Staff Briefing Package

Consumer Product Safety Improvement Act
Certification & Testing
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I. Table of Contents

(a) Briefing Memo

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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Memorandum

This document has been electronically approved and signed.

Date: APR - 1 2010

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SUBJECT : Requirements for Certification and Continued Testing of Children's Products, Established by the Consumer Product Safety Improvement Act of 2008

I. Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (hereafter referred to as the "Act" or the "CPSIA") was signed into law [Public Law 110-314]. Section 102 of the CPSIA established requirements for third-party testing of children's products that are subject to a children's product safety rule. Section 102(d)(2) of the CPSIA further establishes requirements for additional regulations for third-party testing by stating:

"Not later than 15 months after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall by regulation--

(A) initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements of subsection (a); and

(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;

(ii) for the testing of random samples to ensure continued compliance;

(iii) for verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules; and

(iv) for safeguarding against the exercise of undue influence on a third-party conformity assessment body by a manufacturer or private labeler."

This memorandum presents the CPSC staff's recommendation for establishing these testing requirements. The primary interest of the CPSC staff is to ensure that manufacturers produce safe and compliant products. Testing is not an end in itself, but rather one part of a process to ensure the safety of consumer products. For this reason, CPSC staff believes the primary objective is the determination of whether or not a manufacturer produces safe and compliant products. Where that occurs, CPSC staff believes there is little reason to doubt the reasonableness of a testing program or the high degree of assurance an entity has in its efficacy. On the other hand, where CPSC staff discover unsafe or non-compliant products, staff may have reason to examine a manufacturer's programs and processes. Because CPSC staff recognizes that even the best processes can occasionally yield non-compliant products, staff will be especially concerned with unsafe or non-compliant products emerging from defective processes.

II. Background

Section 14(a)(1) of the Consumer Product Safety Act (CPSA) [15 U.S.C. § 2063(a)(1)], as amended by the CPSIA, establishes requirements for the testing and certification of products subject to a consumer product safety rule under the CPSA or similar rule, ban, standard, or regulation under any other Act enforced by the

Commission (hereafter referred to as applicable rules) and which are imported for consumption or warehousing or distributed in commerce. Under this subsection, manufacturers and private labelers must issue a certificate which "shall certify, based on a test of each product or upon a reasonable testing program, that such product complies with all rules, bans, standards, or regulations applicable to the product under the CPSA or any other Act enforced by the Commission." This requirement is referred to as General Conformity Certification.

Requirements for the certification of children's products are found in section 14(a)(2) of the CPSA [15 U.S.C. § 2063(a)(2)]. The CPSA defines a children's product as a consumer product designed or intended primarily for children 12 years of age or younger.[1] This category of consumer products is vast and diverse. It includes toys, children's books, cribs, high chairs, baby walkers, strollers, children's jewelry, youth ATVs, bicycles, and children's wearing apparel, to name but a few. Before a manufacturer or private labeler may import or distribute in commerce any children's product subject to a children's product safety rule (as defined in section 14(f)(1) of the CPSA), it must submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to a CPSC-recognized third-party conformity assessment body to be tested for compliance with the applicable children's product safety rules. Based on such testing, the manufacturer or private labeler must issue a certificate that affirms that such children's product complies with the applicable children's product safety rules.

The Commission published a final rule, 16 CFR Part 1110, in the *Federal Register* on November 18, 2008, limiting the persons required to comply with the certification requirements of section 14(a) of the CPSA to the importer in the case of products manufactured outside of the United States and to the domestic manufacturer in the case of products manufactured within the United States. In this memorandum, an importer or domestic manufacturer required to certify products is referred to as a certifier.

[1] Section 3(a)(2) of the CPSA [15 U.S.C. § 2052(a)(2)]

Section 14(d)(2)(A) of the CPSA, as amended by the CPSIA, also requires the Commission to initiate, by regulation, a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements for consumer and children's products.[2] Such a program for labeling a consumer product, including children's products, as compliant with all applicable product safety requirements, is based on the requirements for issuing a certificate, as specified in section 14(a) of the CPSA [15 U.S.C. § 2063(a)].

Section 14(d)(2)(B) of the CPSA requires the Commission to establish protocols and standards for: (1) ensuring that a children's product subject to a children's product safety rule undergoes periodic testing; (2) testing when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts; (3) testing random samples to ensure continued compliance; (4) verifying that a children's product tested by a CPSC-recognized third- party conformity assessment body complies with applicable children's product safety rules; and (5) safeguarding against the exercise of undue influence on a third-party conformity assessment body by a manufacturer or private labeler.[3] These requirements for certifiers of children's products are meant to ensure continued compliance of children's products to the applicable children's product safety rules.

Most affected certifiers will experience a cost increase to test, certify, and, if they choose, label their product as compliant. However, implementing a reasonable test program for non-children's products and requiring certification and periodic testing for children's products may greatly reduce the likelihood that non-compliant products will be introduced into the marketplace, which can lead to recalls, lessened consumer confidence in those products, and enforcement actions by the CPSC. Certifiers of consumer products, particularly those that produce small quantities of a product or unique one-of-a-kind custom products, may encounter problems if CPSC mandates a

[2] Section 14(d)(2)(A) of the CPSA [15 U.S.C. § 2063(d)(2)(A)]
[3] Section 14(d)(2)(B) of the CPSA [15 U.S.C. § 2063(d)(2)(B)]

one-size-fits-all testing program. CPSC staff wants to ensure the reasonable testing program's and the certification and periodic testing program's integrity and sustainability while, at the same time, ensuring consumer confidence in the products, including those that bear a label identifying the product as complying with all applicable rules.

III. Consumer Product Labeling Program

Section 14(d)(2)(A) of the CPSA requires the Commission to initiate a program by which a manufacturer or private labeler may label their products as complying with the certification requirements. This program applies to non-children's and children's products.

Consumer products made available on the market may bear the label if compliant with all the rules, bans, standards, or regulations applicable to the product under all Acts enforced by the U.S. Consumer Product Safety Commission. Only the party certifying the product's compliance, or their authorized representative, may affix the label to the consumer product and the marking shall be affixed before the consumer product is placed on the market. The authorized representative is a person designated by the certifier to affix the label. For example, an importer may designate by contract a foreign manufacturer to add the label during the production process to a product made exclusively for the importer.

The label would consist of the text in English "Meets CPSC safety requirements" taking the following form:

Meets CPSC safety requirements

The label would be printed in bold typeface, mixed upper and lowercase characters , using a sans serif font (such as Arial) of no less than 12-points. The label would be marked visibly, legibly, and indelibly. It would be affixed to the product packaging or, if there is no packaging, to the product or on a tag or other material included with the

product. These requirements were chosen to be consistent with the recommendations of ANSI Z535.4-2007, *American National Standard for Product Safety Signs and Labels*. The selection of these label characteristics aids the readability and comprehension of the CPSC marking for consumers.

Any other marking may be affixed to the product provided that the visibility, legibility, and meaning of the label are not impaired. The label's visibility may help the consumer recognize and understand its meaning.

IV. General Conformity Certificate for Non-Children's Products

Section 14(a) of the CPSA requires every manufacturer, importer, or private labeler of a non-children's product which is subject to a consumer product safety rule under the CPSA or a similar rule, ban, standard, or regulation under any other Act enforced by the Commission to certify, based on a test of each product or upon a reasonable testing program, that such product complies with all the applicable rules. The Commission has issued a rule specifying that only domestic manufacturers and importers are required to furnish these certificates [16 C.F.R. section 1110.7].

A. Reasonable Testing Program

A reasonable testing program for non-children's products serves as the basis for issuing the general conformity certificate. A reasonable testing program is a program that, when structured with appropriate specifications, measurements, controls, and test intervals, will provide a high degree of assurance that all consumer products covered by the program will comply with all the requirements of the applicable rules.

A reasonable testing program for non-children's products serves as the basis for issuing the general conformity certificate. A reasonable testing program is a program that, when structured with appropriate specifications, measurements, controls, and test intervals, will provide a high degree of assurance that all consumer products covered by the program will comply with all the requirements of the applicable rules. A high degree of assurance is defined as an evidence-based demonstration of consistent performance of the product with respect to compliance based on knowledge of a product and its

manufacture. As an example, a high degree of assurance could mean a testing plan and test results that demonstrate at least a 95% probability that all of a product produced complies with the applicable rules, bans, standards, and regulations. The Commission is not mandating that a certifier's reasonable testing program meet a 95% statistical level, but that the manufacturer defines its basis for achieving a high degree of assurance in its product's compliance to the applicable rules. There are many ways to do this and the example above is one consideration that may apply to certain manufacturers. Because the reasonable testing program is necessary to issue a general conformity certificate (where a test of each product is not undertaken), the certifier is responsible for the plan's establishment. All the elements of the reasonable testing program should be in place, and certification tests completed with passing results before the general conformity certificate can be issued for a product.

There are alternative definitions for a high degree of assurance. One definition is that for quantitative tests, a high degree of assurance is required to be at least a 95% probability that all the product produced meets the requirements of the applicable rules; and for non-quantitative (pass/fail) tests, a high degree of assurance would mean a 95% confidence that at least 95% of the product produced meets the requirements of the applicable rules. The 95% level was chosen because this level is widely used in the natural and social sciences as the minimum acceptable probability for determining statistical significance and has been found to be effective[4][5][6]. In the previous example, a 95% or greater probability would be required using this alternative definition. For a non-quantitative test, a method such as the "rule of three"[7] could be used to determine the number of samples needed for testing. For a 95% confidence that no more than 5% of the production fails to comply, 3/0.05 = 60 units will be needed for testing. For small production volumes where 60 samples would be considered excessive, other methods can be used. This alternative definition was not chosen because there may be difficulty

[4] Fisher, R. A., Statistical Methods for Research Workers, Edinburgh: Oliver & Boyd, 1925.

[5] Cowles, M., and Davis, C., On the Origins of the .05 Level of Statistical Significance, American Psychologist, 1982, Vol. 37, No. 5, pp. 553-558.

[6] Ayres, I., Ayres-Brown, A., Ayres-Brown, H., Seeing Significance: Is the 95% Probability Range Easier to Perceive?, CHANCE, 2007, Vol. 20, No. 1, pp. 11-16.

[7] Jovanovic, B.D., Levy, P.S., A Look at the Rule of Three, American Statistician, 1997, Vol. 51.pp 137-139.

in applying the statistical methods to all manufacturing processes involved in children's and applicable non-children's products, such as continuous-flow methods. Some CPSC staff regard the probability determination as a manufacturer's (not the CPSC's) prerogative, based on multiple factors such as severity of noncompliance, cost, and past compliance performance. Further, manufacturers of small volumes of a product may have particular difficulty in implementing a statistically-based testing program.

Certain non-children's product standards issued by the Commission already contain product-specific testing programs that were developed by the Commission at the time the standard was issued and for which certification has been required. For the applicable rules that 1) contain testing requirements, and 2) do not contain specific testing programs, the reasonable testing program establishes the minimum set of requirements to be met for compliance.

For the remaining applicable rules, the implementation of reasonable testing programs will vary depending on the product under consideration and the compliance characteristics being tested. Persons issuing general conformity certificates should use their due care in developing and implementing a reasonable testing program that demonstrates that their products comply with the applicable rules. *Black's Law Dictionary* considers the term "reasonable care" to be synonymous with "due care" and defines the term 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."

For consumer products subject to an applicable rule without a specified testing program, a reasonable testing program should contain, at a minimum, five elements. Staff examined other CPSC regulations (including omnidirectional citizens band base station antennas, walk-behind lawn mowers, and automatic residential garage door openers) and found that these elements are common features of reasonable testing programs that CPSC has found to be effective. These elements are necessary to demonstrate a product's compliance with the applicable rules, initially and as production continues. Because the reasonable testing program applies to a wide variety of product types and

manufacturing processes, it is defined to be scalable to production volumes and adaptable to the specifics of the product, whether one-at-a time, in a production line, by continuous-flow processes, or by other means.

The scope and details of each of the five elements should be developed by the certifier based on its knowledge and expertise of the product and its manufacturing processes. The following sections describe each of the five elements of a reasonable testing program further, including the scope of each element and what it must encompass. Some of the features of these elements are discussed in the CPSC Handbook for Manufacturing Safer Consumer Products (http://www.cpsc.gov/businfo/intl/handbookenglishaug05.pdf).

1. Product Specification

A general conformity certificate is issued for a specific product and lists the applicable rules as specified in section 14(a)(1)(B) of the CPSA. A product specification is a document that describes the consumer product and lists the applicable rules with which the product must comply. The product specification establishes the product identity for a specific certificate. Certifiers should ensure that each consumer product subject to an applicable rule is described in a written product specification before distributing the product in commerce.

The product specification should describe the consumer product subject to the certification testing and any further information, such as, but not limited to, a color photograph or illustration, model names or numbers, a detailed bill of materials (a list of the raw materials, sub-assemblies, intermediate assemblies, sub-components, components, parts, and the quantities of each needed to manufacture a final product)[8], a parts listing, raw material selection and sourcing requirements, and other information necessary to adequately identify the product, and differentiate it from other products. If a certifier wishes to use component-level ore subassembly testing to demonstrate

[8] Reid, R. Dan; Sanders, Nada R. (2002). Operations Management. John Wiley & Sons. pp. 457–458. ISBN 0-471-32011-0, and Monk, Ellen; Wagner, Bret (2009). Concepts in Enterprise Resource Planning. Course Technology Cengage Learning. pp. 97–98. ISBN 1-4239-0179-7.

compliance to an applicable rule, that component or subassembly should be listed on the product specification.

Products that are not materially different may have the same product specification. Materially different means that the differences between items could affect compliance with the applicable rules, such as differing compositions in components or differing assembly techniques. An example of a difference that is not material would be several sizes of the same article of clothing made with the same materials and assembly processes. If the features that are being considered as not materially different are addressed and described in the product specification, all products manufactured with those features can use the same product specification. Such features may include the range of sizes, colors, or other features that the certifier believes cover the breadth of variations of the product where differences do not affect the compliance with applicable rules. A change in the product design, manufacturing process, or sourcing of component parts that a certifier exercising due care knows, or should know, could affect the product's ability to comply with the applicable rules is a material change that necessitates the creation of a separate product specification for that changed product. Because it cannot be assumed that units of the same product manufactured in more than one location are identical in all material respects, the certifier must have a separate product specification for the product for each manufacturing site. Each product specification requires a separate general conformity certificate(s).

2. Certification Tests

For both a reasonable testing program and a test of each product, tests for compliance to the applicable rules are necessary before a general conformity certificate can be issued. A certification test is a test performed on samples of the product that are identical to the finished product in all material respects to demonstrate that the product is capable of passing the tests prescribed by the applicable rules. Identical in all material respects means there is no difference with respect to compliance to the applicable rule between the samples and the finished product. The certification tests provide evidence that compliance to the applicable rules has been achieved by the

product described in the product specification. Certification tests as part of a reasonable testing program are the alternative to a test of each product produced, as specified in section 14(a)(1)(A) of the CPSA. If a sample submitted for testing is not identical in all material respects to the finished product for the purposes of certification testing, there is no assurance that products acquired by consumers will also be compliant to the applicable rules. This requirement also applies to samples of children's products supplied for certification testing.

The certifier should submit sufficient samples to provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the finished product to meet all applicable rules. Knowledge of the product design and the certifier's ability to control the variables associated with producing complying products should determine how many samples are required for testing compliance to the applicable rules. For processes that consistently create highly similar parts, like die casting, fewer samples may be required to provide a high degree of assurance that the finished product complies with the applicable rules. For manufacturing process with greater inherent variability, like hand assembly, more samples may be required to demonstrate compliance.

In some circumstances, component-level testing or testing on portions of the product can be substituted for finished product testing. If the component part, without the remainder of the finished product, is sufficient to determine compliance, such as testing a paint for lead content, the entire product is not required for those tests. However, compliance to some applicable rules will always require the entire product. For example, testing a walk-behind power lawn-mower requires the entire mower because some tests require the entire mower to be moved across obstructions, and the weight of all the parts is needed to accurately determine how the mower responds to the obstructions. Other tests require the interaction of several separate subsystems to demonstrate compliance and will require the finished product for testing. The certifier must be able to show how the combination of component testing, testing on portions of

the finished product, and testing on finished product samples, combines to demonstrate compliance with all the applicable rules.

A certifier of non-children's products may choose to use a third party conformity assessment body for certification testing. Such conformity assessment bodies, when used to test a non-children's product, are not required to be a CPSC-recognized third party conformity assessment body qualified to test children's products.

For a previously-certified product that undergoes a material change (necessitating the development of a new product specification) that does not affect the finished product's ability to comply with an applicable rule, certification testing of the new product may be limited to using the certification tests of the previously-tested product and tests of the changed component, material, process, etc., to demonstrate that the changed product is capable of meeting all applicable rules. For example, if a material change is limited to using a different paint on the product, new certification testing of that product may be limited to evaluating the paint to the applicable safety rules. However, if the material change to the product affects the entire product's ability to meet an applicable rule, for example, a change to an all-terrain vehicle's service brake, sample(s) of the complete all-terrain vehicle will be needed for certification tests. Certifiers must exercise due care to ensure that reliance on anything other than re-testing the finished product, such as component level testing, after a material change to the product does not introduce a noncompliant product into the stream of commerce.

If the certifier obtains failing results on one sample of the product even though other samples passed the same test, the certifier must not certify the product until the certifier establishes a high degree of assurance that the product does in fact comply with all applicable rules. If a sample of the product failed a certification test, the certifier must identify the nonconforming features of the product and take remedial action.

3. Production Testing Plan

A production testing plan is a set of procedures and processes intended to demonstrate that consumer products manufactured after certification continue to comply with the applicable rules. This can be achieved by recurring testing or the use of process management techniques designed to control potential variations in new product that could affect the product's compliance to the applicable rules. The production testing plan and test data show that the products being produced are the same (with respect to compliance) as the product identified on the general conformity certificate.

Certifiers shall exercise due care to develop a production testing plan to assure that new product (new production of items with the same product specification) is the same with respect to compliance as the product that passed the certification testing and to demonstrate that the product being manufactured meets the requirements of the applicable rules.

A certifier may choose one or a number of measurement methods, which may be non-destructive in nature, that can be used in lieu of actual product performance tests and tailored to the needs of the individual products to assure compliance with applicable rules. Certifiers must exercise due care to ensure that the production tests used to monitor compliance provide a high degree of assurance that noncompliant products are not introduced into the stream of commerce. A certifying party must be able to show that their production tests are capable of detecting noncompliant products as effectively as the tests used in certification testing. For example, if the probability that all production products are compliant using the tests used for certification is 95%, the probability that all production products are compliant using alternative testing methods should be at least 95%. If there is uncertainty that the test method will achieve the same level of discrimination of compliance or noncompliance with the applicable rules, the specific tests required by the applicable rules should be used.

The plan should describe the tests or measurements that will be made as part of this program, the intervals at which the tests or measurements will be made, the number of samples to be tested, and the basis that such tests provide a high degree of assurance

of compliance if they are not the tests described in the applicable rule. Because it cannot be assumed that production units of the same product manufactured in more than one location are identical in all material respects, the certifier must have a separate production testing plan for the product for each manufacturing site.

Certifiers must also exercise due care in selecting testing intervals between production tests that are short enough to ensure that if the samples selected for testing meet the applicable rules, there is a high degree of assurance that all the untested production products will also meet the applicable rules. The intervals at which the tests are conducted or measurements made should also be appropriate to the specific tests being conducted. Knowledge of the product design and manufacturing process should be used to determine the proper interval of production tests on a per rule, ban, standard, or regulation basis. Some tests, such as for lead content, might be more appropriately conducted on the component parts before they are incorporated into the final product. However, the certifier is responsible for assuring that the component parts are not subjected to any contamination or degradation that could affect compliance after testing, and during assembly. For small quantities or unique one-of-a kind products, certifiers may be able to rely on production and testing of similar products or processes used in the past as long as there is sufficient data to assure the small number of products or single product will meet the applicable rules.

4. Remedial Action Plan

A remedial action plan is a set of procedures describing the steps to be taken whenever samples of the consumer product or results from any other tests used to assess compliance yield failing results. Failing results are evidence that the product produced is not the same (for compliance purposes) as the product specification for which certification tests were conducted. Thus, the general conformity certificate no longer applies to any product produced since the last set of passing test results. The remedial action plan is necessary to re-establish that products being produced are the same as those tested in the certification tests, and that the general conformity certificate applies to this production.

If any tests yield failing results, remedial action can include redesign, changes in the manufacturing process, or changes in component part sources, such that the finished product meets all of the applicable rules. For failing production tests, remedial action could also include reworking the product already produced. Re-testing (certification tests or production tests) of the redesigned, reworked, or repaired product will be necessary to assure compliance. Assuming that a product that has not passed the certification testing has not been introduced into commerce, there is no need to report the failure to the CPSC. If some or all of the manufactured/imported product associated with the failing results, such as the production since the last production tests, has already been distributed in commerce, the certifier must notify CPSC (per the requirements of section 15(b) of the CPSA). Details of how to report to the CPSC are found at https://www.cpsc.gov/cgibin/sec15.aspx.

The remedial actions must provide a high degree of assurance that all consumer products produced after the corrective action will comply with the applicable rules. The procedures for a remedial action plan may be different for each rule, standard, ban, or regulation applicable to the product.

If any remedial action required by this section results in a material change, that change will require the preparation of a new product specification. The new consumer product should be subjected to certification tests and must yield passing results.

5. Recordkeeping Requirements

Documentation is necessary to establish the identity of the product, and show that the product complies with the applicable rules, both initially, and continually as production progresses. The documentation establishes the applicability of the general conformity certificate to the product and provides validation that a test of each product produced is not required. The documentation should include the other elements of the reasonable testing plan, the certification and production test data, and implementation details of the remedial action plan in each event of its use.

Each certifier of a consumer product subject to an applicable rule should establish and maintain the following records which should be available to any officer or employee duly designated by the Commission upon request in accordance with section 16(b) of the CPSA (15 U.S.C. 2965(b)), and 16 CFR Part 1110:

- A copy of the general conformity certificate(s) for each product;
- A record of each product specification containing all information described in section IV.A.1 of this document below;
- Descriptions of how the product was certified as meeting the requirements, such as how each requirement was evaluated, the conformity assessment bodies that conducted the tests (if used), the test results, and the actual values of the tests, as described in section IV.A.2 of this document below;
- Records to demonstrate compliance with the requirements for the production testing plan in section IV.A.3 of this document below, including an itemization of the applicable rules, a description of the types of production tests conducted, the number of samples tested, the production interval selected for performance of each test, and the test results. The production test program documentation should show how the production tests used demonstrate that the continuing production complies to the applicable rules with a high degree of assurance. For

example, references can be made to the techniques in relevant quality management and control standards such as ANSI/ISO/ASQ Q9001-2008: Quality management systems – Requirements, ANSI/ASQ Z1.4-2008: Sampling Procedures and Tables for Inspection by Attributes, and/or ANSI/ASQ Z1.9-2008: Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming, as a means of showing that the production tests have the necessary accuracy, precision sensitivity, repeatability, and/or confidence to distinguish complying and noncomplying products. These standards are widely-recognized in industry and were developed by organizations with international exposure and millions of members. Retaining test results can help identify the events that led to the creation of noncompliant products, the number of products affected, and their disposition;

- Records of all remedial actions taken in accordance with section IV.A.4 of this document below, including the specific action taken, the date the action was taken, the person who authorized the actions, and any test failure which necessitated the action. Records of remedial action must relate the action taken to the product specification of the consumer product which was the subject of that remedial action, and the product specification of any new product which results from any remedial action.
- The records must be available in English. The product specification and the general conformity certificate must be maintained for as long as the product is being distributed plus 3 years. Other records must be available in English and should be maintained for 3 years after their generation. The purpose of records being kept for 3 years is to ensure that the products have time to clear the distribution channels and get into consumer use. If there is a compliance problem in a product, 3 years should be sufficient to uncover any problems with the product. The Commission's staff would have time to obtain the records to review the firm's reasonable testing program and take any necessary enforcement action during this 3-year period.
- A new product specification will initiate a record set for the new product.
- The records should be kept in the main office of the certifier.

Requests for confidentiality of records provided to the Commission will be handled in accordance with section 6(a)(2) of the CPSA (15 U.S.C. 2055(a)(2)), the Freedom of Information Act as amended (5 U.S.C. 552), and the Commission's regulations under that act (16 CFR part 1015).

For non-children's products, at the option of the certifier, some or all of the testing for the reasonable testing program may be performed by a third-party testing laboratory. A manufacturer that uses a third-party testing as part of a reasonable testing program for a non-children's product is not required to use a CPSC-recognized conformity assessment body.

The certifying party should use due care to ensure that all testing used to support the general conformity certificate has been properly performed with passing results and is responsible for maintaining all records of such tests in accordance with the recordkeeping requirements noted above.

V. Children's Product Certification

Section 14(a)(2) of the CPSA requires that all certifiers of children's products to certify that the children's product conforms to all applicable children's product safety rules and that this certification be based on the results of testing by a CPSC-recognized third-party conformity assessment body accredited to perform such tests.

For children's products, before any domestic manufacturer or importer begins importing for consumption or warehousing or distribution in commerce, sufficient samples of the children's product or samples that are identical in all material respects to the product must be tested for compliance with the applicable rules by a CPSC-recognized third-party conformity assessment body. Sufficient samples means the certifier should submit enough samples to provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the product to meet all applicable rules. Knowledge of the product design and the certifier's ability to control

the variables associated with producing complying products should determine how many samples are required for testing compliance to the applicable rules. For processes that consistently create highly similar parts, like die casting, fewer samples may be required to provide a high degree of assurance that the finished product complies with the applicable rules. For manufacturing process with greater inherent variability, like hand assembly, more samples may be required to demonstrate compliance. Based on passing results from such testing, the domestic manufacturer or importer may issue a children's product certificate for the product.

In some circumstances, testing on portions of the product, or component-level testing can be substituted for finished product testing. If the portion or component, without the remainder of the finished product, is sufficient to determine compliance, such as testing a plastic part for lead or phthalate content, the finished product is not required for those tests. If the only test required for a product is for sharp edges on one portion of the product, the finished product is not required to determine compliance. However, compliance to some applicable rules will always require the entire product. For example, crib tests require testing the entire crib.

If the certifier obtains failing results on one sample of the product, even though other samples passed the same test, the certifier must not introduce the product into commerce until it establishes a high degree of assurance that the finished product does in fact comply with all applicable rules. If a sample of the product failed a certification test, the certifier should identify the nonconforming features of the product and take remedial action. Assuming that a product that has not passed the certification testing has not been introduced into commerce, there is no need to report the failure to the CPSC.

VI. Additional Regulations for Third-Party Testing of Children's Products

As noted earlier, section 14 (a)(2) of the CPSA requires product certification based on successful third-party testing for compliance with the applicable children's product safety rules. Requirements under section 14(d)(2)(B) of the CPSA require additional testing periodically and when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts. To ensure that all children's products have been tested for conformance to all applicable children's product safety rules as required by section 14(a)(2) of the CPSA, these tests must be conducted by a CPSC-recognized third-party conformity assessment body.

A. Periodic Testing of Children's Products

Children's products in production (after being certified as compliant with the applicable children's product safety rules, based on third-party conformity assessment body tests) are subject to testing periodically by a CPSC-approved third-party conformity assessment body. The certifier is not required to use the same conformity assessment body that performed the initial tests to support the product's certification, but may use any CPSC-recognized conformity assessment body accredited to test for the children's product safety rules applicable to the particular product.

A certifier of a children's product may implement a reasonable testing program as described above to establish a high degree of assurance that continuing production of the children's product complies with the applicable rules. In the absence of a reasonable testing program, third-party periodic testing should be structured to provide such assurance. The amount of required third-party testing will vary depending on whether the certifier implements a reasonable testing program for its children's product.

1. Periodic Testing of Children's Products with a Reasonable Testing Program

Periodic testing of children's products should be performed by a CPSC-recognized third-party conformity assessment body accredited to perform such tests. For a certifier

who has voluntarily implemented a reasonable testing program for their product as described in section IV of this document, the reasonable testing program would establish a high degree of assurance that continued production complies with the applicable rules. Third party periodic testing complements and confirms the rigor of the production testing plan portion of the reasonable testing program. Because periodic testing is not required by itself to establish a high degree of assurance that continuing production complies with the applicable rules, the frequency of third party periodic testing is likely to be less than if there were no reasonable testing program implemented.

With the production testing plan providing a high degree of assurance of compliant products, the minimum frequency for the periodic testing is once per year. A yearly periodic test frequency is chosen as the minimum because this will include seasonal production of children's products and many product purchasing cycles are annual in nature. For some children's product safety rules, ensuring continued compliance may require more frequent periodic testing than for other rules. Manufacturers may wish to conduct periodic tests on their products more often. More frequent periodic testing may identify non-compliant products more readily than less frequent tests and may help limit the scope of any potential recall activity. More frequent testing may reduce the firm's liability for damages resulting from a non-compliant product, reduce potential damage to a firm's reputation, or increase the firm's confidence in a newly-implemented reasonable testing program's effectiveness.

2. Periodic Testing of Children's Products Without a Reasonable Testing Program

Certifiers of children's products should perform third party periodic tests for each rule, ban, standard, or regulation applicable to their products.

Certifiers shall exercise due care to develop a periodic test plan to assure that newly manufactured children's products are materially the same with respect to compliance as the product that passed the certification testing. The plan should list the tests that will be conducted, the intervals at which the tests will be conducted, the

number of samples tested, and the basis by which such a testing structure provides a high degree of assurance of compliance. The periodic testing plan and test results should demonstrate that the manufacturing process consistently produced products compliant with the applicable children's product safety rules in the interval since certification (for the first periodic tests) or the last set of periodic tests conducted. Because it cannot be assumed that production units of the same product manufactured in more than one location are identical in all material respects, the certifier must have a separate periodic test results for the product for each manufacturing site.

The certifier should exercise due care in conducting periodic testing at intervals short enough to provide a high degree of assurance that, if the samples selected for testing pass the periodic tests, all other untested children's products produced during the interval between periodic tests (or since certification, for the first periodic tests) meet the applicable children's product safety rules. Because the manufacturing process may control compliance to different children's product safety rules to varying degrees, the period for determining continued compliance to one rule may not be the same as the period chosen for another rule. For example, the intervals selected to test for small parts where there is variability in the factors assuring that no small parts are created, and for lead in paint, where one tested container is used for a large production volume; may not be the same. Assuring that products do not generate small parts may require more frequent testing than that required to assure that the paint used does not contain lead in excess of the acceptable limits. When a children's product certificate is issued, the timing for the interval between periodic tests begins.

An appropriate testing interval may vary for a certifier depending on its knowledge of the product and manufacturing processes. As periodic testing is intended to assure continued compliance, the certifier should consider these factors in determining the interval:

- High variability in test results, as indicated by a relatively large sample standard deviation in quantitative tests, should result in shorter intervals.

- Measurements that are close to the allowable numerical limit for quantitative tests should result in shorter intervals.
- Known manufacturing process factors that affect compliance should result in intervals adjusted to the process factors. For example, if calibration of a machine used in manufacturing a children's product affects compliance, the frequency of periodic testing may be increased before a re-calibration servicing and decreased immediately afterwards.
- Consumer complaints or warranty claims that indicate potential noncompliance should result in shorter intervals.
- Non-material changes may be used as a factor in determining the interval. Examples of such non-material changes include, but are not limited to:
  - Manufacturing or component/subassembly lot changes
  - A fixed volume of production can be chosen as the interval for periodic testing.

Other factors necessary or appropriate to consider, in the exercise of due care, which may influence a particular product's ability to comply with applicable product safety rules should be considered in determining the testing interval. Periodic testing should be more frequent if the following situations apply to the children's product:

- Noncompliance may result in serious bodily injury[9] or death.
- The number of products produced annually is very large, leading to a very wide distribution of the product.
- Products are dissimilar from other products with which the certifier is familiar and/or have many different components than other products.
- Noncompliance cannot be determined easily, such as by visual inspection.

If a material change is instituted on a product during the interval between periodic tests, the periodic tests must determine with a high degree of assurance that both the product

[9] Bodily injury that involves a substantial risk of death, unconsciousness, extreme physical pain, protracted and obvious disfigurement, or protracted loss or impairment of the function of a bodily member, organ, or mental faculty. 18 USC, Part I, Chapter 65, §1365(h)(3).

production before and after the change was instituted complies with the applicable rules.

3. Periodic Tests of Low-Volume Children's Products

Staff believes that certifiers of low-volume (less than 10,000 units) children's products should not be required to conduct periodic testing on products until 10,000 units of that product have been produced since the last CPSC-recognized third-party conformity assessment body testing of that product. This includes both small domestic manufacturers and importers with low production and large domestic manufacturers or importers producing small amounts of particular children's products. The rationale for this value is found in Appendix A. This does not relieve the low-volume certifier of the requirement to obtain CPSC-recognized third-party conformity assessment body test results for the initial certification tests and when there has been a material change in the product and does not relieve the low-volume certifier from complying with any statutory or regulatory limits for a substance in the product. For example, a small manufacturer who may be considered to be a low-volume manufacturer must still have all its products comply with the lead limits for children's products.

B. Testing of Random Samples

The purpose of testing randomly-selected samples is to ensure continued compliance to the applicable children's product safety rules. Therefore, the samples chosen for periodic testing should be selected using a process that assigns each sample in the production population since initial certification or the previous periodic test an equal probability of being selected. This is known as a simple random sample.[10] For greater assurance of compliance, additional samples may be selected based on the certifier's knowledge of the product and its production. For example, if a certifier knows its control over compliance degrades with continuing production, the certifier may want to always test the last unit produced. The certifier may have to determine (using a procedure that randomly selects items from a list) which samples are the random samples used for

[10] Cochran WS (1977), *Sampling Techniques, 3rd Edition.* John Wiley and Sons, NY, page 18.

periodic testing before production of a children's product begins in a period. Then, as those production units are made or imported, they are selected for testing as they become available. For example, if the planned production quantity in a period is 50,000, and 12 random samples are to be selected for periodic testing, before the products are made, a random process identifies which 12 of the 50,000 will be selected for periodic testing. If the products continue to be distributed in commerce as they are manufactured, the certifier may wish to test the samples as they are selected to minimize the potential quantity of noncompliant products in circulation if a test returns failing results.

The sample is whatever is being tested, whether it is the finished product, a portion of the product, or a component part of the product. The population of products/samples under consideration is that quantity manufactured/imported since the last periodic test (or since certification for the first periodic test).

There are alternative definitions for the phrase "random samples." One alternative definition is that a random sample is a sample not intentionally identified beforehand for testing. Another possible definition is that a random sample adequately represents the production sample pool from which it was chosen. Neither alternative was chosen because the purpose of random sampling is to establish a basis for inferring compliance on untested products from a set of tested products. If the products selected for testing are not randomly selected, there is no statistical basis for inferring the performance of the untested products. Another intent of the alternative definitions was to avoid the potential problem of the "golden sample," a production unit known beforehand to be compliant, but possibly unrepresentative of other production units. Random sampling also avoids the potential problem of golden samples.

C. Material Changes

To repeat, a material change is a change in the product design, manufacturing process, or sourcing of component parts that a certifier exercising due care knows, or should know, could affect the product's ability to comply with the applicable rules. Whenever a

children's product undergoes a material change in its product design or its manufacturing process, including the sourcing of component parts, sufficient samples of the changed product must undergo third-party testing by a CPSC-approved conformity assessment body to provide a basis for the issuance of a children's product certificate for the product. Only the applicable rules affected by a material change require testing.

Non-material changes, for example, creating several sizes of a children's garment using the same materials and assembly techniques, do not affect compliance to any applicable rules. Changes that eliminate a children's product's need to comply with a children's product safety rule are not considered to be a material change. For example, replacing the carbon steel on a product with stainless steel would not be considered a material change because stainless steel does not contain lead and under 16 CFR 1500.91(e)(1), certain stainless steels have been determined to not exceed the lead limits under section 101(a) of the CPSIA.

If a supplier tests components using a CPSC-recognized third-party conformity assessment body and issues a certificate for the component or provides a copy of the test data, that certificate or test data, combined with any other required CPSC-recognized third-party conformity assessment body tests, can serve as the basis for a certifier to issue its children's product certificate.

If the material change is limited to a component, the basis for issuing a children's product certificate could be the CPSC-recognized third-party conformity assessment body tests on the earlier (pre-changed) product plus third-party conformity assessment body tests of the changed component. For example, if the paint is changed on a children's product, the basis for issuing a children's product certificate may be based on previous product testing plus tests on the new paint for compliance to lead, heavy metal, and phthalate concentrations. Certifiers must exercise due care to ensure that reliance on anything other than re-testing the finished product after a material change does not result in a noncompliant product. Certifiers should exercise due care to ensure that any component undergoing component-level testing must be the same as the

component on the finished product in all material respects. Contamination or degradation of components could result in noncompliant finished products.

1. Product Design

The product design includes all of the component parts, their composition, and their interaction and functionality when assembled. The applicable rules are determined for the finished product, as received by the consumer. Thus, if a children's product has a component that contains lead or has a sharp edge, but is inaccessible when assembled, then the lead content or sharp edge rule would not be applicable for that finished product. Changes to the product design may introduce newly applicable rules. For example, if a wooden button on a children's product is replaced with a plastic button, the component part previously excluded from testing for lead content has been replaced with a component part that requires testing and the lead content rule is now applicable to the product. The certifier should evaluate the effects of each change made to the product to determine if the change is material. Changes in component parts could constitute a material change if either the part or its effect on the finished product affects compliance. The wooden-to-plastic button example is a material change for lead content. Further, the plastic button may perform differently than the wooden button with respect to creating a small parts hazard for the finished product. Another example of a component change that could affect the finished product is a change that exposes a previously-inaccessible sharp edge.

2. Manufacturing Process

The manufacturing process consists of those techniques, fixtures, tools, materials, and personnel used to create the components and assemble the finished product. For each change in the manufacturing process, the certifier should exercise due care to determine if compliance to an existing applicable rule could be affected, or if the change results in a newly-applicable rule. For example, if a new technique is instituted to fasten buttons to a doll's dress, the small parts applicable rule may be affected, and the change is a material change. If new solvents are used to clean equipment employed in the manufacture of children's products, rules regarding lead content and phthalates

could be affected, and the use of the new solvents is a material change. If a new mold for an accessible metal component of a children's product is introduced into the assembly line, the applicable rule regarding sharp edges may be affected, and the change is a material change.

3. Sourcing of Component Parts

A change in the sourcing of component parts is interpreted as a replacement of one component part of a children's product with another component part. This includes changes in component composition, component supplier, or using a different component from the same supplier that supplied the component being replaced.

D. Verification of Third-Party Test Results

Section 14 (a)(2)(B)(iii) of the CPSA requires the Commission to issue protocols and standards for verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules. Staff interprets verification as showing that the test results from a conformity assessment body are consistent with another conformity assessment body's test results for the children's product.

Certifiers should on a recurring basis, send product samples for testing to an alternate CPSC-recognized third party conformity assessment body to verify that the test results (certification, material change, or periodic) from the prior CPSC-recognized third party conformity assessment body correctly indicated passing results. The certifier, in the exercise of due care, should send sample(s) of the same children's product to an alternate CPSC-recognized third party conformity assessment body at a frequency that provides a high degree of assurance that the children's product complies to the applicable children's product safety rules.

The verification should be for each applicable children's product safety rule for which the product is tested. It is not required that verification for all applicable tests be conducted at the same time and by the same alternate CPSC-recognized third party conformity assessment body, as long as each applicable standard is verified.

Verification requirements also apply to firewalled and government-owned or –controlled, CPSC-recognized third party conformity assessment bodies.

Periodic test results may be used for verification purposes if an alternate CPSC-recognized conformity testing body is used. A certifier may use any number of CPSC-recognized third party conformity assessment bodies for periodic and verification testing purposes. Whenever a certifier has samples tested at an alternate CPSC-recognized third party conformity assessment body, the alternate CPSC-recognized third party conformity assessment body's results serve to verify the prior CPSC-recognized third party conformity assessment body's results.

If a CPSC-recognized third party conformity assessment body reports a failing test result on any sample tested, the certifier must immediately initiate an investigation to determine the cause(s) for the failure. The current product is no longer considered the same as the product listed on the children's product certificate, and the product manufactured or imported since the last passing set of test results (certification, material change, or periodic) cannot be distributed in commerce until remedial actions have been taken. If some or all of the manufactured/imported product has already been distributed in commerce, the certifier must notify CPSC (per the requirements of section 15(b) of the CPSA). Details of how to report to the CPSC are found at https://www.cpsc.gov/cgibin/sec15.aspx.

If the results from the two CPSC-recognized third party conformity assessment bodies differ in indicating compliance or noncompliance, the certifier must investigate the discrepancy. If the investigation concludes that one of the CPSC-recognized third party conformity assessment body's test results was in error, the certifier must notify CPSC of the occurrence by sending an email to the Assistant Executive Director, Office of Hazard Identification and Reduction.

E. Safeguarding Against Undue Influence

Section 14(d)(2)(B)(iv) of the CPSA calls for protocols and standards intended to safeguard CPSC-recognized third-party conformity assessment bodies against the exercise of undue influence by a manufacturer or private labeler. In conjunction with the internal provisions by conformity assessment bodies to ensure that its management and personnel are free from undue influence (as part of their compliance with ISO/IEC 17025:2005), the Commission requires that all parties responsible for certifying a children's product as compliant with all rules, bans, standards, or regulations applicable to the product under any Act enforced by the U.S. Consumer Product Safety Commission should exercise due care to establish procedures ensuring that:

1) Safeguards are established to prevent attempts to exercise undue influence on a third party conformity assessment body by the manufacturer, private labeler or other interested party; including a written policy statement from company officials that the exercise of undue influence is not acceptable, and directing that appropriate staff receive annual training on avoiding undue influence;
2) the Commission is notified immediately of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over test results; and
3) allegations of undue influence may be reported confidentially to the Commission. by one of the following means:
    - Phone: (301) 504-7923 M-F 8:00 am - 4:30 pm Eastern Time Zone in the United States
    - Fax: (301) 504-0124 and (301) 504-0025
    - By mail: U.S. Consumer Product Safety Commission
      4330 East West Highway
      Bethesda, MD 20814
    - By email: access the CPSC website (www.cpsc.gov) and click on the "contact us" link. When reporting undue influence directly to the CPSC, the caller can remain anonymous if he/she so chooses.

F. Remedial Actions Following a Failing Third Party Test Result

If any test by a CPSC-recognized third party conformity assessment body results in a failure to meet the applicable rules, the product cannot be certified until remedial actions have been taken. If some or all of the manufactured/imported product has already been distributed in commerce, the certifier must notify CPSC (per the requirements of section 15(b) of the CPSA). Details of how to report to the CPSC are found at https://www.cpsc.gov/cgibin/sec15.aspx. The certifier should develop a remedial action plan to implement if a certification, material change, periodic, or verification test returns failing results.

Following a failing test result from a CPSC-recognized third-party conformity assessment body, remedial actions must be taken by the certifier to ensure with a high degree of assurance that the children's product complies with all applicable rules. Remedial action can include redesign, changes in the manufacturing process, or changes in component part sourcing. For existing production, remedial actions may include rework, repair, or scrap of the children's product. Retesting of the redesigned or remanufactured product will be required to certify the product as compliant.

If any remedial action results in a material change to the product, that change will require the children's product to be subjected to certification tests, which must yield passing results.

G. Recordkeeping for Third-Party Testing of Children's Products

Records are necessary to demonstrate that children's products comply with the applicable rules. All records shall be available in the English language and copies of all records shall be kept at the certifier's main office. Records should be available to any officer or employee duly designated by the Commission upon request in accordance with section 16(b) of the act (15 U.S.C. 2965(b)), and 16 CFR Part 1110.

1. Certification Testing of Children's Products

Documentation is necessary to establish the identity of the children's product, and show that the product complies with the applicable rules. Each certifier of a children's product subject to an applicable rule should establish and maintain the following records:

- A copy of the certificate(s) for each product with all the required information listed in sections 14(a)(2)(B) and 14(g) of the CPSA and 16 CFR Part 1110. The product covered by the certificate should be clearly identifiable and distinguishable from other products.
- Certification test results showing compliance to the applicable rules. Because it cannot be assumed that units of the same product manufactured in more than one location are identical in all material respects, the certifier must have separate certification tests results for the product for each manufacturing site.

The records should be maintained for as long as the product is being distributed in commerce plus 3 years. The purpose of records being kept for 3 years is to ensure that the products have time to clear the distribution channels and get into consumer use. If there is a compliance problem or defect in a product, 3 years should be sufficient to uncover any problems with the product. The Commission's staff would have time to obtain the records for review and take any necessary enforcement action during this 3-year period.

2. Periodic Testing of Children's Products

The periodic test plan as described above and copies of the test results for a children's product should be maintained. The periodic test plan should be maintained for as long as the product is being distributed plus 3 years. The test results should be maintained for 3 years after their generation.

3. Material Changes

Descriptions of all material changes in product design, manufacturing process and sourcing of component parts plus the certification tests run and the test values, should be maintained for as long as the product is in distribution plus 3 years.

4. Verification of Third-Party Test Results

Verification test descriptions (including attestations that the periodic testing procedures were also used for verification testing, if applicable) should be maintained for as long as the product is being distributed plus 3 years. The test results should be maintained for 3 years after their generation.

5. Remedial Actions

The certifier should maintain records of remedial action plans, any failing test result, the remedial actions taken, the date of those actions, and the person who authorized the remedial actions.

6. Safeguarding Against Undue Influence

The certifier should maintain copies of the procedures described in Section IV.E, including training materials and records indicating the names of all employees trained on these procedures and the dates of the training.

VII. Commission Options

The following options are available for Commission consideration.

1) Publish the Notice of Proposed Regulation as drafted by the Office of the General Counsel.
2) Publish the Notice of Proposed Regulation with changes as directed by the Commission.
3) Other options as directed by the Commission.

VIII. Staff Recommendation

CPSC staff recommends that the Commission publish the Notice of Proposed Rulemaking as drafted by the Office of the General Counsel.

IX. Appendix 1: Justification for exempting periodic testing of children's products until a production volume of 10,000 is reached

A. Background

Additional periodic third-party testing for a children's products is not required until at least 10,000 units of the product have been manufactured or imported since the last time the product was tested by a CPSC-recognized third party conformity assessment body. The exemption is limited to the requirement in section 14(d)(2)(B)(i) of the Consumer Product Safety Act (CPSA) to ensure that children's products are subjected to testing periodically for compliance with the applicable safety rules.

B. Intent of the Exemption

The intent of the limit is to provide some relief to low-volume certifiers of children's products from the costs of the third party testing requirements added to the CPSA by the Consumer Product Safety Improve Act of 2008 (CPSIA). The reason that low-volume certifiers are singled out for relief is that the cost of third-party testing will generally have a larger adverse impact on low-volume certifiers than on higher volume certifiers. This is because the cost of testing a product is generally the same whether a large or small number of units are produced. However, if a large number of units are produced the manufacturer can amortize the cost of the testing over more units. This results in a lower per unit cost of testing.

A quick example can illustrate this disparate impact of third-party testing costs on high and low volume manufacturers. If the cost of third party testing for a particular children's product is $1,500 and if 100,000 units of the product were manufactured, the per unit cost of the testing would be 1.5 cents per unit. For most products, a 1.5 cent per unit increase in costs would not be significant. However, if only 1,000 units were produced, the cost of the testing would be $1.50 per unit. For some products this could represent a significant percentage of the revenue received from the product and could have a significant adverse impact on the company, especially if the company were small or a significant number of its products were low-volume products.

Low-volume products represent a diverse array of products. Often they are produced by small businesses that are sometimes home-based. Other products might be aimed at a niche market (e.g., learning disabled or blind children) or a specialty market (e.g., the educational market) rather than the mass market.

C. Process Used to Develop the Exemption

The cost of third-party testing for toys is often hundreds of dollars and CPSC staff has seen some examples where the costs exceeded $2,000. However, based on other examples and staff knowledge of the testing costs, a range of $1,000 to $2,000 per product is more typical, especially if component testing is allowed. Therefore, in determining the volume, the assumption was made that the cost of obtaining third-party testing was in the middle of this range, or about $1,500 per product.

Typically, profit, which is what is left over for the business owners from sales revenue after all expenses have been paid, is 5 to 10 percent of revenue. Based on some statistics from the Internal Revenue Service (IRS) and information from some publicly traded toy manufacturers, this seems to apply to toy manufacturers as well. Some firms will have lower profits; a few will have higher profits. However, because this is the typical range, the goal was to come up with a volume estimate that would limit the per unit, periodic, third-party testing cost to around 5 percent of revenue or less. Something that increased costs by such a percentage of revenue would be considered a significant impact by most companies.

The average retail price of a toy is about $8. Assuming margins of about 35 percent at both the retail and wholesale level, the revenue that a manufacturer would receive for a toy that retails for $8 would be about $3.38 (i.e., $8 x 0.65 x 0.65). If the third-party testing costs for the product are $1,500 and 10,000 units of the product were manufactured or imported, then the per unit testing costs would be about 15 cents per unit ($1,500/10,000) or about 4.4 percent of the per unit revenue ($0.15/$3.38). If only

7,500 units were produced, then the per unit testing costs would be 20 cents per unit or about 5.9 percent of revenue.

D. Number of Tests and Samples

This calculation assumes that conformance with each applicable safety rule would be tested only one time. It does not count the cost of the samples as part of the testing costs.

E. Reasonableness of the Proposal

To test the reasonableness of this number, it was compared it to the average annual production of a toy. There are an estimated 3 billion individual toys sold annually and around 50,000 to 60,000 stock keeping units (SKUs). Therefore, the average volume for a toy is about 50,000 units. The proposed volume level for the exemption is therefore about 20 percent of the average toy production volume. This suggests that the toys that would be impacted by the exemption might not be mass market toys.

(a) TAB A: [Response to Comments Received from the Testing Policy Workshop]

TAB A

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

Memorandum

Date:

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Maruta Z. Budetti, Executive Director

FROM : Randy Butturini
Office of Hazard Identification and Reduction

Robert J. Howell
Assistant Executive Director
Office of Hazard Identification and Reduction

SUBJECT : Response to Comments Received from the Testing Policy Workshop

I. Introduction

On December 10th and 11th, 2009 , the Consumer Product Safety Commission held a Testing Policy Workshop and invited public comment on aspects of section 14 of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008. Staff presentations were given, and breakout sessions were held on the following topics:

- Sampling and Statistical Considerations
- Verification of third party test results
- Reasonable Test Programs and Third-party Testing
- Challenges for small manufacturer / low volume production
- Component Testing and Material Changes
- Protection Against Undue Influence

These topics were derived from section 14(d)(2)(B) of the CPSA

"Not later than 15 months after the date of enactment of the Consumer Product Safety Improvement Act of 2008, the Commission shall by regulation--
(A) initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements of subsection (a); and

(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;
(ii) for the testing of random samples to ensure continued compliance;
(iii) for verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules; and
(iv) for safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler."

Public Comments were accepted until January 11, 2010. This memorandum presents the CPSC staff's recommendation for establishing these testing requirements.

II. Comments Received and Staff Responses

Thirty-eight comments were submitted to docket CPSC-2009-0095 and divided into a fourteen sections with a total of sixty-eight comment areas. Each comment was read, evaluated and grouped with similar comments from other submitters. A staff response to each category of comment follows the category summary

A. Component-level Testing

1. Comment: Twenty-seven of the thirty- eight comments provide their thoughts on component-level testing. Almost all of the commenters favor component-level testing. Many commenters acknowledge the benefit of component-level testing to small businesses. Commenters cite component-level testing as a way to reduce redundant testing when a component is used in multiple products. They also want the option of component-level testing when the amount of the component in the finished product is small and testing of the finished product requires destruction of a large number of units to collect a sufficient quantity of the component to be tested. Several commenters indicate that testing at the component-level prevents costs associated with reworking products that do not meet safety standards due to a non-compliant component.

Staff Response: CPSC views component-level testing, when appropriate, as a cost-effective option to facilitate assurance of compliant consumer products. A domestic manufacturer or importer may choose testing of a component, which by its construct or materials, is subject to a consumer product safety rule under section 14 of the CPSA when the component is not altered during the manufacturing process or the supplier of the component is changed. Tested components must be representative of those used in a finished product and the certification of the component must be traceable in the finished product.

2. Comment: The commenters differed as to who should conduct component-level testing and whether a supplier provided certification can be used. One commenter suggested that component-level testing be limited to the product manufacturer, and not to the component supplier, many of whom are overseas entities. The commenter's concern is that supply chain integrity may not always be maintained and untested or counterfeit cornponents could be introduced into a manufacturer's production. Other commenters suggested that product manufacturers should be able to use testing results obtained from component suppliers or manufacturers, rather than requiring the product manufacturer to test each component separately. Three comments indicate that the supplier that certifies a component and not the manufacturer that uses the supplier certified component should be held liable for non-compliance.

Staff Response: The Commission believes that excluding the option of using supplier provided component level certificates may be unduly burdensome for some manufacturers or importers. Manufacturers or importers who rely on a certification from a component supplier should apply sound business practices when selecting to use a component supplier's certification. Ultimately, the domestic manufacturer or importer is responsible for the compliance of its finished product.

3. Comment: Other commenters suggest that in order to protect against counterfeit supplier component certifications, CPSC should set up an annual review process of the laboratories that it recognizes to prevent such falsifications.

Staff Response: Section 14(a)(2)(B)(iii) of the CPSA requires the Commission to issue protocols and standards for verifying that a children's product tested by a CPSC recognized third party conformity assessment body complies with applicable children's products safety rules. The provisions proposed in this notice regarding verification and the Commission's proposed rule providing for audit of third party conformity assessment bodies should be an adequate check on conformity assessment body activities in this regard. See 74 FR 40783 (August 13, 2009).

4. Comment: One commenter suggested that the CPSC establish different requirements for different components based on their inherent safety risks. Those with the least risk would be exempt from mandatory third-party testing.

Staff Response: Certification at the component part level is an option for manufacturers and importers. CPSIA does not contemplate that products presenting a real, albeit low, risk should be exempted from the requirements for third party testing.

5. Comment: Many commenters stated that reliance on component-level testing requires that the tested components be representative of those used in the finished product and that adequate traceability of components is maintained.

One commenter stresses the need to prepare component samples (such as a large 'representative' paint sample substituted for multiple products each with a tiny amount of paint) using the same technique and equipment as is used for the products. Concern was raised that subsequent to testing raw materials (e.g., pre-molded plastic pellets or wet paint in the can) could be contaminated in the production process resulting in the manufacture of non-compliant products. If wet paint is found to be compliant, the drying process could evaporate enough solvent to raise the concentration above the allowable limit. Another commenter states that compositing of similar materials should be valid so long as the acceptance limit for the test is adjusted downward to account for multiple materials being tested.

Staff Response: Testing at the component part level is an option when the component is not altered during the process of assembling the finished product. If during processing or assembly of the component part into the finished product, there is a chance that the component part could be contaminated in such way that it is no longer compliant with the subject safety rule(s), the manufacturer or importer should test the finished product for compliance.

Component part samples must be representative of the component part that will be used in the finished product. Component level testing of composited samples is acceptable provided that the subsequent procedures will ensure that no failure to comply with a limit will go undetected. An example of an acceptable procedure is provided in CPSC-CH-E1003-09, Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings (available on the Commission website at http://www.cpsc.gov/about/cpsia/CPSC-CH0E1003-09.pdf). We note that the criteria for lead content refer to the percentage of lead (calculated as lead metal) by weight of the total nonvolatile content of the paint or the weight of the dried paint film. Thus, the commenter's concern about evaporation of solvents from the paint is not warranted.

Domestic manufacturers and importers must maintain documents that demonstrate the traceability of component part level certified materials in their products.

6. Comment: Several commenters noted that many components are not children's products until they are actually incorporated into a completed product. Mandatory third-party testing of all components that might be used in a children's product would be inefficient and wasteful. Often component suppliers do not know where their production will be used in the manufacture of other products.

Staff Response: Whether a component part supplier subjects its component part to third party testing and/or certification is a business decision. Likewise, it is the manufacturer's decision as to whether to purchase third party certified component parts from a supplier or whether to conduct third party testing and certification at the component part or finished product level. The

Commission is not requiring third party testing or certification of component parts that are not used in children's products.

7. Comment: One commenter suggested that reasonable attestations from raw material manufacturers should be used in determinations on whether or not to test for phthalates. Third-party tests by an accredited laboratory should not be required. As part of a reasonable testing program, assurances provided by suppliers that plastic resins meet FDA requirements should be considered as a basis to reduce the amount of periodic testing of toys or children's products, or components thereof, made from food-grade plastics. Further, the suggestion was made to exclude the limits or requirement for testing for inaccessible components that may contain phthalates, similar to the exclusion for lead.

Staff Response: The Commission will consider these comments as part of its rulemaking activities for phthalates.

8. Comment: Many commenters mentioned that manufacturers with very small production quantities would not be able to afford the destructive testing of a significant percentage of their production. Component testing with production process controls measures should be acceptable as verification to issue a general conformity certificate (GCC). Another commenter mentioned that destructive testing of gold jewelry is very expensive and that component testing would alleviate that situation.

Staff Response: Component part level testing and certification is appropriate when the assembly of the component part into the finished product does not alter the component part or when the finished product is not subject to other testing and certification requirements with respect to CPSC safety rules that inherently require testing of a finished product.

9. Comment: One commenter stressed that some components require the completed product to evaluate compliance to the applicable rules.

Staff Response: If a finished product is subject to additional CPSA safety rules beyond those that can be certified based on testing at the component part level, then the finished product must be tested to demonstrate conformance with these additional safety rules.

10. Comment: One commenter said that pre-certified components should also be allowed as part of a reasonable testing program. The supplier would undertake third-party testing and supply a copy of their certificate to the manufacturer. No additional testing on the components would be required.

Staff Response: The domestic manufacturer or importer may rely upon supplier certification of a component part provided that the component part is not altered during the assembly of the finished product. The manufacturer must

maintain traceability of component parts and is ultimately responsible for the compliance of their finished product to CPSC's safety rules.

B. Flexibility in Testing

1. Comment: Ten commenters stressed the need for flexibility in test protocols. The types of products are so varied that no one prescribed system could be devised to effectively and efficiently apply to all of them. The number of samples to test should be left to the manufacturer, who has intimate knowledge of the product's manufacturing process, to decide.

Staff Response: Staff agrees that it is difficult to develop rigid protocols for testing across all products, manufacturers, and importers. The staff believes that any reasonable testing program will include some common elements, including product specifications, certification tests, production testing, remedial action plans, and documentation. However, the draft proposed rule provides a lot of flexibility to manufacturers and importers as to how to design and implement each element. Decisions on things such as the number of samples to test are left to the manufacturer provided that the testing plan provides a high degree of assurance that noncomplying products are not introduced into the stream of commerce.

2. Comment: One commenter stressed the need for flexibility in sample selection for periodic and material change testing. The Commission should accept good faith efforts to test representative samples and not require sampling of every 'batch' or 'run.'

Staff Response: The draft proposed rule provides some flexibility to manufacturers in designing their production testing plans. For example, the manufacturer may tailor the tests to the needs of the individual product and the tests do not need to be the same tests that are specified in the applicable rules, provided that they are at least as effective in assessing compliance. When a children's product manufacturer has a reasonable testing program in place that provides a high degree of assurance that all products comply with the applicable safety rules, the frequency of the third-party periodic testing may be based on the manufacturer's knowledge of the product, its manufacturing process, and the manufacturer's ability to ensure compliance, provided, however, that the product is tested by a third-party testing laboratory at least once a year. For material change testing, the certifier must select enough samples to provide a high degree of assurance that the changed product meets the applicable safety rules.

3. Comment: One commenter suggested that 'reasonable' for some products would involve less than the five elements outlined by CPSC for a reasonable testing program. As some regulations require placement of a label, 'testing' in that circumstance would have to consist of observing that the label was placed properly.

Staff Response: Staff believes that the five elements will be present in most reasonable testing program even if some of the elements might seem trivial and can be accomplished with seemingly little effort. For example, in the case of a product where the only applicable rule was that the product bear a specific label, it would still be necessary to identify the product and that the rule was applicable to it (product specification). It would be necessary to examine a finished product to ensure that the label was properly placed (certification test). It would be necessary to check a sample of the products during production to ensure that the label was being properly applied during production (production testing). And it would be necessary to have a plan of response if it was found that the correct label was not applied on some products (remedial action plan).

4. Comment: Several commenters suggested that X-ray fluorescence (XRF) technology be deemed an acceptable method to test for the presence of lead. XRF devices are non-destructive to the sample and are considerably less complicated and less expensive than other techniques, such as inductively-coupled plasma (ICP).

Staff Response: Staff agree that the XRF testing methods are considerably less expensive than ICP methods. However, the current accreditation requirements for third party conformity assessment bodies that have been approved by the Commission only allow the use of XRF testing methods in the case of homogenous polymer products.

C. Random Samples

1. Comment: Nine commenters stated that the word 'random' should not be interpreted by its strict statistical definition, but should be adapted to the product type, how it's produced, and its intended use. Risk-based sampling, where a greater potential hazard would require greater testing, was proposed as an alternative. One commenter urged the Commission to continue to permit manufacturers to determine the method of sampling for testing and the frequency of sampling based on a good faith assessment of risk associated with their products. One commenter stated that 'random' should be interpreted to mean 'free from overt selection bias.' The commenter said that it is more important that a sample be reasonably representative of the population from which it is selected.

Staff Response: There are two dictionary definitions of "random." The first is the more common, casual definition, "...proceeding, made, or occurring without definite aim, purpose or reason: e.g. the random selection of numbers. A second definition is, "statistics. Of or characterizing a process of selection in which each item of a set has an equal probability of being chosen..." The dictionary definition of "random sampling" is "...statistics. A method of selecting a sample from a statistical population in such a way that every possible sample that could be selected has the same probability of being selected..." This seems to be a technical definition. It also seems more appropriate to use a definition

where both terms (random and sampling) are defined rather than two separate definitions, one of random and the second of sampling.

Random sampling not only provides compliance estimates for the population of production units from which a sample was chosen for testing, but also provides measures of the accuracy of the estimates. This means that in advance of collecting the sample, the number of units to be collected for the sample can be specified in order to meet the desired accuracy targets. Moreover, if the appropriate mathematics are used to analyze the data, the estimates are unbiased. A sample that is biased cannot provide an accurate estimate.

More generally, a representative sample, a non-fraudulent sample, or a non-golden sample, does not have the underlying statistical attributes to generalize validly from the sample to the population. Estimates made using a probability sample would have a measure of sampling variability, captured in quantities like a standard deviation, a coefficient of variation, or some probability measure.

2. Comment: One commenter mentioned the problems associated with random sampling of single-unit production, and with very small production volumes (less than 10, for example). Also, many manufacturing processes are of a continuous-flow type, and randomly selecting a sample would be disruptive to the production system.

Staff Response: Periodic testing, of which random sampling would be a feature, is not required for production of less than 10,000 units. Section 14(d)(2)(B)(ii) of the CPSA requires the Commission to establish protocols and standards for the testing of random samples to ensure continued compliance. No matter how random sampling is defined, the statute requires testing of samples, the samples must be selected from production or supply and must be tested by a CPSC-recognized third-party conformity assessment body.

3. Comment: One commenter said that products that are subjected to continuous testing with a specified frequency should be exempt from any additional random testing.

Staff Response: Section 14(d)(2)(B)(i) of the CPSA requires periodic testing of children's products. Section 14(d)(2)(B)(ii) of the CPSA requires the testing of random samples to ensure continued compliance. There is no provision in the statute that allows an exemption from periodic testing of children's products.

4. Comment: One commenter suggested that with the assistance of industry, the CPSC should craft some guidelines as to the circumstances or elements to consider when determining what constitutes a reasonable random sampling.

How and who should collect the sample should also be dictated not by regulation but by the manufacturer, with the aid of flexible, reasonable guidelines jointly crafted by industry and the CPSC.

Staff Response: The definition of a random sample is found in many statistics textbooks. Staff is interpreting random samples as a *simple random sample*, where every product in a lot under consideration has an equal chance of being selected for testing.

The common themes in selecting samples are a (1) formal procedure for selecting items for samples (random numbers), (2) mathematical formulas for describing the characteristics of the untested population and the associated amount of sampling variability and (3) formulas for determining the number of items in the sample.

These steps are involved then in selecting a random sample.

- Identification of the population to be tested and sampled.
- Determine what quantities will be measured and estimated from the sample.
- Determination of the type of random sampling to be employed and the associated mathematical methods.
- Calculations about how many items should be in the sample (sample sizes).
- Finally there is the selection of the sample, sending the sample to the conformity assessment body, and then calculating and evaluating the results. Some of these steps require mathematical analysis.

Random samples in testing have the following two advantages:

- First, assuming that sample was selected randomly from the targeted part of the population, the results from the testing does not project to the entire population. It is not a probability sample, and there is no data to be used to characterize the unsampled part of the population.
- Second, there might be some aspect of the production process unknown to the manufacturer or importer that results in non compliant items. The targeted sampling scheme can never discover that this is occurring.

As part of the sampling process, manufacturers and importers should document the process used to calculate size of the sample (number of products in the sample), the statistical procedures involved, how the sample was selected, and the test results and associated statistical calculations, especially those used to provide a high degree of assurance that the population is compliant.

One of the most frequently used sampling procedures is in ANSI/ASQ Z1.4, which is an update of MIL STD 105. This standard for sampling and inspection requires the definition of a production lot, then specification of the Acceptable Quality Level (AQL), which is the maximum percent of defective products in the lot that would be acceptable. Staff believes although widely used, this approach is inappropriate to meet the specifications for section 14(d)(2) of the CPSA because the tables do not contain sample sizes for an AQL of zero (i.e., zero defective items) and some samples would be passing, even though some of the items tested might not be compliant. Instead, certifiers should institute zero-defect sampling systems, also known as zero based acceptance plans. The American Society for Quality, and MIL-STD-1916/MIL-HDBK-1916, DOD *Preferred Methods for Acceptance of Product*, are two sources at which information on zero-defect sampling systems can be found.

Random sampling is at the heart of the industrial quality control movement and there are literally hundreds of publications on how it can be used. There are also many standards on random sampling, for example, ASTM E 105, *Standard Practice for Probability Sampling of Materials*.

D. The Reasonable Testing Program

1. Comment: Twenty-two commenters inquired about the reasonable testing program. Several expressed concern that many manufacturers may not be able to specify their products down to the component or raw material level. Proprietary information from offshore manufacturers may keep importers may from knowing every component of the products they purchase.

Staff Response: It is not necessary to specify every component part or raw material of a product. The certifier is free to describe their product by model number, general description, photograph, etc., as long as the product is identifiable and differentiable from other products.

2. Comment: One commenter stated their belief that an acceptable reasonable testing program should be any program that results in an acceptable confidence level that a product complies with applicable standards. The five essential elements should not be required to be applied to all testing programs. Other items such as factory certification (to recognized standards), audits, risk assessment plans, certification of a manufacturer's quality system, etc., should be allowed as elements of a reasonable testing plan.

Staff Response: CPSC staff agrees that other elements such as risk assessment plans, quality system certification, and factory certifications that could provide a manufacturer with a high degree of assurance that the product produced complies with all applicable requirements. However many of the methods suggested would require CPSC to assess and recognize/certify the certification services providers and require the manufacturer and importer to purchase these certification services. The staff approach seeks to identify a

method whereby a manufacturer or importer can independently establish a "reasonable" testing program and to establish a set of minimum requirements for these reasonable testing programs that reflects commonly used elements of a QA/QC system.

3. Comment: Several commenters noted that for seasonal or short-run products, only prototype samples may exist before production commences. Neither the same materials nor the same manufacturing processes were used to manufacture the samples as would be used to manufacture the consumer product.

Staff Response: For children's products, section 14(a)(2) of the CPSA is specific as to the products to be tested as it requires manufacturers to submit "sufficient samples of the children's product, or samples that are identical in all material respects to the product," to third party conformity assessment bodies for testing. A prototype manufactured with different materials or manufacturing processes than the finished product cannot be considered the same in all material respects as the finished product with respect to compliance. Consequently, section 14(a)(2) of the CPSA does not allow for testing of prototype samples unless they are identical in all material respects to the finished product. The proposed rule would extend the requirement to test only prototype samples that are identical in all material respects to the finished product that will be imported for consumption, warehoused, or distributed in commerce to manufacturers of non-children's products under section 14(a)(1) of the CPSA.

Thus, the statute contemplates that the test(s) are to be conducted on the product that is imported, warehoused, or distributed in commerce. Prototype samples generally are not imported for consumption, warehoused, or distributed in commerce. With regards to prototype sample testing, section 14(a)(2) of the CPSA requires tests to be performed on samples that are identical in all material respects to the product.

4. Comment: Multiple commenters stated that the relative hazard should be a factor in determining the test frequency. Higher risks should necessitate a higher test frequency. One commenter stated that because the perceived risk is low, third-party testing should not be mandatory for their products. One commenter stated that the history of production with or without lead content should be considered in the development of testing requirements. A record of low-lead production should result in relaxed testing requirements. However, one commenter stated that potential severity is not a useful indicator of the frequency of periodic testing.

Staff Response: While CPSC staff agrees that a higher risk level should necessitate a greater testing frequency, it should be noted that risk and potential severity are not indicators of the level of compliance to the legal standards, regulations, rules, and bans. A manufacturer's knowledge of the production

process can certainly inform the decision on testing frequency and sample size. For example, a manufacturer who uses statistical process control methods and has determined that the production processes are in-control and capable of meeting the requirements, combined with a lower level of third-party testing, may have sufficient information to achieve a high degree of assurance that all their product produced complies with the requirements. CPSC staff identified various factors for consideration in determining testing frequency and sample size in their proposed guidance document on testing and certification found at http://www.cpsc.gov/library/foia/foia10/brief/102testing.pdf. It should be noted that section 102 of the CPSIA does not permit the exclusion of any children's product from third-party testing for any reason, including the level of risk. Two commenters proposed that CPSC require a hazard analysis of children's products if manufacturers are permitted to perform the analysis themselves and a third-party check of the results is not required.

5. Comment: One commenter believed that due to the economic ramifications associated with the development of a reasonable testing program, the CPSC should convene a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel on this issue. SBREFA stands for Small Business Regulatory Enforcement Fairness Act. Information on SBREFA can be found at http://www.osha.gov/dcsp/smallbusiness/sbrefa.html.

Staff Response: We decline to convene the panel suggested by the comment. According to the Small Business Administration's website:

> The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires that the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) receive input from affected small businesses before proposed rules are published. This requirement is in addition to the other mandates of the Regulatory Flexibility Act.
>
> When an EPA or OSHA proposal is expected to have a significant impact on a substantial number of small entities, the agency must notify the Office of Advocacy. Advocacy then recommends small-entity representatives to be consulted on the rule and its effects.
>
> The agency then convenes a Small Business Advocacy Review Panel, consisting of officials from the agency, the Small Business Administration's (SBA) chief counsel for advocacy, and the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs. The interagency panel reviews the draft proposed rule and the related analyses prepared by the agency. In addition, the panel collects advice from identified small business representatives and submits a report to the agency within 60 days.

> Panel reports often include comments on the agency's preliminary analysis of the impact of the rule on small businesses, and recommendation for regulatory alternatives. The agency reviews the report, makes any appropriate revisions to the rule, and publishes the proposed rule with the panel report as part of the record.
>
> The panel process takes place in the early stages of the rulemaking. It does not replace, but enhances, the important step of the publishing the proposed rule and accompanying economic analyses for public comment

(Accessed on the Internet at http://www.sba.gov/advo/laws/is_about.html.) Thus, we note that the federal agencies subject to a SBREFA panel requirement are the Environmental Protection Agency and the Occupational Safety and Health Administration of the Department of Labor; in other words, the CPSC is not subject to a SBREFA panel requirement.

Nevertheless, the CPSC has made considerable effort to obtain input from and is sensitive to the needs of small businesses. As an example, the Commission held a public workshop on product testing issues (see 74 FR 58611 (November 13, 2009)). Part of the public workshop focused on issues affecting importers and small businesses (see 74 FR at 58615). In addition, the proposed rule will contain a small business analysis pursuant to the Regulatory Flexibility Act, and the CPSC, pursuant to its other obligations under the Regulatory Flexibility Act and Executive Order 13272, will work with the SBA to examine the proposed rule's potential impact on small business.

6. Comment: Two commenters desired that CPSC consider the testing requirements in existing product safety standards to be acceptable in meeting the requirements of section 14 the CPSA, including existing regulations with their own reasonable testing program requirements.

Staff Response: Section 14 of the CPSA establishes certain requirements with respect to product testing. While the CPSC will develop its regulations so that its implementation of section 14 of the CPSA does not conflict with pre-existing testing regulations, we cannot, as a general matter, consider all pre-existing testing regulations to be acceptable for purposes of complying with section 14 of the CPSA. For example, with respect to children's products, the statute expressly mandates testing by a third party conformity assessment body; if a pre-existing regulation does not require such testing, the manufacturer of that children's product will need third party testing. In other words, a pre-existing testing regulation cannot overrule section 14 of the CPSA.

7. Comment: One commenter mentioned that importers typically do not control the production process of the products they import. Consequently, a reasonable testing program should be defined separately for their special circumstances.

Staff Response: Although the reasonable testing plan includes titles such as "product specification" and "production testing plan," the elements can be adapted to the importers' circumstances. The product specification is a description of the product (however accomplished) and a list of the product safety rules that apply, information the importer should know. The certification tests and the test data is needed for the importer to issue the certificate. The production testing plan may be executed by the importer or contracted to another party. An importer should plan for the possibility of discovering noncompliant products, which is the essence of a remedial action plan. Finally, an importer should document their actions and plans for good management purposes.

8. Comment: One commenter specifically stated that the reasonable testing program should be implemented for children's products.

Staff Response: Section 14(a)(2) of the CPSA requires manufacturers to submit "sufficient samples of the children's product, or samples that are identical in all material respects to the product," to third party conformity assessment bodies for testing. The terms "reasonable testing program" do not appear with respect to children's products, although the Commission could, under section 14(b) of the CPSA, prescribe a reasonable testing program for children's products. A reasonable testing program for children's products, however, could not eliminate the need for third party testing for purposes of complying with section 14(a)(2) of the CPSA.

9. Comment: One commenter remarked on the differences between conformity assessment and certification. They went on to suggest that CPSC regulations clarify that a "reasonable testing program" actually will mean a conformity assessment process such as that in Annex A of ISO/IEC 17000 and describe the five elements in generic terms that avoid the implication that "testing" will always be the evaluation activity. This commenter stated that the phrase "production testing plan" is misleading in that only testing is anticipated, and that the interpretation be expanded to include activities certification bodies use to assess continuing compliance. This commenter went on to promote the use of third-party certification to meet the statue's requirements.

Staff Response: In sections 14(a) and 14(d)(2)(B) of the CPSA, testing is specifically mentioned as the evaluation activity. Thus, irrespective of other means of determining compliance, products must be tested for compliance to the applicable rules. The conformity assessment process mentioned in Annex A of ISO/IEC 17000 includes attestations in their principles of conformity assessment. However, the CPSA requires the certifier (domestic manufacturer or importer) to perform the attestation that their products comply with the applicable rules. If the certifier uses a third party conformity assessment body to perform the testing of their products, then the determination and attestation functions would be performed by two separate parties. Thus, the conformity assessment process in

ISO/IEC 17000 is not equivalent to the reasonable testing program mentioned in section 14(a) of the CPSA. That being said, the certification testing and the production testing plan in the reasonable testing program do allow a wide latitude of actions in determining initial and continuing compliance to the applicable rules for a product.

10. Comment: One commenter noted that unless the Commission can show that current industry testing programs are insufficient, no prescribed reasonable testing program should be implemented.

Staff Response: We disagree with the comment. Nothing in section 14(a)(1) or 14(b) of the CPSA, nor section 3 of the Consumer Product Safety Improvement Act (CPSIA) which gives the Commission the authority to issue regulations to implement the CPSIA requires the Commission to find industry testing programs to be insufficient before issuing a regulation. Indeed, it would be impractical and resource-intensive for CPSC, given the vast array of manufacturers subject to section 14(a)(1) of the CPSA, to review each industry testing program or each manufacturer's testing program (assuming that there was no industry-wide testing program) for its sufficiency before engaging in rulemaking.

Furthermore, section 14(a)(1) of the CPSA expressly requires a general conformity certification to be based on a test of each product or upon a "reasonable testing program." Assuming that the commenter is not advocating a test of each product, we believe that a rule describing what constitutes a reasonable testing program will help implement the CPSIA. A regulation also can establish a minimum standard for reasonable testing programs, thereby providing a "level playing field" for industry when it comes to product testing and providing some assurance to consumers that the products they buy and/or use have been certified on the basis of a minimum testing standard. Manufacturers are free to conduct additional tests beyond those described in a regulation.

11. Comment: One commenter suggested that 'process capability testing,' where, for a continuous-flow process, first-run samples are tested. If a failure occurs, more samples are tested as the continuous-flow process runs; and when all samples pass, production after that point can be deemed acceptable. This would serve as a form of certification testing. The commenter urged that the Commission allow a manufacturer to search 'backwards' and forwards' in their continuous-flow process for good product in the event that a test during manufacturing show non-compliance.

Staff Response: For non-children's products, certification tests are required to demonstrate compliance to the applicable rules. If in the assessment of the manufacturer, process capability testing gives a high degree of assurance that all products produced for distribution into commerce are compliant to the applicable rules, that is considered acceptable certification testing. Similarly,

techniques used during production to ensure with a high degree of assurance that all continuing production is compliant can be considered as acceptable production testing plans.

12. Comment: One commenter said that Commission must issue regulations clarifying what will constitute "unacceptable or failing" test results for product testing. Additionally, the Commission's regulations should explicitly allow for re-testing prior to re-manufacturing or redesigning. Retesting would be a means t help the manufacturer determine the extent of non-complying products and the nature of the noncompliance.

Staff Response: We agree, in part, and disagree, in part, with the comment. We agree that, as part of any testing program (whether the program is a "reasonable testing program" or continued product testing), a manufacturer should have procedures in place to address what actions are to be taken if unacceptable or failing test results occur. For example, a manufacturer might decide to begin an investigation to discover the reasons why the sample failed a test and then take corrective action to prevent future failures.

However, we cannot say that retesting, as a general matter, should be allowed because allowing retesting may tempt unscrupulous parties to attempt to "test the product into compliance," (i.e., to keep repeating testing until a sample passes the test and then reject the earlier unacceptable or failing test results). We believe the intent behind section 14 of the CPSA is to conduct tests to provide assurance that the products being imported, warehoused, or distributed in interstate commerce comply with all applicable standards, rules, and bans. If manufacturers were free to keep retesting a product until a favorable test result emerged, such retesting could create a disincentive towards remanufacturing or redesigning the product to be safer.

13. Comment: One commenter remarked that the CPSC should offer guidance on the adequacy of specific programs to firms who request it. The agency has historically provided analogous guidance for firms seeking to comply with other regulatory requirements. Doing so for testing and certification would be consistent with that prior practice, would alleviate the need for firms to guess at what type of program would be reasonable in the view of the Commission. The commenter added a desire for the Commission to clarify that a test is any reasonable, objective method for evaluating compliance with a standard. The commenter said that any attempt to specify protocols and standards for testing children's products, such as sample size and frequency, should be tied to specific standards. The commenter expressed interest in having the Commission provide a clearer definition of reasonable certainty, especially in the context of specific standards. However, the commenter advised against attempting to establish any numerical standard such as a specified confidence level with a specific number of samples to test.

Staff Response: Other CPSC regulations have been product-specific, allowing the Commission to be able to develop guidance for those particular manufactured goods. Section 14(a) of the CPSA covers all products subject to a consumer product safety rule or children's product safety rule enforced by the Commission. As such, the CPSC cannot provide guidance to every product and every manufacturing process used in their production. The manufacturer is most knowledgeable about its product, its manufacturing processes, and the factors of each that may affect compliance to the applicable rules. With that knowledge, and the knowledge of the product safety rules that apply to their product, the manufacturer is best prepared to devise a certification and continuing testing program that would ensure with a high degree of assurance that its products comply. With regards to testing, the manufacturer or third party conformity assessment is not required to use the test specified in the standard if the manufacturer can demonstrate that their test or evaluation procedures can discriminate compliant and non-compliant products as well as the tests in the standard. Neither the reasonable testing program for non-children's products nor the certification and periodic tests for children's products specify sample size or test frequency. CPSC staff recognizes that no one-size-fits-all testing program will be sufficient for all manufacturers affected by sections 14(a) and 14(d)(2)(B) of the CPSA. CPSC staff is recommending that the certifier establish testing programs with sufficient rigor and with testing parameters such as test frequency and the number of samples per test specified such that, if the samples from a production population pass their tests, there is a high degree of assurance that all the untested products in the population will also comply with the applicable product safety rules.

E. The Definition of a Children's Product

1. Comment: One commenter interpreted the CPSIA's definition of 'children's product' as a product with which a child plays. The commenter asked about products used by children in non-play situations, such as classroom learning.

Staff Response: The commenter may be confusing the statutory definitions of "children's product" with "children's toy." In brief, section 3(a)(2) of the CPSA defines a "children's product" as "a consumer product designed or intended primarily for children 12 years of age or younger." Thus, under the CPSA, a children's product is not confined to those products with which a child plays; so, for example, an article of clothing intended for children under 12 years of age would be a "children's product" within section 3(a)(2) of the CPSA. In contrast, section 108 of the CPSIA defines a "children's toy" as a "consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays."

F. Existing Testing Programs

1. Comment: One commenter asked if Toy Safety Certification Program initiated by the Toy Institute of America (TIA) could be a accepted as a reasonable testing program as specified in section 14(a) of the CPSA. Two

other commenters recommended that CPSC recognize the value of industry-specific certification programs prescribing testing methods for a product category and verifying conformance. Testing methods tailored to specific types of products can be designed and executed more efficiently than can a general-purpose program.

Staff Response: The draft proposed rule would allow some flexibility to manufacturers to tailor their testing programs to the needs of their product and manufacturing processes and there will frequently be overlap between the requirements of the CPSA, the draft proposed rule, and some industry specific certification programs, such as the Toy Safety Certification Program established by the Toy Institute of America. However, regardless of the requirements of an industry-specific testing program, manufacturers will need to ensure that their testing programs also conform to the requirements of the CPSA and any implementing regulations promulgated by the Commission.

2. Comment: One commenter stated that CPSC should also establish a safe harbor enforcement policy as regards recognized programs. An enforcement policy that accepts participation in such programs as demonstrable good faith without imposition of civil or criminal liability under CPSIA's expanded penalty limits, could act to promote participation in effective certification programs.

Staff Response: The draft proposed rule does not include any provision for a "safe harbor" enforcement policy based on a manufacturer's participation in a voluntary or industry-sponsored program, nor has the Commission recognized any such program as indicating compliance with the requirements of the draft proposed rule.

G. Challenges for Small Manufacturers/Low Volume Production:

1. Comment: Five comments were received specific to small manufacturers who may not have the technical, legal, or financial resources as large-volume manufacturers. One commenter stressed the need for step-by-step guidance from the CPSC on how to 'follow the rules.'

Staff Response: The CPSC staff will provide general guidance on how to comply with the requirements of the CPSIA. However, CPSC staff cannot be knowledgeable of every aspect of every manufacturing process. It is the responsibility of the manufacturer to fully understand its manufacturing process and to know how the regulations would apply to its products. The manufacturer must be knowledgeable of any changes in its manufacturing process that could result in the production of violative goods.

2. Comment: One commenter mentioned that for very small production volumes (often one or two custom items), testing of a representative sample should be allowed to suffice for all items.

Staff Response: This may be accomplished with component testing in certain situations, i.e., paint. However, certain products would never be fully represented by component testing (i.e., the liberation of small parts during use and abuse testing).

3. Comment: Two commenters expressed their concurrence with the draft Guidance Policy document text that did not require periodic testing for production volumes less than 10,000 units or once a year, whichever is less.

Staff Response: With certification and periodic testing costs largely independent of manufacturing volume, there is a disproportionate effect on small-volume manufacturers relative to large-volume manufacturers. While certification testing and testing after a material change are still required, staff recommends that periodic testing not be required until at least 10,000 units have been manufactured.

H. Compliance Verification

1. Comment: Four commenters stated that verification of third-party conformity assessment bodies should be performed by the CPSC, and not the manufacturers. A commenter recounted that variations in sample preparation by conformity assessment bodies can and do lead to differing test results.

Staff Response: Staff acknowledges that variations in sample preparation can lead to some differences in test results. However, these variations should not be significant enough to alter the general conclusion of either compliance or noncompliance with the standard in question. In the case of a discrepancy in results, the proposed rule would require an investigation on the part of the certifier. If the investigation concludes that one of the testing lab's test results was in error, the certifier must notify CPSC of the occurrence. Because of the many types of children's products and manufacturing processes that will be covered by the rule and limited CPSC resources, it is not feasible for CPSC to conduct verification of third-party conformity assessment bodies.

2. Comment: One commenter stated that to have one accredited laboratory verify the tests of another seems unnecessary. The Commission should consider inter-laboratory variations caused by normal equipment variations, methods, etc., to consider whether additional procedures were necessary. Another commenter, noting lab-to-lab variations in test results for the same product, said CPSC should also conduct more diligence with its recognized labs such as conducting blind correlation studies and lab audits.

Staff Response: Section 14 (a)(2)(B)(iii) of the CPSA requires the Commission to issue protocols and standards for verification that a children's product tested by a conformity assessment body complies with applicable children's product safety rules. Staff considered a number of options to meet this

requirement. For example, staff considered using the results of the reasonable testing program to verify the CPSC-recognized third-party conformity testing body test results, but was concerned that the reasonable testing program may not be robust enough to also serve as a verification tool. Staff recognizes that there will be some inter-laboratory variations, but does not believe that these variations not be significant enough to alter the general conclusion of either compliance or noncompliance with the standard in question. Therefore, verification is defined as showing that the test results from a conformity assessment body are consistent with another conformity assessment body's test results for the children's product. While CPSC-conducted blind correlation studies and lab audits would be a potential alternative, CPSC currently lacks the resources to engage in these activities.

3. Comment: One commenter asserted that proficiency testing is the only true outside independent verification option for laboratories. This proficiency testing would be limited to the chemical tests only.

Staff Response: Proficiency testing is certainly one option for independent verification for chemical laboratories. However, the proposed standard applies to manufacturers or private labelers of consumer products. The development of standards and protocols for proficiency testing of laboratories is outside the scope of the proposed rule.

4. Comment: One commenter proposed that, upon demand by the CPSC, the conformity assessment body produce a) copy of the mandatory or voluntary standard being tested against, b) a copy of the test protocol used for the test procedure and c) a copy of the test results that can be tied back to the specific sample tested.

Staff Response: The proposed rule would apply to manufacturers or private labelers of consumer products. The activities and requirements for conformity assessment bodies are outside the scope of the proposed rule. However, the development and maintenance of these type of records would be a requirement for manufacturers or private labelers of products subject to a consumer product safety rule.

I. Protection of Conformity Assessment Bodies Against Undue Influence

1. Comment: One commenter suggested that ISO Guide 65 be used to prevent undue influence over third party testing lab by a manufacturer or labeler. Other commenters said that laboratory certification beyond ISO 17025 is neither productive nor necessary. Another commenter suggested that the Commission should consider the requirements of Clause 4.2 of ISO/IEC Guide 65 and look to the Occupational Safety and Health Administration's (OSHA's) Nationally Recognized Testing Laboratory (NRTL) program as an example of the level of inquiry that should be required, the type of requirements that should be

implemented, and to ensure impartiality and prevent conflict of interest. It added that CPSC should require applicants, including the firewalled and government laboratories, to submit the evidence used to validate the fulfillment of ISO/IEC 17025 4.1.5 b as part of their application to the CPSC.

Staff Response: The staff disagrees with these comments. ISO/IEC Guide 65 and the NRTL program both deal with certifying bodies that perform many functions in addition to the testing functions performed by third party conformity assessment bodies. The requirements the Commission has used for accrediting third party conformity assessment bodies include that an ILAC-MRA signatory accrediting body has accredited the conformity assessment body as complying with the requirements of ISO/IEC 17025, including the requirement of section 4.1.5(b) that the laboratory 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." This system appears to be working as intended. There appears to be no need to implement duplicative or additional requirements.

2. Comment: The commenter also stated that CPSC should extend existing CPSC fines and penalties that the CPSC can currently impose on manufacturers and retailers to apply to exerting or attempting to exert undue influence on third-party conformity bodies.

Staff Response: Section 19(a)(14) of the CPSA prohibits any attempt to exercise undue influence on a third party conformity assessment body (as defined in section 14(f)(2) of the CPSA) with respect to the testing, or reporting of the results of testing, of any product for compliance with the CPSA or any other act enforced by the Commission. Under section 20(a)(1) of the CPSA, violations of section 19 of the CPSA are punishable by a fine not to exceed $100,000 for each violation. Section 21(a) of the CPSA provides criminal penalties for knowing and willful violations of section 19 of the CPSA, including imprisonment for up to 5 years. Therefore, the CPSA already addresses fines and penalties, so no action by the Commission is required.

J. Labeling Program

1. Comment: One commenter stated that the CPSC should provide examples of allowable text for such labels, but should not specify specifics such as size, color, font or location as these will depend on the product. It would be a huge burden to impose specifications such as "label" text or size.

Staff Response: CPSC staff disagrees with the commenter. Section 14(d)(2)(A) of the CPSA specifies that the label is to show that the consumer product complies with the certification requirements in section 14(a) of the CPSA. Although the Commission has, in other cases, declined to specify the size and format of certain labels (such as tracking labels required under section 103 of the

CPSIA), the staff believes that a consistent and simple label will be easier for consumers to recognize and also easier to understand. For example, assume that a manufacturer wants to label its children's product to show that it complies with the lead limits in section 101 of the CPSIA. In the absence of a simple, uniform label, the label could say, "Complies with section 101 of the Consumer Product Safety Improvement Act," "Contains less than 300 ppm lead consistent with federal law," or even "Certified as having no lead above federal limits," and each label arguably would be correct. However, unless a consumer was familiar with the lead limits or the CPSIA, the label's usefulness to a consumer would be questionable, and potential consumer confusion would be magnified even more if the product had multiple labels for each certification or if seemingly similar products had different labels. Consequently, the staff believes that a single, simple, uniform label will be easy for consumers to recognize and to understand.

2. Comment: One commenter recommended that the Commission not initiate a labeling program, as it will contribute to confusion with the tracking label within the small business community. They believe that the customer base will see the label as an additional requirement and impose it on the manufacturers of all products.

Staff Response: Section 14(d)(2)(A) of the CPSA requires CPSC to initiate a program by which a manufacturer or private labeler may label their products as complying with the certification requirements. This label is distinct from the tracking label required by section 103 of the CPSIA, and the staff's suggested text and format for the label under section 14(d)(2)(A) of the CPSA will make it easy for consumers, small businesses, and any other interested party to distinguish tracking labels from the labels under section 14(d)(2)(A) of the CPSA. Additionally, staff notes that manufacturers can choose to not label their products under section 14(d)(2)(A) of the CPSA.

3. Comment: One commenter suggested that the label require the name of the manufacturer or importer, the production date, the compliance identifier, and the model number. This would provide sufficient information for the manufacturer to correlate a particular product to component certificates of compliance and to identify it for consumers should a recall be required.

Staff Response: The type of label the commenter is describing is a tracking label which is currently required for children's products. In contrast, the label under section 14(d)(2)(A) of the CPSA is intended to show that the product complies with CPSC safety requirements. The information sought by the commenter in the label, therefore, is outside the scope of the requirements of section 14(d)(2)(A) of the CPSA.

4. Comment: Two commenters stated that if a consumer compares a children's product with a label stating compliance to all applicable rules to a comparable product with no applicable rules (and thus no label), the absence of

the label will be misperceived as non-compliance by the consumer and will thus disadvantage the second product.

Staff Response: The decision to label a consumer product as complying with the certification requirements in section 14(a) of the CPSA is up to the manufacturer or private labeler. Thus, the Commission cannot require all manufacturers of similar or comparable products to label or not to label their products.

5. Comment: One manufacturer noted that some children's products are currently required to contain a label and that label should be considered sufficient.

Staff Response: Section 14(d)(2)(A) of the CPSA states that a manufacturer or private labeler may label its products as complying with CPSC certification requirements. It is optional and is not required by CPSC.

6. Comment: One commenter stated that labeling be limited to children's products, since section 14(d) of the CPSC deals with additional third-party test requirements.

Staff Response: Section 14(d)(2)(A) of the CPSA states that a manufacturer or private labeler may label its products as complying with CPSC certification requirements. It is optional and is not required by CPSC. Additionally, section 14(d)(2)(A) of the CPSA refers to consumer products, not just children's products. Other uses of the phrase "consumer product" refer to both non-children's and children's products, such as in section 14(a)(4) of the CPSA.

7. Comment: One commenter suggested that the label requirement be harmonized as best as possible with existing federal regulations such as U.S. Customs and Border Production country of origin labeling and the Federal Trade Commission's Textile and Wool Products Identification Act's fiber content labeling requirements. These existing regulations have survived the test of time and that work extremely well for regulatory purposes and meet commercial needs alike. The use of the label should be restricted to identifying the manufacturer/importer and the batch to help facilitate and narrow the scope of recalls. There needs to be accommodations, or exclusions for products that are impossible to mark, like the exclusions provided in the J list of the U.S. Customs regulations for country of origin markings or products that would be destroyed by marking.

Staff Response: Staff disagrees with the commenter. Under section 14(d)(2)(A) of the CPSA, the label is intended to show compliance with CPSC certification requirements. It is not intended to be a tracking label or demonstrate compliance with laws or regulations administered by other federal agencies.

K. Certificates

1. Comment: One commenter said that the electronic availability of certificates should satisfy the "accompany" and "furnish" requirements as opposed to requiring a paper certificate.

Staff Response: The Commission has issued a rule (16 CFR 1110) specifically allowing use of an electronic certificate provided the Commission has reasonable access to it, it contains all of the information required by section 102 of the CPSIA, and it complies with the other requirements of the rule. The rule is available on the CPSC World Wide Web site at http://www.cpsc.gov/businfo/frnotices/fr09/certification.pdf. Because this rule allows the use of electronic certificates as requested by this commenter, no additional action is required.

2. Comment: One commenter urged the Commission to recognize the registered certification marks of recognized product certification bodies, like those accredited under the OSHA Nationally Recognized Testing Laboratory program for applicable product scopes, in lieu of paper certificates of conformity, as is currently interpreted to be the requirement under the CPSA. The commenter states that such certification marks provide evidence of a demonstration of conformity to the applicable product safety standard and CPSC requirements and also offer traceability to the manufacturer and testing data, a recognized key objective of the certificate of conformity requirements.

Staff Response: To the extent this commenter wishes to change the process by which testing laboratories can become accredited as third party conformity assessment bodies whose tests can be the basis for certificates that children's products conform to CPSC requirements, the comment addresses a topic outside the scope of this rulemaking. Also, the Commission concludes that such marks, alone, would not provide the information required for certificates under section 14 of the CPSA. Additionally, under the statute and CPSC's regulations, manufacturers (including importers) issue the certificates. Third party conformity assessment bodies only test children's products for compliance with the applicable children's product safety rules; section 14(a)(2) of the CPSA does not make third party conformity assessment bodies responsible for issuing certificates.

3. Comment: One commenter stated:

. . . the CPSC has no jurisdiction to issue certification regulations, except as part of a reasonable labeling rule adopted under section 14 of the CPSA. Section 14(a) of the CPSA gives the manufacturer the option to select his own form and medium to convey certification of compliance with a CPSC standard. It does not authorize the Commission to adopt any rule prescribing the content of the certificate or method of its distribution. (Footnote omitted.)

Staff Response: Staff disagrees with the commenter. The Commission has the authority to issue implementing regulations under section 3 of the CPSIA, which provides that "[t]he Commission may issue regulations, as necessary, to implement this Act and the amendments made by this Act."

4. Comment: One commenter urged the CPSC to include the certification requirements of section 14(a) of the CPSA on a label on the product.

Staff Response: A label on a finished product can serve as the certificate required by section 14(a) of the CPSA. However, many products would not be able to accommodate a label of the size needed to contain all the information required for certificates. Further, labels on products may not meet the business needs of distributors and retailers, who may need to inspect the certificates without opening packaging or shipping containers and who may need to make copies of the certificates for their records. Accordingly, the staff does not propose to require that certificates be in the form of labels on products.

5. Comment: One commenter stated that the CPSC has no jurisdiction to require that a certificate be on a separate piece of paper that accompanies the product.

Staff Response: The Commission has not proposed to require certificates to be only in the form of a separate piece of paper. As noted previously, certificates can also be in electronic form or be labels on finished products.

6. Comment: The commenter also stated that the CPSC cannot require the certificate to contain the specific week of manufacture or the particular unit of equipment used to manufacture the product.

Staff Response: Except for the date of manufacture, the Commission has not proposed or suggested that such information be a part of a certificate. To date, insofar as a general certificate of conformity is concerned, the Commission staff has recommended, but not required, that the following information appear:

1. Identification of the product covered by this certificate:
2. Citation to each CPSC product safety regulation to which this product is being certified:
3. Identification of the U.S. importer or domestic manufacturer certifying compliance of the product:
4. Contact information for the individual maintaining records of test results:
5. Date and place where this product was manufactured:
6. Date and place where this product was tested for compliance with the regulation(s) cited above:
7. Identification of any third-party laboratory on whose testing the certificate depends:

However, the Commission disagrees with the commenter's underlying premise that it cannot require certain information as part of a certificate. The Commission

notes the information required on certificates under section 14(g) of the CPSA and that section 3 of the CPSIA gives the Commission general rulemaking authority to implement the CPSIA.

7. Comment: The commenter went on to say that at least 180 days would be needed to comply with any new requirements.

Staff Response: The staff is proposing that any final rule based on the proposal become effective 180 days after the date of publication of the final rule in the Federal Register. Interested parties who believe that the effective date should be longer or shorter should submit a comment to the proposed rule. The comment should include the specific facts on which they base their conclusion.

L. Reliance on Test Results of Others for Certification Purposes

1. Comment: Two commenters said that one foreign manufacturer may supply the same product to several importers, who would then be required to redundantly test the same product. This is considered wasteful and inefficient. Two commenters stated that importers should be allowed to base their certificates on test reports and results of other entities. One commenter added that CPSC should by policy recognize the vendor's assumption of liability in making such certification and deem that retailers, importers and distributors of product subject to such certification may rely upon it without facing civil or criminal liability.

Staff Response: The importer does not need to commission the testing themselves and could use the test reports from the manufacturer. However, the certificate **must** be issued by the importer. An importer is ultimately responsible for ensuring that a product meets the CPSC requirements. It should understand the regulations that apply to its product and that the testing process was appropriate to ensure that the tests conducted would ensure that the product met those requirements. It must also ensure that the proper testing laboratory was used (accredited, and accredited for the correct test). If a product fails to meet either the certification requirements or the regulations for product conformance then the importer is ultimately responsible for any actions that the CPSC may take including recalls, seizure, and any penalties that might be applicable.

2. Comment: One commenter recommended that ink manufacturers be allowed to group, test and certify product families for component testing. Product families represent the same core formula. Product family certification provides a reasonable, economically viable, testing model for these ink manufacturers.

Staff Response: As was discussed earlier, this is rather ambiguous, since the commenter has not defined "family". However, if by family it means an ink that has a similar base formula and varies only in color then it cannot be allowed since some pigments could contain lead and others would not. The Commission has previously made a determination that the "family" of CYMK inks do not need

to be tested since they do not contain lead.

3. Comment: One commenter asked for clarification for importers who rely on foreign manufacturers' certificates of conformity. The commenter is looking for additional clarification regarding what level of diligence can reasonably and effectively be exercised by the importers.

Staff Response: An importer is ultimately responsible for ensuring that a product meets the CPSC requirements. If a product fails to meet these requirements then it is responsible for any actions that the CPSC may take including recalls, seizure, and any penalties that might be applicable.

4. Comment: One commenter stated that importers of many products will be overburdened with testing costs; whereas a manufacturer, focusing in one area, can efficiently test its products. The importer would still be responsible for the product's certificate, but would use test data furnished by the manufacturer. Importers have little control over the design, manufacturing process, or sourcing of component parts, but manufacturers control all those aspects of production.

Staff Response: As was discussed, this is a cost of doing business. The Commission has allowed importers to rely on manufacturer's data and certificates in the case of component part testing. The importer should (must) be aware of the manufacturing process. In many cases the importer provides the specifications for the finished product. In those cases the importer must specify that the product conform to the regulations. In the cases in which the importer has little or no control over the manufacturing process and is relying on the manufacturer's test data, it is the responsibility of the importer to understand the manufacturing and testing process. An importer will need to know what factors could impact the product at the manufacturing level that would result in a violative product. It needs to understand the testing process and ensure that all necessary tests were conducted in an appropriate manner to ensure with a high degree of assurance that a non-violative product is placed into commerce.

M. Additional Third Party Testing Requirements for Children's Products

1. Comment: Many commenters believed that risk should be factored into any testing program. A product that poses a higher level of risk should undergo closer scrutiny.

Staff Response: The staff agrees with this comment. Products with a higher risk should undergo closer scrutiny, and this is reflected in the rule. For example, the rule indicates that certifiers should increase the frequency of periodic testing when noncompliance may result in serious injury or death.

Material Changes

2. Comment: One commenter provided a list of activities that would more precisely define a material change. The list included changes in tooling, product materials, assembly method, or the manufacturing facility.

Staff Response: The staff agrees that the listed activities mentioned by the commenter would generally constitute a material change in the product and would likely trigger the requirement for third party testing of children's products. However, rather than simply listing activities that constitute a material change, the draft rule more generally defines a material change as one that could affect the product's ability to comply with applicable product safety rules. The rule then would describe generally the types of changes in product design, manufacturing processes, and sourcing of component parts that the staff believes could result in a material change.

Because of the many types of children's products and manufacturing processes that will be covered by the rule, the staff believes that the description of the activities that would trigger additional third party testing due to material changes needs to be described in general terms, while at the same time remaining consistent with the intent of the law. It also provides some flexibility to manufacturers who experts in their product areas and are oftentimes better situated to understand when a change in their product could affect the product's ability to comply with applicable rules.

Periodic Testing

3. Comment: One commenter declared that the Commission should provide reasonably specific guidelines with regard to both periodic testing frequency and sample size to be used in such testing. The commenter suggested a period of at least twice per year or once every 50,000 units in any event, whichever occurs first.

With regards to the sample size for periodic testing, they suggested (at least for toys) to use the 12-unit sample size which has been the requirement of the CPSC Engineering Test Manual for many years as a starting point. A sample size of 18 pieces could be required for higher-risk products such as infant and toddler toys, and a lesser sample could be allowed for large, bulky, or expensive products both to minimize cost.

Staff Response: With respect to the frequency of periodic testing, the draft rule does provide reasonably specific guidelines. If the manufacturer has a reasonable testing program, periodic testing must be conducted at least once a year, or, for small volume products (i.e., those for which fewer than 10,000 units are produced or imported annually) only once for every 10,000 units that are manufactured or imported. However, for manufacturers without a reasonable testing program, periodic testing will be needed more frequently, at intervals that the testing structure provides a high degree of assurance of compliance.

With regard to the sample size for periodic testing, the 12 or 18 unit sample suggested by the commenter might be a good starting point for some manufacturers. However, the requirement is to select a sufficient number of samples for testing to achieve a high degree of assurance of continuing compliance to the applicable children's product safety rules. That number may be fewer than 12 or more than 18, depending on the children's product and the rule, standard, ban, or regulation under consideration.

4. Comment: One commenter noted that first-party production testing is used extensively to control manufacturing and is effective in detecting problems that could lead to nonconforming products. That information can be used to reduce the number of samples required for periodic testing to one.

Staff Response: If the purpose of a third-party periodic testing program were to demonstrate the continuing ability of a reasonable testing program to produce compliant products, the number of samples to be tested during periodic tests might be limited to one. However, if (as is consistent with the interpretation of the purpose of periodic testing in the proposed draft rule) the purpose the third-party testing is to provide a high degree of statistical assurance that all products produced comply with the rule, it has been shown by the Directorate for Epidemiology that the testing of a single sample would generally not be acceptable.

5. Comment: One commenter stated that once the children's product has passed its certification testing, periodic testing is not required. Only a material change would require retesting.

Staff Response: The staff believes that this comment is contrary to the intent of the requirement for periodic testing in section 14 of the CPSA. Section 14(d)(2)(B)(i) of the CPSA says explicitly that the rule is intended to establish protocols and standards to ensure that children's products are tested "periodically," in well as when there has been a material change to the product.

6. Comment: One commenter suggested that In establishing procedures and standards for periodic testing of children's products, CPSC should consider the potential for lead exposure in order to distinguish between products that pose a reasonable risk of non-compliance with the lead content limits and products that pose only a theoretical risk of non-compliance.

Staff Response: The staff does not disagree with the spirit of this comment. However, based on the explicit wording and apparent intent of the lead requirements of the CPSIA, and with the few exemptions provided by rule, all products intended for children's use are required to be tested for lead content.

N. Jurisdiction

1. Comment: One commenter took the position that the Commission has no jurisdiction over architectural glass (e.g., glass used in windows and doors). The commenter contends that architectural glass is not a consumer product.

Staff Response: The Commission does not agree that architectural glass is not a consumer product. The term "consumer product" means any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but such term does not include any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer. Section 3(a)(5) of the CPSA, 15 U.S.C. 2052(a)(5). Architectural glass is used by consumers to see out through a sliding patio door or see what is on the other side of a door with a glass panel. The Commission's safety standard for architectural glazing materials was upheld when challenged on judicial review, and such materials, which include architectural glass, were found to be consumer products. ASG Industries, Inc. v. CPSC, 593 F.2d 1323 (D.C. Cir. 1979).

(a) TAB B: [Regulatory Flexibility Analysis for Continuing Testing Rule]

TAB B

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: Draft 19 March 2010

TO : Randy Butturini
Project Manager
Continuing Testing Rule

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

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

FROM : Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT : Regulatory Flexibility Analysis for Continuing Testing Rule

Attached is a draft regulatory flexibility analysis for the continuing testing rule.

Initial Regulatory Flexibility Analysis for the Draft Proposed Rule Implementing Section 14(d)(2) of the Consumer Product Safety Act

Robert Franklin
Directorate for Economic Analysis
DRAFT 30 March 2010

TABLE OF CONTENTS

Initial Regulatory Flexibility Analysis for the Draft Proposed Rule Implementing Section 14(d)(2) of the Consumer Product Safety Act

This report provides an analysis of the impact on small businesses and other entities of a draft proposed rule that would implement Sections 14(a)(1) and 14(d)(2)(B) of the Consumer Product Safety Act, as amended by the Consumer Product Safety Improvement Act of 2008, ("CPSIA"). These provisions, which may be called the *compliance and continued testing rule,* require the Consumer Product Safety Commission ("CPSC" or "Commission") to:

(A) initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements of Section 14(a) of the CPSA; and
(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;
  (ii) for the testing of random samples to ensure continued compliance;
  (iii) for verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules; and
  (iv) for safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

Whenever an agency publishes a proposed rule, the Regulatory Flexibility Act (5 USC 601 – 612) requires that the agency prepare an initial regulatory flexibility analysis that describes the impact that the rule would have on small businesses and other entities. The initial regulatory flexibility analysis must contain –

(1) a description of why action by the agency is being considered;
(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
(5) an identification to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

An IRFA must also contain a description of any significant alternatives that would accomplish the stated objectives of the applicable statutes and which would minimize any significant economic impact of the proposed rule on small entities. Alternatives could include (1) the establishment of differing compliance or reporting requirements that take into account the resources available to small businesses; (2) the clarification,

consolidation, or simplification of compliance and reporting requirements for small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part of the rule thereof, for small entities.

Reason for Agency Action

The Commission is proposing this rule in order to implement sections 14(a)(1) and 14(d)(2)(B) of the Consumer Product Safety Act (CPSA). Section 14(d)(2)(B) was added to the CPSA by the Consumer Product Safety Improvement Act (CPSIA) of 2008.

Objectives of and Legal Basis for the Rule

The objective of the rule is to reduce the risk of injury from consumer products, especially from products intended for children aged 12 years and younger. The rule will accomplish this objective by requiring that manufacturers[11] of non-children's consumer products that are covered by product safety rules to develop and maintain reasonable testing programs that provide a high degree of assurance that their products conform to all the applicable safety standards. For children's products, an additional layer of protection is provided by requiring that certain testing be performed by an accredited third-party conformity assessment body. The testing programs should allow manufacturers to discover nonconforming products and take the necessary corrective actions to keep nonconforming products from entering commerce or to remove them expeditiously if they have been introduced into commerce.

The legal basis for the rule is derived from the Consumer Product Safety Act and the Consumer Product Safety Improvement Act of 2008.

Small Entities to Which the Rule Will Apply

By regulation, the Commission has determined that the party that is responsible for ensuring that a consumer product is properly tested, and based on the results, certifying that it conforms to all applicable safety rules is either the domestic manufacturer or the importer of the product. Therefore, the proposed rule would apply to all manufacturers and importers of consumer products that are subject to a product safety rule. This includes virtually all manufacturers of children's products, since almost all children's products are subject to at least one product safety rule, such as the rule that limits the lead content of a children's product. Children's products are defined as products that are designed or intended primarily for children 12 years of age or younger. Manufacturers and importers of general use products would be affected if their products are subject to a product safety rule.

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[11] The term "manufacturer" when used in this report includes private labelers and importers of products manufactured by foreign manufacturers.

Children's Product Safety Rules

Virtually all children's products are subject to some children's product safety rules, primarily because the lead content of all children's products is strictly limited. All manufacturers and importers of children's products will be required to test the products for lead content. Testing by third-party conformity assessment bodies will be required for at least some of the tests on all children's products. The Commission has only exempted a few materials that inherently do not contain lead from the requirement to test. The exempted materials are limited to things such as many fabrics, precious metals, paper, gemstones, and a limited number of other items. These can be found in the Code of Federal Regulations (15 CFR, Part 1500.91). The Commission has also issued a rule exempting inaccessible components in children's products from the lead content requirements (15 CFR, Part 1500.87). All other materials used in products intended for children must be tested for lead content. The definition of a children's product is broad and includes bicycles, books, furniture, apparel, jewelry, televisions, electronic games, toys, and so on, if intended for a child 12 years of age or younger.

In addition to the requirements to test for lead content, manufacturers will be required to test for conformity with a wide variety of other children's product safety rules. For example, there are product safety rules that establish standards for children's products such as toys, cribs, bicycles, bicycle helmets, youth all terrain vehicles, bunk beds, and baby walkers among other things. The CPSIA also limits the amount of 6 phthalates that can be present in toys and childcare articles, which the CPSIA defines as anything to facilitate the feeding and sleeping of children age 3 and younger and to help such children with sucking or teething. Thus, many plastics will need to be tested for phthalate content. A full list of the children's product safety rules is in Appendix A. In addition to those rules, over the next several months, the Commission is expected to issue product safety rules that cover other children's products, including strollers and high chairs.

Product Safety Rules Applicable to General Use Products

Manufacturers and importers of consumer products that are subject to a product safety rule but that are not primarily intended for children must certify that the products conform to the safety rules based on the results of a test of each product or a reasonable testing program. The draft proposed rule would establish the basic requirements for a reasonable testing program. Therefore, the rule would also impact manufacturers and importers of products that are not primarily intended for children if the product is subject to a product safety rule. Consumer product safety rules include flammability standards for carpets and rugs, requirements for all terrain vehicles, bunk beds, and the lead content of paint, among other things. A full list of safety rules applicable to general use products is in Appendix B.

Number of Small Firms Affected

The number of firms that could be impacted was estimated by reviewing every category in the North American Industrial Classification System (NAICS) and selecting those that included firms that could manufacture or sell any consumer product that could be covered by a consumer product safety rule. This includes any establishment that could manufacture or sell a product intended for children and any general use product described in Appendix B. Firms are classified in NAICS code that describes their primary activity. Therefore, firms that might manufacture or import consumer products covered by a safety rule as a secondary or tertiary activity might not have been counted. There is no separate NAICS category for importers. Firms that import product might be classified as manufacturers, wholesalers, or retailers.

Manufacturers

According to the criteria established by the Small Business Administration, manufacturers are generally considered to be small entities if they have fewer than 500 employees. Table 1 shows the number of manufacturers that are classified by the North American Industrial Classification System (NAICS) categories that cover most children's and general use products that are subject to a product safety rule. Although there are more than 36,000 manufacturers that would be considered small in these categories, not all of these firms are engaged in manufacturing children's products or general use products that are subject to a product safety rule. It would be expected that most of the firms engaged in *Doll, Toy, and Game* manufacturing produce some products that are intended for children age 12 and younger. On the other hand, *All Other Miscellaneous Chemical Product and Preparation Manufacturing* includes some products subject to consumer product safety rules such as matchbooks and fireworks, but also includes products that are not subject to consumer product safety rules, such as distilled water and hydraulic fluids. *All Other Miscellaneous Electrical Equipment and Component Manufacturing* includes consumer products such as garage door openers as well as non consumer products such as particle accelerators. The *Surgical Appliance and Supplies Manufacturing* category includes bicycle helmets, but most of the other products in this category are not under CPSC jurisdiction.

Table 1: Manufacturers

NAICS Code	Description	Small Firms	Total Firms
31411	Carpet and Rug Mills	261	284
31519	Other Apparel Knitting Mills (Outerwear, Underwear, and Sleepwear)	235	246
3152	Cut and Sew Apparel Manufacturing	9,313	9,388
3159	Apparel Accessories and Other Apparel Manufacturing	907	920
316211	Rubber and Plastic Footwear Manufacturing	52	56
316212	House Slipper Manufacturing	2	2
316219	Other Footwear Manufacturing	68	69
321911	Wood Window and Door Manufacturing	1,241	1,297
32551	Paint and Coating Manufacturing	1,042	1,093
325998	All Other Misc. Chemical Product and Preparation Manufacturing	957	1,045
326191	Plastics Plumbing Fixture Manufacturing	465	488
326299	All Other Rubber Product Manufacturing	633	681
332321	Metal Window and Door Manufacturing	1,071	1,138
332998	Enameled Iron and Metal Sanitary Ware Manufacturing	60	72
333112	Lawn and Garden Tractor and Home Lawn and Garden Equip. Mfg.	117	134
33422	Radio, Television Broadcasting and Wireless Comm. Equip. Mfg.	811	894
335222	Household Refrigerator and Home Freezer Manufacturing	12	18
335999	All Other Misc. Electrical Equipment and Component Mfg.	737	791
336991	Motorcycle, Bicycle, and Parts Manufacturing	456	466
33712	Household and Institutional Furniture Manufacturing	6,052	6,179
33791	Mattress Manufacturing	448	462
339113	Surgical Appliance and Supplies Manufacturing	1,601	1,691
33991	Jewelry and Silverware Manufacturing	2,737	2,752
33992	Sporting and Athletic Goods Manufacturing	1,886	1,930
33993	Doll, Toy and Game Manufacturing	763	776
339999	All Other Miscellaneous Manufacturing	4,440	4,499
	Total Manufacturers	36,367	37,371

Source: U.S. Census Bureau, 2006 County Business Patterns.

Wholesalers

Wholesalers would be impacted by the rule if they import any children's products or general use products that are subject to a product safety rule. Wholesalers that obtain their products strictly from domestic manufacturers or from other wholesalers would not be impacted by the rule since the manufacturer or importer would be responsible for testing and certifying the product. Table 2 shows the number of wholesalers by NAICS code that would cover most children's products and general use products that are subject to a product safety rule. According to the SBA criteria, wholesalers are generally considered to be small entities if they have fewer than 100 employees. Although there are more than 77,000 wholesalers that would be considered

small in these categories, not all of these firms are engaged in importing children's or general use products that are subject to a consumer product safety rule. A significant proportion of the firms classified as *Toy and Hobby Goods and Supplies Merchant Wholesalers* probably import at least some children's products. However, the only firms classified as *Motor Vehicle and Motor Vehicle Parts and Suppliers* would be those that import all terrain vehicles or other off-road vehicles, especially those intended for children age 12 years and younger.

Table 2. Wholesalers

NAICS Code	Description	Small Firms	Total Firms
4231	Motor Vehicle and Motor Vehicle Parts and Suppliers	16,947	17,858
4232	Furniture and Home Furnishing Merchant Wholesalers	10,534	10,981
42362	Electrical and Electronic Appliance, Television, and Radio Set Merchant Wholesalers	2,147	2,269
42391	Sporting and Recreational Goods and Supplies Merchant Wholesalers	4,397	4,552
42392	Toy and Hobby Goods and Supplies Merchant Wholesalers	2,170	2,248
42394	Jewelry, Watch, Precious Stone, and Precious Metal Merchant Wholesalers	7,735	7,815
42399	Other Miscellaneous Durable Goods Merchant Wholesalers	10,146	10,367
42432	Men's and Boy's Clothing and Furnishings Merchant Wholesalers	3,235	3,393
42433	Women's, Children's, and Infant's Clothing, and Accessories Merchant Wholesalers	5,965	6,186
42434	Footwear Merchant Wholesalers	1,434	1,493
42499	Other Miscellaneous Nondurable Goods Merchant Wholesalers	12,497	12,753
	Total	77,207	79,915

Source: U.S. Census Bureau, 2006 County Business Patterns

Retailers

Retailers that obtain all of their products from domestic manufacturers or wholesalers will not be directly impacted by the rule, since the direct impact of the rule would be experienced by the manufacturer or importer. However, there are some retailers that manufacture or directly import some products and, therefore, will be responsible for ensuring that these products are subjected to testing by third-party conformity assessment bodies. The number of such retailers is not known. The next Table shows the number of retailers by NAICS code that would cover most children's products. According to the SBA criteria, retailers are generally considered to be small entities if their annual sales are less than $7 million ($27 million in the case of *general merchandise stores*). Because of the way in which the data were reported, the Table shows total number of firms in each of the categories that operated all year and the number with sales of less than $5 million ($25 million in the case of *general merchandise stores*). Although there are more than 125,000 that would be considered to be small businesses in these categories, it is not known how many of these firms are

engaged in importing or manufacturing children's or general use products that are subject to a consumer product safety rule. Many of these firms probably obtain all of their product from domestic wholesalers or manufacturers and would not be directly impacted by the rule.

Table 3. Retailers

NAICS Code	Description	Small Firms	Total Firms
441221	Motorcycle, ATV, and Personal Watercraft Dealers	3,969	4,001
4421	Furniture Stores	16,282	17,542
44813	Children's and Infant's Clothing Stores	2,146	2,200
44814	Family Clothing Stores	5,998	6,240
4482103	Children's & juveniles' shoe stores	300	305
4483	Jewelry, luggage, & leather goods stores	16,341	16,778
45111	Sporting goods stores	14,451	14,831
45112	Hobby, toy, & game stores	4,832	4,903
452	General Merchandise Stores	7,387	7,494
45322	Gift, Novelty, and Souvenir Store	21,412	21,637
453998	All Other Misc. Store Retailers (except Tobacco Stores)	11,934	12,228
4542	Vending machine operators	4,081	4,278
45439	Other direct selling establishments	15,938	16,431
	Total	125,071	128,868

Source: U.S. Census Bureau, 2002 Economic Census, Release date 11/25/2005

Compliance, Reporting, and Record Keeping Requirements of Draft Proposed Rule

The compliance, reporting, and recordkeeping requirement of the draft proposed rule would differ depending upon whether the product is a general use consumer product (i.e., one that is not designed or intended primarily for children 12 years of age or younger), or a children's product (i.e., one that is designed or intended primarily for a person 12 years of age or younger).

Requirements for Manufacturers of General Use Products

The CPSA, as amended by the CPSIA of 2008, requires that manufacturers, importers, or private labelers of general use consumer products certify that each product complies with all applicable safety rules based on a test of each product or the results of a reasonable testing program. By regulation, the Commission limited this

requirement to either the domestic manufacturer or importer of the product. The draft proposed rule would establish the minimum requirements for a reasonable testing program.

As described in the draft proposed rule, a reasonable testing program would contain at least 5 elements. The first element is the *Product Specification*, which describes the product sufficiently to differentiate it from other products and lists each safety rule with which the product must comply. The second element is *Certification Tests* that are performed on samples of the product that demonstrate that the product is capable of conforming to all applicable safety rules. The third element is a *Production Testing Plan* that describes what tests will be performed and at what intervals to provide a high degree of assurance that the products continue to meet all applicable safety rules. The fourth element is a *Remedial Action Plan* that describes the steps that the manufacturer or importer will take whenever it obtains test results or other information that the product might not comply with a safety rule. The final element of a reasonable testing program is *Recordkeeping Requirements*. The manufacturer or importer would be required to include documentation for each of the other elements in the reasonable testing program, including certification and production test data.

Requirements for Manufacturers of Children's Products

The CPSIA requires that manufacturers of children's products certify that each children's product complies with all applicable safety rules based upon the results of testing by CPSC-recognized third party conformity assessment bodies. It also requires manufacturers to test the products periodically and when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts. The draft proposed rule would provide more specific requirements for the testing of children's products. It also provides requirements that would verify that a children's product tested by a conformity assessment body complies with the applicable safety rules and for safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer.

Certification Tests

The CPSIA requires that before any children's product is imported for consumption or warehoused or distributed in commerce, it must be tested for compliance with all applicable safety rules by a third party conformity assessment body that has been accredited by the CPSC. The draft proposed rule would require that manufacturers or importers submit enough samples to the third party conformity assessment body to demonstrate with a high degree of assurance that the product complies with all applicable safety rules.

Periodic Third Party Testing

Manufacturers and importers would be required to develop a periodic third party testing plan for each children's product. The plan should include a list of each rule with which the product must comply, the applicable tests, the intervals at which the tests will be conducted, and the number of units to be tested during each interval. The intervals and number of units to be tested should be sufficient to provide a high degree of assurance that the products that are currently being manufactured or imported continue to comply with the applicable safety rules. A high degree of assurance could be based on a statistical measure, such as a 95% probability that all of the products comply with the applicable safety rules or if only qualitative test data is available, that no more than some percentage of the products do not comply with the applicable safety rules. Manufacturers are free to establish the testing intervals provided, with an exception for low-volume manufacturers or importers, that periodic testing is conducted at least once annually. The periodic third party testing must be performed by a CPSC recognized third party conformity assessment body. At least some of the units selected for periodic testing must be selected randomly, using a process that assigns each unit produced an equal probability of being selected for testing.

If a children's manufacturer has established a *reasonable testing program* for a children's product that provides a high degree of assurance that all products comply with the applicable safety rules, then the frequency of the periodic testing can be reduced (or the interval between the periodic tests can be increased). However, periodic third party testing would still be required at least once each year, in most cases.

The requirement that periodic testing be conducted at least annually on children's products is waived in the case of products for which fewer than 10,000 units are manufactured or imported in any given year. For these products, no periodic testing will be required until at least 10,000 units have been manufactured or imported since the last periodic testing. This waiver does not extend to the required third-party certification tests discussed above or to the requirement to obtain third-party testing when there has been a material change in the product's design or manufacturing process, which is discussed below.

Third Party Testing Due to Material Changes

Manufacturers and importers of a children's product must have the product tested by a third party conformity assessment body if there has been a change in the product's design or manufacturing process that could affect its ability to comply with any applicable children's product safety rule. A material change includes the sourcing of component parts.

Third-party testing due to material changes can be limited to those rules with which compliance might have been affected by the change. For example, if the paint used on a toy were changed, the paint would have to be tested for lead (and when the

accreditation requirements are released for ASTM F963, for soluble heavy metals). However, the substrate would not have to be re-tested for lead content nor would the product have to be retested for compliance with other rules that apply to the product, such as the physical and mechanical requirements of ASTM F963, if compliance with the rule would not be affected by the change in paint.

Verification of Third Party Test Results

In order to verify that a children's product tested by a conformity assessment body complies with the applicable safety rules, the draft proposed rule would require that on a recurring basis, manufacturers or importers should use an alternate CPSC-recognized third party testing laboratory. If the results from the two testing laboratories differ significantly, especially if one indicates compliance and the other does not, the manufacturer or importer must investigate the reason for the discrepancy. If the manufacturer determines that one of the testing laboratories' results was in error, the manufacturer or importer must notify the CPSC of its findings.

Protection Against Undue Influence

The draft proposed rule would require that all manufacturers and importers of children's products establish procedures to prevent attempts to exercise undue influence on a third party conformity assessment body and to report to the Commission immediately of any attempt by any interested party to exert undue influence over test results, and that employees are aware that they report any allegations of undue influence to the Commission confidentially. These procedures may include training programs for their employees and the provision of other materials, such as manuals, that explain the responsibilities to avoid exerting undue influence and for reporting any attempts at undue influence that come to their attention.

Consumer Product Labeling Program

The draft proposed rule would establish a program by which any manufacturer, importer, or private labeler of a consumer product may label product as complying with the applicable certification requirements for the product. If a consumer product is compliant with all product safety rules that are applicable to the product, the manufacturer, importer, or private labeler may affix a label to the product that states that the product "*Meets CPSC safety requirements.*" This program is voluntary in that manufacturers, importers, and private labelers are not required to affix this label to their products. However, opting not to affix the label to the product would not relieve the firm of their responsibility to ensure that all of the products conform to the applicable safety rules and with all other provisions of the draft proposed rule.

The Effects of the Draft Rule

Reasonable Testing Program

The draft rule would require that any manufacturer or importer of a general use product subject to a product safety rule establish a reasonable testing program for the product unless it tests every product. The draft rule would also provide manufacturers and importers the option of establishing a reasonable testing program for children's products in order to reduce the amount of third party testing required. The draft rule would not impose any requirements on manufacturers or importers of products that are not subject to any consumer product safety rules.

Manufacturers and importers of products that are subject to some rules that were promulgated under the authority of the Consumer Product Safety Act are already required to have reasonable testing programs. For those rules promulgated under the authority of the Federal Hazardous Substances Act or other acts under the jurisdiction of the Commission, a reasonable testing program was not required prior to the enactment of the CPSIA. However, most manufacturers and importers probably have some quality control programs that are intended to demonstrate that the products as manufactured meet the manufacturer's or importer's specifications, including their specifications for complying with any safety regulations. In some cases these programs will meet the requirements of the reasonable testing program that would be required by the draft rule. Other manufacturers and importers may have to modify their current programs to ensure that they meet the requirements of the draft proposed rule. For example, some manufacturers might have to modify their programs to ensure that the testing program adequately covers all consumer product safety rules that are applicable to their products. Some manufacturers might have to increase their testing frequency. Some manufacturers might have some informal testing programs that would have to be formalized and better documented. There may also be some manufacturers or importers that do not have a program in place; these firms will have to develop a reasonable testing program from scratch.

The draft rule would provide manufacturers and importers with some flexibility for designing a program that matches the needs of the product and the firm. For example, large manufacturers might have extensive product specification records in an electronic format. Some small manufacturers might have handwritten product specification records stored in a 3-ring binder or file folder. Either system could meet the requirements of the rule if they provide all of the required information (e.g., enough information to identify the product and the safety rules that are applicable to the product or each component of the product).

The draft rule does not specify the specific tests that manufacturers must conduct as part of the reasonable testing program or how frequently any testing must occur. Instead the rule provides manufacturers with the flexibility to develop a testing plan that meets the needs of the firm, provided that the tests used and the testing intervals provide a high degree of assurance that all of the products will comply with all

applicable safety rules. The tests might be performed in-house or by a third-party laboratory. The frequency and the number of units selected for testing might depend upon the lot size and the precision of the manufacturing techniques used at the factory.

Manufacturers and importers will have to develop and maintain the following sets of records to document their testing programs: (1) a record of the product specifications for each consumer product that includes information concerning the qualification tests performed on the product and the certificate of conformity that covers the product; (2) records to demonstrate compliance with the requirements of the production tests; (3) records of all remedial actions taken when production tests indicated nonconformity with the standards. The records must be maintained in English and for as long as the product is being distributed in commerce plus 3 years. The records must be made available to any designated officer or employee of the Commission within 48 hours of request.

In order to develop their testing programs, manufacturers, importers and private labelers will need to know what CPSC safety rules apply to their products and the conditions under which their products could fail to conform to each applicable safety rule. This will require that manufacturers and importers and private labelers have a thorough knowledge of the materials that are used to manufacture their product and the production processes used in manufacturing the product. This knowledge can then be used by the manufacturers or importers to develop the testing program.

Compliance with this provision will require a variety of professional skills on the part of the manufacturers. Lawyers may be required to review CPSC regulations in order to determine which regulations are applicable to a product. Depending upon the specific product and the safety rules that are applicable to it, people with knowledge of subjects such as engineering and chemistry may be required to develop the product specifications, conduct the certification tests, and to design a program for production testing. Statistical skills or statistical consultants may be required to determine the frequency, sample size, and collection method for production testing. For some production tests, professionals such as engineers or chemists might be required, depending upon the product safety rules applicable to the product. In some cases, the production tests could be carried out by the firm's production workers or technicians, perhaps working under the supervision of an engineer, chemist, or similar professional. When the manufacturer or importer does not have the internal capability to perform some of the required production testing, the testing may need to be performed by third-party testing laboratories.

The cost to firms of complying with this provision of the draft proposed rule would be dependent upon the extent of the changes that firms will have to make to their existing testing programs to comply with the requirements of the draft proposed rule. For firms that already have testing programs that meet the requirements of the draft rule there could be no additional costs. For other firms, the cost of complying with the requirements of the draft proposed rule will depend upon several factors, including the characteristics of their products and the steps that the firm will have to take to comply

with the requirements. Because of the wide variety of products and manufacturers that would be covered by the draft proposed rule and because the characteristics of each product and the circumstances of each firm is different, the CPSC staff cannot reliably estimate the cost to manufacturers and importers of the reasonable testing program requirement of the draft proposed rule. The staff solicits comments from persons that can provide more information on the cost and other impacts of this requirement on manufacturers and importers.

Third Party Testing of Children's Products

The CPSIA requires that before a children's product can be introduced into commerce, it must be certified as complying with all applicable safety rules based upon the results of testing by a CPSC-recognized third party conformity assessment body. The draft proposal rule would establish protocols for the continued testing of children's products by third party conformity assessment bodies periodically and when there has been a material change in the products design or manufacturing process, including the sourcing of component parts.

The draft proposed rule would provide manufacturers with two options for developing a third party testing program. If the manufacturer or importer has established a *reasonable testing program* for the product that provides the manufacturer or importer with a high degree of assurance that all of the products comply with all applicable safety rules then the manufacturer or importer would be able to reduce the frequency of the periodic third-party testing, provided that third party testing was obtained at least once annually (or every 10,000 units produced or imported if fewer than 10,000 units are manufactured or imported annually). In this case the reasonable test program provides the high degree of assurance that all products comply with the applicable safety rules and the additional third party testing provides additional assurance that all products comply with applicable safety rules and that the manufacturer's reasonable testing program is adequate. Third party testing would also be required whenever there is a material change in the product.

On the other hand, if the manufacturer or importer has not established a reasonable testing program for the product, then the periodic third party testing would itself need to be frequent enough or at short enough intervals to provide high degree of assurance that the product that all products comply with the applicable safety rules. Therefore, it is likely that periodic testing would need to occur on a more frequent basis if the manufacturer does not have a reasonable testing program. Importers that do have a lot of influence over the manufacture of their products or that obtain products from foreign producers that do not conduct the required third party testing may be unable to establish an adequate reasonable testing program and, therefore, might have to rely on more frequent third party testing.

The requirements for third party testing will apply to virtually all manufacturers and importers of children's products, since virtually all children's products are subject to

some product safety rules. For example, the restrictions on lead content cover almost all children's products. Even products that contain some of the materials that have been exempted from the restrictions or that have been determined to inherently not contain lead in excess of the legal requirement might have to be tested for compliance with other rules. For example, although the fabric in wearing apparel might be exempted from the requirement to test for lead content, it will have to be tested for compliance with flammability requirements. Any other objects on the apparel, such as buttons, snaps, zippers, or appliqués will also need to be tested for lead content.

In meeting the requirements, manufacturers and importers can use component part testing where possible. This means that manufacturers could, for example, submit samples of paint that they are using on their products to a third party testing laboratory to be tested for lead content and soluble heavy metal content. This could reduce the amount of testing required since the testing results could be relied upon for showing that the paint on all of the products on which it is used does not violate the lead-content requirements of 16 CFR Part 1303 or the soluble heavy metal content requirements of ASTM F963.

The draft proposed rule would allow manufacturers and importers to rely upon certifications issued by their suppliers to issue their own certifications, provided that their supplier's certifications meet the requirements of the draft proposed rule. For example, a button supplier could certify that its product meets the lead content requirements for children's products and, provided that the supplier's certification met all requirements of the draft proposed rule, an apparel manufacturer could rely upon that certification to issue its own certificate and would not be required to subject the button to additional third-party testing for lead content. Likewise, if a foreign manufacture certified that a children's product that it produces complied with all applicable product safety rules and that certification met all of the requirements of the draft proposed rule, an importer of the product could rely upon the certification to issue its own certificate for the product and would not be required to obtain additional third-party testing of the product. However, in many cases the manufacturer or importer that is relying upon a certificate issued by a supplier may need to take some steps to ensure that their supplier's certification is reliable.

Manufacturers and importers will have to develop and maintain records that demonstrate their compliance with the third-party testing requirements. The records should include documentation identifying the product and the justification for the planned third party testing interval, records of the results of the third party tests, and records of all remedial actions that were taken in the event of a test indicating nonconformity with a safety rule. The records must be maintained in English and for as long as the product is being distributed in commerce plus 3 years. The records must be made available to any designated officer or employee of the Commission within 48 hours of request. The Commission staff welcomes comment on these requirements including comments on the possible burden that these recordkeeping requirements might impose.

It is expected that the cost of the third party testing could have a significant impact on a substantial number of small entities. The cost of third party testing is influenced by many factors, including the amount and skill of the labor required to conduct the tests, the cost of the equipment involved, the cost of transporting the product samples to the test facility, and the geographic area where the tests are conducted. Some tests require a substantial amount of time to conduct the tests including the preparation of the sample. It might take a couple of days, for example, to test a bicycle for compliance with the bicycle standard (16 CFR Part 1512). Similarly, a chemist testing the lead content of a product might be able to test only a few components a day due to the amount of time required to prepare the samples and clean and calibrate the equipment between tests.

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

Some information on the cost of third party testing for some of the applicable tests is provided below. The information was collected from a number of sources, including published price lists from some testing laboratories, conversations with representatives of testing laboratories, and actual invoices provided by consumer product manufacturers. The data are not based upon a statistically valid survey of testing laboratories. Additionally, the costs discussed below are only the costs that would be charged by the testing laboratory. Not included are the costs of the products consumed in destructive tests or the cost of shipping the samples to the laboratories.

Costs Associated with Various Third-Party Tests

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

The cost of testing for lead content using x-Ray fluorescence (XRF) technology is significantly less expensive. Some firms have offered to screen products for lead content for as little as $2 per test. These offers were generally directed to stores or businesses that wanted to check their inventory for conformity with the retroactive lead content requirements that were contained in the CPSIA. Some testing laboratories will charge for XRF testing at an hourly rate, which can be around $100. Ten to 30 components can be tested in an hour. However, with the exception of some plastics, XRF is not acceptable for all certification purposes.

Phthalates: The cost of testing for phthalate content will range from around $100 (a discounted price by a laboratory in China) to about $350. These are the costs per component and include testing for all 6 of the individual phthalates.

Bicycle Standard (16 CFR 1503): According to one testing laboratory, it takes 1 to 2 days to test a bicycle. The estimated price for testing one bicycle may range from around $700, if the testing is performed in China, to around $1,100 if the testing is performed in the United States. A manufacturer that needs several models of bicycles tested at the same time might be able to obtain discounts from these prices. However, this does not include the testing of component parts for lead and phthalates, which would add to the costs of bicycle testing.

Bicycle Helmets: One laboratory quoted a price for testing one model of a bicycle helmet to the CPSC bicycle helmet standard of $600. A price list from another laboratory stated that conducting the certification testing to the Snell Foundation's bicycle helmet standard (which is similar to the CPSC standard, but considered by some to be more stringent) was $830.

Full-Size Cribs: As with bicycles, testing cribs requires a substantial amount of labor time to assemble the crib, take the appropriate measurements and perform the required tests. The cost of testing a full-size crib will be around $1,200 in the United States. The cost can vary depending on the features of the individual cribs that require testing and between laboratories. Some manufacturers might receive discounted prices. This does not include testing the crib for lead and phthalates, which, to the extent necessary, would add to the cost of testing a crib to all applicable safety rules.

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

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

Cost of Third Party Testing by Product

The cost to obtain the required third party testing for a product depends on the types and number of tests that must be performed on each product, the size of the sample that is required to provide a high degree of assurance that all products comply with the applicable safety rules, and the extent to which component testing can be used. Because of the wide variety of manufacturers and importers and products that would be affected by the draft proposed rule, we cannot provide comprehensive estimates of the impact of the draft proposed rule on all products or firms. That said, the discussion below is intended to provide some perspective on the potential impact. The Commission staff would welcome additional public comments on the discussion below. The staff would also welcome more specific information of the impact and cost of the third party testing requirements of the draft proposed rule.

The third party testing costs discussed in this section apply to the costs associated with either the periodic testing requirement or the requirement that additional third party testing be obtained if there is a material change in the product's design or manufacturing process. However, in the latter case, the testing might be limited to those tests whose results might have been impacted by the change.

Number of units for testing: The rule would require the manufacturer or importer to submit enough units to the conformity assessment body to provide a high degree of assurance that the products in that production lot comply with the applicable product safety rules. The exact number will depend upon characteristics of the product, the lot size, whether the tests produce quantitative or qualitative data, whether the manufacturer has an established reasonable testing program, and the interpretation of a high degree of assurance. A discussion of the statistical aspects of designing a sampling plan was presented by Dr. Michael Greene of the CPSC staff at the Product Testing Workshop on 10 December 2009.[12]

Quantitative testing data is data where the relevant variable can be measured with some degree of precision. For example, the lead content of a substance can be measured in terms of parts per million (ppm). Qualitative data is where the outcome of a test is simply a "pass" or a "fail." For example, in a drop test the result might simply be whether a sharp edge was exposed (a "fail") or a sharp edge was not exposed (a "pass). When the data is qualitative the sample size will usually have to be larger than when the data is quantitative.

For example, as of 14 August 2011 the lead content of children's products must be no greater than 100 parts per million (ppm). If a high degree of assurance means at least a 95% probability that all products are in compliance and a manufacturer is testing a component for lead content, then the manufacturer could determine appropriate sample size if he or she knew the mean lead content of the component, the standard

[12] Michael A. Greene, Ph.D., Directorate for Epidemiology, U.S. Consumer Product Safety Commission, "Statistical Aspects of a Reasonable Test Plan," Presentation given at the CPSIA Product Testing Workshop at the Consumer Product Safety Commission, Bethesda, Maryland on 10 December 2009. A recording and the slides of the presentation is available at http://www.cpsc.gov/about/cpsia/cpsiatesting.html

deviation about the mean, and the size of the lot that was to be tested. Table 4 shows the sample sizes that would be required to provide the high degree of assurance for different lot sizes by mean and standard deviation (assuming a normal distribution). Larger sample sizes would be required for products with higher means, larger standard deviations, and larger lot sizes. Smaller sample sizes would be required for products with lower means, standard deviations and lot sizes.

Table 4. Sample Sizes Required to Provide at Least 95% Probability that the Lot is Compliant (given the availability of quantitative test data).

Mean (ppm)	Standard Deviation (ppm)	Lot Size (units)	Sample Size (units)	Probability that the Lot is Compliant
10	1	1,000	4	.998
10	1	2,500	4	.995
10	1	10,000	4	.992
10	1	25,000	5	.978
10	1	50,000	5	.957
15	3	1,000	5	.993
15	3	2,500	5	.983
15	3	10,000	6	.992
15	3	25,000	6	.981
15	3	50,000	6	.962
35	5	1,000	6	.965
35	5	2,500	7	.976
35	5	10,000	8	.972
35	5	25,000	9	.978
35	5	50,000	9	.957

Where only qualitative (e.g., pass/fail) testing data is available, the sample sizes required to provide a high degree of assurance will be higher than those in Table 4. Such tests include some of the use and abuse tests for testing children's products (e.g., the drop test). As discussed by Dr. Michael Greene at the CPSIA Product Testing Workshop, this is because there is more uncertainty in the test data.[13] That is, with only pass fail data, it is not known if the result was close to the threshold or far from the threshold. In these cases it might be necessary to define a high degree of assurance as a probability that no more than a given proportion of noncompliant products. For example, as discussed by Michael Greene at the Product Testing Workshop, a 95% probability that no more than a certain proportion "p" of the units in a lot do not comply is approximately given by the formula $p \approx 3/k$, where "k" is the sample size. Thus, if 50 items were tested and no noncomplying items were found, there is a 95% probability that no more than 6% of the items in the lot do not comply. In other words, if the lot size

[13] Ibid.

were 1,000 and 50 units were tested and no noncomplying product were found, there is a 95% probability that no more than 60 units in the entire lot are not in compliance. If the lot size were 10,000 units, there would be a 95% probability that no more than 600 noncomplying product. If a higher level of assurance were required, the sample size would have to be larger. If a lower level of assurance were acceptable the sample size could be smaller.

The examples in Table 4 illustrate the disproportionate impact that the draft proposed rule could have on small businesses or businesses with low-volume products. In the first example in the Table, the same number of units would have to be submitted to a third party testing laboratory whether 1,000 units or 10,000 units were in the lot. In other words, the total third-party testing costs would be the same, but the cost per unit for a manufacturer producing only 1,000 units would be 10 times the cost per unit for a manufacturer producing 10,000 units.

The examples also illustrate the potential that component testing could offer for reducing the cost of testing. For example, assume a manufacturer produces five products in lots of 10,000 units, but uses a common component on each of the products that it purchases in lots of 50,000, the manufacturer could conduct the applicable chemical tests on the component rather than on the final product. If, following the sample sizes in Table 4, the mean of the component were 10 and the standard deviation was 1, this would reduce the cost of testing that component by a factor of 4 over the cost of that would apply if only tests on the final product were acceptable. This is because without component testing, the manufacturer would have had to conduct tests on the component as it was used in each of the 5 products. If each product were produced in lots of 10,000 units, this would amount to 4 tests on the component for each product or 20 total tests on the same component. With component testing, the manufacturer could simply conduct the tests on the component, which was assumed to be purchased in a lot of 50,000 units, which would only require 5 tests of the component to provide a 95% probability that all of the units in the lot were in compliance.

Random Samples: The draft proposed rule requires that the samples selected for periodic testing be random. A random sample is one in which each unit has an equal chance of being included in the sample. The draft proposed rule specifies that each unit produced or imported by the firm since the last random sample was drawn must have equal chance of being selected. There will be some additional cost associated with selecting a random sample rather than a convenience sample. The Commission staff welcomes comments on this provision and is especially interested in comments describing the cost or other burdens that this provision would impose.

Hypothetical Product Testing Examples: In order to provide some information on what the magnitude of the third-party testing costs may be for some manufacturers of children's products, this section discusses the potential cost of obtaining third party testing for two product categories: bicycles and toys. These examples are hypothetical and are intended to illustrate some potential cost implications of the draft proposed rule. The examples might not representative of every

manufacturer in each category. The costs per test that are assumed in the examples can vary significantly. The Commission staff welcomes any comments that provide better information on the potential impacts on individual manufacturers or importers.

Bicycles: Children's bicycles must be tested for compliance with the CPSC bicycle standard (16 CFR 1503), which was estimated above to cost between $700 and $1,100. Additionally, the paint used on the bicycle must be tested for compliance with the lead-in-paint standard and the accessible component parts on the bicycle must be tested for lead content. The number of paints and components that require testing can vary among different models, but information provided by Compliance staff suggests that 75 component parts might be a reasonable estimate for the average. This example will use estimates in the middle of these ranges for the testing costs discussed above and assume that the cost of testing to the bicycle standard is $900 and the cost for testing a component for lead content is $50. It is further assumed that quantitative data is available for all applicable tests and that the variation is low enough that testing 4 units will provide the high degree of assurance desired that products comply with the applicable safety rules.[14]

If component part testing is not available to this manufacturer, the cost of testing the bicycle to each applicable safety rule one time would be about $4,650 (testing to the bicycle standard itself at $900 and testing 75 components for lead content). If a sample of 4 units were required to be tested to provide the required high degree assurance, then the cost of the third party testing to the manufacturer would be $18,600.

The manufacturer in this example might be able to reduce the testing costs with component part testing if some of the component parts were used on more than one model. If component testing reduced the cost of the lead content testing by this manufacturer by a factor of 4, then the cost of the lead testing could be reduced by a factor of 5. In this situation, the cost of testing to the bicycle standard itself would still be $900, but the average cost of testing the lead content of the component parts would be reduced to $12.50 per component. Therefore the cost of testing the bicycle once would be $1,837.50. The cost to test 4 units to provide the required high degree of assurance would be $7,350.

The total cost of the third-party testing to the manufacturer would depend upon the number of youth model bicycles that the manufacturer offered. If the manufacturer had 5 different models, and if component testing could reduce the costs of the lead-content testing by a factor of 4, the total cost of the third-party testing to the firm would be about $36,750.

Toys: Toys must meet requirements concerning lead and phthalate content, and several physical and mechanical requirements, including the requirements of ASTM F963, which was made a mandatory standard by the CPSIA. In this example, it is assumed that the testing costs are at the low to middle part of the ranges discussed

[14] To the extent that some of the tests in the bicycle standard might be qualitative in nature, the sample size for testing would need to be larger.

above and that the hypothesized toy contains 1 metal component that must be tested for lead content using ICP analysis (at $50) and 2 plastic components for which XRF analysis can be used for determining the lead content (2 tests at $6 each). The plastic components also must be tested for phthalate content (2 tests at $225 each). Additionally, it is assumed that the toy contains 4 different paints that must be tested for both lead content ($50/test) and soluble heavy metals ($125/test). Finally, it is assumed that the toy is subject to some mechanical requirements that include use and abuse testing for which only qualitative data is available at $50 per test. Thus, the cost of testing this toy for compliance to each applicable rule one time would be $1,262: $1,212 is associated with the chemical (lead, heavy metal, and phthalate) testing and $50 is associated with the mechanical testing (including use and abuse testing).

If the means and standard deviations of the lead, heavy metal, and phthalate contents of all of the product components are sufficiently low that testing 4 units could statistically provide the required high degree of assurance, then the cost the chemical testing for this toy would be $4,848 ($1,212 x 4). If the means or standard deviations of the lead, heavy metal, or phthalate content were higher, which is likely the case for some materials, more units might have to be tested to provide the required high degree of assurance and the resulting cost would also be higher.

Because the testing data for mechanical requirements are qualitative in nature, the number of units that might have to be tested to provide the required high degree of assurance would be more than required for the chemical tests. If a high degree of assurance were defined to be a 95% probability that no more than 6 percent of the units in the lot did not comply, then 50 units would have to be tested. In this case, the cost of mechanical testing would be $2,500 ($50 x 50).

Combining the cost of the chemical tests and the cost of the tests to the mechanical or physical requirements, the total cost this hypothetical manufacturer to obtain the required high degree of assurance that all products complied with all applicable safety rules would be $7,348. If, as in the bicycle example, component testing could be used to reduce the cost of the chemical testing by a factor of 4, then the total cost of testing the toy could be reduced to $3,712 ($4,848/4 + $2,500).

Again the total cost to the manufacturer or importer would depend upon factors such as the complexity of the products, the variation in the materials used, the opportunities to use component testing, and the number of different toys that were offered. For example, if the manufacturer offered 5 similar toys and the third party testing costs were similar for each toy and component testing allowed the manufacturer to reduce the costs of chemical testing by a factor of 4, the total cost to the manufacturer for testing the toys would be $18,560. The annual cost would be higher if the testing had to be repeated more than once annually or there were material changes in the design of the products or production processes during the year.

Impact of Third Party Testing on Firms

Whether such costs would have a substantial adverse impact on a firm depends upon the individual circumstances of the firm. One factor that can give an indication of whether something will have a significant impact is the magnitude of the impact in relation to the revenue of the firm. A typical profit rate is about 5% of revenue. In other words, for every $1 of revenue, only 5 cents might remain after paying all expenses. Therefore, a new cost that amounted to one percent of revenue could, all other things equal, reduce the profit by 20% and might be considered to be a significant impact by some firms. This would be consistent with what some other agencies consider to be significant. The Occupational Safety and Health Administration (OSHA), for example, considers an impact to be significant if the costs exceed 1% of revenue or 5% of profit.[15]

Using the toy example above, with component testing, if the third party testing costs were spread over 10,000 units, the cost of the testing would be about $0.37 per unit ($3,712/10,000). According to a toy industry representative, the average retail price of a toy is about $8. However, depending upon the channels of distribution and the practices in the particular market or industry, the price that a manufacturer receives for a product can be less than half of what the product eventually sells for at retail. Therefore, if the manufacturer received $4 for the toy that cost $0.37/unit to test, the third party testing costs would be 9.2% of revenue ($0.37/$4) and could exceed the expected profit. Even if the manufacturer received $30/unit for the toy (which might indicate a retail price of around $60 or more), the third-party testing cost would still exceed 1% of the revenue/unit and might be considered to be a significant impact.

It is possible that the impact could be reduced if the manufacturer had an established reasonable testing program that met the requirements of the draft proposed rule and the manufacturer determined that a high degree of assurance did not require a statistical basis. In such cases, some manufacturers may determine that fewer periodic third party tests per rule than were assumed in the above example would provide sufficient evidence that the reasonable testing program was adequate to provide a high degree of assurance that all of the products complied with the applicable safety rules. For example, if the hypothetical manufacturer of the toy used in the above example determined that obtaining one periodic third- arty test per applicable rule were sufficient, then the per unit testing cost (without any component testing) would be about $0.13 ($1,262/10,000).[16] If the manufacturer received $4 for each unit, then the periodic third party testing costs would amount to about 3.1% of revenue ($.13/$4), which still could be considered to be a significant impact. If component testing reduced the cost of the chemical tests by a factor of 4, then the cost of the periodic third party testing could be reduced to $353 ($50 + $1,212/4) or about $0.04/unit, if 10,000 units were produced.

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[15] OSHA, Assigned Protection Factors, Final Rule, Federal Register (71:50121-50192), 24 August 2010.

[16] Testing a product for compliance with each applicable rule one time is likely to require that the manufacturer submit more than one sample of the product to the testing laboratory. This is because some required tests cannot be performed on the same sample has been used for another test. For some chemical tests, it may be necessary to use more than one sample of the product to obtain enough of a component to test.

This would be about 1% of revenue if the manufacturer received $4 for each unit. This might be considered to be significant by some firms.

The reader should bear in mind that the only costs considered in this hypothetical example is the cost of the third party testing. Any costs associated with the requirements for a reasonable testing program would be in addition to these costs and increase the impact, as would any additional third party testing costs associated with material changes in the product's design, the manufacturing processes, or the sourcing of component parts. Other costs that were not considered were the cost of the samples consumed in the testing and the cost of shipping the samples to the testing laboratory.

Caveats and Possible Market Reactions to Third Party Testing Requirements

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

The requirement for third party certification testing could be a barrier for new firms to enter the children's product market, unless they expect to have relatively high volume products. This could be especially important for firms that expected to serve a niche market, including products intended for children with special needs. The requirement for third party testing when there is a material change in a product's design or manufacturing process could cause some small or low-volume manufacturers to forgo or delay implementing some improvements to a product's design or manufacturing process in order to avoid the cost of the third-party testing.

The cost of testing some toys and other children's products could be higher than those in the above examples. The cost would be higher, for example, for products that had more components or the variability in the test results was greater, which would require more samples to be tested. The cost of testing would also be higher if there was less opportunity for component testing. The cost of testing could be lower for products that were subject to fewer safety rules or that contained fewer components. For some apparel articles, for example, the only tests required might be for lead content on some components for which component testing might be possible.

Although the above examples illustrate the potential for component testing to reduce the costs of testing, it might not be an option for all products or manufacturers. Component testing is most likely to be an option for components that are common to multiple products (e.g., paints, bolts of a standard size). The potential for component

testing to reduce the cost of testing would be less for products that have components that are unique to that product.

Verifying that a Children's Product Tested by a Conformity Assessment Body Complies with Product Safety Rules

The fourth provision of the rule requires that manufacturers or importers of children's products to use more than one third-party CAB for assessing conformity with each applicable children's product safety rule. Manufacturers and importers would be in compliance with this provision if, in the exercise of due care, they send samples of the same children's product to an alternate CPSC-recognized third party conformity assessment body at a frequency that provides a high degree of assurance that the children's product complies with the applicable children's product safety rules.

This provision does not affect the amount of third-party testing required for children's products. While there may be some added costs associated with periodically finding and using a different third party CAB, the cost of this provision should not be significant for manufacturers.

Protection Against Undue Influence

The draft proposed rule would require that all manufacturers and importers of children's products to establish procedures to prevent attempts to exercise undue influence on a third-party conformity assessment body and to report to the Commission immediately of any attempt by any interested party to exert undue influence over test results, and that employees are aware that they report any allegations of undue influence to the Commission confidentially. These procedures may include training programs for their employees and the provision of other materials, such as manuals, that explain the responsibilities to avoid exerting undue influence and for reporting any attempts at undue influence that come to their attention. There would be some cost to firms to develop the materials or training programs to comply with these requirements. The Commission staff welcomes comments from the public providing information on the cost and other impacts of this provision.

Consumer Product Labeling Program

The Consumer Product Labeling Program that would be established by the draft proposed rule allows firms to label any product that complies with the certification requirements for the product with a label that states that the product "*Meets CPSC safety requirements*." This provision is not expected to have a significant impact on firms since the program is voluntary and the cost of adding or modifying a label on a product are expected to be low.

Conclusion

The draft proposed rule could have a significant adverse impact on a substantial number of small businesses. The provisions of the draft rule that are expected to have the most significant impact are provisions related to requirements for the third party testing of children's products with and without a reasonable testing program. The impact of these provisions would be expected to be disproportionate on small and low-volume manufacturers. This is because testing costs are relatively fixed. Therefore, the per unit impact of testing costs will be greater on low-volume producers than high volume producers.

The provisions that would require manufacturers and importers of non children's products to establish and maintain reasonable testing programs could also have an adverse impact on some manufacturers and importers. The impact of these provisions are expected to be less significant than the impact of the provisions related to third party testing because many manufacturers and importers are believed to already have at least some quality assurance or testing programs in place. The provisions related to the reasonable testing program are also intended to provide manufacturers and importers with a high degree of flexibility in designing and implementing the programs, which would also serve to reduce the potential impact on the firms.

The other provisions of the draft proposed rule, related to verifying that a children's product tested by a CAB complies with product safety rules, protection against undue influence over a conformity assessment body, and the consumer product labeling program are less likely to have a significant adverse impact on a substantial number of small businesses. The Commission staff, however, would welcome comment on these provisions.

Federal Rules which may Duplicate, Overlap, or Conflict with the Proposed Rule

The draft proposed rule would establish the baseline requirements for the testing programs required for certifying that consumer products comply with all product safety rules. Some individual product safety rules contain some specific testing requirements. Manufacturers and importers would be expected to meet the more stringent requirements whether they are the provisions of this draft proposed rule or the requirements in the specific safety rule. However, the rules would not require manufacturers or importers to duplicate their efforts to comply with both sets of requirements. Testing and recordkeeping required to comply with the more stringent rule would also meet the requirements of the less stringent rule. Manufacturers and importers will not be required to duplicate tests or record to comply with both sets of rules.

There are no known Federal rules that conflict with the draft proposed rule.

Alternatives for Reducing the Adverse Impact on Small Businesses

The Commission staff recognizes that the draft proposed rule could have a significant and disproportionate impact on small and low volume manufacturers. Some provisions that are intended to lessen the impact on small businesses have been incorporated into the draft proposed rule. These include some relief from the periodic testing requirement, the ability to use component testing, and the ability for manufacturers and importers to rely upon the certifications issued by their suppliers to issue their own certificates. The Commission staff welcomes comments on these provisions and other provisions or alternatives that could lessen the adverse impact on small or low-volume businesses.

Provisions Incorporated in the Draft Proposed Rule

Partial Exemption from Periodic Testing

The draft proposed rule would require that all children's products be tested periodically by a third party conformity assessment body and establishes 1 year as the maximum interval between periodic tests. However, if fewer than 10,000 units of a product have been manufactured or imported since the last time the product was submitted to a third party conformity assessment body, the manufacturer or importer would not be required to obtain additional third party testing until 10,000 units have been manufactured or imported. This provision would allow low-volume manufacturers or importers to spread their periodic testing costs over more units. The exemption would not relieve the manufacturer or importer from the obligation to have the product tested by a third party conformity assessment body before the product is introduced into commerce or when there has been a material change in the product's design or production processes.

Component Testing

The draft proposed rule would allow firms to submit components for third party testing when required testing can be performed on the component and does not need to be performed on the entire product. This can reduce the cost to manufacturers where one component might be common to more than one product. Such components might include paints, polymers used in molding different parts, and standard-sized bolts. In these cases the components might be received in larger lots than the production lots of the products in which they are used. Therefore, the testing costs for those components will be spread over more units than if they were required to be tested on the final products only.

Reliance on Certifications by Suppliers

The draft proposed rule would allow manufacturers and importers to rely upon certifications that a component or product met all of the requirements contained in the CPSA, as amended by the CPSIA, and the requirements of the draft proposed rule. For components used in children's products, this would require that the suppliers' certifications be based on tests by CPSC accredited third party conformity assessment bodies and that the supplier has established and maintains a program to repeat the third-party testing periodically or when there has been a material change in the product's design or manufacturing process. This provision could be of benefit to small manufacturers if some of their component suppliers voluntarily test and certify the product as meeting certain safety rules, thus relieving the small manufacturer of having to obtain the third party tests. It could also benefit small importers that obtain some children's products from foreign manufacturers. If the foreign manufacturer obtains the required third party tests, including the initial certification tests, the periodic tests, and tests when there has been a material change, and certifies that the product conforms to all applicable safety rules, the importer can rely on that certification to issue their own certification without having to obtain additional third-party testing on the product.

Alternatives That May Further Reduce the Impact on Small Businesses

The Commission staff also welcomes suggestions and comments on other alternative provisions that could provide some relief to small businesses that would be adversely impacted by the draft proposed rule. Alternatives could include things such as (1) the establishment of differing compliance or reporting requirements that take into account the resources available to small businesses; (2) the clarification, consolidation, or simplification of compliance and reporting requirements for small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part of the rule thereof, for small entities. In providing such comments, the staff requests that the comments provide specific suggestions and well developed justifications for the suggestions. Some possible alternatives that could be considered are discussed below.

Less Stringent Requirements for Third Party Testing

The draft proposed rule would require that that enough third party tests be obtained to provide a high degree of assurance that all of products in the lots tested complied with the applicable rules. This could require most manufacturers and importers to submit multiple samples for third party testing each year, especially if they have not implemented a reasonable testing program. However, the Commission could adopt an alternative that that would limit the number of samples required for third party testing. For example, the Commission could simply require that manufacturers and importers

submit sufficient samples to a third party conformity assessment body so that compliance with each rule could be assessed at least once annually.

The draft proposed rule would require that periodic third-party testing be conducted at least once a year. A year was chosen as the maximum interval between periodic testing because many children's products are produced on an annual or seasonal cycle. The Commission could, however, consider a different maximum interval between the periodic tests. For example, the Commission could consider requiring that periodic tests be conducted at least once every 2 years or once every 5 years.

The advantage of less stringent requirements is that they could significantly reduce the cost of the third party testing requirement. The disadvantage is that the testing would provide less information about whether all of the products produced were in compliance with the applicable safety rules.

The Commission staff welcomes comments on these and similar alternatives. For example, should the Commission consider a less stringent requirement? If so, what should the alternative requirement be? Should the less stringent requirement apply to all manufacturers and importers or only those that meet certain criteria, such as to small or low-volume manufacturers?

Limits on Third Party Testing for Small or Low Volume Manufacturers

The Commission could consider additional alternatives that would provide relief to small or low-volume manufacturers. Substantial relief could be provided to small or low-volume manufacturers, for example, if the Commission could exempt them from the third party testing requirements altogether. Alternatively, it could limit the third party testing required to no more than a certain percentage of the firm's revenue, or similar criteria. (This memorandum does not opine whether such an exemption could be legally supported.) The Commission staff would welcome comments on this or similar alternatives. For example, should the Commission adopt criteria that put a maximum limit on the required third-party testing costs by small or low-volume manufacturers? If so, what should the criteria be? If such a provision were adopted, how should the manufacturer or importer allocate its limited testing funds? For example, should the same priority be given to all safety rules? Or, should the manufacturer or importer give a higher priority to testing for compliance to some safety rules than to others? For example, should the manufacturer or importer give a higher priority to testing for compliance with the lead-in-paint standard than to the phthalate standard?

Alternative Test Methods for Small or Low Volume Manufacturers

Some small manufacturers have encouraged the Commission to allow alternative test methods such as those relying on XRF technology. XRF testing methods are significantly less expensive than the ICP analysis that the Commission currently

requires for most lead content testing (with the exception of homogenous polymer products). The Commission staff does use XRF, however, for screening samples.

The Commission staff welcomes comments on the possibility of using alternative testing technologies for reducing the burden on small and low volume manufacturers. For example, could the Commission allow small or low volume manufacturers to use less expensive, but potentially less accurate third-party testing methods? If so, under what conditions?

Appendix A
Children's Product Safety Rules

16 CFR Part #	Description
1420*	***All Terrain Vehicles:*** The ANSI/SVIA voluntary standard is to be considered a mandatory product safety rule. The rule includes various mechanical, performance, and labeling requirements for ATVs.
1500.18(a)(6) and 1500.86(a)(4)	***Baby Walkers and Baby Bouncers:*** The rules are designed to ensure that there are no mechanical, crushing, laceration, and other hazards to children from baby walkers and bouncers.
1512*	***Bicycles:*** Establishes various mechanical safety requirements for bicycles. Rule also requires that bicycles be labeled so that the manufacturer can be identified and the month and year of manufacture can be determined. Provides requirements for an instruction manual to be provided to the consumer. Rule applies to all bicycles except one-of-a-kind bicycles and track bicycles.
1203*	***Bicycle Helmets:*** All bicycle helmets must meet performance requirements concerning such things as impact attenuation and positional stability.
1213* 1513	***Bunk Beds:*** Establishes requirements to reduce the risk of entrapment and suffocation in bunk beds. The rule also requires that the manufacturer and month and date of manufacture be identifiable from a product label and that instructions be provided to the consumer.
1500.18(a)(5)	***Caps and Toy Guns:*** Banned if sound is greater than 138 decibels within 25 centimeters.
1630* 1631*	***Carpets and rugs:*** The rules establish performance requirements to limit the flammability of carpets and rugs.
1500.18(a)(7) 1500.86(a)(5)	***Clacker Balls:*** The rule establishes requirements for clacker balls, including for the cord, weight of the balls, and testing requirements
1615 1616	***Children's Sleepwear:*** Rule establishes performance standards to limit the flammability or risk of burn injuries associated with children's sleepwear.
1500.18(a)(13-14) 1508 - 1509	***Cribs:*** Must meet performance requirements to prevent entrapment and to decrease the risk of suffocation.
1500.18(a)(9) 1500.86(a)(7-8)	***Dive Sticks:*** Establishes requirements that dive sticks either not stand upright on the bottom of a pool or be made from non-rigid material so as to prevent puncture or penetration injuries to a person when used in shallow water.

CPSIA Sec. 104	***Durable Nursery Products:*** The CPSC is mandated to promulgate standards for durable nursery products. These standards may be based on current voluntary standards. Durable nursery products include: toddler beds, high chairs, booster chairs, bath seats, gates and other enclosures for confining a child, play yards, stationary activity centers, infant carriers, strollers, swings, and bassinets and cradles.
1500.18(b) 1505	***Electrically Operated Toy, Video Games, and other Children's Articles:*** Establishes requirements to reduce the risk hazards that might be associated with electrically operated children's articles including the risk of burns and electrocution.
1500.14(b)7)* 1500.17(a)(3)* 1500.17(a)(8-9)* 1500.17(a)(11-12) 1500.83(a)(27)* 1500.85(a)(2)* 1507*	***Fireworks Devices:*** These rules establish various safety requirements fireworks devices including limits on the chemical composition, fuses, and requirements for stability of the device while in use. Some fireworks devices are banned.
1500.18(a)(16)	***Infant Cushions:*** Cushions promoted for the use of children under 1 year of age are banned if they are loosely filled with granular material such as polystyrene beads, covered with a flexible fabric, and can be flattened.
CPSIA Sec 101	***Lead Content:*** The lead content of any component of a children's product may not exceed 300 ppm. Components that are not accessible are exempted as are some components of electrical products if lead is required for the part to function properly. (In August 2011, the allowable lead limit is reduced to 100 ppm where technologically feasible.)
1303	***Lead-in-Paint:*** The lead content of the dried paint film or similar surface coating on any children's product may not exceed 0.009% by weight.
1632* 1633*	***Mattresses:*** Rules contain performance requirements to demonstrate ignition resistance to both cigarettes (1632) ignition and open flames (1633).
1500.18(a)(8) 1511	***Pacifiers:*** Rules establish safety requirements for pacifiers, including tests for structural integrity and a prohibition of any cord, string or ribbon attachment.
CPSIA Sec. 108	***Phthalates (DEHP, DBD, and BBP):*** These phthalates are permanently banned in childcare articles and toys in concentrations greater than 0.1%.
CPSIA Sec. 108	***Phthalates (DINP, DIDP, DnOP):*** These phthalates are banned from childcare articles and toys that can be placed in a child's mouth. This is an interim ban pending a Commission consideration of the findings of the Chronic Health Advisory Panel and the promulgation of a final rule by the Commission.

1510 1500.18(a)(15) 1500.86(a)(1)	***Rattles:*** Rules require that any sharp edges or points in a rattle must be internal and establishes a performance requirement to ensure that the rattle will not present a suffocation hazard.
1500.19	***Small Balls and Marbles, Latex Balloons:*** Toys or games intended for children between the ages of 3 years and 6 years must bear a warning label, if they contain small parts. Balloons, small balls or marbles intended for children 3 years of age or older or any toy or game containing a balloon, small ball or marble must bear an appropriate choking hazard label. The warning for latex balloons and toys or games for children that contain balloons warns that children under 8 years of age can choke on balloons. There is no upper age limit for balloons, small balls and marbles.
1500.19	***Small Parts:*** Toys or games intended for children under the age of 3 years that contain small parts are banned. Toys or games intended for children between the ages of 3 years and 5 years must bear a warning label, if they contain small parts.
1207*	***Swimming Pool Slides:*** Establishes requirements intended to reduce the risk of injury or death from the use of swimming pool slides.
CPSIA Sec. 106	***Toys:*** Toys must meet the requirements of ASTM F-963, which includes comprehensive safety requirements.
1611*	***Vinyl Plastic Film:*** Establishes performance standards to limit the flammability of vinyl plastic film subject to the Flammable Fabrics Act.
1610*	***Wearing Apparel (except hats, gloves, and footwear):*** Establishes performance standards to limit the flammability of most wearing apparel.

* Regulations marked with an asterisk may be applicable as children's products safety rules to the extent a manufacturer's products are designed or intended ***primarily*** for children 12 years of age or younger (*e.g.*, crib mattresses, youth bicycles and ATVs, sparklers). When products are designed or intended primarily for children 12 years of age or younger, the CPSIA requires third-party testing by a CPSC-recognized conformity assessment body.

Appendix B
Product Safety Rules to Which Domestic Manufacturers and Importers Must Provide General Conformity Certificates

16 CFR Part #	Description
1420*	***All Terrain Vehicles:*** The ANSI/SVIA voluntary standard is to be considered a mandatory product safety rule. The rule includes various mechanical, performance, and labeling requirements for ATVs.
1201*	***Architectural Glazing Materials:*** Applies to A glazing material in products such as storm or combination doors, bathtub/shower doors and enclosures, patio type sliding doors. The rule contains performance requirements for impact resistance.
1512*	***Bicycles:*** Establishes various mechanical safety requirements for bicycles. Rule also requires that bicycles be labeled so that the manufacturer can be identified and the month and year of manufacture can be determined. Provides requirements for an instruction manual to be provided to the consumer. Rule applies to all bicycles except one-of-a-kind bicycles and track bicycles.
1203*	***Bicycle Helmets:*** All bicycle helmets must meet performance requirements concerning such things as impact attenuation and positional stability.
1213	***Bunk Beds:*** Establishes requirements to reduce the risk of entrapment and suffocation in bunk beds. The rule also requires that the manufacturer and month and date of manufacture be identifiable from a product label and that instructions be provided to the consumer. Bunk beds intended for children are regulated in 16 CFR Part 1513.
1630* 1631*	***Carpets and rugs:*** The rules establish performance requirements to limit the flammability of carpets and rugs.
1204*	***CB Omnidirectional Base Station Antennas:*** Establishes performance standards to reduce the risk of electrocution resulting from contact with power lines while the antenna is being installed or taken down.
1209*	***Cellulose Insulation:*** The rule establishes performance requirements that limit the corrosiveness and combustibility of cellulose insulation.

1302	***Contact Adhesives:*** This rule establishes product characteristics intended to prevent the sale of extremely flammable contact adhesives.
1210* 1212*	***Cigarette and Multipurpose Lighters:*** These rules establish performance standards intended to make cigarette and multipurpose lighters difficult for children under the age of 5 years to operate.
1500.18(a)(9)* 1500.86(a)(7-8)	***Dive Sticks:*** Establishes requirements that dive sticks either not stand upright on the bottom of a pool or be made from non-rigid material so as to prevent puncture or penetration injuries to a person when used in shallow water.
1500.14(b)7)* 1500.17(a)(3) 1500.17(a)(8-9) 1500.17(a)(11-12) 1500.83(a)(27) 1500.85(a)(2) 1507	***Fireworks Devices:*** These rules establish various safety requirements fireworks devices including limits on the chemical composition, fuses, and requirements for stability of the device while in use. Some fireworks devices are banned.
1211*	***Garage Door Openers:*** The rule contains performance requirements to reduce the risk that a person could be injured by being entrapped when a garage door is closing.
1205*	***Lawnmowers:*** Establishes performance standards for power walk-behind lawnmowers intended to reduce the risk of injury due to contact with the blade of the mower.
1303	***Lead in paint:*** Lead content, by weight, of the dried paint film may not exceed 0.009%. Rule applies to consumer paints and paint used on non-metal furniture. Some applications are exempted including mirror back coatings, metal furniture, blinds, chandeliers, fixtures, appliances, manufactured windows, artist paints. Agricultural and industrial uses are also not covered. Touch up paints for the exempted applications that contain lead must be labeled.
1202*	***Matchbooks:*** Establishes requirements for matchbooks to reduce the risk of burn injuries.
1632* 1633*	***Mattresses:*** Rules contain performance requirements to demonstrate ignition resistance to both cigarettes (1632) ignition and open flames (1633).

1750	***Refrigerators:*** Establishes performance requirements that ensure that a refrigerator can be opened from the inside so as to reduce the risk that a child could become trapped in a refrigerator and suffocate.
1301	***Refuse Bins:*** Establishes product characteristics and performance tests to prevent the sale and distribution of unstable refuse bins.
1207*	***Swimming Pool Slides:*** Establishes requirements intended to reduce the risk of injury or death from the use of swimming pool slides.
1611*	***Vinyl Plastic Film:*** Establishes performance standards to limit the flammability of vinyl plastic film subject to the Flammable Fabrics Act.
1610*	***Wearing Apparel (except hats, gloves, and footwear):*** Establishes performance standards to limit the flammability of most wearing apparel.

*Existing rule contains requirements for testing, recordkeeping or both.