non-children’s products, is not being finalized at this time. Therefore, the final rule does not impose any requirements on non-children’s furniture.

(Comment 105) - Two commenters expressed concern about costs. One commenter noted that reliance on third party conformity assessment body testing raises costs and imposes production delays. Another commenter, a charitable organization that makes wooden toys for donation to needy children, commented that it lacks the resources to pay for certification testing and would need to discontinue activities unless granted an exemption or some other type of relief.

(Response 105) - Section 14(a)(2) of the CPSA requires third party conformity assessment bodies to test children’s products for compliance with applicable children’s product safety rules. We recognize that testing costs may be substantial and may have a significant adverse affect on some manufacturers, especially small businesses that may have limited financial resources. We also recognize that the testing will take time and could result in some delays in the production process.

Recently enacted H.R. 2715 requires us to seek public 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. H.R. 2715 directs us to

seek public comment on seven specific issues, including techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations. We intend to issue a notice seeking public comment on this issue in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

H.R. 2715 also requires us to consider alternative requirements for the covered products of small batch manufacturers and, if no alternative requirements are available or economically practical, exempts small batch manufacturers from the third party testing requirements, with some exceptions. Covered products are those for which fewer than 7,500 units were produced in the previous year, and a small batch manufacturer is one whose gross sales revenue from all consumer products in the previous calendar year was less than \$1 million. In the case of toys, however, no alternative requirements or exemptions would be permitted for third party testing for the lead content of paint, small parts, and pacifiers. Where possible, we tried to reduce testing costs by allowing the use of component part testing

(Comment 106) - One commenter noted that the initial regulatory flexibility analysis acknowledged that the examples used only considered the out-of-pocket testing costs. Costs not considered in the examples include: samples destroyed or damaged in testing; transportation of the samples; administrative costs for managing testing; administrative costs for managing the testing data and recordkeeping; an allocation of general management time; legal expenses, among other costs. The commenter estimated that, depending on the scale of the business, these costs will add 15 to 50 percent to the out-of-pocket testing costs.

The commenter also noted that the initial regulatory flexibility analysis considered the probability that some manufacturers or private labelers will have to test multiple samples to obtain the high degree of assurance required by the proposed rule. The commenter asserted that over the last 20 years of product testing at his company, multiple safety tests of the same product have not revealed anything useful. The commenter asserted that the testing rule is complex; that many small businesses will not have the skills necessary to understand what is expected of them in terms of compliance; and that many small businesses will exit the market for children's products.

(Response 106) - The initial regulatory flexibility analysis focused on the cost of third party testing because it will likely be the most significant cost for small manufacturers of children's products. Considering only the third party testing costs, the initial regulatory flexibility analysis found that the rule could have a significant impact on a substantial number of small entities. The initial regulatory flexibility analysis explicitly stated that the only costs considered in the analysis were the costs that the laboratories would charge to conduct the testing. The commenter is correct that the rule would impose other costs, including the cost of the samples destroyed in testing and freight, as well as the costs involved in administering and managing the testing and paperwork. The commenter's estimate that these costs would add 15 to 50 percent to the out-of-pocket testing costs, depending upon factors such as the product involved and the scale of the business, seems reasonable.

The commenter also is correct that the initial regulatory flexibility analysis considered the impact on firms that had to test more than one sample of a product in order for the manufacturer to obtain a high degree of assurance that the product complies with the applicable product safety rules. However, the final rule does not specify the number of samples that must be tested. It is

possible that if the commenter, as asserted, has never found multiple tests on its products to reveal anything useful, then the products manufactured could be of such uniform composition and quality that the number of samples that the commenter will be required to submit for testing will be small. However, because the rule requires that every children's product subject to a children's product safety rule be tested periodically by a third party conformity assessment body, the commenter might need to conduct more testing than the commenter believes is necessary.

We acknowledge that the rule is complex, and some small businesses might have to hire outside consultants, such as lawyers, statisticians, or quality control experts to help them comply with the regulations. As a result, some small firms may exit the market for children's products.

(Comment 107) - One commenter stated that the testing rule would accelerate the decline of domestic manufacturing firms, as more manufacturers go offshore to minimize the cost of testing. The commenter asserted that the furniture industry will have no choice but to close down more and more factories in the United States and take those jobs off shore to benefit from the lower testing costs. The commenter stated that some small manufacturers have abandoned plans to offer products intended for the youth market.

(Response 107) - The initial regulatory flexibility analysis noted that the costs of some third party tests are less expensive abroad than they are in the United States. For example, while typical prices for lead content tests range from \$50 to more than \$100 in the United States, the same lead content test, in some cases, can be obtained for as little as \$20 in China (75 FR at 28355). Higher third party testing costs in the United States would be an incentive for manufacturers to produce children's products abroad, to take advantage of the lower testing costs.

Given all of the factors that go into a decision by a manufacturer to produce consumer products abroad rather than in the United States, the impact of third party testing costs on such a decision might be small. It seems unlikely that the independent effect of higher third party testing costs, by itself, would result in a large number of factories in the United States closing down. With regard to small domestic manufacturers, it is possible that the third party testing costs associated with the children's furniture could lead some to manufacturers to reduce their children's furniture product lines or even cease their production of children's furniture. Any small manufacturer of children's furniture who qualifies as a small batch manufacturer might be offered relief by the alternative requirements or exemptions that are provided by H.R. 2715; however, matters regarding the small batch manufacturer's exception in H.R. 2715 are outside the scope of this rulemaking. We intend to issue a notice seeking public comment on other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations, pursuant to H.R. 2715.

(Comment 108) - One commenter stated that the cost to test a finish used in the furniture industry is about \$50 (which is consistent with the discussion of testing costs in the initial regulatory flexibility analysis). A youth bed, which is also subject to the lead content requirements of section 101 of the CPSIA, might require 29 tests at a third party testing facility, which would bring the total cost of lead testing to \$1,450. In addition, testing to the bunk bed standard would add \$600 to \$800 to the cost. A crib or toddler bed would cost an additional \$750 to \$765 (\$450 to \$520 in China) to test to the relevant children's product safety rules. The cost of testing other items of youth furniture, such as desks, entertainment centers, and bookcases, averages approximately \$235. These costs do not include the cost of the samples,

freight, random sampling, or the cost for employees to track and administer the recordkeeping requirements.

(Response 108) - As described in the initial regulatory flexibility analysis (75 FR at 28352 through 28362), the testing of some children's products by third party conformity assessment bodies can be costly. The testing costs described by the commenter do not appear to be unreasonable estimates, based on cost estimates we obtained. In cases where the same component is used in more than one product, manufacturers may be able to reduce their testing costs by using component part testing. However, component part testing will not offer any relief from the costs of tests that must be performed on the finished product, such as tests for conformity to the crib and bunk bed standards.

(Comment 109) - One commenter stated that furniture manufacturers who deal in high-quality but lower volume furniture manufacturing may offer products with between 30 and more than 2,000 possible combinations of finishes. Many of these finishes are custom or made to order, so that a batch can range from a 5-gallon bucket to a 55-gallon drum. Each custom finish consists of at least 10 different materials. The manufacturer must create a panel for each possible combination of finishing materials and then have it analyzed by a third party testing facility. An x-ray fluorescence (XRF) gun is then used to verify that the finished piece, in fact, complies with the lead-in-paint standard. It is estimated that 6 to 10 employees will be required to track the testing and compile the certificates of conformity. It is estimated that the cost to comply with the rule for non-children's products could range from \$200,000 to \$410,000, annually.

(Response 109) - We received many comments on proposed subpart B, which was concerned with reasonable testing programs for non-children's products. The comments raised

many practical issues, which illustrates the difficulty of drafting a regulation that can apply to many different types of products and manufacturing processes and still provide sufficient guidance to enable manufacturers to implement the requirements effectively. Consequently, we are deferring action with respect to finalizing subpart B. Instead, we will reserve subpart B in the final rule and continue evaluating the issues raised in the comments.

It should be noted, however, that although we are not finalizing subpart B at this time, manufacturers of non-children's products that are subject to a product safety rule, ban, standard, or regulation are still obligated by the CPSA, as amended by the CPSIA, to certify that their products comply with all applicable safety rule, based on a test of each product or a reasonable testing program.

In the case of testing the lead content of paint, which the commenter mentioned, the use of component part or composite testing—as would be allowed by the final rule on component part testing—might allow some manufacturers to reduce their testing costs. For example, if the same 10 raw materials (and only those materials) are combined in different portions to produce 30 different finishes, a manufacturer could test the lead content of each of the materials, and if each of the materials met the lead content requirement, then the manufacturer would not need to test each of the 30 finishes separately.

(Comment 110) - One commenter stated that because the cost of testing and recordkeeping will be passed on to the consumer, this could create an “upside down” market in furniture, in which youth furniture is more expensive than adult furniture. This could lead some consumers to purchase “adult” furniture for children instead of purchasing youth furniture that has been third party tested.

(Response 110) - Section 14(a)(2) of the CPSA requires third party testing of children's products, including children's and youth furniture. Depending upon the structure of the market and market conditions, some or all of the testing costs may be passed on to consumers. We cannot determine whether passing on these costs will make children's furniture—in any absolute sense—to be more expensive to purchase than adult furniture;, but passing on these costs to consumers is likely to increase the relative price of children's furniture, and it could provide a price incentive for parents to substitute adult furniture for children's furniture.

(Comment 111) - One commenter stated that the proposed rule will impose significant new costs on the mattress industry because mattresses are already subject to an expensive mandatory testing program pursuant to 16 CFR part 1633. The commenter asserted that because most manufacturers of mattresses are small businesses, the proposed rule would have a substantially greater impact on the mattress industry, given the nature of the products, the types of standards that the products must meet, the destructive nature of the testing involved, and the cost of the samples tested.

The commenter also noted that mattress testing entails other costs, such as: the cost of the samples tested, the laboratory test fees, freight costs to ship samples to the laboratory, and the manufacturers' staff sent to witness the test. The total cost of conducting a full test for 16 CFR part 1633 can range from \$850 to \$1,650 per sample tested, plus added travel costs and salary expenses for company personnel to witness the test. The commenter urged us to take into account the significant new costs that the rules will impose on the mattress industry, which is comprised overwhelmingly of small businesses.

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(Response 111) - We acknowledge that the rule could impose additional costs on some firms. However, section 14(a)(2) of the CPSA requires third party testing of children's products that are subject to an applicable children's product safety rule.

Additionally, on August 12, 2011, the President signed into law H.R. 2715, which amended the CPSIA in several respects. One provision in H.R. 2715 requires us to seek public 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. H.R. 2715 directs us to seek public comment on seven specific issues. These issues include:

- The extent to which manufacturers with a substantial number of substantially similar products subject to third party testing may reasonably make use of sampling procedures that reduce the overall test burden without compromising the benefits of third party testing; and
- Other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

We intend to issue a notice seeking public comment on these issues in the near future. H.R. 2715 further requires us to review the public comments and states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

Another provision of H.R. 2715 created a new section 14(i)(4) of the CPSA to provide for special rules for small batch manufacturers. The provision contemplates the possible

development of alternative testing requirements for “covered products” made by “small batch manufacturers.” The provision also provides for possible exemptions of small batch manufacturers from the third party testing requirements and imposes certain limits on third party testing requirements. A covered product is a consumer product where no more than 7,500 units of the same product were manufactured by a small batch manufacturer in the previous calendar year, and a small batch manufacturer is a manufacturer that had no more than \$1 million in gross revenue from sales of all consumer products in the previous calendar year. Any small mattress manufacturer who meets the definition of a “small batch manufacturer” might benefit from this provision when it is implemented.

(Comment 112) - One commenter stated that the discussion of sample size is unrealistic. An example was used in the initial regulatory flexibility analysis that provided the sample sizes that would be required to meet a specified statistical confidence level, assuming that both the historical variability (standard deviation) and the historical mean of the variable (lead content) are known. The commenter stated that continuously variable data on commonly available testing reports is generally not provided by the laboratories, and data for samples with a result below the method detection limit is generally provided in the form “< X ppm,” where X is the method detection limit. The commenter noted that these data cannot be included for calculations of the mean or standard deviation. The commenter stated that the example used is invalid, unless the data can be captured and tracked in full resolution, which is not the current state.

(Response 112) - To the extent that continuously variable data from testing results are unavailable, the discussion of sample size in the initial regulatory flexibility analysis may be unrealistic. Because the example is not widely applicable, and because we are not requiring that the periodic third party testing be used to provide a high degree of statistical assurance (*e.g.*, 95

percent confidence) that no children's products violate consumer product safety standards, we have omitted the example from the final regulatory flexibility analysis.

D. Small Entities to Which the Rule Will Apply

By regulation (16 CFR part 1110), the domestic manufacturer or importer is responsible for ensuring that a consumer product is tested properly, and, based on the testing results, must certify that the product conforms to all applicable consumer product safety rules. Manufacturers of children's products that are subject to a children's product safety rule must certify that the children's products comply with all applicable children's product safety rules, based on testing conducted by third party conformity assessment bodies that are accredited to conduct such tests. The definition of a "children's product" is broad, and it includes bicycles, books, furniture, apparel, jewelry, televisions, electronic games, toys, and so on, if designed or intended primarily for a child 12 years of age or younger. Virtually all children's products are subject to one or more children's product safety rules. For example, the lead content of paint and all non-excluded accessible component parts of children's products are subject to limits. Therefore, virtually all manufacturers of children's products will have to certify, based on tests by accredited third party conformity assessment bodies that their products comply with the lead content limits. We have excluded from the requirement to test for lead content a few materials that inherently do not contain lead. The excluded materials are limited to materials such as: most fabrics, precious metals, paper, gemstones, and a limited number of other items, and the list can be found at 16 CFR § 1500.91. We also have issued a rule excluding from the lead content requirements (16 CFR § 1500.87) inaccessible component parts in children's products. Section 1(b)(3) of H.R. 2715 excludes certain used children's products from testing for lead content. All other materials used in products intended for children must be tested for lead content.

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In addition to the requirements to test for lead content, manufacturers must test for conformity with a wide variety of other children's product safety rules. For example, there are product safety rules that establish standards for children's products, such as toys, cribs, bicycles, bicycle helmets, youth all-terrain vehicles, bunk beds, baby walkers, and flammable clothing textiles. The CPSIA also limits the amount of six phthalates that can be present in children's toys and child care articles; thus, many plastic component parts will need to be tested for phthalate content. A full list of the children's product safety rules for which third party testing and certification will be required is given in Table 1.

Table 1. Product Safety Rules Applicable to Children's Products

16 CFR Part # (or Test Method or Standard)	Description
1420	All-Terrain Vehicles
1203	Bicycle Helmets
1512	Bicycles
1513	Bunk Beds
1500.86(a)(5)	Clacker Balls
1500.86(a)(7) and (8)	Dive Sticks and Other Similar Articles
1505	Electrically Operated Toys or Articles
1615	Flammability of Children's Sleepwear, Sizes 0 through 6X
1616	Flammability of Children's Sleepwear, Sizes 7 through 14
1610	Flammability of Clothing Textiles
1632	Flammability of Mattresses and Mattress Pads
1633	Flammability (Open Flame) of Mattress Sets
1611	Flammability of Vinyl Plastic Film
1219	Full-Size Cribs
1215	Infant Bath Seats
1216	Infant Walkers
Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08, CPSC-CH-E1001-08.1 or 2005 CPSC Laboratory SOP)	Lead Content in Children's Metal Jewelry
Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08 or CPSC-CH-E1001-08.1)	Lead Content in Children's Metal Products
Sec. 101 of CPSIA (Test	Lead Content in Children's Non-Metal Products

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Method CPSC-CH-E1002-08 and/or CPSC-CH-E1002-08.1)	
1303	Lead Paint
1220	Non-Full-Size Cribs
1511	Pacifiers
Sec. 108 of CPSIA (Test Method CPSC-CH-C1001-09.3)	Phthalate Content of Children's Toys and Child Care Articles
1510	Rattles
1501	Small Parts Rule
1630	Surface Flammability of Carpets and Rugs
1631	Surface Flammability of Small Carpets and Rugs
1217	Toddler Beds
(ASTM F963)	Toys

E. Number of Small Firms Affected

We estimated the number of firms that could be impacted, by reviewing every industry in the North American Industrial Classification System (NAICS), and selecting industries with firms that could manufacture or sell any children's product potentially covered by a consumer product safety rule. Firms are classified in the NAICS category that describes their primary activity. Therefore, firms that might manufacture or import consumer products covered by a safety rule as a secondary or tertiary activity may not have been counted. There is no separate NAICS category for importers. Firms that import products might be classified as manufacturers, wholesalers, or retailers.

1. Manufacturers

According to the criteria established by the U.S. Small Business Administration (SBA), manufacturers are generally considered to be small entities if they have fewer than 500 employees. Table 2 shows the number of manufacturing firms by the North American Industrial Classification System (NAICS) categories that cover most children's products that are subject to a product safety rule. Although there are more than 26,000 manufacturers that would be

considered small in these categories, not all of these firms are engaged in manufacturing children's products that are subject to a product safety rule. It would be expected that most firms engaged listed in the category, *Doll, Toy, and Game*, produce some products that are intended for children age 12 and younger. On the other hand, the *Surgical Appliance and Supplies Manufacturing* category includes crash helmets, but most other products in this category are not under our jurisdiction.

Table 2. Manufacturers

NAICS Code	Description	Small Firms	Total Firms
31411	Carpet and Rug Mills	244	262
315	Apparel Manufacturing	7,126	7,195
316211	Rubber and Plastic Footwear Manufacturing	43	45
316212	House Slipper Manufacturing	1	1
316219	Other Footwear Manufacturing	53	54
326299	All Other Rubber Product Manufacturing	622	666
336991	Motorcycle, Bicycle, and Parts Manufacturing	447	452
33712	Household and Institutional Furniture Manufacturing	6,058	6,154
33791	Mattress Manufacturing	427	441
339113	Surgical Appliance and Supplies Manufacturing	1,817	1,916
33991	Jewelry and Silverware Manufacturing	2,470	2,484
33992	Sporting and Athletic Goods Manufacturing	1,707	1,748
33993	Doll, Toy and Game Manufacturing	694	705
339942	Lead Pencil and Art Good Manufacturing	124	129
339999	All Other Miscellaneous Manufacturing	4,646	4,695
	Total Manufacturers	26,479	26,947

Source: U.S. Department of Commerce, Bureau of the Census, 2008 County Business Patterns, Number of Firms, Number of Establishments, Employment, and Annual Payroll by Small Enterprise Employment Sizes for the United States, NAICS Sectors: 2008. (Available at: http://www2.census.gov/econ/susb/data/2008/us_naicssector_small_emplsize_2008.xls, last accessed on 16 August 2011.

In addition to the manufacturers in Table 3, there were 25,184 nonemployer businesses classified in NAICS 315 (Apparel Manufacturing) and 61,180 classified in NAICS 3399 (Other Miscellaneous Manufacturers) in 2008. Nonemployer businesses are generally very small businesses with no employees. They are typically sole proprietorships, and they may or may not be the owner's principal source of income. The average receipts for the nonemployer businesses

classified in *Apparel Manufacturing* was about \$31,000, and the average receipts for the nonemployer businesses classified *Other Miscellaneous Manufacturers* was about \$41,000.¹

2. Wholesalers

Wholesalers would be impacted by the rule if they import any children's product that is subject to a product safety rule. Wholesalers who obtain their products strictly from domestic manufacturers, or from other wholesalers, would not be impacted by the rule because the manufacturer or importer would be responsible for certifying the products. Table 3 shows the number of wholesalers by NAICS code that would cover most children's products that are subject to a product safety rule. According to SBA criteria, wholesalers are generally considered to be small entities if they have fewer than 100 employees. Although there are more than 78,000 wholesalers that would be considered small in these categories, not all of these firms are engaged in importing children's products that are subject to a consumer product safety rule. A significant proportion of the firms classified as *Toy and Hobby Goods and Supplies Merchant Wholesalers* probably import at least some children's products. However, the only firms classified as *Motor Vehicle and Motor Vehicle Parts and Suppliers* that would be impacted by the final rule are those that import all-terrain vehicles intended for children 12 years old or younger.

Table 3. Wholesalers

NAICS Code	Description	Small Firms	Total Firms
4231	Motor Vehicle and Motor Vehicle Parts and Suppliers	17,734	18,769
4232	Furniture and Home Furnishing Merchant Wholesalers	11,353	11,844
42362	Electrical and Electronic Appliance, Television, and Radio Set Merchant Wholesalers	2,444	2,591

¹ U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics Table." Available at: <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

42391	Sporting and Recreational Goods and Supplies Merchant Wholesalers	5,019	5,196
42392	Toy and Hobby Goods and Supplies Merchant Wholesalers	2,227	2,302
42394	Jewelry, Watch, Precious Stone, and Precious Metal Merchant Wholesalers	7,363	7,447
42399	Other Miscellaneous Durable Goods Merchant Wholesalers	9,040	9,302
42432	Men's and Boy's Clothing and Furnishings Merchant Wholesalers	3,557	3,722
42433	Women's, Children's, and Infant's Clothing, and Accessories Merchant Wholesalers	6,797	7,029
42434	Footwear Merchant Wholesalers	1,521	1,593
42499	Other Miscellaneous Nondurable Goods Merchant Wholesalers	11,203	11,490
	Total	78,258	81,285

Source: U.S. Department of Commerce, Bureau of the Census, 2008 County Business Patterns, Number of Firms, Number of Establishments, Employment, and Annual Payroll by Small Enterprise Employment Sizes for the United States, NAICS Sectors: 2008. (Available at: http://www2.census.gov/econ/susb/data/2008/us_naicssector_small_emplsize_2008.xls, last accessed on 16 August 2011).

In addition to the wholesalers tabulated in Table 3, the U.S. Census Bureau estimated that there were 206,072 nonemployer businesses classified in NAICS categories that could include wholesalers of children's products. Nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business wholesalers were about \$86,000.² An unknown number of nonemployer wholesalers could import children's products.

3. Retailers

Retailers that obtain their products from domestic manufacturers or wholesalers will not be directly impacted by the rule because the manufacturers or wholesalers would be responsible for the testing and certification of the products. However, there are some retailers that manufacture or directly import some products; and therefore, they will be responsible for

² U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics Table." available at <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

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ensuring that these products are properly tested and certified. The number of such retailers is not known. Table 4 shows the number of retailers by NAICS code that would cover most children's products. According to SBA size standards, retailers are generally considered to be small entities if their annual sales are less than \$7 million to \$30 million, depending on the specific NAICS category. Because of the way in which the data were reported by the Bureau of the Census, the estimates of the number of small firms in each category in Table 4 are based on similar, but different criteria. Although there are more than 100,000 firms that would be considered "small businesses" in these categories, it is not known how many of these firms are engaged in importing or manufacturing children's products. Many firms probably obtain all of their products from domestic wholesalers or manufacturers and would not be directly impacted by the rule.

Table 4. Retailers

NAICS Code	Description	SBA Size Standard (millions of dollars of annual sales)	Criteria Used for Estimate of Small Firms (millions of dollars of annual sales)	Small Firms	Total Firms
441221	Motorcycle, ATV, and Personal Watercraft Dealers	<30	<25	4,794	4,879
4421	Furniture Stores	<19	<10	16,033	16,611
44813	Children's and Infant's Clothing Stores	<30	<25	2,057	2,074
44814	Family Clothing Stores	<25.5	<25	6,588	6,684
44815	Clothing Accessories Stores	<14	<10	2,757	2,774
44819	Other Clothing Stores	<19	<10	6,331	6,393
4482103	Children's & Juveniles' Shoe Stores	<25.5	<25	227	230
4482104	Family Shoe Stores	<25.5	<25	2,905	2,941

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45111	Sporting goods stores	<14	<10	14,388	14,545
45112	Hobby, toy, & game stores	<25.5	<25	4,612	4,629
452	General Merchandise Stores	<30	<25	6,873	6,971
45322	Gift, Novelty, and Souvenir Store	<30	<25	19,297	19,339
454111	Electronic Shopping	<30	<25	11,374	11,646
454113	Mail Order Houses	<35.5	<25	5,281	5,645
4542	Vending machine operators	<10	<10	3,796	3,887
	Total			107,313	124,700

Source: U.S. Census Bureau, 2007 Economic Census, Release date 11/02/2010.

In addition to the retailers tabulated in Table 4, the U.S. Census Bureau estimated that there were 324,918 nonemployer businesses classified in NAICS categories that could include retailers of children's products. Nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business wholesalers were about \$40,000.³ An unknown number of nonemployer wholesalers could import children's products.

F. Compliance, Reporting, and Recordkeeping Requirements of Rule

The final rule establishes some requirements for the certification of children's products. It also establishes protocols and standards for ensuring that children's products are subject to testing periodically, when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts, and for safeguarding against the exercise of undue influence on a third party conformity assessment body by a children's product manufacturer or private labeler. The requirements are discussed in more detail below, and the impact that these could have on manufacturers is discussed in a later section of this preamble.

³ U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics Table." Available at: <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

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The final rule will impact virtually all manufacturers and importers of children's products because nearly all children's products are subject to some children's product safety rules. For example, the restrictions on lead content cover almost all children's products. Even products that contain some of the materials that have been excluded from the restrictions (see 16 CFR § 1500.88) or that have been determined inherently not to contain lead in excess of the legal requirement (see 16 CFR § 1500.91) might have to be tested for compliance with other rules. For example, although the fabric in wearing apparel might be excluded from the requirement to test for lead content, it may have to be tested for compliance with flammability requirements. Any other non-excluded objects on the apparel, such as buttons, snaps, zippers, or appliqués will also need to be tested for lead content.

In meeting the requirements of the final rule, manufacturers and importers can use component part testing, as provided by 16 CFR part 1109. This means, for example, that manufacturers could submit samples of paint that they are using on their products to a third party testing laboratory to be tested for lead and heavy metal content. This could reduce the amount of testing required because the results from the component part tests could be relied upon for demonstrating the compliance of all products on which that paint was used, rather than retesting the paint multiple times because it was used on multiple products. The final rule also allows manufacturers and importers to rely upon testing of component parts that was procured by their suppliers, provided that the testing meets all of the requirements in 16 CFR part 1109. The requirements include that the testing be performed by a third party conformity assessment body whose accreditation has been accepted by the CPSC. To rely upon component part testing—whether conducted by the children's product manufacturer or by a supplier of the component part—there must be sufficient documentation so that the component part can be traced back to

the party who procured the third party test results demonstrating that the component part complies with the applicable safety rules. Provisions in 16 CFR part 1109 also allow an importer to rely upon testing procured by, or a certificate issued by, a supplier of a finished good in issuing their own certificate for a product. Therefore, if a foreign manufacturer has tested and certified a children's product in accordance with the requirements of 16 CFR part 1109, an importer may rely upon that testing or certification in issuing their own certificate for the product.

G. Partial Exemption for Small Batch Manufacturers

H.R. 2715, which was enacted on August 12, 2011, provides some relief for small batch manufacturers from the third party testing requirements contained in the final rule. H.R. 2715 requires that we consider alternative requirements for small batch manufacturers. Until we determine what alternative requirements are suitable for small batch manufacturers, small batch manufacturers are not required to obtain third party testing results to confirm that their children's products conform to several children's product safety rules. However, small batch manufacturers are still subject to the third party testing requirements of the final rule with respect to the lead content of paint; full-size and non full-size cribs; pacifiers; small parts; children's metal jewelry; and baby bouncers, walkers, and jumpers.

H.R. 2715 defines a "small batch manufacturer" as a manufacturer who had no more than \$1million in total gross revenue from sales of all consumer products in the previous calendar year (which will be adjusted annually by the percentage increase in the Consumer Price Index for all urban consumers).

We will implement the small batch manufacturer provision of H.R. 2715 in a separate proceeding.

H. Certification Tests

To certify that a children's product complies with all applicable children's product safety rules, the final rule requires that manufacturers submit samples of the product to a third party conformity assessment body whose accreditation has been accepted by the CPSC. The final rule requires that the number of samples submitted 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. Fewer samples are needed if the manufacturing process consistently results in products that are uniform in composition and quality. More samples will be needed if there is more variability in the finished products. If any product fails certification testing, the manufacturer must investigate and address the cause of the failure, even if other samples passed the certification tests.

The cost of the third party testing is discussed in more detail later in part III.N. of the preamble. Manufacturers also may incur costs for any consultants to provide advice for determining the number of samples that should be submitted for testing and to ensure that it was in compliance with the requirements. There also will be some administrative and recordkeeping costs associated with this requirement.

I. Periodic Third Party Testing

The final rule requires manufacturers and importers of children's products to periodically submit samples of their products to third party conformity assessment bodies whose accreditation has been accepted by the CPSC for testing to ensure their products continue to comply with all applicable children's product safety rules. Manufacturers need to conduct periodic third party testing frequently enough to ensure, with a high degree of assurance, that the product continues to comply with all applicable children's product safety rules, but in no case can the interval

between periodic tests exceed the maximum periodic testing interval applicable to the manufacturer.

Depending upon other testing procedures that a manufacturer may opt to use, one of three possible maximum periodic testing intervals will apply to a children's product manufacturer. The first option applies to manufacturers who do not conduct other production testing of a children's product. Manufacturers who do not undertake other production testing must conduct periodic third party testing of the product at least once a year. The final rule requires manufacturers to develop a periodic test plan that will ensure that the children's products manufactured after the certification, or since the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules. The periodic test plan must include the tests to be conducted, the intervals at which the tests will be conducted, and the number of samples to be tested. Although the manufacturer has some discretion in determining the interval between periodic tests, the interval must be short enough to ensure that if the samples selected for periodic third party testing pass the tests, then there is a high degree of assurance that the untested products manufactured during the interval comply with all applicable children's product safety rules; and the interval must be no longer than one year.

The second option applies to manufacturers who implement a production testing plan (which can use first or third party testing). If a manufacturer has implemented a production testing plan that meets the requirement of § 1107.21(c) of the final rule, the manufacturer must conduct third party periodic testing at least once every two years. The production testing plan must describe the production management techniques and tests that must be performed to provide a high degree of assurance that products manufactured after certification continue to meet all applicable children's product safety rules. The production testing plan must also include

additional information, such as the intervals at which tests must be conducted or measurements will be made. The test methods used in the production testing plan need not be the same test methods used for certification, but they must be effective in determining compliance with the applicable children's product safety rules.

Manufacturers or importers who choose this second option, will need to ensure that their quality assurance or testing program meets the requirements of the final rule for production testing and that their testing program provides a high degree of assurance that all products manufactured or imported continue to comply with all applicable children's product safety rules. In addition, at least once every two years, this option requires the manufacturer or importer to submit samples to a CPSC-accepted third party conformity assessment body to be tested for conformity with all applicable children's product safety rules. The final rule does not specify how many samples must be submitted to the third party conformity assessment body, nor does it set forth what constitutes an appropriate periodic testing interval (other than stating it must not be greater than two years). However, the expectation is that this option will require less testing by third party conformity assessment bodies because, under this option, the (first party or third party) production testing provides the manufacturer or importer with a high degree of assurance that the products continue to comply with the applicable children's product safety rules and can provide manufacturers with information that can be used to determine the interval and number of samples required for the periodic third party testing.

The third option applies to manufacturers who conduct testing to ensure continuing compliance with the applicable children's product safety rules using a testing laboratory accredited to ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*, but whose accreditation has not been accepted by the CPSC. In most

cases, these will be in-house testing laboratories. If a manufacturer conducts testing using such a testing laboratory, the manufacturer must conduct periodic third party testing at least once every three years. Any testing laboratory used under this option must be accredited by an accreditation body that is accredited to ISO/IEC 17011:2004, *Conformity assessment – General requirements for accrediting conformity assessment bodies*. The tests used under this option must be the same tests used for certification to the applicable children's product safety rules. The testing must be conducted frequently enough to provide a high degree of assurance that the product continues to comply with all applicable children's product safety rules.

The final rule does not specify how many samples a manufacturer using the third option must submit to the third party conformity assessment body, nor does it set forth what constitutes an appropriate periodic testing interval (other than stating it must not be greater than three years). However, as with the second option, the intent behind including this option in the final rule is to reduce the cost that the rule imposes on children's product manufacturers, by reducing the amount of testing that they must obtain from third party conformity assessment bodies. The testing that the manufacturer performs in an ISO/IEC 17025:2005-accredited testing laboratory provides the high degree of assurance that the products comply with the applicable children's product safety rules, and it also can provide manufacturers with information that can be used to determine interval and number of samples required for the periodic third party testing.

Like the second option, the intent of the third option is to reduce the final rule's cost to manufacturers, by reducing the amount of testing that they must conduct using third party conformity assessment bodies. However, the manufacturers that are most likely to benefit from this third option are manufacturers who have their own in-house ISO/IEC 17025:2005-accredited testing laboratories. These are likely to be larger manufacturers, so this option is not expected to

provide much relief to smaller manufacturers. To the extent that the smaller manufacturers compete with the larger manufacturers, this option may adversely affect the competitiveness of the smaller manufacturers relative to larger manufacturers because any cost reduction will disproportionately benefit larger manufacturers.

Under all periodic testing options, a manufacturer may need statistical or other knowledge in order to develop their testing plans, including determining the appropriate testing intervals and number of samples required to provide the manufacturer with a high degree of assurance that its children's products are in compliance with all applicable children's product safety rules. If these services are not available in-house, the firm may have to hire outside consultants. Additionally, firms will incur administrative and recordkeeping costs associated with the periodic testing requirement, in addition to the cost of the third party testing, which is described in more detail later in this analysis.

J. Third Party Testing Due to Material Changes

If a children's product undergoes a material change in product design or manufacturing processes, including the sourcing of component parts that could affect the product's ability to comply with the applicable children's product safety rules, the final rule requires the manufacturer to submit samples of the materially changed product to a third party conformity assessment body for testing. The number of samples must be sufficient to provide a high degree of assurance that the materially changed product complies with all applicable children's product safety rules. The testing can be limited to the portion or component part of the finished product that was changed and for compliance with those children's product safety rules for which compliance might have been affected.

The primary cost of this requirement will be the cost of the third party testing. There also will be some administrative and recordkeeping costs associated with this requirement. The professional skills required by the manufacturer are the same skills required for the initial certification and periodic tests.

K. Protection Against Undue Influence

The final rule requires that each manufacturer of children's products establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body. At a minimum, these procedures must include written policy statements from company officials that the exercise of undue influence is not acceptable and directing that every appropriate staff member receives training on avoiding undue influence and signs a statement attesting to their participation in the training. The procedures also must include a requirement to retrain the appropriate staff if there are substantive changes in the requirements for safeguarding against the exercise of undue influence. The training procedures must include a requirement to notify us immediately of any attempt by the manufacturer to hide or exert undue influence over test results, and a requirement to inform employees that allegations of undue influence may be reported confidentially to us and to describe how such a report can be made.

Firms will incur some costs in establishing the safeguards against undue influence. Although several commenters stated that establishing these safeguards would be burdensome, none provided estimates of what the cost would be. The final rule gives firms great flexibility in meeting these requirements. For example, the final rule does not prescribe the form of the training, and firms may include this training along with other types of employee training.

L. Recordkeeping

The final rule requires manufacturers of children's products to keep the following records:

- A copy of the Children's Product Certificate for each product. The children's product covered by the certificate must be clearly identifiable and distinguishable from other products;
- Records of each certification test. The manufacturer must have separate certification test records for each manufacturing site;
- Records of one of the following for periodic tests of a children's product:
 - periodic test plan and periodic test results;
 - production testing plan, production test results, and periodic test results; or
 - testing results of tests conducted by a testing laboratory accredited to ISO/IEC 17025:2005 and periodic test results.
- Records of descriptions of all material changes in product design, manufacturing processes, and sourcing of component parts, the certification tests, the test results, and the actual values of the tests, if any; and
- Records of the undue influence procedures, including training materials and training records of all employees trained on these procedures.

These records must be maintained for five years. The records must be made available for inspection by the CPSC, upon request. The records may be maintained in languages other than English, if the records can be provided immediately to us and translated accurately into English within 48 hours of a request by the CPSC or a longer period, as negotiated with CPSC staff.

We have estimated that, on average, it will take three to five hours for recordkeeping per product. However, the time needed for recordkeeping for any particular product could be

substantially higher or lower. For example, recordkeeping for products that are subject to multiple standards, or products that require a substantial amount of testing, could need substantially more hours. For other products, such as those subject to only one standard, and for which little testing is required, the number of hours needed for recordkeeping might be less.

M. Consumer Product Labeling Program

The final rule establishes a program by which any manufacturer or private labeler of a consumer product may label product as complying with the applicable certification requirements for the product. If the manufacturer has certified that a consumer product complies with all applicable consumer product safety rules, the manufacturer or private labeler may affix a label to the product which states that the product: “*Meets CPSC Safety Requirements.*” The label must be visible and legible. This program is voluntary in that manufacturers and private labelers are not required to affix this label to their products. However, opting not to affix the label to the product would not relieve the firm of its responsibility to ensure that the products comply with the applicable safety rules and with all other provisions of the rule. This provision is not expected to have a significant impact on firms, however, because the program is voluntary, and the costs of adding or modifying a label on a product are expected to be low.

N. Cost of Third Party Testing and Potential Impact of the Rule

The costs of the third party testing requirements are expected to be significant for some manufacturers and are expected to have a disproportionate impact on small and low-volume manufacturers. This section discusses the cost of third party testing and the potential impact of the third party testing and other requirements of the final rule on manufacturers.

1. Cost of Third Party Testing

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The cost of third party testing is influenced by many factors, including the amount and skill of the labor required to conduct the tests, the cost of the equipment involved, the cost of transporting the product samples to the test facility, and the geographic area where the tests are conducted. Some tests require a substantial amount of time to conduct the tests, including the preparation of the samples. It might take a couple of days, for example, to test a bicycle for compliance with the bicycle standard (16 CFR part 1512). Similarly, a chemist testing the lead content of a product might be able to test only a few metal component parts per day, due to the amount of time required to prepare the samples and clean and calibrate the equipment between tests.

It should be noted that the price that a given manufacturer pays for testing is often the result of negotiations between the testing laboratory and the manufacturer. Manufacturers who do a large volume of business with a testing laboratory frequently can obtain discounts on the testing laboratory's normal charges; but manufacturers who do only a small volume of business may not be able to negotiate a discount on the testing.

Information on the cost of third party testing to determine compliance with some children's product safety rules is provided below. The information was collected from a number of sources, including published price lists from some testing laboratories, conversations with representatives of testing laboratories, actual invoices provided by consumer product manufacturers, and public comments we received. The data are not based upon a statistically valid survey of testing laboratories. Additionally, the costs include only the costs that would be charged by the testing laboratory. Not included in the information are the costs of the samples consumed in destructive tests, the cost of shipping the samples to the testing laboratories, and

any related administrative or recordkeeping activity. According to one commenter, these costs could add 15 to 50 percent to the third party testing costs.

2. Lead Content and Lead-in-Paint

The cost per component part for testing lead content and lead-in-paint using inductive coupled plasma (ICP) analysis will range from a low of about \$20 per test, to more than \$100 per test. The lowest per-unit cost represents a substantially discounted price charged to a particular customer by a testing laboratory in China, and therefore, the price might not be typical. Within the United States, typical prices range from around \$50, to more than \$100 per test.

The cost of testing for lead content using X-Ray fluorescence (XRF) technology is significantly less expensive. Some firms have offered to screen products for lead content for as little as \$2 per test. These offers are generally directed to stores or businesses that want to check their inventory for conformity with the retroactive lead content requirements contained in the CPSIA. Some testing laboratories will charge for XRF testing at an hourly rate, which can cost around \$100. Ten to 30 tests can be conducted in an hour.

We have approved XRF test methods for determining the lead content of homogenous polymer products. Assuming that 10 to 30 tests can be conducted in an hour at a rate of \$100 per hour, the cost of XRF testing for homogenous polymer products would be between \$3 and \$10 per test.

For testing the lead content of paint, we have approved the use of a specific XRF test method described in ASTM F2853 that uses energy dispersive XRF using multiple monochromatic beams. Generally, fewer tests can be conducted in an hour using this test method. If 6 to 12 tests can be conducted in an hour at a rate of \$100 an hour, then the cost of testing a paint for lead content using the approved XRF technique would be about \$8 to \$17.

Other than for homogenous polymer components and the lead content of paint, we have not approved the use of XRF techniques for testing any other materials. For other materials, such as metal components, manufacturers will need to use ICP analyses techniques to test for lead content.

3. Phthalates

The cost of testing for phthalate content will range from around \$100 (a discounted price by a testing laboratory in China) to about \$350. These are the costs per component part, and they include testing for all six of the individual phthalates whose content is restricted.

4. Bicycle Standard (16 CFR part 1503)

According to one testing laboratory, it takes one to two days to test a bicycle. The estimated price for testing one bicycle may range from around \$700, if the testing is performed in China, to around \$1,100, if the testing is performed in the United States. A manufacturer who needs several models of bicycles tested at the same time, might be able to obtain discounts on these prices. This does not include testing for lead or phthalates in nonmetal component parts. H.R. 2715, however, exempted the metal components of bicycles from the third party testing requirements for lead content.

5. Bicycle Helmets

One testing laboratory quoted a price of \$600 for testing one model of a bicycle helmet to the CPSC bicycle helmet standard. A price list from another testing laboratory stated that conducting the certification testing to the Snell Foundation's bicycle helmet standard, which is similar to the CPSC standard, is \$830.

6. Full-Size Cribs

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As with bicycles, testing cribs requires a substantial amount of labor time to assemble the crib, take the appropriate measurements, and perform the required tests. The cost of testing a full-size crib to the pre-2010 standard was about \$750 to \$1,200 for testing performed in the United States. The cost of testing a full-size crib to the current standard may be somewhat higher. The cost can vary, depending on the features of the individual cribs that require testing and among the various testing laboratories. Some manufacturers might receive discounted prices. This does not include testing the crib for lead and phthalates, which, to the extent necessary, would add to the cost of testing a crib to all applicable safety rules.

7. Toys

The children's product safety rules applicable to toys, including the ASTM F963 standard made mandatory by the CPSIA, include a wide variety tests, including tests for soluble heavy metals in surface coatings and for various physical and mechanical criteria. Based on the itemized prices on several invoices provided to us by testing laboratories or otherwise made public, the cost of the physical and mechanical tests range from about \$50 to \$245. The cost of the chemical test for the presence of heavy metals ranges from about \$60 to \$190 per surface coating. Again, these costs do not include testing for lead and phthalates, which add to the total cost.

The flammability requirements of ASTM F963 were not made mandatory by the CPSIA, but we were directed to examine the flammability requirements and consider promulgating rules addressing the issue. If some flammability tests are eventually required, the cost per test could be in the range of \$20 to \$50, based on some observed costs for the ASTM F963 flammability tests.

8. Cost of Third Party Testing by Product

The cost to obtain the required third party testing for a product depends on the types and number of tests that must be performed, the number samples that are required to provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the product to meet the applicable children's product safety rules or ensure continuing compliance with the applicable children's product safety rules. The cost of the testing also will be affected by the extent to which the manufacturer can use component part testing. Because of the wide variety of manufacturers and products that would be affected by the rule, we cannot provide comprehensive estimates of the impact of the rule on all manufacturers or products. The discussion below is intended to provide only some perspective on the potential impact.

9. Number of Samples Required

The final rule does not specify the exact number of samples that must be submitted to third party conformity assessment bodies, nor does it specify the testing interval, other than to provide maximum intervals. Instead, the final rule requires manufacturers to determine the number samples and the necessary testing interval based on factors such as: the variability of the product, manufacturing processes, and information obtained from other testing. However, it is likely that between certification testing, testing after a material change, and periodic testing, many manufacturers will need to submit more than one sample of a given product to third party conformity assessment bodies during a given year. Because some children's product safety rules require more than one unit of the product to complete all of the required tests, one sample may consist of multiple units of the product.

For purposes of certifying a children's product (including testing after a material change), the final rule requires manufacturers to submit enough samples to a third party conformity assessment body to provide a high degree of assurance that tests conducted for certification

purposes accurately demonstrate the ability of the product to comply with all applicable children's product safety rules. In determining how many samples to submit, a manufacturer is to consider the variability in the product and manufacturing processes. If the manufacturing process for a children's product consistently creates finished products that are uniform in composition and quality, such as with die casting, a manufacturer may be able to submit a relatively small number of samples to the third party conformity assessment body. If the manufacturing process for a children's product results in variability in the composition or quality of children's products, such as what might be expected with hand assembly, a manufacturer may need to submit a greater number of samples.

For periodic testing, the final rule requires that the number of samples selected must be sufficient to assess—with a high degree of assurance—the continuing compliance of the children's product with all applicable safety rules. Additionally, the testing interval for periodic testing must be short enough to ensure that, if the samples selected for periodic testing pass the test, there is a high degree of assurance that the other untested children's products manufactured during the interval comply with the applicable children's product safety rules. Manufacturers who have implemented a production testing plan or test in an ISO/IEC 17025:2005-accredited testing laboratory may consider the information obtained from the testing in determining the testing interval and the number of samples that are needed.

10. Hypothetical Toy Testing Example

To provide some information on what the magnitude of the third party testing costs may be for some manufacturers of children's products, this section discusses the potential cost of obtaining third party testing for a hypothetical toy. This example is hypothetical and is intended to illustrate some potential cost implications of the rule. The example is not intended be

representative of every product or manufacturer. The costs per test that are assumed in the examples are based on the cost of tests discussed above ; but the actual costs can vary significantly between conformity assessment bodies. The testing costs for any particular manufacturer also depend upon factors such as the complexity of the products, the variation in the materials used, manufacturing processes used, opportunities to use component part testing, and so on. We used a similar example in the initial regulatory flexibility analysis. The discussion has been changed to reflect the fact that energy dispersive XRF analysis can be used to test for lead in paint in addition to XRF testing in homogenous polymer products. We also have modified the discussion to deemphasize references to statistical measurements because, although statistical measurements might be useful, the number of samples that must be tested need not be one that provides a particular confidence level, such as 95 percent confidence level that all products in a lot are compliant.

Toys must meet requirements concerning lead and phthalate content, as well as several physical and mechanical requirements, including the requirements of ASTM F963, which was made a mandatory standard by the CPSIA. In this example, we assume that the testing costs are at the low to middle part of the ranges discussed above, and we also assume that the hypothetical toy contains one metal component part that must be tested for lead content using ICP analysis (at \$50) and two plastic component parts for which XRF analysis can be used for determining the lead content (two tests at \$6 each). The plastic component parts also must be tested for phthalate content (two tests at \$225 each). Additionally, we assume that the toy contains four different paints that must be tested for both lead content (\$13/test, assuming energy dispersive XRF analysis) and soluble heavy metals (\$125/test). Finally, we assume that the toy is subject to some mechanical requirements that include use and abuse testing (\$50 per test).

Thus, the cost of testing the hypothetical toy for compliance to each applicable rule one time would be \$1,114: \$1,064 is associated with the chemical (lead, heavy metal, and phthalate) testing, and \$50 is associated with the mechanical testing (including use and abuse testing).

Having one sample tested by a third party conformity assessment body will probably not be sufficient to meet the requirements of the final rule. Therefore, the cost of the third party testing for the manufacturer of this hypothetical toy would be greater than \$1,114. For example, if four samples are needed, the cost would be \$4,456. The cost would be higher if some tests had to be conducted more than four times to provide the required high degree of assurance. The manufacturer might be able to reduce the third party testing costs if it is able to use component part testing for the chemical content tests. For example, if the plastic resins, metal component part, and paints are used on other products, the manufacturer could test the component parts independently of the individual finished products and spread the cost of the chemical content tests over more than one finished product. If the average cost of the chemical content tests could be reduced by a factor of four through component part testing, then the cost of testing the toy in this example for conformity with all applicable safety rules one time would be \$316 (cost of chemical testing of \$1,064/4 and cost of the mechanical and use and abuse testing of \$50). However, the cost of third party testing for the manufacturer would likely be higher because testing one sample will seldom be sufficient to provide the required high degree of assurance. For example, if each component part required four tests, and the mechanical testing required must be repeated four times to provide the required high degree of assurance, then the cost of the third party testing for the hypothetical toy would be \$1,264.

11. Impact of Final Rule on Firms

Whether the third party testing costs would have a substantial adverse impact on a firm depends upon the individual circumstances of the firm. One factor is the magnitude of the impact in relation to the revenue of the firm. A typical profit rate is about five percent of revenue. In other words, for every one dollar of revenue, only five cents might remain after paying all expenses. Therefore, a new cost that amounted to one percent of revenue could, all other things equal, reduce the profit by 20 percent and would be considered to be a significant impact by most firms. This would be consistent with what some other agencies consider to be significant. The Occupational Safety and Health Administration (OSHA), for example, considers an impact to be significant if the costs exceed 1 percent of revenue or 5 percent of profit.⁴

Some insight on the disparate impact that the final rule could have on small businesses can be provided by examining how the rule might impact three hypothetical toy manufacturers of different sizes. The costs associated with third party testing that the hypothetical manufacturers would face will be described, and the potential impact on the hypothetical manufacturers will be discussed. This discussion is summarized in Table 5.

Table 5. Impact of Rule on Three Hypothetical Firms

		Hypothetical Firm A - Large Manufacturer	Hypothetical Firm B - Small Manufacturer	Hypothetical Firm C - Small Batch Manufacturer
1	Number of Different Products	1,000	100	10
2	Annual Production Volume per Product	100,000	10,000	1,000
3	Total Annual Production Volume (Row 1 x Row 2)	100,000,000	1,000,000	10,000

⁴ OSHA, Assigned Protection Factors, Final Rule, Federal Register (71:50121-50192), 24 August 2006.

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4	Revenue per unit sold	\$4	\$4	\$4
5	Total Annual Revenue (Row 4 x Row 3)	\$400,000,000	\$4,000,000	\$40,000
6	Cost of testing each product for compliance with all rule once	\$1,114	\$1,114	\$102
7	Cost of Testing Each Product 4 Times (Row 6 x 4)	\$4,456	\$4,456	\$408
8	Total Third Party Testing Cost (Row 7 x Row 1)	\$4,456,000	\$445,600	\$4,080
9	Cost of Samples (4 samples of 2 units of each product)	\$32,000	\$3,200	\$320
10	Recordkeeping (5 hours/product at \$36.43/hour)	\$182,150	\$18,215	\$1,822
11	Total Testing Cost for One Year (Sum of Rows 8 through 10)	\$4,670,150	\$467,015	\$6,222
12	Testing Cost as Percent of Revenue (Row 11/Row5)	1.2%	11.7%	15.6%

12. Three Hypothetical Manufacturers

The first hypothetical manufacturer, Firm A, is a large toy manufacturer that offers 1,000 different toys with an annual production or sales volume of 100,000 units each. Its total annual production volume is then 100 million units (1,000 products x 100,000 units each), which is shown in Row 3 of Table 5. The second hypothetical manufacturer, Firm B, is a smaller toy manufacturer offers 100 different products with an annual production or sales volume of 10,000 units each. Finally, the third hypothetical toy manufacturer is a small batch manufacturer that offers only 10 products that with an annual production or sales volume of about 1,000 units each.

13. Revenue

The average price of a toy is \$7 to \$8.⁵ However, because the retailer and any wholesalers or distributors would also get a share of the revenue, the manufacturer would be expected to get a fraction of the retail price. Therefore, the revenue received by a manufacturer of a toy that retails for \$7 to \$8 might be about \$4 per unit. For some toys, the revenue per unit received by the manufacturer might be lower, and for others it might be higher. To begin the example, we assume that the average revenue is \$4 per unit. The Total Annual Revenue of the Firm (Row 5) is found by multiplying the Revenue per unit (Row 4) by the Total Annual Production Volume (Row 3).

14. Third Party Testing Costs

The final rule requires manufacturers to have children's products tested by a third party conformity assessment body before the products are distributed, periodically after that, and when there has been a material change in the product. In these hypothetical examples, we assume that the manufacturers must submit samples of their products to third party conformity assessment bodies annually, whether for initial certification of products, periodic testing, or recertification after a material change.

The cost of the third party testing for a toy is a function of the characteristics of the toy, such as the number and type of component parts, the materials used in its construction, and the specific toy standards and tests that apply to it. The cost of third party tests would not be expected to be affected by the size of the manufacturer (although some conformity assessment bodies might offer discounts to firms for whom they conduct a lot of testing). In the hypothetical example, we assume that the conformity assessment bodies will charge the manufacturer \$1,114

⁵ Retail sales of toys in the United States are about \$22 billion per year (Toy Industry Association press release dated 27 June 2011). A representative of the Toy Industry Association estimated that there are about 3 billion individual toys sold annually in the United States. This suggests an average retail price of \$7 to \$8 (\$22 billion x 3 billion).

to test the toy for conformance with each applicable children's product safety rule (Row 6), which is the same cost used in the earlier discussion of the cost to test a hypothetical toy. In the case of Firm C, a small batch manufacturer, the third party testing costs may be lower. Unless we establish alternate requirements for small batch manufacturers, H.R. 2715 may effectively exempt the qualifying products of small batch manufacturers from many third party testing requirements, including the requirements for phthalates, heavy metal content of paints, and the lead content of substrates (but not from other requirements, such as lead-in-paint or children's metal jewelry). In the case of the toy example, Firm C will need to have the paints used tested for lead content and the toys themselves tested for small parts. Using the costs assumed in the hypothetical toy example, the cost to Firm C for testing each product once to the two applicable requirements would be \$102 (4 paints at \$13 each and for small parts at \$50).

This hypothetical example assumes that it is necessary conduct each applicable test four times to provide the manufacturer with the necessary high degree of assurance, whether for the initial certification of the product, or to meet the periodic testing requirement. Therefore, the total cost that the manufacturer will be charged by a third party conformity assessment body is \$4,456 per product for Firms A and B, and \$408 per product for Firm C (Row 7). Because each manufacturer produces more than one product, total third party testing costs (Row 8) is equal to the cost per product times the number of products produced multiplied by the number of products produced (Row 7 x Row 1).

In this hypothetical example, we further assume that, to conduct each test at least once, the manufacturer must submit two units of the toy to the conformity assessment body. In other words, a sample consists of two units of the product. The cost of the samples consumed by testing is the revenue that the manufacturer forgoes because the units were used for testing and

not sold. Therefore, the cost of the samples consumed in the testing (given in Row 9) is calculated as the product of the 8 units required to conduct the tests, the revenue per product, and the number of different products (*i.e.*, 8 x Row 4 x Row 1).

Although component part testing has the potential to reduce third party testing costs, component part testing is not considered initially in these examples. One reason we did not consider it is that it has not been determined how extensively component part testing will be used in practice. Component part testing generally might not be an option for component parts that are not used in multiple products, or for which only a small portion of the production is used in children's products. It also might not be applicable to some importers or manufacturers who obtain products from suppliers that do not have the capability for component part testing, or for which the manufacturer or importer, exercising due care, has not yet developed the degree of confidence in the supplier to rely upon test reports and records provided by the supplier.

15. Recordkeeping

Firms will incur costs for preparing and maintaining the records and documentation required by the final rule. In this example, we assume that the recordkeeping will require approximately five hours per toy. Assuming that the total compensation, per hour, for the employees involved in the recordkeeping is \$36.43,⁶ the recordkeeping cost would be about \$182 per product. The total recordkeeping burden (given in Row 10) is the cost per product (\$182), multiplied by the number of products (Row 1). This estimate of the recordkeeping burden assumes that the manufacturer will not be required to acquire any additional equipment or software to comply with the recordkeeping requirements of the final rule.

⁶ This is based on the assumption that about half the labor is management or professional and the other half is sales or office labor. For the all workers in private industry, the total hourly compensation for management, professional, and related occupations is \$50.08 and \$22.78 office and administrative occupations (Bureau of Labor Statistics, Employer Cost for Employee Compensations, March, 2011).

16. Total Testing Cost

The total cost of testing for one year is the sum of the cost of the third party testing, the cost of the samples consumed in the testing, the cost of the recordkeeping, and the cost of developing the sampling plans. This is given in Row 11 of Table 5.

Manufacturers may incur other costs that were not considered above. For example, the proposed rule contained provisions requiring manufacturers to select the samples for periodic testing, using techniques that would result in a statistical simple random sample. There will likely be costs associated with such requirements. These potential costs include: the cost of hiring consultants to design a sampling plan for selecting a sample that meets established requirements and the cost of the added time and effort that might be required in selecting such a sample. However, H.R. 2715 revised section 14(i)(2)(B)(ii) of the CPSIA by replacing the phrase: “the testing of random samples to ensure continued compliance” with the phrase: “the testing of representative samples to ensure continued compliance.” Because of this change in the statute, we are not finalizing the section of the proposed rule pertaining to random samples. These costs will be addressed in more detail when we consider how to implement section 14(i)(2)(B)(ii) of the CPSA, as amended by the CPSIA and H.R. 2715.

17. Impact on Hypothetical Firms

The impact of the testing costs on each of the hypothetical firms is summarized in Row 12 of Table 5. For the large manufacturer, Firm A, the testing costs could amount to 1.2 percent of the firm’s revenue (total testing cost, divided by the total revenue) if the firm received about \$4 per product. This could be considered a significant impact. (A typical profit is about 5 percent of total revenue. Thus, a 1.2 percent increase in costs could decrease profit for a typical

firm by 24 percent.) If the average revenue that this firm received is somewhat higher, however, the impact probably would not be considered significant.

For Hypothetical Firm B, a smaller manufacturer, the testing costs would amount to about 11.8 percent of the firm's revenue, if the firm received an average of \$4 for each unit produced. For the small batch manufacturer, Firm C, the testing costs would amount to about 15.6 percent of its revenue. In both cases (*i.e.*, Firms B and C), costs amounting to 11.8 percent and 15.6 percent, respectively, of revenue would be considered a significant impact. These hypothetical examples illustrate the disproportionate impact that the final rule may have on small businesses. As illustrated, the final rule could also have a significant impact on even a large manufacturer. The significance of the impact increases as the production or sales volume of the manufacturer decreases.

The example of Firm C can be used to demonstrate the relief that H.R. 2715 may be able to provide to small batch manufacturers. If Firm C is unable to benefit from the testing exemptions provided by H.R. 2715, then Firm C would have faced the same per-unit testing costs as the other firms in this example: \$1,114 instead of \$102. Under that scenario, the total testing cost for Firm C would have been more than \$46,000, which would have exceeded its revenue of \$40,000.

Some small manufacturers probably have average revenues per product that exceed \$4. This might be the case especially if it is a specialty or niche market, in which only a few manufacturers participate, or if the product requires a substantial amount of skilled labor to create. Table 6 shows what the impact would be on Firm C, the hypothetical small batch manufacturer, if it received an average of \$50 per unit for each unit it sold. Its total revenue would increase to \$500,000 per year. The cost of the samples consumed in testing would

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increase to \$4,000 (Row 9), which would increase the cost of testing to \$9,902 (Row 11). The testing costs would amount to about 1.9 percent of the firm's revenue, which might be considered significant, but it is much lower than it would have been if its revenue per unit was lower. It should be noted that if the manufacturer receives \$50 per unit sold of a product, the retail price is likely substantially higher (unless the manufacturer sells a substantial portion of the product directly to the final consumer).

Table 6. Impact on Hypothetical Firm C if Revenue per Unit Is \$50

		Hypothetical Firm C - Very Small Manufacturer
1	Number of Different Products	10
2	Annual Production Volume per Product	1,000
3	Total Annual Production Volume (Row 1 x Row 2)	10,000
4	Revenue per unit sold	\$50
5	Total Annual Revenue (Row 4 x Row 3)	\$500,000
6	Cost of testing each product for compliance with all rule once	\$102
7	Cost of Testing Each Product 4 Times (Row 6 x 4)	\$408
8	Total Third Party Testing Cost (Row 7 x Row 1)	\$4,080
9	Cost of Samples (4 samples of 2 units of each product)	\$4,000
10	Recordkeeping (5 hours/product at \$36.43/hour)	\$1,822
11	Total Testing Cost for One Year (Sum of Rows 8 through 11)	\$9,902
12	Testing Cost as Percent of Revenue (Row 12/Row5)	1.9%

There also will be other costs that could be associated with the rule for which no quantification was attempted in the above hypothetical examples. One cost that was not considered is the additional administrative costs that are likely associated with the final rule's requirements; these include the cost of tracking when each product or component part needs to

be tested. It also includes the cost of monitoring the suppliers and component parts that are used, the production techniques used, and any changes in product design to determine when products need to be tested due to material changes. There also may be administrative costs in matching up test reports to finished goods and giving the approval to ship products that the manufacturer has certified.

Another cost that could impact manufacturers for which quantification was not attempted is the cost of receiving test reports that indicate inaccurately that the product did not comply with a children's product safety rule. When a manufacturer receives a test report that indicates inaccurately that a product does not meet a standard, the manufacturer could assume that the test was accurate and needlessly dispose of, or attempt to rework, the products covered by the test result; or, it might suspect that the test report was inaccurate and investigate the reason for the test failure. This could involve retesting samples of the product by other conformity assessment bodies and having the conformity assessment body that produced the inaccurate result attempt to determine if any error was made in testing the product. In any case, this could result in delays in shipping product and lost sales.

Component part testing may offer some manufacturers relief from some testing costs. Component part testing may allow the cost of the third party testing to be spread over more units of the component part, which ultimately lowers the cost of third party testing per unit of the finished product. For example, if the hypothetical firms in the above examples were able to reduce the cost of third party testing by a factor of four using component part testing, in several (but not all) of the scenarios examined, the impact on those small firms could be reduced to the point that it would no longer be considered significant. However, component part testing is not likely to be an option for all manufacturers, for all component parts, or for all tests. Moreover,

although it can reduce the cost of the third party testing, it may not reduce other costs associated with the final rule, such as the cost of samples, the cost of the recordkeeping, and other administrative costs.

It should be noted that the examples above were for illustration purposes only. The number of times a product may have to be tested for certification purposes or for periodic testing purposes may be more or less than four times. The cost of testing some toys and other children's products could be higher or lower than the cost used in the above examples. The cost would be higher, for example, for products that had more component parts or for which the variability in the test results is greater, which could require more samples to be tested. The cost of testing could be lower for products that are subject to fewer safety rules or that contain fewer component parts. For some articles of apparel, for example, the only tests required might be for flammability and lead content on some component parts, for which component part testing might be possible. Although the examples suggest that some small businesses will be significantly adversely impacted by the final rule, some small businesses may have sufficient volume, sufficiently low testing costs, or sufficiently high revenue that the impact will not be significant.

18. Possible Market Reactions and Caveats

Manufacturers can be expected to react to a significant increase in their costs due to the final rule in several ways. Some manufacturers might attempt to redesign their products to reduce the number of tests required, by reducing the features or the number of component parts used in the products that require testing. Manufacturers and importers could also be expected to reduce the number of children's products that they offer or, in some cases, exit the market for children's products entirely. Some may go out of business altogether.

The requirements of the final rule could be a barrier that inhibits new firms from entering the children's product market, unless they expect to have relatively high-volume products. This could be an important factor for firms that expected to serve a niche market, such as firms with products intended for children with special needs. Although H.R. 2715 may provide significant relief to small batch manufacturers, the requirements could still be a barrier for some small batch manufacturers, home-based manufacturers, and craftspeople. The requirement for third party testing when there is a material change in a product's design or manufacturing process could cause some small or low-volume manufacturers to forgo or delay implementing some improvements to a product's design or manufacturing process in order to avoid the costs of third party testing.

Although component part testing has the potential to reduce the costs of testing, component part testing might not be an option for all products or manufacturers. Component part testing most likely is an option for component parts that are common to multiple products (*e.g.*, paints, bolts of a standard size). The potential for component part testing to reduce the cost of testing would be less for products that have component parts that are unique to the particular product. Component part testing is also not likely to offer significant cost savings for low-volume component parts or for component parts from which the component part manufacturer derives only a small percentage of revenue on regulated or children's products. Moreover, to use component part testing, the manufacturer must be able to trace each component part for which component part testing was used, to the party who procured the test. Maintaining this traceability will involve some administrative and recordkeeping costs, which will reduce the potential benefit of component part testing.

Manufacturers may be able to mitigate the adverse impacts if they are able to raise their prices to cover these costs. However, because few companies have perfectly inelastic demand curves, most firms will likely have to absorb some of the cost increases that result from the final rule.

O. Conclusion

The final rule will have a significant adverse impact on a substantial number of small businesses. The provisions of the rule that are expected to have the most significant impact are provisions related to requirements for the third party testing of children's products and the associated administrative and recordkeeping requirements. The impact is expected to be disproportionate on small and low-volume manufacturers. This is because testing costs are relatively fixed. Therefore, the impact of testing costs, per unit, will be greater on low-volume producers than on high-volume producers.

H.R. 2715 may provide significant relief from the third party testing costs to certain manufacturers who meet the definition of a "small batch manufacturer." However, although the impact will be substantially reduced, some small batch manufacturers may still be significantly impacted by the requirements in the final rule.

The other provisions of the rule related to protections against undue influence over a conformity assessment body and the voluntary consumer product labeling program are likely to have less significant impacts on small businesses.

P. Federal Rules Which May Duplicate, Overlap, or Conflict with the Final Rule

The final rule implements certain provisions of the CPSIA pertaining to the certification and continued testing of children's products for compliance with children's product safety rules. Certain children's product safety rules contain some requirements for certification tests and

reasonable test programs. However, any duplication, overlap, or conflict should be minimal. For example, the third party certification tests required by the final rule would satisfy the requirements for certification tests in any existing children's product safety rule. Any production testing required by an existing children's product safety rule can be used to increase the maximum period between periodic tests according to the provisions of the final rule.

Q. Alternatives for Reducing the Adverse Impact on Small Businesses

We recognize that the final rule will have a disproportionate impact on small and low-volume manufacturers. To a large degree, the impact is not avoidable because the CPSA, as amended by the CPSIA, requires that the certification of children's products be based on test results from accredited third party conformity assessment bodies. However, we have incorporated into the final rule, some provisions that are intended to lessen the impact on small businesses. These include: provisions allowing for longer maximum intervals between periodic testing if the manufacturer conducts certain other testing; allowing manufacturers to use component part testing; and permitting manufacturers and importers to rely upon the certifications issued by other parties as a basis for issuing their own finished product certificates, as provided by 16 CFR part 1109.

We also identified and considered several alternatives that could have reduced the impact on small businesses, but which for reasons discussed below, were not adopted in the final rule. These include: providing additional testing relief for low-volume products; reducing the number of samples that must be tested by third party conformity assessment bodies; basing the frequency of third party testing on the risk of injury from the product; and allowing the use of XRF testing for lead content for more materials.

R. Provisions Incorporated in the Final Rule

1. Longer Maximum Periodic Testing Interval if the Manufacturer Conducts Other Testing

The final rule provides for a longer maximum periodic testing interval if the manufacturer implements a production testing plan, as provided for in § 1107.21(c) of the final rule. The manufacturer may consider the information obtained from the production testing in determining the appropriate interval and number of samples required for third party periodic testing, provided that third party periodic testing occurs at least once every two years.

If the manufacturer conducts testing in an ISO/IEC 17025:2005-accredited testing laboratory in accordance with § 1107.21(d) of the final rule, the maximum periodic testing interval is three years. However, this provision is expected to be of benefit primarily to larger manufacturers.

2. Component Part Testing

The final rule allows firms to conduct component part testing pursuant to the requirements in 16 CFR part 1109. This can reduce the cost to manufacturers where one component part might be common to more than one product. Such component parts might include paints, polymers used in molding different parts, and fasteners. In these cases, the component parts might be received in larger lots than the production lots of the products in which they are used. Therefore, the testing costs for those component parts will be spread over more units than if they were required to be tested on the final products only.

3. Reliance on Certifications by Other Parties

The final rule allows manufacturers and importers to rely upon testing obtained by or certifications made by another party as the basis for their own certificates, as allowed by 16 CFR part 1109. These certifications can be for component parts or for finished products. This provision would be of value to importers, who may base their own certificate of conformity on

the certificate for a finished product issued by a foreign manufacturer, provided that the requirements of 16 CFR 1109 are met.

S. Alternatives that May Further Reduce the Impact on Small Businesses

Additional Testing Relief for Low-Volume Manufacturers of Children's Products

The proposed rule would include a provision that would provide some relief to low-volume manufacturers of children's products, by exempting products from the periodic testing requirement until 10,000 units of the product have been manufactured or imported. Once 10,000 units have manufactured or imported, the periodic testing requirements would apply to the product. This provision did not relieve the manufacturer or importer from the obligation to have the product tested by a third party conformity assessment body for: (1) certification purposes, and (2) when there had been a material change in the product's design or manufacturing processes or sourcing of component parts. Thus, the manufacturer would have still been obligated to submit samples to a third party conformity assessment body to demonstrate that the product conforms with the applicable children's product safety rules prior to introducing the product and when there has been a material change. The provision only relieved the manufacturer from the periodic testing requirements until 10,000 units of the children's product had been manufactured or imported.

On August 12, 2011, H.R. 2715 was enacted into law. H.R. 2715 has the potential to provide substantial relief to "small batch manufacturers," which H.R. 2751 defines as manufacturers that had no more than \$1 million in total gross revenue from sales of all consumer products in the previous calendar year. H.R. 2751 also defines "covered product" as a consumer product manufactured by a small batch manufacturer where no more than 7,500 units of the same product were manufactured in the previous calendar year. Because the provisions for small

batch manufacturers in H.R. 2715 may provide relief to many of the same manufacturers at which the low-volume exemption in the proposed rule was aimed, we decided to defer action on the low-volume exemption.

For most small batch manufacturers, the relief provided by H.R. 2715 may be greater than the relief that would have been provided by the low volume-exemption from in the proposed rule because the H.R. 2715 provides small batch manufacturers with relief from both certification and periodic testing, with some exceptions, while the low volume exemption in the proposed rule only provided some relief from periodic testing. However, the partial exemption from periodic testing that the proposed rule would provide for products where fewer than 10,000 units had been imported or manufactured could provide some relief for some manufacturers of low-volume products that are not categorized as small batch manufacturers by H.R. 2715. There are likely some manufacturers that have low-volume products, but that also have gross sales that exceed \$1 million. These manufacturers will receive no relief from the small batch manufacturer exceptions in H.R. 2715, but would have been provided some relief by the low-volume exemption in the proposed rule. Consequently, including the partial exemption from periodic testing for low-volume products from the proposed rule, could provide some relief to manufacturers of low-volume products that do not meet the definition of a small batch manufacturer.

We have decided to reserve the provision of the proposed rule that would provide partial relief from periodic testing for low-volume products. The reason is that H.R. 2715 directed us to seek public 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. It also contains special rules for small batch manufacturers and directs

us to consider alternative testing requirements or to exempt small batch manufacturers from certain third party testing requirements. Thus, given these new statutory obligations resulting from H.R. 2715, we are reserving § 1107.21(e) so that we may consider how to address cost, low-volume products, and small batch issues more fully.

1. Reduce the Number of Repeated Third Party Tests Required for Certification

The final rule requires that manufacturers submit samples of children's products to third party conformity assessment bodies to: (1) certify that they comply with all applicable children's product safety rules before they are distributed; (2) after material changes; and (3) periodically to ensure continued compliance with all applicable children's product safety rules. The number of samples required is not specified, but would be based upon factors, such as the degree to which the manufacturing processes create products that are uniform in composition and quality, the testing interval, and the number of samples required to ensure with a high degree of assurance that a certified product continues to comply with all applicable children's product safety rules. It is likely that most manufacturers will need to have a product third party tested multiple times for both certification and periodic testing purposes.

An alternative that could provide some relief to small businesses is to require, for purposes of certifying a product, manufacturers to submit sufficient units of the product to conformity assessment bodies to ensure that the product can be tested for compliance with each applicable children's safety rule, at least once, or as many times as required by the specific regulation, if different. The same requirement could apply to periodic testing: at least once during the periodic testing interval established by the rule (*e.g.*, once a year) manufacturers would be required to submit sufficient units of the product to ensure that each applicable children's product safety rule is evaluated at least once. In some cases, all of the required tests

could be performed on one unit of the product. In other cases, more than one unit of the product might be required to test the product to all applicable children's product safety rules. For example, more than one unit of a toy might be required to subject the toy to each use and abuse test that is applicable to the toy; the tests specified in the bicycle helmet standard require eight helmets. Nevertheless, each test would only need to be conducted one time. This could reduce the financial burden of the third party testing requirements on small businesses.

Under this alternative, manufacturers could still be required to have a high degree of assurance that their children's products complied with all applicable children's product safety rules. However, the testing or inspections needed to provide the manufacturer with a high degree of assurance of compliance could be first or third party testing, or by other process control means, at the option of the manufacturer. The purpose of the required third party tests would be to provide objective evidence of compliance.

We did not accept this alternative because, although it arguably would provide a greater level of evidence of compliance than what existed before the enactment of the CPSIA, it would not require enough third party testing to provide a high degree of assurance that children's products complied with all applicable children's product safety rules. An analysis of CPSC compliance data for children's shoes found several examples where test results for one sample of an article indicated compliance with the lead content requirements, but tests results for a different sample of the same article showed lead levels that exceeded the standard.⁷ This suggests that testing one sample may not always be sufficient to detect noncomplying products.

2. Allow Increased Use of XRF Analysis

⁷ CPSC Memorandum to the Commission, from John W. Boja, Howard N. Tarnoff, Mary F. Toro, and Marc J. Schoem, "The Technological Feasibility of Reducing the Lead Content to 100 ppm: Compliance Data" (29 June 2011).

XRF analysis is a testing technique that can be used to measure the heavy metal content of materials. The cost of using XRF analysis testing is generally less expensive than using ICP analysis. Currently, we have approved XRF analysis for determining the lead content of homogenous polymer products and one type of XRF analysis (energy dispersive XRF using multiple monochromatic beams using the test method in ASTM F2853-10) for paints. We have not approved the use of XRF analysis for determining the lead content of metal component parts. However, allowing the use of XRF analysis for determining the lead content of metal component parts could substantially reduce the cost of the third party testing. The reduction could be especially significant for manufacturers of children's products that have a lot of metal component parts.

We decided not to allow the expanded use of XRF analysis to determine lead content at this time. However, we are continuing to evaluate the potential use of XRF analysis, and should we determine that XRF analysis can be sufficiently accurate in determining lead content, in a separate rulemaking, we could consider expanding the allowable use of XRF analysis for third party testing. Moreover, H.R. 2715 directed us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable children's product safety rule. Further, H.R. 2715 directs us to seek public comment on the extent to which technology, other than the technology already approved by the Commission, exists for third party conformity assessment bodies to test or to screen for testing consumer products subject to a third party testing requirement. Therefore, we may consider alternatives to reduce the cost of third party testing requirements more fully at a later date.

3. Basing the Frequency of Periodic Testing on Risk of Injury or Illness

The final rule requires that periodic testing be performed at least once every one to three years, depending on the other testing that a manufacturer opts to perform. An alternative that would reduce the burden of the rule on some small businesses is to lengthen the time period between required periodic tests for products, component parts, or rules for which the risk of serious injury or illness from a violation of a children's product safety rule is low. This would reduce the burden on some manufacturers because it could reduce the amount of required third party testing.

This alternative was not accepted because, given the number of children's product safety rules and the large number and wide variety of children's products to which they apply, its administration would be complex and would require a large investment of resources to analyze and rank the risk of serious injury or illness that could result from each product or product category failing to comply with each applicable children's product safety rule and then determining the appropriate periodic testing requirements for the product or product category.

4. Alternatives Not Considered Because They Would Conflict with the Statute

We are aware of some alternatives that could reduce the burden of the rule but that were not considered in this rulemaking because adopting the alternative would conflict with the statute. For example, although we have been able to exempt some materials from the testing requirements that inherently do not contain lead in excess of the limits established by the CPSIA, we are not able to exempt materials from testing that can exceed those limits even if the health hazard associated with the materials or component parts is believed to be minimal. Likewise, we are not able to exempt from the testing requirements products for which compliance with the applicable safety rule is thought to be very high even without a mandatory third party testing requirement.

IV. Paperwork Reduction Act

The final rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The preamble to the proposed rule contained a discussion of the estimated burden associated with the rule’s collection of information requirements (75 FR at 28360 through 28361).

Several commenters addressed issues relating to the Paperwork Reduction Act discussion.

(Comment 113) - Some commenters noted that the preamble to the proposed rule states that we will likely request access to records only when we are investigating potentially defective or noncompliant products. The commenters concluded that having to integrate multiple systems to compile data should not be needed, as long as companies can provide the data upon request. One commenter noted that proposed § 1107.10 (b)(5)(i)(C) would require not only records of each certification test, but also “a description of how the product was certified as meeting the requirements, including how each applicable rule was evaluated, the test results and the actual values of the tests.”

One commenter stated that it receives more than a thousand finished good test reports annually from CPSC-accepted third party labs. These reports often run 50 to 125 pages in length and contain hundreds of data points and assessments. The commenter asserted that adding additional descriptive text to explain “how” the product was certified, simply adds no value. The commenter concluded that if the test report references an ASTM standard, and the results are acceptable, that should be sufficient without additional explanations.

(Response 113) – The final rule reserves subpart B, which would contain proposed § 1107.10 and requirements for a reasonable test program for non-children’s products, including the recordkeeping requirements. Therefore, the final rule does not impose any recordkeeping requirements related to non-children’s products.

With respect to children’s products, the recordkeeping requirements at § 1107.26 of the final rule do not require descriptive text to explain “how” the children’s product was certified. The certification test methods are prescribed for children’s products. It should only be necessary for the manufacturer or importer to identify and store the new requirements that are not already part of their current recordkeeping systems and to be certain that the remaining documentation can be produced, upon request, in a manner that identifies clearly the requisite parts.

(Comment 114) - Several commenters addressed our estimated resource requirements to manage the general recordkeeping requirements for testing and certification. One commenter stated that the toy industries’ experience in meeting the recordkeeping requirements of the interim enforcement policy is that the requirements are extremely burdensome, and the recordkeeping requirements contained in the proposed rule are much more extensive and will be even more costly. The commenter stated that our estimate of 200,000–300,000 hours to manage recordkeeping, equating to no more than 200 people across all industries impacted by the CPSIA, is much too low. Within the toy industry alone, the commenter estimated 10 times that many persons have been engaged along the global supply chain to manage the data and recordkeeping associated with the CPSIA’s existing requirements. Although we referenced a calculation of 100,000 to 150,000 products to which the recordkeeping requirements would apply, the commenter stated that companies typically certify each SKU, and there is recordkeeping for every version, even if it is identical in all material respects.

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One commenter estimated that the true number of toys and games was closer to 2.5 million. The commenter's estimate was based on a listing of 808,465 toys and games on a popular commercial website (on August 3, 2010), plus its estimate that the website only lists about one-third of the toys available. Given some specialty and other submarkets, the commenter thought that the final number of items in the *Toys, Games, and Educational* items category could be in excess of 4 to 5 million individual products or stock-keeping units. The commenter also provided an estimate of 8 million apparel items available for children. However, the commenter did not provide the method or data sources it used for the latter estimates. Another commenter noted that its company had about 1,700 individual products annually, requiring testing, certification, and recordkeeping, or more than 1 percent of the CPSC's entire estimated number of products across all affected industries.

(Response 114) - We acknowledge that our original estimate of the number of products that would be impacted was low, and we have increased significantly our estimate of the recordkeeping burden associated with the testing and certification requirements of the final rule. Based on the comments, and other research, we have revised our estimate of the number of children's products. In the categories of toys, art and creative materials, furniture, and jewelry, we estimate that there are perhaps 241,000 different products. There are additional products in other categories, such as nursery or juvenile products, nontraditional toys (*e.g.*, video games), CDs, bicycles, ATVs, party favors, and greeting cards intended for children, and some educational materials that could be affected by the final rule for which specific estimates have not been made. The estimates do not consider that some products might be produced at more than one location or certified by more than one importer. Therefore, we concluded that there could be 300,000 non-apparel products that are covered by the rule.

The original estimate did not account for the very large number of apparel products that would be covered by the final rule. The number of apparel products intended for children, including footwear, is estimated to be about 1.3 million. This would bring the total number of children's products to about 1.6 million.

The final rule has been changed to address some of the burdens mentioned by the commenters, such as not requiring records to be kept in the United States or translated into English, unless requested.

As noted above, we intend to issue a notice seeking public comment on other methods of lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(Comment 115) - One commenter asserted that its company's testing program has been highly effective for more than 26 years, but it does not maintain the records that would be required by the proposed rules, and it would be very costly to do so. One commenter questioned whether the extensive recordkeeping on every item was necessary for the proper performance of the CPSC's functions.

Another commenter echoed the concern that the cost of the recordkeeping requirements would be high without providing any clear benefit to the agency's mission or product safety. The commenter estimated that a major retailer would need to maintain records on 300,000 distinct products, which would cost the retailer \$22 million annually, using the estimated per product recordkeeping burden employed in the notice of proposed rulemaking. Another commenter stated that we should reduce the reporting burden by allowing manufacturers or importers to maintain their own recordkeeping systems if they meet the traceability requirements and ensure that products are certified properly before they enter into commerce.

(Response 115) - With respect to recordkeeping requirements for reasonable testing programs for non-children's products, we have reserved subpart B, which would contain requirements for reasonable testing programs for non-children's products. Therefore, the final rule does not impose any recordkeeping requirements on manufacturers of non-children's products.

With respect to children's products, we acknowledge that the recordkeeping requirements could require considerable resources to track the data and manage recordkeeping. As a result, the costs associated with the recordkeeping requirements could be a significant expense for some firms. However, as stated in the preamble to the proposed rule, the purpose of the documentation and recordkeeping requirements in the rule is to establish the identity of the product and to demonstrate that each product complies with the applicable rules when it is certified and on a continuing basis thereafter. Additionally, we note that retailers are not required to comply with the recordkeeping requirements of the rule, unless they are also the importer of the product.

We also have revised the final rule to reduce the costs associated with the recordkeeping requirements. For example, the final rule does not require manufacturers to maintain the records at a location in the United States, as long as they can provide the records to us, after receiving a request to do so. Also, with the exception of the certificates of conformity, the records will not have to be maintained in the English language.

Finally, the final rule does not require that the records be in a specific format. The final rule specifies the records or information that is required. However, manufacturers may maintain the records within their own recordkeeping systems if, as suggested by the commenter,

they meet the traceability requirements and ensure that products are certified properly before they enter into commerce.

(Comment 116) – Several comments provided estimates on the amount of time required for recordkeeping or information from which estimates could be derived. One commenter (a large toy manufacturer) stated that they had added six full-time employees to manage the data and recordkeeping associated with the CPSIA's existing testing and certification requirements, and they further indicated that they had 1,700 products tested annually for which recordkeeping would be required. The test reports are from 50 to 125 pages in length and require maintaining for all products tested. The commenter estimated that their company accounted for greater than 1 percent of all the hours that the CPSC had estimated for all children's products. The commenter concluded that, based on this estimate, the actual number of hours required for recordkeeping by all companies would be higher than the CPSC's estimate.

Another commenter estimated that the recordkeeping will require about 2.25 hours per test submitted; but due to varying lot sizes and requirements, they estimate that multiple tests per year could be required on a product. They estimate that the burden will be 3 hours for one category of products that it manufactures and 5 hours for another, with an average across their product line of 3.5 hours.

One commenter said that the time required for recordkeeping would be higher for manufacturers that specialize in high quality, but low volume products. The commenter estimated that it would take 6 to 10 employees to track the testing data and compile it into certificates of conformity, or about 6 to 10 times the per-product labor required by the high volume, mass production manufacturers. The commenter estimated about 3 to 7.5 hours of recordkeeping would be required for high-quality, low-volume products.

(Response 116) - Based on these comments, we have determined that for many children's products, substantially more than 2 hours will be required for the associated recordkeeping. For products, such as toys, jewelry, children's furniture and other children's products, which are subject to third party testing to several different standards, we have determined that 5 hours is a reasonable estimate.

More hours will be required for some products to which many rules apply. Simpler products with few, or only one, applicable rule should require fewer hours for recordkeeping. For apparel and footwear products, we have determined that it is reasonable to use a lower estimate of the number of hours required for recordkeeping, such as 3 hours. This estimate recognizes that there could be substantial recordkeeping required for some items, such as those that require testing for flammability and that contain various components (*e.g.*, zippers, snaps, buttons, accessories) while other items, might require little testing.

Title: Testing and Labeling Pertaining to Product Certification.

Description: The final rule implements section 102(b) of the CPSIA, which requires certification of compliance for children's products subject to a children's product safety rule. A certification that a children's product complies with the applicable children's product safety rules must be supported by testing by an approved third party conformity assessment body. The final rule imposes recordkeeping requirements related to those testing and certification mandates. The recordkeeping requirements are intended to allow identification of each product and establish that each product is certified properly, before it enters commerce. In addition, the recordkeeping requirements require certification that a product has been retested properly for conformity with all applicable rules on a continuing basis, including after a material change in the product's design or manufacturing processes, including the sourcing of component parts.

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Each manufacturer or importer of a children's product subject to a children's product safety rule would be required to establish and maintain the following records:

- a copy of the Children's Product Certificate (§ 1107.26(a)(1));
- records of each certification test (§ 1107.26(a)(2));
- records of the periodic tests (§ 1107.26(a)(3));
- records of descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, the certification tests run, and the test values (§ 1107.26(a)(5)); and
- records of undue influence procedures (§ 1107.26(a)(6)).

Description of Respondents: The recordkeeping requirements apply to all manufacturers or importers of children's products that are covered by one or more children's product safety rules promulgated and/or enforced by the CPSC. We reviewed every industry category in the NAICS and selected those industry categories that included firms that could manufacture or sell such children's products. Using data from the U.S. Census Bureau, we determined that there are more than 37,000 manufacturers, almost 80,000 wholesalers, and about 128,000 retailers in these categories. However, not all of the firms in these categories manufacture or import children's products that are covered by children's product safety rules. Therefore, these numbers would constitute a high estimate of the number of firms that are subject to the recordkeeping requirements.

Estimate of the Burden: The hour burden of the recordkeeping requirements will likely vary greatly from product to product, depending upon such factors as the complexity of the product and the amount of testing that must be documented. We do not have comprehensive

data on the universe of products that will be impacted. Therefore, estimates of the hour burden of the recordkeeping requirements are somewhat speculative.

The preamble to the proposed rule (75 FR at 28361) estimated that, on average, approximately 2 hours would be needed for recordkeeping per product; although we recognized that, for some products, particularly those subject to more than one standard or rule, would need a substantial amount of testing, and thus, the recordkeeping burden could be much higher than 2 hours. Conversely, products subject to one standard or that need little testing, could have a recordkeeping burden of less than 2 hours.

Based on the comments we received on the proposed rule, however, we have revised the estimated number of children's products that are affected, as well as the hourly recordkeeping burden estimate. We now estimate that approximately 300,000 non-apparel children's products will be covered by the rule and that an average of 5 hours will be needed for the recordkeeping associated with these products. We also estimate that there are approximately 1.3 million children's apparel and footwear products and that will require an average of 3 hours for the recordkeeping. Thus, the total hour burden of the recordkeeping associated with the final rule is 5.4 million hours (300,000 x 5 hours plus 1,300,000 x 3 hours).

Additionally, for the proposed rule, to calculate the cost of the recordkeeping burden, we used the total hourly compensation for private sector workers in management, professional, and related occupations, which is \$48.91 per hour. This is based on the expectation that much of the recordkeeping will be done by chemists, engineers and quality control managers. Most commenters did not mention the occupational mix of the workers that would be involved in the recordkeeping associated with the rule. However, one commenter stated that the rule would result in an increase in his clerical and management staff. Therefore, to recognize that clerical,

professional, and management staff will be involved in meeting the recordkeeping requirements of the rule, we will assume that personnel in “management, professional, and related occupations” will be responsible for half of the recordkeeping, while personnel in “office and administrative support” occupations will be responsible for the other half. As of March 2011, these categories would average \$36.43 per hour

(<http://www.bls.gov/news.release/ecec.t09.htm>).⁸ At \$36.43 per hour (i.e., the revised hourly compensation rate), the total cost of the recordkeeping associated with the testing and certification rule is approximately \$197 million (5.4 million hours x \$36.43 = \$196,722,000).

Estimate Limitations: There are some limitations to the above estimates that warrant mentioning.

While the estimates of the number of products are more accurate than the original estimates, they are not based on a well-designed survey or comprehensive database. Additionally, the extent to which some products might be certified by multiple importers, or are manufactured at different sites, has not been established.

Recordkeeping for the flammability of children’s sleepwear might be captured in the OMB submission on another rule, but the recordkeeping associated with the lead content rules should be captured here. However, no adjustment for this has been made because we have not tried to separate children’s sleepwear from other apparel items.

The recordkeeping considered here is best thought of as the recordkeeping mandated by the testing and certification requirements of section 102 of the CPSIA. It would be impossible to separate the time associated with the initial certification, from the time related to periodic testing and documenting material changes, especially because it often involves issuing a new certificate.

⁸ U.S. Department of Labor, Bureau of Labor Statistics, “Employer costs for Employee Compensation – March 2011, Table 9” (8 June 2011). Available at: <http://www.bls.gov/news.release/ecec.t09.htm>. Last accessed 8 July 2011.

For finished goods manufacturers who also perform their own component testing, it is difficult to separate the recordkeeping burden associated with component part testing from the recordkeeping burden associated with the testing and labeling rule. This could lead to an overestimate of the costs associated with the testing and labeling rule and possibly result in underestimates associated with the component part testing rule. Better estimates may be possible if the recordkeeping burden is reevaluated after the rules are finalized.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have applied to the U.S. Office of Management and Budget (OMB) for a control number for this information collection, and we will publish a notice in the *Federal Register* providing the number when we receive approval from the OMB.

V. Environmental Considerations

This final rule falls within the scope of the Commission's environmental review regulations at 16 CFR 1021.5(c)(2), which provides a categorical exclusion from any requirement for the agency to prepare an environmental assessment or environmental impact statement for product certification rules.

VI. Executive Order 12988

Executive Order 12988 (February 5, 1996), requires agencies to state in clear language the preemptive effect, if any, of new regulations. The final rule is issued under authority of the CPSA and the CPSIA. The CPSA provision on preemption appears at section 26 of the CPSA. The CPSIA provision on preemption appears at section 231 of the CPSIA. The preemptive

effect of this rule would be determined in an appropriate proceeding by a court of competent jurisdiction.

VII. Effective Date

The preamble to the proposed rule indicated that a final rule would become effective 180 days after its date of publication in the *Federal Register* (75 FR at 28361). However, on August 12, 2011, the President signed H.R. 2715 into law. H.R. 2715 revised the CPSIA in several different ways and also affected section 14(i)(2)(B)(ii) of the CPSA. H.R. 2715 also created a new section 14(i)(3)(B) of the CPSA, which requires us, no later than one year after H.R. 2715's date of enactment, to review the public comments (on opportunities to reduce the costs of third party testing requirements) and directs us to "prescribe new or revised third party testing regulations" if we determine that "such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." Consequently, we have finalized those provisions that H.R. 2715 did not affect directly. We also have decided to make the final rule effective on [insert date 15 months after date of publication in the FEDERAL REGISTER] so that parties can begin taking steps to develop internal processes, such as recordkeeping, and so that we and interested parties can consider how H.R. 2715 interacts with the final rule.

List of Subjects in 16 CFR Part 1107

Business and industry, Children, Consumer protection, Imports, Product testing and certification, Records, Record retention, Toys.

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Accordingly, 16 CFR part 1107 is added to read as follows:

PART 1107 - TESTING AND LABELING PERTAINING TO PRODUCT CERTIFICATION

SUBPART A - GENERAL PROVISIONS

Sec.

1107.1 Purpose.

1107.2 Definitions.

SUBPART B - [Reserved]

SUBPART C - CERTIFICATION OF CHILDREN'S PRODUCTS

1107.20 General Requirements.

1107.21 Periodic Testing.

1107.23 Material Change.

1107.24 Undue Influence.

1107.26 Recordkeeping.

SUBPART D - CONSUMER PRODUCT LABELING PROGRAM

1107.30 Labeling consumer products to indicate that the certification requirements of section 14 of the CPSA have been met.

Authority: 15 U.S.C. 2063, Sec. 3, 102 Pub. L. 110-314, 122 Stat. 3016, 3017, 3022.

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SUBPART A - GENERAL PROVISIONS

§ 1107.1 - Purpose.

This part establishes the protocols and standards for ensuring continued testing of children's products periodically and when there has been a material change in the product's design or manufacturing process and safeguarding against the exercise of undue influence by a manufacturer on a third party conformity assessment body. It also establishes a program for labeling of consumer products to indicate that the certification requirements have been met pursuant to sections 14(a)(2) and (i)(2)(B) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(a)(2) and (i)(2)(B)).

§ 1107.2 - Definitions.

Unless otherwise stated, the definitions of the Consumer Product Safety Act and the Consumer Product Safety Improvement Act of 2008 apply to this part. The following definitions apply for purposes of this part:

CPSA means the Consumer Product Safety Act.

CPSC means the Consumer Product Safety Commission.

Due care means the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances. Due care does not permit willful ignorance.

High degree of assurance means an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.

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Identical in all material respects means there is no difference with respect to compliance to the applicable rules, bans, standards, or regulations between the samples to be tested for compliance and the finished product distributed in commerce.

Manufacturer means the parties responsible for certification of a consumer product pursuant to 16 CFR part 1110.

Manufacturing process means the techniques, fixtures, tools, materials, and personnel used to create the component parts and assemble a finished product.

Material change means any change in the product's design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product's ability to comply with the applicable rules, bans, standards, or regulations.

Third party conformity assessment body means a testing laboratory whose accreditation has been accepted by the CPSC to conduct certification testing on children's products. Only third party conformity assessment bodies whose scope of accreditation includes the applicable required tests can be used for children's product certification or periodic testing purposes.

SUBPART B - [Reserved]

SUBPART C - CERTIFICATION OF CHILDREN'S PRODUCTS

§ 1107.20 - General Requirements.

(a) 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.

(b) If the manufacturing process for a children's product consistently creates finished products that are uniform in composition and quality, a manufacturer may submit fewer samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules. If the manufacturing process for a children's product results in variability in the composition or quality of children's products, a manufacturer may need to submit more samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules.

(c) Except where otherwise specified by a children's product safety rule, component part testing pursuant to 16 CFR part 1109 may be used to support the certification testing requirements of this section.

(d) If a product sample fails certification testing to the applicable children's product safety rule(s), even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take the necessary steps to address the reasons for the failure. 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.

§ 1107.21 - Periodic Testing.

(a) *General requirements for all manufacturers.* All manufacturers of children's products must conduct periodic testing. All periodic testing must be conducted by a third party

conformity assessment body. Periodic testing must be conducted pursuant to either paragraph (b), (c), or (d) of this section or as provided in regulations under this title. The testing interval selected for periodic testing may be based on a fixed production interval, a set number of units produced, or another method chosen by the manufacturer based on the product produced and its manufacturing process, so long as the applicable maximum testing interval specified in paragraph (b), (c), or (d) of this section is not exceeded. Component part testing pursuant to 16 CFR part 1109 may be used to support the periodic testing requirements of this section.

(b) A manufacturer must conduct periodic testing to ensure compliance with the applicable children's product safety rules at least once a year, except as otherwise provided in paragraphs (c), and (d) of this section or as provided in regulations under this title. If a manufacturer does not conduct production testing under paragraph (c) of this section, or testing by a testing laboratory under paragraph (d) of this section, the manufacturer must conduct periodic testing as follows:

(1) *Periodic Testing Plan.* Manufacturers must develop a periodic testing plan to ensure with a high degree of assurance that children's products manufactured after the issuance of a Children's Product Certificate, or since the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules. The periodic testing plan must include the tests to be conducted, the intervals at which the tests will be conducted, and the number of samples tested. The manufacturer must have a separate periodic testing plan for each manufacturing site producing a children's product.

(2) *Testing Interval.* The testing interval selected must be short enough to ensure that, if the samples selected for testing pass the test, there is a high degree of assurance that the other untested children's products manufactured during the testing interval comply with the applicable

children's product safety rules. The testing interval may vary depending upon the specific children's product safety rules that apply to the children's product, but may not exceed one year. Factors to be considered when determining the testing interval include, but are not limited to, the following:

- (i) High variability in test results, as indicated by a relatively large sample standard deviation in quantitative tests;
- (ii) Measurements that are close to the allowable numerical limit for quantitative tests;
- (iii) Known manufacturing process factors which could affect compliance with a rule. For example, if the manufacturer knows that a casting die wears down as the die nears the end of its useful life, the manufacturer may wish to test more often as the casting die wears down;
- (iv) Consumer complaints or warranty claims;
- (v) Introduction of a new set of component parts into the assembly process;
- (vi) The manufacture of a fixed number of products;
- (vii) Potential for serious injury or death resulting from a noncompliant children's product;
- (viii) The number of children's products produced annually, such that a manufacturer should consider testing a children's product more frequently if the product is produced in very large numbers or distributed widely throughout the United States;
- (ix) The children's product's similarity to other children's products with which the manufacturer is familiar and/or whether the children's product has many different component parts compared to other children's products of a similar type; or

(x) Inability to determine the children's product's noncompliance easily through means such as visual inspection.

(c)(1) If a manufacturer implements a production testing plan as described in subparagraph (c)(2) of this section to ensure continued compliance of the children's product with a high degree of assurance to the applicable children's product safety rules, the manufacturer must submit samples of its children's product to a third party conformity assessment body for periodic testing to the applicable children's product safety rules at least once every two years. A manufacturer may consider the information obtained from production testing when determining the appropriate testing interval and the number of samples needed for periodic testing to ensure that there is a high degree of assurance that the other untested children's products manufactured during the testing interval comply with the applicable children's product safety rules.

(2) *Production Testing Plan.* A production testing plan describes the production management techniques and tests that must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all the applicable children's product safety rules. A production testing plan may include recurring testing or the use of process management techniques, such as control charts, statistical process control programs, or failure modes and effects analyses (FMEAs) designed to control potential variations in product manufacturing that could affect the product's ability to comply with the applicable children's product safety rules. A manufacturer may use measurement techniques that are nondestructive and tailored to the needs of an individual product to ensure that a product complies with all applicable children's product safety rules. Any production test method used to conduct production testing must be effective in determining compliance. Production testing cannot consist solely of mathematical methods (such as an FMEA, with no additional components, or

computer simulations). Production testing must include some testing, although it is not required that the test methods employed be the test methods used for certification. A manufacturer must document the production testing methods used to ensure continuing compliance and the basis for determining that the production testing plan provides a high degree of assurance that the product being manufactured continues to comply with all applicable children's product safety rules. A production testing plan must contain the following elements:

(i) A description of the production testing plan, including, but not limited to, a description of the process management techniques used, the tests to be conducted, or the measurements to be taken; the intervals at which the tests or measurements will be made; the number of samples tested; and the basis for determining that the combination of process management techniques and tests provide a high degree of assurance of compliance if they are not the tests prescribed for the applicable children's product safety rule;

(ii) The manufacturer must have a separate production testing plan for each manufacturing site producing a children's product;

(iii) The production testing interval selected for tests must ensure that, if the samples selected for production testing comply with an applicable children's product safety rule, there is a high degree of assurance that the untested products manufactured during that testing interval also will comply with the applicable children's product safety rule.

Production testing intervals should be appropriate for the specific testing or alternative measurements being conducted.

(3) If a production testing plan as described in this paragraph fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, the CPSC

may require the manufacturer to meet the requirements of paragraph (b) of this section or modify its production testing plan to ensure a high degree of assurance of compliance.

(d)(1) For manufacturers conducting testing to ensure continued compliance with the applicable children's product safety rules using a testing laboratory accredited to ISO/IEC 17025:2005, "General requirements for the competence of testing and calibration laboratories," periodic tests by a third party conformity assessment body must be conducted at least once every three years. Any ISO/IEC 17025:2005-accredited testing laboratory used for ensuring continued compliance must be accredited by an accreditation body that is accredited to ISO/IEC 17011:2004, "Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies." The test method(s) used by an ISO/IEC 17025:2005-accredited testing laboratory when conducting testing to ensure continued compliance must be the same test method(s) used for certification to the applicable children's product safety rules. Manufacturers must conduct testing using the ISO/IEC 17025:2005-accredited testing laboratory frequently enough to provide a high degree of assurance that the children's product continues to comply with the applicable children's product safety rules. A manufacturer may consider the information obtained from testing conducted by an ISO/IEC 17025:2005-accredited testing laboratory when determining the appropriate testing interval and the number of samples for periodic testing that are needed to ensure that there is a high degree of assurance that the other untested children's products manufactured during the testing interval comply with the applicable children's product safety rules.

(2) If the continued testing described in subparagraph (d)(1) fails to provide a high degree of assurance of compliance with all applicable children's product safety rules, the CPSC may require the manufacturer to meet the requirements of paragraph (b) of this section or modify the

testing frequency or number of samples required to ensure a high degree of assurance of continued compliance.

(3) The Director of the Federal Register approves the incorporations by reference in this paragraph in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of ISO/IEC 17025:2005 and ISO/IEC 17011:2004 from the International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, Switzerland; Telephone +41 22 749 01 11, Fax +41 22 733 34 30; <http://www.iso.org/iso/home.html>. You may also inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741- 6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(e) [Reserved]

§ 1107.23 - Material Change.

(a) *General Requirements.* If a children's product undergoes a material change in product design or manufacturing process, including the sourcing of component parts, which a manufacturer exercising due care knows, or should know, could affect the product's ability to comply with the applicable children's product safety rules, the manufacturer must submit a sufficient number of samples of the materially changed children's product for testing by a third party conformity assessment body. The number of samples submitted must be sufficient to provide a high degree of assurance that the materially changed component part or finished product complies with the applicable children's product safety rules. A manufacturer of a

children's product that undergoes a material change cannot issue a new Children's Product Certificate for the product until the product meets the requirements of the applicable children's product safety rules for the component part or finished product for the material change based on testing by a third party conformity assessment body. The extent of such testing may depend on the nature of the material change. When a material change is limited to a component part of the finished children's product and does not affect the ability of other component parts of the children's product or the finished children's product to comply with other applicable children's product safety rules, a manufacturer may issue a new Children's Product Certificate based on the earlier third party certification tests and on test results of the changed component part conducted by a third party conformity assessment body. A manufacturer must exercise due care to ensure that any component part undergoing component part-level testing is identical in all material respects to the component part on the finished children's product. Changes that cause a children's product safety rule to no longer apply to a children's product are not considered to be material changes.

(b) *Product Design*. For purposes of this subpart, the term "product design" includes all component parts, their composition, and their interaction and functionality when assembled. To determine which children's product safety rules apply to a children's product, a manufacturer should examine the product design for the children's product as received or assembled by the consumer.

(c) *Manufacturing Process*. A material change in the manufacturing process is a change in how the children's product is made that could affect the finished children's product's ability to comply with the applicable children's product safety rules. For each change in the manufacturing process, a manufacturer should exercise due care to determine if compliance to an

existing applicable children's product safety rule could be affected, or if the change results in a newly applicable children's product safety rule.

(d) *Sourcing of Component Parts.* A material change in the sourcing of component parts results when the replacement of one component part of a children's product with another component part could affect compliance with the applicable children's product safety rule. This includes, but is not limited to, changes in component part composition, component part supplier, or the use of a different component part from the same supplier who provided the initial component part.

§ 1107.24 - Undue Influence.

(a) Each manufacturer must establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body.

(b) The procedures required in paragraph (a) of this section, at a minimum, must include:

- (1) Safeguards to prevent attempts by the manufacturer to exercise undue influence on a third party conformity assessment body, including a written policy statement from company officials that the exercise of undue influence is not acceptable, and directing that every appropriate staff member receive training on avoiding undue influence, and sign a statement attesting to participation in such training;
- (2) A requirement that upon substantive changes to the requirements in this section regarding avoiding undue influence, the appropriate staff must be retrained regarding those changed requirements.
- (3) A requirement to notify the CPSC immediately of any attempt by the manufacturer to hide or exert undue influence over test results; and

- (4) A requirement to inform employees that allegations of undue influence may be reported confidentially to the CPSC and a description of the manner in which such a report can be made.

§ 1107.26 - Recordkeeping.

(a) A manufacturer of a children's product subject to an applicable children's product safety rule must maintain the following records:

- (1) A copy of the Children's Product Certificate for each product. The children's product covered by the certificate must be clearly identifiable and distinguishable from other products;
- (2) Records of each third party certification test. The manufacturer must have separate certification tests records for each manufacturing site;
- (3) Records of one of the following for periodic tests of a children's product:
 - (i) a periodic test plan and periodic test results;
 - (ii) a production testing plan, production test results, and periodic test results; or
 - (iii) testing results of tests conducted by a testing laboratory accredited to ISO/IEC 17025:2005 and periodic test results.
- (4) [Reserved];
- (5) Records of descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, and the certification tests run and the test values; and
- (6) Records of the undue influence procedures, including training materials and training records of all employees trained on these procedures.

(b) A manufacturer must maintain the records specified in paragraph (a) of this section for five years. The manufacturer must make these records available, either in hard copy or electronically, such as through an Internet website, for inspection by the CPSC upon request.

Records may be maintained in languages other than English if they can be:

- (1) provided immediately by the manufacturer to the CPSC; and
- (2) translated accurately into English by the manufacturer within 48 hours of a request by the CPSC, or any longer period negotiated with CPSC staff.

SUBPART D - CONSUMER PRODUCT LABELING PROGRAM

§ 1107.30 - Labeling consumer products to indicate that the certification requirements of section 14 of the CPSA have been met.

(a) Manufacturers and private labelers of a consumer product may indicate, by a uniform label on, or provided with the product, that the product complies with any consumer product safety rule under the CPSA, or with any similar rule, ban, standard or regulation under any other act enforced by the CPSC.

(b) The label must be visible and legible, and consist of the following statement:

Meets CPSC Safety Requirements

(c) A consumer product may bear the label if the manufacturer or private labeler has certified, pursuant to section 14 of the CPSA, that the consumer product complies with all applicable consumer product safety rules under the CPSA and with all rules, bans, standards, or regulations applicable to the product under any other act enforced by the Consumer Product Safety Commission.

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(d) A manufacturer or private labeler may use a label in addition to the label described in paragraph (b) on the consumer product, as long as such label does not alter or mislead consumers as to the meaning of the label described in paragraph (b) of this section. A manufacturer or private labeler must not imply that the CPSC has tested, approved, or endorsed the product.

Dated: _____

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission