The contents of this document will be discussed at the open Commission Meeting (briefing) scheduled for September 19, 2012.

This document has been electronically approved and signed.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISION MEETING ON THIS MATTER IS SCHEDULED ON: October 3, 2012

DATE: August 29, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Patricia M. Pollitzer, Acting Assistant General Counsel, RAD

FROM: Mary A. House, Attorney, RAD
David M. DiMatteo, Attorney, RAD

SUBJECT: **Consideration of Opportunities to Reduce Third Party Testing Costs Consistent with Assuring the Compliance of Children's Products**

Public Law (PL) 112-28 (August 12, 2011) directed the Commission to seek comment on "opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation." Based on their review of the comments received, Staff's briefing package recommends specific actions that the Commission could take that may present opportunities for reducing third party testing burdens and are consistent with assuring compliance with all applicable children's product safety rules. Your vote to approve these recommendations reflects your willingness to move forward with the recommendations and commit the necessary resources to complete the tasks identified by the staff in the briefing package.

Please indicate your vote on the following options:

I. Approve staff's recommendations and direct staff to pursue the recommended opportunities to reduce third party testing burdens, without changes.

_____ _____
(Signature) (Date)

II. Approve the staff's recommendations and direct staff to pursue the recommended opportunities to reduce third party testing burdens, with changes. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

III. Do not approve the staff's recommendations.

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachment: *Consideration of Opportunities to Reduce Third Party Testing Costs Consistent with Assuring the Compliance of Children's Products*

Staff Briefing Package

Consideration of Opportunities to Reduce Third Party Testing Costs Consistent with Assuring the Compliance of Children's Products

August 29, 2012

Table of Contents

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically approved and signed.

Memorandum

Date: August 29, 2012

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: DeWane Ray
Assistant Executive Director
Office of Hazard Identification and Reduction

Randy Butturini , Project Manager
Office of Hazard Identification and Reduction

SUBJECT: Consideration of Opportunities to Reduce Third Party Testing Costs Consistent with Assuring the Compliance of Children's Products

1 Introduction

Public Law (PL) 112-28 (August 12, 2011) directed the Commission to seek comment on "opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation." This briefing package presents the U.S. Consumer Product Safety Commission (CPSC) staff's consideration of such comments and recommendations for specific actions that may present opportunities for reducing third party testing burdens that are consistent with assuring compliance of children's products with all applicable children's product safety rules.

2 Background

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 of the Consumer Product Safety Act (CPSA), and requires, in part, that manufacturers of children's products subject to an applicable children's product safety rule submit samples to a CPSC-accepted third party conformity assessment body (testing 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 (now section 14(i)(2)(B) of the CPSA) 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. A final rule, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107 (the 1107 rule) was approved by the Commission on October 19, 2011, and published in the *Federal Register* on November 8, 2011 (76 FR 69482).

A 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 (the 1109 rule), was also published in the *Federal Register* on November 8, 2011 (76 FR 69546). The purpose of the 1109 rule is to give all parties involved in testing and certifying consumer products, pursuant to sections 14(a) and 14(i) of the CPSA, the flexibility to conduct or rely on required certification testing where such testing is the most convenient and least expensive. Thus, the purpose of the 1109 rule is to reduce third party testing burdens consistent with ensuring compliance to the applicable rules, bans, standards, and regulations.

3 Project Overview

CPSC staff considered ways to reduce third party testing burdens for manufacturers of children's products, consistent with ensuring compliance to the underlying standards. Because section 14(i)(3) of the CPSA directs the Commission to seek opportunities to reduce third party testing burdens "consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation," staff does not recommend in this briefing package changes to any of the underlying children's product safety rules to achieve burden reduction. The Commission, however, may direct staff to consider such changes at any time.

Staff considered four sources of information in attempting to identify opportunities to reduce third party testing burdens: (1) comments submitted in response to the request for comments (RFC) titled, *Application of Third Party Testing Requirements; Reducing Third Party Testing Burdens*, Docket CPSC-2011-0081 (76 FR 69596, Nov. 8, 2011) (The comment summaries and staff responses are found in Tab C.); (2) staff review of the 1107 and 1109 rules (The review is found in Tab B.); (3) input from Commissioners' offices; and (4) input from other CPSC staff. Ideas from any source with the potential to reduce third party testing costs consistent with assuring compliance to the applicable children's product safety rules are described in the recommendations below. Several ideas from a Commissioner's office were independently mentioned in the comments as well.

For reference, a summary of actions that Congress and the CPSC have already taken to reduce third party testing burdens that are consistent with assuring compliance since the notices of proposed rulemaking (NPRs) for the 1107 and 1109 rules were issued is included in Tab A.

4 Recommended Opportunities the Commission Could Pursue to Reduce Third Party Testing Burdens Consistent with Assuring Compliance

CPSC staff's recommendations for opportunities that the Commission could pursue to reduce the third party testing burden consistent with assuring compliance are listed below. The recommendations require additional consideration and the devotion of Commission resources to implement. Some recommendations, if implemented, likely would affect only a few children's product certifiers, while others potentially would have a broader effect. Some recommendations may, upon further study, be ineffective in reducing manufacturers' third party testing costs. Other recommendations may be impracticable. Staff's approach in its review of the ideas was to provide enough information to assist the Commission in the determination of whether to approve the resource allocation necessary to pursue these recommendations further.

Each recommendation is numbered for identification purposes only. Commenters whose submissions contributed to the development of the recommendations are identified at the end of each recommendation by a commenter number, as well as the comment summary number, where a more complete discussion of the issue may be found in Tab C. Tab D contains a list of the commenters, their affiliation, and their commenter number.

4.1 Continue Information and Education Activities Regarding Testing Rules 16 CFR Parts 1107 and 1109

Staff recommends that the Commission develop information and education programs for finished product and component part manufacturers and suppliers to increase their understanding of the 1107 and 1109 rules and their applicability. The target audience for this information and education campaign includes all stakeholders such as foreign and domestic manufacturers, distributors, importers, and retailers and, in particular may be helpful for multiple parties dealing with the same children's product.

With a fuller understanding of the regulations' requirements and flexibilities, opportunities for using the same component part test results across many products could be better realized, or instances of redundant testing could be avoided. Greater knowledge and understanding on the part of finished product and component part certifiers could result in a significant reduction in the overall third party testing burden, while continuing to assure compliance with the applicable children's product safety rules. The sources for this recommendation were from Commenter 04, a Commissioner's office, and Comment 92 in Tab C.

4.2 Investigate the Feasibility of Establishing Determinations

4.2.1 Establish a List of Equivalent Tests to those in CPSC-Administered Children's Product Safety Rules

Staff recommends that the Commission consider creating, maintaining, and recognizing a list of equivalent tests in international standards, conformity to which would be indicative of conformity to the corresponding test in a CPSC-administered children's product safety rule.

While no other international standard is identical to a CPSC-administered children's product safety rule, there are many tests within certain other international standards that are the same, or that are more stringent than, their equivalent test within the CPSC-administered children's product safety rule. For example, the toy abuse tests in the European standard EN71, part 1,[1] and the International Standard ISO 8124-1[2] are the same, or more stringent than, their corresponding tests in ASTM F963-11.[3] Recognizing other international standards, or tests within a standard, as equivalent to a CPSC rule, could allow children's product certifiers to avoid repeating some third party tests for the same product and directly avoid additional testing costs, while assuring compliance to the applicable children's product safety rules.[4] This scheme could be used for certification, material change, and periodic testing purposes. Harmonized or equivalent tests would be required to be conducted by a CPSC-accepted testing laboratory. Thus, a project to consider establishing equivalency between tests in our regulations and comparable international standards must also consider how third party conformity assessment bodies will be accredited to perform tests to such standards.

It is possible that an effective implementation of this recommendation could result in a significant reduction in third party testing costs that might be realized by many manufacturers. The sources for this recommendation were from Commenters 02, 04, 05, 07, 08, 10, 14, 19, 21, and 22, a Commissioner's office, and Comment 31 in Tab C.

4.2.2 Research the Feasibility of Developing a List of Materials Determined Not to Contain the Eight Heavy Elements Listed in ASTM F963-11

Staff recommends that the Commission consider directing CPSC staff to research the feasibility of expanding the current process used to make determinations for materials that do not, and will not, contain lead above 100 parts per million (ppm), to the eight heavy elements listed in section 4.3.5 of ASTM F963-11, and thus, would not be subject to third party testing.

Section 4.3.5 of ASTM F963-11 specifies limits on the concentration of eight heavy elements in paints and accessible substrate materials for children's toys. The elements are: antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium. A solubility test is required to determine if paints or accessible component parts of a children's toy contain any of these elements in concentrations above the prescribed limits. Staff considered whether it is possible

[1] *Safety of toys: Mechanical and physical properties*.
[2] *Safety of toys -- Part 1: Safety aspects related to mechanical and physical properties.*
[3] *Standard Consumer Safety Specification for Toy Safety*.
[4] It should be noted, however, that CPSC staff does not require that a laboratory run the same test twice simply to prove compliance to two different standards when the test methods are identical. However, staff recognizes that certification pursuant to the CPSIA must be based upon a test conducted by a CPSC-accepted testing laboratory which could present a problem for a manufacturer who has test results available to prove compliance to an international standard employing an identical test method but the test results cannot be used to certify compliance because they are not from a CPSC-accepted laboratory.

that determinations can be made regarding materials that will not contain concentrations of these heavy elements above the limits listed in Tables 1 and 2 of ASTM F963-11. If such determinations can be made, then materials known not to exceed the content limits of the heavy elements would not be subject to third party testing. Therefore, the third party testing burden for certifiers might be reduced without affecting the assurance of compliance of the finished product to section 4.3.5 of ASTM F963-11.

It is possible that some materials cannot be determined to contain all eight heavy elements in levels below their limits. In that circumstance, only the heavy elements known to be within their limits might be listed in the determination. This list would be similar to the list for lead exclusions found in 16 CFR § 1500.91. To include a material on this list, evidence would have to be established that a heavy element cannot be present in amounts greater than the values in Tables 1 and 2 of ASTM F963-11. Because toy manufacturers are subject to the requirements of ASTM F963-11, it is possible that implementation of this recommendation could have a significant effect on the third party testing costs for many manufacturers. The source for this recommendation was CPSC staff.

4.2.3 Research the Feasibility of Developing a List of Materials Determined Not to Contain Prohibited Phthalates

Staff recommends that the Commission consider directing CPSC staff to research the feasibility of expanding the current process used to make determinations that materials do not, and will not, contain lead above 100 ppm, to plastics that do not, and will not, contain the prohibited phthalates, and thus, would not be subject to third party testing.

To include a material on this list, evidence would have to be established that the banned and interim-banned phthalates cannot be present in amounts greater than 0.1 percent. Among the considerations are: the potential for phthalates to interfere with the plastic's intended function; the use of recycled plastics that might contain phthalates; and the potential for inadvertent contamination with or inclusion of phthalates greater than 0.1 percent. Because we do not know at this time whether a list can be made, the procedures required to include a material on the list, or how many materials could be included on a list, we cannot estimate of a list's effect on third party testing costs. The sources of this recommendation were Commenters 16, 20, and 21, and Comment 69 in Tab C.

4.3 Investigate the Use of Fourier Transform Infrared Spectroscopy to Determine Compliance to the Phthalates Content Limit

Staff recommends that the Commission investigate whether Fourier Transform Infrared Spectroscopy (FTIR) can be effective as a screening technology for determining that a plastic component part contains no phthalates. Because phthalates are not naturally occurring, many plastic component parts should contain no phthalates, and screening technology can be used to determine their compliance with section 108 of the CPSIA, without resorting to the more expensive chemical test.

During the CPSC symposium on phthalates screening and testing methods,[5] the use of FTIR was discussed as a potential screening method for detecting phthalates. FTIR enables a spectrum (absorption or dispersion) to be obtained from a sample in a nondestructive manner. The spectrum can be analyzed to determine the chemical composition of the sample. In the staff review of the 1107 rule, the use of FTIR as a screening tool, establishing whether a sample contained no phthalates, was considered a potentially valid means of determining compliance with section 108 of the CPSIA, as long as an FTIR instrument and measurement technique were shown to be able to detect phthalates at concentrations as low as 0.1 percent for all of the prohibited phthalates.

FTIR can be used to detect the phthalate concentration of a sample. However, current technology does not distinguish the prohibited phthalates from other phthalate compounds and may not dependably detect phthalate concentration levels at the 0.1 percent level in all cases. Continued development of FTIR technology is ongoing. If FTIR technology can be developed to determine that no phthalates are in a sample, and a combination of instruments and measurement techniques can be shown to be effective at detecting phthalate concentrations at the 0.1 percent level, then a possibility exists that this technology could be used as a screening test that is less expensive than current phthalate testing methods. An effective use of FTIR as a screening technology for compliance has the potential to reduce significantly third party testing costs for many manufacturers subject to the requirements of section 108 of the CPSIA. Staff developed this recommendation based on the materials presented at the symposium.

4.4 Define a Periodic Testing Option Based on Volume of Products Manufactured Rather than Solely on a Time Period

Staff recommends that the Commission consider an option where a periodic testing interval based on production volume be allowed in addition to a time period. This option is similar to the low-volume product exemption from third party testing in the NPR for the 1107 rule.[6] The intent of the proposed low-volume exception in the NPR was to avoid having a manufacturer amortize its periodic testing costs over a very small volume of products.

Such an option could include:

- for products manufactured in volumes less than 10,000 units in a calendar year, the periodic test interval becomes 10,000 units. The maximum testing interval for periodic testing is every 10,000 units. The manufacturer may wish to conduct periodic testing more frequently when considering the factors listed in 16 CFR § 1107.21(b)(2);
- requiring a maximum periodic test interval, irrespective of production volume. This periodic test interval could be 3 years, corresponding with the maximum periodic testing interval for high-volume products;

[5] Part 1 of the webcast can be seen at: http://www.cpsc.gov/vnr/asfroot/phthal03012012_1.asx.
Part 2 of the webcast can be seen at: http://www.cpsc.gov/vnr/asfroot/phthal03012012_2.asx.
Part 3 of the webcast can be seen at: http://www.cpsc.gov/vnr/asfroot/phthal03012012_3.asx.
[6] 75 FR, 28336, May 20, 2010.

- recordkeeping requirements documenting that the product is a low-volume product; and
- certification testing and testing after a material change are still required for low-volume products.

The Commission could further consider whether some products should be excluded from a low-volume periodic testing option, in the same manner as the products described in section 14(a)(3)(b), clauses (i) through (v), of the CPSA, or durable infant or toddler products, as defined in section 104(f) of the CPSIA.

Because the recommendation would apply to low-volume products only, the overall reduction in third party testing costs is expected to be modest. However, small manufacturers who do not qualify as small batch manufacturers could realize reduced third party testing costs. The sources of this recommendation were Commenters 17, and 23, and Comment 73 in Tab C.

4.5 Third Party Conformity Assessment Bodies

4.5.1 Investigate CPSC Acceptance of Other Accreditation Bodies to Accredit Testing Laboratories to ISO/IEC 17025:2005

Staff recommends that the Commission evaluate whether accreditation bodies other than ILAC-MRA signatories should be allowed to accredit testing laboratories to International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005, *General requirements for the competence of testing and calibration laboratories*, and the scope of the tests involved.

Currently, only testing laboratories accredited by signatories to the International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA) are allowed to test children's products for certification purposes. The Commission chose ILAC-MRA signatory accreditation bodies because they represent an established international organization whose accreditation body members follow recognized standards and are not limited to a specific locality. While we are not questioning the effectiveness of ILAC-MRA accreditation bodies, we are aware of other international accreditation body consortiums (such as the Asia Pacific Laboratory Accreditation Cooperation, the European Cooperation for Accreditation Multilateral Agreement, and the International Accreditation Forum) whose members conform to the requirements of ISO/IEC 17011:2004, *Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies*, similar to the ILAC-MRA signatories.

The Commission likely would need to establish objective criteria to determine which organizations' members will be allowed to accredit testing laboratories for children's product certification purposes, and whether the devotion of Commission resources will provide meaningful testing burden relief to manufacturers. While this action might not directly reduce third party costs for product certifiers, it has the potential to increase the number of accreditation

bodies available to testing laboratories, and it might reduce the testing laboratories' accreditation expenses and administrative burdens.

The expansion of the number of accepted accreditation bodies would be expected to have a modest impact on third party testing costs for many manufacturers. However, some children's product manufactures may realize an increase in the efficiency of their third party testing activities. The sources of this recommendation were Commenters 20, and 22, and Comments 6 and 7 in Tab C.

4.5.2 Investigate Accreditation of Certification Bodies Accredited to ISO/IEC 17065 for Children's Product Certification Testing

Staff recommends that the Commission consider whether certification bodies, accredited to the upcoming standard ISO/IEC 17065, *Conformity assessment—Requirements for bodies certifying products, processes and services,* could have their accreditation accepted for children's product certification purposes. The Commission has designated testing laboratories accredited to ISO/IEC 17025:2005 (and accredited by a signatory to the ILAC-MRA) as third party conformity assessment bodies whose test results will be accepted for children's product certification purposes. However, there is another type of third party conformity assessment body—certification bodies—accredited to ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*. This standard is due to be replaced in 2012, by the standard, ISO/IEC 17065. Certification bodies perform conformity assessment testing, plus other activities, such as factory inspections and market surveillance, to ensure that continuing production maintains compliance with its certification requirements. Similar to testing laboratories accredited to ISO/IEC 17025:2005, certification bodies complying with ISO/IEC Guide 65:1996 contain provisions to ensure technical competency and protections against undue influence.

The third party testing results conducted by a CPSC-accepted certification body could be used as a basis for issuing Children's Product Certificates. The additional activities that certification bodies undertake could be considered part of a production testing plan, as described in the 1107 rule, and they could be used to increase the maximum periodic testing interval from 1 to 2 years. Periodic testing could be integrated into the certification body's program for the manufacturer. Thus, using certification bodies for the certification and continued compliance of children's products may be a means by which the third party testing and administrative burdens associated with certification, material change, and periodic testing could be reduced.

The use of certification bodies for third party testing is expected to have only a modest impact on many manufacturers' testing costs. However, some children's product manufactures may realize an increase in the efficiency of their third party testing activities. The sources of this recommendation were Commenter 22 and Comment 45 in Tab C.

4.6 *De minimis* Testing Exemptions

4.6.1 Investigate Allowing a *de minimis* Testing Exception for Lead in Paint on Children's Products

Staff recommends that the Commission direct CPSC staff to evaluate the issues regarding determining *de minimis* levels of paint that do not require third party testing and recommend changes to the applicable regulations, as warranted. Section 8.3, *Test Methods for Determination of Heavy Element Content in Toys, Toy Components and Materials:*, in ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*, specifies that if less than 10 mg of sample material is available, the test is not run.

Circumstances may arise where a finished product certifier, such as an importer, cannot use component part testing for small amounts of paint on the imported children's product. An importer, for example, may need to certify a product based on its own testing of a finished product, if it does not receive test reports or certification from a foreign manufacturer. In circumstances such as this, multiple units of the finished product might be required to generate a paint sample sufficient for third party testing, using either wet chemistry or x-ray fluorescence spectrometry (XRF) methods.

It might be possible to determine that a *de minimis* amount, or less, of paint on a children's product does not require third party testing. For example, the section of the 1109 rule, 16 CFR § 1109.11, *Component part testing for paint*, could be amended to include a *de minimis* exception to third party testing. Another option would be for the Commission to issue a guidance policy on this issue.

Because component part testing, including the use of XRF, is available for paint as a means of reducing third party testing costs, the overall effect of this recommendation is expected to be modest. Some children's product certifiers, such as importers, may use a *de minimis* exception to third party testing to a greater extent than other parties. The sources of this recommendation were Commenters 15, 20, and 21, and Comment 8.

4.6.2 Investigate Allowing a *de minimis* Testing Exception for Phthalates in Children's Toys and Child Care Articles Subject to Section 108 of the CPSIA

Staff recommends that the Commission direct CPSC staff to evaluate the issues regarding establishing *de minimis* levels of plasticized materials that would not require third party testing and recommend changes to the applicable regulations, as warranted. As described above, circumstances may arise where a finished product certifier, such as an importer, cannot use component part testing for small amounts of plasticized material on the imported children's product. If the importer must certify a product based on testing the finished product, multiple units of the finished product might be required to generate a sample sufficient for third party testing.

It might be possible to determine that a *de minimis* amount, or less, of a plasticized material on a children's product does not require third party testing. For example, the regulation at 16 CFR § 1109.13, *Component part testing for phthalates in children's toys and child care articles*,

could be amended to include a *de minimis* exception to third party testing. Another option would be for the Commission to issue a guidance policy on this issue.

Because component part testing is available as a means of reducing third party testing costs, the overall effect on third party testing costs of this recommendation is expected to be modest. Some children's product certifiers, such as importers, may find greater use of a *de minimis* exception to third party testing. The sources of this recommendation are Commenters 20 and 21, and Comment 83 in Tab C.

4.7 Potential Additions to the Lead Content Determinations in 16 CFR § 1500.91

4.7.1 Investigate Adding Manufactured Woods to Lead Determinations List

Staff recommends that the Commission investigate whether the adhesives used in manufactured woods can be determined not to contain lead in amounts above 100 ppm.[7]

While wood is listed in 16 CFR § 1500.91 as having been determined not to contain lead in amounts greater than 100 ppm, the adhesives used in manufactured woods are not included in that determination. Manufactured woods (also called engineered woods or composite woods) are comprised of wood veneers, lumber, panels, fibers, or strands bound together with an adhesive.[8] Manufactured woods are often more dimensionally stable and consistent in their mechanical properties than are solid woods of the same shape. If a determination can be made that adhesives used in manufactured woods do not contain lead in concentrations greater than 100 ppm, then no third party testing of manufactured woods, or their component parts, should be required. Such a determination would reduce the third party testing burden of certifiers of children's products containing manufactured wood, without compromising compliance to the 100 ppm lead content limit.[9]

Only children's product manufacturers using manufactured woods in their products would realize any third party testing cost reductions. However, for manufacturers using many sources or types of manufactured woods, the testing cost reductions could be significant. CPSC staff provided this recommendation.

4.7.2 Investigate Adding Synthetic Food Additives to the Lead Determinations List

[7] It should be noted that the producers of manufactured wood have been free to approach the Commission for a lead determination under the process outlined in 16 CFR § 1500.89.
[8] http://www.naturallywood.com/wood-products/product-types/engineered-wood.
[9] We note that manufactured wood is considered a single component part. Thus, the 100 ppm lead limit applies to the weight of the wood, plus the adhesive. If an adhesive contained lead in excess of 100 ppm, it is possible that its inclusion in manufactured wood would result in a total lead content of less than 100 ppm. However, the adhesive would require third party testing to determine its content and its proportion of the finished manufactured wood would have to be known.

Staff recommends that the Commission investigate whether the process by which materials are determined not to contain lead in amounts above 100 ppm can be expanded to include synthetic food additives. If such a determination can be made, the list of materials determined not to contain lead in amounts greater than 100 ppm in 16 CFR § 1500.91 may be expanded.

In 21 CFR part 172, *Food additives permitted for direct addition to food for human consumption*, lead is allowed as a trace element in some food additives. The maximum level of lead allowed ranges from 0.1 ppm to 10 ppm. The regulation at 16 CFR § 1500.91(d)(8) includes other plant-derived and animal-derived materials, which would include most direct food additives, in the list of materials determined not to contain lead in amounts greater than 100 ppm. However, synthetic food additives, such as synthetic dyes, are not covered by the determinations in 16 CFR § 1500.91. Under the U.S. Food and Drug Administration's (FDA) general guidelines of Good Manufacturing Practices (GMP), these materials are considered safe to add to foods. However, 21 CFR part 172 does not require third party testing of food coloring and other additives for lead content prior to their use in foods. Moreover, the FDA does not regulate the lead content of materials, but rather, it regulates the solubility of lead in food contact materials, drugs, and cosmetics. The federal standards 21 CFR parts 174,[10] 177,[11] and 178[12] do not specify a numerical lead content, but the standards include terms such as: "Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use." It is possible that some indirect food additives could be determined not to contain lead in amounts greater than 100 ppm.

Because food additives are expected to be used infrequently in children's products, the overall effect on third party testing costs is estimated to be modest. The sources of this recommendation are Commenter 16 and Comment 3 in Tab C.

4.8 Eliminate the Requirement for a Periodic Testing Plan for Children's Product Certifiers Who Do Not Conduct Periodic Testing

Staff recommends that the Commission consider clarifying that manufacturers who do not conduct periodic testing are not required to create a periodic testing plan. Currently, § 1107.21(b)(1) requires manufacturers to develop a periodic testing plan 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. However, for some manufacturers or importers, they will find it prudent or efficient to recertify the children's product, rather than conduct periodic testing during continuing production. These circumstances could include importers or manufacturers with short production runs. In these circumstances, the creation of a periodic testing plan would not help assure continued compliance.

[10] *Indirect Food Additives: General.*
[11] *Indirect Food Additives: Polymers.*
[12] *Indirect Food Additives: Adjuvants, Production Aids and Sanitizers*. An adjuvant is an agent added to an indirect food additive, such as food packaging, to predictably alter that additive. For example, the adjuvant zinc hydroxy phosphite may be added as an anti-corrosive to certain polymers used in food packaging coatings.

Because the creation of a periodic testing plan and its recordkeeping requirements for a manufacturer who does not plan to conduct periodic tests is expected to be low, implementation of this recommendation is expected only to have a modest impact on some children's product certifiers. The source of this recommendation is CPSC staff's review of the 1107 rule.

4.9 Modify the Maximum Periodic Testing Interval Based on the Risk of Noncompliance to a Regulation or a Portion of a Regulation

Staff recommends that the Commission direct agency staff to determine whether it is feasible to vary a periodic test interval based on the risk of noncompliance. For a given children's product safety rule, or a test within a rule, if the likelihood of noncompliance is found to be low, then the Commission may choose to increase the maximum periodic testing interval with little risk that the change will result in the introduction of noncompliant products in the marketplace.

Such a study could determine:

- The children's product safety rules or tests within a rule to be listed;
- Factors to determine the chance of noncompliance;
- Products and potential noncompliance levels which changes to the maximum periodic testing interval change, and their rationales; and
- Procedures to deal with "outlier" manufacturers, whose products don't have the same likelihood of noncompliance as other manufacturers of the same products.

Because the number of products that could be affected by this recommendation has not been determined, and the recommendation is limited to the maximum periodic testing interval, the overall third party testing cost reduction cannot be estimated but is expected to be modest.

4.10 Explore Application of Information Technology to Reduce Administrative Costs Associated with Third Party Testing

Staff recommends that the CPSC explore the application of information technology to address the administrative costs involved with third party testing. One means to reduce the third party testing costs is to reduce the administrative burden associated with third party testing. For example, one commenter (14) offers to make an information technology (IT) tool it developed free to small manufacturers. The IT tool purportedly helps a company design a production testing plan and generate the documents required by the testing and certification and component part testing rules. The commenter mentions a public/private partnership with the CPSC but does not provide further details describing the proposed arrangement. Other companies may have developed similar tools. The Commission could seek additional information regarding these products. By eliminating inefficiencies, or streamlining the testing plans, third party testing burdens might be reduced without adversely affecting the assurance of compliance.

Because the nature of the CPSC's involvement with information technology tools is undefined, making an estimate of the potential third party testing cost reduction would be problematic. Software products to help manufacturers with their testing programs currently are

available. Manufacturers are free to make use of them as they wish. The sources of this recommendation are Commenter 14 and Comment 62 in Tab C.

4.11 Opportunities to Reduce Third Party Testing Burdens Consistent with Assuring Compliance for Which the Commission Lacks Legal Authority

Staff recommends that the Commission seek legal authority from Congress to allow for certification of a manufacturing process to be an acceptable method of satisfying the third party testing requirements of section 14(a)(2) and (i)(B)(2) of the CPSA. Manufacturing process certification is a process in which a certification body evaluates, tests, inspects, and conducts continuing surveillance activities of a factory or manufacturing system to ensure that the products created by the factory or manufacturing system meet their requirements. The certification body "certifies" the compliance of the products fabricated by the factory or manufacturing system. Process certification could reduce the third party testing burden by accepting certification of a manufacturing process without requiring additional third party testing of the finished children's product.

Additionally, process certification is consistent with assuring compliance because third party testing, plus other actions are taken to assure compliance of the finished product as it is manufactured. However, third party testing might not be conducted on the finished product. Rather, the third party testing might involve testing the manufacturing steps that create the finished product, to establish with a high degree of assurance, that the finished product is compliant with the applicable children's product safety rules.

Because the statutory scheme does not contemplate third party certification of a manufacturing process, but rather, envisions third party testing of finished products, changes to sections 14(a) and (i) of the CPSA are required to implement this recommendation.

The use of process certification for purposes of children's product certification has the potential for a significant impact on third party testing costs, especially for manufacturers that have implemented process certification methods as part of their product's QA/QC system. Other manufacturers of simple products, or products made in small volumes, or with simple manufacturing processes, are much less likely to implement process certification systems. The sources of this recommendation are Commenter 9 and Comment 99 in Tab C.

5 Description and Review of the Request for Comments, Docket CPSC-2011-0081

As noted above, the Commission published a request for comments in the *Federal Register*, pursuant to section 14(i)(3)(A) of the CPSA, as amended by Public Law 112-28. In the RFC, the CPSC invited the public to share ideas on how to reduce the costs of third party testing required for children's products that are subject to a children's product safety rule. The RFC described seven issues upon which the CPSC sought public comment. In reviewing the comments, staff added two more categories: general comments not falling distinctly into any of the seven issues,

and comments that were determined to address Other Issues. Listed below are the seven issues identified in Public Law 112-28, and a summary of the topics discussed by the commenters.

Issue 1: ***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***

The commenters are supportive of leveraging tests conducted to demonstrate compliance to other regulations as evidence of compliance to CPSC-administered rules. Among the topics the commenters discuss are:

- the recognition of materials regarded as "safe" by other government agencies;
- the differences between other agencies' conformance activities and the CPSC's required third party tests; and
- the use of certification marks and tests from non CPSC-accepted testing laboratories as evidence of conformance.

Staff notes that other government agencies, such as the FDA, set limits on the lead content of some materials, but do not require third party testing or certification for compliance, as required by the CPSA. Moreover, the FDA does not regulate the lead content of materials, as required by the CPSIA, but rather, the potential dietary exposure of lead in food contact materials, drugs, and cosmetics. Staff is not aware of another government agency that requires third party testing of lead or the prohibited phthalates. Furthermore, CPSC-accepted testing laboratories have additional requirements regarding undue influence and their firewalled or governmental status.

Issue 2: ***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***

The commenters support allowing third party testing by a voluntary party, such as a foreign supplier. Other commenters discuss how testing results for a material or component part could be shared by all of the importers of that material or component part, a practice currently allowed by the 1109 rule. Among the topics the commenters discuss are:

- retailer-required testing considered redundant by suppliers;
- the use of due care in relying on test reports provided by another party;
- the definition of "substantially similar";
- the use of pre-identified compliant materials as a means of reducing third party testing costs; and
- the desire to use data in the determination of compliance issues.

The commenters do not provide a definition of "substantially similar" that is materially different from how the Commission interprets the terms used in the sections 14(a) and (i), and in

the CPSC's rules. The use of component part testing among several importers has the potential to reduce third party testing costs by amortizing component part test costs across multiple products using the same component parts.

Issue 3: ***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***

None of the commenters discuss how testing of a subset of different component parts by a testing laboratory could show compliance with an applicable children's product safety rule. Most of the commenters discuss the testing of component parts in their submissions. Among the other topics the commenters discuss are:

- the perceived difficulty in keeping track of lot and batch information for component parts;
- other traceability issues;
- a reminder that component part testing is not applicable for all tests; and
- examples of the use of component part testing.

Without a relationship between component parts (*e.g.*, the same materials, the same shape, the same manufacturing process), passing test results for one component part cannot be used to infer the compliance of a dissimilar component part.

Issue 4: ***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***

The commenters do not discuss sampling procedures for substantially similar products. Among the other topics the commenters discuss are:

- the use of test reports for some component parts to infer the compliance of similar component parts;
- suggestions for CPSC follow-up activities after a children's product has been certified; and
- the testing of representative samples.

The majority of commenters described scenarios where the 1107 and 1109 rules allow test reports and certificates for finished products and component parts to be used for other finished products and component parts that are not materially different with respect to compliance to an applicable children's product safety rule. For example, finished products sold by a foreign supplier to many importers who privately brand the products are not materially different. Each importer can use the same third party test reports or certificates as a basis for issuing a Children's Product Certificate. Either the foreign supplier or one of the importers can procure the third party testing necessary for certification.

In a similar manner, periodic testing results of finished products and component parts that are not materially different can be used by multiple children's product certifiers, as long as lot and batch controls are considered. In our example above, if the foreign supplier continues production of the children's product and conducts periodic testing of samples that are not materially different from the product units sent to all the importers, each importer can use the test reports to ensure continued compliance of their product.

In the examples provided above, the costs of third party testing are "shared" by the certifiers of products or component parts that are identical in all material respects to the untested product units.

Issue 5: ***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]***

Many commenters support the idea of using conformity with other national or international standards as evidence of compliance with CPSC children's product safety rules. The commenters do not discuss how to address the differences between the other standards and the CPSC-administered children's product safety rules. Further, the commenters do not discuss the use of CPSC-accepted testing laboratories for establishing conformity with other national or international standards. Among the other topics the commenters discuss are:

- recognition of conformance to various international standards as evidence of conformity to CPSC-administered rules;
- CPSC participation in international regulatory councils and promotion of uniform standards;
- the use of certification programs and certification marks to indicate conformity with CPSC-administered rules;
- international agreements to avoid unnecessary obstacles to trade; and
- laboratory protections against undue influence.

Other international standards contain tests of children's products that are the same as, or more stringent than, tests in CPSC-administered rules. If the Commission is able to resolve issues regarding required third party testing and laboratory accreditation, then conducting redundant tests to show compliance with similar standards might be reduced or eliminated.

Issue 6: ***The extent to which technology, other than technology already approved by the Commission, exists for third party conformity assessment bodies to test or screen for testing consumer products subject to a third party testing requirement***

Many commenters remark on the use of XRF technology as either a screening or a testing tool for determining compliance to the lead content limit. One commenter offers phthalate test

methods to address testing prints on textiles. Among the other topics the commenters discuss are:

- the use of first party XRF testing in lieu of third party testing;
- CPSC designation of acceptable first party testing methods;
- the use of certified reference materials to assure screening technology competency;
- the adoption of statistical uncertainty bands for lead tests; and
- the use of information technology to reduce the administrative costs associated with third party testing programs.

The Commission evaluates new and emerging technologies on an ongoing basis. As testing technologies are developed with the necessary sensitivity and selectivity, their use may be included among the allowable testing methods.

Issue 7: ***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***

Many commenters suggest techniques for lowering the costs associated with third party testing. The suggestions include ones with broad applicability, as well as product-specific ideas. Among the other topics the commenters discuss are:

- the use of compound test reports;
- the use of risk assessment in product design to reduce testing costs;
- creation of a list of materials determined not to contain the prohibited phthalates;
- an update of the list of materials determined not to contain lead above 100 ppm;
- small-volume exemptions from periodic testing requirements;
- exclusion of inaccessible paint from third party testing requirements;
- the use of a leaching test for lead, instead of a content test;
- the use of quality management system standards to reduce third party testing costs;
- the establishment of *de minimis* levels of paints and plasticized parts that would not require third party testing;
- the use of certification bodies for children's product testing; and
- determination of component part periodic testing frequencies based on risk.

The 1107 and 1109 rules are designed to provide manufacturers the flexibility to use their knowledge of a children's product and its manufacture in determining how to meet the third party testing requirements. As experience is gained with the implementation of these rules, other opportunities to reduce manufacturers' third party testing costs may become evident.

6 Conclusions

Section 14(i)(3)(A) of the CPSA directed the Commission to seek public comments on opportunities to reduce the cost of third party testing requirements consistent with assuring

compliance to the applicable children's product safety rules. Within the criteria established by section 14(i)(3)(A) of the CPSA, the comments received were reviewed, 16 CFR parts 1107 and 1109 were examined, and other sources were considered for such cost-reducing opportunities. Because section 14(i)(3) of the CPSA directed that the Commission seek opportunities to reduce third party testing burdens "consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation," staff did not recommend changes to any of the underlying children's product safety rules to achieve third party testing burden reduction.

The result of these analyses is the list of recommended activities the Commission could consider to address third party testing costs consistent with assuring compliance. This list is not exhaustive. Changes in materials technology, new screening methods, new ideas not considered previously by staff, or other means, might result in lowering the testing costs associated with assuring the compliance of a children's product during certification, material change, or periodic testing.

There might be opportunities to reduce the cost of third party testing without adversely affecting a children's product safety rule's impact on safety, by incorporating changes within the rule. Cost reducing changes that do not adversely affect a rule's safety result could be tailored to the specific rule, rather than provided in a generalized form applicable to many rules.

Third party testing by an accredited laboratory offers two main attributes. First, the accreditation process provides evidence that the testing laboratory has met the competency requirements associated with each test within its scope of accreditation. Second, third party testing provides an objective assessment of compliance to a children's product safety rule. There might be other ways to establish technical competence and meet objectivity requirements that could address the costs associated with testing without adversely affecting consumer safety.

This report should not be considered the final effort on testing cost reduction opportunities. After some experience with the implementation of the testing and labeling regulation, other opportunities for third party testing cost reduction, consistent with assuring compliance, may become evident. The Commission can always direct CPSC staff to undertake third party testing cost reduction actions that are not on the list of recommendations. In a similar manner, the Commission, at any time, can request action from Congress to reduce the third party testing costs that the Commission feels it lacks the authority to implement.

TAB A: Actions the CPSC Has Taken Since May 2010 to Reduce Third Party Testing Burdens Consistent with Assuring Compliance

TAB A

United States
Consumer Product Safety Commission
Bethesda, MD 20814

Memorandum

Date: August 29, 2012

TO: Randy Butturini, Project Manager
Office of Hazard Identification and Reduction

FROM: Robert Franklin, Economist
Directorate for Economics,
Office of Hazard Identification and Reduction

SUBJECT: Actions the CPSC Has Taken Since May 2010 to Reduce Third Party Testing Burdens Consistent with Assuring Compliance

1 Introduction

On May 20, 2010, the Commission published a notice of proposed rulemaking (NPR) for 16 CFR part 1107 (the 1107 rule), *Testing and Labeling Pertaining to Product Certification*, in the *Federal Register,* to implement the requirements of section 102 of the CPSIA, requiring third party testing of children's products to establish compliance to applicable children's product safety rules. Such third party testing is for purposes of initial certification and to ensure continued compliance of children's products.[1] At the same time, a second notice of proposed rulemaking for 16 CFR part 1109 (the 1109 rule), *Conditions and Requirements for Testing Component Parts of Consumer Products*, was published that would allow certifications of children's products and testing for continued compliance to be based upon tests performed on component parts of the product rather than the finished product, if testing of a component part was sufficient to determine compliance with the applicable rules.[2] Since then, the Commission and Congress have taken steps to reduce the cost of required third party testing for children's products. The more significant of these third party testing burden-reducing steps are described below.

2 Allowing Component Part Testing and Reliance on Another Party's Testing or Certification to Certify a Finished Product

The 1109 rule on component part testing allows a finished product certifier, who is required to certify products pursuant to 16 CFR part 1110, to rely on component part testing or voluntary certification conducted by the certifier or another party. The purpose of the rule is to allow

[1] 75 FR 28336.
[2] 75 FR 28208.

testing and certification to occur at the most convenient and least expensive point in the supply chain. Using this rule, for example, multiple manufacturers can rely on testing or certification of component parts of a product conducted by a mutual supplier. Further, a manufacturer can test raw materials for lead and phthalates and use those test results for multiple products, as long as the manufacturing process does not introduce additional lead or phthalates. Finished product certifiers can rely on another party's testing or certification, as long as the certifier exercises due care to ensure that testing is not only appropriate under the 1107 rule, but also in accordance with any underlying children's product safety rule.

Moreover, the 1109 final rule clarified that a finished product certifier, such as an importer, can rely on testing and certification of a finished children's product conducted by a foreign manufacturer or supplier to issue the required Children's Product Certificate. Individual importers are not required to obtain additional third party testing of the product before issuing their own Children's Product Certificate, provided the importer exercises due care in relying on another party's testing or certification, and ensures that the testing or certification by the supplier meets the requirements of the 1107 and 1109 rules.

Although reliance on testing or certification conducted by suppliers has the potential for substantially reducing the cost of third party testing, the actual savings cannot be estimated. At this time, we do not have estimates of the number of suppliers who have undertaken voluntarily to have their products tested by third party conformity assessment bodies or certify that their products comply with children's product safety rules in accordance with the 1107 and 1109 rules.

3 Expanding the Use of XRF Technology

Using x-ray fluorescence spectrometry (XRF) technology for determining the lead content of a material is substantially less expensive than using "wet chemistry" methods, such as inductively coupled plasma mass spectrometry for samples where reliable measurements can be taken *in situ* without significant sample preparation. The decrease in cost is due mostly to the lower amount of labor and materials required to conduct the testing. XRF testing technologies require little, if any, sample preparation for suitable, homogeneous materials of sufficient thickness for the instrument. Wet chemistry methods involve substantial sample preparation, including grinding the sample to a powder, carefully measuring a specified amount of the powder, dissolving it in acid, and carefully measuring and diluting the solution for analysis. As a result, a technician using an XRF technology can test several samples for lead content in the amount of time that a technician using "wet chemistry" techniques can test a single sample. On the other hand, this extensive sample preparation used in the CPSC-approved wet chemistry techniques homogenizes the samples and controls for interferences to provide highly dependable results for the most difficult samples.

By May 2010, when the NPR for the testing and labeling rule was issued, the CPSC had approved the use of XRF technology only for determining the lead content of homogenous polymer products. Since that time, the CPSC has increased the number of materials for which an XRF technology may be used for determining lead content. In addition to homogenous polymer products (*e.g.*, plastics), the CPSC has approved the use of XRF technology for determining the

lead content of paint and similar surface coatings, and it has proposed the use of XRF technology for determining the lead content of glass materials, crystals, and certain metals.[3] XRF technology is still not acceptable for use in determining the lead content of some materials, including component parts made of inhomogeneous materials, including electroplated metals and glazed ceramics, or where its use is inconclusive, such as with borderline results for metal samples.

4 Use of ASTM F963 Screening Test to Assess Lead Content

ASTM F963-11, which is now a mandatory children's product safety rule, includes limits on the soluble migration of eight heavy metals, including lead, when tested in dilute acid. The standard allows a screening test to be used to measure the total content of each of the eight heavy metals, as opposed to the soluble content. The screening test involves the complete digestion of the samples in acid and analysis of the heavy metal content, using procedures similar to the CPSC-approved "wet chemistry" methods for determining lead content. If the total content of a heavy metal is less than the allowable soluble content of the metal, there is no need to test the soluble content, which will always be less than, or equal to, the total content. CPSC staff determined that the method used in the screening test is based upon the wet chemistry procedures approved for testing for lead content, with some modifications. CPSC staff found that the modifications will not adversely affect the test's reliability for determining the lead content. Thus, CPSC has proposed (in the proposed rule for 16 CFR part 1112) allowing the ASTM F963 screening test for heavy metals as another option for manufacturers to use to test for lead content.[4] Manufacturers that use the ASTM F963 screening test are not required to test for lead content separately using a different technique. The number of firms that will use the ASTM F963 screening test for heavy metals to test for lead content is not known. Therefore, the potential cost reduction resulting from this provision cannot be estimated.

5 Products Do Not Have to Be Retested Due to Minor Changes in Voluntary Standards

The CPSIA mandates that some voluntary standards become mandatory CPSC standards, including, for example, the ASTM F963 standard for toys. Voluntary standards may be revised over time. The CPSC has determined that it is not necessary for manufacturers to retest products to some or all tests in a revised standard if they have current test results showing compliance with the previous version of the standard, and the relevant tests in the two versions of the standard are unchanged or functionally equivalent. The CPSC has also determined that third party conformity assessment bodies that have been approved to test for conformity to the unchanged or functionally equivalent tests in the previous version of the standard can continue to test products for conformity to the current version of the standard until they are reassessed by their accreditation body. When the conformity assessment body is reassessed, their accreditation is expected to be updated to reflect the most recent version of the standard.

[3] This proposal is in the NPR for 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies,* 77 FR, 31086 (May 24, 2012).
[4] *Ibid*.

Not requiring retesting for the unchanged or functionally equivalent tests will reduce the need to perform entirely redundant testing that would otherwise be required for no reason other than because a revision to the standard became effective since the most recent third party tests were conducted. However, the number of products to which this would apply is not known. Therefore, an estimate of the potential reduction in third party testing costs cannot be made.

6 Requirement for a Simple Random Sample Changed to Representative Sample

The NPR for the 1107 rule required that the samples selected for periodic testing be chosen using simple random sampling, a procedure that required each unit produced during the periodic testing interval to have an equal chance of being selected for testing. The CPSC received comments from several sources stating that selecting simple random samples could be excessively burdensome. In August 2011, Congress amended section 14(i)(2)(B)(ii) of the CPSA to read: "for the testing of *representative* samples to ensure continued compliance"—instead of—"for the testing of *random* samples to ensure continued compliance." Although a simple random sample can be a representative sample, the CPSC interpreted the amendment to signal Congress's intent that the CPSC should provide a less restrictive, less costly means to meet the requirements for selecting samples for periodic testing. Therefore, the CPSC proposed a rule that would allow manufacturers to use any method of their choosing for selecting samples for periodic testing, provided that the method chosen provides a basis for inferring compliance about the untested population of products produced during the applicable periodic testing interval.

Because the proposed rule on representative sampling allows manufacturers more options, including options that are easier to implement than random sampling for selecting the samples for periodic testing, the implementation of representative sampling should reduce the cost of third party testing relative to the original requirement to test random samples. However, because there are a very large number of manufacturers, and the methods that each will use to select the samples is not known, the potential savings cannot be quantified.

7 Small Batch Manufacturers Not Required to Conduct Some Third Party Testing

Public Law 112-28 gives the Commission the flexibility to exempt small batch manufacturers from third party testing requirements for some covered products. The statute defines a "small batch manufacturer" as one that has total gross revenue of less than $1 million from all consumer products sold in the previous calendar year. The statute defines a "covered product" as one in which fewer than 7,500 units were manufactured or imported in the previous calendar year.

Although small batch manufacturers are not exempted from the third party testing requirements for several children's product safety rules, including the lead content of paint, small parts, pacifiers, cribs, and durable infant and toddler products, they are not required to conduct

third party testing for other children's product safety rules. Rules for which small batch manufacturers do not have to conduct third party tests include phthalate content and the lead content of substrates. Third party testing for these rules is not required until the Commission either provides alternative testing requirements or determines that third party testing is reasonably necessary to protect public health or safety. Third party testing costs for these two rules are relatively high. Therefore, the potential reduction in third party testing costs could be substantial for some manufacturers. Although small batch manufacturers are not required to conduct third party testing to demonstrate compliance with the applicable children's product safety rules, their products must comply with each applicable children's product safety rule.

To be exempt from third party testing requirements, small batch manufacturers must register with the CPSC. The CPSC is required by Public Law 112-28 to investigate whether alternative testing requirements exist for small batch manufacturers or to provide exemptions if the Commission determines that no alternative testing requirements are available or economically practicable. The Commission is not allowed to provide an alternative testing requirement where it determines, based on notice and a hearing, that full compliance with the third party testing requirements is reasonably necessary to protect public health or safety. Therefore, some of the savings could be reduced in the future, if the CPSC determines that alternative testing requirements are available, or that full compliance with some rules is required.

8 Off-Highway Vehicles, Bicycles and Books not Required to be Third Party Tested for Lead Content

Until passage of Public Law 112-28, some youth all-terrain vehicles (ATVs), children's bicycles, and ordinary books (and ordinary paper-based printed materials) were subject to the lead content requirements, and therefore, each accessible component part required third party testing to ensure that the lead content met the statutory requirements. In August 2011, the lead content standard decreased, to allow up to 100 ppm total lead content. Because bicycles can have more than 100 individual component parts that would require testing, ATVs can have many more component parts, and numerous books are published each year, the cost of third party testing for lead content alone, could be more than several thousand dollars per model for bicycles and ATVs, or for all a publisher's newly-printed books. Public Law 112-28 excluded ATVs from the lead content requirements, and therefore, the requirement to conduct tests for lead. It also exempted the metal component parts of bicycles and ordinary books from the requirement for third party testing for lead content, although bicycles are still required to comply with lead content limits, which were set at 300 ppm for the metal component parts of bicycles.

9 Only Accessible Component Parts Are Required to Be Tested for Phthalates

Section 108 of the CPSIA banned the presence of six types of phthalates in concentrations above 0.1 percent in component parts of children's toys and child care articles. Until passage of Public Law 112-28, the prohibition on the specified phthalates applied to each component part of the products, whether or not they were accessible. Public Law 112-28 specified that the

prohibition of the specified phthalates applied only to the parts that were accessible. This provision limits the required third party testing of phthalates to the plastic component parts or other materials that could contain phthalates that are accessible to a child through normal and reasonably foreseeable use and abuse. The cost of a third party test of a component part for phthalate content can be as much as $350. Eliminating the requirement to test several inaccessible component parts of a product for phthalate content can reduce third party testing costs by several hundred dollars per product.

TAB B: Review of 16 CFR Parts 1107 and 1109 With Respect to Reducing Third Party Testing Burdens Consistent with Assuring Compliance

United States
Consumer Product Safety Commission
Bethesda, MD 20814

Memorandum

Date: August 29, 2012

TO: Randy Butturini, Project Manager
Office of Hazard Identification and Reduction

FROM: Jacqueline Campbell, Textile Technologist
Directorate for Engineering Sciences,
Office of Hazard Identification and Reduction

SUBJECT: Review of 16 CFR Parts 1107 and 1109 with Respect to Reducing Third Party Testing Burdens Consistent with Assuring Compliance

1 Introduction

Staff reviewed each section of 16 CFR parts1107 and 1109 (the 1107 and 1109 rules, respectively) to determine whether opportunities for reducing third party testing consistent with assuring compliance to the applicable underlying rules, standards, bans, and regulations exist. The following sections summarize staff's regulation reviews.

2 Consideration of 16 CFR Part 1107

Staff's review of 16 CFR part 1107 identified eight concepts that involved the Commission's interpretation of the statutory provisions for third party testing and administrative costs. Four of the eight concepts involved the Commission's use of certain terms and how they are defined:

- the use and definition of "due care,"
- the use and definition of "high degree of assurance,"
- the definition of "identical in all material respects," and
- the definition of "material change."

Two of the eight concepts involve interpretation of testing requirements:

- the intervals for periodic testing; and
- the use of first party testing to determine a material change (§ 1107.23(a)).

The remaining two concepts involve administrative costs:

- the requirement for a periodic testing plan (§ 1107.21(b)(1)); and
- recordkeeping requirements.

The concepts and staff's considerations are summarized below.

2.1 Use and Definition of "Due Care"

Section 1107.2 defines "due care" as "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." Although the preamble to the final 1107 rule states the Commission's expectation "that all parties will exercise prudence and competence in the testing and certification of products" (76 FR 69485), currently, the 1107 rule only requires the exercise of "due care" in §1107.23 for material change testing.

The use of "due care" as a performance standard for third party testing of children's products in the 1107 and 1109 rules was introduced to provide guidance on how a manufacturer's conduct would be evaluated by the Commission. Because of the variety of children's products and manufacturing processes subject to the 1107 and 1109 rules, due care determinations rely heavily on a manufacturer's knowledge of its products and how such products are manufactured.

For example, the Commission is unable to quantify "sufficient samples" for all children's products because the level of knowledge varies among manufacturers of children's products. The number of samples deemed "sufficient" is likely to vary among manufacturers depending upon product knowledge. Further, the Commission cannot determine for every children's product when a material change test or a periodic test must be conducted to ensure compliance because the number of products, the varying quantities, and the product processes for children's products vary greatly. Accordingly, staff recommended that the Commission implement a performance requirement—"due care"— in the 1107 rule, which relies on each manufacturer's knowledge and expertise and requires the manufacturer to act like a prudent and competent manufacturer engaged in the same line of business in making certain decisions about third party testing. The "due care" requirement essentially requires manufacturers not to be negligent in implementing testing requirements.

In reviewing the "due care" requirement again, however, staff notes that it is specifically required only in § 1107.23 on material change testing:

> 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 and issue a new Children's Product Certificate.

Staff does not recommend removing the requirement to exercise "due care," or changing the definition of "due care" in 16 CFR part 1107. The reasonable person standard implemented in the "due care" concept is a negligence standard; it does not create a high burden. Removing the

term would remove clarity, and it potentially could increase testing burdens by inserting confusion. Removing the requirement would make the rule vague with regard to the Commission's expectations, and it is unlikely to result in a reduction in the third party testing burden. Moreover, staff does not recommend changing the definition of "due care." The Commission already adopted a standard definition of the term.

2.2 Use and Definition of "High Degree of Assurance"

"High degree of assurance" is defined in § 1107.2 as: "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture." The term is intended to be a performance standard of the statutory requirement to "ensure compliance." Staff agreed that this means the manufacturer must have knowledge about its compliance program and must be able to articulate the reason for a high degree of assurance based on evidence (rather than simply a belief). The term is not intended to mean "guarantee," and it is not equivalent to "certainty." The term is used as a performance standard throughout the rule. Just like "due care," the definition of "high degree of assurance" relies on the manufacturer's knowledge of its product. Fundamentally, any uncertainty in the phrase "high degree of assurance," derives from the manufacturer's knowledge that the entire product it introduces into commerce is compliant with the applicable children's product safety rules.

Staff is not in favor of removing the concept of "high degree of assurance," or some reasonable facsimile of the concept, from the rule. Using an evidence-based performance standard for the rule actually could provide testing burden relief, rather than create additional burden. Without such a performance standard, the statutory requirement to "ensure compliance" could be interpreted by manufacturers to require certainty of compliance for every product. Here, the Commission has interpreted the requirement to mandate some evidence of consistent performance, a performance standard that can be met by various products, production techniques, and testing protocols.

Staff also discussed whether the term "high degree of assurance" should be changed to "reasonable degree of assurance" or something akin to that phrase. The idea was discussed that perhaps just changing the name of the performance standard, but not changing the actual definition, may ease the testing burden without adversely affecting assurance of compliance because some people may not understand that the term does not require certainty. However, it is unclear whether such a semantic difference would result in actual testing burden reduction. Moreover, changing the term may lead to a compromise in compliance because some may see the change in the phraseology as a reduction in the standard as opposed to a clarification of the standard. Staff suggests that education regarding the standard and its meaning be used to reduce any confusion in the regulated community.

Another idea discussed was either removing the term "consistent" from the definition of "high degree of assurance" or changing the term to require "reasonably consistent performance." Staff decided against recommending removing the word "consistent" because it provides clarification on the type of performance expected. Removing the word may also give the impression that inconsistent performance is acceptable, which is likely not the case. Moreover, changing the term to "reasonably consistent performance" has the potential to muddle the

definition without gaining a reduction in testing burden. Any argument that the testing burden would be reduced by changing the definition in this manner is purely speculative. In general, staff's view is that minor changes to this definition may add confusion to the testing regime, without providing a benefit by reducing testing burden. Staff concluded that stakeholder education regarding the requirements of the 1107 rule would likely go farther to reduce burden than semantic changes in the term "high degree of assurance."

2.3 Definition of "Identical in All Material Respects"

Staff reviewed how the term "identical in all material respects" is used in the statute and in the rule. Section 14(a)(2)(A) of the CPSA requires that manufacturers of children's products subject to a children's product safety rule "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 . . . to be tested for compliance with such children's product safety rule . . .." The 1107 rule defines the term "identical in all materials respects" to mean "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."

The term "identical in all material respects" is used twice in the 1107 rule. First, it is used in § 1107.20(a) as it is used in the statute—to describe initial certification testing. It is also used in § 1107.23(a)—on material change testing, to require that when component part testing is used to support a certificate after a material change to such part, the component part must be identical in all material respects to the component parts used on the finished products.

Because the term is statutory, staff did not discuss removing it from the 1107 rule. In both places the term is used to describe certification testing, just as it is used in section 14(a)(2)(A) of the CPSA. Thus, staff's review centered on whether a modification to the definition of the term would reduce the testing burden consistent with assuring compliance. For example, staff considered whether changing the word "no" in the definition of "identical in all material respects" to "no reasonable belief," would reduce the third party testing burden. Staff did not support this change because a manufacturer is required to have an evidentiary basis to demonstrate that the products were the same for purposes of testing and compliance.

If the Commission allowed samples for certification testing to be considered "identical in all material respects," simply based on "belief," rather than on an evidence-based approach, such a sampling system would undercut the basic integrity of any third party testing regime. Moreover, as with the previous terms discussed, changing the language of the rule may inject confusion in the rule without any corresponding reduction in the third party testing burden. The Commission has used the term in both the 1107 and 1109 rules to allow component part testing as long as the samples tested are identical in all material respects.

Component part testing has the potential to reduce testing costs significantly for some manufacturers. However, the integrity of any testing system relies on proper sampling techniques. Implementing a third party testing regime that produces effective results, yet allows

for component part testing, likely requires testing samples that are identical in all material respects, as defined in the 1107 rule.

2.4 Definition of "Material Change" and the Use of First Party Testing to Detect a Material Change

Staff reviewed how the term "material change" is used in the third party testing statutory scheme and in the rule. Section 14(i)(2)(B)(i) of the CPSA requires that the Commission:

> (B) establish protocols and standards—
> (i) 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 . . .

Thus, the statute requires testing when there has been a "material change" in product design, manufacturing, or sourcing of component parts. The Commission interpreted this requirement in the 1107 rule in several places. Section 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.

Section 1107.23 on material changes states:

> 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 and issue a new Children's Product Certificate.

Thus, the regulation restates the statutory requirement, but relies on the definition of "material change" to require that changes that "a manufacturer exercising due care knows, or should know, could affect the product's ability to comply. . ." require certification testing and a new Children's Product Certificate.

The concept of material change testing cannot be removed from the third party testing regime because the requirement is statutory. Accordingly, staff's focus centered on whether any modification in the definition or implementation of "material change" testing could reduce the testing burden consistent with assuring compliance. Staff considered different material change testing scenarios and use of the terms "due care" and "could" in the definition. For example,

staff considered removing the words "or should know," or changing the word "could" to "would." Previously, staff decided not to remove "due care," as discussed above. Further, some thought that the insertion of "due care" into the "material change" testing requirement demonstrated the Commission's intent that business judgment be used in deciding what constitutes a material change, and thus, require third party testing. The use of business judgment has the potential to reduce the third party testing burden by eliminating unnecessary testing. Consequently, staff does not think that removing the phrase "or should know" is appropriate, unless "due care" is also removed because "or should know" is essentially part of the concept of "due care." A manufacturer exercising "due care" should know when a design, manufacturing, or component part sourcing change could affect a product's ability to comply with applicable rules.

Staff considered whether use of the word "could," in the definition of a material change, sets too high a threshold for material change testing because it requires third party testing whenever a design, manufacturing, or sourcing change "could" potentially change the product's ability to comply with the applicable rules. Staff discussed whether changing "could" to another term or phrase might reduce unnecessary third party testing and still be consistent with the requirement of assuring compliance. For example, if the word "could" were changed to "would," then third party testing and recertification would be necessary only when an actual change occurred to the compliance of the product, not just when a change might have affected the product's compliance. However, use of "would" instead of "could" would mean that a "material change" is a change that makes the children's product noncompliant. Manufacturers may not know whether a product is noncompliant without testing.

Practically speaking, changing "could" to "would" in the definition of a "material change" is not workable because a third party test is unnecessary for a product known to be noncompliant. The basis of certification testing of children's products is that all the applicable product safety rules are evaluated by a CPSC-accepted third party testing laboratory before the Children's Product Certificate is issued. Thus, a Children's Product Certificate signifies that the product's compliance is supported by third party tests of each applicable children's product safety rule. If a change is made to the product that cannot affect compliance to the applicable rules, the support of each test requirement by third party testing is maintained. However, if a change is made to the product that can affect its compliance, the test results for those rules that could be affected by the change might no longer be applicable. Therefore, third party testing for the rules that could be affected by the change is needed to reestablish the validity of the product's certification, and "could" continues to be the proper term to use in the definition of "material change."

Staff discussed whether to recommend allowing manufacturers to conduct first party testing to determine whether a material change "could" affect compliance. Staff discussed that for newly sourced component parts, third party testing of applicable children's product safety rules should always be required because newly sourced component parts could always affect compliance. For other changes, first party testing, analytical techniques, or other evaluation methods are allowed to determine whether a change is material, that is, whether the change could affect compliance to an applicable children's product safety rule (and not whether the change renders the product noncompliant). For example, first party testing of a product design change, which strengthens the product, making it less susceptible to breakage and small parts generation,

can be used to determine that the change was not material. As another example, changes to the manufacturing process can use non-third party testing methods to show that the finished product has not changed in a way that could affect compliance.

There may be some utility in pursuing the techniques manufacturers can use to determine whether a change to a children's product is a material change. If third party testing for erroneously determined material changes can be avoided, that would have a burden-reducing effect consistent with continuing to assure compliance of the children's product.

However, in general, staff believes that, as with other topics, educating stakeholders about what a material change encompasses and how testing should proceed is likely to be more effective in reducing testing burdens and at the same time ensure compliance, as opposed to changing the meaning of terms in the rule, or creating nuanced carve-outs in limited circumstances.

2.5 Intervals for Periodic Testing

Staff discussed the possibility of lengthening the periodic testing intervals from their current 1-, 2-, and 3-year periods. The comments were not helpful in this endeavor, and staff did not determine a better interval system, nor did they come up with a rationale for altering the current interval periods. The Commission may revisit this issue at any time.

2.6 Requirement for a Periodic Testing Plan for Parties Who Do Not Conduct Periodic Testing

Currently, 16 CFR § 1107.21(b)(1) requires manufacturers to develop a periodic testing plan 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. However, some manufacturers or importers likely do not plan to conduct periodic testing. Thus, a periodic testing plan would be of no utility. These types of product certifiers could include seasonal producers or importers who plan to certify each lot or batch of children's product received.

The requirement to develop a periodic testing plan for certifiers who do not conduct periodic testing would be a burden with no corresponding assurance of compliance. Staff recommends that the Commission consider clarifying 16 CFR part 1107, through amending the rule, issuing guidance, or other means, so that manufacturers who do not conduct periodic testing are not required to create a periodic testing plan.

2.7 Recordkeeping Requirements

Staff considered the recordkeeping requirements in 16 CFR § 1107.26, whether such records were necessary for compliance purposes, and whether the 5-year record retention period could be shortened as a burden-reducing measure. Staff concluded that, at a minimum, records required

in § 1107.26(a)(1) and (2), certificates and test results, should be maintained for some period of time. Section 1107.26(a)(3) requires records to support periodic testing and the periodic testing interval that applies. Section 1107.26(a)(5) requires records relating to material change testing. Staff considered these records, and concluded that such records were necessary to document periodic testing, product changes, and what is essentially recertification of a product.

Finally, staff considered the 5-year record retention requirement in § 1107.26(b). Some consumer product safety rules have a 3-year record retention period. In the testing rules, the Commission decided to go with a 5-year record retention period for all testing, unless a specific standard required a different period. The reason that a 5-year period was chosen was because of statute of limitation considerations if the Commission wishes to pursue certain claims against a noncompliant firm. Staff concluded that the 5-year record retention period should be retained, because the primary costs associated with recordkeeping occur at the time the records are created, and reducing the time period is unlikely to have a significant effect in reducing the third party testing burdens. For firms that store records electronically, which we assume to be the vast majority of firms, the cost of maintaining records for 5 years versus 3 years is likely to be small.

3 Consideration of 16 CFR Part 1109

Staff reviewed each section of the 1109 rule and identified three concepts for consideration. These three concepts involve the Commission's implementation of component part testing and the associated administrative costs. As noted above, the purpose of the 1109 rule is to reduce the third party testing burden by allowing testing to take place at a point in the supply chain where it is the most convenient and least expensive. The trade-offs for allowing component part testing are administrative costs associated with tracking testing of component parts and their use in finished products. Accordingly, staff's focus on the 1109 rule concerned the potential to reduce administrative costs in using the rule.

The three concepts targeted for additional scrutiny are:

- the use and definition of the concept of "due care";
- the use and definition of the "traceability" concept; and
- the requirements for recordkeeping.

3.1 Use and Definition of "Due Care"

For the reasons already described above in section 2.1, staff does not recommend removing the concept of "due care" from the 1109 rule. The term is used more extensively in the 1109 rule because the purpose of the rule is to allow certifiers to rely on another party's testing or certification. The ability to rely on another party to complete required testing comes with the requirement of maintaining records and exercising "due care." "Due care" is a negligence standard. Thus, use of the term does not set a high burden, but it does create a floor for the conduct expected when relying on another party's testing. At a minimum, due care requires certifiers not to be negligent when relying on another party's testing or certification. Certifiers must ensure that the party on whom they are relying is following the Commission's rules,

protocols, and standards for testing consumer products and for obtaining access to the records that demonstrate this compliance. Without some minimum standard of conduct, certifiers may rely on supplier testing and certification that is noncompliant or even nonexistent, which would undermine the integrity of the entire third party testing regime.

3.2 Use and Definition of "Traceability"

Staff considered whether removing or redefining the concept of "traceability" in the 1109 rule would reduce the third party testing burden consistent with assuring compliance. "Traceable" is defined in § 1109.4(m) as:

> the ability of a certifier to identify all testing parties of a component part of a consumer product or a finished product, including the name and address of each testing party and any party that conducted testing on the component part or finished product. Parties that conduct testing may include a manufacturer, a supplier, a testing laboratory, or a third party conformity assessment body. Traceability extends to the component part of the product that was tested for compliance, such that if a subassembly is tested, that subassembly must be traceable, not each component part of the subassembly, if those parts were not individually tested for other rules, bans, standards, or regulations.

Thus, "traceability" in the 1109 rule refers to the party who procured a component part test, regardless of whether that party conducted the test. This definition was changed in the final 1109 rule in response to a comment on the proposed rule. The concept of "traceability" in the proposed 1109 rule required traceability to the source of the component part, meaning the manufacturer or supplier. However, because the 1107 and 1109 rules were focused on testing for compliance to the applicable standards, the Commission determined that ensuring the integrity of the testing regime only required traceability to the party who procured the component part testing.

Further, because suppliers often are not aware of how a component part may be used in a finished product, the requirement to comply with a children's product safety rule likely does not arise until the component is intended for use in a children's product. Thus, the testing party is the appropriate party to hold responsible for passing along compliant products. Altering the definition of "traceable" in the final 1109 rule was a burden reduction measure for certifiers consistent with assuring compliance. Staff does not recommend further alteration of the definition of "traceable." Staff did not identify another concept that would allow for reliance on component part testing and still ensure compliance.

Staff does not recommend removing the concept of "traceability" from the 1109 rule as a third party testing burden reduction measure. Part of assuring compliance involves the ability to determine where in the product certification scheme a failure allowed noncompliant products to enter into commerce. Traceability requires the collection of information that could help determine the source of the failure or verify the integrity of the testing process.

At a minimum, the Commission and certifiers should be able to hold the party having the component parts tested accountable for the testing. Without this accountability, testing parties have little incentive to procure or conduct the required testing accurately. The integrity of the third party testing regime would likely be undermined by removing the concept of "traceability," and it would limit any ability to enforce the testing rules for those who rely on component part testing.

3.3 Recordkeeping Requirements

Staff reviewed the documentation requirements in § 1109.5(g) and determined that each data element in that section is already required by 16 CFR § 1107.26, is necessary for product identification, or is statutorily required information on a certificate. The only avenue for burden reduction consistent with assuring compliance would be the attestations required in § 1109.5(g)(10). Removal of these attestations would likely provide only minimal third party testing burden relief without removing the requirement to meet the provisions of § 1109.5(b), *Test Result Integrity*.

Staff also considered the 5-year record-retention period in § 1109.5(j). Staff does not recommend changing the 5-year time period for the same reasons articulated in section 2.7 above.

TAB C: Response to Comments Received on Reducing Third Party Testing Burdens, Docket CPSC-2011-0081, and Staff's Responses

United States
Consumer Product Safety Commission
Bethesda, MD 20814

Memorandum

Date: August 29, 2012

TO : Randy Butturini
Office of Hazard Identification and Reduction

FROM : Jacqueline Campbell
Directorate for Engineering Sciences

SUBJECT: Response to Comments Received from the Request for Comments on Reducing Third Party Testing Burdens

1 Introduction

On November 8, 2011, a request for comments (RFC) titled, *Application of Third Party Testing Requirements; Reducing Third Party Testing Burdens*, Docket CPSC-2011-0081, was published in the *Federal Register*.[1] The RFC contained seven topics for comment associated with reducing the burden of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. The comment period on this RFC ended on January 23, 2012.

Twenty-two commenters responded to the RFC, discussing the issues related to third party testing burdens and assuring compliance.[2] A table identifying the commenters and their affiliations is included in Tab D. Each commenter has been assigned a commenter number. This memorandum summarizes each comment and presents CPSC staff's consideration and response.

For ease of reading, each comment will be prefaced with a numbered "Comment," and each response will be prefaced by a numbered "Response." The commenters for each summary are identified by the commenter numbers in parentheses. The comments are grouped by topic.

1.1 General Comments about Reducing Third Party Testing Burdens

Several commenters provide general statements or observations about third party testing and compliance of a children's product to an applicable product safety rule, without making any suggestion for reducing third party testing burdens consistent with assuring compliance. Among the topics they mention are:

[1] 76 FR, 69596.
[2] These comments can be found at: http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=cpsc-2011-0081.

- a request for guidance on testing requirements, testing costs, and laboratories (Commenter 3);
- an opinion that a product's or company's "safety track record" should be considered as an empirical assurance of a product's compliance (Commenter 4);
- a desire for globally harmonized test methods for lead and phthalates (Commenter 10); and
- A concern that additional testing requirements may lead to increased testing costs (Commenter 11).

1.2 Issue 1

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

Comment 1: One commenter (14) favors any measures that would reduce or eliminate duplicative testing, including recognition of testing by the FDA, the Occupational Health and Safety Administration (OSHA), the Environmental Protection Agency (EPA), or other agencies (including foreign agencies) when the testing assures compliance with a relevant CPSC children's product safety standard. However, the commenter states that, to some extent, they share the concern implicit in the specific questions posed by the agency in the November 8, 2011, *Federal Register* RFC that the laboratory recognition and oversight system required by the other agencies should ensure, at least, the level of qualification and scrutiny currently required by the CPSC laboratory accreditation and recognition system.

The commenter notes that there are a great many laboratories around the world with a wide variety of expertise and qualifications. Accordingly, to say that laboratory expertise in measuring lead in food contact surfaces, for example, encompasses the ability or expertise to measure accurately lead in children's metal jewelry, per the CPSC-approved test method, simply may not be accurate. The commenter further maintains that, it goes without saying, that the test procedures and, indeed, general approaches to testing substances or products for compliance with different regulatory schemes, may differ greatly.

Response 1: CPSC staff supports the elimination of duplicative testing to ensure compliance with CPSC regulations, but we share the concerns expressed by the commenter. Congress provided a third party testing scheme in section 14 of the CPSA, which relies, in part, on the ability of CPSC-accepted third party conformity assessment bodies to provide testing expertise and an objective assessment of compliance.

To the extent that testing required by another agency's regulations are conducted by a CPSC-accepted third party conformity assessment body (testing laboratory), and the tests and results can be used to ensure compliance with applicable CPSC-enforced regulations, staff is supportive of this process. Recommendations with regard to such regulations are addressed in the relevant comment response.

1.2.1 Materials Tested

Comment 2: Three commenters (16, 20, and 21) propose that CPSC provide an exclusion from certification and testing requirements for food-grade materials compliant with FDA requirements. In particular, one commenter (16) states that FDA requirements ensure that food-grade materials are low in lead. The other commenters (20 and 21) point out FDA regulations regarding plastics for food contact use at 21 CFR parts 177 and 178, and one (20) states that these regulations are superior to section 14(f)(2) of the CPSA. One commenter (20) suggests that we should consider accepting such an approach as suitable evidence of a reasonable quality assurance process.

Response 2: Any material that meets the FDA requirements for a food-grade material is most likely safe for use in children's products that are under the CPSC's jurisdiction. The use of such materials in children's products is unlikely to result in a measurable increase in the blood lead level of any child. The CPSC already has determined that actual plant- and animal-derived materials do not exceed the lead content limits in section 101(a) of the CPSIA, provided they have not been treated or adulterated with materials that could result in the addition of lead to the material. This determination is codified in 16 CFR § 1500.91.

Certifiers can rely on the CPSC's determinations in § 1500.91 to determine whether third party testing is required, but they cannot rely on the FDA's regulations on food-grade materials to meet the CPSC's requirements. Unlike the CPSC's statutory mandate, the FDA's regulations do not require manufacturers of food-grade materials to have the materials tested by a testing laboratory for conformance to the CPSC's requirements. Premarket testing for food additives for lead content is not required by FDA regulations. Although lead is not expected to be present in FDA-compliant, food-grade materials at levels above trace amounts, FDA regulations, with a few exceptions, do not contain explicit requirements for lead content or testing. On the other hand, the CPSC's regulations are mandated by section 14 of the CPSA, and they require that children's products be tested by a CPSC-accepted testing laboratory to meet a specific compliance limit of less than 100 parts per million. The CPSC does not have the authority to ignore a statutory third party testing requirement that children's products meet a specific compliance limit for lead content.

In a few, very specific cases, FDA regulations target lead in food additives and food contact substances. For example, certain direct food additives are subject to a specific lead content limit under 21 CFR part 172.[3] The FDA has also issued guidance on the acceptable levels of extractable lead in certain food contact ceramics from countries where environmental contamination is more likely. However, unlike the CPSC's standard based on lead content, the FDA regulations are generally based on potential dietary exposure, for which food-grade materials must meet an extractability standard, not a content standard. It is important to note that a food-grade material that passes an extractability standard can still have a total concentration of lead that is significantly higher than the extraction limit. In other words, a food contact material passing an extraction test for lead, or one determined to contribute only negligibly to overall dietary lead, is still not guaranteed to contain less than 100 ppm lead.

[3] *Food Additives Permitted for Direct Addition to Food for Human Consumption*.

Phthalates are regulated food additives that may be used intentionally in the production of food contact substances. As such, the FDA has promulgated regulations for the use of phthalates in specific food contact applications, for which the FDA has determined extractive limits and correlated these limits to a safe dietary exposure. Furthermore, many phthalates do not have extraction limitations and are subject to Good Manufacturing Practices (GMP) limitations on their use only. Therefore, it is likely that many food additives and materials would not conform to CPSC limits for phthalate levels in children's toys and child care articles.

Comment 3: One commenter (16) notes that Public Law 112-28 asks the Commission to consider:

> [t]he 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.

The commenter states that this general directive to assess evidence of conformity applies irrespective of whether the relevant agency or standard requires third party testing, or indeed any testing, or application of government or laboratory markings. The commenter adds that 21 CFR § 174.5, *General provisions applicable to indirect food additives*, in the FDA's rules, require food-contact materials to be of a "purity suitable for [their] intended use." The commenter further adds that the FDA lists specific polymers approved as indirect food additives in 21 CFR part 177.[4] The commenter urges the CPSC to modify 16 CFR § 1500.91 to add a new category of materials, "food grade materials," as determined not to contain lead, in the same way that it has determined that precious metals, gemstones, wood, and textiles do not contain lead above 100 ppm. The commenter states that the Commission has the authority to make a determination for "food-grade" materials and resins.[5] The commenter adds that adopting this determination would require traceability and concomitant assurances that the manufacturer of the product, or a component part of the product, did not introduce lead, and thus, vitiate the supplier assurance, much as the exclusion for wood and textiles requires assurances that the material was not treated in any way to add lead.

Response 3: CPSC staff agrees that increasing the number of materials for which third party testing is not required, such as an exemption for certain food-grade materials and resins, would decrease the cost of third party testing. As the commenter points out, 21 CFR § 174.5 requires that an indirect food additive (including food contact materials) be of a "purity suitable for its intended use." With only a few exceptions, FDA regulations for food-grade materials do not contain requirements for lead because the Federal Food, Drug and Cosmetic Act precludes the presence of lead in food or food packaging at anything greater than trace levels. Nevertheless, because FDA regulations do not require the routine testing of food for direct or indirect food additives for lead, absent a change in the law, the CPSC cannot disregard the third party testing regime set forth in section 14 of the CPSA for children's products. Disregarding the third party testing regime as a means of reducing the testing burden would not be "consistent with assuring compliance," as required by Public Law 112-28.

[4] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=177.
[5] A "food grade resin" is a food contact polymer (*e.g.*, polyethylene or polyethylene terephthalate (PET)).

As noted above, the CPSC has already determined that actual plant- and animal-derived materials do not exceed the lead content limits in section 101(a) of the CPSIA, provided these materials have not been treated or adulterated with materials that could result in adding lead into the material. With regard to "food-grade" materials and resins, if a material or resin is plant- or animal-derived, then it is included in the list of materials determined not to include lead in amounts greater than 100 ppm. However, synthetic "food-grade" additives are not included in the list of materials determined not to include lead in amounts greater than 100 ppm. If a determination can be made that synthetic food additives do not contain more than 100 ppm lead, then those materials could be included in 16 CFR § 1500.91. Staff recommends that the Commission consider investigating whether synthetic food additives can be determined not to contain lead in amounts above 100 ppm.

The CPSC staff agrees that "evidence of conformity with other national or international governmental standards" may be able to provide assurance of conformity to some children's product safety rules, if those standards are the same as or more stringent than the CPSC's requirements, and where those standards are tested by a CPSC-accepted testing laboratory. Because section 14(a) of the CPSA requires third party testing of children's products, evidence of conformity must include third party test results.

CPSC staff recommends that the Commission review international standards that are similar to the CPSC's children's product safety rules and identify performance standards that may overlap, such that if a children's product were tested to such a standard by a CPSC-accepted testing laboratory and it passed, the product would meet or exceed the CPSC's compliance requirements.

Comment 4: One commenter (22) notes that they are unaware of other domestic federal agencies that require mandatory third party testing for materials.

Response 4: CPSC staff is also not aware of other federal agencies that require third party testing of the same materials for the same hazards that the CPSC regulates.

Comment 5: A commenter (15) asserts that it is common for customers who make various types of consumer products to specify the use of "food-grade" materials. The commenter states that suppliers of resins routinely provide supplier certificates or other assurances that materials meet the Federal Food, Drug and Cosmetics Act's (FD&C Act) requirements and also requirements for limits on specific heavy metals (lead, mercury, cadmium, and hexavalent chromium) through packaging requirements of the Coalition of Northeastern Governs (CONEG). The commenter believes that together, these standards prescribe even lower levels of total lead and phthalates than the limits mandated by the CPSIA. The commenter argues that these types of assurances, along with tests, such as gas chromatography/mass spectrometry (GC/MS), mass balance, or similar analyses of raw materials, should be recognized to form a part of a consumer product manufacturer's testing program to indicate, with a high degree of assurance, that products, as produced, would meet relevant requirements.

Response 5: CPSC staff agrees that other requirements, such as those established by the FDA for "food-grade" materials and for packaging established by the FDA and CONEG, are intended to ensure that people, including children, are not exposed to hazardous levels of substances, such as heavy metals and phthalates. While manufacturers have latitude to integrate such considerations in implementing a production testing plan, FDA regulations on "food-grade" materials and CONEG requirements cannot be used to meet certification, material change, or periodic testing requirements for regulated children's products.

Unlike section 101 of the CPSIA, which sets a lead content limit for children's products at 100 ppm, FDA regulations on food-grade materials do not contain an explicit limit for lead content. The FD&C Act prohibits lead in most-food grade materials at concentrations that would result in a dietary exposure exceeding trace levels. However, regulations based on potential dietary exposure do not compare directly to a standard like the CPSC's that is based on content. A food contact material determined to contribute only negligibly to overall dietary lead is not guaranteed to contain less than 100 ppm lead.

Similarly, while section 108 of the CPSIA bans certain phthalates in children's toys and child care articles, the FDA regulates phthalates as materials that may be used intentionally in the content or the production of indirect food additives, such as food packaging. As such, the FDA has promulgated regulations for the use of phthalates in specific food contact applications, for which the FDA has determined GMP limits or extractives limits, and correlated these limits to a safe dietary exposure. The acceptable phthalate concentration in a food-grade material, such as an indirect food additive, may well exceed limits established in the CPSIA.

Importantly, FDA regulations do not require routine third party testing for lead or phthalate content of food, food additives, or food packaging. The CPSC's statutory mandates require third party testing for all applicable children's product safety rules, including lead content in children's products and phthalates in certain children's toys and child care articles. While food and food additives complying with the FD&C Act would likely comply with the lead content limit established in the CPSIA, section 14(a) of the CPSA requires third party testing of children's products to determine compliance with the applicable children's product safety rules, including those for lead and phthalates.

CONEG certification provided by packaging suppliers indicates that the four metals: lead, cadmium, mercury, and hexavalent chromium have not been introduced intentionally to packaging materials and, with a few exceptions, their combined incidental concentration is less than 100 ppm. CONEG certification does not mandate third party testing by a CPSC-accepted testing laboratory, which is required by section 14(a)(2) of the CPSA for children's products. In the absence of the third party testing requirement, many CONEG-certified materials would be expected to pass the lead limits established in the CPSIA. CONEG regulations do not cover phthalate content.

However, as stated above, use of these standards and tests by manufacturers can be incorporated into a production testing plan for a children's product and can serve to increase the maximum periodic test interval from 1to 2 years.

1.2.2 CPSC Laboratory & Method

Comment 6: One commenter (22) recommends that the CPSC extend the recognition of registered OSHA NRTL Certification Marks to satisfy the CPSC's certificate of conformity requirement for other product categories under the jurisdiction of the CPSC's CPSIA requirements and the OSHA NRTL Program as a way to alleviate or minimize redundant testing. The Certification Marks additionally offer traceability for product and manufacturer information. This commenter mentions that the ultimate assessment of product compliance is performed best by an accredited third party testing or certification body.

Response 6: Increasing options available to manufacturers to meet a requirement has the potential to lower third party testing costs. However, the commenter does not indicate which children's product safety rule's compliance could be indicated if the product has an OSHA NRTL Certification Mark; and no NTRL currently is accredited to test children's products to a children's product safety rule enforced by the CPSC.

Further, NRTLs are not accredited by an ILAC-MRA signatory accreditation body, and thus, their accreditation cannot be accepted by the CPSC for testing children's products for certification to an applicable children's product safety rule, according to the CPSC's current third party testing requirements and the proposed rule on laboratory accreditation, 16 CFR part 1112.[6]

The OSHA NRTL program involves establishing NRTLs as certification bodies that can conduct testing and perform other activities involved in certification to non-CPSC-enforced standards, such as follow-up inspection programs. An NRTL's scope includes "programs," under which the NRTL can use other parties in performing activities necessary for product testing and certification. These other parties include other NRTLs, other non-NRTL independent testing labs, and product manufacturers. Using NRTLs for children's product certification to an applicable children's product safety rule would have to take the "programs" into consideration to avoid subcontracting tests to non-CPSC-accepted testing laboratories or having product manufacturers conduct tests themselves without establishing a firewalled testing laboratory.

Finally, the certification mark from an NRTL does not meet the requirements of a certificate, as specified in section 14(g) of the CPSA.

We recognize that there are other laboratory accreditation organizations or accreditation bodies. Some of these organizations may adhere to similar procedures and standards as those established in the ILAC-MRA signatory program. Staff recommends that the Commission consider establishing criteria by which non-ILAC-MRA accreditation bodies may accredit testing laboratories to test children's products for children's product certification purposes to increase the number of CPSC-accepted third party conformity assessment bodies available for conducting required testing.

Comment 7: One commenter (20) suggests that laboratories recognized by NIST should be mutually recognized by the CPSC, in accordance with generally recognized international accrediting bodies, to assure suitable numbers of accredited laboratories are available along the

[6] *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 77 FR 13086, May 24, 2012.

global supply chain. The commenter claims that such an action would reduce recordkeeping requirements. The commenter adds that mutual recognition of accreditation bodies has been effective across jurisdictions and borders in reducing redundant accreditation and assuring a greater number of qualified laboratories.

Response 7: In general, increasing the number of CPSC-accepted third party conformity assessment bodies could have some impact on the cost of third party testing. For example, it potentially could increase competition among laboratories for manufacturers' testing business, and it could reduce the turnaround time for testing. The criteria for recognizing the accreditation of conformity assessment bodies could be reexamined with the aim of approving more testing laboratories.

NIST contains an independent, self-contained program, the National Voluntary Laboratory Accreditation Program (NVLAP), which accredits testing laboratories to the requirements of various established standards. NVLAP is an ILAC-MRA signatory, and can accredit a testing laboratory to ISO/IEC 17025:2005, whose scope includes some CPSC product safety rules (16 CFR parts 1630 and 1631). Thus, NVLAP-accredited laboratories, whose scope includes the tests in 16 CFR parts 1630 or 1631, are eligible for CPSC acceptance of their accreditation for the tests included in their scope of accreditation.

The commenter does not indicate which other international accreditation bodies should be mutually recognized by the CPSC. As discussed earlier, the CPSC designates an accreditation program to an entity that is established and has acceptance on a multinational level, ILAC-MRA. The CPSC did not designate other accreditation bodies to maintain a degree of consistency in the procedures used by the designated accreditation bodies, among other things.

Regarding the commenter's concern about assuring a suitable number of testing laboratories, staff has recommended that the Commission consider establishing criteria by which non-ILAC-MRA accreditation bodies may accredit testing laboratories to test children's products for children's product certification purposes. An increase in the number of testing laboratories accredited to conduct testing may serve to reduce the testing burdens to the extent that there may be a problem with the number of testing laboratories available, or their capacity in some locations, to conducts tests for some products.

1.3 Issue 2

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

Comment 8: Several commenters (4, 7, 14, 22, and 19) generally support the concept that an importer should be able to rely on a foreign factory's third party test results or certificate of conformity to issue their own certificates, as is allowed in the component part testing rule, 16 CFR part 1109.

One commenter (7) states that test reports of products and components that are substantially similar or are identical in all material respects from an accredited third party conformity assessment body should be recognized and shared by all importers.

Another commenter (22) states that importers of products that are substantially similar could leverage certifications to reduce redundant testing and documentation if certificates could be issued by manufacturers or third party testing laboratories. The commenter explains that such a practice would require a contractual, explicit agreement between the manufacturer, the third party testing organization, and subsequent importer, as well as require a strong traceability or market surveillance program to maintain confidence of ongoing compliance.

Finally, one commenter (19) states that they support the language in the preamble to the component part testing rule, which states: "If the supplier providing a certificate is also a required certifier (a domestic manufacturer or importer), then the party receiving a certificate does not need to reissue a certificate." 76 FR 69548 (November 8, 2011). The commenter believes that this practice will help to reduce costs and the testing burden by reducing redundant testing and record keeping.

Response 8: We agree with the commenters that an importer may rely on a foreign manufacturer's test results or certificates of conformity as a basis for issuing their General Conformity Certificates (GCCs) or Children's Product Certificates (CPCs). To rely on such test results or certificates, the foreign manufacturer must use a CPSC-accepted testing laboratory for tests on component parts intended for children's products or finished children's products. Further, the foreign manufacturer must provide the documentation required by 16 CFR § 1109.5(g), either in hard copy, or electronically, to the importer.

We further agree that multiple importers of products with similarities regarding compliance may leverage the same third party testing. For example, importers of products molded from the same lot or batch of plastic resin can use the same test results or component part certificates for the chemical tests for that lot or batch for their products, irrespective of the shape of the molded products. As another example, if the same finished product is imported by multiple importers and rebranded by each, the test results or finished product certificate for the finished product may be used by each importer as a basis for issuing their GCC or CPC for the finished product. We agree with the commenter that, for such a testing and certification scheme to be effective, agreements are likely between the testing parties and the parties issuing GCCs or CPCs.

Finally, certificates for finished products issued by a required certifier—currently a domestic manufacturer or an importer (see 16 CFR § 1110.7)—do not need to be reissued by a party farther down the supply chain, unless the product is materially changed after certification. However, for finished products that are tested or certified by a voluntary certifier, such as a foreign supplier, the importer must issue a certificate under current regulations. This is because the Commission will hold the entity responsible for importing the product for the product's compliance with all applicable regulations.

Comment 9: One commenter (19) states that the component part testing rule's recognition that manufacturers can act as finished product certifiers upon whose certificates the retailer

importer can rely (with due care) to issue their required certificates, recognizes that both component parts and finished products can be tested and certified appropriately by the manufacturer. The commenter believes that this reduces testing burdens because manufacturers and suppliers are the product experts that can develop compliance procedures, and retailer importers can focus appropriately on exercising due care to select vendors that can certify compliance.

The commenter explains that additional changes to the component part rule should focus on confirming the kinds of activities that constitute due care. The commenter states that:

> a thorough factory evaluation/audit such as one consistent with the BRC/RILA Global Standard for Consumer Products, Issue 3,[7] or an equivalent evaluation or audit based on good manufacturing systems and process controls (such as the audits currently conducted by some retailer importers), can be used as a basis for due care, when paired with documentation support as outlined in Section 1109.5(g) (of the component part testing rule, 16 CFR part 1109).

Response 9: We agree with the commenter that, by allowing parties with control over component part selection and finished product manufacturing the ability to test or certify component parts and finished products, greater efficiencies may be achieved in children's product testing and certification than would be possible if an importer was responsible solely for testing and certification. Product manufacturers can tailor their production processes to control the variables affecting compliance to the applicable children's product safety rules more directly than most importers can. Third party testing by a CPSC-accepted testing laboratory is required by the party procuring tests for children's product certification purposes.

As for the commenter's suggestion that additional changes to 16 CFR part 1109 focus on activities that constitute due care, because this rule applies to a wide variety of products, manufactured using a wide variety of methods, any list describing activities that constitute due care will be necessarily incomplete. Such an incomplete list could lead to the incorrect assumption that items not on the list are prohibited. Section 1109.5(b) of the rule, *Test Result Integrity*, provides guidance on the responsibilities of a certifier or testing party to ensure that test results for component parts or finished products remain valid. Further information regarding due care is available at: http://www.cpsc.gov/info/toysafety/3ptfaq.html#duecare. We agree with the commenter that factory evaluations and/or audits, good manufacturing practices, and process controls, when combined with the required documentation, can be effective as a basis for due care exercised by a manufacturer.

Comment 10: One commenter (4) states that the issue of what products are "substantially similar" should be left up to manufacturers to determine because no problem has been identified for the CPSC to solve. Without empirical data that demonstrates an actual problem to solve, the

[7]The Retail Industry Leaders Association (RILA) Board of Directors approved the formation of a partnership with the British Retail Consortium (BRC) to establish a retail-led global product safety standard: the Global Standard for Consumer Products, Issue 3 (CP-3), found at: http://www.rila.org/supply/productsafety/BRCRILAGlobalStandard/Pages/default.aspx.

commenter believes that the CPSC should not unnecessarily complicate the rules, as this would not provide better safety. The commenter states that manufacturers already have an incentive to exercise due care in their testing protocols.

Response 10: Through Public Law 112-28, Congress directed the Commission to solicit comments about "substantially similar" products and how the testing of such products may reduce third party testing burdens consistent with assuring compliance. The Commission has met the statutory obligation. Moreover, staff believes the phrase "substantially similar" merits some consideration because redundant testing is an added third party testing burden without any added assurance of compliance.

We agree with the commenter that the CPSC should not unnecessarily complicate rules. We also agree that manufacturers should exercise due care.

Comment 11: One commenter (7) states that products should be considered "substantially similar in all material respects" if one of the following applies:

a) They are manufactured by the same factory and are made of the same material from the same supplier, same size and same construction but are in different color. In this case, the products and components should share the same third party physical and mechanical test report from third party conformity assessment body.

b) They are manufactured by the same factory and are made of the same material and same color from the same supplier but are different in construction and size. In this case, the products and components can share the same chemical test reports from third party conformity assessment body.

c) The products and components are manufactured by the same factory and are identical in material, size, construction, color and supplier. In this case, the products and components can share the same mechanical, physical and chemical report from third party conformity assessment body.

The commenter states that in order to rely on test reports for products that are substantially similar, the factory concerned should provide a declaration letter, confirming the products and component parts that are substantially similar or identical in all material respects. The commenter believes that the manufacturer should be responsible for verifying the declaration.

The commenter suggests that reports of products and component parts that are substantially similar or identical in all material respects from an accredited third party conformity assessment body should be recognized and shared by all importers.

Response 11: With regard to the suggested definition of "substantially similar in all material respects" contained in (a), the commenter describes products that are identical in all material respects regarding physical and mechanical tests, a similarity that is allowed under the definition of "identical in all material respects" in 16 CFR §§ 1107.2 and 1109.4(i). These differently colored products, even if given different model numbers or product names, can share the same mechanical and physical test reports, as long as the colorants do not affect the ability of the product to comply with the applicable physical and mechanical tests.

Regarding the suggested definition of "substantially similar in all material respects" contained in (b), the commenter describes products that are identical in all material respects regarding the chemical tests, a similarity that is also allowed under the definition of "identical in all material respects" in 16 CFR §§ 1107.2 and 1109.4(i). These differently shaped products, even if given different model numbers or product names, can share the same chemical test reports.

With regard to the suggested definition of "substantially similar in all material respects" contained in (c), the commenter describes products that are identical in all material respects with respect to physical, mechanical, and chemical tests, a similarity that is allowed under the definition of "identical in all material respects" in 16 CFR §§ 1107.2 and 1109.4(i). These products, even if given different model numbers or product names, can share the same mechanical, physical, and chemical test reports.

If a product produced by a foreign manufacturer is sold to multiple importers, features that differentiate the product among the importers, yet do not affect compliance to the applicable children's product safety rules, are not material differences. Thus, model numbers or product names, private labeler identifications, and packaging are examples of product features that may make the product look different for different importers, but do not affect compliance to the applicable children's product safety rules. For these types of products, test reports for one product can be applied to the other materially similar products. Due care must still be taken to ensure that for the chemical tests, the raw materials subject to lead and phthalate concentration limits, are from the same lot or batch tested for compliance.

Regarding the declaration letter from the foreign manufacturer, 16 CFR § 1109.5(g) lists the documentation to be provided by the testing party or voluntary certifier to a party relying on such documentation as a basis for issuing a certificate. The declaration letter described by the commenter appears to contain some of the required documentation, specifically product identification, lot or batch information, and traceability records. This declaration letter, as described, could be part of the required documentation that would be provided, in addition to test reports and other elements of 16 CFR § 1109.5(g). We agree that, under the rule, the party receiving the documentation has the responsibility to exercise due care in the review and verification of the received documentation, as described in 16 CFR § 1109.5(i).

We agree with the commenter that test reports for component parts or finished products that are identical in all material respects can be shared among many importers of those products. Redundant testing for each importer is not necessary.

Comment 12: One commenter (7) states that manufacturers, working together with the factory, should determine what products are "substantially similar" for testing purposes, based on whether the product: is intended for the same user age; has similar playing features; consists of the same material from the same supplier; has a similar construction; is the same size; and other considerations.

Another commenter (22) states that the term "substantially similar" refers to the composition of the materials and components used to make a finished product. "A particular product may be substantially similar if they all use the same raw materials and components, but regardless of the broad or narrow definition of 'substantially similar,' the key aspect is the determination of compliance from an accredited third party conformity assessment body."

Response 12: "Substantially similar," as used by the commenter, refers to similarities with respect to compliance to an applicable children's product safety rule or test within a rule. In 16 CFR §1107.2, the definition of "identical in all material respects" states:

> … 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.

The examples provided by the commenters are examples of products that meet the definition of "identical in all material respects." We agree with the commenters that children's products made from the same lot or batch of material, such as plastic pellets molded into numerous toys, are identical in all material respects with respect to the chemical tests for lead and phthalate content. The shape of the molded toy does not affect its compliance to a chemical limit other than determining which component parts are accessible.

Similarly-shaped products, even if made from different materials, might be identical in all material respects regarding some of the use and abuse tests for toys. If a product is too large to fit into the cylinder indicating a potential choking hazard, an object of the same shape, but made of a different material, is also likely to be too large to fit into the cylinder.

A manufacturer should consider how the products being compared are similar with respect to the tests to which they are subject, in determining whether they are "substantially similar" or "identical in all material respects" for that test.

Comment 13: One commenter (19) states that 16 CFR § 1107.21, *Periodic Testing*, reflects the intent of HR 2715 (PL 112-28) because it affords greater flexibility to demonstrate compliance to safety rules, by permitting activities such as management controls, measurements, and other alternatives to testing, as long as the certifier has a production testing plan. The commenter states that attention to the benefits of good process control, as a compliance strategy,

is consistent with the commenter's belief that safety cannot be tested into the product—and that alternatively, the compliance of a product begins at the initiation of manufacture.

Response 13: We agree with the commenter that there are techniques in addition to finished product testing that can be employed to ensure a product's compliance to the applicable product safety rules. Some of these techniques, such as control charts, statistical process control programs, or failure modes and effects analyses (FMEAs), designed to control potential variations in product manufacturing, are listed in 16 CFR § 1107.21(c)(2). In general, these methods are intended to eliminate or minimize the possibility that the manufacturing process can create noncompliant products. By consistently making the product, as designed, and minimizing unit-to-unit variations, a manufacturer can avoid more expensive finished product testing and possible rework actions.

Comment 14: Three commenters (13, 20, and 21) state that multiple retailers require third party testing to be conducted by specific testing laboratories, meaning that manufacturers must conduct multiple third party tests by different testing facilities to meet retailer requirements on the same, identical, product.

One commenter (13) adds that if testing has already been performed by a testing laboratory accredited by an ILAC-MRA signatory, this testing should not have to be repeated simply because it was not done by a specific testing laboratory preferred by the retailer. This commenter believes that the exclusive relationship that certain retailers have established with specific testing laboratories goes against the "undue influence" provision in the final testing rule. Further, the commenter adds, its members are complaining that retailers are applying a "one size fits all" testing approach that requires manufacturers to conduct tests that are not applicable to their products, based upon, the commenter believes, the retailer's own definition of a children's product or a toy. The commenter asserts that sometimes, the retailer's definition does not follow the statutory definition.

The commenters further advise that retailers also have specific periodic testing requirements that are more stringent than the "Testing and Labeling Pertaining to Product Certification" rule (16 CFR part 1107) and the alternate test frequencies enumerated there.

The commenters state that they have requested repeatedly that Commission staff clearly and expressly advise retailers that there is no preference accorded to one CPSC-accepted testing laboratory over another. One commenter (21) advises: "[t]here is probably no single action which the Commission could undertake which would have a greater impact in reducing testing costs than to discourage this duplicative testing by making clear that it is wasteful, unnecessary, diverts resources from more productive safety efforts, and adds cost to products without improving safety." This commenter recommends that this issue be part of the CPSC's education campaign. Another commenter (13) asserts that a *Federal Register* notice should state that a single test of a product by a CPSC-accepted testing laboratory is acceptable legally for children's product certification purposes and, that additional, duplicative tests are not required by law.

However, another commenter (22) observes that testing is a prevalent aspect of the global supply chain when importers, manufacturers, and retailers are unsure of the

various materials, components, and inputs from various suppliers along the supply chain. While eliminating redundancies is worthwhile, this commenter does not believe that all cases of repeated testing are redundant. The commenter explains that some parties, such as retailers, manufacturers, and importers, may impose their own third party testing requirements as a contractual obligation of doing business with them. The commenter argues further that repeated testing may also be an important element of establishing continued confidence in effective supply-chain management. The commenter believes that the CPSC has already saved manufacturers and importers time and certification costs by allowing the testing of raw materials, which can verify compliance, while shifting the burden of compliance to material and component suppliers.

Response 14: In the preamble of the proposed rule for 16 CFR part 1107,[8] and repeated in the preamble to the final rule,[9] the Commission made the following statement:

> 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.

Contractual matters between retailers and suppliers regarding additional testing are beyond the authority of the CPSC. The statutes and regulations set the minimum requirements for compliance. Retailers are free to contract to do more than the law requires.

Staff agrees with the commenters that the CPSC has developed a third party conformity assessment body accreditation program, through which testing results from any CPSC-accepted testing laboratory (whose scope includes the tests) may be used for children's product certification purposes. The use of the international standard ISO/IEC 17025:2005, and accreditation by a signatory to the ILAC-MRA are intended to allow third party testing facilities to meet the requirements for accreditation. Testing laboratories whose accreditation has been accepted by the CPSC have met technical competence requirements, established management systems, and have incorporated protections against undue influence so that their testing results can be relied upon.

The choice of testing laboratory and the frequency of periodic testing were not specified in 16 CFR part 1107 because the rule applies to a wide variety of products manufactured with various fabrication techniques. The periodic test intervals listed in 16 CFR § 1107.21 are the maximum intervals allowed. Periodic testing may need to be conducted more frequently in order for a manufacturer to have a high degree of assurance of compliance. For example, § 1107.21(b)(2) explains that:

> [t]he 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

[8] 75 FR at 28337, May 20, 2010.
[9] 76 FR at 69486, November 8, 2011.

the testing interval comply with the applicable children's product safety rules.

The rule lists 10 factors to consider in setting a testing interval. It is the responsibility of the manufacturer or importer to determine the number of product samples to test and the frequency with which to conduct the testing in order to achieve a high degree of assurance of initial compliance for certification testing and for continuing compliance for periodic testing.

If a retailer wants its suppliers to conduct additional testing to establish the retailer's high degree of assurance of compliance for the products they sell, that is their prerogative. A retailer's requirements for a high degree of assurance of compliance may well involve periodic testing intervals shorter than the maximum allowed in 16 CFR § 1107.21. A retailer's high degree of assurance of compliance may be accomplished by conducting their own third party testing, through the contractual relationships with their suppliers, or by other means, such as supplier-retailer quality assurance/quality control (QA/QC) programs or the retailer's first party testing.

Staff notes that a single test may not be sufficient for children's certification purposes. Depending on the product and the applicable children's product safety rules, certification testing may require multiple product samples and several tests to determine with a high degree of assurance for the certifier, that the product meets its certification requirements.

Regarding the assertion of going against the "undue influence" provision in section 16 CFR §1107.24, the commenter does not explain how, nor does the commenter provide evidence in support of, a retailer requiring by contract, testing at a named testing laboratory, as an exercise of undue influence over the accuracy or integrity of the test results.

As for the retailer's designation of which products require testing, the CPSC has issued an interpretative rule, *Interpretation of "Children's Product,"* which can be found at http://www.cpsc.gov/library/foia/foia10/brief/interpretive.pdf. Section 108(e)(1)(B) of the CPSIA sets forth the definition of a "children's toy," and can be found at: http://www.cpsc.gov/cpsia.pdf. The CPSC requires children's products and toys to be tested by a testing laboratory whose accreditation is accepted by the CPSC before the required CPC can be issued. Retailers are not prohibited from having their suppliers test products that are not subject to these requirements.

Finally, staff agrees that additional testing of component parts or finished product samples is not necessarily without value. As one commenter notes, testing may be used as a quality assurance method to check that compliance is maintained throughout the supply chain and that (for the chemical content requirements) unintentional contamination has been avoided.

Comment 15: One commenter (20) states that it supports an enforcement policy based on brand ownership versus requiring the importer of record to conduct duplicative testing. The commenter believes that where a domestic company has assumed primary responsibility for a product and issued its own certificate related to the same product, importers should not have to duplicate a certificate. Further, the commenter explains that retailer importers should be able to

rely unconditionally on the brand owner's certificate to eliminate multiple tests on the same product without a demonstrable safety benefit. The commenter advises that the Commission states clearly that the form of importation and delivery should not dictate testing and certification compliance. The commenter recommends that this message be included in the CPSC's education campaign.

Response 15: The Commission's regulation, at 16 CFR part 1110, currently requires that a domestic manufacturer issue a certificate for domestically manufactured products, and it also requires that the importer of record issue a certificate for consumer products manufactured outside of the United States. This policy is unlikely to change for imported products because the Commission requires that the party responsible for importing goods into the United States be responsible for ensuring that the products comply with all applicable regulations.

We are aware that some brand owners manufacture and test products for compliance outside of the United States, and that these products are then imported by various importer/retailers. To address this situation, and to limit any perceived need for redundant testing, the component part testing rule, 16 CFR part 1109, allows an importer to rely on another party's test results or certificates to certify a finished product. Thus, importers of such branded products are not required to retest such branded products, but they are required to certify, or to recertify, finished products based on the test results or certificates provided by brand owners. Importers must exercise due care in relying on another party's test results or certificates, as required by 16 CFR part 1109.

The rules for testing and certification and component part testing are new and can be complex. Accordingly, staff recommends that to the extent the Commission conducts an education campaign, the nuances of the 16 CFR parts 1107 and 1109 be explained in more detail.

Comment 16: Some commenters (20, 21) state that the CPSC should clarify that importers are not required to determine "representative sampling" procedures.

One commenter recommends that the CPSC look at the definition of "manufacturer" used in the "Testing and Labeling Pertaining to Product Certification" rulemaking. The commenter notes that 16 CFR § 1107.2 defines "manufacturer" as "the parties responsible for certification of a consumer product pursuant to 16 CFR 1110." According to 16 CFR § 1110.7(a), when products are manufactured outside of the United States, the importer must issue a certification of conformity. The commenters believe that some could read this to mean that a "representative sampling" procedure must be determined by the importer, even if component part testing is conducted by suppliers. These commenters explain that many testing decisions are made upstream in the supply chain. Now that the CPSC accepts component part testing, these commenters state that decisions related to the testing interval and sample size are made appropriately by the manufacturer ultimately responsible for production samples to be tested, regardless of importation method. The commenters argue that while it is important that the finished product certifier exercises due care in its reliance on supplier certifications, this should not mean that the finished product certifier should necessarily dictate its suppliers' sampling procedures or that the importer of record should require duplicative testing.

Response 16: This comment refers to the NPR for the testing of representative samples, Docket CPSC-2011-0082, which was published in the *Federal Register* at the same time as this RFC. For the purpose of reducing the costs of third party burden testing consistent with assuring compliance, staff agrees with the commenters' statements that parties conducting component part testing are in a position to select samples efficiently. Under the component part testing rule, an importer can rely on test reports or certificates from another party. Importers do not need to retest products that have already been tested or certified appropriately. However, the importer, who is required to issue a CPC, must exercise due care to ensure that testing, including periodic testing is conducted properly.

If an importer relies on certificates for component parts or finished products that are supplied by another party, such as a foreign manufacturer or a supplier, then it is the voluntary certifier of the component part or finished product who is responsible for periodic testing of representative samples for the component parts or finished products they certified, and not the importer. The importer must exercise due care to ensure that applicable testing is completed in an appropriate manner. However, if the importer arranges for periodic testing itself, the importer retains the responsibility for selecting and testing representative samples periodically to ensure continued compliance.

CPSC staff notes that the proposed rule for the testing of representative samples is for periodic testing, which is testing conducted on continuing production of a children's product. If each imported lot or batch of a children's product is supplied with its own finished product certificates or third party test reports, then the periodic testing requirements might not apply. This would be a case of certifying each lot or batch and would not represent continued production, even if the name or model number of the children's product did not change.

Comment 17: One commenter (22), a certification body, states that its programs aimed at the use of pre-identified compliant materials and components to reduce testing costs may be useful models for CPSC, and that adoption of such programs could be used to meet CPSIA certification requirements. The commenter states that its programs and services are commonly used by qualified manufacturers to reduce cost and time burdens. Even with use of such programs, the commenter states that the judgment of compliance ultimately should be at the determination of an accredited third party conformity assessment body at various stages of the supply chain.

The commenter describes three programs it believes could be used to reduce testing burdens. The first program focuses on the selection of suitable, pretested component parts, compliance with applicable construction standards, and compliance with specific program guidelines provided in commenter's certification documents. One listing may cover many variations and models of the product without resubmitting each product for certification. To address custom products, the commenter has developed what he calls a unique and highly flexible approach to certification that provides:

1) compliance with applicable safety standards;
2) customer control of the certification timing; and
3) high value in listing a wide variety of custom constructions.

The commenter believes that this type of program, or a program with similar parameters, could be applicable to small batch manufacturers producing products under CPSIA requirements.

The second program uses in-house resources to conduct the required tests. The commenter explains that such a program would provide a mechanism for acceptance of first party data, as an alternative to third party testing. The commenter describes a similar program for use of its certification mark, which requires that the client have in place a testing laboratory with physical resources, equipment, and qualified personnel to conduct the tests. The commenter assesses the physical resources, equipment, and testing personnel each time before data can be accepted, and then reassesses them annually. All data submitted is reviewed thoroughly by the commenter before being used. The program allows manufacturers to continue to use their in-house testing laboratory for some testing, but also maintains a level of integrity and assurance by having those results reviewed and validated by an independent, third party organization that ultimately makes the compliance determination. Further, working with the commenter throughout the product development and testing process, as opposed to the various testing gates, allows the manufacturer to correct product failures and fix design defects on a timelier basis, again saving the manufacturer time and subsequent costs associated with testing.

Finally, the commenter describes a program that allows one certification to cover the same product sold under another company label. The practice allows manufacturers and their private label distributors to use the commenter's certification mark, if the products are identical, except for company identification or other superficial feature. All construction, packaging, and labeling of the product must be done at the basic applicant's manufacturing location or locations. The commenter states that this service offers a way to provide customers a full line of products carrying the manufacturer's brand name, leveraging the safety certification mark earned by the manufacturer producing the product. The commenter states that this program would significantly decrease the redundant testing for identical products and could allow a particular product sold by multiple distributors or importers to be tested only once.

Response 17: The first program the commenter describes appears to be a particular application of component part testing allowed by 16 CFR part 1109. In the particular example the commenter provides, a family of products is constructed from the same materials and component parts. All of the materials and component parts are tested beforehand. In this manner, each product in the family can use the same test report for a given material or component part.

We agree that using pre-identified compliant materials and component parts could be a useful way to reduce third party testing costs. Presumably, "pre-identified compliant materials and component parts" means material and component parts that have already been tested for compliance by a CPSC-accepted testing laboratory. In this case, test reports for a lot or batch of material or components parts can be used for many products, eliminating the need for separate tests to be conducted for each CPC. This practice is already allowed by 16 CFR 1109. Third party testing at a CPSC-accepted testing laboratory may be performed at any stage of the supply chain. For tests that require the finished product, component part testing is not allowed.

The second program described by the commenter is a form of manufacturer laboratory accreditation, with the certification body acting as an accreditation body. Similar to accreditation bodies, the certification body provides an initial assessment of the manufacturer's testing laboratory, and conducts regular reassessments. This practice would not be allowed by the proposed rule on laboratory accreditation, 16 CFR part 1112. Only ISO/IEC 17025:2005 testing laboratories accredited by an ILAC-MRA signatory may conduct testing for children's product certification purposes. The primary reasons for using third party testing laboratories are to ensure the technical competence and the objectivity of the testing organization. The commenter's second program of manufacturer laboratory accreditation would not necessarily meet the requirements of section 14(f)(2)(D) of the CPSA regarding firewalled conformity assessment bodies. As noted in Comment 6, the Commission, however, could consider evaluating whether entities other than ILAC-MRA signatories could accredit first party testing laboratories in a manner that ensures the laboratories' technical competence and objectivity, and in addition, meets the additional requirements for firewalled testing laboratories detailed in the CPSA.

The third program described by the commenter refers to multiple parties, such as importers of privately labeled products, using one set of certification tests for each importer's superficially unique product. When the same product is imported by several retailers, for example, with nonmaterial packaging variations, these are considered by the CPSC to be products that are identical in all material respects. Importers may rely on testing and certification conducted by the manufacturer or private labeler under 16 CFR parts 1107 and 1109, as long as the importer exercises due care in doing so.

Test reports or certificates for component parts or finished products (of any party, because the differences between parties are not material) may be used for certification of all the parties' products. As long as those differences between each party's product, such as labeling, model number, and packaging do not affect compliance to an applicable children's product safety rule, any combination of component part and finished product testing on any of the parties' products may be used for certification purposes—but all required tests must be conducted. For example, a component part test on Party A's version of a product can be used by Party B in certifying its version of the product. The finished product test on Party B's version of the product can be used by Party A in certifying its version of the product. Party C can use both Party A's component part test results and Party B's finished product test results in certifying its version of the product.

1.4 Issue 3

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

Comment 18: One commenter (4) states that the component part testing rule (16 CFR part 1109) was well-intentioned but will be difficult to use in practice. The commenter states that the rules implementing the CPSIA are so draconian that the cost of missteps will far outweigh the

benefits of component part testing and further asserts that each use of component testing substantially increases the complexity of testing protocols and recordkeeping, as well as the risk that they will not be in compliance with the requirements.

Given what the commenter says was: "the very difficult and challenging requirement to accurately track lots at the component level," the commenter expresses the concern that if a problem was discovered, they would find it difficult to prove that they were in compliance with all of the requirements of the rule.

For this reason, the commenter states that the choice to rely on the less expensive component part tests could prove to be shortsighted, and suggests that it might be better for companies to pay higher costs now for better assurance of more orderly paperwork. The commenter suggests that there is a low probability that the records would be helpful in the event of a safety problem or that the cost of maintaining such voluminous records would be worth the cost if such a problem were to occur.

The commenter states that he feels that the CPSC's recent testing and certification rules make these types of testing decisions risky for a company. The commenter expresses concern that the recordkeeping requirements will subject them to second-guessing by the CPSC. The commenter complains that the rules are complicated and hard to follow. The commenter wants a simple rule that can be explained to his staff.

Response 18: The component part testing rule was established to provide manufacturers with additional options for certifying their children's and non-children's products. For many manufacturers, the component part testing rule will reduce their overall third party testing burden. However, the CPSC acknowledges that the component testing rule may not be advantageous to all manufacturers. The voluntary nature of the rule allows manufacturers the ability to use component part testing when it is to their advantage to do so.

The component part testing rule does have recordkeeping requirements, but the requirements are almost identical to the information required by the testing and labeling rule (16 CFR part 1107). Most of the required information can be found on a testing laboratory test report. However, the component part testing rule has one additional requirement, traceability. Traceability means that a certifier needs to keep track of the party who procured testing on the component parts and the party who conducted the testing.

CPSC staff believes that the recordkeeping requirements match the types of records that are routinely created when products are tested, even if the CPSC did not require the records for the rule. These records are necessary because if a noncompliant component part creates a safety hazard, the CPSC's ability to determine how the noncompliant component parts were allowed into commerce, the extent of the safety hazard, and what steps need to be taken to address the hazard and prevent its reoccurrence, in part, depend upon the component part's traceability.

The records also ensure that the CPSC can determine whether there was compliance with the testing and labeling rules should violative product be found. Although some manufacturers might find that the burden of the paperwork exceeds the potential reduction in the cost of testing

provided by component part testing, CPSC staff reviewed each recordkeeping requirement in 16 CFR part 1109, and did not identify a way to reduce the paperwork requirements and still ensure that the components are traceable and without affecting adversely its ability to ensure that manufacturers have complied with the rule.

Comment 19: A commenter (14) agrees with the spirit of the issue that product component parts or materials that are the same or substantially similar with respect to compliance with CPSC standards, like those for lead or phthalates, should not have to be tested redundantly.

Response 19: The intent of component part testing was to allow one set of testing results for a lot or batch of component parts, to be available for use by any party wishing to use those component parts in a children's product without repeated testing. Component part testing and certification can be performed at the level in the product supply chain where it is most economical to all parties. As long as due care is taken to avoid contamination, test results regarding lead or phthalate content of all the component parts in a lot or batch remain valid.

Comment 20: A commenter (16) suggests that the CPSC establish that finished product producers may rely on supplier assurances of compliance so long as the finished product producer has exercised due care to assure that the final children's product meets the standards for lead and phthalates for component parts made of plastic resins. The manufacturer might then need to attest that they have not knowingly altered the manufacturing environment in a way that introduces lead or phthalates or that might result in contamination of the materials used.

Response 20: Unless supplier assurances include third party testing results or component part certificates from a CPSC-accepted testing laboratory, those assurances are not sufficient for children's product certification purposes. Section 14(a)(2) of the CPSA requires that children's products be tested for compliance to the applicable children's product safety rules by a CPSC-accepted testing laboratory. Supplier assurances that are based on first party testing, a declaration of conformity, or testing at a non-CPSC-accepted testing laboratory would not ensure compliance because these means may not include measures to ensure the testing results' objectivity and protection from undue influence of a CPSC-accepted testing laboratory.

The component part testing rule, 16 CFR part 1109, requires that once a batch or lot of material or component parts has been tested for compliance, due care must be exercised to avoid contamination for the testing results to remain valid. Due care does not include willful ignorance.

Comment 21: A commenter (19) supports component part testing but states that to maximize the efficiency of the rule, the CPSC ought to consider whether the traceability requirements applicable to component certification are necessary to assure compliance.

Response 21: Staff considered whether the traceability requirement in 16 CFR part 1109 is necessary to ensure compliance. After consideration, staff does not recommend a change to the rule. The concept of traceability arises out of section 14(g)(1) of the CPSA, *Requirements for Certificates*.

Moreover, the Commission already relaxed the concept of traceability in the final component part rule, from traceability to the product manufacturer, to mean that the certifier had to be able to trace a product to the parties who procured the testing and conducted the tests. This type of traceability is essentially setting a floor for due care. Certifiers should know who had the product tested and who conducted the testing, at minimum, before relying on a test report or certificate. This information is likely contained in the test report. Requiring such minimal traceability will yield basic information to the CPSC if noncompliant products are found. This information might provide the CPSC, and any finished product certifier, additional information to help determine where, in the testing and certification process, errors occurred that allowed the certification of noncomplying products. Without that ability, the CPSC may not be able to address those errors and prevent additional noncompliant products from being introduced into commerce.

Comment 22: A commenter (22) points out that component part testing is inadequate for certain hazards, such as use and abuse tests of toys and fire and electrical shock hazards. The commenter states that the ultimate assessments of product compliance are performed best by an accredited, third party certification testing body.

Response 22: In the rule regarding testing of component parts, 16 CFR §1109.5(c) states:

> *Limitation*. A certifier must not use tests of a component part of a consumer product for any rule, ban, standard, or regulation that requires testing the finished product to assess compliance with that rule, ban, standard, or regulation.

Component part testing is likely to be most useful for chemical content tests, such as lead and phthalates. We agree with the commenter that, for some applicable product safety rules, the finished product is required to evaluate compliance. In addition to the examples listed by the commenter, the determination of whether a component part is accessible requires the evaluation of the finished product incorporating the component part.

Regarding which body is best for performing the ultimate assessments of product compliance, this RFC addresses reducing the burden of third party testing consistent with assuring compliance to the applicable children's product safety rules. The commenter does not explain how accredited third party certification body testing would accomplish testing burden reduction consistent with assuring compliance. Thus, we are unable to respond to this portion of the comment.

Comment 23: A commenter (7) states that the manufacturer, working together with the factory, should determine representative sampling of products with a substantial number of different components, based on knowledge of the products, the applicable product safety standard, and the manufacturing processes that go into making the products.

Response 23: We agree with the commenter that the factors mentioned above should be considered when selecting samples for periodic testing purposes. The proposed rule on representative sampling states that the method used for selecting representative samples must be

one that provides a basis for inferring the compliance of the untested production units from the test results of the tested samples. The manufacturer or importer of a children's product subject to a children's product safety rule, retains the responsibility of ensuring that periodic tests are conducted properly. The proposed rule on representative samples allows selection and testing to contracted to another party, but manufacturers still must exercise due care in relying on another party's test reports or certifications.

Comment 24: A commenter (22) suggests that if a product can be proven to be composed of the same material throughout the finished product, then a component could be submitted as a representative sample for composition testing. The commenter adds that traceability would be important because there are ways that raw materials could be contaminated in the assembly.

Response 24: For the chemical tests, material used for component parts may be submitted as a sample of the manufactured component part.

Traceability in the component part testing rule relates to the ability to identify the parties who procured and conducted the testing on the component part. A manufacturer is required to use due care to prevent contamination of tested materials used to fabricate component parts.

Comment 25: A commenter (21) provides an example of a representative sample with a sampling from a construction set of 50 different physical component configurations injection-molded with four different colors of polyvinyl chloride (PVC) resin. The commenter feels that a sample could be considered representative as long as all four colors of material are sampled and compliance with the lead substrate or phthalate limits can be established.

Response 25: We agree with the commenter that component part testing for chemical content can be employed in this manner. Using the method the commenter describes, all component parts manufactured with the four resins would have chemical composition test results associated with them, regardless of their final molded configuration. In this case, the resins can be considered component parts of the molded components. The commenter can use composite testing of the four resins per the method described in 16 CFR § 1109.21 or they can test each resin individually.

However, testing the resins does not infer compliance for any mechanical test associated with the component parts. Mechanical test compliance is dependent upon material and shape, such as the test to determine if small parts are generated during normal use and abuse.

1.5 Issue 4

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

Comment 26: One commenter (4) states that he would like the right to use test reports on one item to apply to others if he reasonably believes the test results would be the same for multiple items. According to the commenter, this is an assessment that he successfully has made for years. The commenter states that his company creates "kit" items with identical components but different piece counts. The commenter believes that such items should be allowed to use the

same test report based on the company's "business judgment." Similarly, for a "kit" that includes additional components, but is otherwise identical to other items already tested, the commenter believes that he should be able to use the underlying test report for the tested items, plus tests of the additional or different components.

Response 26: The component part testing rule already allows a manufacturer to do what the commenter is recommending. However, the ability to rely on component part test reports is not based on a "reasonable belief" that the test results are the same. Rather, a manufacturer can rely on test reports for products that are identical in all material respects. For instance, if a manufacturer were assembling different "kits" using various component parts that have already been tested or certified by a component part supplier, the component part testing rule allows for any assortment of those components to be combined and a children's product certificate to be issued based on the test results or certification from a component part supplier. For some applicable product safety rules, the finished product is required to evaluate compliance. If some combination of component parts affects compliance to a rule, that combination requires its own evaluation at the finished product level.

Comment 27: One commenter (22) provides information on follow-up inspections for its certification program, and suggests that the CPSC could adopt a similar post-market surveillance program to review products, testing of samples, and sample selection methods, to ensure compliance with the CPSC's testing and labeling pertaining to certification rules. The commenter states that many third party certification bodies routinely engage in random sampling of products in the market bearing their certification mark to verify that these products still comply with relevant standards and regulations. The commenter further explains that in their program, follow-up services "help to supplement pre-market representative sampling to promote the integrity of product certification and verification of product safety."

Response 27: CPSC staff is unsure how monitoring the marketplace for product compliance would lower third party testing costs or burdens. However, the CPSC already has a number of programs in place to monitor products both at import and available for retail sale. Considering the vast amount of merchandise entering into the marketplace, there is no way that the CPSC can monitor each and every product available for sale to consumers. It is the obligation of the domestic manufacturer or importer to ensure that their products are compliant with all applicable product safety rules. CPSC monitoring is not a substitute for due care by a manufacturer or importer.

Additionally, by the time the CPSC discovers a noncompliant product, it has already entered into commerce. The goal of section 14 of the CPSA is to prevent noncompliant products from entering into commerce in the first instance, rather than removing noncompliant products from the marketplace. Recalls are not as effective a tool as proactive and preventative efforts are in preventing noncompliant products from entering commerce.

Comment 28: One commenter (7) states that manufacturers, working together with the factory, should determine what constitutes a representative sample of a substantial number of substantially similar products based on knowledge of the products, the applicable product safety standard, and the manufacturing processes that go into making the products. The commenter

believes that knowledge from first party testing and/or second party testing can be used to develop sampling plans for third party testing that reduces the overall test burden, while still allowing the compliance of untested products to be inferred from the products tested by the third party conformity assessment body.

Response 28: We interpret "first party testing" as used by the commenter to mean testing conducted by the manufacturer, and "second party testing" to be testing conducted by a retailer to whom a manufacturer sells children's products. We agree with the commenter that product knowledge, the applicable children's product safety rules, and the manufacturing process, combined with first or second party testing, can be used to determine the procedure for selecting product samples for periodic testing. The combination of the factors listed above can be used to infer the compliance of the untested production units from the samples tested by a CPSC-accepted testing laboratory.

Comment 29: One commenter (19) states that changing the "random" sampling requirement to "representative sampling" will reduce the testing burden because, for some manufacturers, particularly suppliers of raw materials or components, or manufacturers of simple products, substantially similar products may be representative of the whole body of product to be certified.

Response 29: Public Law 112-28 amended the requirement in section 14(i)(2)(b)(ii) of the CPSA from the testing of "random samples" to "representative samples." This comment is addressed in the proposed rule interpreting representative samples.

Comment 30: A commenter (20) states that as long as representative materials or components used in finished production can be sampled, such a process should be maintained as suitable for determining compliance with the lead in paint, lead in substrate, and phthalate limits for toys and other child care articles. The commenter opines that Congress clearly recognized the advantage of permissive use of "representative sampling" for the purpose of certifying compliance for like materials and components to these requirements.

Response 30: The commenter is describing a form of component part testing used to meet the requirements of periodic testing. This practice is permitted, as described in 16 CFR part 1109. Component part testing is not allowed for tests that require a finished product to conduct.

1.6 Issue 5

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].

Comment 31: Several commenters (2, 4, 5, 7, 8, 10, 14, 19, 21, and 22) suggest that the CPSC recognize conformance to an international standard as evidence of conformity to the CPSC's regulations. The most frequently mentioned international standard, European toy standard EN71, was recommended (by commenters 2, 4, 8, and 21) as evidence of conformity to the CPSIA.

Another commenter (8) specifically mentions that if EN71-3 is updated, it could substitute for the lead portion of the CPSIA. Another commenter (5) states that ISO 8124, IEC 62115, part

of GB 6675-2003, and GB 19865-2006, are identical to ASTM-F963. Other international standards the commenters mention and suggest that the CPSC should approve are items specified in ISO 8124 part 3, EN71 part 3 and section 4.3 of GB 6675-2003 because they are identical to section 4.3.5.2 of ASTM F963-08. Another commenter (2) states that the sound pressure level of close-to-the-ear toys of EN71 is measured at a distance 2.5 cm, while the measurement in ASTM F963 is measured at a distance of 50 cm. The commenter suggests that a simple calculation be used to allow testing with either method to satisfy the testing requirements of either standard. The commenter also states that the use and abuse tests in ASTM F963, ISO 8124-1, and EN71-1 require a force application; the commenter suggests that the tests be harmonized with the most onerous standard.

Response 31: We agree with the commenters that many international standards contain tests that are identical or similar to tests required by the CPSC, and that compliance to such standard might indicate compliance to a test in a CPSC-administered children's product safety rule. Results for those tests, when conducted by a CPSC-accepted testing laboratory, could then be used to establish finished product or component part compliance for children's product certification purposes.

Staff recommends that the Commission consider creating and maintaining a list of equivalent tests in other national or international standards, conformity to which would be indicative of conformity to the corresponding test in a CPSC-administered children's product safety rule. This equivalency might reduce redundant testing, and it also could lead to lower third party testing costs. Harmonized or equivalent tests must be conducted by a CPSC-accepted testing laboratory in order to be used for children's product certification purposes.

Comment 32: One commenter (2) suggests that the rule defining a "small batch manufacturer" should apply to the U.S.-based importer (manufacturer of record) or the foreign physical manufacturer, but not both. The commenter states that this would allow access in the United States to toys and children's products that have already been tested for their safety.

Response 32: The term "small batch manufacturer," when applied to imported products, has been interpreted to include both the foreign manufacturer and the importer.

Comment 33: One commenter (2) suggests that we "allow second tier international small batch manufacturers to certify to CPSIA based on evidence from existing tests to sufficiently similar safety standards."

Response 33: The commenter defines "second tier international small batch manufacturers" as international manufacturers with small production volumes of children's products, but sales of between $5 million and $50 million. Section 14(i)(4)(E)(ii) of the CPSA defines a "small batch manufacturer" as: "a manufacturer that had less than $1 million in total gross revenue from sales of all consumer products in the previous calendar year." However, "second tier international small batch manufacturers" are firms with sales above $1million in total gross revenue, and are required to conduct third party certification testing for their children's products, regardless of the products' production volumes.

The current CPSC test procedures for lead and phthalates list numerous methods that may be used to assess compliance with sections 101 and 108 of the CPSIA.[10] Some of these methods are used in other testing procedures, such as ones used by the U.S. Environmental Protection Agency and Health Canada. If the commenter's phrase "sufficiently similar standards" refers to other standards that use lead and phthalate testing methods, and the existing methods in the "sufficiently similar" standards are included in the CPSC test procedures, then the results of those tests (when conducted by a CPSC-accepted testing laboratory) may be used as a basis for issuing a CPC. In response to several commenters' requests, staff is recommending that the Commission consider creating and maintaining a list of equivalent tests, conformity to which would be indicative of conformity to the corresponding test in a CPSC-administered children's product safety rule.

Comment 34: One commenter (19) suggests that the CPSC participate in the cross-functional regulatory discussion with Canada in the Regulatory Cooperation Council and the Beyond the Border working group. Another commenter (22) suggests that the CPSC also participate in the US-Canada Regulatory Cooperation Council, as well as the High-Level US – EU Regulatory Cooperation Forum, and the US-Mexico High Level Cooperation Regulatory Council. The commenter also suggests that the CPSC support the goals and standards of the Trans-Pacific Partnership Agreement negotiations.

Response 34: The CPSC participates regularly in international coordination of product safety requirements and participates in the North American and U.S.-EC fora, as appropriate.

Comment 35: One commenter (13) states that art materials intended for children are subject to the Federal Hazardous Substances Act (FHSA), the Labeling of Hazardous Art Materials Act (LHAMA), ASTM D-4236, *Standard Practice for Labeling Art Materials for Chronic Health Hazards*, and the CPSIA. The commenter states that the CPSIA-required testing is redundant to the testing conducted for compliance with the FHSA, LHAMA, and ASTM-D-4236.

Response 35: CPSC staff disagrees that compliance with LHAMA is redundant to the requirements of the CPSIA for third party testing and certification of children's products. 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 reviewed. However, section 14 of the CPSA has additional third party testing requirements, beyond what is required under LHAMA, which involves no testing; so certification of art materials under LHAMA is not equivalent to third party testing pursuant to section 14 of the CPSA. The CPSA requires testing by a CPSC-accepted testing laboratory, and the manufacturer or importer must issue a CPC based on those test results. There is no "test" conducted with LHAMA, and therefore, no CPC can be issued based on compliance with LHAMA.

[10] The lead in children's metal products test procedure can be found at: http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_1.pdf. The lead in non-metal products test procedure can be found at: http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_1.pdf. The phthalates content test procedure can be found at: http://www.cpsc.gov/about/cpsia/CPSC-CH-C1001-09.3.pdf.

We further 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. 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 testing laboratory to demonstrate compliance to the lead and phthalate requirements, but they would not require third party testing and certification to the LHAMA requirements.

Comment 36: Some commenters felt that many of the requirements of the CPSIA are duplicative of existing CPSC standards. Two commenters (20 and 21) stated that under the Flammable Fabrics Act (16 CFR § 1608.3), continuing guaranties are permitted and can be relied upon. The commenter felt that additional requirements for testing and certification are redundant.

Response 36: Prior to the enactment of the CPSIA, guaranties issued under the Flammable Fabrics Act (FFA) were provided to certify that a textile, or the apparel made from a textile, met the requirements of the standards. The FFA does not require that the testing to support a guaranty be performed by a third party accredited testing laboratory. The CPSIA imposed new third party testing obligations on manufacturers of children's products. Section 14(a)(2) of the CPSA, as amended by the CPSIA, requires that a 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 a third party test conducted by a CPSC-accepted laboratory. Accordingly, textiles that are designed or intended primarily for children 12 years of age or younger are subject to the third party testing and certification requirement in section 14(a)(2) of the CPSA, as well as the continuing third party testing requirements in section 14(i)(2)(B)(i) of the CPSA.

The commenter implies that once a manufacturer guaranties a product, further testing is redundant, based on the fact that the product has been tested for guaranty purposes. However, guaranties under 16 CFR § 1608.3 cannot be used as a substitute for the continuing testing requirements in section 14(i)(2)(B)(i) of the CPSA, because they do not require periodic and material change testing conducted by a CPSC-accepted testing laboratory.

Experience gained from years of testing in accordance with 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*, (1610 standard) demonstrates that certain fabrics consistently yield acceptable results when tested in accordance with the 1610 standard. This experience with certain fabrics allowed an exemption from testing in the 1610 standard for the purpose of issuing guaranties. Currently, the Commission does not require third party testing to demonstrate that a product meets a specific exemption, as described in § 1610.1(d)(1) and § 1610.1(d)(2) of the standard. *See* 75 FR 51016, 51017 (Aug. 18, 2010) ("Manufacturers do not need to submit exempt clothing textiles designed or intended primary for children 12 years of age or younger to a third party conformity assessment body to confirm that the exemption applies.") Therefore, many clothing and textile fabrics intended for use in children's wearing apparel (excluding children's sleepwear) will not require third party testing under section 14 of the CPSA. If the apparel or fabric meets one of the standard's exemptions from testing, and has not undergone any aftermarket treatment that might alter its flammability characteristics, a

manufacturer can list the exemption in the testing section of a component part or finished product certificate.

Because children's products and nonchildren's products now have different testing requirements, the guaranty provisions under the FFA should be considered separately from the CPSC requirements under Section 14 of the CPSA. A manufacturer is not required to issue a guaranty on either the fabric they manufacture or the garments they sell. However, if a manufacturer does issue guaranties, and they conduct third party testing using a CPSC-accepted testing laboratory to support the guaranty, or rely on the exemptions listed at 16 CFR § 1610.1(d), the manufacturer, and any subsequent certifier, may rely on such testing to support the CPC. Manufacturers of children's products must still meet the continuing testing requirements of section 14(i)(2)(B)(i) of the CPSA, or rely on an exemption. The 1610 standard gives guidance on what is considered reasonable and representative testing for the purpose of issuing guaranties. The regulation at 16 CFR part 1608, *General Rules and Regulations under the Flammable Fabrics Act,* § 1608.3, *Continuing Guaranties,* provides instructions for filing a continuing guaranty under Section 8 of the FFA.

Comment 37: Some commenters (20, 21) applaud the CPSC for recognizing GB/T 22048-2008, *Toys and Children's Products-Determination of Phthalate Plasticizers in Polyvinyl/Chloride Plastic*, as a valid test procedure for determining phthalate content, and they suggest that the CPSC consider Health Canada's test method for total phthalate content in PVC products.

Response 37: Health Canada's test method for total phthalate content in PVC products is Health Canada method C-34. The Commission already allows use of this method in CPSC test method CPSC-CH-C1001-09.3, *Standard Operating Procedure for Determination of Phthalates*.

Comment 38: One commenter (20) states that the CPSC should promote uniform test methods, labeling, and standards for juvenile products, wherever practicable and possible, as part of its standard-setting and enforcement policies.

Response 38: The CPSC is supportive of efforts to align and harmonize national and international standards, and it participates in such efforts, as appropriate. Enforcement actions are at the discretion of each country involved.

Comment 39: One commenter (3) asks that "if a (sic) approved or acceptable MSDS is applicable to toys we as a group make including any glue or finish why is it necessary to continue with the expense of a third party testing function."

Response 39: Third party testing is required to ensure compliance with applicable children's product safety rules because Congress has mandated this result in section 14(a)(2) of the CPSA. A Material Safety Data Sheet (MSDS) is generally a document that gives information about the nature of a chemical product, such as physical and chemical properties, health, safety, fire, and environmental hazards. An MSDS might not be based on third party testing, and it is not indicative of compliance with sections 101 or 108 (lead and phthalates content, respectively) of the CPSIA. A material, such as a glue or finish, may contain lead or restricted phthalates in excess of their limits and not have that indicated on its MSDS. For these reasons, an MSDS is

not acceptable as a substitute for third party tests conducted by a CPSC-accepted testing laboratory.

Comment 40: One commenter (7) states that toys that are qualified for other countries' safety marks, such as CE (Europe), ST (Japan), or CCC (China) that are supported by third party testing should be recognized by the CPSC as conforming. The commenter suggests that the CPSC work with other countries or regions to harmonize regulations, standards, and test methods.

Response 40: With regard to toys with safety marks from other countries, to the extent that other countries' toy safety requirements are identical or substantially similar to the requirements of ASTM F963's requirements, it is possible that test results from a CPSC-accepted testing laboratory showing compliance to those tests can be used as a basis for issuing a CPC. However, safety marks generally do not contain all of the information that is required to be on the children's product certificate, which is mandated in the CPSA. Therefore, safety marks themselves are not a substitute for certificates. Certificates are required to accompany products or shipments of products pursuant to section 14(g)(3) of the CPSA. Unlike safety marks that are intended to convey basic compliance to consumers, certificates contain additional information on testing and the responsible certifying party that aid CPSC should a noncompliant product be found. As noted in the response to Comment 31, the Commission should consider establishing a project to compile and maintain a list of tests in international standards for which passing test results can indicate compliance with a test in a CPSC-administered children's product safety rule. Results for those tests, when conducted by a CPSC-accepted testing laboratory, could then be used to establish compliance for children's product certification purposes.

Comment 41: One commenter (22) suggests that the conformity assessment bodies should have adequate control over their certification mark and have processes in place to prevent the use of unauthorized or counterfeit marks.

Response 41: While we agree that conformity assessment bodies should have adequate control over their certification mark, section 14(g) of the CPSA, *Requirements for Certificates*, specifies the information that must be on a CPC. Certification marks do not contain that information and cannot be used in place of a CPC. As such, a certification mark, whether counterfeit or not, cannot indicate compliance to a CPSC-administered children's product safety rule.

Comment 42: One commenter (13) suggests that the Art & Creative Materials Institute, Inc. (ACMI) Certification Program melds the requirements of the LHAMA/ASTM D-4236, the FHSA, and the CPSIA. The commenter opines that the ACMI Certification Program meets all of the requirements of the CPSIA, except the requirements for a tracking label and a certificate of conformity (COC) and that the CPSC should recognize the value of the ACMI Certification Program.

Response 42: With regard to the ACMI certification program, this program certifies that products conform to ASTM D4236. This certification program does not require third party testing at a CPSC-accepted testing laboratory for lead (and phthalates for children's toys and

child care articles). Thus, the ACMI certification program does not meet the requirements of sections 14(a)(2) or 14(i)(2)(B)(i) of the CPSA with respect to certification, periodic, and material change testing of children's products.

Comment 43: One commenter (22) suggests that, in order to ensure that a testing laboratory is not subjected to undue influence, that the CPSC adopt an oversight program, similar to that instituted by OSHA for the NRTL program. Additionally, the commenter suggests that the laboratory have ISO/IEC 17025:2005 accreditations for the specific tests it conducts and that the laboratory provide to the CPSC a declaration of its fulfillment of ISO/IEC 17025:2005 4.1.5b and ISO/IEC 17025:2005 4.1.5d (provisions regarding undue influence).

The commenter (22) also suggests that the International Electrotechnical Committee for Conformity Testing to Standards for Electrical Equipment Certification Body (IECEE CB) Scheme, a worldwide system for conformity testing and certification of electrotechnical equipment and components, could also serve as a model program for the CPSC to follow. This scheme has standards harmonization, verified technical competence, and accreditation. It also allows for a testing laboratory that is free from undue influence.

Response 43: We believe that the suggestion to establish an oversight program would be redundant to activities carried out by the testing laboratory's accreditation body. OSHA acts as an accreditation body for the NRTL laboratories. The CPSC has designated testing laboratory accreditation to ILAC-MRA signatory accreditation bodies.

Section 4.1.5(b) of ISO/IEC 17025:2005 states that laboratories shall:

> . . . 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;

Section 4.1.5(d) of ISO/IEC 17025:2005 states that laboratories shall:

> . . . have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;

It is the role of the testing laboratory's accreditation body to evaluate whether the testing laboratory satisfies the requirements of ISO/IEC 17025:2005, including the mandates regarding undue influence. It would be duplicative for the CPSC to perform the same evaluation. Accreditation bodies have the expertise to evaluate testing laboratories to all provisions of ISO/IEC 17025:2005, including § 4.1.5(b), and 4.1.5d.

With regard to the suggestion that a testing laboratory have accreditations for the specific tests it conducts, this is currently required. When an applicant testing laboratory submits a CPSC Form 223 for CPSC-acceptance of its accreditation, its accreditation must include the scope of the tests for which it is requesting acceptance.

The IECEE CB Scheme is a multilateral agreement to allow international certification of electrical and electronic products so that a single certification allows worldwide market access. Because national standards are harmonized, passing test results from a testing laboratory can be used in any nation whose standard is part of the harmonization. As noted above, for children's product safety rule tests with substantially similar tests in other standards, the Commission could determine which tests in other standards demonstrate compliance to a test in a CPSC-administered children's product safety rule for passing test results.

Comment 44: A commenter (5) cites articles 2.2 and 6.1 of WTO/TBT agreements that say that regulations should not be applied that create unnecessary obstacles and that differing conformity assessment procedures should be accepted, as long as they provide an assurance of conformity with technical regulations or standard equivalents. Specifically, testing bodies accredited in accordance with ISO/IEC 17025:2005 should be accepted by the CPSC.

Response 44: Section 2.2 of *Agreement on Technical Barriers to Trade*, states, in part:

> Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.

Section 6.1 states, in part:

> Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.

The CPSC mission is one of protecting human health and safety. Our regulations regarding the testing and certification of children's products are intended to fulfill that mission. We regard that as a legitimate objective in harmony with Section 2.2 of *Agreement on Technical Barriers to Trade*.

The CPSC has designated signatories to the ILAC-MRA as accreditation bodies for testing laboratories whose test results are to be used as a basis for issuing a CPC. Using every other body to accredit testing laboratories to ISO/IEC 17025:2005 could introduce difficulties in meeting CPSC objectives regarding accreditation. These objectives include using an accrediting entity that is established and has acceptance on a multinational level. The accrediting entity should follow internationally recognized standards for assessing the competence of testing

laboratories and for the processes and standards used by accreditation bodies that evaluate such testing laboratories. Further, CPSC originally wanted to avoid designation to accreditation programs or entities that are recognized only in a specific region, nation, or locality. The reasons for this objective include maintaining a degree of consistency in the procedures used by the designated accreditation bodies.

However, CPSC staff recommends to the Commission that it consider initiating a project to explore whether the Commission's objectives can be maintained with accreditation bodies other than ILAC-MRA signatories. Accepting the accreditation of testing laboratories whose accreditation bodies are not ILAC-MRA signatories, may increase the number of available third party conformity assessment bodies, which, in turn, might reduce a manufacturer's administrative or testing costs.

Other accreditation consortiums exist, whose membership is international in nature, and whose members adhere to the requirements of ISO/IEC 17011:2004, *Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies*. For example, the Commission could establish uniform criteria for accreditation bodies and use such criteria to evaluate and designate other entities as accreditation organizations.

Finally, as noted elsewhere in this document, staff has recommended that the Commission determine whether passing tests results from tests in other standards can be used to satisfy compliance to a CPSC-administered children's product safety rule.. This action would comport with section 6.1 of *Agreement on Technical Barriers to Trade*.

Comment 45: A commenter (22) recommends that where third party product safety certification programs exist and are relied upon by other federal agencies, that CPSC should accept them as satisfying the certificate of conformity requirements. Any third party product certification scheme that incorporates testing, certification, factory inspection, market surveillance, and corrective action, and that complies with ISO/IEC guides would provide a high level of safety compliance. While the CPSC does not require mandatory third party product safety certification programs, the CPSC could recognize manufacturers who adopt voluntarily the additional rigor of such an established certification scheme. The CPSC should allow products that are certified under a particular program by a CPSC-recognized certification body to be exempt from requirements under the CPSC program. This could provide savings by avoiding participation in redundant programs.

Response 45: The commenter is referring to certification programs that generally follow the international standard ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*. This standard is due to be replaced in 2012, by the standard ISO/IEC 17065, *Conformity assessment -- Requirements for bodies certifying products, processes and services*. Generally, this certification program involves product compliance testing, plus other activities intended to ensure continued compliance during continuing production. Similar to testing laboratories accredited to ISO/IEC 17025:2005, certification bodies complying with ISO/IEC Guide 65:1996 contain provisions to ensure technical competency and protections against undue influence.

Staff recommends that the Commission consider whether certification bodies accredited to the upcoming standard ISO/IEC 17065 could have their accreditation accepted for children's product certification purposes. Using certification bodies for the certification and continued compliance of children's products may be a means by which the third party testing burden associated with periodic testing could be reduced.

Participation in such a certification program would not be redundant with the testing and product certification requirements of the CPSA and the CPSIA. A certification mark from a certification body cannot fulfill the requirements established by section 14(g) of the CPSA. However, the third party testing results (if conducted by a CPSC-accepted testing laboratory) could be used as a basis for issuing CPCs. The additional activities certification bodies undertake could be considered part of a production testing plan, as described in 16 CFR part 1107, and could be used to increase the maximum periodic testing interval from one to two years. Periodic testing could be integrated into the certification body's program for the manufacturer.

Comment 46: A commenter (22) states that, when determining whether the standards of other federal or international agencies can be leveraged, the CPSC should consider not only alignment of the standards, but also whether the processes for demonstrating compliance are equivalent. The commenter adds that, in the absence of aligned standards and compliance protocols, accreditation and national treatment for foreign testing laboratories from those countries with reciprocity provisions is the optimum approach to third party testing. The commenter says that these arrangements provide a level playing field for all manufacturers and conformity assessment providers without compromising the program's integrity.

Response 46: As noted above, we recommend that the Commission consider establishing a project to compare potentially similar tests for assurance of compliance. A list could be established, documenting tests for which passing test results indicate compliance to a test in a children's product safety rule. This has the potential of avoiding redundancy and potentially lowering third party testing costs. We agree with the commenter's assertion that processes for demonstrating compliance are important. That is one reason the Commission has required testing laboratories to be accredited to ISO/IEC 17025:2005 by a signatory to the ILAC-MRA as a means of establishing a common basis for testing and certification activities.

If test methods in other standards are found to be equivalent in assuring compliance to an applicable children's product safety rule, sections 14(a)(2) and 14(i) of the CPSA still require third party testing by a CPSC-accepted testing laboratory. Further, the scope of the testing laboratory's accreditation must include the equivalent tests. Reciprocity, in this context, means that if the CPSC accepts the accreditation of foreign testing laboratories to test consumer products for compliance to the requirements of section 14 of the CPSA, the host country of the foreign testing laboratory must provide similar treatment to U.S.-based testing laboratories. The commenter does not describe how or why having reciprocal testing-body recognition is necessary to implement section 14 of the CPSA. We use accreditation by an ILAC-MRA signatory accreditation body to an international standard, ISO/IEC 17025:2005, and additional information provided by the applicant laboratory, to determine whether to accept their accreditation. Staff does not believe that reciprocity provisions are needed because any testing

laboratory in any nation could become accredited to ISO/IEC 17025:2005 for the scope of their test methods and apply for CPSC acceptance of that accreditation.

1.7 Issue 6

The extent to which technology, other than technology already approved by the Commission, exists for third party conformity assessment bodies to test or screen for testing consumer products subject to a third party testing requirement.

Comment 47: One commenter (4) states that no alternative technology is available that would provide the same level of assurance of compliance and reproducibility to substitute for third party testing. The commenter is aware of some screening technologies that were good for screening, but not assurance of compliance.

Response 47: The CPSC continues to evaluate technology developments relating to the testing of children's products on an ongoing basis. For example, X-ray fluorescence spectrometry (XRF) may be used to determine the lead content of homogeneous plastics, in place of ICP-MS. One form of XRF is Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams (EDXRF-MMEB). This XRF technology is referenced in the testing method ASTM F2853-10e1,[11] and is acceptable for determining the lead content of paint and other surface coatings for children's product certification purposes. When referred to, in general, XRF includes EDXRF-MMEB.

XRF has been approved by the Commission to measure lead content in homogeneous polymeric and plastic materials since 2009. The Commission has proposed using XRF to test the lead content of homogeneous glass materials, crystals, and metals. For those metals, the XRF measurement has a relatively wide uncertainty; so if the XRF measurement was sufficiently below 100 ppm, XRF could be used to indicate that the sample meets the established standard. XRF used in that manner by a third party testing laboratory could be described as a form of screening that would indicate compliance with section 101 of the CPSIA. These uses can be employed for children's product certification to the lead content limits.

Comment 48: One commenter (4) considers XRF devices to be too expensive and too fragile to merit daily use in his company's facility. The commenter is also concerned about health risks to his employees because "XRF guns are portable x-ray machines."

Response 48: The CPSC has allowed the use of XRF technology to measure lead content in homogeneous plastics since 2009. Other manufacturers and retailers have successfully integrated XRF testing into their production and screening processes as a means of ensuring that their products are compliant with the lead content requirement. Handheld XRF devices do emit x-ray radiation in a small area, and like many other testing methods, they require proper operator training and safety considerations. Manufacturers of handheld XRF devices provide shielding and training on proper operation and recommend the use of radiation monitoring badges. Additionally, many states regulate the use of these devices.

[11] *Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogeneous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams*.

Comment 49: One commenter (22) states that they are not aware of any technology in the marketplace not already approved by the CPSC that would allow for third party conformity assessment bodies to test or screen consumer products and certify to testing requirements.

However, two commenters (20 and 21) state that many manufacturers have invested significant resources into alternative testing technologies like XRF, which many have found to be a helpful screening tool for lead content. While the commenters consider XRF "not perfect," many have incorporated it into their quality control programs. The commenters ask the CPSC to continue to look at alternative testing technology and update the test standards, as appropriate. The commenters assert that the use of nondestructive testing techniques is much more preferable because they are generally more cost effective than wet chemistry methods.

Another commenter (22) encourages the CPSC to continue to evaluate new technologies for their technological competency, and to assess the cost of testing at an accredited third party testing laboratory, just as the Commission did in approving the XRF technology test methods described in ASTM F 2853-10 for conforming with the requirements of 16 CFR 1303, *Ban of Lead-containing Paint and Certain Consumer Products bearing Lead-containing Paint*.

Response 49: Recent developments in technology, such as EDXRF-MMEB, have demonstrated the ability to measure lead in paint sufficient for children's product certification testing. The Commission has proposed the use of XRF technology to determine the lead content of homogeneous glass materials, crystals, and metals.

The use of Fourier Transform Infrared Spectroscopy (FTIR), Raman Spectroscopy, and Direct Analysis Real Time Mass Spectrometry (DART-MS) currently are being evaluated as potential screening techniques for phthalate content.

The CPSC continues to evaluate technology developments relating to the testing of children's products on an ongoing basis.

Comment 50: One commenter (22) states that once a product is certified by a third party conformity assessment body, screening technology is a valuable tool for manufacturers to assess continued compliance of their product in between the mandated third party testing time periods. The commenter states that screening technologies may also play an important role in routine quality control for the manufacturers and market surveillance for distributors, retailers, and regulators, but they should not replace third party testing for certification or to prove initial compliance. The commenter thinks that screening technologies are not suitable and are less technically capable than other, more sophisticated testing technologies.

Another commenter (12) states that there are manufacturers of children's products who use EDXRF-MMEB equipment in-house, *i.e.*, for first party screening and verification testing, to augment their third party testing programs. The commenter asserts that these instruments can be used in factories and other locations as effectively as they can be used in laboratory conditions with relatively brief staff orientation and training on how to use EDXRF-MMEB instruments properly. The commenter believes that the use of EDXRF-MMEB equipment employing the ASTM F 2853-10e1 procedure in the context of "production testing plans" under the new CSPC

Testing and Certification Rule, to augment third party certification and periodic testing, is appropriate.

Response 50: We agree with the commenters that first party use of screening technologies may be used to verify continued compliance between periodic testing intervals. If used as part of a production testing plan, as explained in 16 CFR § 1107.21(c), screening technology could be used to increase the maximum periodic testing interval from one to two years, with a corresponding decrease in the third party testing burden. In addition, the Commission allows the use of XRF by third party testing laboratories for certification, material change, and periodic testing of paints and homogeneous plastics. Further, the Commission has proposed using XRF for homogeneous glass materials, crystals, and metals in the NPR for 16 CFR part 1112. Using XRF for lead content measurements is generally less expensive to conduct than Inductively-Coupled Plasma – Mass Spectrometry (ICP-MS), which might lead to reduced testing costs.

Comment 51: One commenter (15), a trade association, states that certifiers should be able to use screening techniques, such as XRF, in lieu of third party testing. The commenter asserts that third party testing does not add a greater level of consumer protection. The commenter states that authorizing first party testing, using techniques such as XRF, could significantly reduce costs. The commenter suggests that the Commission could provide guidance on calibration and other related aspects regarding the use of screening tools.

Response 51: We agree with the commenter that the use of XRF technology represents a significant cost reduction over ICP-MS for suitable samples, where dependable results can be obtained without significant sample preparation. However, third party testing for certification of children's products is required by section 14(a)(2) of the CPSA. Third party testing, in general, provides two benefits over first party testing. First, testing by an accredited testing laboratory ensures that technical competency requirements have been met. Even with guidance provided by the CPSC, first party technical competency cannot be assumed to the same degree. Second, third party testing provides a level of objectivity and resistance to undue influence over the test results. First party testing (other than through the use of a firewalled laboratory) does not provide the same assurance of objectivity. That being said, first party screening techniques, such as XRF, may be used to ensure continued compliance between periodic testing intervals. If used as part of a production testing plan, screening technology may be used to increase the maximum periodic testing interval from one to two years, with a corresponding decrease in the third party testing burden.

Comment 52: One commenter (20) says that an enforcement policy that recognizes screening tools, such as XRF, as evidence of reasonably prudent conduct in verifying compliance, may be beneficial and encourage increased screening.

Response 52: CPSC staff agrees with the commenter that screening methods, such as XRF for lead content may be useful as part of a production test plan. However, first party screening methods cannot be used as a substitute for required certification, material change, or periodic third party testing. It may be possible for testing laboratories to employ relatively less expensive screening technologies as a means of reducing the number of relatively more costly quantitative tests, and thereby, potentially reduce the overall testing burden through lower costs.

Comment 53: One commenter (14) states that the rule allows the use of production testing plans that may include in-house or third party testing or measurement techniques that would not necessarily be sufficient to satisfy the requirements of either certification or periodic testing by a CPSC-accepted testing laboratory. However, the commenter adds that it has been the commenter's (a certification body) experience that, unless one or more methods are specified as being acceptable by the agency, many entities in the supply chain, particularly those overseas, may be reluctant to "take the chance" that they will be viewed by the agency as being inadequate.

The commenter suggests that the CPSC should specify at least the test methods and procedures that are generally considered by the agency to be an adequate means of conducting production testing. As a starting point, the commenter suggests that the CPSC should recognize that all methods considered adequate for conducting third party testing should be recognized as adequate for production testing. In addition, the commenter suggests that the CPSC should develop a list that is not exhaustive of alternative test methods, not formally endorsed by the agency for certification or periodic testing, but that nonetheless, would be considered adequate for production testing. The commenter asserts that the list does not have to be made through rulemaking procedures, but could be made on a policy basis as suggested—but not mandatory—production test methods.

Response 53: Production testing plans are intended to generate information regarding the continued compliance of the children's product being manufactured to the applicable children's product safety rules. 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 continue to comply. Based on that knowledge, manufacturers are uniquely situated to know what measurements to make, what process control variables to control, and what type of QA/QC system is best suited for production testing of their particular products. If a manufacturer wishes to use the test methods and procedures employed by CPSC-accepted testing laboratories to determine compliance to the applicable product safety rules, those methods would be considered acceptable for production testing.

Because any guidance provided by the CPSC must apply to a multitude of product types, guidance on other means to ensure continuing compliance would necessarily be general in nature. Further, 16 CFR § 1107.21(c)(2) lists several processes that could be employed in a production testing plan. Because manufacturers can customize their production testing plans to the specific children's products they certify, staff considers it impractical to develop an admittedly non-exhaustive list of production testing methods.

Comment 54: A commenter (22) states that one way to ensure the competency of screening technologies is to promote the use of traceable Standard Reference Materials (SRMs) for calibration and operation. The commenter states that testing competency and appropriate equipment calibration and technician training should be applied to any testing or screening technologies allowed to determine compliance.

Response 54: The CPSC encourages the use of SRMs (or more generally CRMs – certified reference materials - as SRM is a National Institute of Standards and Technology (NIST)

trademark). SRM/CRM use was encouraged in the recent phthalates testing symposium (presentation available on the CPSC website at: http://www.cpsc.gov/ABOUT/Cpsia/dreyfus03012012.pdf). Staff considers using SRM/CRM good practice. However, suitable SRMs cannot be found for all relevant tests, as discussed in the symposium. Manufacturers employing production testing plans to reduce third party testing burdens consistent with assuring compliance should use recognized good laboratory practice, such as calibrating and checking their instruments and techniques and properly training their personnel. Third party testing laboratory accreditation includes demonstrating technical competence and proper management systems.

Comment 55: One commenter (9) suggests some screening techniques that could "signal something is not quite right with a process" or product. The commenter adds that one simple monitoring method is visual observation by a person trained to detect variations. The commenter states that spectrophotometer for color measurement has proved popular for analytical evaluation of color and quality control for dyed textile and pigment coated material. This is typically measured as the amount of light reflected off a surface of colored substrate. A large amount of contaminant in the pigment may be detected by the reflectance spectral measurement, where it would appear in the shape change of the reflectance curve and shift of the λ max (the wavelength at which the signal is at its peak value).

Response 55: We agree with the commenter that screening techniques can be used during product manufacturing to monitor compliance to an applicable product safety rule. First party screening techniques can be implemented as part of a production testing plan, as explained in 16 CFR § 1107.21(c). Regarding the commenter's specific discussion of evaluating color by spectral measurements, the CPSC has not determined that either lead or phthalate content below the required limits can be assessed by changes in an object's reflectance.

Comment 56: One commenter (9) states that XRF is the preferred method for screening because it is not destructive of the product, and a reading is usually obtained in about 4 to 8 seconds with 95 percent accuracy at the 2-sigma level.

Response 56: We agree with the commenter that XRF technology is nondestructive of the material and can generate readings in a short period for appropriate materials. Sample preparation for ICP-MS or other wet chemical techniques destroys the sample and requires considerably more time to generate a measurement. XRF technology is currently allowed for certification testing of homogeneous plastics (and paint if EDXRF-MMEB is used). The Commission has proposed using XRF technology for certification testing of glass materials, crystals, and some metals. First party testing screening, using XRF technology, can also be integrated into a production testing plan to increase the maximum periodic testing interval.

Comment 57: One commenter (19) states that the CPSC should encourage the development of new testing technologies but should be careful not to mandate through regulation, the use of any specific technology, tools, or test methods in order to allow the marketplace to continue innovation of technologies.

Response 57: CPSC staff agrees with the commenter that the development of new testing technologies could be beneficial in reducing the third party testing burden while ensuring compliance.

When the CPSC specifies a method or methods for a particular test, it is because we have determined that the method(s) possesses the required attributes (*e.g.*, accuracy, precision, repeatability) to determine compliance to the applicable product safety rule. For lead and phthalate content testing, we have specified multiple methods, such as XRF, EDXRF-MMEB, and ICP-MS for lead content that possess the required attributes. The CPSC evaluates technology developments relating to the testing of children's products on an ongoing basis.

Comment 58: One commenter (14) states that the CPSC should formally approve ASTM F 2853-10 for lead substrate testing. This method uses the next generation of XRF technology (EDXRF-MMEB), and is capable of meeting the precision and repeatability specified in 16 CFR part 1303. The commenter asserts that this form of XRF has a number of advantages over traditional ICP-MS testing, including non destruction of samples, speed, and relative cost of testing, the ability to conduct on-site testing, and the ability to measure several areas on a product sample without significant added cost. The commenter states that if EDXRF-MMEB were allowed for substrate testing, it would represent an immediate and significant step toward reducing the cost and time required for third party testing.

Response 58: The test method in ASTM F 2853-10 uses a form of XRF technology (EDXRF-MMEB). This method is allowed to be used to determine lead content in homogeneous plastics. The Commission has proposed using XRF technology, including EDXRF-MMEB, for certification of glass materials, crystals, and some metals in the proposed rule 16 CFR part 1112. 77 FR 31086 (May 24, 2012) The CPSC has not concluded that the ASTM F 2853-10 test method can provide the sufficient accuracy, precision, and repeatability to be used for children's product certification purposes for other materials.

The CPSC continues to evaluate technology developments relating to the testing of children's products.

Comment 59: One commenter (17) recommends allowing third party XRF testing to be used to screen products before requiring far more expensive chemical testing. The commenter states that while XRF technology is improving quickly and becoming more accurate, it is still not capable of being 100 percent reliable for an accurate result. However, it has been shown to be very capable for determining if a product requires further testing. The commenter states the belief that the CPSC has received enough scientific evidence to allow XRF testing to be used as a screening process for further testing. By allowing a third party testing laboratory to accept XRF results for lead under 40 ppm, the CPSC could drastically reduce the cost of third party testing, by reducing the need for further wet chemistry testing, while still maintaining the high degree of assurance of compliance.

Response 59: The CPSC has proposed the use of XRF technology to determine the lead content of homogeneous glass materials, crystals, and metals, as described in the proposed rule

16 CFR part 1112.[12] This technology could also be used for screening by a CPSC-accepted testing laboratory as a means of reducing third party testing burdens, while assuring compliance to the lead content standard. XRF technology is not suitable for measuring the lead content or for use as a screening method for electroplated alloys or glazed ceramics.

If the screening measurement of a suitable, homogeneous material, plus the measurement uncertainty is below 70 ppm, and other testing and calibration requirements are met, then the tested material can be determined to meet the 100 ppm lead content limit. Although the exact concentration of lead in the tested material is not established by this method, compliance to the 100 ppm lead content limit for the purposes of children's product certification has been established.

Comment 60: One commenter (10), a trade organization, remarks that the phthalates test method does not address specifically prints on textiles. The commenter is concerned that different test results may occur due to various sample preparation methods. The commenter proposes a phthalates testing method for prints on textiles or leather.

The commenter further states that a problem that its members are experiencing is variation in the results reported by different laboratories. They found that different laboratories use different calibration points for lead testing and different sample preparation methods for phthalate testing. The commenter proposes two detailed test methods (the methods can be found at: http://www.regulations.gov/#!documentDetail;D=CPSC-2011-0081-0010.) that it believes would minimize the interlaboratory variability, if adopted. Some of the problems experienced by these companies might be related to testing involving apparel or textiles.

Response 60: The commenter suggests specific sample preparation steps for screen-printed fabric as part of the proposed phthalates test method. The recommended phthalates sample preparation steps for screen-printed fabric are acceptable to CPSC staff, with one modification to section 5.2 of the proposed procedure. For the situation of samples for which the print is removed from the substrate by extracting with tetrahydrofuran (THF), staff recommends that the weight of the print sample should be calculated, when possible, by weighing the fabric with print before extraction, and then drying and weighing the fabric after extraction. We consider these more detailed instructions, as modified in this response, to be within the scope of the existing method and to be a good clarification for the special case of screen-printed fabric.

With regard to the two other suggested test procedures, CPSC-accepted testing laboratories are accredited and reassessed to specific test methods by their accreditation bodies. This method

[12] A technical report, *Study on the Applicability of X-ray Fluorescence Spectrometry for Measuring Lead in Metal and Glass Substrate***,** is found in Tab C of the staff briefing package, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, and can be found at: http://www.cpsc.gov/library/foia/foia12/brief/tprequirements.pdf.
The procedure for using XRF technology to screen for lead content in nonmetals is described in the test procedure, *Standard Operating Procedure for Determining Total Lead (Pb) in Nonmetal Children's Products*, and can be found at: http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_2.pdf.
The procedure for using XRF technology to screen for lead content in certain metals is described in the test procedure, *Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)*, and can be found at: http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_2.pdf.

is used to ensure that testing results from these laboratories meet the accuracy, precision, and repeatability requirements necessary to determine a product's compliance to a children's product safety rule. Because there are many sources of testing variation, some of which are external to the test method or laboratory, we are unable to explain reports of interlaboratory variation without an analysis of the data and circumstances associated with those reports.

In regard to the suggested lead test method, the suggested test may work well for some testing laboratories that use the same model instrumentation. However, other CPSC-accepted testing laboratories use different instruments for which different dilutions and concentration ranges may be appropriate. We prefer to leave it up to each testing laboratory to use their own QA/QC programs and their knowledge and understanding of their instruments and analytes, as well as rely on their accreditation bodies to use the instruments that they own in an appropriate manner for the testing suitable for their customers. The suggested calibration is reasonable and within the scope of the existing CPSC test methods, and CPSC staff has no opposition to the commenter's members or other firms working with their testing laboratories to use such procedures, if they choose.

For the phthalates test method, the commenter recommends allowing liquid chromatography mass spectrometry (LCMS) with a given set of conditions for test execution. We welcome the development of an LCMS method and encourage the commenter to work with testing laboratories (such as those that discussed this technology at the "CPSC Symposium: Phthalates Screening and Testing Methods": http://www.cpsc.gov/ABOUT/Cpsia/phthalatestest.html), and preferably through the ASTM process, to develop a method that will work on a variety of different LCMS instruments. The method should include details about how to differentiate between isomers of phthalates where one isomer (such as Dibutyl phthalate) is banned and another (such as Di-isobutyl phthalate) is not banned, but co-elute (do not separate) and have the identical mass, which has shown to be a problem for LCMS technology.

Comment 61: Three commenters (15, 16, and 17) state that the Commission should take into account the variability of testing results that are due to uncertainties intrinsic to the test methods and the standard materials used in calibrating the testing equipment. The commenters recommend adopting formal statistical uncertainty bands for lead content measurements. They state that this would help their costs, both in reducing the cost of third party testing, and reducing the amount of product that one commenter feels must be destroyed because it is slightly over the requirement. One of the commenters states that one of its members sent an identical sample of a soldering alloy to eight different CPSC-accredited labs and the results that they got back ranged from less than 50 ppm to 262 ppm.

One of the commenters (16) suggests that:

> . . . the Commission should issue guidance that addresses statistical uncertainty averaging and margins of error with respect to failing test results. A statement on statistical uncertainty will help reduce some of the costs associated with test failures by addressing the documented problem of both material and inter-laboratory variability in product testing.

Response 61: The statutory lead content limit for children's products is 100 ppm. Manufacturers of children's products must have a high degree of assurance that their products meet this limit before issuing a CPC, as explained in 16 CFR § 1107.20.

Because analytical measurement technologies, such as those for lead content determination, possess uncertainty in their numerical results, a measurement that is slightly over the limit (100 ppm for lead content and 90 ppm for paints and other surface coatings), does not necessarily indicate that sample's actual lead content is also over the permissible limit. What a reading slightly over the limit means is that the manufacturer does not have a high degree of assurance, as required by 16 CFR part 1107, that all of the units from the production lot from which the sample was taken are compliant with the lead content limit. Further investigation is needed for the manufacturer to determine with a high degree of assurance that the untested units are compliant. This investigation might include: examining the testing procedures, calibrating the test instrumentation, testing additional samples, or other actions.

With regard to testing variability, staff acknowledges that testing variability can occur in testing protocols and requirements, including the current 100 ppm lead content requirement. Staff considers a certain amount of test variability to be expected. However, standard practices in testing laboratories include detecting, understanding, and controlling excess test variability. Staff believes that it is important to distinguish testing variability from material variability. Testing variability can be determined by testing materials that have been well characterized, such as Standard Reference Materials (SRMs) produced by NIST. Testing materials that are not well characterized may lead to misattribution of material variability to testing variability. NIST SRMs, and similar products from other recognized metrology laboratories, are available with certified lead content and with certified uncertainty levels for the lead content.

Three lead reference materials with certified lead content ranging from 13 ppm to 85.9 ppm were analyzed using applicable CPSC standard test methods by nine chemists in the Directorate for Laboratory Sciences, Division of Chemistry. The results for each reference material are in agreement with the certified value. There are overlapping 95 percent confidence intervals between CPSC staff results and the certified values. CPSC staff believes that the testing conducted indicates that CPSC test methods can be applied effectively to samples with less than 100 parts per million of lead.

Therefore, staff declines to recommend establishing statistical uncertainty bands because the lead content limit is determined statutorily, individual measurements of lead content above 100 ppm are not automatic determinations of noncompliance, and the CPSC test methods have been shown to minimize testing variability.

Comment 62: One commenter (14), a testing laboratory, offers that it will make an information technology (IT) tool it has developed freely available to small manufacturers. The IT tool purportedly helps a company design a production testing plan and generate the documents required by the testing and certification and component part testing rules. The commenter asserts that this tool could be modeled on the U.S. Internal Revenue Service's Free File Program, in which providers of electronic tax preparation services provide access to those systems for free to moderate income filers, in coordination and cooperation with the IRS. The

commenter states that they believe a similar public/private partnership with the CPSC, would be legal, appropriate, and necessary to maximize compliance with the complex new testing and certification requirements, particularly for companies that otherwise simply do not, and will not, have the resources to understand fully and comply with these and other CPSC regulations and requirements. The commenter asserts that such a solution represents an ideal means of "reducing the cost of third party testing requirements consistent with assuring compliance with applicable requirements."

Response 62: The commenter suggests that the CPSC "review and recognize" this IT tool in a form of public/private partnership but does not describe any details of either the "review and recognize" activity, or the nature of the public/private partnership. Thus, we are unable to consider the nature of the commenter's request. The CPSC does not endorse consumer products manufactured by private manufacturers.

In general, however, the use of information technology might have the potential to reduce the third party testing burden of manufacturers, possibly by eliminating tests that do not need to be conducted, or by simplifying the administrative effort involved in conducting third party testing. Thus, staff recommends follow-up with the commenter to determine the nature and details of the proposal.

1.8 Issue 7

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 63: One commenter (14) states that the CPSC should make a formal statement that "compound" test reports are acceptable for children's product certification purposes. Compound test reports permit a testing laboratory to indicate on a single report, test results that conform to several different standards, including those of the CPSC. The commenter asserts that there has been no formal declaration to that effect by the agency. As a result, some testing laboratories or companies require the issuance of multiple test reports for one product.

Response 63: The CPSC has not specified the form of a test report. As long as a test report contains information sufficient to support a CPC, as specified in 16 CFR §1107.26 and 16 CFR §1109.5(g), it may contain additional information. Compound test reports are acceptable for children's product certification purposes.

Comment 64: A commenter (4) states that by emphasizing the testing process over safety outcomes, paperwork has become the object of all "good" CPSC-approved safety programs. The commenter asserts that many products that are recalled were tested and found to comply with the law. Thus, the commenter maintains, testing is not a guarantee of safety. The commenter states that the CPSC has rejected "the most obvious way to cut costs for regulated companies—let companies with solid safety records self-administer. Your rules can stand as a safe harbor."

Response 64: We agree with the commenter that recalls of products have included products that have passing compliance testing results. This can be expected for products where process control is not maintained after initial certification, or for manufacturing procedures that do not

control all of the variables affecting compliance, such as inadvertent contamination. One purpose of required periodic testing is to provide some objective evidence of continued compliance with the applicable product safety rules.

We agree with the commenter that testing is not a guarantee of safety. Sections 14(a) and (i) of the CPSA require third party testing for children's products for initial certification, periodically, and after a material change. The testing is intended to provide the manufacturer with a high degree of assurance, not a guarantee, of initial compliance and to ensure continuing compliance during continued production of the product.

The commenter's suggestion of allowing companies with a "solid safety record" to be exempt from the requirements for third party testing would require Congress to amend the CPSA. Furthermore, allowing such exemptions would pose practical difficulties. Defining a "safety record" could be problematic. Determining a "safety record" would probably require positive evidence, such as certification test data, rather than a lack of "unsafe" indicators, such as recalls or incidents associated with a product. CPSC staff is unaware of how to determine when a "safety record" would be classified as "solid." Accumulating epidemiological data is not satisfactory because not all potentially hazardous products actually cause an injury, much less result in one that is detected by a monitoring program such as the National Electronic Injury Surveillance System (NEISS). Furthermore, a "safety record" would probably be product specific and can be determined only after the product has been introduced into commerce for some time.

Other practical matters, such as whether a new product's "safety record" is initially "solid," or whether the discovery of a noncompliant product produced by a manufacturer affects the "safety record" of other products produced in the same facility, would have to be addressed. For these reasons, CPSC staff recommends against pursuing the commenter's suggestions.

The commenter asserts that the CPSC has rejected "the most obvious way to cut costs for regulated companies—let companies with solid safety records self-administer. Your rules can stand as a safe harbor." A safe harbor is a provision of a statute or a regulation that affords protection from liability or penalty under the law, on the condition that the party subject to the statute or regulation performed its actions in good faith or in compliance with defined standards in the statute or regulation. Safe harbor provisions are included in statutes or regulations to protect legitimate or excusable violations, or to incentivize the adoption of desirable practices. Thus, a safe harbor provision covers actions that have already occurred. It is unclear how a safe harbor provision would reduce third party testing costs, unless the third party testing was not undertaken, which is not allowed by statute.

It is unclear how our regulations (the commenter does not state whether he refers to children's product safety rules or the third party testing regulations in 16 CFR parts 1107 and 1109) could serve as a safe harbor for manufacturer's with "solid safety records [that] self-administer" in light of the fact that the manufacturer would have made no attempt to comply with the requirements of section 14(a)(2) of the CPSA and the testing regulations (16 CFR parts 1107 and 1109). In order for a manufacturer to qualify for a safe harbor provision, a good faith

attempt at compliance with the regulation or compliance with a specific safe harbor provision of the regulation is required.

Comment 65: A commenter suggests that the 5-year record retention period be shortened to reduce third party testing burdens.

Response 65: In the development of 16 CFR part 1107, staff considered a record retention period to span the life of the product's manufacture plus 5 years, or the product life, plus 3 years. For the proposed rule, staff recommended the 5-year option because it is consistent with the 5-year statute of limitations in 28 U.S.C. 2462. In the final rule, the Commission shortened the period to a simple 5-year retention period beginning on the date the record was created. The Commission reasoned that 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.

The 5-year requirement is not intended to supersede record retention times that are specified in existing regulations. If this requirement were changed to a shorter period, that conceivably could interfere with any investigations involving noncompliant products found in commerce. For these reasons, staff considers the 5-year record retention period better than other options.

Comment 66: A commenter (5) notes that 16 CFR §1109.5(j)(2) requires records to be "Translated accurately into English by the certifier or testing party within 48 hours of a request by the CPSC or any longer period negotiated with CPSC staff." The commenter asserts that the 48-hour period would be difficult to meet and suggests a 7-day period for translations into English.

Response 66: In 16 CFR § 1107.26(b)(2), the regulation states that records may be maintained in languages other than English, if they can be:

> . . . Translated accurately into English by the manufacturer within 48 hours of a request by the CPSC, or any longer period negotiated with CPSC staff.

Because longer translation periods can be negotiated with the CPSC, staff is unsure what a longer period would achieve in terms of reducing the third party testing burden.

The CPSC maintains an interest in obtaining records in a timely manner, especially if the records relate to a public safety issue. A longer default translation period could impact on consumer safety in cases where timing is critical in preventing or reducing an unreasonable risk of death or injury.

Comment 67: A commenter (7) states that the CPSC accreditation system for testing laboratories imposes a "barrier" to accepting test reports in support of children's product certification. The commenter suggests that the CPSC allow acceptance of any test report from a testing laboratory accredited to ISO/IEC 17025:2005 by a signatory to the ILAC-MRA. The commenter adds that the CPSC should continue to accredit firewalled testing laboratories.

Response 67: The commenter does not explain what the "barrier" is to accepting test reports from an ISO/IEC 17025:2005 testing laboratory accredited by a signatory to the ILAC-MRA, or how this would reduce third party testing burdens. The remaining requirement for CPSC acceptance of a testing laboratory's accreditation is the submission of Form 223 and any accompanying documentation to the CPSC, a process that can be completed in an estimated 1-hour timeframe and involves no fees. Governmental and firewalled laboratory applicants have additional requirements to fulfill sections 14(f)(B) and (D) of the CPSA.

If the commenter were to identify "barrier" issues that affect manufacturers' third party testing burdens, the CPSC could address those issues. The Commission intends to continue to accredit firewalled testing laboratories, as appropriate.

Comment 68: A commenter (14) suggests that formal recognition of the importance of risk assessment in product design and manufacture by the CPSC could lead to a system of tailored testing plans that take into account the relative risk of different products.

The commenter suggests that the CPSC should formally recognize that when risk assessment and management services and tools are used properly, the risk of nonconforming or otherwise hazardous products being sold to consumers can be reduced dramatically. As a result, the commenter adds, third party testing costs can be reduced by explicitly allowing recognized, third party risk management systems like these, to substitute, for example, for more frequent third party periodic testing as part of a production testing plan, or in other ways to lessen the burden of such testing. However, the commenter states that there must be a level of assurance that the risk assessment is being conducted with rigor and validity, and therefore, preferably by third parties. Otherwise, the commenter states, standards violations and subsequent recalls are likely to increase.

Response 68: We agree that designing safety into a children's product is an important part of a comprehensive quality control program.

However, we decline to recommend the commenter's suggestion to the Commission to recognize formally that risk assessment and management services and tools reduce the risk of nonconforming products being sold to consumers. We have not conducted an evaluation of such programs, nor have we come to the conclusion that such risk assessment and management services reduce the risk of noncompliance in all cases. Furthermore, it is unclear that all children's products subject to a children's product safety rule would benefit from formal applications of risk assessment and management services and tools.

A production testing plan can include risk assessment and management tools. Such a production testing plan can serve to increase the maximum periodic testing interval from one to two years. Although 16 CFR part 1107 does not require manufacturers to include risk assessments on their products, manufacturers are free to engage in such analyses when developing or manufacturing a product.

Regarding the commenter's suggestion to tailor testing requirements to the relative risk of nonconformance posed by a product, 16 CFR § 1107.21(b)(2) lists several factors to consider when determining the periodic testing interval, among them:

- the potential for serious injury or death resulting from a noncompliant children's product;
- 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; and
- the inability to determine easily the children's product's noncompliance through means such as visual inspection.

Comment 69: Three commenters (16, 20, and 21) suggest that the Commission should revise the phthalates notice of requirements (NOR) to identify specifically the many types of plastics that are known not to contain the restricted phthalates in excess of specified limits, or, alternatively, to identify the few types of plastics that might contain the restricted phthalate plasticizers.

One commenter (21) states that such a list would also lessen confusion over the scope of the current phthalate standard, Statement of Policy, *Testing of Component Parts With Respect To Section 108 of the Consumer Product Safety Improvement Act*,[13] and how to apply the Statement of Policy to quality assurance and testing programs. The commenter opines that such action purportedly would ensure that testing is conducted only on plasticized plastic components of covered toys or child care articles that may contain the restricted phthalates, thereby minimizing the costs and burdens of the NOR.

One commenter adds that needless testing of plastics, to which phthalates have not been added intentionally, should be specifically discouraged. The commenter also suggests that the CPSC acknowledge that the published list of materials known not to contain phthalates is not exhaustive, and that other materials may be added to the list in the future.

One commenter opines that a great variety of plastics, including, but not limited to, those identified in the Statement of Policy, would not contain the restricted phthalates above the applicable limits. The commenter asserts that the NOR, however, references a more limited universe of materials identified as known not to contain phthalates. Because the NOR does not reference any plastic materials, the commenter avers that this has caused some confusion and may lead to unnecessary testing.

The commenter requests that the Commission publicly list all the types of plastics identified below in the phthalates Statement of Policy as materials known not to contain the restricted phthalates in above the applicable limits. The commenter states that doing so will ensure that participants in the plastics supply chain subject to the NOR are not burdened unfairly with added and unnecessary testing costs. The list contains the following materials:

- Acrylic

[13] http://www.cpsc.gov/about/cpsia/componenttestingpolicy.pdf.

- Acrylonitrile butadiene styrene copolymers
- Butadiene-ethylene resins
- Butene-ethylene copolymers
- Ethylene copolymers
- Ethylene acrylic acid copolymers
- Ethylene-propylene copolymers
- Ethylene vinyl acetate copolymers
- Ethylene vinyl acetate vinyl alcohol copolymers
- Ethylene vinyl alcohol copolymers
- Ionomers
- Liquid crystal polymers (Hydroxybenzoic acid copolymers)
- Nylon
- Polyamide
- Polybutene
- Polybutylene terephthalate
- Polycarbonate
- Polyesters13
- Polyethylene
- Polyethylene terephthalate14
- Polylactic acid
- Polyphenylene sulfide
- Polypropylene15
- Polystyrene
- Polytetramethylene glycol-dimethyl terephthalate-1,4-butanediol copolymer
- Propylene-ethylene copolymers
- Styrene-butadiene copolymers
- Vinylidene chloride /methyl acrylate copolymers
- 1,3,5-Trioxane, polymer with 1,3-dioxolane (Polyoxymethlyene copolymer).

Alternatively, the commenter suggests that the Commission could identify the small number of plastic resins that might contain the restricted phthalate plasticizers, such as flexible (but not rigid) polyvinyl chloride, or thermoset polyurethanes. The commenter states that such a rule or guidance could also incorporate specifications for hardness or rigidity, recognizing that rigid plastics do not require the addition of any type of plasticizer, and that the addition of a plasticizer, which promotes flexibility, compromises hardness or rigidity.

Response 69: While we have some concerns about a list, as described below, we agree with the commenters that creating a list of materials that do not require testing for phthalate content could reduce third party testing burdens. Accordingly, staff recommends that the Commission designate a project to consider whether a list can be created in a meaningful and helpful manner.

We also agree that there is some confusion concerning which materials require testing for phthalate content. Considering that phthalate testing is costly, providing more explicit guidance regarding which materials need to be testing for phthalate content, or alternatively, which materials need not be tested for phthalate content, could reduce third party testing costs for some

manufacturers. This would be similar to the determinations made by the Commission that certain materials inherently would not contain lead in excess of the statutory standard, and therefore, third party testing of the materials is not required.

However, before CPSC staff can recommend that the Commission make similar determinations for phthalates, we require more information about why specific materials would not contain the restricted phthalates. For example, if a material cannot contain phthalates at levels exceeding the statutory limit because phthalates at that level are incompatible with the material, or would interfere with its performance, the material could be a candidate for inclusion in a list of substances for which testing for phthalate content is not required. On the other hand, if the material is one that is expected not to contain phthalates, simply because phthalates commonly have not been used in the material, but use of phthalates in the material could be accomplished successfully, then the material might not be a candidate for inclusion in such a list.

We note that when added intentionally to plastics, the resulting phthalate content of material is frequently in the 20 to 30 percent range. This is substantially higher than the statutory limit of no more than 0.1 percent for the restricted phthalates. Therefore, the lack of evidence of the intentional addition of the restricted phthalates is not sufficient to determine that the material does not contain more than 0.1 percent of the restricted phthalates. It may be possible for materials to contain more than 0.1 percent of the restricted phthalates through unintentional contamination or the use of recycled materials.

Specifying a minimum rigidity as a criterion for determining whether a plastic must be tested for phthalates is not workable. As noted above, to have the desired softening effect, a material's phthalate content frequently must be in the range of 20 to 30 percent. This is substantially above the statutory limit of no more than 0.1 percent. Therefore, it is likely that amounts above 0.1 percent, but less than several percent, would not significantly soften the plastic, but the plastic would still be in violation of the requirements of section 108 of the CPSIA.

Additionally, staff does not recommend that such a list be included in a phthalates NOR. An NOR details the steps that testing laboratories must take in order to have their accreditation accepted by the CPSC to conduct testing for purposes of children's product certification. Because an NOR contains requirements for testing laboratories, the addition of information for manufacturers would be directed to the wrong stakeholders. If a list of materials determined not to contain the six banned phthalates in concentrations above 0.1 percent were developed, such a list could be issued as a guidance document on the CPSC website, or it could be codified in section 16 of the CFR, similar to the materials determined not to contain more than 100 ppm of lead.

Comment 70: A commenter (16) suggests that the Commission assess how other techniques, such as use of audits, good manufacturing practices, and manufacturer attestations can be relied upon to minimize the burden of third party testing throughout the supply chain while maintaining appropriate accountability by the ultimate manufacturer or importer.

Response 70: In 16 CFR § 1107.20(c), the Commission states that if a manufacturer implements a production testing plan, the maximum periodic testing interval is extended from

one to two years. This is a means by which the third party testing burden may be reduced. The use of audits, good manufacturing practices, and other methods listed in § 1107.20(c) are methods that can be used already in a production testing plan. If the manufacturer attestation consists of test reports from a CPSC-accepted testing laboratory or component part certificates, these may be used for children's product certification, material change, or periodic testing purposes.

Any party in a product's supply chain may employ component part testing to reduce the third party testing burden for a children's product. A component part test report or certificate may be used by anyone using component parts covered by the test report or certificate. In this way, third party testing burdens can be amortized over many products, effectively reducing the per-unit testing burden.

However, while removing the third party testing regime would reduce the third party testing burden, it is not allowed by law and is not consistent with ensuring compliance.

Comment 71: One commenter (17) states that the CPSC should "fix" the determination of fabric as a barrier for inaccessible parts. The commenter says that CPSC correctly stated that if a part is covered by fabric, children will not be able to touch the part, and therefore, will not be exposed to any lead. However, CPSC then added a requirement that the product also not be capable of being placed in a child's mouth. The problem, according to the commenter, is that this requirement is based on a requirement for toys. Many apparel items, such as shoes, fall within the dimensions that suggest they can be placed in a child's mouth, but when they are being worn, as intended, they cannot be placed in the mouth. However, because an item of footwear or other apparel item is always smaller than 5 centimeters in one dimension, the determination that fabric can be a barrier making a lead containing component inaccessible is useless to the apparel industry.

Response 71: The commenter refers to 16 CFR §1500.87(i), which states that a children's product with a lead-containing component part covered by a fabric is considered to be inaccessible, unless the product or component part is smaller than 5 centimeters (cm) in one dimension. Staff agrees with the commenter that the purpose of the requirement is based on a consideration of whether the fabric-covered component part is mouthable and that the requirement is based on a similar mandate for component parts of toys containing phthalates.

However, the hazard associated with lead is ingestion and its consequent health effects. If a children's product has a dimension less than 5 cm, it is considered mouthable, and the possibility exists of mouthing or sucking and ingesting lead from the underlying component part. We disagree with the commenter that children cannot access their feet with their mouth. Younger children are often observed mouthing their toes,[14] which indicates that it is indeed possible for them to mouth footwear while wearing it. Furthermore, when the child is not wearing their footwear, the lead-containing, fabric-covered component parts are considered accessible. Children play with footwear when it is not being worn. For these reasons, we do not recommend

[14] Rubin, Richard R., Fisher, John J. III, and Doering, Susan G., *Your Toddler*, ISBN 0-02-043920-2, Macmillan Publishing Company, New York, 1980.

changing the inaccessibility provision of 16 CFR part 1500.87(i) as a means of reducing third party testing burdens.

Comment 72: One commenter (17) states that the Commission should correct its usage of the terms "prints" and "screen prints" in its determinations that most fabrics are unlikely to contain lead. The commenter asserts that the Commission uses the term "prints" in a context in which it really is referring to "screen prints." In fact, the commenter continues, "prints" include several forms of dyeing that fall distinctly under the category of items exempted from testing. The commenter says that the Commission's use of the term "prints" has captured many inherently lead free operations involving fabric and has resulted in costly confusion and much unnecessary testing.

Response 72: The basis of the Commission's determinations concerning lead content of products at 16 CFR § 1500.91 is that certain materials and products do not, and cannot, contain lead at levels in excess of the mandatory lead content limits. The language of the rule is intended to apply not just to screen-printing, for which lead-containing materials are clearly used for some products, but to any other processes that could result in images, prints, or designs on textiles that could include lead-containing materials. Staff recognizes that printing and screen-printing technologies do not necessarily involve the use of lead-based materials. However, the similarity in the processes and products that are or are not amenable to the use of lead-containing materials complicates staff's ability to specify which products will never contain excess lead.

Staff work subsequent to the publication of the rule (*e.g.*, the FAQ at http://www.cpsc.gov/info/toysafety/leadinpaintfaq.html#textile) is intended to help firms to differentiate products, based on their knowledge of the materials used. In the cases that the materials used to create prints are known to be dyes similar to the dyes used to color whole textiles, third party testing is not required. On the other hand, materials used commonly in screen-printing that become surface treatments and that do not dye the textile substrates, are not included in the testing exemption because it is possible that these products could contain lead-containing materials.

Comment 73: Two commenters (17 and 23) state that the Commission should provide a "small batch exemption" for all manufacturers producing a small batch. The small batch exemption only applies to manufacturers with sales from all products of less than $1 million a year. However, many larger manufacturers have lines that are only produced in small batches and face the same costs in producing those batches as small batch manufacturers.

Response 73: The commenter is referring to the difference between the small batch exemption provided by Congress in section 14(i)(4) of the CPSA, and the low-volume exemption from periodic testing of children's products proposed by the Commission in 16 CFR § 1107.21(d) of the proposed rule, *Testing and Labeling Pertaining to Product Certification* (75 FR at 28365). In the Commission's low-volume proposal, products produced or imported at low volumes were not subject to the periodic testing requirements until more than 10,000 units have been produced or imported. The intent of the proposed low-volume exception is to avoid having a manufacturer amortize its periodic testing costs over a very small volume of products.

CPSC staff agrees with the commenters that there are products manufactured in low volumes that would not qualify as a "small batch" under the definition in section 14(i)(4) of the CPSA. These could include products produced by a manufacturer with more than $1 million in total gross sales. CPSC staff recommends that the Commission consider a form of periodic testing interval based on a production volume instead of a time period.

Comment 74: One commenter (17) suggests that the Commission apply the inaccessibility exemptions from lead testing for inaccessible components to paint that is inaccessible as well. As an example, the commenter provides the example of a children's shoe that contains a painted figure on the side of the shoe depicting a children's TV show or movie character, which is covered with a clear plastic coating to maintain the smooth feel of the shoe. Any lead in the paint would be just as inaccessible as any component, but the manufacturer would still be required to perform the third party testing.

The commenter (17) states that because the CPSC made the determination that children's products bearing lead containing paint are hazardous in a regulation, not by Congress in a statute, the CPSC has the authority to change the determination. The CPSIA did revise the regulation's numeric threshold, but the CPSC could still revise its regulation to state that children's products bearing paint with the specified amount of lead "in accessible components" are banned hazardous substances. The commenter states that these items are just as deserving of relief from the burden of third party testing as those that enjoy relief from phthalates and lead in substrate requirements. The commenter states that the CPSC has the authority and understanding to provide this relief without any reduction in product safety.

Response 74: The inaccessibility exemption in Section 101 of the CPSIA applies to lead content in component parts. The regulation at 16 CFR part 1303[15] does not have an explicit exemption for inaccessible paint and other surface coatings on children's products. Therefore, paint that is inaccessible in a children's product is required to meet the 90 ppm lead content limit. Granting an exemption from testing inaccessible paint in order to reduce the third party testing burden would not be consistent with assuring that inaccessible paint is compliant with 16 CFR part 1303.

However, the Commission may wish to conduct an evaluation of 16 CFR part 1303 to determine if inaccessible paints and other surface coatings pose an unreasonable risk of harm.

Comment 75: A commenter (17) states that the CPSC should not require all periodic testing to be performed by a third party testing laboratory. The commenter states that the CPSIA does not require periodic testing to be performed by a third party testing laboratory; it only requires that the certification tests be done by a third party testing laboratory.

Response 75: The commenter is referring to section 14(i)(2)(B)(i) of the CPSA, as amended by Public Law 112-28, which requires periodic testing of children's product. Section 14(i) is titled, *Additional Regulations for Third Party Testing*. The Commission has interpreted section 14(i)(2) of the CPSA to require periodic testing to be performed by a third party conformity assessment body.

[15] *Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint.*

Comment 76: A commenter (17) urges the Commission to expedite the repeal of the ban of the three interim banned phthalates or to stay the test requirement until a final determination is made about the status of the phthalates. The commenter cites the cost of testing as the reason for its desire to stay the testing requirement.

Response76: Section 108(a)(2) of the CPSIA directed the Commission to appoint a Chronic Hazards Advisory Panel (CHAP) and listed eight areas of study for the panel. The CHAP is developing its report based on its examinations, considerations, and reviews of the relevant data. That report is due in 2012.

Section 14(a)(2) of the CPSA requires that children's toys and child care articles subject to the prohibition on the three interim banned phthalates be certified based on CPSC approved-third party testing. The interim status of these three banned phthalates does not change this legal obligation to third party test and certify, nor does the Commission have legal authority to do so. In addition, regarding the commenter's request for a stay on testing for the three interim banned phthalates, at this time, we cannot assume that the ban of the three interim banned phthalates will be repealed. A stay from testing, followed by a decision to permanently ban one or more of the three phthalates, could lead to confusion in the marketplace about which products have been tested. Such confusion could lead to children's toys or child care articles containing the now newly permanently banned phthalates being entered into commerce. For these reasons, staff does not recommend at this time that the Commission issue a stay on testing for the three interim banned phthalates.

Comment 77: One commenter (17) states that all product safety regulations should be designed to mitigate and protect against specific risks and be clearly supported by the data and facts. The commenter states that the apparel and footwear industry is chafing under many CPSIA rules that appear designed to address product safety concerns with toys. The commenter also urges that the same risks that apply to toys do not apply to apparel. The commenter states that it is important to use risk potential when doing a retrospective review. The commenter suggests that if an unintended consequence is the result of a broad regulation that shows no evidence of mitigating a risk, it should be examined, and if the affected products are determined to have shown no history of risk, it should be removed or exempted from the rule.

Response 77: If the commenter is referring to either the lead or phthalate content requirements, Congress set a statutory content limit for these substances. While the Commission has the authority to implement such limits in a rational manner, it cannot simply ignore a congressional mandate. Further, it is unclear in what manner the commenter believes that apparel is different from toys. The suggestion may or may not be reasonable, but the commenter fails to provide data that supports the proposition so that a more meaningful analysis can be made of what the differences are and how those differences might suggest a more cost-effective implementation of third party testing for apparel.

We note that the lead content requirements apply to children's products, but the phthalate content requirements apply only to children's toys and child care articles.

In regard to the commenter's statement on the importance of using risk potential when doing a retrospective review, we are not conducting a retrospective review of the CPSIA. We are considering ways to reduce the third party testing burden on manufacturers in a way that is consistent with assuring compliance to the existing safety requirements.

Comment 78: A commenter (18) states that third party testing burdens on manufacturers of decorated glassware could be reduced significantly if such products were held to a leachable lead limit, as opposed to the total lead content limit set forth in Section 101 of the CPSIA. The commenter reasons that any exposure to lead from glassware would be limited to leaching, not through ingestion. The commenter concludes that a leaching test would provide a more accurate risk assessment than a lead content test. The commenter asserts that, in its estimation, a leaching test on decorated glassware would be much less expensive than a number of required lead content tests on the glass's constituent component parts.

Response 78: Section 101 of the CPSIA establishes the lead content limits of component parts of children's products. The CPSC has some discretion in implementing these limits, but it cannot ignore them. Even if we were to agree that a leaching test is sufficient to determine the exposure potential for glassware, a leaching test is not an accurate determination of lead content in a component part, such as glass, and therefore, it cannot determine compliance to the statute. A leaching test, thus, is not acceptable to determine compliance of children's products to the applicable lead content limit.

Comment 79: A commenter (19) suggests that the CPSC employ a robust and thoughtful process for granting exemptions from the CPSC standards for individual products, categories of products, or classes of materials. This process could lower the total cost of third party testing. This reduction could occur without negatively impacting the safety of the products affected. The commenter encourages the CPSC and Congress to carefully consider whether the exemption process can be applied in a manner that counteracts these unintentional consequences to U.S. consumers and U.S. businesses as rulemaking proceeds.

Response 79: CPSC has only limited authority to grant exemptions from some CPSC standards that were established by statute. These include the limits of lead content in substrates and phthalates.

However, a children's product certifier may petition the CPSC to include a class of materials in the list of materials that the agency has determined do not exceed 100 ppm lead content, contained in 16 CFR § 1500.91, *Determinations regarding lead content for certain materials or products under section 101 of the Consumer Product Safety Improvement Act*.

Furthermore, section 101(b)(1) of the CPSIA, as amended by Public Law 112-28, allows for a functional purpose exception to the lead content limit for a "specific product, class of product, material, or component part," if certain conditions are met. The exceptions are to the lead content limit of 100 ppm, not to the requirement to conduct third party testing. The exception process could lead to a lower total cost of third party testing if the Commission does not establish any alternate limit, or if the new limit allows less expensive test methods to be used to assess compliance, and the cost savings are passed on to the children's product certifier.

Comment 80: A commenter (19) suggests that if Quality Management Systems (QMS) standards are applied, testing of finished products to ensure compliance with the applicable children's product safety rules is not necessary, and such testing should decline.

Response 80: The commenter may be suggesting that if a manufacturer implements a widely-used QMS operation, the required frequency of third party testing could be reduced, as in a longer maximum period for periodic testing. The final rule for 16 CFR part 1107 does allow for an increased maximum testing interval for periodic testing, if the manufacturer implements a production testing plan, or uses an ISO/IEC 17025:2005-accredited testing laboratory for product testing. Implementation of a QMS operation for children's products can be part of a production testing plan, which would increase the maximum periodic testing interval from one to two years.

While we agree that a QMS operation can be implemented to ensure continued compliance to the applicable children's product safety rules, a QMS operation cannot replace third party testing altogether. Third party testing is required by sections 14(a)(2) and 14(i) of the CPSA for purposes of certification, when a material change is made, and periodically, as more fully described in 16 CFR part 1107.

Comment 81: Three commenters (15, 20, and 21) suggest that the CPSC establish a *de minimis* exception for testing small painted areas of children's products for compliance with the lead paint standard. The commenters assert that if a paint supplier declines to provide component part test reports or certificates, the manufacturer would be required to supply multiple finished product samples to a testing laboratory in order to generate enough paint to conduct the lead-in-paint test. The commenters consider that situation "unduly burdensome."

One commenter (15) states that the Commission should adopt an exclusion from testing requirements for paint or surface coatings present in a product at a total weight of less than 10 mg. The commenter argues that this is the same exclusion provided in ASTM F963 and ASTM F2923[16] for migratable heavy metals (other than lead) in paint. The commenter explains that the rationale for the exclusion from heavy metal testing in paint and surface coatings embodied in these other safety standards is that, at such low quantities, the amount of material involved cannot pose a reasonable risk of harm. The commenter believes that the CPSC has discretion under Section 3 of the CPSIA, "this rule" (presumably 16 CFR part 1107), and Executive Order 13789,[17] to adopt such an exclusion. The commenter argues that doing so would immediately relieve excessive testing burdens that require jewelry companies to order more samples than are required to fulfill a customer order to conduct destructive tests.. The commenter urges the Commission to consider whether similar exclusions for other components are appropriate to reduce test costs while assuring safety.

Response 81: The regulation at 16 CFR part 1303 does not allow an exception from the third party testing requirement for small amounts of lead paint on a children's product. Paint on a

[16] *Standard Specification for Consumer Product Safety for Children's Jewelry.*
[17] Currently, no Executive Order 13789 has been issued. We assume that the commenter is referring to Executive Order 13563, *Improving Regulation and Regulatory Review*, which can be found at: http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order.

children's product is required to contain less than 90 ppm lead, irrespective of the volume of paint used.

Using the toy standard, ASTM F963 provision may not be appropriate for other types of non-toy products, such as children's jewelry, because the potential exposure patterns may differ significantly; *i.e.,* jewelry items tend to be easily mouthed and swallowed.

One possible means of addressing the testing burden posed by small amounts of paint on a children's product is through component part testing, where test results for a container of paint may be used to support certification of all the children's products using the paint from that container. If a paint supplier does not provide component part test reports, the manufacturer or importer may procure component part testing themselves, by acquiring a sample of the lot or batch of paint used on the children's product and contracting with a CPSC-accepted testing laboratory to conduct the testing. Further, the CPSC allows use of the testing method in ASTM F2853-10, which is nondestructive and requires only small painted areas for analysis.

Although there are nondestructive alternatives to test small paint quantities, the Commission may wish to explore the ramifications and potential consequences of allowing a *de minimis* testing exception for small painted areas. Such an exploration could consider the maximum volume to be considered a *de minimis* amount, and address potential exposure factors, such as age of the child and their expected interaction with the children's product.

Comment 82: Two commenters (20 and 21) recommend that the CPSC incorporate into the test method for 16 CFR part 1303, the test method in ASTM F963 (We assume that this is the -08 version, because the -11 version does not involve a test method in the named section.) section 8.3.3.1 under, *Method to Dissolve Soluble Matter.*

Response 82: Section 8.3.3.1 of ASTM F 963-08 states:

> Scrape the coating off the test sample, and grind it through the sieve. Obtain a portion of not less than 100 mg of the resulting material.

The CPSC Test Method CPSC-CH-E1003-09.1, *Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings*, contains the following instructions in steps 2 and 3:

> 2. For products coated with paint or a similar surface coating, remove and digest the coating, separately from the substrate material. Care should be taken to remove as little of the substrate as possible. It may be necessary to add a few drops of solvent, such as methylene chloride, to soften the paint and aid in its removal from the substrate. If used, such solvent must be evaporated fully prior to analysis. The scraped paint should be finely divided to help in digesting.

> 3. Scrape approximately 5-100 mg of paint from the product. If it is not possible to collect this much paint, it may be necessary to combine more than one unit of such product to collect sufficient paint.

Because step 2 instructs the user that the scraped paint should be divided finely, further instructions on grinding are not necessary. If the commenters were concerned about the amount of paint ("not less than 100 mg" in the suggestion, and "approximately 5-100 mg" in the CPSC test method), they do not explain how that difference would reduce the third party testing burden. Staff does not recommend incorporating clause 8.3.3.1 from ASTM F 963-08 into the CPSC test method for determining the lead content of paint because it is unclear how this change would reduce third party testing burdens. Moreover, we do not recommend incorporating a step from a test method into 16 CFR part 1303, because the regulation does not contain a test method in which the scraping, grinding, and weighing steps from ASTM F 963-08 can be incorporated.

Comment 83: Two commenters (20 and 21) suggest that the CPSC establish a *de minimis* exception for the phthalate content in children's products where the amount of accessible, plasticized material is small. The commenters assert that if a component part supplier declines to provide component part test reports or certificates, the manufacturer would be required to supply multiple finished product samples ("literally hundreds or thousands") to a testing laboratory in order to generate enough of a sample (such as a paint applied in very small amounts) to conduct the phthalate content test.

Response 83: Section 108 of the CPSIA does not allow an exception from the third party testing requirement for small amounts of accessible plasticized material on a children's product, irrespective of the amount of plasticized material on the product.

One possible means of addressing the testing burden posed by small amounts of plasticized material on a children's product is through component part testing, where test results for a sample of the material may be used to support certification of all the children's products using that material. If a material's supplier does not provide component part test reports, the manufacturer or importer may themselves conduct component part testing by acquiring a larger sample of the plasticized material used on the children's product and contracting with a CPSC-accepted testing laboratory to conduct the testing.

The Commission may wish to explore the ramifications and potential consequences of allowing a *de minimis* testing exception for small accessible areas of plasticized material. Such an exploration could address the issue of a maximum volume to be considered a *de minimis* amount, and examine potential exposure factors to consider, such as age of the child and their expected interaction with the children's product. Implementation of a testing exception might require authorization from Congress.

Comment 84: A commenter (20) suggests that the CPSC, on its own initiative, should revisit the list of materials submitted previously for inclusion in 16 CFR § 1500.91, *Determinations regarding lead content for certain materials or products under section 101 of the Consumer Product Safety Improvement Act*, and add the items in the list of materials to the list of

materials excluded from testing. The commenter reasons that the determination of not being reasonably likely to present any health hazard, as defined by Public Law 112-28, could be used to expand the list of excluded materials. That statute amended section 101(b)(1)(B) of the CPSIA to define "no measureable health effect" to establish a functional purpose exemption for lead as no measurable increase in blood lead levels of a child. The commenter suggests that the CPSC update as expeditiously as possible its website and rules to reflect the new exemptions.

Response 84: Substances listed in 16 CFR § 1500.91 have been determined by the Commission not to contain lead in excess of 100 ppm and as a result, they do not require third party testing for lead content. The commenter's reference to section 101(b)(1)(B) of the CPSIA pertains to granting a functional purpose exception from the lead content limit of 100 ppm. The purpose of an exception under section 101(b)(1)(A) is to establish an alternate lead content limit, and such exception does not exempt materials from third party testing. While the functional purpose exception might assist manufacturers in lowering manufacturing costs, it is unlikely to reduce third party testing burdens, unless the alternate lead content limit allows the use of less expensive testing technology.

For the Commission to grant a functional purpose exception to the 100 ppm lead content limit for a material, the Commission must determine that three criteria have been met:

- The material requires the inclusion of lead because it is not practicable or not technologically feasible to manufacture it at 100 ppm lead or less, or make the lead inaccessible;
- The material is not likely to be mouthed or swallowed; and
- An exception for the material will have no measurable effect on public health and safety.

Public Law 112-28 does not provide a means for determining that an exception to the lead content limit can be used to expand the list of materials in 16 CFR § 1500.91. The limit of 100 ppm lead was determined by statute, and not by a Commission analysis of public health and safety effects. Further, a determination of the public health and safety effects of a lead-bearing material without knowledge of how or how much the material was used in a children's product, or even what the children's product is, and how a child interacts with it, is not possible.

A party may request an exclusion to the lead content limit for a material by following the procedures in 16 CFR § 1500.90. A party may request an exception for the lead content limit by following the procedures in section 101(b)(1)(C) of the CPSIA, as amended by Public Law 112-28.

Comment 85: A commenter (20) asserts that the FDA's preference for good manufacturing practices is superior to sample testing. The commenter observes that manufacturers use the same inputs, supplied materials, and processes for their products over a long period of time. This suggests, according to the commenter, that testing of finished production need not be conducted as frequently, and that smaller samples may be suitable. The commenter states that this would be true, given requirements for pacifier production under 16 CFR part 1611 (*Standard for the flammability of vinyl plastic film*) and sleepwear production under 16 CFR part 1615 (*Standard for the flammability of children's sleepwear: sizes 0 through 6x (FF 3-71)*), and 16 CFR part

1616 (*Standard for the flammability of children's sleepwear: sizes 7 through 14 (FF 5-74)*). The quality assurance (QA) process built into the standards should be recognized as demonstrable of reasonable testing and certification under CPSIA Section 102, as amended, and it also should accorded safe harbor status, the commenter asserts.

Response 85: While the commenter references 16 CFR part 1611 (*Standard for the flammability of vinyl plastic film*) as being the standard for pacifiers, we assume that they mean 16 CFR part 1511, *Requirements for Pacifiers*. The pacifier standard does not contain an internal QA process. The standards the commenter mentions do contain elements of a reasonable testing program. However, for children's products, the elements of a reasonable testing program do not exempt a manufacturer from the legal requirement to conduct CPSC-accepted testing laboratory testing for children's product certification, material change, and periodic tests, as required by section 14 of the CPSA and the accompanying testing regulations. The third party testing requirements apply to children's products, irrespective of whether their standard contains a QA process; and therefore, any such QA program could not be considered a safe harbor from the statutory third party testing requirements.

Comment 86: A commenter (22) states that third party testing by accredited and independent testing, inspection, and certification bodies provides more reliable product assessments and program integrity, the efficient flow of goods, and a reduced economic burden for the federal government.

The commenter cites multiple programs they have initiated to address streamlining the compliance and third party testing processes involved with product certification. The commenter says that the programs offer different options for manufacturers, but they all ensure that an independent third party testing organization is making objective and well-informed judgments of product compliance with consumer product safety rules, standards, and regulations.

The commenter details one product certification program, whose foundation is to emphasize component part testing as a means of reducing finished product testing costs. The program includes technical training and a follow-up regime. The commenter asserts that an up-front investment in training and education to the applicable rules allows manufacturers to reduce costs over the long term. However, this program is only a pilot program and is focused on small household appliances, not children's products.

The commenter mentions its company's program that uses risk-based analyses, hazard-based programs, and other techniques to promote compliance with the applicable children's product safety rules.

Response 86: The commenter is referring to the activities undertaken by certification bodies for the products and manufacturing processes they certify. Generally, this involves product compliance testing, plus other activities intended to ensure continued compliance during continuing production. The Commission may wish to address whether certification bodies, accredited to the upcoming standard ISO/IEC 17065, could have their accreditation accepted for children's product certification purposes. Using certification bodies for the certification and continued compliance of children's products may be a means by which the third party testing

burden associated with periodic testing could be reduced, potentially with increased operation efficiencies, reduced rework of noncompliant products or subassemblies, streamlined testing, or other methods.

With regard to the programs offered by the commenter, if certification bodies are allowed to test children's products for certification purposes, there is the possibility that a manufacturer's use of these programs could result in a reduction in the third party testing burden.

Comment 87: A commenter (22) states that it owns a proprietary database of 70,000 materials certified by an independent testing organization that is available for use by manufacturers. The commenter adds that selecting component parts contained in this database decreases the amount of finished product testing required.

Response 87: We agree that if a manufacturer of a children's product is able to select component parts pretested by a CPSC-accepted testing laboratory, the manufacturer may rely on the component part test reports or certificates to support the certification of the finished product, without duplicative component part testing for tests that do not require the finished product to assess compliance.

Comment 88: A commenter (23) suggests that the CPSC establish a subcategory of component parts that require less frequent testing, based on less frequent interaction with the component parts by children during use. The commenter suggests the following prioritized scheme for distinguishing subcategories of component parts based on the areas of the children's product with which the child interacts:

1. Mouthable components parts within the primary interaction area;
2. Components parts within the primary interaction area; and
3. Other accessible component parts.

The commenter states that, like numerous international and standards that provide different treatment to areas of the product likely to be accessed by the child (*e.g.*, seating or mattress surfaces), the same approach can be applied to component parts of a children's product. The commenter believes that the most frequently touched component parts could be afforded the highest testing frequency. According to the commenter, component parts with less frequent touching by children during use could be tested less often, "without sacrificing safety."

Response 88: We interpret "frequency of testing" to refer to the periodic testing interval for children's products because certification testing and material change testing are not optional, and periodic testing is the only concept that requires ongoing third party testing. We further interpret the commenter's subcategory of component part testing as referring to the chemical tests for lead and phthalates, because the commenter refers to mouthable component parts. We also interpret subcategories of component parts as being designated after a children's product has been designed and an analysis has been completed to identify the primary and secondary interaction areas, and the mouthable component parts within the primary interaction area. If such an approach were adopted, periodic testing frequency of component parts for lead and phthalate content would need to be determined on a per-product basis. Because 16 CFR part 1107 must

apply to many different types of products, including determinations on a per-product basis cannot be implemented in a practical manner other than by providing general guidelines. These guidelines are included already in the statute in section 16 CFR § 1107.21(b)(2). This section lists factors to be considered by a manufacturer in determining the appropriate periodic testing interval, based on their knowledge of the product and its manufacture. One of those factors is the potential for serious injury or death resulting from a noncompliant product. This factor could include the increased or decreased risk of exposure to lead and phthalates, based on the child's expected interaction with the product. In 16 CFR part 1107, manufacturers may choose a periodic testing interval based on risk of exposure, risk of serious injury or death, or other factors.

Under the CPSIA, the risk of exposure is not a factor in ensuring compliance with the lead limits and most recently with the phthalate limits under Public Law 112-28. Any component part whose lead or phthalate content exceeds the statutory limits, and which could be accessed by a child, is considered violative. However, Public Law 112-28 does provide for the Commission, on its own initiative, or upon petition, to grant an exception to the 100 ppm lead content limit for a specific product, class of product, material, or component part under certain circumstances.

Comment 89: Two commenters (20, and 21) state that the United States should have uniform national standards and should seek to deter states from imposing their own unique standards. The commenters assert complying with a patchwork of state standards is much tougher (and not safer) than having a uniform national standard.

Response 89: We agree that in some cases, the burden of complying with multiple standards may be greater than it would be with only one standard. This result, however, is a product of our federal form of government. Generally, the Commission's statutes preempt state laws that seek to protect against a risk of illness or injury associated with a product or substance that is designed to protect against the same risk of illness or injury as a federal law. In such cases, a state may not impose a law that is different from the federal law. Unless a state law is preempted by federal law, which is a case-by-case inquiry, states are free to enact their own laws related to the health and safety of their citizens. While in some instances the cost to manufacturers or consumers may be higher, there may be other benefits to consumers; and there may be benefits, such as laws in some states serving as a testing ground for what type of federal action would be most successful in protecting public safety.

The commenter has not been specific about what standards it seeks to unify. In general, however, staff does not recommend a blanket approach that discourages state innovation. While specific cases may arise where such counsel is warranted, the Commission does not have the authority to decide what state laws are, or are not, preempted by the federal statutes that the Commission enforces. Whether a state law is preempted by a federal law is an issue decided by the courts. In the past, the Commission has provided advisory opinions with regard to its views on preemption in particular cases, but this is not a routine action by the Commission.

1.9 Other Issues

The following comments relate to topics not covered by the seven issues listed in the RFC. Some comments are specific to a particular regulation. Others address how products are certified

in general. The summaries for those comments, and staff's responses, are contained in this section.

Comment 90: A commenter (4) notes the high cost to his and other businesses from having to comply with third party testing requirements, which he contends cannot be recovered from consumers. The commenter notes that his company will have a permanent increase in compliance costs because of the third party testing requirements with, according to the commenter, no corresponding safety benefit. The commenter asserts that there "have been no lead injuries associated with our products EVER." Additionally, he notes that testing costs are wasted money because the products are already safe.

Response 90: The commenter mentions the cost of having to comply with the third party testing requirements. Third party certification testing for children's products is required by statute, and the Commission lacks the authority to exclude the commenter's products from the certification testing requirement.

The benefits of third party testing include an assurance of technical competence and objectivity not available through first party testing, or no testing. If neither of these factors could be involved with the commenter's children's products, the commenter may be correct about the lack of a corresponding safety benefit.

Regarding the commenter's statement about there being no lead injuries associated with their products, excessive exposure to lead does not manifest as an ordinary injury, like a fall or a burn. According to the publication, *CPSC Guidance for Lead (Pb) in Consumer Products:* "[t]he effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems."[18]

Comment 91: A commenter (4) asserts that it is difficult to suggest cost-reduction ideas when the CPSC equates "ensuring" compliance with "guaranteeing" compliance. The commenter says the cost of "guaranteeing" compliance is very high and going the "last mile" is being done without considering the actual benefit and the cost of raising the requirement from "ensuring" safety to "guaranteeing" safety. The commenter states:

> If you require a guarantee of "safety", then every shortcut potentially opens up the possibility for "bad" outcomes. The CPSC's apparent strategy to compensate for perceived testing loopholes by making the rules longer and more complex leads to requests for comments like this one, requesting ideas that will inevitably make ornate rules more byzantine and difficult to understand or administer in order to rule out theoretical problems.

Response 91: Section 16 CFR § 1107.20 states that the manufacturer must submit sufficient samples of a product to a third party conformity assessment body to provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of

[18] http://www.cpsc.gov/businfo/leadguid.html.

the children's product to meet all applicable children's product safety rules. The definition of "high degree of assurance" in 16 CFR § 1107.2 is:

> An evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.

This definition does not state or infer that a manufacturer is required to guarantee compliance. A "high degree of assurance" of compliance does not mean that a manufacturer must have certainty that the production units of the product are compliant to the applicable children's product safety rules. The CPSC understands that achieving certainty of compliance for children's products would be prohibitively difficult for most products. Indeed, for children's product safety rules for which compliance is a pass/fail determination, testing for certainty requires a test of every unit produced (an impossible requirement for destructive tests).

Because 16 CFR part 1107 does not require a guarantee of safety, there may be opportunities to reduce the third party testing burden consistent with assuring compliance to the applicable children's product safety rules. In 16 CFR §§ 1107.21(c) and (d), we detail ways to increase the maximum periodic testing interval from 1 year, to 2 or 3 years, respectively. These are allowable means to reduce the third party testing burden consistent with assuring compliance.

Comment 92: A commenter (4) asserts that a publicity campaign and a renewed effort at education is a more efficient way to address the problem of compliance. The commenter notes the third party testing requirements create unnecessary burdens on the majority of good businesses that do obey the law, while the few businesses that plan on breaking the law will remain unaffected by the testing requirements because they never intended to comply with the law. To support this position, the commenter states that most of the improvement in recalls occurred prior to the CPSIA's testing requirements.

Response 92: We agree with the commenter that education and outreach regarding the testing requirements are important parts of compliance. CPSC staff (especially the Office of Compliance and the Small Business Ombudsman) have made efforts to provide guidance to stakeholders through presentations at trade shows, webinars, in-person visits to manufacturing facilities, the CPSC website, and electronic mail and telephone communication. We encourage the Commission to continue to devote resources to this important mission.

The Commission could consider providing information and education activities to assist relevant stakeholders in the implementation of testing programs consistent with the requirements of 16 CFR parts 1107 and 1109.

Comment 93: A commenter (8) proposes the following:

> a) The test(s) by third party are carried out only at the time of the first customs clearance.

b) If the components of products are not changed (from the first submittal), the test(s) by Third Party for every (succeeding) customs clearance does not need to be retested.

Response 93: Staff is not sure what the commenter means by: "first customs clearance article," but we will assume that it means, for the purpose of this response, the first article manufactured outside the United States that is cleared for entry and consumption by U.S. Customs and Border Patrol. If the article is a finished children's product subject to a children's product safety rule, it must be accompanied by a CPC based on testing by a CPSC-accepted testing laboratory. This means that certification testing must have been conducted prior to the product's arrival in the United States. If an importer wishes to procure third party testing on their own, they would have the option of importing only finished product samples to be used for testing in advance of those units intended for distribution in commerce, or use an entity, such as a Foreign Trade Zone, to hold the finished product units until third party testing is completed and a CPC can be issued.[19]

We agree with the commenter that if the product has not changed since initial certification testing, succeeding "customs clearance" shipments representing continuing production do not require separate third party tests or certificates. However, the product is subject to periodic testing by a CPSC-accepted testing laboratory, even if no material changes to the product have been made.

Comment 94: A commenter (11) recommends that the CPSC review the commenter's previously submitted comments on third party testing, and testing and certification, for further details on reducing testing costs.

Response 94: The commenter's previously submitted comments address features of a reasonable testing program for non-children's products, a small-volume exemption in the proposed rule on testing and labeling pertaining to product certification, a suggestion on how to interpret what constitutes a random sample, and a request for a cost-benefit analysis of the proposed rule. The small-volume exception is the only comment that remains a viable option for reducing third party testing burdens, because a reasonable testing program for non-children's products does not require third party testing, the testing of random samples has been replaced with representative samples by statute, and a cost-benefit analysis does not change the fact that the law is required, nor does a cost-benefit analysis reduce costs.

The commenter's small-volume comment states that 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. The commenter adds that, depending upon the internal controls a given manufacturer sets as part of its component and finished product testing program, a frequency of less than 1 sample per 10,000 units produced, in fact, may be appropriate.

The requirements of 16 CFR § 1107.21(b)(1) state that:

[19] Information on Foreign Trade Zones can be found at: http://ia.ita.doc.gov/ftzpage/tic.html.

> 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 CPC, or since the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules.

In a similar manner, 16 CFR § 1107.21(c)(1) states that a production testing plan must ensure continued compliance of the children's product with a high degree of assurance to the applicable children's product safety rules. The section also states:

> 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.

In both of these circumstances, the manufacturer determines the number of samples required to achieve that high degree of assurance. If the manufacturer can achieve a high degree of assurance by testing no more than one product for every 10,000 units of production of a given product, that would be allowed. However, third party periodic testing must be conducted at least once annually, unless the manufacturer has instituted a production testing plan or uses an ISO/IEC 17025:2005-accredited testing laboratory.

Comment 95: A commenter (11) suggests that the CPSC not consider 16 CFR parts 1632[20] and 1633[21] to be children's product safety rules because mattresses are not intended to be used exclusively by children 12 years of age or younger. The commenter states that changing the interpretation of these rules would eliminate the requirement to third party test children's mattresses periodically. Such a result would greatly reduce unnecessary compliance costs for children's mattress manufacturers, and the commenter does not believe this would compromise the safety of these products.

Another commenter (17) recommends that the CPSC redefine a "children's product" to exclude general use products that include versions for children, such as apparel. The commenter cites provisions of the Flammable Fabrics Act (FFA) and asserts that nothing in the FFA suggests that there needs to be a differentiation between adult and children's clothing.

Response 95: The Commission has issued an interpretative rule on the definition of a children's product.[22] Using the guidance on the factors that are considered when evaluating what is a children's product, mattresses intended primarily (not exclusively) for use by children 12 years of age and younger are considered children's products and are subject to the requirements of sections 14(a)(2) and 14(i)(2)(B) of the CPSA. While we agree that if the Commission were to change the interpretation of the definition of a "children's product," this could have an effect on the costs associated with the currently required certification and periodic testing of children's

[20] *Standard for the Flammability of Mattresses and Mattress Pads (FF 4–72, Amended).*
[21] *Standard for the Flammability (Open Flame) of Mattress Sets*.
[22] http://www.cpsc.gov/library/foia/foia10/brief/interpretive.pdf.

mattresses or apparel, such determinations are legal and policy issues that are left up to the Commission to resolve. As we stated earlier in this document, eviscerating the third party testing regime obviously would reduce third party testing costs; however, it would not meet the statutory third party testing requirements, nor would it ensure continued compliance.

Comment 96: A commenter (11) states that the CPSC should not require "periodic flammability testing for both children's and other mattresses . . . given the robust and rigorous nature of the existing flammability standards that mattresses must already meet."

Response 96: Section 14(i)(2)(B)(i) of the CPSA requires periodic testing of children's products. The Commission has determined that mattresses intended for children 12 years of age and younger are "children's products," subject to the mattress standards. For mattresses that are children's products, the mattress standards are children's product safety rules that require third party periodic testing under section 14 of the CPSA. In 16 CFR § 1107.21(a), *Periodic Testing*, it states: "All manufacturers of children's products must conduct periodic testing." Periodic testing is required to ensure continued compliance of continuing production after certification. Furthermore, periodic testing of children's products must be conducted by a CPSC-accepted conformity assessment body. However, there are options for manufacturers to extend the time interval between periodic tests, described in 16 CFR §§ 1107.21(b)-(d). Mattresses other than children's mattresses are not subject to section 14(a)(2) of the CPSA, or 16 CFR part 1107, and thus, do not require third party or periodic testing.

Comment 97: A commenter (11) asserts that the most effective way for the CPSC to reduce testing costs would be to revoke 16 CFR part 1632 because the requirements of 16 CFR part 1633 make 1632 redundant. The commenter states that after testing "hundreds of different mattress prototypes under Part 1633" they realized "that all prototypes that passed the open-flame criteria set in Part 1633 also pass the cigarette-ignition standard embodied in Part 1632." The commenter also highlights that previously, the Commission issued an advanced notice of proposed rulemaking (ANPR) in 2005 on the commenter's comment regarding revoking 16 CFR part 1632. The commenter informs that since publication of the ANPR in 2005, all 50 states have passed laws requiring cigarettes to meet a "Reduced Ignition Propensity" requirement, which improves public safety by significantly reducing the number of fires and related deaths.

Response 97: We have a separate rulemaking at 70 FR 36357 (June 23, 2005), which considers revocation of 16 CFR part 1632. Issues related to the need for 16 CFR part 1632, in light of the existence of a separate mattress standard (16 CFR part 1633), are more appropriate for that proceeding. At this time, staff is not aware of data indicating that 16 CFR part 1633 eliminates or sufficiently reduces the risk of injury from cigarette ignition of mattresses, such that we could recommend revocation of 16 CFR part 1632, without affecting negatively the safety of mattresses.

Comment 98: One commenter (17) recommends that the CPSC not consider children's sleepwear and loungewear to be within the definition of "child care articles" for purposes of phthalates testing, because sleepwear does not facilitate children's sleep, even though the word "sleep" is in the generic name of the garment.

The commenter believes that an examination of the risk profile of the garment itself, not a narrow fixation on the name, should determine whether the article is included in the standard and subject to testing. Moreover, the commenter argues that sleepwear does not fall into any of the congressionally mandated categories for phthalates testing, explaining that Congress defined "child care articles" as those that are intended by the manufacturer to "facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething."

The commenter states that the concept of facilitating sleep in this context involves articles that children suck on in order to fall asleep, such as pacifiers. According to the commenter, the common denominator in these actions is to focus on mouthing articles that might contain one or more of the banned phthalates. The commenter argues that sleepwear is not an article intended to be associated with mouthing. The commenter states that the non-slip padding that is sometimes found on the bottom of kids' footed pajamas—which the CPSC's General Counsel cited in her 2008 letter, and which is likewise the only feature in sleepwear ever noted by CPSC staff—is intended specifically to facilitate walking, not sleeping.

The commenter states that a nearly identical European Union (EU) phthalates ban has a guidance[23] on child care articles, stating that the EU does not consider sleepwear to facilitate sleep. The commenter quotes the EU guidance: "The main purpose of pajamas is to dress children when sleeping and not to facilitate sleep. Pajamas should therefore be regarded as textiles and, like other textiles, do not fall under the scope of the Directive." The commenter states that Canada is working with industry and stakeholders on a similar approach.

Response 98: Section 108(e)(1)(c) of the CPSIA defines a "child care article" as:

> a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.

The Office of the General Counsel has issued an advisory opinion interpreting the term "child care article" to include children's sleepwear. *See* http://www.cpsc.gov/library/foia/advisory/321.pdf Additionally, CPSC staff interprets a product that facilitates sleep as a product intended to have a direct involvement in the child's sleeping environment. Bedding, crib bumper pads, swaddling blankets, and sleepwear are all designed with soft surfaces and either cool or warm fabrics so that the products do not make harsh sounds or irritate the child's skin, keeping them warm or cool, depending upon the season, and thereby, facilitating uninterrupted sleep.

Articles intended for mouthing are included with articles intended for facilitating sleep because children will suck on anything within reach. When children sleep, they are generally not supervised, so anything in their sleep environment could be mouthed, including and especially, sleepwear. Padding on the feet of pajama is designed to keep children's feet warm to facilitate sleep. The padding does not facilitate walking at all; in fact, children walk better on bare feet. (The non-slip treads on footies are put there to facilitate walking, by preventing slipping, but the footies themselves are for warmth to facilitate sleep.)

[23] http://ec.europa.eu/enterprise/sectors/toys/files/gd008_en.pdf.

Comment 99: A commenter (9) proposes establishing a certified manufacturing process as a substitute for third party testing. The commenter asserts that a third party certification body would certify that children's products produced in the certified facility meet the requirements of the applicable children's product safety rules. With this scheme, additional third party testing would not be required.

Response 99: The commenter is referring to a certification body issuing a certification for a factory or a manufacturing system. With this method, the certification body evaluates, tests, inspects, and conducts continuing surveillance activities on the factory or manufacturing system to ensure that the products created by the factory or manufacturing system meet their requirements. The certification body "certifies" the compliance of the products fabricated by the factory or manufacturing system. This certification system includes third party testing and follow-up activities aimed at ensuring continued compliance to the requirements for certification.

While this method has been applied successfully to create consistent, high-quality products, section 14(a)(2) of the CPSA states that samples of a children's product shall be tested at a third party conformity assessment body, and that based on the results of those tests, a CPC shall be issued by the manufacturer. Because the statute requires testing product samples, substitutions, however effective they may be in creating compliant products, are not allowed.

However, staff understands that for some finished products or component parts, certification of a manufacturing process (as opposed to certification of a finished product or component part) may be advantageous to the manufacturer. This type of certification has the potential to ensure initial and continued compliance of finished products or component parts manufactured by the process. Thus, staff recommends that the Commission investigate whether it should request statutory authority to allow manufacturing process certification to be used for children's product certification purposes.

TAB D: Commenters to Docket CPSC-2011-0081

TAB D

Commenters to Docket CPSC-2011-0081

Commenter Number	Commenter	Affiliation	Docket Comment
2	Randy Hertzler	Handmade Toy Alliance	CPSC-2011-0081-0002
3	Darryl Sackmann	Woodworkers Guild of Western Colorado	CPSC-2011-0081-0003
4	Richard Woldenberg	Learning Resources, Inc.	CPSC-2011-0081-0004
5	Wang LiZhou	China WTO/TBT National Notification & Enquiry Center	CPSC-2011-0081-0005
6	Jed Holland and Sally F. Kay	The Hosiery Association	CPSC-2011-0081-0006
7	Bernie Ting	Hong Kong Toys Council	CPSC-2011-0081-0007
8	Takahiro Shirai	Sakura Color Products Corp.	CPSC-2011-0081-0008
9	Polly Law	Consumer Testing Laboratory	CPSC-2011-0081-0009
10	Andre Leroy, Rob Sinclair, Kitty Man and Chris Tang	Global Apparel, Footwear & Textile Initiative	CPSC-2011-0081-0010
11	Christopher Hudgins	International Sleep Products Association	CPSC-2011-0081-0011
12	Satbir Nayar	XOS	CPSC-2011-0081-0012
13	Deborah M. Fanning	The Art & Creative Materials Institute, Inc.	CPSC-2011-0081-0013
14	Gene Rider	Intertek Consumer Goods, NA	CPSC-2011-0081-0014
15	Sheila A. Millar	Fashion Jewelry and Accessories Trade Association	CPSC-2011-0081-0015
16	Kyra M. Mumbauer	Society of the Plastics Industry, Inc.	CPSC-2011-0081-0016
17	Kevin M. Burke	American Apparel & Footwear Association	CPSC-2011-0081-0017
18	Jennifer M. Jaffee	Libbey	CPSC-2011-0081-0018
19	Jim Neill	Retail Industry Leaders Association	CPSC-2011-0081-0019
20	Michael Dwyer	Juvenile Products Manufacturer's Association	CPSC-2011-0081-0020
21	Ed Desmond	Toy Industry	CPSC-2011-0081-0021

		Association, Inc.	
22	August Schaefer	UL LLC	CPSC-2011-0081-0022
23	Courtney Yin Duke	Orbit Baby, Inc.	CPSC-2011-0081-0023